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What are the optimal ways of working in delivering
orthotic interventions to enhance rehabilitation
outcomes and reduce complications for stroke
survivors?

Establishing National Statements of Best Practice

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Abstract

Background

Stroke is the leading cause of adult disability in the UK with two thirds of stroke survivors leaving hospital with ongoing functional deficit. For many stroke survivors regaining mobility is a key aim in their rehabilitation, and orthotics have a crucial role to play in achieving this. There are up to two million orthotic users in the UK and with the predicted increase in prevalence of stroke by 60% in the next 10 years, this number is also expected to rise significantly.

Currently there is no evidence for the optimal ways of working when delivering orthotic interventions following a stroke and no guidelines of best practice to inform clinicians, for services to adhere to, and for patients to use to advocate for their care. This contributes to poor consistency in the delivery of orthotic intervention for stroke survivors across the UK.

Aim

The aim of this PhD was to establish the optimal ways of working in the delivery of orthotic intervention after stroke, in order to enhance rehabilitation outcomes and reduce complications for stroke survivors.

Methods

This mixed methods PhD was completed through a five-stage process. Stage one of the PhD programme of work comprised a systematic review of the literature. This provided a comprehensive synthesis of relevant evidence in the field, and a detailed foundation of existing knowledge before undertaking further research. The second stage consisted of a national professional cross-sectional survey designed to provide a baseline of data in the post-covid landscape of how orthotists perceive their role and confidence to inform stroke rehabilitation outcomes. The third stage involved the completion of stakeholder focus groups to determine the perspectives of multi-disciplinary expert clinicians, stroke survivors and carers on the role of orthotics in stroke rehabilitation. Within this,

they also explored the similarities and differences to the perceptions identified by orthotists within the cross-sectional survey. The findings from these three studies were converged through a triangulation exercise in the fourth stage of the PhD programme, where the synthesised results were formed into themes from which proposed statements of best practice were developed. The fifth and final stage was to refine and finalise the statements of best practice through expert orthotist agreement via a national professional eDelphi consensus study.

Following the internationally adopted Grades of Recommendation, Assessment, Development and Evaluation (GRADE) approach, the studies were conducted systematically to produce the first national clinical guidelines for orthotic intervention after stroke in the UK. Additional preparatory studies of a Multi-Disciplinary Team (MDT) professional survey and clinical observations were conducted to supplement the substantive work packages within the PhD and offer additional context to the developed statements of best practice.

Results

The preparatory MDT survey laid a foundation for the PhD programme and indicated the perceived importance of timing and means of orthotic delivery after stroke. The clinical observation inquiry provided context for which the subsequent studies were developed and delivered, with a key finding on the importance of the inter-professional relationships within stroke rehabilitation. The systematic review identified six evaluative studies assessing the impact of timing of lower limb orthotic delivery which were all derived from a single trial, and no studies exploring the specific role of the orthotist. The national professional cross-sectional survey received 56 responses, representative of 10% of the UK registered orthotic workforce. It found that multidisciplinary care was not typical, with 46% of respondents reported 'rarely' seeing stroke patients in joint assessment with another clinician. However, confidence in managing lower limb gait difficulties was high, with 89% of respondents feeling able to recommend a lower limb orthotic treatment. Ninety-eight percent (n=55) of

respondents agreed that orthotic assessment should be an essential element of gait re-education after stroke, however, they reported limited involvement within early stroke rehabilitation currently.

The stakeholder focus group study was the first to explore the collective perspectives of stroke rehabilitation clinicians, stroke survivors, and carers on their perception of optimum orthotic intervention after stroke. Three focus groups were completed. Following a framework analysis of the focus group transcripts, eight core themes were identified: four foundation themes, a further two centred on the person and two on the wider service structure, and a final two overarching themes. The four foundation themes each represent an aspect of orthotic intervention which is not direct but influential to its implementation. *Orthotists need to determine best practice; Biomechanics – The Debate; Visibility and knowledge about orthotics and the profession; Different ways of working.* Two further themes relating to the person were identified: *Home; Independence,* and two relating to the service structure: *MDT; Accessibility.* These themes are directly associated with orthotic intervention in the way it is delivered and the effect it can have on the stroke survivor. Finally, two overarching themes inform the other themes: *Acceptability and fidelity of orthotic intervention after stroke; Timeliness, impact of delays and secondary complications.*

A triangulation exercise synthesised the findings of these three studies systematically into five themes of within which the proposed statements of best practice were developed. These themes were: *The Orthotist; The Orthoses; The Patient; The Orthotic Service; Ways of Working.* Finalised statements were then refined and agreed through professional consensus via an eDelphi exercise with expert orthotists from across the UK. Thirty-two responses were received with a retention rate of 87.5% across the two rounds. Ninety percent (n=29) of participants reported being qualified for six years or more indicating a high level of expertise. Sixty-four statements reached consensus agreement across the two-rounds of the eDelphi with an average consensus of 94.31%.

Conclusions

The first national clinical statements of best practice encompass different elements which inform optimum the ways of working when delivering orthotic intervention for stroke survivors. The 64 finalised statements of best practice have been developed systematically following the GRADE approach and from the findings of this five-stage mixed methods study. The statements were constructed directly from the themes and recommendations identified within the results of the concluding national eDelphi exercise which returned a high level of professional consensus, with participants representative of approximately 5% of the national orthotic expert workforce within the UK.

The developed statements of best practice address a paucity of guidance for the therapeutic use of orthotic intervention within mobility rehabilitation post-stroke. The effectiveness and acceptability of these statements within the applied healthcare setting should now be tested in a future evaluative trial.

Dissemination

The following presentations and publications have been conducted based on this programme of work:

Peer reviewed journal publications

GOLDING-DAY, M., YOUNG, J., CHARLTON, P., HOUSTON, B., THOMAS, S., WALKER, M. (2024) *Orthotist involvement in early gait rehabilitation following stroke: a cross-sectional survey of orthotists in the United Kingdom*. Journal of Prosthetics and Orthotics International. June:1 (14). [Journal article](#).

GOLDING-DAY, M., HOUSTON, B., YOUNG, J., CHARLTON, P. (2023) *Early gait re-education training following stroke: a report from the Forward Orthotics Thinking Conference 2021*. Synapse. Spring:1 P.15-18. [Journal article](#).

GOLDING-DAY, M., WALKER, M and WHITEHEAD, P. (2022) Orthotic intervention following Stroke: A survey of physiotherapist, occupational therapist and orthotist practice and views in the UK. International Journal of Therapy and Rehabilitation. 6:1. [Journal article](#).

GOLDING-DAY, M., PRINCE, N., THOMAS, S., HORNE, J., THOMAS, L and WALKER, M. (2022) *Early specialist orthotic interventions for the lower limb in adult stroke patients: a systematic literature review*. The Journal of the International Foot & Ankle Foundation. 1(9): 3. [Journal article](#).

Conference Presentations

GOLDING-DAY, M., THOMAS, S., WHITEHEAD, P., WALKER, M. (2024) *Developing best practice statements for orthotic intervention supporting mobility recovery following stroke: The OTIS study*. United Kingdom Stroke Forum, Liverpool. [Poster presentation](#).

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Dedication

I dedicate this PhD thesis to me. We did it.

Statement from funder

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The views expressed in this thesis are those of the author(s) and not necessarily those of the Stroke Association, National Health Service, National Institute for Health Research, the Department of Health and social care.

Table of Contents

Abstract.....	1
Background.....	1
Aim	1
Methods	1
Results	2
Conclusions.....	4
Dissemination	5
Peer reviewed journal publications	5
Conference Presentations.....	5
Acknowledgements.....	7
Dedication	8
Statement from funder	9
Table of Contents.....	10
List of Figures	19
List of Tables	20
List of Appendices	21
Table of Abbreviations.....	23
Glossary Table	24
Chapter One: Introduction to the research question and PhD methodologies .	29
1.1 Stroke	30
1.2 Orthotics.....	31
1.3 Guidelines.....	36

1.4 Research questions, aims and objectives of the PhD	38
1.5 Development of the research questions.....	40
1.5.1 Philosophy underpinning biomechanical principles.....	41
1.5.2 Orthotic interventions after stroke clinical guidelines.....	42
1.5.3 Original methodology	43
1.6 Mixed methods research	46
1.7 Thesis structure	48
Chapter Two: Preparatory studies of a national multi-disciplinary survey and clinical observations.....	50
2.2 Orthotic intervention following stroke: An inter-professional survey of physiotherapist, occupational therapist and orthotist practice and views in the UK	51
2.3 Background.....	51
2.4 Methodology	52
2.4.1 Development of the survey	53
2.4.2 Ethical considerations.....	54
2.4.3 Data collection and management	55
2.4.4 Recruitment of participants.....	55
2.4.5 Data analysis	56
2.5 Findings	58
2.5.1 Quantitative data.....	58
2.5.2 Qualitative data	60
2.6 Discussion.....	63
2.7 Conclusion	66
2.7.1 Directing the PhD research question and methods	67

2.8 Clinical observations within existing acute and community stroke and orthotic services	68
2.8.1 Aims of the inquiry	69
2.9 Methodology	70
2.9.1 Data collection and management	70
2.9.2 Ethical considerations.....	71
2.10 Findings	71
2.11 Discussion	76
2.12 Conclusion	80
Chapter Three: Early specialist orthotic interventions for the lower limb in adult stroke patients - a systematic literature review	82
3.1 Aims of the study	83
3.2 Background.....	84
3.3 Methodology	87
3.3.1 Objectives of the review	87
3.3.2 Development of the search	88
3.3.3 Eligibility criteria	88
3.3.4 Evidence sources	92
3.3.5 Search strategy	92
3.3.6 Evidence selection	94
3.3.7 Data extraction	94
3.3.8 Risk of bias	95
3.3.9 Data synthesis.....	95
3.4 Findings	95
3.4.1 Results of the searches	95

3.4.2 Risk of bias quality assessment of included studies	100
3.4.3 Results of the synthesis	102
3.5 Discussion	107
3.5.1 Study strengths and limitations	109
3.5 Conclusion	112
3.6 The impact of the global Covid-19 pandemic and subsequent changes to the PhD	113
3.6.1 Initial PhD methodology	113
3.6.2 Coronavirus outbreak	116
Chapter Four: Orthotist involvement in early gait rehabilitation following stroke - a cross-sectional survey of orthotists in the United Kingdom	118
4.1 Aims of the study	119
4.2 Background	120
4.3 Methodology	122
4.3.1 Development of the survey	122
4.3.2 Ethical considerations	123
4.3.3 Data collection and management	123
4.3.5 Recruitment of participants	124
4.3.6 Data analysis	125
4.4 Findings	126
4.4.1 Participant demographic characteristics	127
4.4.2 Frequency, timing, and setting of orthotist stroke intervention	127
4.4.3 Orthotist involvement in early gait rehabilitation	129
4.4.4 Orthotist confidence in early gait rehabilitation	130
4.4.5 Orthotist perception of role and involvement after stroke	132

4.4.6 Qualitative responses	133
4.5 Discussion	136
4.5.1 Study strengths and limitations.....	139
4.6 Conclusion	142
Chapter Five: Experienced based evidence and perspectives on the role of orthotics in stroke rehabilitation – stakeholder focus groups with practitioners, stroke survivors, and carers	144
5.1 Aims of the study	145
5.2 Background.....	146
5.3 Methodology	147
5.3.1 Development of the technique	147
5.3.2 Development of the topic guide.....	148
5.3.3 Ethical considerations.....	149
5.3.4 Data collection and management	150
5.4.5 Recruitment of participants.....	150
5.4.6 Data analysis	152
5.4 Findings	157
5.4.1 Theme One – Orthotists need to determine best practice	159
5.4.2 Theme Two – Different ways of working	160
5.4.3 Theme Three – Visibility and knowledge about orthotics and the profession	162
5.4.4 Theme Four – Biomechanics – The debate	163
5.4.5 Theme Five – Accessibility	165
5.4.6 Theme Six – MDT	167
5.4.7 Theme Seven – Independence	168

5.4.8 Theme Eight – Home	169
5.4.9 Overarching theme A – Timeliness, impact of delays and secondary complications.....	170
5.4.10 Overarching theme B – Acceptability and fidelity of orthotic intervention after stroke	172
5.5 Discussion	173
5.5.1 Study strengths and limitations.....	177
5.6 Conclusion	180
Chapter Six: Triangulation of systematic review, cross-sectional professional survey, and stakeholder focus group findings to form proposed statements of best practice.....	181
6.1 Aims of the study	182
6.2 Background.....	183
6.3 Methodology	184
6.3.1 Triangulation protocol	184
6.4 Findings	187
6.4.1 Identification of themes	196
6.4.2 Converting themes into statements.....	199
6.5 Discussion	199
6.5.1 Study strengths and limitations.....	200
6.6 Conclusions	202
Chapter Seven: Professional consensus on national statements of best practice for delivering orthotic interventions after stroke – an eDelphi study	203
7.1 Aims of the study	204
7.1 Background.....	205
7.3 Methodology	206

7.3.1 Development of the technique	206
7.3.2 Ethical considerations.....	217
7.3.3 Data collection and management	218
7.3.4 Recruitment of participants.....	221
7.3.5 Data analysis	224
7.4 Findings	225
7.4.1 Participant demographic characteristics	227
7.4.1 Round one.....	228
7.4.2 Round two	236
7.5 Discussion	243
7.5.1 Study strengths and limitations.....	245
7.4 Conclusion	247
Chapter Eight: The development of national statements of best practice on delivering orthotic interventions after stroke: Discussion and Conclusions	249
8.1 Summary of methodology.....	249
8.1.1 Mixed methods.....	250
8.1.2 Methodology strengths and limitations	250
8.2 Synthesis of results.....	259
8.2.1 Relationships	262
8.2.2 Access	263
8.2.3 Knowledge and understanding of orthotics	263
8.2.4 Professional consensus.....	265
8.2.5 Stakeholder consultation.....	265
8.2.6 Context and future implementation	266
8.2.7 Building the evidence base.....	267

8.2.8 The GRADE method	267
8.2.9 Lived experience	268
8.2.10 Statements of best practice: Delivering orthotic interventions after stroke	269
8.3 Reflexivity	286
8.4 Context and consideration of other literature	288
8.5 Interpretation and implications	290
8.4.1 Implications for clinical practice	290
8.4.2 Implications for further research	291
8.6 Conclusion	292
References	294
Appendices.....	324
Appendix A. Original methodology	324
Appendix B. Checklist for reporting survey studies (CROSS)(117)	327
Appendix C. Text version of multi-disciplinary survey questions	331
Appendix D. Preparatory MDT survey letter of favourable ethical approval	339
Appendix E. Multi-disciplinary survey participant information sheet and consent form	340
Appendix F. Multi-disciplinary survey results tables	342
Appendix G. Systematic review data extraction form	346
Appendix H. Risk of bias quality assessment form (157)	350
Appendix I. Checklist for Reporting Results of Internet E-surveys (CHERRIES) (172)	352
Appendix J. National cross-sectional professional survey questions	357
Appendix K. Cross-sectional survey letter of favourable ethical approval ...	363

Appendix L. National cross-sectional survey Participant Information Sheet	364
Appendix M. National cross-sectional professional survey consent	366
Appendix N. Focus Group and eDelphi protocol.....	367
Appendix O. Focus group discussion topic guide.....	392
Appendix P. Focus group and eDelphi letter of favourable ethical approval	394
Appendix Q. Remote focus group Participant Information Sheet	395
Appendix R. Remote focus group consent form	400
Appendix S. Convergence coding matrix	401
Appendix T. National eDelphi Participant Information Sheet, Consent form, Title and Final page	403
Appendix U. eDelphi email advert	408
Appendix V. eDelphi round one detailed consensus statistics	409
Appendix W. Original and revised eDelphi statements	425
Appendix X. eDelphi round two detailed consensus statistics	430

List of Figures

Figure 1. Blueprint for original and new PhD methodology	45
Figure 2. Development of Best Practice Statements	49
Figure 3. Development of Best Practice Statements - stage 1	83
Figure 4. Systematic review PRISMA flow diagram	97
Figure 5. Development of Best Practice Statements - stage 2	119
Figure 6. Development of Best Practice Statements – stage 3	145
Figure 7. Focus group theme matrix	156
Figure 8. Development of Best Practice Statements - stage 4	182
Figure 9. Five triangulation overarching themes	197
Figure 10. Development of Best Practice Statements - stage 5	204
Figure 11. eDelphi consensus flow diagram	208
Figure 12. Clinical and PPI co-development exercise examples	210
Figure 13. Example consent page with progress bar	211
Figure 14. eDelphi ranking example	220
Figure 15. Statements of Best Practice: Delivering Orthotic Intervention After Stroke	270

List of Tables

Table 1. Systematic review inclusion and exclusion criteria	91
Table 2. Systematic review search strategy.....	93
Table 3. Abstract screen reasons for exclusion	96
Table 4. Summary characteristics of included studies	98
Table 5. EPOC risk of bias summary.....	100
Table 6. Summary of included study participant characteristics	102
Table 7. Participant professional demographics	126
Table 8. Frequency and timing of orthotist stroke intervention	128
Table 9. Setting of orthotist stroke intervention and MDT working	128
Table 10. Orthotist involvement in early gait rehabilitation	129
Table 11. Orthotist confidence in delivering and advising on orthotic intervention	131
Table 12. Orthotist perception of role and involvement after stroke.....	132
Table 13. Focus group participant characteristics	157
Table 14. Synthesis of themes from triangulation convergence exercise.....	187
Table 15. Illustrative examples of Theme One – The Orthotist from Focus Group data	189
Table 16. Illustrative examples of Theme One – The Orthotist from Cross- sectional survey data	193
Table 17. eDelphi round one statements and overarching themes.....	212
Table 18. eDelphi Participant demographics.....	225
Table 19. eDelphi round one statement consensus percentage.....	228
Table 20. eDelphi consensus statements included in the statements of best practice	238
Table 21. MRC framework checklist (108).....	255

List of Appendices

Appendix A. Original methodology.....	324
Appendix B. Checklist for reporting survey studies (CROSS)(117)	327
Appendix C. Text version of multi-disciplinary survey questions	331
Appendix D. Preparatory MDT survey letter of favourable ethical approval...	339
Appendix E. Multi-disciplinary survey participant information sheet and consent form.....	340
Appendix F. Multi-disciplinary survey results tables	342
Appendix G. Systematic review data extraction form	346
Appendix H. Risk of bias quality assessment form (157).....	350
Appendix I. Checklist for Reporting Results of Internet E-surveys (CHERRIES) (172).....	352
Appendix J. National cross-sectional professional survey questions	357
Appendix K. Cross-sectional survey letter of favourable ethical approval.....	363
Appendix L. National cross-sectional survey Participant Information Sheet ...	364
Appendix M. National cross-sectional professional survey consent.....	366
Appendix N. Focus Group and eDelphi protocol	367
Appendix O. Focus group discussion topic guide	392
Appendix P. Focus group and eDelphi letter of favourable ethical approval...	394
Appendix Q. Remote focus group Participant Information Sheet.....	395
Appendix R. Remote focus group consent form.....	400
Appendix S. Convergence coding matrix	401
Appendix T. National eDelphi Participant Information Sheet, Consent form, Title and Final page	403
Appendix U. eDelphi email advert	408
Appendix V. eDelphi round one detailed consensus statistics	409
Appendix W. Original and revised eDelphi statements.....	425
Appendix X. eDelphi round two detailed consensus statistics	430

Table of Abbreviations

ACPIN	Association of Chartered Physiotherapists Interested in Neurology
ADL	Activity of Daily Living
AFO	Ankle Foot Orthoses
AHPs	Allied Health Professionals
BAPO	British Association of Prosthetists and Orthotists
CDT	Centre for Doctoral Training
ESD	Early Supported Discharge
FMHS	Faculty for Medicine and Health Science
GRADE	The Grading of Recommendations Assessment, Development and Evaluation
HCPC	Health and Care Professions Council
HEE	Health Education England
HRA	Health Research Authority
IRAS	Integrated Research Application System
JLA	James Lind Alliance
MDT	Multi-Disciplinary Team
MRC	Medical Research Council
NHS	National Health Service
NIHR	National Institute for Health and Care Research
NSRPG	Nottingham Stroke Research Partnership Group
OTs	Occupational Therapists
PGR	Post-graduate Researcher
RCOT	Royal College of Occupational Therapy
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
QIS	Quality Improvement Scheme

Glossary Table

Acute setting	A location where healthcare interventions are provided that is within a hospital trust site.
Ankle Foot Orthoses (AFO)	An external brace or splint that fits next to the foot and ankle to control its range of motion and helps to stabilise its position. Patients who have weakness in the ankle dorsiflexor or plantar flexor muscles due to stroke may benefit from the support this device offers in standing and walking. By securing an anatomically correct position, this device can prevent muscle shortening or contracture where muscle imbalance is present after stroke.
Balance	Balance refers to an individual's ability to maintain their centre of gravity within their base of support. It is directed by the body's Central Nervous System which receives feedback about the body's orientation from the: Somatosensory / Proprioceptive System; Vestibular System; and Visual System. This sensory feedback is integrated and subsequent corrective, stabilizing torque by selectively activating muscles is generated.
Biomechanics	The science of movement of a living body, including how muscles, bones, tendons, and ligaments work together to produce movement. Biomechanics is part of the larger field of kinesiology, specifically focusing on the mechanics of the movement.
Community setting	Any geographical location where healthcare interventions are provided that is not within an acute hospital site.

Contracture	A permanent shortening of a muscle or joint due to loss of motion over time due to abnormal shortening of the soft tissue structures spanning one or more joints. Damage to the brain can result in weakness, decreased motor control, sensation, and spasticity. Through disuse, an affected joint becomes less elastic and stiff and eventually contracted.
Custom orthoses	An orthotic splint or brace that has been made specifically for an individual usually by taking a mould. These usually take longer to provide patients as they have to be manufactured individually and are usually more costly than stock devices.
Foot drop	A common physical symptom of stroke, this is where the patient does not lift the distal aspect of their foot suitably during the gait cycle and so the foot will remain in a 'dropped' position. This commonly leads to the patient tripping and sometimes falling. The dropped foot is usually a result of muscular imbalance of the ankle, where the dorsiflexors are weakened following stroke.
Functional mobility	The physiological ability of people to move independently and safely in a variety of environments in order to accomplish functional activities or tasks and to participate in activities of daily living (ADL), at home, work and in the community.
Gait cycle	The gait cycle describes the cyclic pattern of movement that occurs while walking. A single cycle of gait starts when the heel of one foot strikes the

	ground and ends when that same heel touches the ground again. The cycle itself contains two phases – a stance phase and a swing phase: • Stance phase: Accounts for 60% of the gait cycle and constitutes heel strike, body weight support, and toe-off. • Swing phase: Accounts for 40% of the cycle and constitutes leg lift and non-weightbearing as the leg is swung forward in preparation for heel strike.
Leaf spring AFO	AFO Leaf Spring is an AFO designed to support flaccid drop foot. It provides a semirigid section usually down the posterior of the lower leg and under the foot to support toe clearance during swing phase. They usually have a thin flexible composition with a minimal trim line to be able to accommodate in footwear more easily.
Modular orthoses	An orthotic splint or brace that is available 'off-the-shelf' and sometimes kept in stock at orthotic departments to allow immediate provision. These devices are manufactured to 'normal' size dimensions but have options for individual adjustment to improve the fit and function for different patients. They are usually less expensive than custom devices but slightly more expensive than stock devices.
Orthotist	Orthotists are autonomous registered practitioners who provide gait analysis and engineering solutions to patients with problems of the neuro, muscular

	and skeletal systems. They are extensively trained at undergraduate level in mechanics, biomechanics and material science along with anatomy, physiology and pathophysiology. It is a protected title within the UK regulated by the Health Care and Professions Council.
Rigid AFO	A rigid AFO is an orthotic device that allows limited to no movement. They are often used in more severe situations and in conditions with some mediolateral instability. The rigid AFO allows the Three-Point Pressure System to function in the optimal way and influence ground-reaction forces.
Sagittal plane	The sagittal plane is the vertical plane which passes through the body longitudinally. It divides the body into a left section and a right section.
Step length	The distance between the initial contact of one foot and the initial contact of the contralateral foot. Normal step length is on average about 70 cm.
Stock orthoses	An orthotic splint or brace that is available 'off-the-shelf' and usually kept in stock at orthotic departments which allows immediate provision. These devices are manufactured to 'normal' size dimensions and are usually less expensive than custom devices. They can be used as a long-term prescription, as a temporary device whilst waiting for more the permanent device to be made, or to test the suitability of a certain kind of support before deciding on a longer-term prescription.

Stride length	The distance covered when two steps are taken, one with each foot from the consecutive initial contacts of the same foot such as toe-off or heel strike.
Stride time	The time taken for two steps to be completed, one with each foot from the consecutive initial contacts of the same foot such as toe-off or heel strike.
Walking cadence	Used a proxy indicator for ambulatory intensity, walking cadence differs from walking speed as it is determined by the number of steps taken per unit of time rather than distance covered. Within clinical settings, the standard measure of cadence is steps per minute.
Walking speed	Walking speed is a measure of how fast a person is travelling. It is determined by the distance travelled in unit time and within clinical settings is usually measured in metres per second.
Walking velocity	Walking velocity is similar to walking speed but its difference in definition is due to the directionality of velocity. It is usually measured within clinical settings by determining the displacement of an individual, the distance moved in a straight line or given direction from a starting point, divided by the time taken to complete the task.

Chapter One: Introduction to the research question and PhD methodologies

The provision of orthotic interventions to assist with the rehabilitation of motor deficit after a stroke is considered an important aspect of treatment for walking difficulties. The orthotist, through the skilled application of orthotic prescription, has a key role to play in helping recovery, promote mobility, optimise safety and manage secondary complications such as contractures. However, there are no agreed guidelines to direct best practice for orthotic intervention either within the United Kingdom or internationally, and therefore the delivery of orthotic interventions can lack consistency and equitability.

The studies presented within this PhD thesis have been designed to explore the optimal ways of working when delivering orthotic interventions to enhance rehabilitation outcomes and reduce complications for stroke survivors. Based upon the combined study findings the first national statements of best practice on delivering orthotic interventions after stroke have been developed.

The rationale behind the research, the research question, and PhD aims and objectives will be discussed in this chapter. The preparatory studies undertaken to develop the original research question and planned methodologies are presented in Chapter Two. The studies which have been undertaken to form the body of original work for this PhD are presented in Chapters Three, Four, Five, Six, and Seven. The impact of the Covid-19 pandemic and rationale behind the new methodologies chosen is presented in the final section of Chapter Three (3.6). Conclusions and the primary output produced from this PhD are presented in

	Chapter	Eight.

1.1 Stroke

A stroke is a serious life-threatening medical condition caused by the blood supply to part of the brain being cut off either through a bleed (haemorrhage) or clot (Ischemia). Subsequent damage to the brain can affect motor control and speech, as well as changing how you think and feel. The effects of a stroke depend on where it takes place in the brain, and how big the damaged area is (1). Stroke is a leading cause of mortality and disability worldwide and the primary cause of adult disability in the UK (2,3). Estimates predict the global burden of stroke related illness and disability is set to double by 2035 (4), at substantial individual, economic, and societal costs. Stroke is considered the largest cause of complex disability in adults (5), with two thirds of stroke survivors leaving hospital in the UK with some form of physical disability (2). Up to 33% of stroke survivors still have functional difficulties and are dependent on others one year after the stroke event (6), and similar numbers continue to live with impairment long-term (2). Reduced mobility and gait dysfunction are amongst the most commonly reported symptoms caused by stroke (2). Hemiparesis, hemiplegia, and muscle spasticity, can all contribute to difficulties affecting a patient's ability to stand, walk and perform daily activities. Where muscle imbalance and abnormal tone are present, secondary complications such as contracture can also occur with lifelong implications causing the patient pain and difficulty in performing tasks of daily living (2).

Given our understanding of the impact of stroke on movement and physical function, many stroke survivors benefit from rehabilitation therapies which promote independence, aid mobility, and prevent secondary complications (7). We also know the most effective rehabilitation starts early after the stroke event, offering the greatest opportunity for recovery (8). Therefore, the timing and mechanism for any rehabilitation delivery is important to consider ensuring optimum outcomes for stroke survivors.

Whilst the individual cost to health and quality of life for each stroke survivor is arguably immeasurable, the wider societal burden of stroke is also vast. It is estimated that approximately 34% of the global total healthcare expenditure is spent on stroke (9), with UK costs in aggregate terms up to £25.6 billion (10). Therefore, interventions aimed at reducing societal as well as personal costs and burden should be prioritised and explored in greater detail. The importance of promoting successful rehabilitation and preventing secondary post-stroke complications is significant, both for patients' ongoing quality of life and their subsequent use of health and social care services. Given the treatment of stroke accounts for approximately 5% of total NHS costs (11), interventions that promote more effective rehabilitation, maximise therapy resource efficiencies, and deter the development of costly secondary complications is of interest.

1.2 Orthotics

An orthosis is an externally applied device designed to compensate for bodily impairments and support residual function in the neuro-muscular and skeletal systems costs (12). By applying biomechanical principals, an orthosis can be used to help stroke survivors with motor dysfunction and improve the safety and efficiency of standing and walking. The number of people using orthotic devices after stroke is unknown but a report by the Foundation for Assistive Technology states that there are approximately 1.2 million orthotic users in England alone. It is also suggested that that this number should only be considered a guide and that the total number of patients benefiting from such assistive technologies is likely to be much greater (13). A further report asserts the figure is closer to 2 million (14). As a service which such large numbers of individuals interact with in the UK, the wider societal impacts are also important to consider. A report commissioned by the NHS Purchasing and Supply Agency found that for every £1 spent on orthotics, the NHS could save up to £4 (15), indicating further

investigation into prioritising orthotic service provision and potential investment are warranted.

Orthotics can help to regain and promote normal bodily movement and function, facilitating an earlier return to independence and ability to complete daily activities, as well as enabling return to meaningful activity and work in certain circumstances (16). Helping a patient to achieve functional mobility is identified as a key aim in orthotic provision (17). Functional mobility encompasses a person's physiological ability to complete a wider variety of tasks outside of just 'walking' (18). These include standing, transfers, and weightbearing in order to participate in activities of daily living (19).

Furthermore, where muscle imbalance and abnormal tone are present, orthotic splints can also prevent or reduce the extent to which contractures develop, as well as supplement therapist input between therapy sessions (20). Contracture prevention following stroke is of prime importance to stroke survivors with up to 60% developing secondary contractures and complications effecting their long-term rehabilitation and recovery (21,22). Consistent and effective orthotic intervention could complement and enhance other therapy inputs after stroke by optimising alignment and ensuring stable repeatable movements essential for motor learning (16).

The most commonly used orthosis in stroke rehabilitation to assist with gait rehabilitation are ankle-foot orthoses (AFO) with reports of use of between 22-39% within inpatient rehabilitation contexts (23–25). AFOs are specifically designed to aid in the recovery of standing and walking ability and have been found to improve gait kinematics and kinetics, walking speed, energy expenditure and reduce the risk of falls in people affected by stroke (26,27). Prioritising effective rehabilitation starting early after the stroke (8), means establishing the timing and mechanism for orthotics delivery within this context is important. Working as an adjunct to other therapy inputs to enable timely and

efficient rehabilitation, orthotics have a role to play in augmenting the stroke survivor's recovery.

The use of orthotics in motor rehabilitation after stroke has been recognised as a treatment option for many years. There is, however, widespread variation in the delivery of orthotic intervention both internationally and at a local level (28). It was identified in 2004 that there is no agreed 'best practice' for identification of patients for whom orthotic fitting would be appropriate, design of the orthosis, and timing of orthotic intervention after stroke. An international consensus conference on orthotic management of stroke patients was conducted to produce the first internationally agreed consensus evidence on this topic. However, there have been no further updates since then and no national comprehensive statements or guidelines produced for the UK. Certain reports and evidence have been produced however, which can offer insight into the importance of this clinical area and indicate the need for further guidance and recommendation.

A National Health Service Quality Improvement Scotland (NHS QIS) scoping exercise in 2007 identified the use of AFOs following stroke as a clinical improvement priority, leading to the development of best practice statements on AFO use specifically after stroke (29). Whilst comprehensive in detailing recommendations for AFO use, the statements are limited to this singular orthotic device and are restricted to application in Scotland alone. Internationally, a state-of-the-science evidence report was published in 2010 by Ramstrand & Ramstrand (30). They also focused on the use of AFO's specifically in the management of stroke related motor deficits. Their systematic review was aimed at evaluating the evidence related to the effects of AFOs on static and dynamic balance, a crucial element of functional standing and mobilising. They found positive effects on their use, though this was largely dependent on the design characteristics of the orthosis used. Rigid AFOs, akin to the type often used in orthotic provision after stroke in the UK, appeared to facilitate static balance tasks but under dynamic conditions the paper reports aspects of balance

were compromised. However, leaf spring AFOs, which allow controlled motion in the sagittal plane and are becoming more commonly prescribed within the UK, were found to facilitate both static and dynamic balance within the included studies. Similar findings were reported by Tyson et al. (27), in their systematic review and meta-analysis of the effect of an ankle-foot orthosis on gait biomechanics after stroke. They found AFOs can improve ankle and knee kinematics, kinetics and energy cost of walking in stroke survivors. A further two systematic reviews presenting the evidence of effective AFO influence after stroke on postural control and functional outcome measurements were published in 2014 (31), and 2021 (32), respectively.

Orthotic interventions in post-stroke rehabilitation go beyond just the use of AFOs. There has been a singular systematic review on the effectiveness of knee ankle foot orthoses (KAFOs) by Kobayashi et al. in 2022 which found evidence for efficacy of KAFO use in functional mobility and Activities of Daily Living (ADL) was low (33). This was primarily due to the lack of high validity and reliable trials conducted, with included studies showing poor methodological quality, missing information on patient-reported outcomes, adverse events, and limitations of management. There is also some evidence on the use of upper limb orthotic devices in enabling post-stroke rehabilitation (34–36). However, the focus of this PhD programme of work is specifically the lower limb as the primary area of the body which orthotic intervention is provided for in the UK (37).

In conjunction with this systematic review, wider scoping of the evidence was undertaken as an adjunct to understand the landscape within in which the PhD is being conducted. A report commissioned by National Health Service Quality Improvement Scotland in 2009 detailed the value of orthotic intervention following stroke, again with specific focus on the use of ankle foot orthoses (29). It stated that orthotic intervention delivered by the orthotist can be instrumental to a stroke survivor's rehabilitation, indicating that early involvement may be of benefit. The systematic review details how ankle foot orthoses can offer a number of beneficial effects when used as an adjunct to therapy inputs in the

rehabilitation of people who have had a stroke, through improvement in static and dynamic balance (38–41), ankle kinematics (42,43), and preventing plantarflexion contracture (44). Furthermore, a systematic review of the use of ankle foot orthoses in adults with hemiplegia determined that AFOs can be of significant benefit to stroke survivors (45), and a more recent similar review concluded that ankle foot orthoses aid early rehabilitation through improved walking and balance (46).

Other studies of note that were not included within the review due to methodological exclusion were the Carse et al. pre-post test experimental study (47). It found that in the small group of test subjects who were fitted with a solid ankle-foot orthosis early after stroke, there were significant improvements in walking speed, step length, and cadence when compared to walking with shoes. The most commonly used orthotic intervention post stroke, there are several systematic reviews exploring the effects of AFO use in stroke on gait (48), ankle kinematics (49), functional outcome measures (32), and postural control (31). However, none exploring the effects of an earlier application of the AFO. From one of the same research groups there is a further systematic review evaluating the effect of knee ankle-foot orthoses which is less commonly used post stroke but has a place in providing more comprehensive support stabilising the knee (33). Reflective of all the reviews which have been conducted assessing the effects of AFOs on clinical outcomes, a recent review was completed by Shahabi et al. which identified the same papers named here. It concluded that although the reporting quality of systematic reviews and meta- analyses evaluating AFO use in stroke survivors was moderate, the methodological quality of most was suboptimal (50).

Given the importance of systematic reviews in influencing practitioners, researchers, and policymakers, it is essential they use robust methodology and thus produce reliable results. This was recognised by Shahabi et al. who conducted a review of published systematic reviews and meta-analyses evaluating the effects of AFOs on clinical outcomes in stroke survivors (50). The

quality of the evidence was judged using the (Grades of Recommendation, Assessment, Development and Evaluation) GRADE method (51), and it was determined that the quality of the evidence within the included reviews was unsatisfactory. This is indicative of much of the empirical evidence within this field with small sample sizes and unclear methods detailed within study reports. In seeking to establish optimal ways of working when delivering orthotic interventions after stroke, it was important therefore that other sources of evidence were utilized. By combining findings from the existing evidence base with new original data, more well founded and generalizable recommendations can be identified.

1.3 Guidelines

Current national stroke guidelines outline recommendations in stroke treatment and delivery from prevention to rehabilitation (7,52). These guidelines act as a comprehensive roadmap for commissioners, services, clinicians, and patients to reference against and are inclusive of many different aspects of stroke prevention, management, and treatment. However, they do not make specific recommendations on orthotic involvement and intervention pathways for patients following stroke. Notably, orthotists are not currently identified as part of the core stroke rehabilitation multi-disciplinary team (MDT), and recommendations only refer to 'access to' orthotic intervention as part of the optimum stroke rehabilitation programme (52). The mechanisms to facilitate orthotic treatment and orthotist involvement are not detailed as they are for other therapy interventions, and so are open to localised interpretation. It is unclear how orthotic intervention is facilitated in different clinical settings with equity and consistency for stroke patients who require it, with anecdotal evidence suggesting variation between and within services. Given the widespread use of orthotics and the evidence of their effectiveness in improving gait rehabilitation specifically after stroke (48), it is enigmatic that there are not

clearer recommendations for the most optimal ways of working when delivering orthotic interventions within stroke rehabilitation. Further conspicuous in their absence are professionally agreed orthotic clinical practice guidelines which may then inform condition specific guidelines. Only once orthotists agree internally the optimal ways of working when delivering orthotic interventions for patients following a stroke, can more comprehensive recommendations be developed and included within national guidance (7,52).

Within stroke practice more widely, clinical guidelines for stroke rehabilitation have been highlighted as an area which needs attention and research. Agreed methods for developing, delivering, monitoring, and evaluating interventions directed at improving recovery are needed to standardise care internationally (53). A primary cause for the lack of internationally agreed guidance in the area of orthotic practice after stroke is the limitations of the existing evidence to inform such guidance. A scoping review conducted during the preparatory phases of this PhD as part of an NIHR/HEE pre-doctoral bridging award, found limited research on specialist orthotic input following stroke, and none exploring the wider role of the orthotist in delivering interventions. It found the majority of studies conducted within this field were focused on the assessment of Ankle Foot Orthoses as the primary orthotic device used following stroke. However, the findings of these studies were limited by their small sample sizes and inconsistent methods. This paucity of high-quality evidence therefore contributes to the lack of comprehensive guidance in this field.

Before guidance can be produced, there must first be an agreement of what constitutes optimal ways of working in the delivery of orthotic interventions after stroke. Efficacy in ways of working is determined by the ability to produce the desired outcome for stroke survivors. These can be clinically based, or more personal goals identified by the stroke survivor and their family. Optimum ways of working are inclusive of the wider stroke rehabilitation team and dictate the mechanism by which any orthotic intervention should be delivered to achieve

the most effective outcomes. The research questions, aims and objectives for this PhD are listed below.

1.4 Research questions, aims and objectives of the PhD

What are the optimal ways of working in delivering orthotic interventions to enhance rehabilitation outcomes and reduce complications for stroke survivors?

This PhD had five aims and objectives:

1. To identify, synthesise, and appraise the existing evidence on orthotic interventions targeted at improving or maintaining functional mobility in the lower limb early after stroke.

To achieve this, a systematic review of the literature was undertaken to provide a comprehensive synthesis of relevant evidence and a detailed foundation of existing knowledge before undertaking further work.

2. To establish a cross-section of perspectives from the expert orthotic workforce on current practice and optimum orthotic intervention in early gait rehabilitation following stroke in the UK.

To achieve this, a national cross-sectional professional survey was conducted with orthotists as experts in orthotic intervention following stroke. This survey had a targeted focus of data collection to benchmark current practice in a post-covid landscape and to identify the perceived role of the orthotist in early gait rehabilitation. It also explored the confidence, frustrations and ambitions of the expert workforce to begin forming a foundation of what optimum orthotic intervention following stroke 'looks like'.

3. To determine stakeholder perspectives on the role of orthotics in stroke rehabilitation, exploring the similarities and differences in their perception to those identified by orthotists.

To achieve this, three focus groups were conducted. Two with clinical members of the wider stroke rehabilitation team and one with stroke survivors and carers. Using a topic guide informed by the findings of the systematic review and cross-sectional professional survey, these focus groups gathered stakeholder perspectives on the role of orthotics within stroke rehabilitation focusing on early gait.

4. To converge data from the previous studies to develop proposed statements of best practice on delivering orthotic interventions after stroke.

To achieve this, a healthcare specific triangulation method described by Farmer et al (54), was used to combine the systematic review, professional cross-sectional survey, and stakeholder focus group data. This method provided a comprehensive way to highlight concurrence, recognise contradictions and note silences within the source data to inform proposed statements of best practice.

5. To refine and finalise statements of best practice through professional consensus on the optimal ways of working when delivering orthotic interventions after stroke.

To achieve this, a national eDelphi was conducted to gain orthotist consensus on the content and composition of statements of best practice on delivering orthotic interventions after stroke. Expert agreement was obtained through a two-round exercise to produce professionally ratified statements of best practice. These detail the optimal ways of working when delivering orthotic interventions to enhance rehabilitation outcomes and minimise complications for stroke survivors, as agreed by orthotic experts.

The above research question for this PhD was changed as a result of the covid-19 pandemic. The original research question was:

Can early specialist orthotic assessment lead to improved rehabilitation outcomes and reduced complications for patients following a stroke?

The work for this PhD began before the pandemic and therefore the original research question directed the initial preparatory work and systematic review study which are presented in Chapters Two and Three respectively. Section 3.6 of Chapter Three presents further details on the change of method and rationale.

1.5 Development of the research questions

Clarity on what constitute optimal ways of working in delivering orthotic interventions after stroke is needed. In forming this research question, it was hoped to achieve consensus to direct the orthotic profession and wider stroke rehabilitation team on how and when to deliver orthotic intervention in the most optimum, efficient and consistent way after stroke. Initially the focus of the PhD was centred around 'when' as directed by the preparatory work (37), but the changes to the question brought about by the Covid-19 pandemic facilitated a broadening of this question to include 'how'.

This PhD is seeking to explore the professionally agreed optimal method of delivering orthotic interventions after stroke, encompassing aspects such as timing, specialist orthotist involvement, wider engagement, and MDT working. Research is needed to draw together the views of orthotists, other stroke rehabilitation professionals, and stroke survivors in order to develop a blueprint for clinical practice and direct future research.

Through a co-design exercise with stroke survivors, carers, and other stakeholders, the research question was developed to try and explore the means and mechanisms by which orthotic intervention should be delivered for those who need it and identify the aspects which enable its optimal provision.

1.5.1 Philosophy underpinning biomechanical principles

Biomechanical principals underpin this PhD. Based on the understanding that the laws of mechanics are applicable to human movement, it is asserted that any deficit in movement can be addressed by applying mechanical forces to correct it (55). Biomechanics are at the core of orthotic training and practice and are integral to how orthotic interventions will affect stroke survivors' rehabilitation (56). Estimates suggest between 20-30% of stroke survivors experience 'foot drop' as a leading physical effect of stroke (57). Foot drop is a presentation where the patient does not lift the distal aspect of their foot suitably during the gait cycle due to muscle imbalance (58). It is a neurological complication of the stroke brain injury resulting in weakened ankle dorsiflexion muscles combined with overactive plantarflexion muscles (59). Commonly, the foot will catch on the floor during the 'swing phase' of the gait cycle and cause the patient to trip and sometimes fall. If biomechanical principals are accepted, then the application of an orthosis to correct mechanical deficits, such as foot drop, and substitute weak muscles following stroke should be explored and the optimum means of its delivery defined. This perspective aligns with positivist philosophy supporting the view where functional relationships can be derived between causal and explanatory factors and outcomes (60). Orthotic interventions applied with biomechanical principals in this way then sit in parallel with the

movement science foundations of physical therapy (61). This is important within stroke rehabilitation specifically where approaches across the multi-disciplinary therapy team should be consistent (52).

Epistemology

In order to determine the nature, origin and limits of the knowledge hoped to be gained within this PhD a pragmatist philosophical approach was taken.(62)In its essence pragmatic research is practical, and is conducted with typical patients and therapists who received and deliver the intervention in usual clinical settings (62). Key considerations within this PhD have been the need to include and address issues relevant to multiple stakeholders—patients, clinicians and teams, and wider service provision (63), recognising that any statements of best practice need to be deliverable and implementable within real-world clinical settings. This viewpoint has guided each stage of the PhD whilst aspirational thinking was encouraged within the eDelphi as the purpose was to determine optimum provision and therefore not be limited by any real-life constraints.

1.5.2 Orthotic interventions after stroke clinical guidelines

To determine the optimal ways of working when delivering orthotic interventions after stroke, the logical first step is to move towards agreement among orthotists themselves. Consensus is required to progress designing and developing interventions and standardise their delivery, followed by testing and then feeding into comprehensive recommendations.

As a substantive output, the findings of this PhD have been used to develop the first professionally agreed clinical guidance for delivering orthotic interventions after stroke in the UK. Within this context it was important to also include the perspectives of other stakeholders, specifically stroke survivors, carers, and other stroke rehabilitation professionals who work closely with orthotists.

The statements of best practice developed from the findings of this PhD body of work have been drafted using the Grading of Recommendations Assessment,

Development and Evaluation (GRADE) approach to ensure a disciplined method and reinforce the generalisability of their recommendations (51,64–102). The gold standard in clinical guidelines are internationally ratified, evidence-based best practice guidelines which provide recommendations for interventions at the point of care (51). As such, the GRADE approach facilitates the rigorous and transparent formulation of practice recommendations from evidence. Publication of a series of articles provided guidance about how to apply and use GRADE (51,64–102). GRADE has become the international standard of best practice guideline development and has been adopted by the World Health Organization (WHO), the Cochrane Collaboration, and the National Institute for Health and Care Excellence (103). Therefore, using the GRADE handbook (104), they provided the optimum framework from which to develop the UK's first statements of best practice on delivering orthotic interventions after stroke.

Due to the lack of empirical evidence in this area, it is difficult to determine decisive conclusions and formally summarise the findings, so it is advised that best practice statements are agreed as a foundation to further evaluation and refinement of principals (105). Statements of best practice begin the process of care improvement and reduction of health inequity by promoting evidence-based interventions and discouraging ineffective or potentially harmful interventions. They can also act as a benchmark for clinical commissioning and evaluation to improve the consistency of care, empower patients, and influence further public policy (106). It is reported statements of best practice should be informed by a systematic review of the evidence with an assessment of the benefits and harms of alternative intervention options (107), the completion of such a review is therefore the first substantive aim of this PhD.

1.5.3 Original methodology

This PhD was interrupted by the outbreak of the Covid-19 pandemic and as such changes were necessary to the research question and methods of enquiry. A summary of the original PhD methodology is detailed below and further specifics

of the impact of Covid-19 on the PhD are presented in Section 3.6 of Chapter Three.

The original PhD methodology had four phases of work. The first was a systematic review in order to synthesise and appraise the existing evidence on early orthotic intervention that have been evaluated following stroke. This study was undertaken prior to the outbreak of the Covid-19 pandemic and so follows the original investigation line of 'earlier' timing of orthotic intervention. Timing, and specifically earlier intervention, was identified as an important aspect of orthotic intervention delivery after stroke in the findings of the preparatory multi-disciplinary survey presented in Chapter Two. The systematic review findings are presented in full detail in Chapter Three.

Following the systematic review to establish the existing evidence on early orthotic intervention, the original PhD plan had three subsequent studies. These were a nominal group technique, a feasibility trial, and a qualitative interview study. Figure 1 presents the blueprint for the original methodology and new methodologies, detailing elements completed prior to and after the interruption of the Covid-19 pandemic. Further details on the original methods are included in Appendix A.

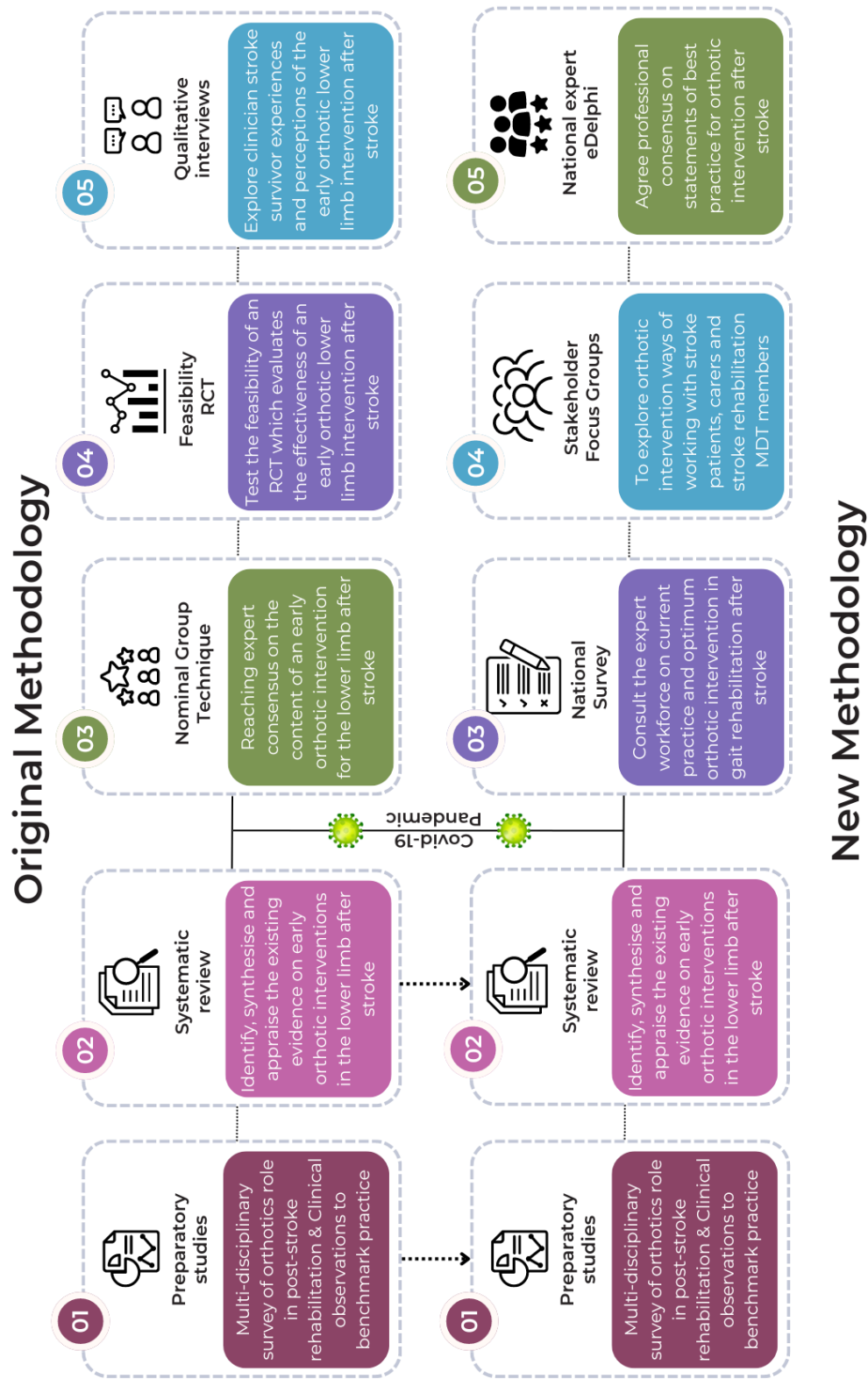


Figure 1. Blueprint for original and new PhD methodology

1.6 Mixed methods research

The revised PhD question was developed using the Medical Research Council guidance for the evaluation of complex interventions (108). These recommendations advocate the combining of qualitative and quantitative methodologies and therefore the methods chosen in the design of this PhD have been selected for their suitability and appropriateness to the answer the research question and objectives. Pragmatic rather than ideological factors have driven the methodological and theoretical perspectives for this PhD as is increasingly the case in health research to accelerate patient benefit (109).

Mixed methods research combines quantitative and qualitative data collection within a single study following the underlying principle that combining these two research approaches will provide a better understanding of the phenomena being researched (110). An explanatory sequential mixed methods approach was used within this PhD, as described by Ivankova et al. (111), characterised by the collection and analysis of quantitative data with subsequent collection and analysis of qualitative data. This second phase of data collection is informed by the findings from the quantitative phase, and its analysis offers interpretation to qualify the overall findings.

To encourage philosophical consistency across data sources, the cross-sectional professional survey findings (Chapter Four) and stakeholder focus group transcripts (Chapter Five) were analysed against the backdrop of the World Health Organisation's International Classification of Functioning (WHO-ICF) (19). This concept is a framework for describing an organising information of functioning and disability and therefore provides a foundation for the analysis of rehabilitation interventions focusing on a person's experiences of health, the impact of health conditions, and the effect of treatment on their function. The WHO-ICF provided a framework for examining the factors that may influence the existing pathways for orthotic intervention delivery after stroke from the

perspective of the patient and what effects the treatment decision making of clinicians.

Due to the global Covid-19 pandemic, face-to-face assessment or data collection was either very difficult or illegal at times during the initial stages of this PhD. Therefore, evaluative methods such as trials or cohort studies were not possible with restrictions on social interaction as well as non-covid related ethical approvals. Standardised data sets such as the Sentinel Stroke National Audit Programme (SSNAP) (112), might offer an opportunity for retrospective cohort analysis but currently no information relating to orthotic provision after stroke is collected routinely. As such, big data analysis was also not an option to generate new conclusions on what constitutes optimal ways of working in delivering orthotic interventions after stroke. It was therefore determined that a synthesis of existing evidence with further qualitative and quantitative data gathered from expert orthotists and other stakeholders, was the most appropriate method of answering this PhD research question within the confines of the global pandemic.

Key to the chosen methodologies was the completion of a national eDelphi study to reach professional consensus on the optimal ways of working in the delivery of orthotic interventions after stroke. Consensus methods offer a robust foundation for determining professional agreement on complex topic areas such as this (113). Other consensus methods such as a nominal group technique (114), were determined to be not appropriate due to the social restrictions in place, and whilst a remote option would have been available it was felt a wider cohort of experts could be included through a less time-sensitive means of data collection. Moreover, other methodologies which were considered within the programme of work were individual interviews in place of the focus groups which may have offered a more discrete perspective, but it was determined that focus groups were preferable. As orthotic intervention after stroke is delivered within the context of the multi-disciplinary team, a group discussion with different team members able to engage in dialogue and debate was considered

a superior option, which more closely mirrors interactions within healthcare settings between clinical teams.

Mixed methods research is commonly used in medical and health sciences as a means for analysing complex multi-dimensional systems and interventions (115). Their strength lies in the ability to investigate causality and effect through quantitative data collection then considering how and why things happen through the qualitative investigation. Important when applied to healthcare research, new insights can be determined by combining two approaches, leading to a broader understanding of the research question and topic being studied (109). Recommended within the Medical Research Council (MRC) framework for complex intervention development and evaluation (108), mixed methods research was well suited to answering this PhD research question.

1.7 Thesis structure

This thesis is the culmination of two preparatory studies and four substantive studies. The research findings have been combined to develop national statements of best practice on delivering orthotic interventions after stroke. The studies included a systematic review, a cross-sectional professional survey, and stakeholder focus groups, which were combined using the triangulation technique described by Farmer et al. (54), to develop the base data for final the study, a national eDelphi consensus exercise. Figure 2 depicts the different elements which make up the core PhD program of work. The rationale for the use of each of these methodologies will be detailed in each corresponding chapter.



Figure 2. Development of Best Practice Statements

Chapter Two: Preparatory studies of a national multi-disciplinary survey and clinical observations

This chapter details the preparatory work undertaken for this PhD to understand routine practice in orthotics delivery after stroke within the UK. This work was completed in the initial stages of the PhD, prior to the outbreak of the Covid-19 pandemic and so were designed in part to inform the original methodologies presented in Chapter One and Appendix A.

Development of this PhD question and proposed study began in 2017, directed by clinical experience and patient feedback, it was identified that further understanding on current practice was needed. Following the Medical Research Council original framework for developing complex interventions, key elements of the development work focused on: identifying the evidence base and benchmarking current practice (116).

Working with experienced clinical colleagues, stroke survivors, and carers through a co-production exercise the importance of establishing a benchmark of current practice was agreed. Funding was secured through a Nottingham City Clinical Commissioning Group - NIHR Research Capability grant to develop and conduct the first national multi-disciplinary survey on the role of orthotics within stroke rehabilitation. The findings from this study were instrumental in directing the original PhD research question and methodologies proposed. Details on the methodology and findings of this study are presented below.

2.2 Orthotic intervention following stroke: An inter-professional survey of physiotherapist, occupational therapist and orthotist practice and views in the UK

As part of the development of the original PhD research question, a study was conducted across 2018-2019 to investigate the views of orthotists, occupational therapists, and physiotherapists as the key members of the physical function stroke rehabilitation team (37).

The UK's national clinical guidelines recommend 'access to' orthotic intervention as part of the stroke rehabilitation programme (7,52), but the mechanisms by which this should be facilitated are unspecified. Within the UK it is usual practice for a team of stroke specialist therapists to deliver rehabilitation to stroke survivors both in the hospital and the community. Currently the orthotist is not a named member of this stroke rehabilitation multi-disciplinary team (MDT) (7,52), and so other team members, such as physiotherapists and occupational therapists, often act as the gateway to orthotic assessment and the provision of orthoses. To better understand the factors that direct orthotic management of stroke patients within the UK, it was important to consider the collective perceptions and practices of the different stroke rehabilitation therapists together.

2.3 Background

An understanding of the perceived current role orthotics and the orthotist have in post-stroke rehabilitation as well as a benchmarking of current practice was needed to establish how relevant this area of research was to stroke survivors and the clinicians who work with them. Specifically, a more detailed appreciation of the delivery mechanisms and relationships which facilitate orthotic intervention was required to inform future studies.

As part of the development of the original research question, the lead researcher worked with the Nottingham Stroke Research Partnership Group (NSRPG). This is a group of stroke survivors and carers who work with stroke researchers from the University of Nottingham. They work collaboratively to ensure research design involves stroke patients and carers and is informed by their needs and wishes. The NSRPG supported a proposed baseline survey to gather more details on the perspective of stroke therapists in the UK and to act as a benchmarking exercise for practice.

Post-stroke rehabilitation is usually delivered within an MDT within the UK (7,52). It was therefore determined to be important to gather the perceptions of physiotherapists and occupational therapists, alongside orthotists, as key members of the rehabilitation MDT who are involved with orthotic provision decision making. Physiotherapists and occupational therapists often have an influential role in acting as the gateway to orthotic referral and assessment. At the time of the study being completed, no research had been conducted exploring orthotic referral and provision norms. The views of physiotherapists and occupational therapists as the experts in post-stroke rehabilitation therapy, had also never been considered or analysed in parallel with those of the orthotist.

To benchmark current practice and gather the combined perspectives of physiotherapists, occupational therapists, and orthotists on the role of orthotics and the orthotist in post-stroke gait rehabilitation, a national multi-disciplinary survey was conducted.

2.4 Methodology

This multi-disciplinary survey study was developed in accordance with the Consensus-Based Checklist for Reporting of Survey Studies (CROSS) (117).

This method was selected as a means of gathering and analysing data across a sample population at a specific time point. It was therefore ideal for using to benchmark phenomena like practice and perception. It also allows a geographically diverse sample population and is a relatively low burden method of data collection for the participant thus increasing likelihood of participation. Other methods of data collection were considered such as in-person individual and group interviews with clinical teams. Whilst potentially offering richer data findings, with the opportunity to go into more depth than with a survey, interviews would have been more time consuming and restrictive geographically. Whilst in a post-Covid world, online interviews are far more common-place, at the time this study was being undertaken, in-person was much more the accepted method. This would have restricted interviews to within a much smaller geographical area than the responses that were gathered through the multi-disciplinary survey that was conducted. The CROSS checklist used to develop the multi-disciplinary survey study protocol is presented in Appendix B.

2.4.1 Development of the survey

The survey questions were developed by the lead researcher with the input of stroke clinicians including an orthotist, physiotherapist, and occupational therapist, as well as stroke clinical academic researchers who have experience conducting similar survey studies. The survey was administered online using the Microsoft Forms platform and the survey link was distributed via email mailing lists. Launched in two phases for practicality, it was live from July–August 2018 and May–July 2019. It consisted of 21 questions, comprising nine multiple choice, 10 free-text, and two Likert scales. A text version of the questionnaire can be found in Appendix C.

Questions were organised into nine topic areas of interest:

- Length of time qualified and setting of employment
- Clinical setting and frequency of contact with stroke patients

- Usual referral routes and practices for orthoses provision
- Common clinical presentations of stroke patients
- Common orthotic prescription
- Timing of referral and orthotic intervention
- Barriers and facilitators to orthotic intervention
- Orthotic influence on rehabilitation goals
- Orthotics place in the stroke rehabilitation pathway

Piloting

The questionnaires were initially piloted with local orthotists, physiotherapists, and occupational therapists with feedback actioned prior to national circulation. The survey link was shared with the stroke rehabilitation team and orthotic department at a single hospital trust with critical feedback welcomed. Subsequent changes from this feedback included alterations to the format of the questions, addition of more free-text response boxes, and the option to save and return. Specifically, more opportunity to respond without a prescribed set of options was deemed important to ensure suitable opportunity for respondents to express their perceptions as well as benchmarking current practices. Following this initial piloting, the survey was also piloted by members of the Research Committee of the British Association of Prosthetists and Orthotists (BAPO).

2.4.2 Ethical considerations

The study was reviewed and given favourable ethical approval from the University of Nottingham, Faculty of Medicine & Health Sciences Research Ethics Committee (FMHS 287-1803). Letter of favourable ethical approval is presented in Appendix D. An electronic Participant Information Sheet (PIS) was provided to all potential participants upon approach via an email invitation and was also linked to on the landing page of the survey. The study PIS was developed by the lead researcher following the format required by the host institute sponsor. Consent was confirmed by selecting yes to consent statements prior to being

able to access the survey questions. Following consent, participants were also required to confirm self-assessed eligibility before entering the main section of the survey. Copies of the PIS and consent forms are presented in Appendix E.

The study was reviewed and approved by the British Association of Prosthetists and Orthotists Research Committee, the Association of Chartered Physiotherapists Interested in Neurology – Stroke interest group, and the Royal College of Occupational Therapists – Specialist Section for Neurological Practice survey review panel, who each assess the suitability and applicability of research to their members prior to circulation.

2.4.3 Data collection and management

This web-based survey was developed using Microsoft Forms as a free to use application which was approved by the host institution and likely familiar to participants as popular survey platform. The study was designed to take five minutes to complete and had a save and return option. Survey responses were anonymised and stored on a password protected spreadsheet which was hosted on secure dedicated University of Nottingham web servers. Access was restricted to only the lead researcher using their personal identifier login with password in accordance with established information governance and data protection guidelines (118). No identifiable information was collected on the digital survey application, with each participant assigned a unique personal identification number.

2.4.4 Recruitment of participants

Eligible participants were identified through their membership of a professional body namely: The British Association of Prosthetists and Orthotists (BAPO) (n=450), Association of Chartered Physiotherapists Interested in Neurology – Stroke interest (ACPIN) (n=1077), and the Royal College of Occupational Therapists – Specialist Section for Neurological Practice (RCOT-SSNP) (n= 952). All professional body members were contacted via a distribution email and potential participants were required to select whether they work with stroke

patients and met the inclusion criteria at the initial stage of the survey. Participation was voluntary and all responses were collected and stored anonymously.

Eligibility criteria

Eligible participants were qualified, Health & Care Professions Council (HCPC) registered physiotherapists, occupational therapists, or orthotists, with specific post-qualification experience of working within stroke rehabilitation. HCPC registration is a requirement to be a member of the specified professional bodies and further eligibility was self-determined.

Whilst it is usual for physiotherapists and occupational therapists to specialise within neurology and thus have regular contact with stroke patients, this is not the case with orthotists who tend to remain more generalist in their professional occupation. Therefore, it was determined not to put a specific neurology specialism requirement within the eligibility criteria. Instead, participants were asked to self-determine and confirm post-qualification experience of working with stroke patients. For the same reason, the distribution of the invitation email and survey link was sent to the full mailing list of BAPO whereas neurology specific sections of the physiotherapy and occupational therapy professional bodies were targeted.

Inclusion criteria

- Be HCPC registered physiotherapist, occupational therapist, or orthotist.
- Have self-determined post-qualification experience of working with stroke patients.
- English reading comprehension and writing ability.

2.4.5 Data analysis

Data were exported to Stata SE Version 13 with consultation from a statistician. Descriptive statistics were used to summarize and present the demographic

characteristics of the participants, the frequency of responses to dichotomous questions, and the distribution of responses on Likert style response scales.

A qualitative narrative review of the free-text response data was also conducted. This method was chosen over more structured options such as thematic analysis as a simple means of data visualization. This approach would allow an enhanced understanding of the open-ended question responses to compliment the broader narrative derived from the quantitative data (119). As a benchmarking exercise, it was determined that it was important to retain as much of the data in its original form during the analysis stage so not to dilute individual experiences within thematic framework. Driven by interpretive inquiry, a narrative analysis allowed an unravelling of the essence of what was being conveyed collectively by respondents without losing any individuality of experience.

As described by Riessman (120), the lead researcher immersed themselves within and consolidated the data by reviewing each of the responses individually and collectively using Microsoft Excel software. Data were then categorised using inductive coding with the codes developed according to emerging topics from within the data extracts. Coded segments from within the data set were then separated into three pre-defined topics determined inductively from the survey question sections: 1. Barriers and facilitators to orthotic intervention; 2. Orthotic influence on rehabilitation goals; 3. Orthotics place in the stroke care rehabilitation pathway. These constituent topics were reviewed and validated by a second and third reviewer from the supervisory team through collective discussion and agreement. Selected illustrative quotations which are felt to provide the most representative insight of the themes are included within the findings.

2.5 Findings

A total of 305 questionnaires were completed, from 64 orthotists (14.2% of target population and 21% of combined professional sample), 131 physiotherapists (12.2% of target population and 43% of combined professional sample), and 110 occupational therapists (11.6% of target population and 36% of combined professional sample).

2.5.1 Quantitative data

The total number of responses for each question varied and therefore 'n =' is included within each table. The survey results tables are presented in Appendix F.

Participant demographics (length of time qualified and setting of employment)

Length of experience ranged from less than one year up to 50 years. The overall mean years qualified was 15.88 (SD 9.79). There was also a spread of clinical seniority with respondents working in a range of clinical settings. Overall, 75% (n=230) of respondents were employed by the National Health Service (NHS) in the UK, however, 41% (n=26) of orthotists reported working for private companies providing NHS clinics (a common arrangement that many NHS orthotics services have where they are contracted out to private industry). The clinical role characteristics of the participants are presented in Appendix F, Table i.

Clinical setting and frequency of contact with stroke patients

Over two thirds (65.5%) of the physiotherapist and occupational therapist respondents reported they see 'more than one stroke patient a day' in their usual clinical caseload (n=156), whereas the most popular option (36%) for orthotists was 'several times a week' (n=23). Only 11 orthotist respondents reported seeing a stroke patient within the first week after stroke, with the majority of contact reported as being 'between 2-6 months' (n=46) and 'between 6-12 months' (n=37) after stroke, or 'later in rehabilitation' (n=47).

Conversely, physiotherapy and occupational therapy respondents reported they would see stroke patients at every stage following the stroke event with far greater levels of contact earlier on in rehabilitation. Clinical setting and caseload of the participants are presented in Appendix F, Table ii.

Usual referral routes and practices for orthoses provision

Thirty-eight percent (n=89) of physiotherapy and occupational therapy respondents reported that they consider orthotic intervention to be potentially beneficial for 60% of stroke patients. However, it was reported only 16% (n=37) of those patients would always be referred for orthotic intervention. It was also noted that physiotherapists are the predominant source of orthotic referrals across all settings. Referral patterns and practices for participants are presented in Appendix F, Table iii.

Common clinical presentations of stroke patients

Respondents were asked to report the frequency they would assess common clinical presentations in their stroke patients using a Likert scale of; 0 = 'never seen' up to 5 = 'seen very often'. The mean scores (n) for all respondents indicated the most prevalent were: Muscle paralysis (upper or lower limb) (5); Walking fatigue/difficulty mobilising (5); Shoulder/upper limb weakness (5); Foot drop (flaccid) (4.5); Shoulder/upper limb (spasticity) (4); Foot drop (spastic) (3.25); Positional or contracture problems (3.25). Cognitive and perceptual issues (4.5) as well as speech and language difficulties (4.75) were also reported as commonly seen by all survey respondents.

Common orthotic prescription

Fifty-four percent (n=124) of respondents reported the area of the body most commonly requiring referral for orthotic intervention was the 'Lower limb (foot/ankle)'. Correspondingly, orthotists reported the device they most commonly prescribed was a 'Custom made' Ankle Foot Orthosis. Orthotists also reported that they were more likely to prescribe custom made orthoses (51%;

n=31) rather than using stock (37%; n=22) or modular devices (12%; n=7). Please see the Glossary table for further details on these types of orthoses. Areas of the body that most commonly require orthotic intervention in stroke patients are presented in Appendix F, Table iV.

Timing of referral and orthotic intervention

The ideal stage for initial orthotic assessment was identified as within the 'First few days/before hospital discharge' (54%; n=153), compared to when most patients actually receive orthotic intervention, 'Whilst under community care or later in rehabilitation' (45%; n=127). Thirteen respondents reported their stroke patients would 'rarely/never' be seen by an orthotist. Referral practices for participants are presented in Appendix F, Table V.

2.5.2 Qualitative data

Survey respondents were asked seven free text questions to explore their perspectives on different aspects of orthotic intervention. Illustrative quotations are included below.

Barriers and facilitators to orthotic intervention

The main barriers identified were delays in orthosis provision and organisational blocks to referral and multi-disciplinary working. Facilitating factors to successful orthotic intervention were reported as earlier and closer working between the orthotist and the wider stroke rehabilitation MDT.

Eighty three percent of physiotherapist (n= 108) and 73% of occupational therapist respondents (n=80) reported experiencing delays when they have referred stroke patients for assessment by the orthotist. The mean average wait for an inpatient orthotic assessment was stated as 2-3 days and for outpatients between 4-6 weeks. This wait was reported to be up to one year in some areas. With earlier discharge practices following stroke becoming more commonplace in the UK (121), it was raised by respondents that delays in initial assessment

before discharge could have a negative impact on a patient's ability to rehabilitate.

"Delay in [orthosis] provision impacts negatively on patient's rehab and also on their long-term function, e.g. increased risk of developing deformities. You sometimes have to stop the rehab and start again weeks later once they have their orthosis." (Physiotherapist, participant 180)

Orthotists described how they felt the same delays in their involvement impeded their ability to treat patients, resulting in lost opportunities for enhancing rehabilitation. Physiotherapists and occupational therapists mirrored this frustration in describing how they felt earlier orthotic input could lead to improved patient outcomes.

"We can do more but we are not being involved early enough. We are asked to get involved only when problems arise." (Senior Orthotist, participant 271)

"I feel [orthotics] is vital and often underused by physios. Early effective orthotic input can maximise early patient recovery." (Senior Physiotherapist, participant 136)

Organisational barriers to the referral process were noted with many respondents unable to refer directly to orthotics services. Four of the physiotherapist and occupational therapist respondents reported having never referred to an orthotics department and did not know how.

"Therapists are unable to directly refer so must refer via [General Practitioner] to consultant, and then consultant to orthotics." (Senior Occupational Therapist, participant 35)

"I have never met an orthotist and don't know how to refer for one. It would be great to have an orthotist working with the rest of the stroke MDT." (Occupational Therapist, participant 55)

Orthotic influence on rehabilitation goals

Respondents were asked to identify the rehabilitation goals they felt orthotics intervention has the most impact on or potential to influence. Examples given were: 'Improve mobility'; 'pain reduction'; 'contracture/subluxation prevention'; 'promote participation in Activities of Daily Living (ADLs)'; 'facilitate cardiovascular exercise'; 'improve independence (to include emotional impact of this)'; 'reduce risk of falls'; and 'augment other treatments'.

"[Orthotics can] Improve quality of life, reduce long term disability and dependency on care and health services, enable participation and improve confidence and motivation." (Clinical Lead Physiotherapist, participant 84)

Orthotics place in stroke rehabilitation pathway

Physiotherapist, occupational therapist and orthotist respondents, reported how they felt orthotics intervention has a key role to play in the stroke rehabilitation pathway, though only 17% (n=52) felt that current provision was adequate. A recurring theme within the responses was the desire to improve orthotic interventions with increased access to orthotists and closer joint working within the MDT at all stages of post-stroke rehabilitation.

"Quicker and easier access to orthotics could assist in speeding up the rehab process. Prompt and close joint working with orthotists would be hugely beneficial to our patients." (Occupational Therapist, participant 34)

Respondents highlighted the lack of consistent clinical pathways to guide orthotic treatment and how this is leading to health inequalities.

"We need to increase funding for orthotic services and agree pathways to access orthotic treatment nationally.... orthotic management is integral to all aspect of the stroke pathway when there's any motor

impairment impacting on alignment and our patients are being let down.” (Consultant Neuro-physiotherapist, participant 115)

Overall, there was agreement between orthotists, physiotherapists and occupational therapists with an expressed desire to see swifter more efficient interventions and collaborative working within the wider stroke MDT. The most consistent message across respondents was the issue of poor consistency to access and involve orthotic intervention within stroke treatment plans. Physiotherapist and occupational therapists’ respondents specifically raised how unclear pathways and limitations with access due to low numbers of orthotists and lack of joint clinics were restricting factors in their clinical practices. The survey findings as the first multi-disciplinary survey on the role of orthotics and the orthotist in post-stroke gait rehabilitation have been published in a peer reviewed journal (37).

2.6 Discussion

The results of this survey highlight the important relationship between physiotherapists, occupational therapists and orthotists in orthotic intervention and provision post stroke. Unsurprisingly, physiotherapists and occupational therapists as named members of the stroke rehabilitation MDT (7,52), reported much closer working with stroke patients, often based within stroke specific teams either in the community or within acute hospital settings. The consensus amongst physiotherapists and occupational therapists was found to be that orthotic intervention was potentially beneficial for the majority of patients, however barriers to referral and access appeared to influence how many of patients would actually be assessed for an orthosis. Muscle paralysis and walking fatigue/difficulty mobilising reported as the most commonly seen physical effect of stroke by therapists correlates with data from the Stroke Association (2). This also correlates with the finding that orthotists are most likely to prescribe an

Ankle Foot Orthosis, with the lower limb (ankle/foot) being the area of the body most often requiring orthotic intervention.

Timing was identified as an important factor influencing orthotic intervention for stroke patients, with waiting times perceived to have a negative impact on overall rehabilitation success following stroke. The disparity between the perceived ideal time-point for initial orthotic assessment and intervention, and the actual time-point is of particular interest. This is of further significance with the move to earlier discharge practices in the UK and increased use of community rehabilitation provision through Early Supported Discharge (ESD) teams (121).

Difficulties in access to orthosis provision was a recurring theme exacerbated by lengthy waiting lists impacting on overall rehabilitation outcomes. It has been highlighted that stroke patients who may benefit from orthotic assessment are being missed, with referrals only being made much later in their rehabilitation. Further research is needed to identify the optimal time for initial orthotic assessment and intervention following stroke and the pathways in which orthotic intervention is facilitated. There are indications within the literature to support earlier orthotic intervention in enhancing the effect of other therapies, promoting more successful rehabilitation, and offering a prophylactic effect on complication development (16,20,28). The results of the survey reinforce this by identifying the optimal time point for orthotic assessment as being perceived to be within the 'early' window of treatment, in line with other MDT assessments (52). Moreover, earlier, and more efficient orthotic intervention for stroke patients has the potential for wider reaching cost-saving implications given that it has been reported for every £1 spent on orthotics service improvements, the NHS could save up to £4 (15).

Strengths and limitations

The results of this survey offer important insight into orthotic intervention practices following stroke in the UK. However, there are certain limitations to be

recognised. The targeted participants were drawn from only three professional bodies and the voice of stroke survivors and carers is not included in this narrative. As the purpose of this survey was to benchmark current clinical practice and was focused on collecting professional perspective, it was decided not to extend the data collection to include stroke survivors and carers. However, the survey was developed with their explicit input and the findings shared with the Nottingham Stroke Research Partnership Group. This served as an important means of ensuring the key findings from the survey used to determine the PhD research question, were aligned with the lived experiences and research priorities of stroke survivors and carers.

This survey had a higher response rate from physiotherapy and occupational therapy colleagues than orthotist colleagues perhaps reflecting the far greater professional numbers of physiotherapists and occupational therapists practicing in the UK, approximately 50,000 physiotherapists, 40,000 occupational therapists, compared to just 1000 prosthetist/orthotists. Responses from other health care professionals working with stroke rehabilitation would likely strengthen the findings, and a more detailed exploration of the orthotist's perspectives and practices would be of interest. A further limitation is the subjectivity of the language which forms the answers to some of the fixed survey questions such as 'quite frequently' or 'several times a week'. Such language has no definitive definition allowing greater interpretation by each respondent but also adding a challenge if repeating the survey. Through the piloting of the survey with clinical colleagues, these options were approved as deemed appropriate and understandable definitions for clinicians from a spectrum of clinical backgrounds and experience levels.

As the survey was exploratory in nature the analysis has been primarily descriptive, and so no definitive conclusions can be drawn. The cohort of respondents is a very small representation of the wider stroke rehabilitation workforce within the UK, and those who responded are likely to be self-selecting as clinicians who are involved with or interested in orthotic management

following stroke. A wider distribution of the survey link through professional and clinical networks targeting all professional groups within the stroke rehabilitation team would likely result in a more diverse response. This could be considered in a future study which revisits the findings at a later time point. The core research team who developed and analysed the survey is made up of an orthotist and two occupational therapists who are likely to be influenced by their clinical experiences of orthotic interventions. However, to address this, the survey was piloted and finessed with a wider group of stroke therapists and clinicians and approved by an established stroke research patient and public engagement group (The Nottingham Stroke Research Partnership Group), who supported its distribution and welcome its findings.

2.7 Conclusion

The findings from this survey highlight the perceived importance of the role of orthotists and the delivery of orthotic intervention in the stroke rehabilitation pathway. However, significant challenges and barriers to efficient and effective delivery were described. Specifically noteworthy was the difference between the perceived optimal time point for orthotic intervention and the actual, as well as the significant disparity in access to orthotist assessment across the country. Difficulties with poorly defined pathways and inconsistent orthotic expertise presence as highlighted within the narrative review likely contribute to this disparity. Orthotists spoke of these delays contributing to a pattern of assessment occurring later in a stroke survivor's rehabilitation, which can then contribute to the development or worsening of secondary complications such as contracture. These factors can then lead to the requirement of more difficult, invasive, and costly interventions.

The findings from this survey suggest a perceived importance of orthotic intervention in the stroke rehabilitation pathway. However, there are challenges and barriers to efficient and effective delivery. Given our understanding of the

potential for orthosis use in aiding mobilisation after stroke (29,30,46,122–124), stroke survivors may benefit from swifter and more efficient orthotic intervention in augmenting other therapies and aiding their overall recovery. Evaluative studies exploring the optimum timing and benefits of orthotic intervention as well as the intimacy of the orthotist's relationship with the stroke rehabilitation team are needed. Ensuring health equality for all stroke survivors, affording them the same level of rehabilitation input regardless of where they are in the country must be a priority. Presently there is a gap in the evidence base with which to authoritatively inform practice in this area.

With much of stroke rehabilitation directed by clinical guidelines (7,52), the lack of agreed best practice for orthotic intervention after stroke is noticeable. Currently there is a gap in the evidence base with which to authoritatively inform clinical practice in this area and further work is warranted to expand on the preliminary findings of this survey.

2.7.1 Directing the PhD research question and methods

The findings from the survey are an important indication of practice and perspectives within the stroke specialist rehabilitation workforce on an under researched and poorly understood clinical area. The original and new PhD questions were developed using the original and revised Medical Research Council guidance for the evaluation of complex interventions (108,116), and were directly informed by the findings from this survey. Benchmarking current practice and gathering a multi-disciplinary clinical perspective on the role of orthotics within stroke rehabilitation ensured the original research question was embedded within clinical experience. This indicated that 'when' was an important consideration. Similarly, focusing on the narrative interpretation of the data, the revised research question encompassed the important element of 'how' orthotics intervention is delivered in post-stroke rehabilitation.

In seeking to establish the elements which influence timing of orthotic intervention (initial research question), and then subsequently optimal ways of

working (revised research question), it was felt important to explore the context within which research would be conducted. As such, clinical observations were conducted as part of a service evaluation of the host orthotics department where the feasibility study within the original research plan was due to take place. The findings from this preparatory inquiry subsequently informed the contextual aspects of the proposed statements of best practice which were formed following the PhD research question revision and change to methodology.

2.8 Clinical observations within existing acute and community stroke and orthotic services

Primarily conducted as a means of establishing local practices within which the planned feasibility study to inform the study intervention and protocol, an observation of orthotic and stroke rehabilitation clinical services was completed. This was determined as an important way of ensuring applicability to local context and refinement of the planned study protocol, as well supplement the findings from the multi-disciplinary survey. The combination of both preparatory studies provides a more intimate and layered understanding of the phenomena under investigation, and the combination of different research methodologies aligns with the recommendations of the MRC framework for the evaluation of complex interventions (108,116).

Clinical observation within a service evaluation, provide the opportunity to capture and assess the processes and outcomes from a particular provision or pathway (125). This preparatory method of inquiry, therefore, was an important means of capturing and defining current practice within an orthotic and stroke rehabilitation service, by seeing actions and behaviours within their natural context. As a complex intervention, specialist orthotic intervention following stroke will be influenced by human and behavioural factors as well as localised departmental practices (126). Therefore, a method which facilitates

understanding of persons actions and experiences, and contextualises the processes within a department or service, lends itself well to exploring this area of interest (127). Importantly, this study also augments the findings from the multi-disciplinary survey, elucidating on the results within a defined clinical context and therefore strengthening the overall conclusions and subsequent PhD research questions and methods of enquiry (125). Human behaviour is difficult to study, especially within a professional context where perception of competence and appropriate performance are likely concerns of those being observed (125). As such, interviews or surveys are susceptible to self-report bias and limited to what participants are willing to share (128). Whilst a degree of social desirability is expected and will likely affect the findings within observation methods, they still offer an instructive and interpretive means of data collection (125). Particularly relevant for examining organization and structures of healthcare delivery, the clinical observation was complementary to the multi-disciplinary survey for informing the PhD research questions and originally planned feasibility RCT protocol.

2.8.1 Aims of the inquiry

It was important to ensure a good understanding of how stroke and orthotic services are provided and operationalised within the local context. This was intended as important preparatory work for the proposed feasibility RCT to build relationships with the host site and gain a clearer understanding of their practices as the protocol was being developed. Observation of usual practices within the orthotics department, stroke inpatient sub-acute and rehabilitation units, and community stroke team was planned. The purpose was to capture and assess the processes and outcomes from a particular clinical pathway for orthotic intervention provision after stroke. By observing a patient pathway at multiple timepoints from acute poststroke to longer-term community follow-up, it was intended to follow a patient's typical journey and capture the influencing factors which determine the decision making and subsequent processes within this setting. Moreover, by becoming embedded within these clinical teams for

snapshot observations over the period of a several weeks, it was intended to gain a clearer understanding of how stroke patient referrals are made, triaged and acted upon. This was important localised context to inform the study protocol for the planned feasibility RCT. Within the revised PhD question, the findings of this inquiry informed the context for the proposed statements of best practice to ensure applicability within real world clinical settings.

2.9 Methodology

The clinical observations took place over the course of three months prior to the outbreak of the Covid-19 pandemic. They were conducted as part of an on-going service evaluation for the local orthotic department, which was observed alongside the corresponding trust sub-acute and rehabilitation stroke units, and community stroke rehabilitation service. Observation techniques used included:

- Shadowing – Following stroke specialist clinicians over the course of 2-3 days each and creating field notes recording their activities, interactions, and decision-making processes.
- Observing group behaviour – Attending core team and multi-disciplinary team meetings and creating field notes on how patient treatment plans are decided.
- Observing patient journeys – Observation and audit of individual patient's journey by review of clinical notes looking from referral to receiving any orthotic intervention.

2.9.1 Data collection and management

Data collection consisted of observation of clinicians, administrators, and patients when shadowing clinical colleagues, as well as review of clinical notes and referral practices within the orthotics department and linked stroke teams. The observations were recorded as reflections within field notes and analysed using a modified version of grounded theory (129). As described by Glaser et al.

(130), and Martin et al. (129), this inquiry involved an iterative process of data gathering through memoing and mapping observations.

Daily recorded notes from each of the observation sessions were scanned and uploaded onto secure University of Nottingham dedicated webserver. No identifiable data was gathered and access to the uploads was restricted to only the lead researcher using their personal identifier login with password. The observation techniques described were undertaken across both inpatient and community settings. Care was taken to ensure the researcher did not influence clinical proceedings to reduce impact on clinical outcomes but also to limit the effect their presence may have on the behaviour of those being observed.

2.9.2 Ethical considerations

The lead researcher is employed by the observed orthotic service and so has appropriate approvals to observe colleagues and patients. This observation was completed under the remit of a wider service evaluation being undertaken within this orthotics service and so no formal ethical approvals were sought. All observations were undertaken with the explicit permission of those being observed, including patients. Field notes were made anonymously and then destroyed following their upload to the secure webserver.

2.10 Findings

Findings from this observation inquiry took the form of field note reflections which were designed to help guide the development of the feasibility RCT protocol. After the change in PhD question following the outbreak of the Covid-19 pandemic, these findings were then used to inform the contextualisation of the statements of best practice developed from the overall PhD findings. No formal analysis was undertaken of the clinical observations as they were not intended to constitute a standalone study. An overview of the reflections made by the researcher are presented below.

Inpatient setting

The observed stroke unit is based within an NHS trust which hosts the largest trauma centre in England. As such, they admit a large number of suspected and confirmed stroke patients not only from the local area but also the wider geographical region. The stroke provision is split across several wards: hyper-acute, sub-acute and rehabilitation. The hyper-acute ward receives about 80% direct admissions with 50% of patients then discharged directly home and 50% transferred to another ward.

There is very limited need for orthotic intervention on the hyper-acute ward with the primary purpose to confirm stroke diagnosis and ensure patients are medically stable. However, outcome measures that are relevant to orthotics are completed with patients in this setting. For example, all patients complete the BARTHEL scale (131), which assesses physical disability based on 10 activities of daily living, the Swedish PASS (132), which is an outcome measure specifically designed to assess and monitor postural control after stroke, and all patients who were medically safe and able to stand complete the BERG balance scale (133), which determines a patient's ability (or inability) to safely balance during a series of predetermined tasks.

Physiotherapy, Occupational Therapy, and Speech and Language Therapy meet daily with the medical team to discuss new admissions and go over current patient needs. It is at this MDT meeting further referral and assessment needs are determined and decisions made on whether patients will be discharged or transferred to the sub-acute and rehabilitation wards. It was evident that at that time there was a drive to discharge patients direct to home. Analysis of recent discharge patterns demonstrated the tendency for stroke patients to stay in the acute hospital setting for much less time (average 7-14 days) (134,135), than would have been considered normal 20 years ago (average 40 days) (136), and even 10 years ago (average 20 days) (134,137). These changes to discharge practices will likely have considerable influence on the way orthotic

interventions are initiated and provided with the move away from in-patient care to more community dominant provision. The stroke rehabilitation ward at the trust was similar in their move towards quicker home discharge practices, with very limited rehabilitation beds (approx. 20). The majority of stroke rehabilitation provision within the district this trust serves is given within Early Supported Discharge (ESD) services at patient's home/care home setting.

Physio-led, the clinicians on the rehabilitation ward reported they perceived the orthotic need of the patients at this stage was still limited. However, several patients reviewed during observation were using an orthotic device to aid rehabilitation, specifically standing and mobilising. Patients received physio input between 4-7 times a week with emphasis on walking retraining and focus on discharge. The team reported a good relationship with the orthotic department (specifically the clinical lead orthotist) which was consistent with reports from the orthotics team. A good working relationship with ease of communication between services was evident within this trust. Open lines of communication with named individuals within the stroke rehabilitation and orthotic teams was felt to contribute to timely and effective orthotic provision and review of patients for whom orthotic intervention was determined as being required. For those patients, the orthotic assessment was regularly conducted jointly with the referring clinician, usually a physiotherapist. This method of joint assessment appeared to validate the orthotist to the patient serving to establish a cooperative relationship between clinician and patient for the future.

A recent change in practice locally had seen all orthotic in-patient referrals assessed by an orthotist within 24 hours (72 hours over the weekend). As a result, all stroke orthotic referrals were addressed very speedily with custom items given priority. With the on-site workshop able to manufacture orthotic devices, this allowed for a seven day turn around which is faster even than the recommended lead time for manufacture (10 days) (138), and much faster than has been recorded at other trusts nationally (139).

Community setting

Links between the acute hospital stroke teams and the community stroke teams were observed as being strong. This was evidenced by each week a link physiotherapist attending the stroke rehabilitation ward to meet transitioning patients who were getting ready for discharge. This served as an opportunity to meet patients, introduce themselves, and get up to speed on their individual rehabilitation needs and progression. The information gathered was then relayed to other members of community stroke team at a weekly case conference meeting. All elements of the individual patient's rehabilitation and social care needs were discussed at these meetings with decisions made about further referral requirements. Orthotic assessment referrals were made quite frequently (approx. four a week), and where possible the referrer would attend assessment at the acute hospital outpatient clinic. General understanding of orthotics seemed to be person specific with some therapists not sure of how to involve the orthotic team and others regularly in communication with named orthotists. This is reflective of the findings from the multi-disciplinary survey conducted (37). There was a consensus amongst the therapists that there would be benefit from an orthotist attending the weekly case conference meeting and joining the community team once or twice a week. It was felt this would expedite assessment and provision as well as encourage knowledge exchange between the professions.

Patient journey

Observation from a patient's perspective highlighted the delays present in the current system. An example was a gentleman who was seen initially for an orthotic assessment whilst an in-patient on the sub-acute ward before discharge. His discharge was then expedited due to bed shortages. As the patient continued their ESD rehabilitation with the community stroke team, his orthotic needs changed, and whilst the original orthotic was now available it was no longer suitable, and a new referral was required. At this stage the referral was

triaged within the orthotic outpatient clinical service which at the time had a waiting list of 6 weeks.

For this patient a joint home assessment would have been beneficial to observe him navigating his home environment and to see the challenges this presented as well as observing the limitations of the existing orthotic device. At the time of observation, no home assessments were offered by the orthotic service. This patient had his assessment conducted within a standard clinic room at the acute hospital site. This assessment was not attended by his physiotherapist and so there was no opportunity for joint input. Additionally, the wider picture was likely missed within that appointment, as on visiting this patient with the community stroke team, it became apparent that their primary carer had physical limitations and early signs of dementia which restricted their ability to aid the stroke survivor in managing their orthotic device, assisting with getting it on and off, and also recognising any problems which would require review. The therapist reported how for many patients, joint assessment in the community would be hugely beneficial to all involved and facilitate better rehabilitation for stroke patients.

Orthotic service

The lead researcher works within the orthotics department which was being observed and as such had a good knowledge of department practices. However, time was spent to gain a clearer understanding of the stroke patient referral pathway both for in-patients and community patients. An audit of past stroke unit orthotic referrals from July 2019 to January 2020 was undertaken which highlighted the frequency of request and clinical need. Of the 44 in-patient referrals received in this 6-month period where the primary diagnosis was stroke, 34 of them were for an AFO style device. The ultimate prescription varied from a full custom thermoplastic device to a modular carbon fibre splint, to a stock fabric foot-up support. This highlights the importance of the orthotists knowledge and skills in determining the correct prescription for each patient. A

key aspect of the referrals examined was the referrer was exclusively a physiotherapist, with the majority originating from one of two individual physiotherapists.

In-patient orthotic referrals within this trust had recently changed to be assessed within 24 hours of receiving (72 hours over the weekend) and subsequent prescriptions usually fulfilled within 7 days. Whilst stroke specific community referrals were seen for assessment within a specialist neurological clinic at the orthotic department, they were treated with the same urgency as other community referrals received. Triage alongside referrals from a GP or district nurse there was a usual wait time of between 6-8 weeks at that time. Other conditions such as diabetes have an expedited triage and assessment pathway in place within this orthotics service and it was apparent that a similar prioritisation of stroke referrals could potentially be of benefit.

2.11 Discussion

This observation exercise was an invaluable opportunity for the researcher to immerse themselves within the orthotic and stroke rehabilitation teams and experience the patient journey from time of stroke, through discharge and into the community. This inquiry allowed a deeper understanding of the whole pathway through time spent within both the acute and community settings (125).

The knowledge gained was used to inform the feasibility RCT protocol, refining the intervention and trial processes to the specific site. Changes to department procedures such as the new commitment to respond to in-patient referrals within 24 hours (72 hours on the weekend) would have been missed were it not for these observations, and they would have likely impacted on study findings had the feasibility RCT gone ahead.

With the changes made to the PhD questions and methodology following the outbreak of the Covid-19 pandemic, the findings from the inquiry were used to inform the context of the proposed statements of best practice. The knowledge gained through the observation of clinical practice provided situational context which directed the phrasing of the statements developed to ensure their grounding and applicability to real-world clinical settings (125).

Reflecting on the findings from the multi-disciplinary survey and the personal experiences of the researcher of working in orthotics teams in different trusts, the service observed demonstrated a very good model of interacting and delivering orthotic provision for acute stroke patients. This departmental connection was reliant on individual working relationships between certain pivotal staff members. The seniority of these individuals within the orthotic and stroke rehabilitation teams appeared to be an important factor not only in setting the culture of multi-disciplinary working for more junior members of staff but also to provide consistency. This was particularly applicable to the acute stroke unit where two-year rotational practices of band 5 members of the therapy team meant relationship building amongst junior clinicians was more difficult.

The importance of building relationships was further highlighted in the joint assessment for orthotic needs which was observed as being commonplace on the rehabilitation ward. Not only are the merits of multi-disciplinary working well documented (140), but this interaction legitimises the orthotist to the stroke survivor who has likely built a strong relationship with the referring therapists and so will be more likely to trust their recommendation of including orthotic intervention. This relationship between stroke survivor and orthotist is often long-standing beyond that of other therapists as the patient moves to new settings and has changing needs through their rehabilitation (16). A perceived benefit to small orthotic departments with low numbers of staff is the consistency for patients to be assessed and treated by the same clinicians regardless of their setting. Within this trust it is the same orthotics department

who serves the acute stroke units and community teams. For stroke patients who require and benefit from orthotic provision, their involvement with orthotic services is often prolonged long after they are discharged from the acute setting and from community therapy provision. Therefore, establishing a relationship with the orthotics team early in their rehabilitation can be considered a positive.

Strengths and limitations

As a methodology, observation within a service evaluation offered a low impact way of gathering data to inform the studies within this PhD programme of work (141). As a complex intervention, the delivery of orthotic interventions following stroke is heavily influenced by human and behavioural factors, and clinical observation provided a method to better understand actions and experiences and contextualise the processes within local service (141). A useful adjunct to the multi-disciplinary survey, it offered important context to the originally planned feasibility RCT and subsequent statements of best practice.

As a method, clinical observation within healthcare settings is commonly used to offer instructive and interpretive data factoring human features (125). However, inevitable difficulties are present within such inquiry. In particular, the impact of social desirability on the behaviour of those being observed can taint the reliability of the findings from observation techniques (141). Especially within a healthcare setting, professionals providing care will likely want to be perceived optimally and so may go to extraordinary efforts to ensure this is the view taken by the researcher observing activities. Efforts were made to restate and emphasise the objective of the observations and that they were purely educational meaning no judgement or assessment was being made by the researcher.

A further difficulty with this method is the influence of observer bias where the researcher will bring their own biases and perspectives to the inquiry (142). Multiple researcher observations by different individuals can offer a counter to this but was not reasonably practicable within the restrictions of a PhD.

However, to ensure alternative perspectives were considered, the reflections and field notes gathered by the researcher were reviewed with the supervisory team who are from different professional backgrounds. Further review was completed as part of the triangulation exercise as described in Chapter Six where the findings of the observation inquiry were used to inform the context of the proposed statements of best practice. This was done in co-production with the clinical (LT) and PPI (CK) collaborators of the PhD project.

In ethnographic methodology, it is understood that the process of data collection will have an influence on the phenomena being observed resulting in unintentional biases (143). Repeated observations where those being observed become less aware to the presence of the observer are ideal to capture a more accurate representation of activity. However, due to time limitations within the PhD this was not possible. The fact the researcher was an employee of the orthotics department being observed can be considered both a strength and limitation of this inquiry. A clinical expert within the field of orthotics, with experience of working across other trusts and services, they were able to observe with a knowledge and appreciation for what was being seen. They were also a familiar figure to the clinicians within that orthotics service and a trusted member of the team. However, this method also presents a conflict of interest that should be accounted for when reviewing the findings. There is the potential for exaggerated social desirability impacting the observed person as the researcher was known to them where a stranger may have been perceived as being more neutral.

As a method of inquiry, observation of usual clinical practices within an orthotics department, stroke inpatient units, and community stroke team was valuable. Providing important localised context to the planned feasibility RCT and subsequent proposed statements of best practice, the method has informed the overall findings and outputs within this PhD.

2.12 Conclusion

For orthotics intervention across all conditions, it is common practice for it to be provided within secondary care. Therefore, it is considered standard for orthotist involvement to be instigated by a referral from another profession. Within the observed acute and community stroke rehabilitation services, it was evident how important the professional relationships both between the services and individuals were to facilitate such referrals. Closer working between orthotist and the wider stroke rehabilitation team was stated as desirable within the findings of the multi-disciplinary survey (37), and this was supported by the findings of the observation inquiry. Where earlier provision was identified as an area of required change to current orthotic provision within the multi-disciplinary survey, the observed in-patient stroke therapy team articulated satisfaction with current timings, largely due to the 24-hour response time to referrals when made. However earlier discharge practices, as seen when following the stroke patients' journey, led to delays in their orthotic provision which had impacts on their other therapy inputs. The lengthier wait for orthotic assessment of stroke patients as an outpatient (6 weeks), particularly raises issues for those who have been discharged to Early Supported Discharge services. It is recommended that ESD patients should expect to receive rehabilitation and treatment at the same quality and intensity as if they were to remain on a stroke unit (52). With the current disparity in the wait between in and out-patients within this trust (24 hours Vs 6 weeks), this requirement is not being met. The community stroke teams highlighted a desire for greater orthotic input and more flexible approaches to provision, including home and joint visits. This warrants further inquiry, exploring orthotics provision within a primary care model of delivery.

From reflections of the researcher, the observed service operates with established links between in-patient rehabilitation, community stroke services and the orthotic department. However, this model is very person dependent and wider guidance and pathway definition could be beneficial to build on and

formalise processes which rely on personal relationships. Weekly orthotic satellite clinics, as suggested by the community stroke rehabilitation team, appear appealing and would likely facilitate closer links between the teams as well as offer more timely and effective orthotic ways of working. Further investigation of this model of delivery should be explored within both primary and secondary care settings.

The findings from this preparatory observational inquiry have informed the next phases of the PhD by identifying usual practices relating to specialised orthotic provision within an orthotic and stroke service. By observing the processes and clinical practices from a particular clinical pathway, important context and site-specific nuances could be applied to the protocol for the originally planned feasibility RCT. Within the revised PhD programme of work, the conclusions of the inquiry provide important situational context for the completed studies presented in Chapters Three, Four, Five, and Seven, and developed statements of best practice produced as an output from the findings of this PhD.

Chapter Three: Early specialist orthotic interventions for the lower limb in adult stroke patients - a systematic literature review

This chapter details the process of identifying, synthesising, and appraising the existing evaluative evidence on orthotic interventions delivered early after stroke, specifically relating to the lower limb and walking recovery. This systematic review was completed prior to the Covid-19 pandemic. As such its focus is to determine what 'early' orthotic interventions have been evaluated following stroke as was identified as a research priority in the findings of the preparatory multi-disciplinary survey presented in Chapter Two. Findings from this systematic review are relevant and informative for the revised PhD research question and constitute an original and important study which contributes to the evidence base in this under-researched field. This Chapter details the first aim and objective of the PhD as presented in Chapter One (1.4). Figure 3 details how the systematic review described in this Chapter is the first stage in the five identified phases of development for the statements of best practice on delivering orthotic interventions after stroke.



Figure 3. Development of Best Practice Statements - stage 1

3.1 Aims of the study

The aim of this study, as related to the first aim of the PhD was:

- To identify, synthesise, and appraise the existing evidence on orthotic interventions targeted at improving or maintaining functional mobility in the lower limb early after stroke.

To achieve this, a systematic review of the literature was undertaken to provide a comprehensive synthesis of relevant evidence and a detailed foundation of existing knowledge before undertaking further work. It was designed to determine what specialist orthotic interventions targeted at improving or maintaining functional mobility in the lower limb after stroke have been provided and evaluated. The focus was to identify studies that compared an 'early' orthotic intervention aimed at improving or maintaining functional

mobility, or reduce complications in stroke patients, with provision of routine care. To provide a comprehensive synthesis of relevant evidence evaluating this specific research question, a systematic literature review was determined to be the most suitable method of searching (144).

3.2 Background

This systematic review constitutes the first stage of the core PhD programme of work. It was developed to determine whether relevant evidence was already available, the content of any early orthotic intervention for the lower limb after stroke, and if that intervention had been evaluated and found to be effective when compared to usual care. The MRC framework (2008 version) for developing and evaluating complex interventions (116), states that research should begin by completing a systematic review to determine what evidence already exists. To be considered a systematic review, this study constituted a robust search, detailed collation, and assessment of all the evidence published which meets the criteria for the review (144). Intended to enhance rigour and minimise bias, this review was designed to be conducted collaboratively at each stage of the review process (145). An important means of distinguishing a systematic review from narrative or descriptive reviews, was the combination of a systematic search strategy to identify articles of interest published within the specific field of early orthotic intervention for the lower limb after stroke, and a comprehensive approach to finding a complete collection of studies published and available (146). The purpose of this systematic review was to ascertain what evidence was available and evaluate the quality of that evidence to initiate the investigation into: Can early specialist orthotic assessment lead to improved rehabilitation outcomes and reduced complications for patients following a stroke? Following the changes to the research question as a result of the Covid-19 pandemic the applicability of this systematic review changed, and it was used to instruct the need for further studies to be conducted following a review of the

evidence risk of bias (147). A systematic review was selected as it provides the core information from which to build the rest of the PhD. It is considered a rigorous method, less susceptible to bias, and therefore offers a greater degree of confidence in its findings.

As detailed in Chapter One, previous systematic reviews into orthotic interventions following stroke have focused on lower limb provision, mainly AFOs, and are largely aimed at identifying interventions for the management of stroke related motor deficits (27,30–32). However, there had been no reviews focusing on ‘early’ provision of an orthotic intervention that encompassed AFOs as well as other orthotic provisions for the lower limb. As highlighted within the preparatory clinical observation inquiry work presented in Chapter Two, the importance of the orthotist themselves and their interactions with the wider stroke rehabilitation team was included as a potential intervention of interest. Again, this has not been investigated in previous reviews which focused more on a specific orthotic treatment such as the application of an AFO splint or comparing different types of splints.

The previous chapters within this thesis have detailed how orthotic interventions can help to promote normal body movement and function, promoting quicker and more efficient mobilising after a stroke has occurred (27,46). It has been suggested therefore, that early provision of orthotic devices can contribute to enhanced rehabilitation, facilitate other therapeutic treatments, reduce incidence or severity of secondary complications, and be more cost effective (15,16,20). Furthermore, it has been theorised that using orthotics to optimise alignment and ensure consistent repeatable movements can allow for more effective neuroplastic motor learning (148). Evidence has shown that effective rehabilitation starting early after stroke is essential to gaining optimal physical recovery for stroke survivors (8), furthering the impetus to investigate the effect of earlier orthotic provision. The importance of ‘early’ orthotic input following stroke was reinforced by the findings from the preparatory multi-disciplinary survey presented in Chapter Two, which

highlighted the discrepancy between perceived optimum time of intervention compared to the 'delayed' current timescales of orthotic provision (37). This aspect of orthotic intervention was therefore the original focus of the PhD question and defined the protocol for the systematic review enquiry.

Using internationally agreed terminology for stages following stroke described by Bernhardt et al. (149), the 'early' stage of interest within the review was determined to be within the acute (1-7 days) and early sub-acute (7 days-3 months) stages of post-stroke recovery.

The preparatory work detailed in Chapter Two, identified that the lower limb was the most common part of the body which orthotic intervention for stroke survivors is required for (37). This contributed to the decision to focus on lower limb within this systematic review. Moreover, a literature scoping exercise conducted as part of the PhD funding application development showed that the majority of existing publications were focused on the lower limb, with the priority for those interventions the promotion of functional mobilising and reduction of further complications. The systematic review search was therefore designed to explore what lower limb orthotic interventions targeted at walking recovery, had been evaluated after being delivered in comparison to usual care provision within this 'early' stage after stroke. The purpose, to determine if there had been any studies which had evaluated intervention effect on enhancing rehabilitation through facilitation of earlier and more efficient mobilising because of orthotic interventions.

This systematic review aligns with the original PhD research question as well as two of the priorities defined within the James Lind Alliance (JLA) priority setting exercise (150). These were [1] determining what is the best time, place, and amount of therapy to get the best outcomes after stroke, and [2] what are the best interventions to improve strength and fitness, promote recovery and prevent further stroke in stroke survivors. The JLA uses established co-production methods with patients, carers, and clinicians to establish research

priorities, and these questions have been highlighted as areas of interest for future research. A priority within any applied clinical research should be keeping the needs of the patient group at the heart of enquiry. This systematic review has endeavoured to do that through systematic appraisal of current evidence to act as a baseline for the further research studies conducted as part of this PhD.

3.3 Methodology

The original search was conducted on 18/10/2019 at the beginning of the PhD and updated on 05/01/2024. Prior to the review being conducted, training in systematic review methods was completed by the reviewers. A course built on the principals of the Joanna Briggs Institute; it was delivered by the School of Medicine Researcher Academy: Systematic reviews – searching for evidence. The second reviewer was an orthotist clinical colleague wanting more research experience who also attended the training alongside the lead researcher. He was mentored through the review process by the lead researcher as a capacity building exercise within a small profession and completed reviewing of the manuscripts with the support of the clinical lead (LT).

3.3.1 Objectives of the review

The three objectives of the review were:

1. To determine what early specialist orthotic interventions targeted at improving or maintaining functional mobility in the lower limb after stroke have been provided and evaluated.
2. To determine the efficacy and effectiveness of these interventions on lower limb mobility of adults who have suffered a stroke.
3. To determine whether specialist orthotic intervention prevents or reduces complications resulting from stroke.

3.3.2 Development of the search

The systematic review search was developed in accordance with the recommendations of the Joanna Briggs Institute (144), and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (151). The search protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO - CRD42020204134) (152), which details the pre-determined search criteria, target population, intervention of interest, and outcomes to be reviewed. The search strategy was reviewed by a member of the University of Nottingham Libraries Research Support Team to ensure the search terms were comprehensive and the strategy was complete.

3.3.3 Eligibility criteria

Participants

Participants included individuals aged 18 years or older with confirmed diagnosis of stroke. The diagnosis of stroke fulfils the clinical criteria of the World Health Organization (WHO) 1970 definition, of "rapidly developed clinical signs of focal/global disturbances of cerebral flow clinically lasting for more than 24 hours or leading to death with no other apparent cause of vascular origin" (153). A diagnosis of stroke for this review population group encompassed ischaemic and haemorrhagic stroke. Studies were included that recruited people regardless of gender, ethnic group, and geographic location if they were an adult with confirmed diagnosis of stroke. Studies which used healthy participants and simulated effects of stroke on mobilising were excluded.

Interventions

Eligible studies included those that compared an early orthotic intervention designed to influence lower limb functional mobility or reduce secondary complications with routine input or usual care. Orthotic intervention was defined as any assessment, treatment, or regimen which involves an orthoses or specialist orthotist perspective. Early was defined as within the acute (1-7 days) and early sub-acute (7 days-3 month) time period as described by Bernhardt et

al. (149). Studies that focused on the use of Functional Electrical Stimulation (FES) or robotic orthotic devices were excluded as these are not commonly available within orthotic practice in the UK and so would not be considered an orthotic intervention.

Routine input or usual care as the comparator for any intervention was classed as localised clinical provision which was delivered as standard to the population group, where there was no intention to improve or enhance outcomes beyond that which would be usually expected.

Outcomes

Informed by the systematic review conducted by Ramstrand & Ramstrand (30), due to its close applicability to the topic of interest, the primary outcome of interest was:

1. Performance in mobility scores for the lower limb.

This could include spatial and temporal parameters of walking including:

- Walking speed,
- Walking velocity,
- Walking cadence,
- Stride time,
- Stride length,
- Step length,
- Balance.

The definitions of the above terms are included in the PhD thesis glossary.

Secondary outcomes of interest were:

1. Reduced complications
2. Health related quality of life
3. Timed up and go score
4. Number of falls

5. Clinician self-reported outcome measures such as:
 - The Barthel Index (131)
 - The Functional Independence Measure (154)

Tertiary outcomes of interest were:

1. Compliance with orthosis use
2. Duration of orthosis use
3. Adverse events such as pain, discomfort, and skin damage
4. Health economic outcomes such as increases or decreases in resource usage
5. Participant and carer satisfaction
6. Health care provider satisfaction

Studies

The standard for evidence-based medicine is described in the hierarchy of evidence pyramid (155). As such it was decided to restrict the included studies to only those which were evaluative: randomised controlled trials, non-randomised controlled trials, and controlled before and after studies. This is in line with other complex healthcare intervention systematic reviews (146). RCTs are regarded as delivering the highest grade of evidence and resistance to bias (146). To produce a robust review with reliable conclusions, RCTs were deemed the focus of inquiry for this systematic review, but other evaluative studies were included to ensure completeness of the review. Reeves et al. argued for the inclusion of non-randomised studies for the purpose of: “examining the case for undertaking a randomised trial by explicit evaluation of the weaknesses of available non-randomised studies” (156). This is consistent with the rationale for this systematic review as previous scoping work determined a low number of randomised studies evaluating orthotic interventions after stroke. Moreover, the review completed as part of this PhD programme of work was designed to inform the development and content of a feasibility randomised controlled trial

as planned within the original programme of methodologies. Therefore, non-randomised studies were included within the review eligibility.

The interventions evaluated within the included studies were required to be designed to influence lower limb mobility when compared with routine input or usual care as the control intervention. The scoping review conducted prior to the PhD also indicated that these studies have sometimes been used for orthotic intervention evaluation in other conditions outside of stroke. It was also decided to not include observational or qualitative studies for this specific review. Whilst no doubt informative in their findings providing context and interpretation to a phenomenon, the primary aim of this review was to determine if effectiveness of an intervention had been evaluated to inform the feasibility RCT protocol. It was not possible to include studies that were not reported in the English language due to the limited options available for interpretation within the confines of this PhD.

A summary of the search inclusion and exclusion criteria is shown in Table 1.

Table 1. Systematic review inclusion and exclusion criteria

Inclusion Criteria
All participants aged over 18 years
Participants have confirmed diagnosis of stroke
Any orthotic intervention designed to influence lower limb functional mobility or reduce secondary complications
Interventions delivered within the early time period after stroke event, specified as initial contact within 3 months
Studies must be randomised controlled trials, non-randomised controlled trials, controlled before and after studies, or interrupted time series studies
Exclusion Criteria
Studies that focused on Functional Electrical Stimulation (FES) or robotic orthotic devices as interventions
Studies reported in languages other than English

3.3.4 Evidence sources

To ensure the widest range of potentially relevant articles were found within the search, a spectrum of different bibliographic databases were included within the search strategy. The following bibliographic databases were searched for studies prior to October 2019 and then updated for studies conducted prior to December 2023: AMED (1985 to present); CINAHL (1982 to present); EMBASE (1980 to present); MEDLINE (1949 to present); and PsycINFO (1967 to present). AMED is an online database for Allied and Complimentary Medicine Research. CINAHL is a Nursing and Allied Health Professionals Research online database. EMBASE is a medical literature database. MEDLINE is an online database for Life Sciences, Biomedical and Health Services Research. PsycINFO is an online database for Behavioural Science and Mental Health.

3.3.5 Search strategy

The search was conducted in English and the strategy consisted of a combination of subject headings and free text terms. The search strategy consisted of three elements. The first was the population of interest, the second was the intervention of interest, and the third was the outcome of interest. Both the population and intervention elements used a series of Medical Subject Headings (MeSH) and free text terms to search for adults who had suffered a stroke and has received an orthotic intervention for the lower limb. Different common types of orthotic device were included as separate search terms as the scoping review had shown that much of the existing literature was based on the evaluation of individual orthotic devices or their comparison to another type of device. The outcome element again used a combination of MeSH and free text terms but required additional terms to be added on the recommendation of the expert systematic review librarian. This was to ensure studies which used less common terminology to describe the outcomes of interest were not missed. The study design was not restricted at search stage to be as inclusive as possible as the scoping review had found that articles had sometimes not explicitly stated

the methodology used within their title or abstract. Study design was included as part of the screening for relevance stage of the review.

An example search strategy, used for Medline, is shown in Table 2. This strategy was adapted for use in the other databases as required depending on their search engine functions.

Table 2. Systematic review search strategy

Search terms	
1	exp Stroke/
2	exp Patient/
3	exp Stroke Rehabilitation/
4	hemip*.mp.
5	1 OR 2 OR 3 OR 4
6	exp Orthotic Devices/
7	exp Foot orthoses/
8	afo.mp.
9	ankle foot ortho*.mp.
10	ankle-foot o*.mp.
11	exp Splints/
12	orthotist.mp.
13	6 OR 7 OR 8 OR 9 OR 10 OR 11 OR 12
14	exp Mobility Limitation/
15	mobility.mp.
16	exp Walking/
17	exp Postural Balance/
18	exp Early Ambulation/
19	exp Locomotion/
20	exp Gait Disorders, Neurologic/
21	exp Gait/
22	exp Contracture/
23	exp Lower Extremity/

24	adult hemiplegia.mp.
25	muscle activity.mp.
26	functional recovery.mp.
27	Exp Muscle Spasticity/
28	14 OR 15 OR 16 OR 17 OR 18 OR 19 OR 20 OR 21 OR 22 OR 23 OR 24 OR 25 OR 26 OR 27
29	5 AND 13 AND 28

3.3.6 Evidence selection

A four-stage screening process was conducted where first, studies identified from the five different databases were compiled and duplicates removed. Two independent reviewers then screened titles, abstracts, and full papers, with all studies not found to be pertinent excluded. This was completed independently by the two reviewers (MGD and NP) to reduce individual bias in the results and ensure no article of relevance was missed from the final included studies. Agreement was reached between the two reviewers as to the final included studies with full text papers checked against the inclusion criteria by both reviewers independently before data extraction.

3.3.7 Data extraction

Data were extracted from the final full text papers using a pre-prepared and piloted data-extraction form. This is presented in Appendix G. The data extraction was completed independently by two reviewers and then discussed to ensure consistency. Mendeley and Covidence reference manager systems were used to manage and organise the search and extracted data. Extracted information included: study reference (author, year, title); study methodology; participant demographics; description of the intervention and control; participant baseline characteristics; recruitment and dropout rates; details of analysis conducted; details of primary and secondary outcomes; information to assess risk of bias.

3.3.8 Risk of bias

The two reviewers independently assessed the methodological quality and risk of bias of the included studies. The reviewers used the standardised risk of bias tool for studies with a separate control group developed by The Cochrane Effective Practice and Organisation of Care (EPOC) Group (157). This assessment included sequence generation, allocation concealment, baseline measurements and characteristics, completeness of outcome data, blinding of primary outcome assessment, protection from contamination, selective outcome reporting, and other potential sources of bias. Each of these factors was categorised as being at low, high, or uncertain risk of bias. The risk of bias quality assessment form is presented in Appendix H.

3.3.9 Data synthesis

The data were synthesised systematically creating a narrative synthesis which has been peer reviewed and published (158). Extracted data were presented in text and tables to summarise the characteristics and findings of the included studies. The narrative explored the relationship and findings both within and between the included studies, and the scope, differences, and similarities among studies were used to draw conclusions.

3.4 Findings

3.4.1 Results of the searches

A search of the databases was completed on 18 October 2019 and then updated on 5 January 2024. Records were imported into the Covidence application for streamlining literature reviews, allowing both reviewers to screen the same cohort independently and at the same time. Following the search, 2365 records were initially identified, with a total of 1723 once duplicates were removed. During the first screening stage, all titles were read and reviewed against the inclusion criteria and those which were not relevant were excluded. One thousand three hundred records were excluded leaving a total of 423 records to

be further screened. The abstracts of these records were read independently by the two reviewers with 411 records excluded as not matching the inclusion criteria. Reasons for exclusion were captured on the Covidence application and are presented in Table 3.

Table 3. Abstract screen reasons for exclusion

Reason for exclusion after abstract review	Number excluded
Non-eligible study design	184
Non-eligible intervention	143
Non-eligible route of administration (not early)	60
Non-eligible patient population	18
Non-eligible outcome measures	6

A total of 11 full-text publications were obtained and assessed independently by both reviewers. The reviewers were unable to obtain the full text of one publication, Wang et al 2006. (159). Only the abstract was readily available, and several attempts were made to acquire the full-text manuscript by contacting the lead author and host institution. No response was received and so it was not possible to include it in the final review. The search process is presented in Figure 4 and conforms to the PRISMA statement (151).

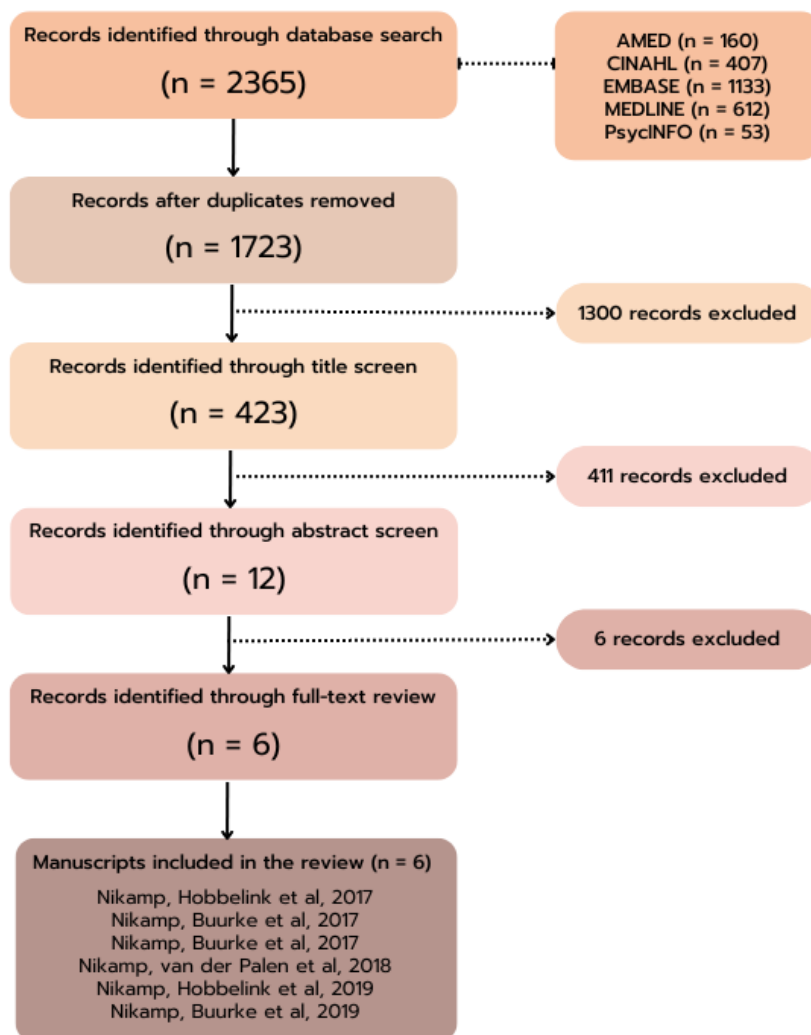


Figure 4. Systematic review PRISMA flow diagram

A final screening review was undertaken of the full text publications by both reviewers. A further five studies were excluded after full text review and discussion between the two reviewers. Three of these studies did not offer, or did not specify that they offered, the intervention within the 'early' timeframe that was specific within the inclusion criteria. The fourth study was excluded after discussion between the reviewers with support from a third reviewer (clinical lead LT) that the intervention could not be considered an orthotic device as it was a temporary splint made from fibreglass casting tape (160). The final potential study, another by Nikamp et al (161), was identified in the updated

search conducted in 2024 but could not be included within the final review. This was because the abstract that have been found on the searches was for a presentation at a conference and as such no full-text manuscript was available. The lead author Nikamp was contacted to request the full-text manuscript, and they advised they have not published in its full form yet. Whilst conference abstracts hadn't been excluded from the review protocol, it was not possible to include this study within the review as the abstract lacked sufficient details for data extraction.

A total of six publications were included within the final review and the summary characteristics of the studies they report on are presented in Table 4. All six publications were produced from the same study group presenting findings from a single RCT reporting on the same participants. As all publications have the same lead author, they have been assigned a # number to aid with distinguishing them during their quality assessment.

Table 4. Summary characteristics of included studies

#	Country of study & Reference	Study type	Participants	Primary outcome	Follow-up (in weeks)
1	The Netherlands, Nikamp C, Buurke J, van der Palen J, Hermans H. <i>Early or delayed provision of an ankle-foot orthosis in patients with acute and subacute stroke: a randomized controlled trial</i> (2017)	RCT (n=33)	Unilateral hemiparetic stroke patients (up to 6 weeks post stroke) with indication for use of an ankle-foot orthosis.	Comfortable walking speed, assessed with the 10-metre walk test.	1,3,9,11
2	The Netherlands, Nikamp C, Buurke J, van der Palen J, Hermens H, Rietman J. <i>Six-month effects of early or delayed provision of an ankle-foot orthosis in patients with (sub)acute stroke: a</i>	RCT (n=33)	Unilateral hemiparetic stroke patients (up to 6 weeks post stroke) with indication for use of an ankle-foot orthosis.	Comfortable walking speed, assessed with the 10-metre walk test.	1,3,5,7,9,11, 13,15,17, 26

	<i>randomized controlled trial (2017)</i>				
3	The Netherlands, Nikamp C, Hobbelink M, van der Palen J, Hermens H, Rietman J, Buurke J. <i>A randomized controlled trial on providing ankle-foot orthoses in patients with (sub)acute stroke: Short-term kinematic and spatiotemporal effects and effects of timing (2017)</i>	RCT (n=33)	Unilateral hemiparetic stroke patients (up to 6 weeks post stroke) with indication for use of an ankle-foot orthosis.	Sagittal ankle movement (dorsiflexion), measured at initial contact and foot-off and values in stance (max) and swing (min and max).	1,9
4	The Netherlands, Nikamp C, van der Palen J, Hermens H, Rietman J, Buurke J. <i>The influence of early or delayed provision of ankle-foot orthoses on pelvis, hip and knee kinematics in patients with sub-acute stroke: A randomized controlled trial (2018)</i>	RCT (n=33)	Unilateral hemiparetic stroke patients (up to 6 weeks post stroke) with indication for use of an ankle-foot orthosis.	Pelvic obliquity, hip ab/adduction and hip and knee flexion/extension at week 26	1,9,17,26
5	The Netherlands, Nikamp C, Buurke J, Schaake L, van der Palen J, Rietman J, Hermens H. <i>Effect of long-term use of ankle-foot orthoses on tibialis anterior muscle electromyography in patients with sub-acute stroke: A randomized controlled trial (2019)</i>	RCT (n=33)	Unilateral hemiparetic stroke patients (up to 6 weeks post stroke) with indication for use of an ankle-foot orthosis.	Tibialis Anterior activity during swing during normal walking to evoke foot clearance	1,9,17,26
6	The Netherlands, Nikamp C, Hobbelink M, van der Palen J, Hermens H, Rietman J, Buurke J. <i>The effect of ankle-foot orthoses on fall/near</i>	RCT (n=33)	Unilateral hemiparetic stroke patients (up to 6 weeks post stroke) with indication for	Effects of Ankle-foot orthoses provision on occurrence and circumstances of falls/near falls.	9,52

fall incidence in patients with (sub-)acute stroke: A randomized controlled trial (2019)		use of an ankle-foot orthosis.		
Key RCT – Randomised Controlled Design n - number of participants				

3.4.2 Risk of bias quality assessment of included studies

The results of the methodological quality appraisal for studies that were included are presented in Table 5. The appraisal was undertaken by the two reviewers independently, using the EPOC risk of bias tool (157).

Table 5. EPOC risk of bias summary

	Included study from Nikamp et al. research group					
	#1	#2	#3	#4	#5	#6
a) Was the allocation sequence adequately generated?	L	L	L	L	L	L
b) Was the allocation sequence adequately concealed?	L	L	L	L	L	L
c) Were baseline outcome measurements similar?	L	L	L	L	L	L
d) Were baseline characteristics similar?	L	L	L	L	L	L
e) Were incomplete outcome data adequately addressed?	H	H	H	H	H	H
f) Was knowledge of the allocated interventions adequately prevented during the study?	H	H	H	H	H	H
g) Was the study adequately protected against contamination?	U	L	U	U	L	U
h) Was the study free from selective outcome reporting?	L	L	L	H	H	L
i) Was the study free from other biases?	U	U	U	U	U	U
Key H = High risk L = Low risk						

U = Unclear risk

All six of the studies were judged to be at high risk of bias in at least one domain but overall, the risk of bias was deemed low for all of the studies.

Selection bias

Statements a), b), c) and d) on the EPOC risk of bias tool relate to 'selection bias'. All six studies were rated at low risk of selection bias due to adequate generation and concealment of the allocation sequence with participants allocated by an independent person. The allocation sequence was determined using stratified block randomisation using sealed envelopes. Other selection biases were also rated as low risk due to equivalence in the baseline participant characteristics and outcome measures across the two groups.

Detection bias

Statement f) on the EPOC risk of bias tool determines the 'detection bias' within studies. The reviewers determined that all the included studies were at high risk of detection bias due to the assessor for primary outcome measure likely having knowledge of the participant group allocation. Concealment of allocation within studies which evaluate complex interventions such as the provision of an orthotic device is usually very difficult. This is due to the fact that a physical device has either been provided or not at the time of assessment and so it was not possible or practical to maintain assessor blinding. Further-more it could reasonably be expected that participants would reveal their allocation through the answering of questions during assessment. It may have been possible to have two separate individuals complete the assessments for the intervention and control groups. However, this could then introduce the risk of a new bias due to lack of consistency in approach and would not have been practicable due to the small size of the research team who were completing this trial. It was considered reasonable by the reviewers to expect similar risk of bias due to lack of concealment in other studies exploring this kind of intervention.

Other biases

Incomplete data bias was present in all the included studies and no explicit method to address this was detailed within the manuscripts. Reporting bias was determined within two of the six studies due to incomplete descriptions of the intervention and control comparator. Other biases noted by the reviewers were the potential for overstatement of findings due to the low number of participants and inadequate recognition of the limitations within the research team. Further bias is present in the potentially perceived over-reporting with the findings from each study relating to the same cohort of participants.

3.4.3 Results of the synthesis

All six of the included studies were authored by the same research group in the Netherlands and constitute the results of different aspects of the same trial conducted on the early provision of Ankle Foot Orthoses (AFO) specifically for stroke patients. All six studies present results from the same cohort of patients within that same trial. The studies included 33 participants, 16 in the intervention group (early provision), and 17 in the control group (delayed provision). A summary of participants characteristics is shown in Table 6.

Table 6. Summary of included study participant characteristics

	Total (n=33)	Intervention/ early (n=16)	Control/ delayed (n=17)
Sex (<i>male/female</i>)	20/13	10/6	10/7
Age	57.2 (9.2)	56.9 (9.6)	57.5 (9.1)
Time since stroke at week 1 (<i>days, mean $\pm$SD</i>)	31.4 (6.3)	32.0 (6.2)	30.8 (6.5)
Affected body side (<i>left/right</i>)	16/17	8/8	8/9
Type of stroke (<i>ischemic/haemorrhagic</i>)	27/6	14/2	13/4
Type of ankle foot orthosis (<i>flexible/semi-rigid/rigid/no orthosis</i>)	27/0/3/3	14/0/2/0	13/0/1/3

Sensation ^a	Tactile (normal/impaired/ absent)	26/4/3	13/1/2	13/3/1
	Proprioception (normal/impaired/ absent)	26/6/1	13/2/1	13/4/0
Mini-mental state examination (<i>mean ±SD</i>)		25.5 (4.1)	25.4 (4.5)	25.5 (3.8)
Motricity index, lower limb (<i>mean ±SD</i>)		30.3 (20.0)	32.0 (17.8)	28.8 (22.3)
^a Tested with Erasmus Modifications to the Nottingham Sensory Assessment, lower limb part				

The included studies indicate positive effects of AFO use in both intervention and control groups of unilateral hemiparetic stroke patients when provided early (intervention - on average 32 days after stroke) and delayed (control - eight weeks after stroke). Significant effects were noted on all outcome measures when provided early (intervention) and more pronounced than the effects seen in the delayed (control) group.

All six of the studies described different aspects of a single trial where subjects were randomly assigned to either early provision (at inclusion; Week 1) or delayed provision (eight weeks later; Week 9). Early provision constituted fitting of an Ankle Foot Orthoses designed to promote safe and biomechanically stable mobilising. Besides the difference in the orthosis provision timing, all participants received usual care from experienced physiotherapists in line with local recommendations. Effects were assessed in study weeks three and 11 for the intervention and control groups respectively. All six of the studies highlighted the 'ankle-foot orthosis protocol' which described the process by which the orthotic device was selected for each participant. The authors recognised that there is no standard practice for providing AFOs with regard to timing or orthosis type in the Netherlands. This is reflective of the situation within the UK also and contributes to the justification of the need for the main

output from this PhD. Additional to the description of the orthosis, all six papers reported that fitting was performed by a licenced orthotist, recognising the specialist skills that are required to provide such an intervention. The authors also described how choice of AFO was informed by a protocol which was developed using biomechanical principals which are integral to the training and skills-set of the orthotist. Participants were all under the review of a physician and physiotherapist who worked with the prescribing orthotists to determine if a change in orthosis was required throughout the trial. This is usual within sub-acute post-stroke rehabilitation where we expect a degree of natural recovery and progression due to therapeutic input which can change the orthotic needs of the individual. Collaborative working within the medical team was described not only with the delivery of the intervention but also as the study elements were being carried out such as outcome measure collection.

Primary outcome

The primary outcome of interest was detailed as: performance in mobility scores for the lower limb. This included spatial and temporal parameters of walking including speed, velocity, cadence, stride time, stride length, step length and balance. The same cohort of participants are reported upon in each of the six studies, which collectively showed improved walking speed (10-metre walk test +0.14m/s, $p=0.093$), cadence (+2.1 steps/min, $p=0.026$), and balance (Berg Balance Scale +5.1 points, $p=0.011$) in the intervention group when compared with the control group two weeks after provision. These changes whilst statistically significant were not all considered clinically significant when compared to the stated minimal clinical important difference for each measure (10-metre walk test 0.11-0.18 m/s (162)(10MWT), cadence 8.6 steps/min (REF - (163), Berg Balance Scale 6-7 points (162)(BBS).

Mean time since stroke at time of AFO provision was 32 days (Standard deviation of 6.2) for the intervention group, and 88.1 days (standard deviation of 6.1) for the control group. In the intervention group, improvements after AFO provision

from week one to week three were significant for all outcome measures (all $p < 0.028$). However, the control group also showed significant improvements during this time period ($p < 0.037$), in all outcome measure except the stair test. This is indicative of the natural recovery which occurs after stroke within this early time period and was noted in the interpretation of the intervention group findings. However, when the median improvements of the intervention and control groups were compared there were larger improvements within the intervention group for all outcome measures (all $p \leq 0.028$).

Secondary and tertiary outcomes

Secondary outcomes included: reduced complications; health related quality of life; timed up and go scores; clinician self-reported outcome measures such as the Barthel Index (131), and the Functional Independence Measure (154); and number of falls. Within this cohort of studies, additional outcomes were reported such ankle dorsiflexion and tibialis anterior muscle activity. As such these have been included in the synthesis. Significant positive effects of AFO provision for ankle dorsiflexion at initial contact, foot-off and during swing were found, (-3.6 degrees (7.3) vs 3.0 degrees (3.9); 0.0 degrees (7.4) vs 5.2 degrees (3.7); and -6.1 degrees (7.8) vs 2.6 degrees (3.5), respectively), and no long term negative effect on tibialis anterior muscle activity ($p = 0.207$) with AFO use was found. Independence in activities of daily life were found to improve (Barthel Index +1.9 points, $p = 0.002$), following the early and delayed provision of an AFO with effects shown to be more pronounced (+0.5) in the intervention group (164). Improved outcomes in reaching independent walking were also found with improved balance as assessed using the Berg Balance Scale (+5.1 points, $p = 0.002$) noted in the first 4-13 weeks with the intervention group more pronounced (+8.5).

The impact on falls was investigated with one of the studies finding that during the first eight weeks, falls occurred significantly more often in the 'early' group of patients who had been provided with AFOs ($n = 11$), compared with the control

patients who had not yet been provided with AFOs (n=4) (Incidence Rate Ratio = 2.9, $p = 0.039$) (165). However, it is important to note that 63.6% of the falls in patients who had been provided with an AFO, occurred when the AFO was not in use, the majority taking place during the time period where patients had no independent walking ability.

Short-term effects were found on ankle kinematics initially after stroke. However, the timing of AFO provision did not influence the results (166). Another of the papers found that whilst earlier provision improved distal issues such as 'foot-drop', there was no evidence of influencing compensatory patterns in more proximal joints, with similar pelvic obliquity and abduction in the frontal plane, and hip and knee flexion seen in the sagittal plane in both groups (122).

None of the included studies conducted longer-term follow ups (longer than 1 year) though medium-term findings from the Netherlands group showed no difference at six-months in functional outcomes of providing ankle foot orthoses at different time periods in early rehabilitation after stroke (167). The authors did acknowledge that the study from which all the papers were reporting was underpowered and further research with larger numbers of subjects is warranted across all the outcomes and findings.

Further analysis in the form of a meta-analysis was considered as a robust way to consolidate the findings of a systematic review and determine overall effect. However, as the included studies all report on the same cohort of participants it was not appropriate to complete a meta-analysis in this instance. The factors which should be considered and how they related to the systematic review undertaken are outlined below. A meta-analysis is only justified where the interventions are clinically comparable (146). Within this review, as all the included studies reported from the same trial then the interventions could be considered clinically comparable though the merit of comparing would be limited as they describe the same intervention. Furthermore, similarly of study design and appropriate methodological quality is important to reach an overall

judgement of effect. Within this review, all six of the studies were judged to have risk of bias and so pooling them would have the potential to inflate this risk. Finally, the relevance of a meta-analysis to combine findings and determine overall effect is negated when all of the included studies report on the same trial. Therefore, conducting a meta-analysis of the findings from this systematic review would not add anything further. The findings from the systematic review are presented as above without further meta-analysis completed. Interpretation of the findings including the relevance that studies from only a single research group were found are discussed in the next section of this chapter.

3.5 Discussion

The aim of this study was to identify, synthesise, and appraise the existing evidence on orthotic interventions targeted at improving or maintaining functional mobility in the lower limb early after stroke (145).

The search, though systematic and comprehensive, only returned studies from a single research group which were all produced from one small, underpowered trial with a single group of participants. This is an indication of the paucity of research in this area. Moreover, the included studies all focused on a single orthotic intervention, the provision of an ankle foot orthoses (AFOs) in similarity to the other papers which were reported on above. Whilst understandable, as ankle foot orthoses are the most commonly prescribed orthotic device after stroke (168), the means of orthotic intervention is much wider, encompassing different types of orthoses as well as the assessment and prescription with specialist skills of the orthotist. AFOs as the only early specialist orthotic intervention for the lower limb after stroke identified through this review, limits its generalisability, and therefore does not reflect the wider spectrum of orthotic interventions. Similarly, generalisability is further limited by the same cohort of participants being reported on across the included papers (169). Within the six included studies, AFO fitting for trial participants was reported to have been

performed by a licensed orthotist though there is limited indication of their assessment or prescription decisions with all six of the papers stating “AFO type was chosen according to a custom developed protocol”. It is a limitation of the included studies that they do not report on the more specific role of the prescribing clinician and what this protocol included. The orthotic devices prescribed were described as one of three types of off-the-shelf orthotic device. This limitation to using only off-the-shelf devices does not reflect usual clinical practice where numerous styles of orthotic device could be fitted (16). The findings from the preparatory MDT survey described in Chapter Two indicated much higher numbers of custom AFO prescription after stroke within the UK. These decisions within stroke rehabilitation are made by assessing the individual needs of the stroke survivor and determining what their goals are in relation to their rehabilitation. These can change as they progress through their recovery, with the orthosis provided often made as a bespoke item for each individual due to the complex nature of stroke presentation and differences in bodily shape and form (29).

Whilst the overall findings of the six included papers indicated a positive impact of earlier AFO provision, the increased risk of falls evidenced in one of the papers (165), raises an interesting question. Reduced risk of falls is one of the primary clinical justifications for providing AFOs (26), and yet an increase in falls risk was noted for those fitted with an AFO device early. It is widely accepted earlier mobilising after stroke is of benefit to the stroke survivor (8), however when independent walking is not possible without assistive aids, is it appropriate given the increased risk of falling? The study reported 63.3% of the falls occurred whilst the participant was not wearing their AFO, and the majority took place early in stroke recovery during the time where patients had no independent walking ability. It is reasonable therefore, to suggest that the AFOs worked in providing the additional support required to reduce falls risk whilst in use, but possibly enhanced the participants confidence in walking earlier than it would otherwise, thus lead to more falls when they did not have the support of the

AFO. The findings certainly highlight that AFO provision should not be carried out in isolation and additional input is essential to promote muscular rehabilitation and control which in turn will work to mitigate any potential increase in falls risk.

The primary focus of the review was to determine if early orthotic interventions for the lower limb had been tested and evaluated. The limited number of papers returned and only one trial having been conducted in this field evidences the paucity of research undertaken in this field. The trial which was reported on within the six papers was underpowered to return any statistically significant results and didn't report any significant differences between the two groups. However, all participants within this trial did have significant improvements in outcomes overall, with more marked improvement for those in the intervention group. There is some indication that despite the small number of studies conducted, provision of lower limb orthotic intervention can improve outcomes for people after a stroke. There is also a suggestion that effects may be more pronounced when provided early after stroke (122,161,164–167,170). This indication of the benefits of earlier provision aligns with wider accepted understanding that earlier intervention and thus mobilising is beneficial to stroke survivors (8). Such sentiments add support to the findings of the preparatory MDT survey which informed the original research question of this PhD, identifying timing as being of importance. The only other trial exploring the early provision of AFOs which is understood to have been conducted at the time of this review being was that by Wang et al. (159). This could not be included within the systematic review as the full-text paper was not available. However, review of the abstract that could be found indicated the early provision of an AFO improved symmetry in static standing, dynamic standing balance, speed, and cadence in walking of participants less than six months after stroke.

3.5.1 Study strengths and limitations

The main strength of this study is it is the first review to collate studies systematically on early orthotic intervention for the lower limb after stroke and

therefore provides the only synthesis of this type. However, the narrow focus of the review whilst important to identify any early interventions which had been evaluated, has limited the findings to those of a single research group. The Cochrane Effective Practice and Organisation of Care (EPOC) group guidance states that studies with only one site should be excluded to limit any biases that may be associated with a particular site (157). However, due to the limited number of studies produced by the search this criterion was not applied to the review. This does act as a potential source of methodological bias in the findings of the review, exacerbated by any biases present in the characteristics of the participants of that one site and study.

An extensive search strategy was used to locate all the relevant studies, and though it was systematic and believed to be comprehensive there is the potential that some studies were missed. Searches beyond bibliographic databases could have strengthened the conclusions. As the focus of the review was to determine what evaluative studies had been conducted, the search was limited to randomised controlled trials, non-randomised controlled trials, and controlled before and after studies that compare an intervention designed to influence lower limb mobility with routine input or usual care as the control intervention. As such there are potentially studies which did explore the effectiveness of an early orthotic intervention outside of those identified which used other methodologies. Whilst it was decided not to include observational or qualitative studies for this specific review, their inclusion would have likely provided further context and interpretation to its findings but not added to determining the overall effect. This kind of restricted focus on evaluative studies to evidence effect has been criticised, that they take an overly narrow definition of evidence (168). The focus of 'what works' within a framework has limitations on how interventions are implemented or are delivered within real world settings. This is particularly relevant to the intervention of interest within this systematic review as a complex healthcare provision heavily influenced by human factors. The updated PhD research question recognises the important

influence of ways of working within orthotic provision after stroke. As such, inclusion of other methods and approaches would have been preferable. This review was initially conducted with the aims and objectives of the original PhD question and so the rationale for the approach taken are logical. The primary aim of this review was to determine if effectiveness of an intervention had been evaluated for the purpose of informing the planned feasibility RCT protocol.

The search was conducted in English and the reviewers struggled to identify abstracts and full-text manuscripts for studies that were published in other languages giving the findings and English language bias limiting its applicability internationally. Another limitation of this review was the inability to perform a meta-analysis meaning only preliminary conclusions can be drawn about the effectiveness of early orthotic interventions after stroke.

Further studies would benefit from evaluating different types of orthotic intervention after stroke outside of just AFO use and explore the role of the clinicians in assessing for and prescribing any devices. Investigations into the effect of orthotic interventions at different time periods in stroke recovery would be beneficial, with longer term follow-ups to determine any longevity in effect. Studies should use larger sample sizes to detect any effect with more confidence and statistical certainty and provide more detailed descriptions of the interventions protocol outside of just the orthotic device being used.

Overall, the findings in this review are consistent with the others which have been carried out in this area (27,29–32). The lack of evidence reflects the paucity of research in orthotics more widely and further highlights the need for evaluative studies within post-stroke orthotic care. This review is the first to analyse the effect of early orthotic interventions after stroke. It is of particular importance for the stroke survivor population with the evidence for earlier mobilising after stroke becoming stronger (8), combined with the move towards earlier discharge practices in the UK after stroke (7).

3.5 Conclusion

The potential for earlier orthotic intervention to promote quicker and more efficient mobilising is important to consider within the landscape of stroke rehabilitation. Much of the current research on this topic focuses on ankle foot orthoses provision specifically, and the impact that has on functional outcomes. The findings from this review have contributed to advancing the body of knowledge in suggesting how earlier provision of orthotic intervention might result in improved walking speed and balance, and ability to perform activities of daily living in the early weeks post-stroke. Its findings highlight how factors such as increases in the number of falls and use of longer-term outcomes need further consideration and investigation.

Whilst this systematic review has provided some supporting evidence for earlier orthotic interventions after stroke, its primary finding has been to highlight that there is very limited research, and no high-quality research in this field. As the first study within the five substantive studies of this PhD, its primary aim was to establish the evidence base by identifying, synthesising, and appraising the existing evidence on what specialist orthotic interventions targeted at improving or maintaining functional mobility in the lower limb after stroke have been provided and evaluated. Within the context of the original PhD question this aim was met. The outcome measures used by the included trial were translated into the protocol for the planned feasibility study and other measures including number of falls were added following the findings from the review. This review also highlighted the importance of including measures which determine ability to complete Activities of Daily Living using standardised and validated measures. This offers a wider perspective on the impact of stroke and the impact on function we can hope to achieve with appropriate and timely rehabilitation interventions. The findings from this review were used in combination with the findings of the preparatory MDT survey and clinical observations presented in Chapter Two to inform the development of the originally planned feasibility RCT. The paucity of evidence within the review, whilst limited in determining

effectiveness, indicated that to achieve the aims and objectives of the revised PhD question, alternative and additional methods are required to develop best practice recommendations in line with the GRADE approach.

3.6 The impact of the global Covid-19 pandemic and subsequent changes to the PhD

Shortly after the completion of the systematic review, the outbreak of the Covid-19 pandemic meant significant changes to the PhD were necessary. Below are detailed the changes made to the scope, design, and direction of this PhD. All changes were implemented with the agreement of the supervisory team, host institution and PhD funder.

3.6.1 Initial PhD methodology

The proposed PhD was to develop and test the feasibility of conducting a RCT and examine the acceptability of an early orthotic intervention delivered in the acute rehabilitation phase following stroke. Beginning in October 2019, preparatory work had been completed including the MDT national survey (37), and drafting and registering of the systematic review protocol with the international database for systematic reviews, PROSPERO (152). Detailed in this chapter is the systematic review which was undertaken in Oct 2019. The aims of this study were directly focused on early orthotic intervention, highlighted within the preparatory MDT survey as an area of interest. As such, the findings from the systematic review are not directly related to the new research question, aims, and objectives but still constitute an original study which informed the subsequent investigation and findings from the PhD.

As detailed in Chapter Two, in addition to the national MDT survey, practice observation was undertaken through a service evaluation exercise both to aid in benchmarking current practice and informing the protocol of the planned feasibility RCT which was to be conducted within the same clinical service. This work, whilst primarily completed to inform the original methodologies of the

PhD, acted as an important source of baseline information to direct the questions of the subsequent cross-sectional professional survey of orthotists presented in Chapter Four.

Figure 1. presents the blueprint of the original methodology, new methodology, and the stage at which the Covid-19 pandemic required methodological changes to the PhD.

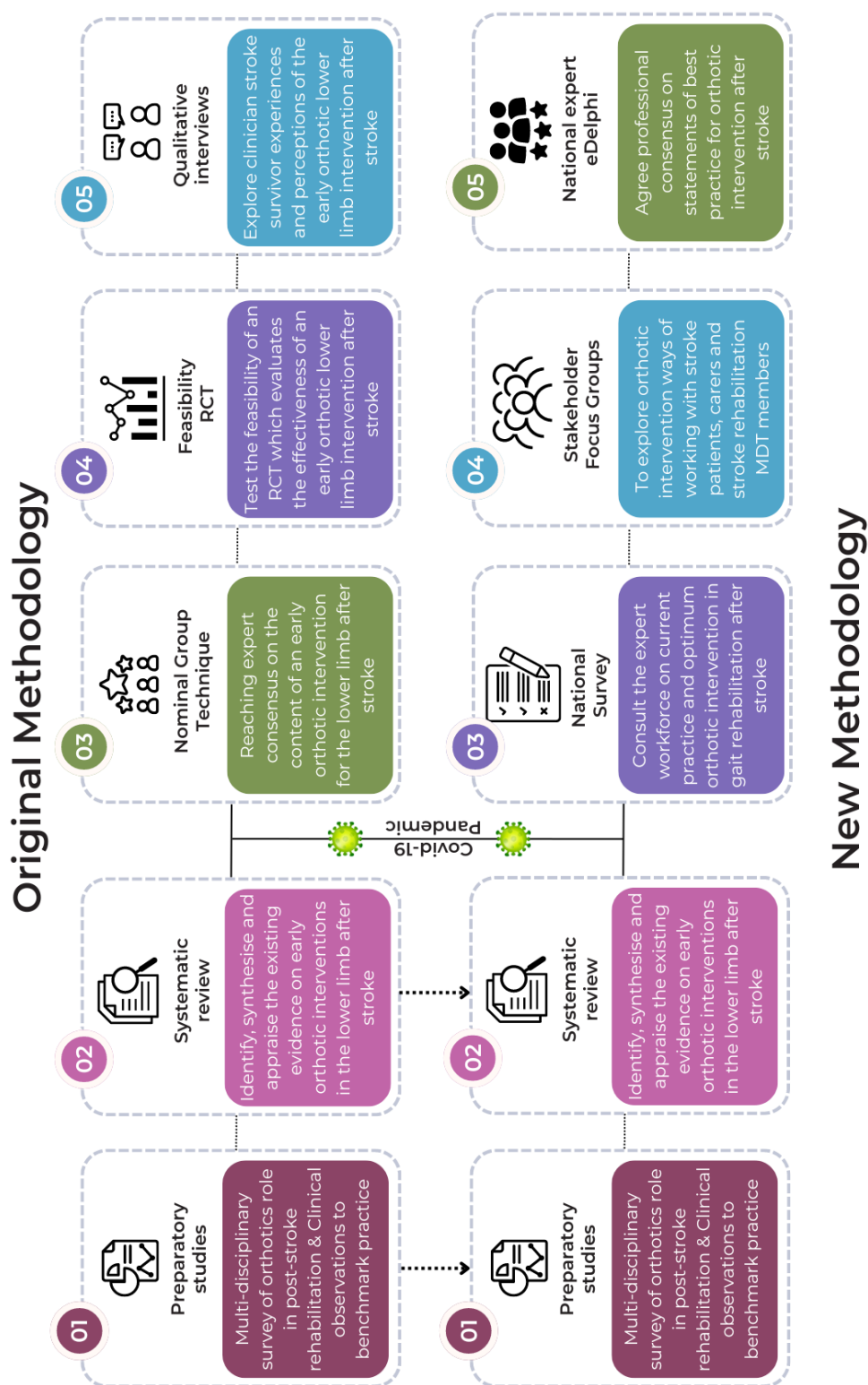


Figure 1. Blueprint for original and revised PhD methodology

The next stage of the PhD was focused on the development of the Nominal Group Technique, feasibility RCT, and qualitative interview protocols. These were submitted to the Nottingham University, Faculty for Medicine and Health Science (FMHS), ethical review board on 10th March 2020. In addition, due to the recruitment of NHS patients, the feasibility RCT study required full Health Research Authority (HRA) ethical review and so a protocol was drafted and submitted using the Integrated Research application System (IRAS). Submitted in March 2020, the application was subsequently returned and not reviewed. This was due to an extraordinary arrangement giving prioritisation of all Research Ethics Committee (REC) reviews to Covid-19 studies only. This protocol remains ready for re-submission in a future study but with significant adjustments to be made as a result of the findings from this PhD.

3.6.2 Coronavirus outbreak

Characterised by the World Health Organisation as a pandemic on 11th March 2020, the Covid-19 outbreak caused unprecedented changes to society and daily life and those changes meant it was not possible to continue with the planned PhD methodology. On 23rd March 2020, the UK government introduced the first of several 'lockdowns' which banned all non-essential travel and social contact, requiring people stay at home. These measures remained in place in different forms until May 2021. Due to the social restrictions, the planned Nominal Group Technique was not feasible to go ahead and as restrictions on non-essential contact continued, the host clinical service for the proposed feasibility study resolved to cease all non-essential research activities. Healthcare provision rapidly changed with non-urgent care suspended, critical care prioritised, and clinical staff redeployed. The drastic changes due to the pandemic not only meant the planned methodology of data collection was no longer feasible but also the benchmarking exercises undertaken via the national MDT survey and practice observation were no longer an accurate reflection of current practice. It was determined therefore a further survey, conducted in 2021 due to a period of maternity leave which interrupted the PhD, would be beneficial. This would

act as a baseline to orthotic practice in a post-covid world, whilst also providing an opportunity to determine the influencing factors as perceived by the orthotists themselves on their role and perspective of orthotics interventions following stroke in the UK. Furthermore, the systematic review findings presented earlier within this Chapter, indicate the need for alternative methods of inquiry to deliver on the aims and objectives of the revised PhD question. In the next Chapter, the second of the five substantive studies, the perspectives of the expert orthotic workforce will be sought on their current practice and role within the stroke rehabilitation pathway. This and the following study presented within Chapter Five were conducted as recommended within the new MRC framework for developing complex interventions (108), by engaging with stakeholders and defining key uncertainties.

Chapter Four: Orthotist involvement in early gait rehabilitation following stroke - a cross-sectional survey of orthotists in the United Kingdom

This Chapter details the process of surveying the views of orthotists on current practice and their perspective of optimum orthotic intervention in early gait rehabilitation following stroke. This cross-sectional professional survey was conducted to gather the views of the expert workforce on orthotic intervention following stroke practice post covid and gather their perspective on the role of the orthotist within the wider stroke rehabilitation MDT.

As depicted in Figure 5, this study constitutes the second stage in the five identified phases of development for the statements of best practice on delivering orthotic interventions after stroke, using the GRADE approach (51). As a development study to the preparatory MDT survey (37), presented in Chapter Two, the aim of this survey was to develop a comprehensive understanding of orthotic practice post-covid, with greater focus on gathering the perspectives of orthotists, the experts in orthotic interventions. This study also served to inform the foundation of the proposed statements of best practice which have been developed as the primary output from this PhD.

The survey was conducted after the outbreak of the Covid-19 pandemic and was chosen as a socially distanced method of data collection which would establish a baseline of orthotic practice alongside the perspectives of orthotists on their role. The findings from the systematic review presented in Chapter Three detail the paucity of evidence on the impact of the orthotists themselves on rehabilitation outcomes after stroke. As such, it was determined to explore this further within the survey detailed within this Chapter.

The survey findings have been published in a peer reviewed journal (171), using the Consensus Based Checklist for Reporting of Survey Studies (CROSS) tool (117) and are presented in this chapter following the Checklist for Reporting Results of Internet E-Surveys (CHERRIES) (172). The CROSS and CHERRIES checklists are presented in Appendix B & I.



Figure 5. Development of Best Practice Statements - stage 2

4.1 Aims of the study

The aim of this study, as related to the second aim of the PhD was:

- To establish a cross-section of perspectives from the expert orthotic workforce on current practice and optimum orthotic intervention in early gait rehabilitation following stroke in the UK.

To achieve this, a national cross-sectional professional survey was conducted with orthotists as the experts in orthotic intervention following stroke. This survey had a targeted focus of data collection to benchmark practice in a post-covid landscape and to identify the perceived role of the orthotist in early gait rehabilitation. It also explored the confidence, frustrations, and ambitions of the expert workforce to begin forming a foundation of what optimum orthotic intervention following stroke 'looks like'.

4.2 Background

As part of the development of the original PhD research question, a survey study was conducted in 2018-2019 to investigate the views of orthotists, occupational therapists, and physiotherapists as the key members of the physical function stroke rehabilitation team (37). This study and the relevance to the overall research question are discussed in Chapter Two. The findings from this original survey identified Ankle Foot Orthoses (AFOs) as the most prevalent orthotic device used in post-stroke gait rehabilitation and supported the NHS Best Practice Statement (BPS) for use of Ankle Foot Orthoses (AFOs) following stroke developed in 2009 (29). It also found that there was a discrepancy between when clinicians felt orthotic intervention would be most beneficial to be provided and when orthotic intervention was actually provided post-stroke (37). These two findings were primary factors which directed the initial PhD research question focusing on the optimum timing of lower-limb orthotic provision after stroke. However, due to the impact of the Covid-19 pandemic on the PhD, a new research question was proposed, focusing on other aspects of the preparatory work findings. The MDT survey highlighted the importance of AFOs as a key component of promoting early gait rehabilitation for some stroke patients but also that, crucially, it is important to include the orthotist in the assessment, provision, and on-going review of any orthotic prescription. Working within the wider post-stroke rehabilitation team, it is important therefore to establish the

optimal ways of working when delivering orthotic interventions following a stroke. To begin the investigation of this, a cross-sectional survey was designed to act as an update and further development of the original MDT survey with more targeted data collection, focusing on the role of the orthotist specifically, and their place within the wider stroke rehabilitation MDT (173). To ground the findings of the survey within the experiences of the expert workforce, questions were also asked to explore the confidence, frustrations, and ambitions of orthotists practicing within the UK. The findings also acted as a foundation to defining the proposed statements of best practice as the primary output from this PhD.

For those affected by stroke, the recovery of walking ability has been identified as a key goal in regaining their independence and progressing their rehabilitation (2). Rehabilitation of gait following stroke may include various types of physical therapy, lower limb casting, medical management such as botulinum toxin, and the use of orthoses (7,52). Within the UK, the orthotist is the specialist clinician trained to assess for and prescribe orthoses such as AFOs. Their specific skill set includes biomechanical assessment to devise a holistic prescription which can aid with early gait rehabilitation following stroke (56). Orthotists have been identified to have an important role within the stroke rehabilitation multidisciplinary team (MDT) (37). However, inequitable access has been highlighted as a barrier to this, with vast discrepancies described between the perceived optimum timing for orthotic intervention and the actual time of treatment provision (37).

The evidence, as described within Chapter Three, identifies a need for guidance on how to deliver equitable, consistent, and effective orthotic interventions for those who need them after stroke (158). To develop such guidance, it was recognised that as important to consult the expert workforce, namely orthotists, with a specific focus on how they perceive their role, current practice, and place within early gait rehabilitation after stroke. Study outcomes were defined through three primary objectives:

1. To investigate the views of orthotists on their role in early gait rehabilitation following stroke in the United Kingdom.
2. To capture current practices and the perspective of orthotists on their confidence to recommend orthotic treatment within the stroke rehabilitation pathway.
3. To explore the confidence, frustrations, and ambitions of the expert workforce to begin determining potential modes of best practice.

4.3 Methodology

This national cross-sectional professional survey study protocol was developed in accordance with the CROSS (117), and CHERRIES checklists (172). The study protocol was then adopted and adapted by Danish colleagues to facilitate a parallel data collection exercise to investigate practice and perceptions of orthotists in both countries.

4.3.1 Development of the survey

The survey questions were developed by a representative working group of five people comprising two clinical specialist orthotists, two clinical academics and a bioengineer with specialist knowledge of orthotic device use in neurological conditions. Using the findings from the preparatory studies and systematic review presented in Chapters Two and Three, the survey questions were developed. They were formatted to be answered via multiple choice, Likert scales or free text responses, and divided into three sections:

- Part I contained 5 questions recording participant characteristics.
- Part II contained 7 questions capturing participants' current clinical orthotic interactions within stroke care.
- Part III contained 8 questions measuring participants' confidence and perceptions of their role in gait rehabilitation following stroke.

The survey questions are presented in Appendix J.

Prior to circulation, the questions were edited and refined following a pilot and review process with eight clinical colleagues at the local orthotics department. Orthotist colleagues were asked to review the questions and attempt to complete the survey using the online platform, providing feedback of any errors or suggestions for changes.

4.3.2 Ethical considerations

Ethical approval was granted by Teesside University Health Research Ethics Sub-Committee (2021-Feb-1723). Letter of favourable ethical approval is presented in Appendix K. A Participant Information Sheet (PIS) was provided to all potential participants upon approach and prior to consent being sought. The study PIS followed the format required by the host institute sponsor and detailed how the responses provided by any participants would be stored confidentially and be anonymised using a randomly generated study ID. A copy of the study PIS is presented in Appendix L.

Using the online survey system, consent was confirmed by selecting yes to consent statements prior to being able to access the survey questions. Following consent, participants were also required to confirm eligibility before entering the main section of the survey. A copy of the study consent form is presented in Appendix M.

The survey was piloted and approved via a rigorous review process undertaken by the British Association of Prosthetists and Orthotists (BAPO) research committee, who ensure suitability and applicability of research to their members prior to circulation.

4.3.3 Data collection and management

This web-based survey was developed using the esMaker survey application. This was selected as a widely used international survey application. An online survey was chosen to facilitate responses from respondents who were geographically dispersed and provide an appropriate method of data collection during the social distancing restrictions of Covid-19. The survey was designed to

take approximately 10 minutes to complete. It had a save and return option which was included as a suggestion made following clinical piloting to facilitate completion in between patients for busy clinicians. Survey responses were anonymised by assigning each participant a randomly generated study ID and then stored confidentially on a password protected spreadsheet which was hosted on secure University of Nottingham dedicated web servers. Access was restricted to only the lead researcher using personal identifier login with password in accordance with established information governance and data protection guidelines (118). No identifiable information was collected on the digital survey application.

4.3.5 Recruitment of participants

The survey was open for 6 months from April – September 2021. The target population were HCPC registered orthotists either practicing or recently retired within the UK. The British Association of Prosthetists and Orthotists (BAPO) is the national professional body of orthotists and holds the largest database of registered professionals within the country, approximately 39% of the national registered workforce¹ (434 out of HCPC 1114 registered Prosthetists/orthotist in March 2021) (174). They agreed to circulate the survey to members following review by the BAPO Research Committee. Other sampling approaches were considered such as use of social media and use of other professional networks but previous experience of surveying this professional cohort had showed these methods wouldn't garner any wider distribution and/or response rate than just using the BAPO network. As such, this was used as the primary means of survey circulation. An invitation email was drafted with a link to the survey embedded within it. This invitation email was then circulated to registered practicing members (n=434) and recently retired members (n=17) of BAPO via their email

¹ As a dual registered profession it is not possible to determine the exact number of orthotists registered within the UK. From professional understanding it is reasonable to assume a 50% split between prosthetists and orthotists of the 1187 registered with HCPC.

mailing list. A link to the survey was also advertised via a QR code on the BAPO social media platforms (Facebook and Twitter).

Eligibility criteria

Eligible participants were qualified orthotists with post-qualification experience of working within stroke rehabilitation. This eligibility was self-determined with the survey built to require potential participants to confirm their eligibility of working with stroke patients or within the stroke rehabilitation setting prior to being able to advance through to the substantive questions.

Inclusion criteria

- HCPC registered prosthetist/orthotist
OR a recently retired prosthetist/orthotist (within 5 years)
- English reading comprehension and writing ability

4.3.6 Data analysis

Data from the survey were organised against the backdrop of the World Health Organisation's International Classification of Functioning (ICF) (19). The data were analysed following the four ICF recommendations to:

- Provide a scientific basis for understanding and studying health and health-related states, outcomes, and determinants.
- To establish a common language for describing health and health-related states to improve communication between different users.
- To permit comparison of data across countries, health care disciplines, services and time.
- To provide a systematic coding scheme for health information systems.

Data were exported to Stata SE Version 13 with descriptive statistics used to summarise the quantitative data, these can be found in Tables 7-12. Qualitative

analysis was conducted on the free-text responses via thematic review using a framework analysis approach as described by Gale et al. (175). The lead researcher conducted the initial thematic coding of the free-text responses, and this was then sense checked by two other reviewers. Each code was reviewed against the factors which may influence the existing pathways for orthotic intervention delivery after stroke from the perspective of the patient using the WHO-ICF as well as responding clinician.

4.4 Findings

Fifty-six participants consented and completed the cross-sectional survey. Participant demographics for the study participants are presented in Table 7. As some of the participants worked in multiple services, questions 5-12 were repeated for one (n=1) or two (n=1) additional services making an n= return of 59 responses. As the survey was built to prevent progression without completion of questions there was no missing data to report.

Table 7. Participant professional demographics

Highest degree or level of education	n=56	%
Diploma	6	11
Degree (BSc)	41	73
Masters (MSc)	9	16
PhD	0	0
Years qualified	n=56	%
0-2 years	4	7
3-5 years	13	23
6-10 years	14	25
More than 10 years	25	45
Primary employer	n=56	%
National Health Service (NHS) provider	17	30
Private company delivering NHS provision	37	66

Private company delivering private provision	2	4
Clinical settings (all that apply)	n=86	%
Hospital setting (in-patient)	16	19
Hospital setting (out-patient)	49	57
Clinical site not within a hospital	17	20
Community team seeing people at their usual place of residence (home, care home, etc.)	3	3
Other	1	1

4.4.1 Participant demographic characteristics

Table 7. shows most orthotist survey respondents were qualified to degree level (73%), with 16% educated to master's level. Participants varied in experience, with 70% having six or more years' experience and 45% having more than ten. Most orthotists described their primary employer as a private company delivering national health service provision (66%) or National Health Service provider (NHS) (30%). The clinical settings in which participants reported working were mainly hospital (out-patient) (57%) or a clinical site not within a hospital (20%).

4.4.2 Frequency, timing, and setting of orthotist stroke intervention

Table 8. shows most orthotists saw stroke patients regularly, with 'Several times a week' being the most frequent response (36%), and 'Once a Day' or more frequently reported by 25% of respondents. The stage at which participants usually saw patients following stroke varied, with 33% at 1-6 weeks, 22% at 7-12 weeks, 25% at 4-12 months and 19% >12 months. Table 9. Shows that stroke patients were usually seen as out-patients in a general orthotic clinic (43%) or as in-patients on a stroke or general ward within the acute hospital site (26%). Care was sometimes provided in more dedicated clinics: in MDT clinics by 21% or as out-patients in a dedicated neurological clinic by 11%. When defining MDT as 'at least 2 different professions treating the patient in the same clinic, including

orthotist', it was most frequently reported that respondents saw stroke patients in this context 'rarely' (46%) or 'some of the time' (25%).

Table 8. Frequency and timing of orthotist stroke intervention

Frequency of treating stroke patients	n=59	%
More than once a day	3	5
Once a day	12	20
Several times a week	21	36
Once a week	10	17
Several times a month	6	10
Once a month	5	8
Less frequently than once a month	2	4
Length of time after stroke when patient assessed by orthotist	n=58	%
1-2 weeks	4	7
3-6 weeks	15	26
7-12 weeks post stroke	13	22
4-6 months post stroke	13	22
7-12 months post stroke	2	4
>12 months post stroke	11	19

Table 9. Setting of orthotist stroke intervention and MDT working

Clinical setting stroke patients seen in (all that apply)	n=117	%
I see stroke patients as out-patients in a general orthotic clinic	50	43
I see stroke patients as out-patients in a dedicated neurological clinic	13	11
I see stroke patients as in-patients on a stroke or general ward within the acute hospital site	30	25
I see stroke patients within a dedicated in-patient stroke service in a Multi-Disciplinary Team (MDT) setting	10	9
I see stroke patients within a dedicated out-patient stroke service in an MDT setting	8	7

I see stroke patients within a dedicated community stroke service in an MDT setting	6	5
Regularity of MDT assessment of stroke patients (<i>defined as: at least 2 different professions treating the patient in the same clinic, including orthotist</i>)	n=59	%
Never	10	17
Rarely	27	46
Some of the time	15	25
Often	5	9
All the time	2	3

4.4.3 Orthotist involvement in early gait rehabilitation

Table 10. shows that orthotists most frequently reported that they are involved in early gait rehabilitation decisions being made ‘only when a specific referral for orthotic assessment is made by another MDT member’ (68%), with 27% reporting ‘I am not involved at all’, and 5% reporting ‘I am routinely involved without a specific referral for orthotic assessment being made’. When involved with early gait rehabilitation for stroke patients, assessment and detailed prescription decisions were most frequently made with the MDT (49%) or independently by the orthotist (38%). Similarly, use of the orthosis was usually determined with the MDT (52%) or independently by the orthotist (34%).

Table 10. Orthotist involvement in early gait rehabilitation

Involvement in early gait rehabilitation decisions for stroke patients	n=59	%
I am not involved at all	16	27
I am involved but only when a specific referral for orthotic assessment is made by another MDT member	40	68
I am routinely involved without a specific referral for orthotic assessment being made (e.g. I join the MDT meetings or routine assessment clinic)	3	5

Decision making for early gait rehabilitation orthotic assessment and prescription (all that apply)	n=65	%
Other members of the MDT or the referrer formulates the orthotic prescription	8	12
I work with the MDT to formulate the orthotic prescription	32	49
I formulate the orthotic prescription independently	25	39
Orthotic use for stroke patients determined by	n=65	%
Other members of the MDT or the referrer will determine and advise the patient how the orthosis should be best used.	9	14
I work with the MDT to determine and advise the patient how the orthosis should be best used.	34	52
I independently determine and advise the patient how the orthosis should be best used.	22	34

4.4.4 Orthotist confidence in early gait rehabilitation

Table 11. shows how confidence in orthotic management specifically of the lower limb after stroke was high amongst respondents, with 89% agreeing or strongly agreeing that they were confident in recommending a lower limb orthotic treatment plan within early stroke rehabilitation. Eighty three percent of respondents also agreed or strongly agreed they were confident advising on use of an orthosis.

Confidence in other types of orthotic intervention was marginally lower, with 73% agreeing or strongly agreeing that they were confident in recommending a comprehensive orthotic treatment plan to the MDT which may include upper limb or spinal orthotic intervention. Confidence in recommending wider rehabilitation interventions was low among orthotist respondents with 75% replying either: 'neutral', 'disagree' or 'strongly disagree' to the statement 'I am confident advising therapy and activity to progress potential recovery (as a lead member of the therapy team)'.

Table 11. Orthotist confidence in delivering and advising on orthotic intervention

I am confident in recommending a lower limb orthotic treatment plan within early stroke rehabilitation	n=56	%
Strongly Disagree	2	4
Disagree	1	2
Neutral	3	5
Agree	27	48
Strongly Agree	23	41
I am confident advising on use of the orthosis within an MDT including duration of use both daily and longer term	n=55	%
Strongly disagree	1	2
Disagree	2	4
Neutral	6	11
Agree	20	36
Strongly agree	26	47
I am confident in recommending a comprehensive orthotic treatment plan to the stroke rehabilitation MDT	n=56	%
Strongly Disagree	1	2
Disagree	7	12.5
Neutral	7	12.5
Agree	23	41
Strongly Agree	18	32
I am confident advising therapy and activity to progress potential recovery (as a lead member of the therapy team)	n=56	%
Strongly disagree	4	7
Disagree	17	30
Neutral	21	38
Agree	9	16
Strongly Agree	5	9

4.4.5 Orthotist perception of role and involvement after stroke

Table 12. shows almost all respondents (99%) agreed that orthotic assessment should be an essential element of gait re-education as part of recovery in stroke. The majority of orthotists (89%) reported that they felt they should be routinely involved without a specific referral for orthotic assessment being made, by being able to join stroke rehabilitation MDT meetings or attend routine assessment clinics. However, dissatisfaction with current involvement in early stroke rehabilitation was frequently reported with 61% of respondents disagreeing or strongly disagreeing with the statement 'I am satisfied with the frequency of involvement I have with early stroke rehabilitation patients.' A further 23% described being neutral and only 16% were satisfied with their involvement.

Table 12. Orthotist perception of role and involvement after stroke

Orthotic assessment should be an essential element of gait re-education as part of recovery	n=55	%
Strongly Disagree	1	2
Disagree	0	0
Neutral	0	0
Agree	15	27
Strongly Agree	39	71
Opinion of involvement of orthotist in early gait rehabilitation decisions (<i>early rehabilitation identified as within six weeks of onset</i>)	n=56	%
I don't think Orthotists should be involved at all	0	0
I think Orthotists should be routinely involved without a specific referral for orthotic assessment being made (e.g. join the MDT meetings or routine assessment clinic)	50	89
I think Orthotists should be involved but only when a specific referral for orthotic assessment is made by another MDT member	6	11
I am satisfied with the frequency of involvement I have with early stroke rehabilitation patients	n=56	%

Strongly disagree	13	23
Disagree	21	38
Neutral	13	23
Agree	5	9
Strongly agree	4	7

4.4.6 Qualitative responses

Following a framework analysis approach as described by Gale et al. (175), a qualitative analysis of the free-text responses was undertaken. In order to capture the themes and concepts within the free-text responses, we developed a framework with codes which was applied to each response. Because responses tended to be brief, generally ranging from 30 to 60 words long, coding was conducted by the lead researcher alone. If a response included more than one theme, multiple codes were applied to capture cross-cutting content. After coding was completed, two other reviewers checked the coding against the responses before agreeing the overarching themes of the data.

The supervisors and lead researcher then iteratively reviewed the themes to combine similar and overlapping items into the final four themes; **Theme one:** *Barriers to integration within the MDT*; **Theme two:** *Timing of referral and assessment*; **Theme three:** *Variation in funding and access*; **Theme four:** *Impact of clinical approach*.

Theme One: Barriers to integration within the MDT

Exclusivity within the stroke MDT, resistance to change, and insufficient orthotist time and service pressures were described as barriers to orthotist integration within the MDT. Participants described previous experiences where MDT approaches were used and how that enabled better outcomes, but they were facing difficulties trying to replicate this model. Moreover, resistance was present in the exclusivity of the stroke MDT preventing relationship building and limiting the professional development usually available within MDT set-ups.

Other respondents reported that they felt increasing waiting lists and lack of orthotists nationally contributed to restrictions on closer MDT working within stroke services.

“We had MDT clinics which enabled a better approach [...] I am trying to establish something similar where I am now, but there is quite a lot of resistance [...] due to waiting lists etc. Where I worked before had such an excellent set up which I helped develop and it helped all the AHPs involved develop as well.” (Respondent 3)

“The stroke MDT is very exclusive and doesn’t include orthotists, the company I work for won’t allow time for us to go and spend time with the stroke team to build relationships either.” (Respondent 14)

“I think that an orthotist in specialist MDT setting would be good, but we do not have anything like the capacity to offer that in terms of clinical staffing.” (Respondent 45)

Theme Two: Timing of referral and assessment

Timing of referral was highlighted as being a barrier to better outcomes for stroke patients. Orthotists reported they felt they were not being involved early enough within the stroke rehabilitation pathway which complicated the eventual orthotic management plan. Delayed treatment was perceived as a significant problem with longer-lasting consequences with some respondents describing how it can lead to the development of further complications.

“Often see stroke patients too late and so they will have contractures etc making it harder to achieve good outcomes.” (Respondent 9)

“I have found that if Orthotics is not involved early on the risk of contracture is significantly higher and they only are referred into community orthotics when they have a significant contracture that cannot be accommodated by [off the shelf] orthotics any longer.” (Respondent 50)

Theme Three: Variation in funding and access

Inequalities were identified as being starkly apparent for some stroke survivors due to variation in funding across services. Furthermore, these disparities were described as being present within referral pathways, as where stroke survivors could expect to be placed was dependant on where they lived. With some stroke survivors being treated away from their home trust, due to the acute nature of stroke, it was reported that this could result in patients within the same hospital receiving different levels of care depending on where their home trust was. Respondents reported frustrations with the different models of orthotics service commissioning leading to inconsistent access.

“What orthotics you get, it’s dependent on the trust and even hospitals to which services [are] provided.” (Respondent 24)

“Funding is a big issue in regard to accessibility to services. There are stroke patients in the same hospital from different trusts yet only the patients from the ‘better funded’ trust get access to orthotic services.” (Respondent 16)

Theme Four: Impact of clinical approach

Difference in clinical approach driven by the lack of clinical best practice guidelines was raised by several respondents. Some described how the clinical approach from the wider stroke rehabilitation team was difficult to navigate. Often it was felt that the beliefs and training of the referrer negatively impacted on the ability of the orthotist to conduct timely assessment, with other orthotists describing how their own training restricted them:

“Most of our neuro physios delay referring as they do not want to brace the patient too early in case their function returns. Therefore, we fit PRAFOs early to maintain range then they will refer for an AFO at a later stage. We feel we should be assessing for AFOs earlier to reduce [the] risk [of] poor gait re-education.” (Respondent 1)

“We need guidelines to give consistency [...] I feel [physiotherapists] do not want an orthotists input because they think we only want to put patients into solid AFOs! I try and engage and teach and learn in combination with the physio team, but it is a constant battle.”
(Respondent 14)

“We need more stroke specific training; I didn’t know anything until I came of Uni and then it was only what my clinical mentor showed me.”
(Respondent 38)

4.5 Discussion

The aim of this study was to establish a cross-section of perspectives from the expert orthotic workforce on current practice and optimum orthotic intervention in early gait rehabilitation following stroke in the UK.

The results indicate that orthotists are involved with the early gait rehabilitation of stroke patients but that this involvement is predominantly in the outpatient setting. This corresponds to their orthotic assessment and treatment occurring later in the rehabilitation pathway (37). This suggests that, when considered in conjunction with previous study findings from the preparatory MDT survey, orthotists and other members of the MDT perceive orthotic intervention is currently being delivered later than would be considered optimal (37). Theme Two of the qualitative analysis highlighted timing of referral and assessment as being significant, and a potential impact of delays on the development of secondary complications, such as contracture. This inevitably will lead to poorer outcomes and quality of life for the patient (176), but also more costly and complex orthotic interventions to try and manage the multi-faceted presentation at this later stage in rehabilitation (177).

Whilst MDT working is considered the gold standard for complex rehabilitation interventions (52), 46% of survey respondents reported that they rarely treated

patients within an MDT setting. This suggests orthotists have limited integration within the stroke rehabilitation MDT and therefore limited involvement with orthotic intervention assessment and provision during early gait. This was reflected in theme one of the qualitative analyses with barriers to integration within the MDT a repeated sentiment. Participants reported exclusivity within the stroke MDT and resistance to change making closer working between the orthotists and the other MDT members as well as collective working within the team more problematic. This segregation is likely further aggravated by orthotists not being included within current national guidelines for the stroke rehabilitation team (7,52), leaving the means and method of their involvement ambiguous and open to localised interpretation. Inconsistency in approach and degree of inclusivity within the stroke MDT is reflected in the survey respondents' own experiences across the UK and demonstrates a need to establish optimal ways of working when delivering orthotic interventions after stroke.

Variability in MDT working, predictably, contributes to inequalities in access to specialist orthotist involvement after stroke with the differences to funding of services and subsequent patient access and treatment described in qualitative theme three. It was highlighted within the survey that access currently is most often determined by members of the wider MDT and mostly facilitated by a specific referral request. This could mean that patients with orthotic needs in early rehabilitation do not have access to the specialists trained to identify their need. Using referrals to facilitate specialist orthotic access is dependent on particular referrers' training and perceptions with current practice heavily influenced by localised relationships and procedures within a team. Theme four from the qualitative analysis notes how the lack of clear best practice guidance and national recommendations could be contributing to this localised model of practice. Only 5% of respondents reported routinely assessing patients for orthotic need during early gait rehabilitation, without a specific referral being made. This is evidence supporting the wider problem of difference in clinical

approach negatively impacting on ease of access to orthotic assessment and intervention for all stroke survivors. Findings from this survey support the development of clearer guidelines for orthotist involvement in gait rehabilitation following stroke, with orthotists intervening earlier on the pathway and within established MDTs.

As an opportunity to revisit the previous MDT survey conducted in 2019 (37), which focused on use of orthotic devices after stroke, the findings from this survey show confidence in recommending lower limb management amongst orthotists. This indicates the strength of their specialist training in biomechanical principals and relevance to gait rehabilitation after stroke (56). Lower levels of confidence were reported in other areas of gait therapy and activities following stroke which is reflective of the orthotists' reduced participation with the wider rehabilitation MDT. Low numbers of orthotists practicing nationally, as well as time and service pressures, likely contribute towards this model of reduced MDT working (178).

Dissatisfaction with orthotist involvement in early stroke rehabilitation was highlighted with most orthotists reporting that they felt they should be routinely involved with the population of stroke patients who require gait rehabilitation without a referral being made. Due to their specialist biomechanical training, orthotists are best placed to determine if an orthotic device would be beneficial for a patient in early gait training (56), but their ability to make such determinations are too heavily dependent on the views of the wider stroke rehabilitation team as the referring party. Almost all respondents (n= 55, 98%) agreed that orthotic assessment should be an essential element of gait re-education as part of recovery in stroke, making it an area where changes to current practice should be focused.

The presented study is based on the UK context; however, the questions were developed in collaboration with colleagues in the UK and Denmark and the study was adopted and adapted by a master's student in their programme to explore

the perspectives of Danish orthotists within stroke rehabilitation. This survey was conducted at the same time and found similar results, suggesting that some of the factors effecting the expert perception of their role within orthotic intervention after stroke highlighted within the findings of this study are relevant internationally (179). In particular, Danish orthotists reported their usual involvement late in the rehabilitation process, and also the belief that they should have stronger and more well defined links with the core stroke rehabilitation MDT as part of optimum gait rehabilitation for stroke survivors.

4.5.1 Study strengths and limitations

This is the first national survey of orthotists as the expert workforce, exploring their involvement with early gait rehabilitation following stroke. The number of participants (n=56) was relatively small compared to the number of prosthetist/orthotists registered to practice in the UK (n=1114 registered (174)). However, as a dual registered profession, approximately 50% of the registered workforce would be 557, indicating a response rate of 10% of registered orthotists in the UK. In addition, a requirement to be eligible was that participants had to have experience working in stroke and the size of this group is unknown. Respondents were likely self-selective as those that are more interested in stroke rehabilitation as a speciality, and this will be reflected in their responses. Moreover, the survey was only circulated to members of the British Association of Prosthetists and Orthotists (BAPO) and whilst they are the professional body for orthotists practicing in the UK and hold the largest distribution list of orthotists in the UK, membership is not a requirement. The bias towards BAPO members was mitigated in part by the circulation of adverts through social media channels as through this they may have reached non-BAPO members of the orthotist community. Inevitably though, there will be orthotists who will have been missed in the approach meaning their views will not be reflected in the results. Future circulations could include targeted invitations sent to orthotic managers across the UK with a request to filter down to their team members to get a greater saturation of distribution. This is a benefit of

such a small profession (180), that knowledge of orthotic managers for each trust or service is relatively well known or obtainable with little difficulty via the BAPO offices. An alternative approach to try and establish current practice would be to use a Freedom of Information request which has been successfully used in other orthotics-based research (181). Nonetheless, this approach whilst useful in obtaining factual data is often perceived as quite contentious by clinicians and would not facilitate a perspective-based enquiry as was done within this cross-sectional survey.

Another limitation of this study was the closed nature of most of the questions. The survey was developed to capture current practice and perspectives of the orthotists on their role and the role of orthotic intervention within early gait rehabilitation. The survey was pilot tested with clinical colleagues and with the BAPO research committee, with feedback received that the survey needed to be quicker to complete and contain more multiple-choice options to ease the completion. As such the format was revised to encourage a greater response rate and facilitate completion of questions between busy clinical caseloads. The data collected from the open-ended questions indicates the profession has a range of interesting views and therefore further qualitative work would be worthwhile exploring. In a future study it would be beneficial to explore in more detail the localised relationships that orthotists have which facilitate and prevent their involvement within the stroke rehabilitation pathway. Identifying models of practice which produce good outcomes would be a useful mechanism to highlight best practice and the positive effects. Whilst the survey findings have been published in a peer reviewed journal (171), using the CROSS checklist (117), a more specialised approach using the Checklist for Reporting Results of Internet E-Surveys (CHERRIES) (172), has been used for this thesis as a tool designed for electronically administered surveys. The use of both these toolkits in the presentation of the results promotes a better understanding of the survey participants in their self-selection and the possible differences from a

representative sample, and it is hoped that by adhering to these checklists the findings are more reliable and useful.

The use of a cross-sectional survey for this study was selected as the most acceptable method of data collection at a time of great social disruption and restriction due to the global Covid-19 pandemic. With many nation-wide restrictions on movement and meeting face-to-face it was determined that a remote data collection method was most appropriate. Additionally, most of the orthotic workforce, who were the intended population to be targeted by this survey, were drafted into front-line clinical roles during the time of data collection and were therefore not practicing within their usual clinical settings. As such, their availability to attend online interviews or focus groups which may have offered an alternative means of data collection were limited. An online cross-sectional survey was selected as it could be completed in participants' own time, in between busy clinical caseloads and without geographical restriction.

The data gathered from the study offers a snapshot of orthotic intervention after stroke practice and the perspectives of the expert orthotic workforce within this post-covid clinical landscape. The findings offer an update to and development of the findings from the preparatory MDT survey with a targeted focus on the role of the orthotist and their place within the wider stroke rehabilitation MDT. The importance of this relationship as a way of working was identified as critically important within the orthotic and stroke rehabilitation team clinical observations presented in Chapter Two and has informed the statements of best practice developed as the main output from this PhD. The findings from this survey study are grounded within the experiences of the expert workforce, with questions exploring the confidence, frustrations and ambitions of orthotists practicing within the UK helping to begin defining workforce specific aspects of the proposed statements of best practice.

4.6 Conclusion

UK Orthotists responding to this survey reported that orthotic treatment is an important aspect of early gait rehabilitation following stroke, but current practice appears to be varied and based on localised relationships and processes. It is reasonable to consider that such variation in practice may be related to discontinuity between existing guidance (7,29,52). It could be argued that clear clinical pathways for orthotic involvement are needed. These would enable orthotists to determine how and when they intervene in a stroke survivor's care and assist in providing a service blueprint for structuring provision in a way which enables greater MDT interaction. The findings from the survey highlight how mechanisms to improve the multi-disciplinary relationships between the orthotist and the wider stroke MDT are needed to facilitate efficient orthotic intervention for stroke survivors who need it, and ultimately lead to better outcomes. Clinical guidelines detailing specific orthotist involvement pathways after stroke, informed by evidence-based research and consensus, would be beneficial to reduce some of the variation in orthotic care that was evident within this survey.

Expert orthotist survey participants reported dissatisfaction with their current involvement with stroke gait rehabilitation and believe their earlier and more cohesive inclusion in the rehabilitation process would benefit stroke survivors. These sentiments are also reflected in the views of orthotists surveyed elsewhere (179), and therefore further investigation is warranted to explore how this way of working could be facilitated within this clinical landscape. Critically, the views of stroke survivors, carers and other stroke rehabilitation team members as key stakeholders are needed to consider the context within which orthotic interventions after stroke are delivered within the UK. The cross-sectional survey findings presented in this chapter act as a foundation to consult these stakeholders on their perceived optimal ways of working when delivering orthotic interventions after stroke.

Chapter Five: Experienced based evidence and perspectives on the role of orthotics in stroke rehabilitation – stakeholder focus groups with practitioners, stroke survivors, and carers

This chapter details perspectives of stakeholders with practice and personal lived experience of stroke on the role of orthotics after stroke. Through conducting focus groups with stroke survivors, carers, and stroke rehabilitation clinical practitioners, this study offers an insight into the wider perception of the role of orthotic intervention. Figure 6 shows that this Chapter details the third stage in the five identified phases of development for the statements of best practice on delivering orthotic interventions after stroke. The findings provide experience-based evidence on orthotics intervention within stroke rehabilitation from stroke survivors, carers, as well as orthotists and members of the stroke rehabilitation MDT.

Designed as method of deeper consultation with stakeholders on this topic, the findings were intended to be interpreted alongside the findings of the study presented in Chapter Four. None of the research methods used within the PhD programme thus far had included the voice of lived experience, it was important therefore that their experiences of orthotic intervention after stroke were captured. The findings from the preparatory work indicated how influential members of the stroke rehabilitation MDT were in informing orthotic intervention for stroke survivors. Therefore, it was intended to explore their experiences as an adjunct to the perceptions of the expert workforce as completed in Chapter Four. Secondary to the primary aim of the study was the inclusion of both cohort's voice in the development of proposed best practice statements, ensuring that they were grounded in personal and professional experiences of everyone who is involved with orthotic intervention after stroke.



Figure 6. Development of Best Practice Statements – stage 3

5.1 Aims of the study

The aim of this study, as related to the third aim of the PhD was:

- To determine stakeholder perspectives on the role of orthotics in stroke rehabilitation, exploring the similarities and differences in their perception to those identified by orthotists.

To achieve this, three focus groups were conducted. Two with stroke rehabilitation clinical practitioners and one with stroke survivors and carers. Using a topic guide informed by the findings of the systematic review and professional cross-sectional survey, these focus groups gathered stakeholder perspectives on the role of orthotics within stroke rehabilitation focusing on early gait.

5.2 Background

To compliment the findings from the professional cross-sectional survey presented in Chapter Four, a more comprehensive exploration of the perspectives of stakeholders was needed to determine the key factors which influence current orthotic intervention after stroke. It was proposed to conduct up to three remote multi-disciplinary focus groups to collect expert perspectives on the role of orthotics within early gait stroke rehabilitation. This method was chosen specifically to include the voices of stakeholders within the findings and encourage inter-professional discussion on the issue (182). The importance of the role of the physiotherapists, specifically in facilitating orthotic intervention within stroke rehabilitation, was made clear in both the preparatory MDT survey and the findings of the professional cross-sectional survey, with emphasis on successful outcomes being dependant on good professional relationships. The study presented within this chapter was designed to explore this further, gaining perspectives on the role of the orthotist within the wider stroke rehabilitation team from stakeholders other than orthotists themselves. Moreover, it was felt important to ground the study within the lived experiences of stroke survivors and carers, ensuring the questions being asked and statements being proposed were reflective of their perceptions of what optimal orthotic care after stroke may look like.

To gather perspectives rooted in the participants' experiences, focus group methodology was chosen to facilitate the uncovering of directional information and knowledge, stimulated by the conversations and discussions of participants (183). Importantly the first two focus groups would be conducted with a multi-disciplinary focus format which was hoped would assist in capturing the complexity and differing experiences of stakeholders in delivering complex interventions in dynamic clinical settings (184). Following guidance from the PPI collaborator for the study, it was agreed that the focus group of patients and carers was conducted separately to the clinician focus groups. This was to establish a distinct forum for their views to be gathered and explored without

the influence of professional opinions. Following completion of the focus groups, the combined results were to be converged with the findings from the systematic review and professional cross-sectional survey via a triangulation technique to inform the proposed statements of best practice to be agreed in the eDelphi consensus exercise.

5.3 Methodology

This focus group protocol was developed with support from the University of Nottingham sponsor and is presented in Appendix N.

5.3.1 Development of the technique

With the revision of the PhD research question and methodology, a method of enquiry was needed that would facilitate the consultation of a spectrum of perspectives and gather evidence from several data points. Focus groups as a methodology were chosen over other qualitative methods such as interviews due to their group format, which facilitates discussion between participants to generate richer data. It has been described how focus groups are particularly useful when applied to the multi-disciplinary context of complex healthcare interventions as they allow for the construction of shared group meaning with participants able to develop ideas as they interact with one another (182). Whilst Covid-19 restrictions meant in person meetings were not possible, an online focus group format facilitated participants to be included from a wide-ranging geography including Scotland, Wales, and England.

The online format of the focus groups was an approach which enabled the inclusion of the voice of the lived experience by involving stroke survivors and carers who had perhaps more cause to be concerned and hesitant to attend an in-person event at the time of the pandemic. This method of engagement was agreed upon through dialogue with the PPI contributor for the study. The PPI lead also advised that the patient and carer focus group activity should be conducted separately to that of the clinicians to allow participants the platform

to share their views freely and to limit any social desirability bias. The prevalence of online video conferencing systems has increased rapidly due to the Covid-19 pandemic which broadened the spectrum of potential participants who were familiar with and comfortable to use such formats.

It was intended to conduct between 3-5 focus groups depending on the number of potential participants who responded to the invitation to take part. This is in line with other studies conducted and within the recommended range required to achieve saturation of data (185). Each focus group was planned to contain between 6-8 people as per recommendations by Kreuger & Casey (183), to facilitate even discussion amongst all participants.

5.3.2 Development of the topic guide

The focus group was directed by the lead researcher as the facilitator, with discussion instigated and steered using a set of pre-determined questions and statements. This topic guide was developed with the PPI contributor, the academic supervisory team, and the study clinical advisor, and is presented in Appendix O.

The topic guide was an important tool to help explore participant's opinions more systematically and keep the discussion focused on the topic of interest (183). Following the example described by Krueger & Casey (183), a bulleted outline for the topic guide was drafted. Using findings from the systematic review and professional cross-sectional survey, specific questions were posed to target areas of interest most pertinent to the research question and provide the richest data for use in the triangulation exercise. Five question types were used to encourage open discussion on the topic including: 1. Opening Question; 2. Introductory Question; 3. Transition Questions; 4. Key Questions; Ending Questions. Findings from the systematic review and cross-sectional survey were presented to focus group participants in the form of questions to explore whether their experiences were reflected in the previous study findings and in what ways. The topic guide also referenced results from a conference polling

exercise which the lead researcher chaired and where many of the focus group participants were recruited from. The conference was the FORTH 2021 multi-disciplinary conference, which was open to anyone to attend but was mainly attended by AHPs. Two hundred and fifty-one conference attendees were asked to indicate their level of involvement with orthotic intervention following stroke and their perception of orthotic influence on the outcomes for stroke survivors' rehabilitation. This polling exercise indicated similar findings to the professional cross-sectional survey and so influenced the questions included within the topic guide to guide the focus group discussions. The conference proceedings and poll results have been peer reviewed and published as a supplementary publication output from this PhD (186).

Following development, the topic guide was piloted with two clinicians to assist the facilitator to practice and ensure the flow of discussion, whilst testing whether the content of the questions and statements encouraged discussion. It was deemed important that the topic guide was a tool to direct discussion but not be too rigid so allowing themes to emerge as the participants interacted with each other. It was important however that the data produced was relevant to the research question and so it was agreed the facilitator should interjection and re-direct if the topic of discussion was leading away from relevant focus. The focus group findings were instrumental in informing the statements of best practice as a primary output from this PhD, and so edits to the topic guide were agreed with the supervisory team to ensure academic rigour.

5.3.3 Ethical considerations

Ethical approval for the study was obtained from the University of Nottingham Faculty of Medicine and Health Sciences Research Ethics committee on the 9th of February 2021 (FMHS 156-0121). Letter of favourable ethical approval is presented in Appendix P. A Participant Information Sheet (PIS) was made available to all potential participants upon approach and prior to consent being sought. The study PIS was developed by the research team following the format required by the host institute sponsor, a copy of this presented in Appendix Q.

Prior to taking part in the online focus group, all participants provided informed consent via a digital form which also included eligibility statements they were required to confirm. A copy of the consent form is presented in Appendix R.

5.3.4 Data collection and management

The study was conducted using the Microsoft Teams remote video conferencing platform, a format approved for use by the host institution. Each focus group was planned to have between 6-8 participants and constitute an informal one-off meeting with participants discussing their experiences of orthotic intervention after stroke. The focus groups were facilitated by the lead researcher and discussion guided with the use of a topic guide (Appendix O). The focus groups were designed to last for between one to two hours with the video digitally recorded and transcribed using the remote platform recording and dictation facility.

5.4.5 Recruitment of participants

Potential participants for the stroke rehabilitation clinical practitioner focus groups were recruited from the British Association of Prosthetists and Orthotists mailing list, and attendees of the MDT Forward Thinking Orthotics (FORTH) conference: Early Gait Re-education Following Stroke. This conference was co-chaired by the lead researcher and took place in January 2021. The FORTH conference was advertised through mailing list networks for BAPO, the Association of Chartered Physiotherapists Interested in Neurology (ACPIN) and the Royal College of Occupational Therapists – Special Section for Neurological Practice (RCOT-SSNP). A conference report detailing the event proceedings and participant poll results which explored attendees' experiences of orthotic intervention after stroke has been published in the peer-reviewed Synapse Journal (186). Attendees of the conference were invited via announcement at the conference and follow up email to view the digital Participant Information Sheet (PIS) for the practitioner focus groups via a link which was shared with them. Interested potential participants were then contacted via their email

address and invited to complete a doodle poll to determine an appropriate date and time for the focus groups to take place. Potential participants were separated into two groups depending on their availability and to provide a spectrum of professional background, geographical location, and experience in each focus group.

Potential participants for the stroke survivor and carer focus group were recruited from the Nottingham Stroke Research Partnership Group. This group was chosen as a diverse group of stroke survivors with different severity, effects of stroke, and length of time since stroke. The PPI member for the study suggested that a focus group made up of stroke survivor and carer participants that were already known to each other would be preferable as they could speak more freely about their experiences therefore reducing the risk social conformity bias. The group have their base in Nottingham but are geographically dispersed across the Midlands and North-West and are representative of different socio-economic backgrounds, age, and gender. They have a spectrum of lived experience relating to stroke with some very early in their recovery and others now decades into their rehabilitation, and differing severity of the impact of the stroke on their lives. The group were approached via their administrator, who holds their email addresses, who informed them of the opportunity to take part in a focus group exploring their experiences of orthotic intervention after stroke. Those who responded to the administrator with an interest in taking part were invited to attend a focus group session scheduled in place of their usual monthly online meeting. This focus group took place via Zoom as the preferred video conferencing application for this group due its more user-friendly interface.

Eligibility criteria

Eligible participants for the stroke rehabilitation clinician practitioner focus groups were: HCPC registered orthotists with post-qualification experience of working within stroke rehabilitation providing orthotic interventions, and

clinical practitioners with experience of working within stroke rehabilitation. The clinical practitioners would have knowledge of orthotic interventions either in the acute or community setting. HCPC registration wasn't made a specific eligibility requirement to allow those from the wider rehabilitation spectrum to be included such as bioengineers and assistant or non-registered practitioners. Eligibility was self-determined, and the consent form was built to require participants to confirm their eligibility before being able to confirm consent to take part in the focus groups.

Eligible participants of the stroke survivor and carer focus group were self-determined survivors of stroke or carers of someone who had experienced a stroke. There was no limit on time since stroke occurrence and carer was self-defined as someone who provided support or was related to someone who has suffered a stroke. It was a requirement that the participant had the capacity to consent as deemed by the lead researcher following Good Clinical Practice training (187).

5.4.6 Data analysis

The focus groups were video recorded and transcribed using the remote platform recording and dictation facility. The transcriptions were made verbatim and then checked by the lead researcher for accuracy before being anonymised and participants given a unique participant ID. This ID was used throughout the transcripts in place of any identifiable data such as participants name. Electronic recordings were stored on secure dedicated web servers at the host institution with access restricted to only the lead researcher requiring personal identifier login with password in accordance with established information governance and data protection guidelines (118).

Data organisation

Data were analysed using a qualitative framework analysis as described by Gale et al. (175), using a method to organise the data thematically. Framework analysis was chosen as a commonly used healthcare analysis approach in which

data is systematically identified and organised into themes, looking for patterns of meaning across the dataset. Particularly appropriate for focus group datasets, framework analysis offers an insight into collective experiences by allowing for broader issues and multiple opinions to be combined into themes (188). Aligning to any theoretical underpinning, it allows robust and transparent categorisation and management of data which enhances the credibility and reliability of any findings (175).

To encourage consistency across data sources, the focus group transcripts were analysed against the backdrop of the World Health Organisation's International Classification of Functioning (WHO-ICF) (19), in a similar way to the free-text responses from the cross-sectional professional survey presented in Chapter Four. As discussed in Chapter One, the WHO-ICF framework and classification provides consistent terminology and a conceptual basis for the definition and measurement of disability. Within the context of this PhD, it provides classifications and codes for describing and organising information on functioning and disability and therefore provides a foundation for the analysis of rehabilitation interventions such as orthotic intervention after stroke, focusing on a person's experiences of health, the impact of health conditions, and the effect of treatment on their function (19). An analysis framework was designed incorporating emergent themes from the focus group transcripts which were coded inductively. As the data were analysed, sections of the transcripts were assigned a code that best captured the essence of what was being discussed. A process of 'charting' was then undertaken where the coded data were rearranged within the framework using Microsoft Excel to create order to the codes following patterns of topic similarity. This stage operated as a means of synthesising and developing the final coding framework. This process was concluded in the development of final codes, informed by the a priori and emergent data findings, which were then divided into similar themes.

Procedure for analysis

The following seven stages of framework analysis were completed iteratively as described by Gale et al. (175), Stages five, six and seven were completed by two reviewers with results compared before conclusions drawn.

Stage 1. Transcription

The recordings of the three focus groups were transcribed initially using functionality built-in to the Microsoft Teams video conferencing platform. These transcripts were then manually verified for accuracy using the original recordings and to allow the lead researcher to immerse and refamiliarize themselves with the data prior to coding beginning.

Stage 2. Familiarisation with the data

Due to the gap between the data collection and analysis, as a result of a period of maternity leave, this stage facilitated the lead researcher to re-immers and familiarise themselves with the data. Repeatedly listening to the audio recordings, the researcher was able to hear the focus group discussions with new clarity and ensure the digital transcripts were accurate. This stage also offered the opportunity to ensure the anonymisation any participant identifiable data, specifically replacing participant names with a unique participant ID within the transcript which was then used throughout the analysis.

Stage 3. Coding

The transcripts were reviewed with a label applied to the data sections to describe what was interpreted from the content. Such labels are referred to as codes and constitute the basic elements of the data classification (188). An inductive approach was applied initially, which allows for coding to be completed without trying to apply an existing framework. This ensured the coding process was directed by the data and allowed each focus group to be analysed independently before being considered in unity.

Stage 4. Developing a working analytical framework

A starting framework was drafted by completing a preliminary coding exercise of the first focus group transcript. Themes then arose from the inductive coding of the transcripts. The lead researcher working with the PPI collaborator and study clinical advisor worked to adapt the framework following coding of the second and third focus group transcripts. This framework was reviewed by the supervisory team before further coding of all three focus groups transcripts was completed with revisions made as appropriate.

Stage 5. Applying the analytical framework

Several iterations of the framework were developed as it was applied to the data before coding was complete. The researcher used Microsoft Excel and the NVivo13 software program which is specifically designed for the analysis of unstructured text, audio, and video data. The lead researcher completed an accredited training course on using NVivo as part of the training and development plan within the PhD.

Stage 6. Charting data into the framework matrix

All three focus groups were then reviewed against the final analytical framework with any new codes and themes integrated as they emerged.

A framework matrix was generated by summarising the final codes with any corresponding quotation recorded against the participants ID with the codes listed in columns. This process of 'charting' was completed with data rearranged within the framework to create order within the codes and the corresponding themes. The matrix was created using Microsoft Excel to allow secondary review by members of the supervisory team. The codes were then grouped into themes according to their root characteristics. All three focus group transcripts were then reviewed against the final analytical framework with any new codes and themes integrated as they emerged through a process of discussion between the lead research and second reviewer member of the supervisory team.

Stage 7. Interpreting the data

The final themes were reviewed by the supervisory team with input given and suggested changes made. They were then checked against the coding matrix by the PPI collaborator with some themes merged following their feedback. The creation of themes from the codes was completed using the Mural application which facilitated electronic organisation mimicking that which might be done with post it notes. The final matrix for the themes was agreed upon and is presented below in Figure 7.

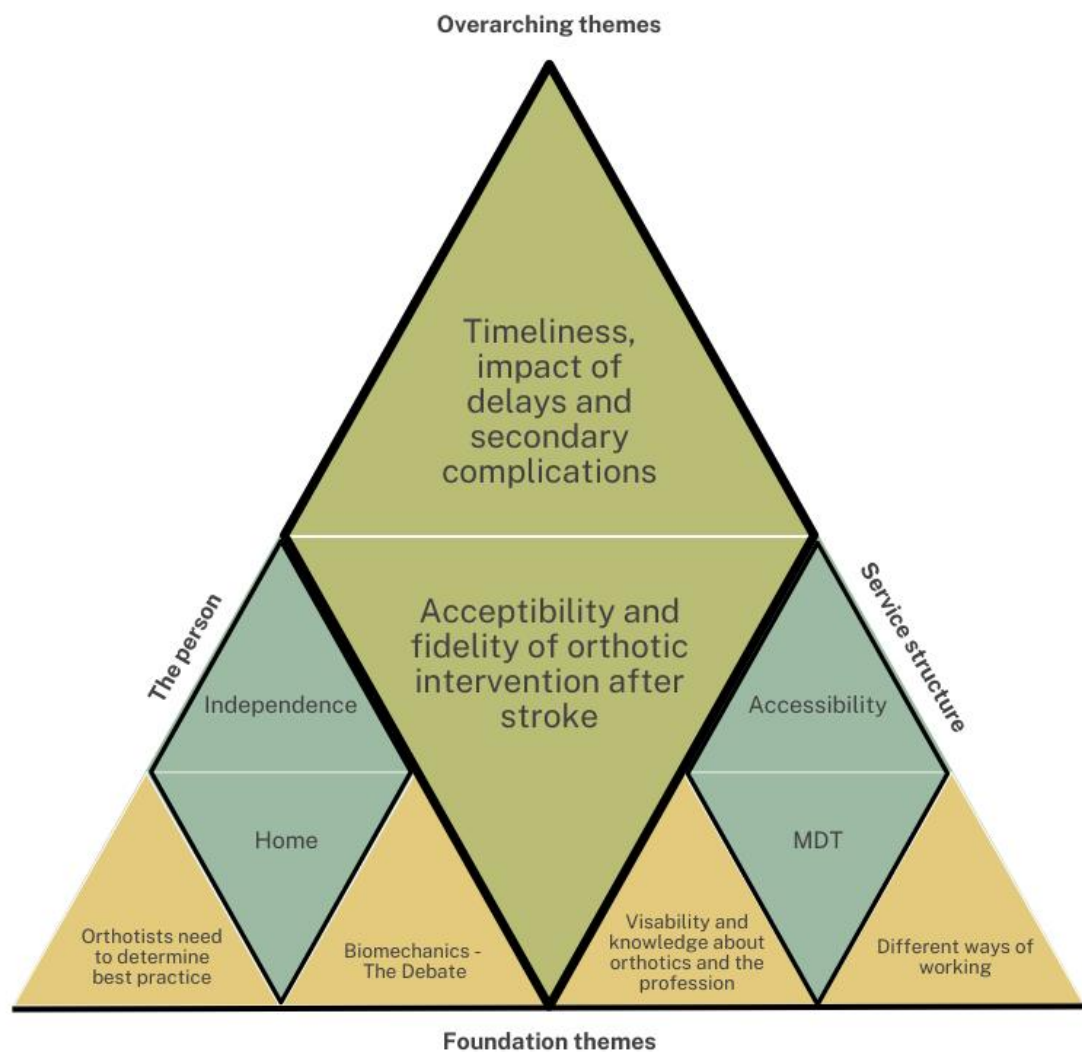


Figure 7. Focus group theme matrix

5.4 Findings

Data were collected between February 2021 and July 2022. The length of time between the clinical practitioner focus groups and stroke survivor and carer group was due to a period of maternity leave which began earlier than expected. Three focus groups were conducted with five participants in the first practitioner group, five in the second practitioner group, and eight in the stroke survivor and carer group. One practitioner contacted following invitation to express interest in participating but it was not possible to include them as they were unavailable at any of the suggested times for the meeting. One practitioner failed to attend for both of the practitioner focus groups. All stroke survivors and carers who were invited to attend the lived experience focus group attended. The focus groups lasted between 68 and 83 minutes long and included a heterogeneous group of participants across the practitioner and stroke survivor and carer groups. Participant characteristics are presented in Table 13.

Table 13. Focus group participant characteristics

	Role	Years qualified/ years since stroke	Geographic location
Participant 001	Orthotist	15 years	North-East England
Participant 002	Physiotherapist	37 years	West Midlands
Participant 003	Clinical bioengineer	35 years	West Midlands
Participant 004	Physiotherapist	27 years	South-West England
Participant 005	Physiotherapist	8 years	South-East England
Practitioner group 2			
Participant 006	Orthotist	28 years	North-East
Participant 007	Orthotist	12 years	East Midlands
Participant 008	Physiotherapist	17 years	Scotland
Participant 009	Physiotherapist	14 years	East of England
Participant 010	Physiotherapist	6 years	West Midlands
Stroke survivor and carer group			
Participant 011	Group facilitator	-	East Midlands

Participant 012	Stroke survivor	23 years	East Midlands
Participant 013	Stroke survivor	4 years	East Midlands
Participant 014	Stroke survivor	17 years	East of England
Participant 015	Stroke carer	-	East of England
Participant 016	Stroke survivor	8 years	East Midlands
Participant 017	Stroke survivor	10 years	East Midlands
Participant 018	Stroke carer	-	East Midlands

Participants of each clinical practitioner focus group were purposefully allocated to give a broad spectrum of professional experience and background and encourage inter-professional debate. Group one contained one senior orthotist, one consultant physiotherapist, two neuro-specialist physiotherapists, and one clinical bioengineer. The second practitioner focus group contained two senior orthotists, one senior community physiotherapist, one band 6 physiotherapist, and one neuro-specialist physiotherapist. The stroke survivor and carer focus group was made up of stroke survivors, carers and a trusted group facilitator as suggested by the study PPI collaborator. The range of length since stroke was 2-26 years and all participants were familiar with orthotics but not all had experience of using them in their rehabilitation.

Framework analysis

Eight core themes were identified: four foundation themes, a further two centred on the person and two on the wider service structure, and a final two overarching themes. Figure 7. depicts how the themes are linked together with the four underlying themes positioned at the bottom of the matrix: *Orthotists need to determine best practice; Biomechanics – The Debate; Visibility and knowledge about orthotics and the profession; Different ways of working*. Each theme represents aspects of orthotic intervention which are not direct but influential to its implementation, acting as a base layer of concepts within the matrix and underpinning the hypothesis of orthotic intervention after stroke. Above the four underlying themes on either side are two themes relating to the

person: *Home; Independence*, and two relating to the service structure: *MDT; Accessibility*. These themes are directly associated with orthotic intervention in the way it is delivered and the effect it can have on the stroke survivor. Finally, two overarching themes which dictate and direct the other themes sit at the top: *Acceptability and fidelity of orthotic intervention after stroke; Timeliness, impact of delays and secondary complications*. These eight core themes and two overarching themes are presented below with illustrative quotations.

5.4.1 Theme One – Orthotists need to determine best practice

“There’s a lack of evidence. The whole of orthotics is basically you learn the basics and then it goes on your gut feeling and personal experience of things after that. You could get four different orthotists in a room, and we’ll come up with four different treatment plans and they could all be successful. But again, what is successful? We need to make evidence that says this is the specific treatment that works.” Participant 001 (Orthotist)

This theme is the first of four which encompass the base layer of concepts within the matrix depicted in Figure 7. It explores the issue of orthotists not having a professionally agreed approach and standard for orthotic delivery after stroke. This was primarily raised by the orthotist participants themselves as an area which needs wider professional consideration. The quotation included above describes the lack of evidence and the impact of this on professional agreement. This difference in approach was also highlighted by the other therapist participants as a restricting factor in their ability to engage with orthotists and orthotic provision.

“Different views about what they think would help [is hard]. So sometimes when our general orthotist has been away, we’ve had a period where we have one orthotist come one time, another orthotist come another, and they will say well ‘I don’t know why they gave you that one,’ and then the other orthotist will come back and say, ‘well that was never going to do the job’...I think that’s probably our biggest frustration about our orthotics clinic is there doesn’t seem to be a

consistency of opinion about what's good for different things.” Participant 004 (Physiotherapist)

The practitioner participants spoke about how practice was often directed by anecdotal and legacy based evidence and as a profession, orthotists need to determine what is best practice amongst themselves. As well as exploring new models of working, they need to review current methods for their appropriateness where they have arisen out of legacy, singular perspectives, or localised resource issues rather than a robust evidence base.

“Our emphasis on evidence-based medicine in recent years tends to obscure the fact that many commonly utilized treatments and medical procedures, and I will add to that hypothesis, are largely anecdotal and legacy based. In some instances, our standard practices are so entrenched that we seldom even question the flimsy basis of our approaches. No matter how intuitive a tactic may seem in the absence of supporting data, dogma is still just dogma.” Participant 002 (Physiotherapist)

5.4.2 Theme Two – Different ways of working

“They [orthotists] are part of the team and so I can't see any rationale why they shouldn't be part of the team when it's very frequent that somebody has walking problems for example.” Participant 18 (Stroke survivor)

Perceptions of different ways of working were brought up by the participants with a focus on multi-disciplinary approaches facilitating greater awareness of orthotics. It was raised how orthotists could and should be more readily involved within stroke rehabilitation, especially where there are walking difficulties identified. However, one aspect which orthotists spoke about was how the way in which they work varies across settings and impacting on how they interact with the wider stroke rehabilitation team.

"I work in four different trusts, and they've all got different setups, as much as we try and say this is a successful setup in one place can we use it in in here too, it's not always the case." Participant 001 (Orthotist)

For many therapists they are used to ordering stock orthotic devices without involving the orthotists in their assessments and whilst an accepted method of intervention, this raised questions about the autonomy of the orthotist and practicing within professional scope more widely.

"So sorry, that's probably being very unkind, but in the worst scenario there may be some who still see themselves [orthotists] as providers of orthoses rather than delivering a clinical opinion." Participant 007 (Orthotist)

Within stroke rehabilitation it was reported as being commonplace that therapy practitioners would prescribe and fit simple orthotic devices without including orthotist specialist assessment. Participants spoke about how this was primarily driven by lack of orthotist time and how they felt it fell within their professional remit. One participant however raised the issue of scope of practice and felt colleagues were sometimes acting outside of their professional remit which contributes to restricted orthotist engagement within stroke rehabilitation.

"One of the things that perhaps gets a little bit overlooked is scope of practice. As a physio we are trained in physiotherapy...my training does not include biomechanics, materials, and material properties, so I have no right at all to specify what something should be made of. It's not in my sphere of practice, I am not licensed to do that, and I think there's an awful lot of that goes on in this space." Participant 004 (Physiotherapist)

This theme presents some of the multiple different ways orthotic intervention is delivered after stroke. Whilst MDT working is presented as best practice, the participants of the practitioner focus group reported how this was not routine within many of their clinical settings. Several of the physiotherapist participants spoke of delivering orthotic devices without orthotist involvement. Whilst this

approach can facilitate stroke survivors' immediate needs, bypassing any accessibility issues, it raises questions about practicing within professional defined boundaries and scope.

5.4.3 Theme Three – Visibility and knowledge about orthotics and the profession

"I would like to think and hope that our services is accessible up here, I think the difficulty is that people are surprised that we have a service and so it's the knowing the knowledge of a service that's available. So that's the education part for us to go to all the different departments and tell them about us." Participant 1 (Orthotist)

Knowledge and awareness of orthotics was described as being central to the subsequent successful delivery of orthotic interventions after stroke and very practitioner specific. Participants spoke about how orthotics are often not known about by either the clinicians or the patients when orthotic clinics or MDT working has not been established in certain centres or trusts.

"I think another thing is in the acute setting, the patients won't have heard of orthotics until the physio raises it so it's not kind of a pure patient choice because they don't really know what's out there until we mention it. Because the orthotist isn't around, it all comes from them [physiotherapists]...so it depends on your therapist really." Participant 010 (Physiotherapist)

Stroke survivor and carer participants echoed this finding, discussing how they were not aware of orthotic provisions when they first had their stroke and that it wasn't suggested as a possible intervention by their physiotherapist at the time.

"The carers and the person it's happened to just don't know anything about these services and it would never occur to us to ask a question about orthotics and just now I'm thinking it's almost like a light going on that this is something that should

have been looked at but we couldn't ask for it because we didn't know about it."

Participant 018 (Stroke survivor)

Practitioner participants raised how lack of professional awareness of orthotics appears to stem from the teaching at undergraduate level across the Allied Health Profession (AHP) disciplines. It was suggested this is true for all professional groups with a there is a lack of adequate teaching of cross principles between therapy students. This results in newly qualified orthotists, physiotherapists and other AHPs without a good grasp of how other professions work. Only if they work within a clinical setting where there is established MDT working between professional groups do they begin to develop this knowledge.

"I can't remember doing too much about [orthotics] in my training, it might have been kind of mentioned briefly. I only met an orthotist once I'd started work."

Participant 010 (Physiotherapist)

This theme indicates the impact of awareness of interventions and different professions. It highlights how orthotists need to articulate their role and promote themselves to improve inter-disciplinary knowledge exchange. Such approaches can then encourage the inclusion of orthotic perspectives where they might not have been invited previously, and impact on the delivery of relevant information to patients and carers which may inform their future treatment and rehabilitation decision making.

5.4.4 Theme Four – Biomechanics – The debate

"I hear 'Oh well, they might not be ready to stand in an optimal alignment', well to be honest that's easily resolved... putting somebody in an optimal alignment immediately puts more normal demands on the system and I would suggest you need normal demands on the system to get a normal response back off it."

Participant 007 (Orthotist)

Much of the discussion in focus group one was given over to biomechanical debate, evidencing the keen interest in this aspect of orthotic intervention

within stroke rehabilitation. Biomechanics is, fundamentally, the science of movement of a living body and includes how muscles, bones, tendons, and ligaments work together to produce movement (55). Biomechanics is part of the larger field of kinesiology and is the core underlying principle on which orthotic training is based (56). Whilst the basic principle is agreed, the influence of movement or restriction on function is a matter of clinical debate and there are fields of thought which differ in approach such as Bobath Vs Movement Science (189). These kinds of issues were raised by practitioner participants in both focus groups which is in line with discussions often heard within clinical staff rooms. An aspect which was agreed upon was how early gait recovery after stroke is the primary area in which orthotic treatment is considered beneficial and participants reflected on their own experiences on how best to address the difficulties they see in their patients.

"I think one of the most important things is to get someone up on their feet and get them walking and by doing that, they're having the whole experience, whether that's somatosensory, vestibular, everything... but if they can only do that because they've got an orthotic on, an AFO on you know then it becomes that toss up, doesn't it? You're not necessarily going to get that perfection that you might want in the trunk, but therefore they are strengthening their trunk and otherwise they're sat in a chair all day." Participant 004 (Physiotherapist)

Whilst some participants lauded the use of orthotics in early gait rehabilitation others were more cautious and felt that orthotics were more helpful used as an adjunct in a resource tight environment which enabled a 24-hour approach to therapy.

"I use the physio session as the opportunity to remove the orthotic and see what further kind of improvement we can make and use the orthotic outside of Physio to get someone from A to B. That is a much better treatment option than them sitting in a chair for that whole period of time and I think much more meaningful

as well. I think it's thinking around kind of rehab as a 24-hour approach and not just the one hour that the physio goes in" Participant 010 (Physiotherapist)

The focus group participants spoke about the potential benefits of orthotic intervention for those that need it after a stroke. It was recognised how it was a potential tool in the rehabilitation tool kit but there were still reservations with it being amongst the primary options of treatment.

"It allows them to mobilize with nursing staff on the ward or with relatives or carers at home outside of therapy sessions. But I don't think it should be a physio's first go to throughout the entire treatment for the first six weeks. I think it just should be used as like that adjunct like you know one of the tools in the toolbox." Participant 008 (Physiotherapist)

This theme considers how the participants from all the focus groups discussed the perceived benefits of 'earlier' orthotic intervention after stroke. However, within the discussions the reasons for this were found to be very individualistic. Whilst some participants see the role of earlier orthotics as important for promoting earlier mobilising using repeated movements, others raised concerns with the restrictions that orthotics bring through their very nature of blocking movement. Participant 008 spoke specifically about how orthotic intervention from their perspective is one of many tools in a toolbox, supporting the idea that orthotists would be better placed within that toolbox, as part of the MDT. This would facilitate a more dynamic assessment and provision of orthotic intervention as part of the whole rehabilitation package rather than a static add-on which it can often be perceived as currently.

5.4.5 Theme Five – Accessibility

"In my experience it's the access that kind of limits it [orthotics] as a treatment option and the ability to be able to have that dialogue with the orthotist. Yeah, so I guess that I think it is, it is definitely a helpful adjunct but yeah, it's the access that creates problems." Participant 008 (Physiotherapist)

The variation in accessibility of orthotic services was raised by several participants both within acute and community settings and between different trusts. Patients who are referred within in-patient settings post-stroke can usually see an orthotist if they have the service established but then there is a drop off in accessibility once they are discharged. This was seen as particularly problematic during the sub-acute period as this is when stroke survivors' needs are often rapidly evolving. This difference between in-patient and out-patient accessibility is a widely recognised but poorly understood issue which has multiple factors feeding into it including lack of orthotist numbers nationally, resource scarcity, and poor consistency in orthotists contact. These issues inevitably lead to difficulties with relationship building which has been identified as integral to successful integration of orthotic intervention following stroke.

"Generally, our orthotists are much more available if you're an inpatient or on the rehab wards but once you're out in the community, waiting lists can be upwards of, you know, months and months." Participant 006 (Orthotist)

Physical separation of the orthotic team from the stroke rehabilitation clinical setting was also identified as being problematic. This finding correlates with that from the preparatory MDT survey presented in Chapter Two, which shows 80% of orthotist respondents are based in either outpatient settings or clinical settings away from the acute hospital building.

"I've had experiences where the orthotist is set very separate to the [stroke rehab] team, I guess to everything really, and then that that is harder to build up a relationship with the orthotist." Participant 008 (Physiotherapist)

Improving access for stroke survivors was identified as important, especially once they are based back in the community and patient participants advocated for the use of 'open' referral systems where they can seek treatment or self-refer when they feel it is appropriate.

“I've got quite a close relationship with [orthotist], I can say they're excellent and with that open referral system it's so effective I can go back anytime I want. I found them very helpful, they're very professional and dedicated.” Participant 013 (Stroke survivor)

This theme covers the general accessibility to orthotics in terms of both physical and procedural accessibility. Experiences appear to be very disparate depending on clinical set-up and locality, all contributing to the inconsistency in orthotic intervention delivery reported by participants.

5.4.6 Theme Six – MDT

“Working in an MDT, where you're in sort of fortnightly, I always find really successful when you can actually hash it out between you. You have two different people who come in, but even if you got two different opinions, you can sort of explain the reason why and agree between you.” Participant 001 (Orthotist)

A recurring theme from the data was the value in Multi-Disciplinary Team (MDT) approaches for both inter-disciplinary development and in seeking the right treatment plans for patients. Examples of integrating the orthotist and their specialist skills better with the wider stroke rehabilitation team led to an improved knowledge exchange, increasing inter-professional competency, and better outcomes for the stroke survivors. Participants spoke about how orthotists bring an outside perspective which is beneficial for patients, but due to their more generalist clinical knowledge they can have limited stroke specific expertise. It was raised by several participants that it is working in collaboration with the rehabilitation team that produces the best outcomes. As mentioned in the previous theme, building of relationships was highlighted as being incredibly important to achieving this and should be recognised in the wider context of the intervention delivery.

“My best experience, it was basically when it was a joint physio and orthotics led clinic, that was my most positive experience. It is not like that now.” Participant 008 (Physiotherapist)

The merits of MDT working more widely and within stroke rehabilitation is well documented (140,190). Participants suggested the benefits of MDT working go beyond just the stroke survivor having access to different professions, and suggest the collaboration between the professions, facilitated through MDT, working of is just as important.

“I think [MDT working] is very, very useful and we’re very fortunate that we have access to an orthotist every week so if we do a referral each week, they will appear and we quite often do it as a joint session, particularly with fitting if it’s a bespoke AFO which allows the patient to progress so much quicker, I think it’s very important.” Participant 009 (Physiotherapist)

5.4.7 Theme Seven – Independence

This theme is one of two which focus on the person and encompasses the element central to every aspect of the topic, the patient. It explores the importance of patient goals and the wider context in which they completed their rehabilitation including the environment and support they have. Being able to be independent is unsurprisingly a key patient goal identified in stroke recovery, with early orthotic provision highlighted as a means to promoting greater levels of independence.

“By giving that stability distally, stability and alignment that it then gives you the ability to access and strengthen more at your knee joints, at your hip joint, in your core and gives you that greater element of independence earlier on without needing others to help you.” Participant 004 (Physiotherapist)

However, in circumstances where there is a need for assistance to put on an orthotic device, this can promote greater dependence on carers who may be family or friends or paid care workers. This is particularly of note with stroke survivors who often have a single side weakness affecting their upper as well as lower limbs.

“I think it is definitely to do with independence and the patient wants to be independent. The orthotic might help them walk, but then if all of a sudden, they've got to wait for somebody to help and put the orthotic on...then that does end up being a barrier.” Participant 008 (Physiotherapist)

5.4.8 Theme Eight – Home

For both stroke survivors and clinicians, they described a primary focus of rehabilitation after stroke being on getting the patient home. It was reported as being the driving force behind a lot of early clinical decision making as well as acting as motivation for many stroke survivors and their family.

“When I had my stroke, I always felt that the focus was on getting at home, it was always the focus of the discharge team...I recall coming home, my focus was on getting on me home.” Participant 013 (Stroke survivor)

This prominent focus however was felt to come with some issues once achieved. Establishing a treatment model which encourages continuity of care when a patient transfers home from an acute to a community setting was highlighted as desirable. Yet, participants spoke of problems becoming more apparent in accessing orthotic intervention once discharged, with stroke survivors who move from a regional specialist service to a local service within different trusts having increased difficulties.

“Our patients can be with us for up to six months, but it is trying to make sure they get followed up properly on discharge. There's a problem particularly for us because we're a regional service so you know our orthotist is from [town name] but they might get discharged to [other town name], or you know [other geographical area], all over the place so actually you know then I think it's more of a problem for them to be followed up properly on discharge.” Participant 005

The home theme highlights how the needs of the patient do not often fit with the service provided. Where a stroke survivor can only usually access 6 weeks of Early Supported Discharge (ESD), an orthotic device that takes 3 weeks to be

assessed for and manufactured, will inevitably impact on their ability to progress their other therapy. This contrasts with reportedly much quicker assessment and manufacturing timescales for patients based in an in-patient setting.

“If you're in ESD for six weeks and it takes three weeks to get an orthotic that's a big chunk of their time and half their input gone.” Participant 008 (Physiotherapist)

5.4.9 Overarching theme A – Timeliness, impact of delays and secondary complications

“Patients that come in months and months and months later when we haven't captured them early enough and I'm starting to get those through quite a bit, I think if only we'd seen you six months ago!” Participant 001 (Orthotist)

The first of the two overarching themes covers topics which arose throughout the focus group discussions. Timing of referral, timing of assessment, and timing of provision were all raised by the participants in the context of orthotic intervention delivery within stroke rehabilitation. There is an uncertainty around the best time for intervention. Whilst ‘earlier’ intervention has been repeatedly raised as potentially being beneficial within the focus groups as well as findings from previous studies presented in Chapters Two, Three and Four, it was raised ‘too early’ can also be a problem by restricting movement in a rigid type of orthotic or encouraging walking before musculature is ready to cope with those demands.

“Getting the timing right is important. Sometimes it's too late, sometimes it's too early.” Participant 006 (Orthotist)

Without definitive guidance on when the optimum time for orthotic assessment and provision is after stroke, focus group participants were unclear as to what might constitute best practice, with issues described arising both with early and delayed provision. However, the effect of waiting times and delays on a patients' rehabilitation was specifically discussed with practitioners speaking of how they

feel delays in initial orthotist assessments can lead to delays in therapy progression. Moreover, delays with manufacturing and provision of orthotic devices, once assessment have been conducted, were raised as compounding this issue.

“We have an orthotist who works in the acute trust, so we can kind of link with him but he’s not on site and you have to organize it and it might take a couple of weeks so if you just want them to kind of review a patient in the session, that can be quite a delay in their rehab to get [the orthotist] in.” Participant 010 (Physiotherapist)

“I say what’s the frustrating thing about it is if we have an AFO made, like a rigid AFO, and you know then depending on what day [the orthotist] is coming to us then it might not get sent off. It has to get sent off to get fabricated, comes back then doesn't quite fit, and we have to wait till that next two weeks.” Participant P004 (Physiotherapist)

Focus group participants spoke of the longer-term impact of orthotic delays through the development of secondary complications, other health conditions, further disease, and poorer outcomes. This, whilst hugely impactful for the stroke survivor, also makes the eventual orthotic treatment more difficult, problematic, and costly. Complications arising due to delayed treatment or none at all are a stark reality for some stroke patients who may benefit from orthotic assessment.

“[Orthotics] doesn't get done early enough, we have patients who have to go for surgery, and clearly have the chance to walk because of the other muscle activity that they've got contractures. My big bugbear is that we often get people coming to us who’ve lost range that, and I don't think should have lost range with orthotics.” Participant 004 (Physiotherapist)

“I had my stroke 13 years ago and within a year and a half, because my foot pattern of walking wasn’t corrected with orthotics, I had to have a complete hip

replacement...I found that a real trouble, almost as bad as the stroke you know.”

Participant 013 (Stroke survivor)

5.4.10 Overarching theme B – Acceptability and fidelity of orthotic intervention after stroke

This final theme considers the softer factors which influence orthotic intervention after stroke. Participants discussed how there is an overall acceptance of the importance of orthotic involvement with stroke rehabilitation but raised that in order to understand the mechanisms within which treatment is delivered we need to better appreciate the barriers and facilitators to its efficient and effective delivery. Participants spoke of the individual specialist skills and knowledge of the orthotist and how these can be key to the successful rehabilitation of some stroke patients.

“I think [having an orthotist] is a real bonus and it's somebody outside the physio skill set who has got different knowledge, biomechanical knowledge, and also knowledge of a whole range of different splints.” Participant 004 (Physiotherapist)

Having a regular orthotic clinic scheduled to take place, with ideally the same clinicians, was felt to facilitate joint working and knowledge exchange between professions. However, this model was considered the exception rather than the norm as participants who have routine orthotic clinics and regular contact with the orthotists described themselves as ‘lucky’.

“We're very lucky in that we do have an orthotist that comes to us fortnightly and actually my learning and kind of expanding my skill set I find it really, really helpful and useful and actually helping, he can help me problem solve with patients. So, I find it very beneficial and we're so lucky here that we have access to that.” Participant 005

This theme encompasses the sentiment that access to an orthotist and orthotics service is generally believed to be beneficial for stroke survivors and

practitioners alike. However, consideration should be given to the consistency and fidelity of orthotic intervention after stroke which reinforces the need for clearer guidance on the means and mechanisms which facilitate its delivery.

5.5 Discussion

The aim of this study was to determine stakeholder perspectives on the role of orthotics in stroke rehabilitation, exploring the similarities and differences in their perception to those identified by orthotists.

The findings from the focus groups detailed the need for more and better evidence in this field. Participants spoke of practice being driven by anecdotal and legacy based evidence and it appears, as a profession, orthotists need to determine what is best practice amongst themselves. As part of future research in this area, this lack of consistency in professional approach means that it is important to review current methods for their appropriateness where they have arisen out of legacy, singular perspectives, or localised resource issues rather than a robust evidence base.

The lack of knowledge and visibility of orthotics as a profession was highlighted as a limitation for its more steadfast integration within stroke rehabilitation services. This is compounded by a paucity of guidance on standardised care resulting in uncertainty on what is considered best practice. This results in stroke survivors, carers, and other practitioners unclear how to best facilitate and advocate for their orthotic needs. Whilst best practice guidelines have been produced in Scotland with clear recommendations with regards to AFOs (29), these are not standard across England and Wales and do not extend past the use of AFOs to the wider scope of orthotic interventions. Frustrations were raised by all stakeholder groups relating to this inconsistency of approach, further highlighting the need for guidance. A profession wide agreed and ratified standard of best practice is needed before it can be cascaded to services and other professional groups as well as included within patient information (191).

Such guidance is required to be embedded within evidence-based practice encouraging consistency of approach and outcomes for stroke survivors.

The findings from the focus groups support the assertion that access is easier, quicker, and more straightforward when a patient is located within a hospital inpatient setting. The mechanisms which might facilitate easier and quicker assessment and provision once patients are in the community are therefore important to explore. The stroke survivor should be empowered with a sense of self-efficacy to facilitate their rehabilitation for the months and years to come (192), and a clearer pathway for identifying and meeting any orthotic needs they have would be desirable. Therapists spoke of appreciating more regular access to orthotists to facilitate open lines of communication and instigate a joint therapeutic approach. This was felt to benefit the stroke survivor in cross-discipline working towards similar goals and also help to build inter-professional relationships and knowledge exchange.

Several of the findings from the focus groups were centred around the patient and their wider influences. Either due to the personal goals of the patient, or possibly driven by acute hospital bed pressures, both practitioners and stroke survivors talk about the route out of hospital and returning home as being an important landmark in their rehabilitation. However, it was raised that difficulties with access to orthotic intervention can arise once stroke survivors are back living in the community, further exacerbated when they move between hospital trusts on discharge.

Within both the hospital and home environments, an impact on independence is key to consider in relation to the role of orthotics after stroke. Participants spoke about whether a stroke survivor is able, and/or willing, to use orthotic devices they have been prescribed and if the independence they gain from its provision is negated by the need for assistance to put it on. The desire for independence is identified as a primary goal within rehabilitation for stroke

survivors (2), and so an orthotic device which required them to rely on others is in contradiction to this.

Whilst patients understandably seek independence, the role of carers in facilitating this as well as their wider rehabilitation is important (193). Family members are often thrust into the carer role due to the sudden nature of stroke, and their support is critical in achieving successful outcomes. Including them in orthotic treatment plans needs to be considered. The role of the carer in stroke rehabilitation is well documented (194–196), and any way to reduce the burden on them should be encouraged. Participants of the focus groups suggest, particularly during the difficult early months of rehabilitation and when first discharged home, to ‘automate’ the process of involving orthotics rather than leaving it up to carers to research or follow-up referral. Continuation of care as the stroke survivor transitions between settings is essential (7), and participants spoke about how a drop off in provision can then lead to the development of secondary complications. Ultimately these can present much worse challenges for the stroke survivor and clinician than the primary stroke presentation (197). Participants spoke about how those who may have a need for orthotics but who do not receive them at the perceived appropriate time can develop contractures or compensatory movement patterns which can then lead to other health issues and increased resource use. This is reflective of the findings from the preparatory MDT survey presented in Chapter Two, which discussed the perceived delay in optimum time of provision and the potential negative impacts of this (37). As such, the findings from this study suggest, the role of orthotics in the prevention of secondary complications after stroke should be explored.

Biomechanics as the underpinning theory that guides orthotic principals is integral to reasoning behind the potential impact of orthotic intervention after stroke (56). However, aspects of interpretation of clinical presentation such as what drives a ‘normal walking pattern’ are still debatable amongst professionals. The biomechanical debate was raised in the focus groups as an element which still requires a solution. The role orthotics has in influencing different stages of

the gait cycle is still undecided and whether its greatest impact is during static weight bearing, non-weight bearing, or during swing phase, particularly relevant in the common presentation of 'footdrop'. These stages of the gait cycle are of relevance to stroke survivors where walking is impacted and a return to 'normal' gait desirable (198). A great deal of time is spent within clinical and academic circles debating what is the most appropriate approach to promoting a 'normal' gait cycle and this is evidenced in the lack of singular approach within clinical settings. Focus group practitioners did agree on the concept of orthotic devices being a tool in the rehabilitation toolbox, however. It was discussed how an orthosis should be used when it is most suitable, when it promotes the goals of other therapy inputs rather than blocks them. In addition to this, it was presented that orthoses have a role in continuing therapeutic intervention towards a 24-hr approach and so can be viewed as more than a piece of equipment but an enabler of a holistic approach.

It was presented within the findings how delays seem to be managed better in the acute service, but issues are more apparent in the community due to long waiting lists. In services where there is an on-site orthotist with scheduled clinics then frustrations with delays to assessment and provision appear reduced. The reality of time taken to manufacture an orthotic device cannot be ignored however, and the impact of waiting times from assessment until provision on other therapy progressions should be acknowledged. On site manufacturing or workshops to adjust devices seem to alleviate some difficulties and as above, participants spoke about how scheduled regular joint clinic sessions can facilitate shorter turn-around times. The pattern of orthotists often working across different trusts was raised and so satellite clinics where an orthotist comes into the stroke service once a week or every two weeks for scheduled clinics were discussed as being a successful model.

In addition to regularly scheduled clinics, the benefit of multi-disciplinary working was raised by participants and is considered the gold standard for stroke rehabilitation (52). It is unsurprising therefore that practitioners spoke of the

merits of this approach in relation to orthotic intervention. Unfortunately, some participants of the focus groups do not recognise this model as being the standard in their own services which was in stark contrast to the satisfaction spoken of by those who did operate in this way. Lack of adequate teaching of cross principles at undergraduate level leaves newly qualified orthotists, physiotherapists, and other members of the stroke rehabilitation team without a good grasp of how the other profession works. Only after spending time together within a clinical setting through multi-professional working do they develop this important inter-professional understanding.

In part, the lack of professional understanding can be explained by the lack of consensus as to what the orthotic intervention is for and what its primary purpose should be. The biomechanical debate raised within the findings of this study underlies the wider discussion around orthotic provision and there appears to be a big difference of opinion both within the orthotic profession and between other stakeholders. Whilst it is not proposed this debate can be settled through this study, it is important that its influence is recognised as it is at the forefront of decision making in practice. The implications of this on directing much needed guidance for delivering orthotic intervention cannot be ignored and further evaluative research is needed. What can be established are the methods and mechanisms by which orthotic intervention is delivered, making recommendations for optimal ways of working to enhance rehabilitation outcomes and reduce complications for stroke survivors.

5.5.1 Study strengths and limitations

This is the first multi-disciplinary focus group study exploring the role of orthotic intervention after stroke, bringing together the voices of different stakeholders within this area. It was an opportunity for participants to express their perceptions on how orthotics intervention is currently delivered after stroke, describing their experiences of successful models of practice as well as frustrations. Whilst multiple different perspectives were invited, including that of the stroke survivor and carer, not all members of the stroke rehabilitation

team were represented. Physiotherapy and occupational therapy professionals were specifically targeted to participate as the professional groups with the most relevant clinical practice to orthotic provision after stroke. However, no occupational therapists responded to the invitation to participate and so their perspective is absent from the findings.

A further limitation of this methodology is the group nature of the data collection which should be considered when interpreting the results. Focus groups were chosen as a method to stimulate interprofessional debate and provide a platform to gather multiple stakeholder perspectives in one session. However, focus group participants may be less likely to speak views which are at a discord to the rest of the group and be swayed by social desirability bias. Similarly, focus groups can encourage dominant characters to direct discussion with other group members conforming to their perspective rather than expressing their own views. The facilitator was careful to try and avoid this scenario, regularly inviting views from all participants, highlighting the validity of differing experiences and perspectives. As the participants were sampled from stroke specific networks and through invitation at an orthotics focused conference, they are likely to be self-selecting as motivated to engage with research in this area. Discussions may therefore be overly swayed to a certain outlook on orthotics intervention after stroke, with the group more likely to confirm their own experiences and existing beliefs rather than challenge them. This is likely to affect the transferability of the findings, but the results do show a mixture of experiences, and the participants are representative of differing clinical experience levels and geographic location.

The stroke survivor and carer focus group was recruited from a singular stroke support group and so wider circulation of the invitation through charity or professional networks may have resulted in a broader spectrum of opinion and experience. However, the decision to limit the invitation to this one group was after suggestion by the PPI study collaborator who felt that inviting group members who were already known to each other would facilitate a more open

discussion. This was hoped would encourage participants to express both negative and positive experiences which they may feel more hesitant to share with others not known to them.

The findings from this study can be considered dependable due to the involvement of differing stakeholders both as participants and in the development of the study protocol. Whilst a wider inclusion of perspectives would likely enhance its transferability, the restriction of participants to those most closely aligned to orthotic intervention after stroke was considered appropriate to prevent dilution and more realistic within the confines of this PhD.

The use of thematic analysis, which shares core principles with Framework Analysis (175), is well established within healthcare research giving the study results more credibility. The study protocol was developed in line with the methods described by Krueger (183), who is considered the authority on focus group research, meaning the study findings can be considered comparable to other focus group research. Furthermore, the number of focus groups conducted and number of participants within each group is in keeping with recommendations for focus group research (183,185).

The findings from this study align with the themes from the studies described in Chapters Two, Three and Four, whilst also highlighting wider contextual aspects of orthotic intervention after stroke. A strength of qualitative research, some important underlying issues which inform orthotic practice after stroke have been revealed. The perspectives of key stakeholders alongside the expert voice of the orthotist forms an important foundation for the development of proposed statements of best practice as described within the next Chapter.

5.6 Conclusion

This study has highlighted the multi-factorial context within which orthotic intervention is delivered to stroke survivors within the UK. Whilst there are similarities to the themes identified within the other studies presented within this PhD, the inclusion of wider stakeholder perspectives has been important. Capturing differing views and experiences, it has highlighted issues which are present within the orthotic community such as lack of agreed approach and the biomechanical debate. To gain a more comprehensive understanding of the landscape in which orthotic intervention is delivered currently, it was important to hear from other stakeholder voices alongside orthotists themselves.

The findings from this study, together with findings from the systematic review presented in Chapter Three, and the results of the professional cross-sectional survey in Chapter Four, will now be combined to inform the development of the proposed statements of best practice in this area.

Chapter Six: Triangulation of systematic review, cross-sectional professional survey, and stakeholder focus group findings to form proposed statements of best practice

This chapter details the process of a triangulation technique to combine the findings from the previous three chapters. It details the fourth step in the five identified phases of development for the statements of best practice on delivering orthotic interventions after stroke (Figure 8).

This study generated proposed statements of best practice on delivering for orthotic interventions after stroke through the summarising and converging of systematic review, cross-sectional professional survey, and stakeholder focus group data. Using a triangulation technique described by Farmer et al. (54), the findings provided the basis from which to form proposed statements of best practice. These were then to be refined and professionally agreed in a later study described in Chapter Seven.



Figure 8. Development of Best Practice Statements - stage 4

6.1 Aims of the study

The aim of this study, as related to the fourth aim of the PhD was:

- To converge data from the previous studies to develop proposed statements of best practice on delivering orthotic interventions after stroke.

To achieve this, a healthcare specific triangulation method described by Farmer et al. (54), was used to combine the systematic review, cross-sectional professional survey, and stakeholder focus group data. This method provided a comprehensive way to highlight concurrence, recognise contradictions, and note silences within the source data to inform proposed statements of best practice.

6.2 Background

A triangulation method was chosen (54), to combine the findings, assess the applicability of the previous study results, as well as strengthen their interpretation when forming proposed best practice statements. As a methodology, triangulation of data within healthcare research goes beyond the traditional objective of seeking to answer pre-formed hypotheses by offering further interpretation of the data and provides a means to combine differing data sets (199). This is important within this PhD as a method to combine qualitative and quantitative datasets and consider their complementarity, contradiction, and silence (54).

As identified in previous chapters, there is dearth of guidance for the delivery of orthotic interventions after stroke (7,52), and it is suggested a primary cause of this is the lack of professional agreed best practice. Whilst there has been device specific guidance published (29), there is no such guidance for wider orthotic interventions within stroke rehabilitation which consider the mechanisms by which orthotic intervention is delivered. It was also recognised that there was a lack of any guidance to direct practice across the UK encouraging a consistent approach between national health boards.

As discussed in Chapter One, the primary reason for the development of any clinical guidelines should be to improve the quality of care received by patients. Statements of best practice begin this process by promoting evidence-based interventions and discouraging ineffective or potentially harmful interventions. They can also act as a benchmark for clinical commissioning and evaluation to improve the consistency of care, empower patients, and influence further public policy (200). The Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach as the international standard of best practice guideline development has been followed within this PhD (51,103).

The GRADE method directs us to systematically sort and converge collated evidence followed by an assessment of the certainty of evidence. The data is assessed on its risk of bias, imprecision, indirectness, inconsistency, and publication bias (201). It was determined that statements of best practice would be the most suitable output to be tested within this PhD and agreed via professional consensus. In future research beyond the scope of this PhD, the developed statements of best practice could then be advanced into comprehensive best practice guidelines and evaluated as a complex intervention with further implementation analysis.

In order to sort and converge the data produced within each of the previous studies comprising this PhD, a triangulation protocol as described by Farmer et al. (54), was used. Triangulation in this way contributes to the validity of the research results by combining various research approaches to form a more complete picture. Like any analytical approach there are strengths and weaknesses to triangulation. By its nature, it is designed to overcome individual biases present within the raw data collection methods and therefore improve confidence in the findings. However, where incompatibility exists between the data sets and theoretical paradigms, triangulation can amplify sources of bias. These aspects are considered as the quantitative and qualitative data of this PhD are summarised and converged within this study; this is discussed later in the Chapter.

6.3 Methodology

To ensure a systematic and repeatable process a triangulation protocol was developed.

6.3.1 Triangulation protocol

Farmer et al. (2006) details six steps to conduct a triangulation protocol method (54). These were followed to converge the data from the systematic review, professional cross-sectional survey and focus groups within this study as

described below. Within this triangulation method, both the source data and the previous interpretations of the source data have been included as described by Bakhet & Zauszniewski (202).

Step 1: Sorting

The systematic review dataset was re-reviewed to re-familiarise with the study descriptions and content within the included papers. The key findings dataset from the professional cross-sectional survey was re-reviewed as were the themes from the focus groups. A list of key findings and themes from the three datasets were drafted and then sorted into similarly categorised areas. These themes were used to form the headings for the convergence coding matrix.

Step 2: Convergence coding

The individual datasets were then re-reviewed in their entirety by the lead researcher and compared and appraised against the coding matrix themes identified to determine the prominence of each theme. Specific examples were selected for each theme and labels used to characterise the relationship between the datasets. The labels considered were:

- Convergence - agreement of findings.
- Complementarity - one data set offers additional information on the same issue.
- Contradiction - findings appear to be in dissonance with each other within the datasets.
- Silence - findings arise from one data set but not another.

Step 3: Convergence assessment

The coding for each theme was reviewed by the lead researcher, the clinical lead, and PPI collaborator for the study to ensure the professional and patient voice was being captured. Any disagreements were discussed with one of the supervisory team to gain an independent view and agree a resolve. A

determination was made on the overall level of convergence between all three datasets and proposed statements drafted using the emerging findings.

Step 4: Completeness assessment

The combined findings from each of the previous studies were presented for expert professional consideration at the UK Stroke Forum 2022 and British Association of Prosthetists and Orthotists national conference 2022. This was done in a formal presentation by the lead researcher with feedback from audience members welcomed and gathered through discussions after the presentation and at other stages throughout the conference. The purpose of this was to scope completeness of the combined data sets through public scrutiny and debate. The outcomes from this discussion and debate were recorded through written notes by the lead researcher and reflected upon with the supervisory team to enhance completeness with differences in scope and coverage considered.

Step 5: Researcher comparison

Researchers from the supervisory team completed comparison of assessments with the lead researcher. The purpose of this step was to re-consider the convergence or dissonance of the data and ensure completeness of the findings. The lead researcher led on the analysis and synthesis of the data sets with supervisory input gained on the specific examples used to complete the convergence matrix.

Step 6: Feedback

The findings from triangulation exercise were presented to the clinical and PPI collaborators for the study for final review, and the lead researchers' clinical team for feedback on the agreed final data set. Only stylistic changes were made at this stage and the final themes were agreed.

6.4 Findings

Forty-eight themes arose from the triangulation exercise and are presented in Table 14.

Table 14. Synthesis of themes from triangulation convergence exercise

Synthesis of themes from the convergence of: Focus group, Cross-sectional survey, Systematic review
The Orthotist 1. Consistency 2. Specialist knowledge 3. Regular orthotist contact 4. Orthotist professional role, education, and experience 5. Orthotic assessment and provision decision making 6. Orthotist confidence in assessment and prescription within post-stroke rehabilitation MDT 7. Requirement for orthotic devices to be fitted by licenced orthotist 8. Unclear role of prescribing clinician with focus on devices
The Orthoses 9. Biomechanics 10. Rehab tool 11. Types of orthoses 12. Clinical presentations and orthotic prescriptions post-stroke 13. Impact of early AFO on gait such as speed assessed with 10-meter walking test 14. Effect of early AFO use on sagittal ankle movement (dorsiflexion) 15. Effect of early AFO use on hip ab/adduction and knee flexion/extension 16. Impact of AFO use on muscle activity (tibialis anterior) during swing to evoke normal walking foot clearance 17. Effect of early AFO on occurrence and circumstance of falls

18. AFO as the only device evaluated and primary orthotic device use in post-stroke rehabilitation 19. Off-the-shelf orthotic devices Vs custom orthotic devices
The Patient 20. Patient compliance 21. Secondary complications 22. Carers 23. Importance of home 24. Orthotic influence on post stroke rehabilitation goals 25. Incidence of secondary complications connected with lack or delayed orthotic provision 26. Longer-term impacts of AFO use on patient rehabilitation outcomes 27. Earlier provision of AFO benefits patient rehabilitation outcomes
The Orthotic service 28. Cinderella service 29. Waiting times and delays 30. Accessibility 31. Referral routes for orthotic provision post-stroke 32. Clinical setting and orthotic workload 33. Timing of referral and orthotic provision 34. Frequency of orthotic inclusion in post stroke rehabilitation 35. Orthotic capacity across acute and community clinical settings to meet need post-stroke 36. Paucity of research reflected in included studies from only 1 trial
Ways of working 37. Timing 38. Video assessment 39. Knowledge and awareness of orthotics 40. MDT approaches 41. Evidence and Best practice 42. Way of working collaboratively and independently

- 43. Early gait rehabilitation decision processes
- 44. Orthotist inclusion in early gait rehabilitation MDT
- 45. Orthotist Vs Orthotic involvement in early gait rehabilitation
- 46. Barriers and facilitators to timely orthotic involvement in early gait rehabilitation
- 47. Orthosis provision in conjunction with other therapy inputs
- 48. Continued instruction of orthotic device use and follow up to provision needed

The themes were derived following a process of modified thematic analysis as described by Braun and Clark (188). After applying initial codes, themes were developed as “an idea or concept that captures and summarises the core point of a coherent and meaningful pattern in the data” and “a common, recurring pattern across a dataset, clustered around a central organising concept” (188). The themes were used to generate the proposed statements of best practice and were organised within five overarching themes. The proposed statements were grouped within these overarching themes throughout this thesis and within the eDelphi study described in Chapter Seven to bring order and provide a simplified mapping of a complex intervention. Illustrative examples of how Theme One was derived and refined is shown below in Tables 15 and 16.

Table 15. Illustrative examples of Theme One – The Orthotist from Focus Group data

Theme 1: The Orthotist, Focus Group illustrative coded quotations
Consistency
“Different orthotists look at things very differently and have different views about what they think would help. So sometimes when our general orthotist has been away we've had a period where we have one orthotist come one time, another orthotist come another, and they will say well I don't know why they gave you that one and now do something and then the other orthotist will come back and say, well that was never going to do the job what we need.

I think that's probably our biggest frustration about our orthotics clinic is there doesn't seem to be a consistency of opinion about what's good for different things."

"I think it's that investment isn't it? The **orthotist** yourself must become more invested if you're going to the same places rather than just going to one unit 1 day in another unit, and then you know not going back to that unit. Yeah, I think it's better from a service perspective overall and a patient perspective."

"I think it's much easier if it's the same **orthotist** because you develop a relationship with them and they learn to appreciate your expertise and you learn to appreciate their expertise and once you know the orthotist a bit better, I think they're much more willing to give you advice and make suggestions and say well, I know you're thinking about this, but what about if we try that?"

"All the places I've worked we've always had a consistent **orthotist** so I haven't had to use multiple."

Specialist knowledge

"I think it's a real bonus [to have] **somebody outside** the physio skill set who has got different knowledge, **biomechanical knowledge**, and also knowledge of a whole range of different splits."

"You know the patients home situation a lot better, I can talk a lot in clinic by don't get as much information as someone who sees them on a very regular basis and I'm sort of making you know I'm sort of making a decision on their future orthotic plans within half an hour. You know it isn't till sometimes you come to the third, second, third forth fitting you realize you know they weren't really telling **me** the correct thing at that point. But if I'd spoken to physio a lot sooner it would have helped a lot."

"One of the things that perhaps gets a little bit overlooked is scope of practice. As a physio we are trained in physiotherapy. I don't have, although I've been fiddling around in the field for a long time, I do not specify what the device should be made of. I specify what I want it to do in consultation with the **orthotist** who might say not a chance. But my training does not include materials and material properties, so I have no right at all to specify what something should be made of. It's not in my sphere of practice, I am not licensed to do that and I think there's an awful lot of that goes on."

"But we just wouldn't you know you'd be looking at them on the internet wouldn't you, you know just having that expertise or **somebody that knows** you know what you're trying to achieve, why you're trying to achieve it, and what you might be able to achieve it with.

"Yeah, because I mean I think as you say HB **the orthotist** is seeing a snapshot, you know it's a bit like us when we go and we are supervising someone and we go and see a patient, you know you can make recommendations about what you think then and there, but you know patients behave differently under different circumstances and I think you know an **orthotist** needs the full picture. You know especially where cognition is involved as well."

"The lack of specific stroke knowledge within **the orthotist** community that unlike physio colleagues on the call today we don't have the opportunity to specialize in something to the same extent that you do, and so I think when **we** come to see a patient, the physios there are the stroke specialists and also having chance to spend much more time with their patients as well."

"I wouldn't go around giving out therapy exercises until I discussed with a physiotherapist and sort of seeing how it goes. You'd be surprised how many people still don't accept **our** feedback."

"It's a really tricky one because when you sign your HCPC thing you say you're an **autonomous practitioner** and you say you would only give what you feel is

appropriate. But then if you work in an environment where your views don't fit with the views of the person leading the treatment, then you have to accommodate to that."

"I mean, things like sit to stand with a rigid AFO or with a cast or with your air cast boot is a is a tricky one, but I've always advocated for doing that...and there's little tricks like that which **orthotists** can sort of fine tune and tweak... there's lots of potential for us to share our skills and make things better for the patient I think."

"I was very, very impressed with the dedication of all of them I'd say and I think anything we can do to improve the orthotics and orthotics being part of the team is essential, it isn't an add on, it's an essential part of the process."

Regular orthotist contact

"I think it's a real bonus [to have] **somebody outside the physio skill set** who has got different knowledge, biomechanical knowledge, and also knowledge of a whole range of different splits."

"We're very lucky in that we do have an **orthotist** that comes to us fortnightly and actually my learning and kind of expanding my skill set I find it really, really helpful and useful and actually helping, **he** can help me problem solve with patients. So, I find it very beneficial and we're so lucky here that we have access to that."

"I think it's very, very useful and we're very fortunate in Glasgow that we have access to an **orthotist** every week so if we do a referral each week, they will appear and we quite often do it as a joint session, particularly with fitting particularly if it's a bespoke AFO so I think it's very important."

"I think sometimes getting **the orthotist** involved early gives them an opportunity to see how the patients progressing, because we're very fortunate

in that they come up each week and if it's not each week it's maybe a fortnight at most."

Table 16. Illustrative examples of Theme One – The Orthotist from Cross-sectional survey data

Theme 1: The Orthotist, Cross-sectional survey illustrative questions and results
Orthotist professional role, education, and experience
<i>Table 7.</i> • 73% qualified to degree level, 16% educated to master's level. • 70% have six or more years' experience, 45% have more than ten. • 66% orthotists primary employer private company delivering national health service provision, 30% National Health Service provider. • 57% work in hospital out-patient setting, 20% in clinical site not within a hospital. <i>Table 8.</i> • 36% orthotists see stroke patients 'Several times a week', 25% see them 'Once a day'. • 33% see stroke patients at 1-6 weeks, 22% at 7-12 weeks, 25% at 4-12 months and 19% >12 months.
Orthotic assessment and provision decision making
<i>Table 9.</i> • 43% stroke patients seen as out-patients in a general orthotic clinic, 26% seen as in-patients on a stroke or general ward within the acute hospital site, 21% seen in MDT clinics, 11% in dedicated neurological clinic. • 46% 'rarely' see stroke patients in an MDT context, 25% see them 'some of the time' in an MDT context.

Table 10.

- 5% involved in early gait rehabilitation decisions routinely 'without a specific referral for orthotic assessment being made', 68% involved 'only when a specific referral for orthotic assessment is made by another MDT member', 27% 'not involved at all'.
- 49% of assessment and detailed prescription decisions made with the MDT, 38% independently made by the orthotist.
- 52% use of the orthosis determined with the MDT, 34% independently by the orthotist.

Qualitative Theme one: Barriers to integration within the MDT

"We had MDT clinics which enabled a better approach [...] I am trying to establish something similar where I am now, but there is quite a lot of resistance [...] due to waiting lists etc. Where I worked before had such an excellent set up which I helped develop and it helped all the AHPs involved develop as well."

"The stroke MDT is very exclusive and doesn't include orthotists, the company I work for won't allow time for us to go and spend time with the stroke team to build relationships either."

"I think that an orthotist in specialist MDT setting would be good, but we do not have anything like the capacity to offer that in terms of clinical staffing."

Qualitative Theme two: Timing of referral and assessment.

"Often see stroke patients too late and so they will have contractures etc making it harder to achieve good outcomes."

"I have found that if Orthotics is not involved early on the risk of contracture is significantly higher and they only are referred into community orthotics when they have a significant contracture that cannot be accommodated by [off the shelf] orthotics any longer."

Orthotist confidence in assessment and prescription within post-stroke rehabilitation MDT

Table 11.

- 89% agree or strongly agree they are confident in recommending a lower limb orthotic treatment plan within early stroke rehabilitation.
- 83% agree or strongly agree they were confident advising on use of an orthosis.
- 73% agreeing or strongly agree they are confident in recommending a comprehensive orthotic treatment plan to the MDT which may include upper limb or spinal orthotic intervention.
- 75% replying either: 'neutral', 'disagree' or 'strongly disagree' to the statement 'I am confident advising therapy and activity to progress potential recovery (as a lead member of the therapy team)'.

Table 12.

- 99% believe orthotic assessment should be an essential element of gait re-education as part of recovery in stroke.
- 89% believe orthotists should be routinely involved without a specific referral for orthotic assessment being made, by being able to join stroke rehabilitation MDT meetings or attend routine assessment clinics.
- 61% disagreed or strongly disagreed with the statement 'I am satisfied with the frequency of involvement I have with early stroke rehabilitation patients', 23% described being neutral, 16% were satisfied with their involvement.

Qualitative Theme three: Variation in funding and access.

"What orthotics you get, it's dependent on the trust and even hospitals to which services [are] provided."

“Funding is a big issue in regard to accessibility to services. There are stroke patients in the same hospital from different trusts yet only the patients from the 'better funded' trust get access to orthotic services.”

Qualitative Theme four: Impact of clinical approach.

“Most of our neuro physios delay referring as they do not want to brace the patient too early in case their function returns. Therefore, we fit PRAFOs early to maintain range then they will refer for an AFO at a later stage. We feel we should be assessing for AFOs earlier to reduce [the] risk [of] poor gait re-education.”

“We need guidelines to give consistency [...] I feel [physiotherapists] do not want an orthotists input because they think we only want to put patients into solid AFOs! I try and engage and teach and learn in combination with the physio team, but it is a constant battle.”

“We need more stroke specific training; I didn’t know anything until I came of Uni and then it was only what my clinical mentor showed me.”

A section from the convergence coding matrix detailing the review of ‘The Patient’ theme is presented in Appendix S.

6.4.1 Identification of themes

The results from the triangulation exercise were organised into 5 overarching themes, clustering statements to complement each other and enhance the overall legibility of the eDelphi. This exercise was undertaken during a co-design engagement activity with the clinical and PPI study collaborators. Using the online application Mural, which acts as a post-it style board for collaboration and working in real time, the themes were configured into overarching themes until the final layout was agreed upon. The five overarching themes are presented below in Figure 9.

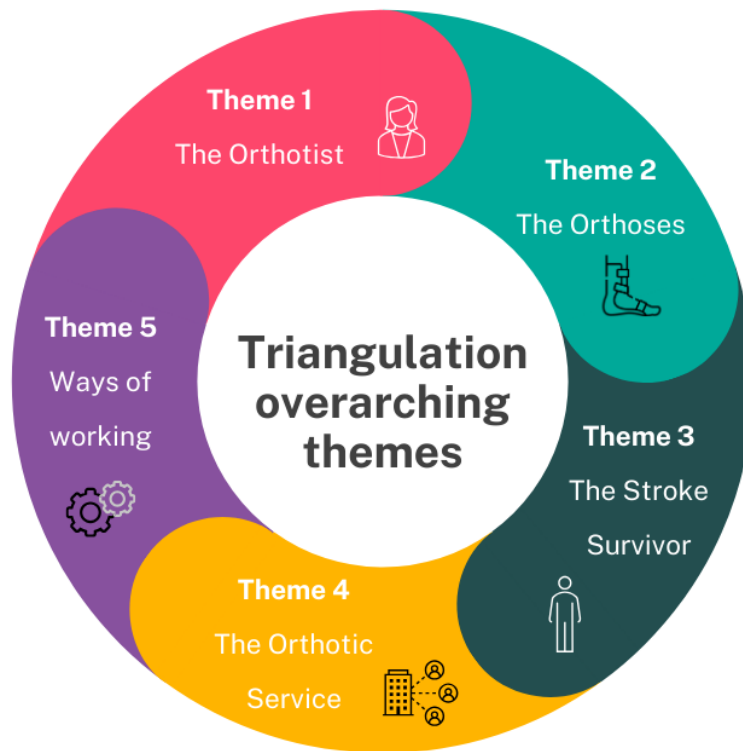


Figure 9. Five triangulation overarching themes

Theme One – The Orthotist

This theme comprises all the aspects identified within the datasets that specifically relate to the orthotist clinicians themselves and how as autonomous practitioners they provide specialist knowledge and skills. Additionally, it encompasses the way in which patients interact with the orthotist with regularity and consistency of contact highlighted. The role of the orthotist was explored with the cross over between orthotist and other therapist prescription of orthotic devices noted. This theme highlights the importance of identifying the interactions of the orthotist as well as the difference between the orthotist themselves verses the orthotic device.

Theme Two – The Orthoses

This theme covers the device which necessitates interaction between the orthotist and patient. The orthosis is an external device which is designed to apply biomechanical corrective forces to promote rehabilitation after stroke. However, there is ongoing debate as to the kind of orthotic device which is most suitable, and at which stage of rehabilitation it is best provided. Whilst the statements of best practice do not suppose to resolve this debate, the concepts brought through from the datasets within this theme recognise the need to assess each patient as an individual, with assessment and prescription decisions made in response to their functional and practical needs.

Theme Three – The Stroke Survivor

The theme is arguably the most important of the five, focusing on the different elements which inform practice on the person at the centre of any intervention, the patient. The theme brings together the factors which impact a stroke survivor's experience and outcomes including the environment and carer support. It also considers longer-term aspects of stroke rehabilitation which can impact on the patient and often go unrecognised in earlier rehabilitation such as secondary complications.

Theme Four – The Orthotic Service

The theme considers the service within which orthotic care is provided. With no current recommendations for orthotists to be situated within the core stroke rehabilitation MDT, their intervention is based within the wider orthotic service and provided to stroke survivors through a referral process. As a result, much of this theme reflects on the mechanics of the referral pathway including timing, frequency, and delays, and how they impact on the accessibility to the service.

Theme Five – Ways of Working

The theme encompasses the many ways orthotic intervention can be provided both independently and collaboratively with the wider stroke rehabilitation team. The impact that orthotics can have on other therapy inputs and the

importance of multi-disciplinary working to produce the best outcomes for the patients are key.

6.4.2 Converting themes into statements

During the previously described none-formalised co-design exercise, the lead researcher, and PPI and clinical expert collaborators for the study began to build the proposed statements from the themes identified. Following the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach (51), each statement was developed against five criteria for Good Practice Statements (GPS) as described by Dewidar et al (105):

1. The statement should be clear and actionable.
2. The message should be necessary for actual healthcare practice.
3. After considering all relevant outcomes and potential downstream consequences, implementing the GPS would result in net positive consequences.
4. Collection and summary of the in-direct evidence would be a poor use of a guideline panel's time and resources.
5. A well-documented, clear and explicit rationale connecting the indirect evidence should be constructed.

The 48 themes converted into 65 proposed statements of best practice which were subject to further piloting and review prior to inclusion in an expert consensus eDelphi exercise as described in Chapter Seven.

6.5 Discussion

The aim of this study was to converge data from the previous studies to develop proposed statements of best practice on delivering orthotic interventions after stroke.

The convergence of the different study datasets facilitated the identification of 48 different themes which provided the basis from which proposed statements

of best practice could be drafted. This triangulation exercise was effective in combining systematic review findings, survey data, and the voice of clinician and patient lived experience. The 48 themes assessed within the convergence coding framework were primarily complimentary in nature, but silences were identified. Aspects of the focus group qualitative data presented in Chapter Five, were not contained within the other study findings, and so did not present as strongly within the triangulation. The focus group study by design was conducted to provide wider context to the statements, and as such the findings from that study were far more focused on the future implementation of any such statements of best practice. However, the silences whilst not included within the defined themes of the triangulation exercise, informed the development of the statements of best practice, particularly within the 'Ways of Working' overarching theme. Further silences not identified through this exercise may be present and their influence would likely be exposed through further enquiry and future evaluative testing of the statements beyond the scope of this PhD.

6.5.1 Study strengths and limitations

Triangulation is one of few methods able to converge heterogenous datasets such as those produced from the studies in the previous chapters of this PhD. One of the strengths of a triangulation technique is the ability to integrate qualitative and quantitative data by different members of the study team both independently and collaboratively. This method was chosen, as an established approach to triangulating healthcare specific datasets and as an exercise which could facilitate collaboration with clinical and PPI study members. There is a transparency in the steps taken to analyse the data and develop the themes which facilitated non-academic collaborators and increases the repeatability of the process, enhancing the reliability of the results. A key feature of mixed methods research that is all too often lacking is a systematic approach to the combining of the results, and appropriate description of the methods to do so. Therefore, a key strength of this study is the structured protocol followed for

integrating the different datasets and the transparent way in which it has been reported.

Whilst using a triangulation methodology to converge the datasets enhances the validity of the conclusions, the individual strengths and limitations of the datasets can also be amplified. The studies identified through the systematic review were all from a single study group and described the findings from a singular small RCT. Moreover, the quantitative and qualitative findings from the cross-sectional professional survey are representative of a self-selecting proportion of the orthotic workforce (approximately 10%), and so limited in their scope. Finally, whilst the focus groups were multi-disciplinary and included the voice of stroke survivors and carers, only three were conducted with participants self-selecting, representing a motivated cohort wishing to share their views on this topic. However, the datasets did not share the same limitations and so still provide valuable source from which to synthesise and draw conclusions.

The collaboration with clinical and patient experts during the triangulation exercise enhances the authority of the findings. Recognising the potential bias brought by the lead researcher through their professional background as an orthotist, as well as being highly motivated in leading the project, the inclusion of an independent professional perspective brought an original and grounding influence. Similarly, the PPI collaborator ensured that the developed statements were directed by patient experience and need. Whilst a review was completed by the supervisory team who represent different professional backgrounds, additional review by other researchers and practitioners would likely enhance the acceptability of the proposed best practice statements. However, due to the time limitations of this PhD this was not possible, and as the statements were intended for refinement and agreement by orthotists experts, dilution of the statements content by including too many other professional voices was intentionally avoided.

6.6 Conclusions

The aim of this study was to converge the findings from the previous studies in a systematic way to develop proposed statements of best practice on delivering orthotic interventions after stroke. To achieve this, a healthcare specific triangulation method described by Farmer et al. (54), was used to combine the systematic review, cross-sectional professional survey and stakeholder focus group data.

The need for guidelines to direct clinical commissioning and practice has been highlighted in the previous studies within this PhD (Chapters Three, Four, and Five). It was therefore determined to follow the GRADE approach to develop guidelines that were evidence based, methodical, and transparent in their drafting (51). It was important to use a methodology to converge the datasets systematically to summarise the findings and produce themes from which to build the guidelines. In using a triangulation technique as described by Farmer et al. (54), the proposed statements of best practice on delivering orthotic interventions after stroke which have been developed in a systematic and reliable way offering a comprehensive underpinning to determine potential guidance for best practice in this area.

In combining quantitative and qualitative data sources, actionable statements have been produced which have been developed with the understanding that the effects of the intervention clearly outweigh any undesirable effects or risk of not implementing the intervention. The proposed statements of best practice were drafted with further evaluative and implementation testing in mind, ensuring interacting components influenced by environmental and contextual factors are considered (108). Before finalising, the statements were refined and agreed through eDelphi expert review and consensus, a process which is presented in Chapter Seven.

Chapter Seven: Professional consensus on national statements of best practice for delivering orthotic interventions after stroke – an eDelphi study

This chapter details the completion of a national eDelphi study to reach professional consensus amongst orthotists on statements of best practice for delivering orthotic interventions after stroke. The proposed statements were developed through a triangulation technique described in Chapter Six, using the findings from the studies presented in Chapters Three, Four and Five. This chapter details the fifth and final step in the five identified phases of development for the statements of best practice on delivering orthotic interventions after stroke (Figure 10).

This chapter describes the process of refining and gaining professional agreement on the proposed statements of best practice which were generated by summarising and converging the systematic review, national cross-sectional professional survey, and qualitative focus group data. This is an important step described in the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach (51), ensuring a disciplined and systematic method, reinforcing the applicability and acceptability of the recommendations. Key within the GRADE framework is the peer review of any proposed statements of best practice. This was completed with orthotist expert clinicians directly involved in orthotic intervention delivery after stroke. It was important to gain feedback from orthotists practicing within the UK on the finalised content and composition of the statements to garner professional buy in and encourage subsequent adoption.



Figure 10. Development of Best Practice Statements - stage 5

7.1 Aims of the study

The aim of this study, as related to the fifth aim of the PhD was:

- To refine and finalise statements of best practice through professional consensus on the optimal ways of working when delivering orthotic interventions after stroke.

To achieve this, a national eDelphi was conducted to gain orthotist consensus on the content and composition of statements of best practice on the delivery of orthotic interventions after stroke. Expert agreement was obtained through a two-round exercise to produce professionally ratified statements of best practice. These detail the optimal ways of working when delivering orthotic interventions to enhance rehabilitation outcomes and reduce complications for stroke survivors, as agreed by orthotic experts.

These statements of best practice on delivering orthotic interventions after stroke are the first UK wide professionally agreed guidelines produced.

7.1 Background

Chapter Six presents the triangulation technique used to converge data sets from the three substantive PhD studies. This process facilitated the production of proposed statements of best practice. Following the GRADE approach (51), the aim was to then to refine and achieve professional consensus for the statements via an online platform called an eDelphi.

Other consensus methods were considered such as the Nominal Group Technique (NGT) initially planned for the PhD (203), but were deemed unsuitable due to the ongoing pandemic making face-to-face meetings very difficult and at times against the law. Whilst an NGT is possible to conduct online, it would still consist of a singular event which would make it difficult to get a spectrum of representatives together at one time. The NGT also presents a very formal, moderator-led assembly, which whilst can be productive, can also limit discussion and suppress the voice of participants. The NGT is traditionally used to explore stakeholder views which is why it was selected within the methodology for this PhD before the global pandemic. However, with the change in direction for this PhD, the Delphi technique was chosen as the most appropriate method to gain consensus from which to develop guidelines with health professionals (204). It is a method which facilitated the inclusion of expert voices from across the UK and was approved for use within research during the pandemic posing little risk to participants.

The Delphi technique is a multi-round survey within which participants are asked to record their level of agreement or disagreement with presented statements (205). An approach which facilitates adjustment and refinement of the statements following respondent feedback, this method allows the gathering of expert views with the aim of achieving consensus. The Delphi method has been

adapted over time and most recently applied to an online setting thus arguably enhancing its inclusivity and therefore the validity of its findings. This is referred to as an eDelphi (206).

Considered a strength of the method, the anonymity of the expert participants is argued to promote honesty and reduce the risk of bias caused due to social desirability or the 'halo affect', where views from dominant or higher-ranking participants are more influential (207). However, Delphi's can be complex and time-consuming with the need to complete multiple rounds resulting in higher drop-out rates. This can lead to reduced generalisability of the findings (208). Nevertheless, Delphi is a well-established approach to identifying consensus in a topic area allowing for reflection and facilitating nuance where participants are asked to reconsider their opinion between each round. It is commonly used in healthcare research to generate important contributions to the evidence base, conceptualising the primary resource of the expert clinicians, their knowledge and professional expertise. As a profession, orthotists are considered the experts in orthotic intervention after stroke and therefore were best placed to determine best practice and participate as the experts in this eDelphi.

7.3 Methodology

7.3.1 Development of the technique

As a tool to support clinical practice, the statements of best practice are intended to offer guidance to clinicians and commissioners as well as enabling patients to advocate for their own care. A modified eDelphi was used to provide a rigorous means of gaining professional consensus as well as taking a participative approach seeking to foster acceptance and ownership of the resulting statements. Explicit consideration for the context of the intervention was undertaken within the preparatory studies described in Chapter Two, the cross-sectional professional survey presented in Chapter Four, and the stakeholder focus groups described in Chapter Five. Moreover, the proposed

statements of best practice were developed in collaboration with clinical and PPI perspectives to ensure their relevance to real-world clinical situations.

For this study, guidance on Conducting and Reporting Delphi Studies (CREDES) was followed as the eDelphi was developed to ensure the study met the requirements to be considered robust and the results valid (209). Figure 11. presents the eDelphi process in flow chart form with defined criteria for when consensus was deemed achieved between each round, ultimately signifying when the eDelphi was considered complete. A pre-defined consensus threshold was chosen in consistency with other eDelphi studies as described by Diamond et al. (205), with 75% the median threshold reported. The protocol for the eDelphi was drafted alongside that of the focus groups and is presented in Appendix N.

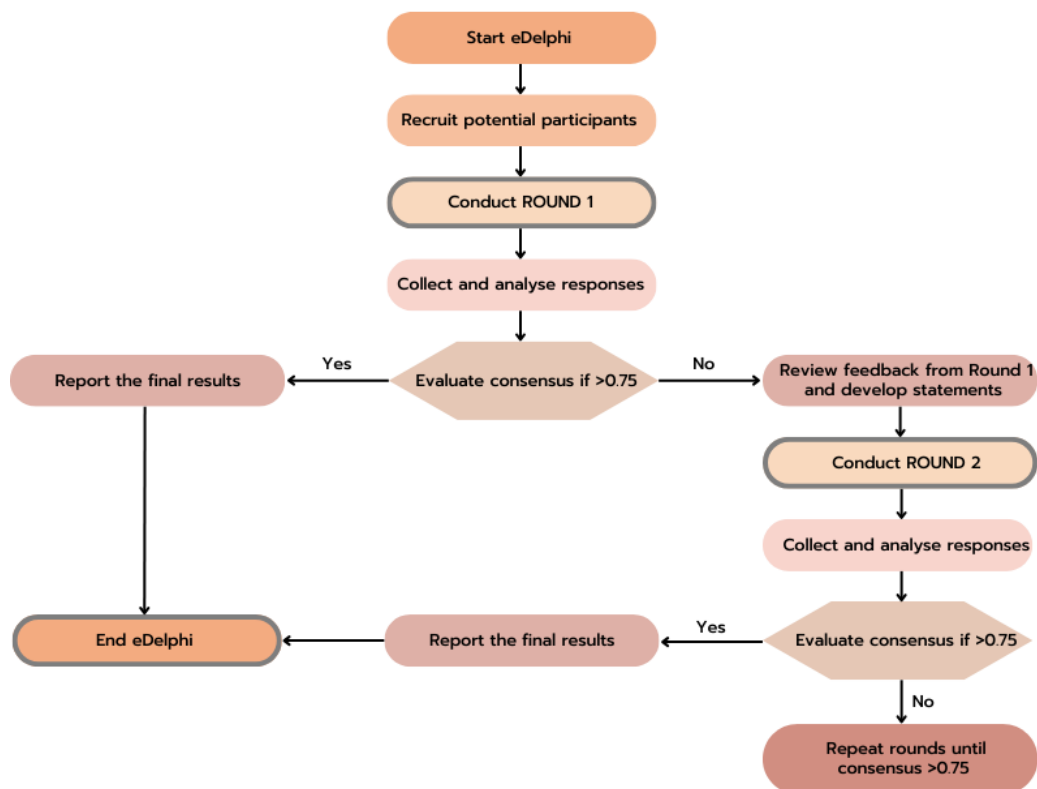


Figure 11. eDelphi consensus flow diagram

Proposed statements for the first round were generated from the convergence triangulation technique as described in Chapter Six. The themes identified using the coding matrix (example shown in Appendix S), were tailored to form proposed statements of best practice. This process was completed in co-production with the clinical and PPI leads for the study. This approach works to align the methods and findings of the research with the experiences and needs of clinicians and patients who deliver and receive the intervention being investigated (210). Encouraging participation and collaboration through co-development has been shown to produce overall more reliable and relevant results (211). The statements that we redeveloped incorporated each element of delivery of orthotic intervention after stroke which stakeholders had deemed important in the studies presented in Chapters Two, Three, Four, and Five. This approach to statement development was conducted in collaboration with the

study PPI and clinical leads who both have extensive and lived experience of orthotic intervention after stroke. Further guidance was provided by the lead researcher's clinical team and the PhD supervisors. The phrasing of the statements and format of the eDelphi were changed through several iterations as described in Chapter Six. Changes in terminology were made to be more inclusive and maximise participants' understanding. Examples include the use of 'qualified' or 'state registered' rather than the more international phrase of 'Category 1 orthotist'. Similarly, the use of 'patient' was removed and replaced with 'stroke survivor' at the request of the PPI collaborator as a better description of how she defines herself now that she is living with stroke long term. Consistency across the statements was highlighted as being important and so changes were made to definitions such as 'acute' when in reference to a main hospital setting, and 'outcome measures' rather than different iterations such as 'outcome' or 'outcome assessment'. Statements developed from the triangulation technique were overall considered too lengthy and so a great deal of time was spent in shortening them to be more succinct whilst still retaining their original essence. In attempts to promote a greater response rate, changes were made to the presentation and mechanism of the eDelphi such as adding in a 'save and finish later' feature. This was hoped to encourage completion of the survey over abandonment with the expert participants likely to be answering in between busy clinic loads. Moreover, to aid with visualisation of the different themes, the statements were changed to be primarily presented in tabular form, with the option to return to singular form should the user prefer this. As statements of best practice, it was deemed important that it was indicated to participants that they should respond in an ideal scenario to not limit their responses by any current restrictions they may face in their practice.

Illustrative examples of some of the changes made and discussion within the co-development process are detailed in Figure 12.

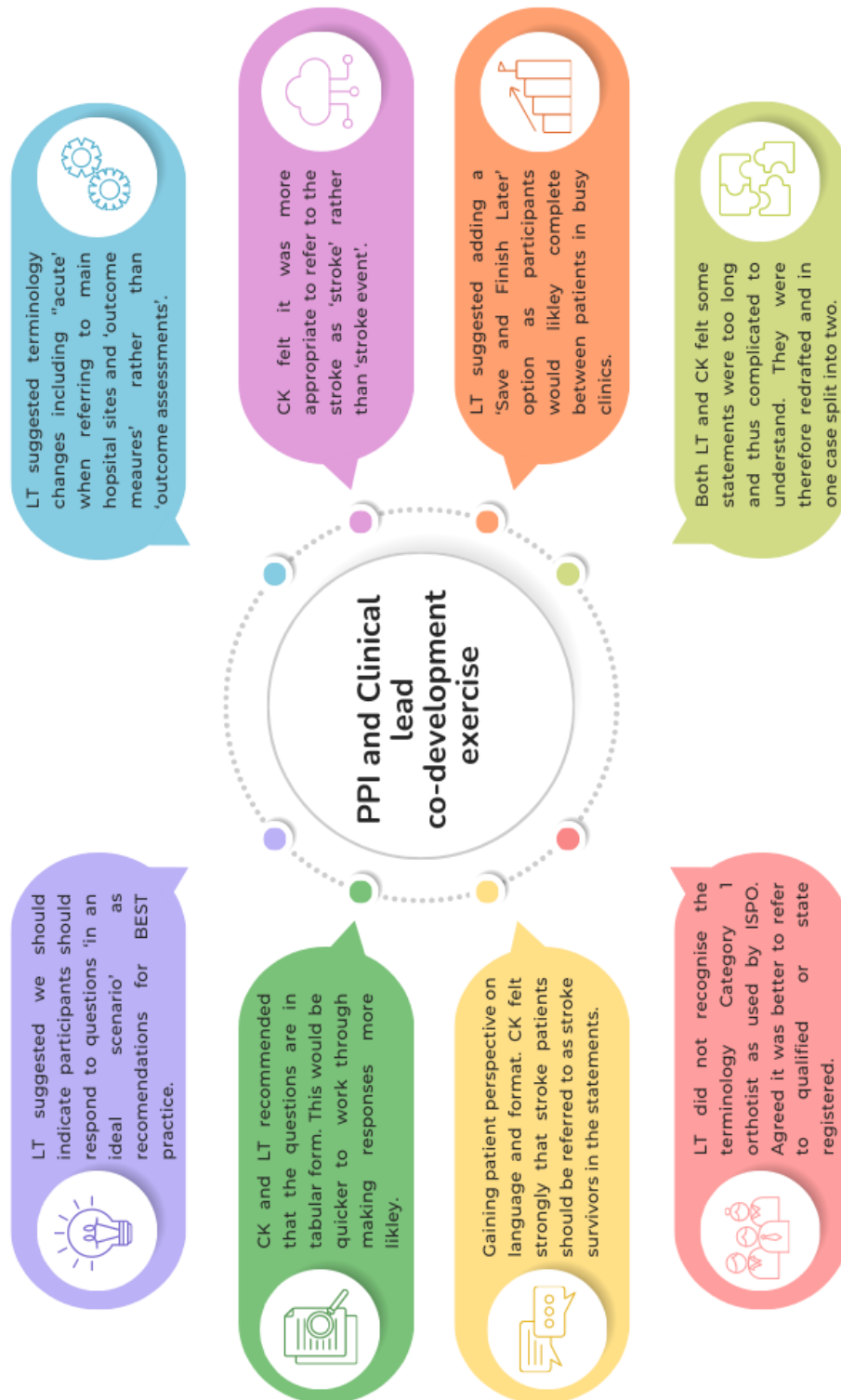


Figure 12. Clinical and PPI co-development exercise examples

The eDelphi was developed using the JISC online survey application (previously the Bristol Online Survey), as an approved application for Delphi survey data

collection at the University of Nottingham. The purpose of the eDelphi was detailed in the introductory page and the statements presented within the overarching five themes identified through the triangulation exercise. The sectioning of the survey provided a logical and structured presentation of the statements to be reviewed and allowed participants to save and return after completing each section, if required. Introductory and concluding statements are included in the Participant Information Sheet presented in Appendix Q. A section of the consent page participants were presented with is shown in Figure 13. The eDelphi was designed to show progress as participants completed each section and had a finish later button available on each page.

The screenshot displays the 'OTIS - eDelphi' survey interface. At the top left is the University of Nottingham logo with the text 'UK | CHINA | MALAYSIA'. Below the logo, the title 'OTIS - eDelphi' is shown in a large, bold font. A green progress bar indicates '22% complete'. The page is titled 'Page 3: Section 1'. The first question, 'Q1. Please indicate your current professional role/status', has two radio button options: 'I am a qualified practicing orthotist' and 'I am a qualified retired orthotist'. The second question, 'Q2. How long have you been qualified to practice as an orthotist?', includes a instruction 'Please select exactly 1 answer(s)' and five checkbox options: '0-2 years', '3-5 years', '6-10 years', '11-20 years', and '21 years or more'.

University of Nottingham
UK | CHINA | MALAYSIA

OTIS - eDelphi

22% complete

Page 3: Section 1

Q1. Please indicate your current professional role/status

☐ I am a qualified practicing orthotist

☐ I am a qualified retired orthotist

Q2. How long have you been qualified to practice as an orthotist?

Please select exactly 1 answer(s).

☐ 0-2 years

☐ 3-5 years

☐ 6-10 years

☐ 11-20 years

☐ 21 years or more

Figure 13. Example consent page with progress bar

The eDelphi was piloted by two independent clinical colleagues which led to refinements such as reducing the number of statements contained within each tabular section and including full phrases rather than acronyms. The system was then finally tested by members of the BAPO research committee via a review process to ensure suitability and applicability of research to their members. Each statement from round one of the eDelphi is presented in Table 17.

Table 17. eDelphi round one statements and overarching themes

Theme One - The Orthotist	
1	The orthotist is an important member of the stroke rehabilitation clinical team.
2	All patients who have experienced a stroke affecting motor control would benefit from having an orthotist assessment.
3	Where an orthotist is not embedded within the stroke clinical unit, regular orthotist contact is important to facilitate timely assessment and treatment.
4	Regular orthotist contact with the stroke unit is important to facilitate knowledge exchange, advice giving and provide training.
5	The orthotist should lead the orthotics assessment and any subsequent orthotics provision for stroke survivors.
6	When not embedded within a stroke clinical unit, please select how regularly you think the orthotist should be in attendance to assess and treat patients. *
7	Consistency of approach between orthotists in their assessment and treatment is important to ensure equitable treatment for stroke survivors.
8	Where an orthosis has been prescribed it should be the same orthotist who fits and trials that device with the stroke survivor.
9	The stroke survivor should be reviewed by the same orthotist that prescribed and fitted the orthotic device for consistency and continuity of care.
10	Orthotists should have the opportunity to specialise in specific conditions such as neurological rehabilitation.

11	There should be stroke specific training available to pre-registration and post-registration orthotists to establish an agreed pathway of treatment for stroke survivors to encourage conformity across settings.
12	The orthotist should be involved in the planning, commissioning and provision of stroke rehabilitation services.
*Different answer option to other statements. Participants invited to select from: Every day, 2-3 days a week, Once a week (weekly), Every other week (bi-weekly), Once a month (monthly), Less than once a month.	
Theme Two – The Orthoses	
1	Orthotic principals such as biomechanics are important considerations when deciding on a stroke survivor's rehabilitation treatment plan.
2	Ankle Foot Orthoses (AFOs) should be considered for stroke survivors with mobility problems.
3	Any orthotic provision following stroke should be assessed for and prescribed with the intent of 'right first time'.
4	Orthoses prescribed for stroke survivors should be considered a rehabilitation tool in their toolbox.
5	The time between assessment and provision of any orthoses for an early rehabilitation stroke survivor should be less than 14 days.
6	Appropriate orthotic provision for stroke survivors can positively influence stance phase and swing phase limb alignment during mobilising.
7	Orthoses in early post stroke rehabilitation can be used to increase dosage of therapeutic alignment and intervention when hands on therapist time is limited or unavailable.
8	Orthotic intervention in early post stroke treatment can contribute to a 24-hour therapy model of rehabilitation.
9	Early orthotic use ensuring correct alignment and normal movement can assist with neuroplasticity retraining of mobility.

10	Following provision of an orthoses, all stroke survivors should have the option of tuning to ensure the best functionality and usability.
11	Availability of orthoses type (custom, prefabricated, material etc.) should be equitable for all stroke survivors regardless of location.
12	Availability of any orthoses for stroke survivors should not be determined by cost and its prescription should be driven by functional need.
13	Custom and personalised orthoses prescriptions should be considered at the first instance over prefabricated orthoses for stroke survivors.
14	Prefabricated orthoses have a valid place within orthotic provision post stroke but should be managed carefully for appropriateness for each individual.
15	Provision of prefabricated orthoses should be overseen by an orthotist or appropriately trained healthcare professional.
16	Information regarding any provided orthoses should be given in both verbal and written formats to stroke survivors.
Theme Three – The Stroke Survivor	
1	All stroke survivors with mobility problems should be assessed by an orthotist in a timely and equitable manner.
2	Orthotic provision should be considered as a first line rehabilitation intervention for stroke survivors with lower limb tone and/or spasticity.
3	Orthotic assessment should be considered for any stroke survivor with secondary complication risk factors such as contracture, even if they are non-mobile.
4	Timely and effective orthotist assessment and orthotic provision can enable a stroke survivor's independence and improve their mental health.
5	For stroke survivors who are prescribed an orthosis, a routine 6-weeks follow-up appointment should be made to review progress and on-going need.

6	Any orthoses prescribed to a stroke survivor should be reviewed at appropriate time periods within the first 12 months of rehabilitation to assess changing need.
7	An orthotic assessment should be available at any stage of a stroke survivor's rehabilitation, even if no need was identified early after stroke.
8	Difficulties with speech and/or cognition following stroke should be accommodated in any orthotic assessment and provision.
9	Where present, carers should be included in orthotic assessment and provision appointments.
10	An orthosis prescribed for a stroke survivor should be the most cosmetic and unobtrusive in design that is possible, whilst still meeting the individual functional requirements.
11	Appropriate accommodations should be made to enhance compliance of orthoses use when designing an orthotic prescription such as fitting into footwear etc.
Theme Four – The Orthotic Service	
1	Orthotics assessment and provision is an integral part of stroke rehabilitation but not a necessity.
2	There should be equity of access to orthotist assessment and orthotic provision across clinical settings (acute hospital, community hospital and community).
3	Orthotic assessment and provision for stroke survivors should be prioritised in orthotic service delivery and referrals actioned with urgency.
4	For long-term orthotic users after stroke, a patient or carer should be able to self-refer for further orthotic assessment and review.
5	Relationships between the core orthotic service and the stroke rehabilitation service should be established and nurtured to enhance stroke survivors' rehabilitation.
6	Orthotic services should be planned, commissioned, and run to provide specialist individualised assessment and treatment for stroke survivors.

7	The core orthotic service should be invested in to facilitate the orthotic delivery and treatment for stroke survivors.
Theme Five – Ways of Working	
1	An orthotist should be included as a member of the core stroke multi-disciplinary rehabilitation (MDT) team.
2	The orthotist should be included in MDT assessments of stroke survivors with motor control problems and contribute to agreed rehabilitation goals and treatments.
3	An orthotic assessment should be conducted as a joint exercise with the specialist skills of the orthotist and therapy staff working together.
4	The use of technology to facilitate joint orthotist assessment such as video evidence or pressure plate technology should be utilised within early stroke rehabilitation.
5	Inclusion of the orthotist within the stroke rehabilitation MDT enhances knowledge exchange and leads to better professional relationships.
6	Orthoses prescription should be undertaken by the orthotist and decided upon using biomechanical principals.
7	Orthotist assessment and provision following a stroke should take a holistic approach seeking to enable tasks of daily living, promote independence and mental health.
8	Access to orthotist led orthotic assessment and/or provision should be equitable regardless of where the stroke survivor is located geographically.
9	Scope of practice is an important consideration when an orthotic device is prescribed or fitted by a healthcare professional that is not an orthotist
10	Assessment by an orthotist for patients presenting with mobility difficulties after a stroke should be conducted within the 'early' rehabilitation phase (48 hours in line with early mobilising recommendations) ¹ .
11	Assessment by an orthotist for patients presenting with mobility difficulties after a stroke should be conducted within the 'acute' rehabilitation phase (7 days) ² .

12	Assessment by an orthotist for patients presenting with mobility difficulties after a stroke should be conducted within the 'early sub-acute' rehabilitation phase (3 months) ² .
13	Orthotist assessment and appropriate provision within early gait rehabilitation is an essential mechanism to avoid compensatory patterns being developed such as over extension at the knee or hip-hiking.
14	Screening tools can be used by other healthcare professionals to help identify if a stroke survivor will benefit from an orthotic assessment and/or provision.
15	Outcome measures should be used to determine effect of orthotic provision following stroke.
16	Requests from other health care professionals for orthotic assessment and/or provision should take the form of referral for assessment rather than a prescription with specified orthoses.
17	Referral for orthotic assessment should be considered for stroke survivors who present with severe impairment where an orthosis may aid in comfort, enable transfer and assist in care delivery.
18	Stroke services should have a specific referral pathway for orthotic assessment and provision for patients once discharged from the acute hospital setting.
19	There should be training for non-therapy acute and sub-acute clinical staff such as nurses and health care assistants on how to correctly put on, remove and use common types of orthotic device such Ankle-Foot Orthoses.

7.3.2 Ethical considerations

Ethical approval for the eDelphi study was obtained from the University of Nottingham Faculty of Medicine and Health Sciences Research Ethics committee on the 9th of February 2021 (FMHS 156-0121). Letter of favourable ethical approval is presented in Appendix P. The digital PIS was made available to all potential participants upon approach and prior to consent being taken. The

study PIS was developed following the format required by the host institute sponsor, a copy of the consent questions completed by the participant is included in Appendix R.

7.3.3 Data collection and management

The JISC online survey application was used to collect the data for the eDelphi. Once each round was complete the data was exported to a Microsoft Excel spreadsheet for analysis. This was password protected and no identifiable information was stored.

To enable the same participants to be contacted for follow-up rounds, respondents were required to enter a valid email address they were happy to be contacted on. It was made explicit to participants that this email address would only be used for contact regarding further rounds of the eDelphi and would be destroyed once the eDelphi was complete. This was stored separately to the participant answers as a confidentiality precaution and to reduce any potential bias during the analysis. It was decided that participants would not be presented with their own ranking of statements from previous rounds to reduce the risk of influencing their subsequent response. Similarly, participants were not provided with any indication of how other participants ranked their agreement/disagreement to each statement other than when statements had been altered between rounds.

To improve response rate and retention, as well as reduce participant fatigue, a seven-point Likert scale was selected (212). Use of a consistent scale is considered to have higher validity within the GRADE approach (51), and was recommended following feedback from the cross-sectional professional survey presented in Chapter Four. Seven-point was selected over five-point to allow for more nuanced responses between participants. It was agreed this could be reviewed in subsequent rounds if it was required to gain a stronger consensus.

For the first round, potential participants received a link to the digital PIS, consent form and eDelphi questionnaire. Upon providing consent and

submission of demographic details, participants were assigned an identification number so their answers could be tracked between rounds. This identification number was not linked to their email address.

Participants were initially asked to complete demographic questions. The proposed statements were then listed on five separate pages corresponding to their identified over-arching theme (see Figure 9. p199). Within each page the statements were grouped into tables of three, four or five for ease of completion. Statements were grouped with other correlated statements from the same triangulation theme to improve participant comprehension and facilitate review. Sixty-Five statements were presented to the expert participants in total, divided into the overarching themes as presented in Table 17.

An example of the ranking table is presented in Figure 14. An option to review each statement as an individual question was provided should the participant prefer to view them this way. Space was also provided for participants to enter feedback on any given statement, this was mostly used in the first round by participants.

Page 5: Theme 1 - The Orthotist

Now we know a bit more about you, we would like to get your expert opinion on some statements about the role of orthotics and the orthotist in the rehabilitation of stroke survivors.

There are 5 themes of statements, each on it's on page. Please respond to statements with an ideal scenario perspective. There are 12 statements to respond to on this page.

A Finish Later option is available at the bottom of this page

This part of the survey uses a table of questions, [view as separate questions instead?](#)

For this next section please rate your agreement for each statement with a score from 1-7

(1 = strongly disagree, 7 = strongly agree) Please select one only answer for each statement

	1 Strongly disagree	2 Disagree	3 Somewhat disagree	4 Neither disagree or agree	5 Somewhat agree	6 Agree	7 Strongly agree
1. The orthotist is an important member of the stroke rehabilitation clinical team	☐	☐	☐	☐	☐	☐	☐
2. All patients who have experienced a stroke affecting motor control would benefit from having an orthotist assessment	☐	☐	☐	☐	☐	☐	☐

Figure 14. eDelphi ranking example

Consensus criteria

For this eDelphi the consensus threshold was set at 75% with any statement not reaching that to be reviewed, revised, or removed between rounds. Termination of the eDelphi was also determined by achieving 75% consensus for every statement (205). This pre-defined consensus threshold was chosen in consistency with other studies as described by Diamond et al. (205), with 75% the median threshold reported. Other study criteria were defined as:

- Any statement below 70% agreement were radically edited or removed,

- Any statement with 5 or more comments after round one had adjustments made to the wording to reflect the feedback,
- A response rate of $\geq 70\%$ between rounds was required to ensure validity (205),
- The eDelphi would be conducted over a maximum of three rounds, with earlier termination if all statements reach 75% consensus.

Rounds

Round one was open for six weeks. Once closed for responses, participants were sent a thank you and holding email to advise when they could expect the link to the second round. Analysis of the round one responses was completed within three weeks of round one closing to limit the amount of time between rounds and encourage continued participation. For round two, participants were sent a new link inviting them to respond to the eDelphi. It was explained that they may see the same statements and they were invited to rank them as they chose without prejudice from any previous answer. Any statements which had been edited between rounds were highlighted and participants were encouraged to review them as new statements using the same seven-point Likert ranking scale as before. To enhance response rate, a reminder email was sent to any participant who had not responded after the two-week specified time period. After this, a further follow-up email was sent one week later. At this point if no response was received it was assumed that participant no longer wished to take part in the study. As detailed in the consent form, any data provided from these individuals was retained and still used in the analysis.

7.3.4 Recruitment of participants

Purposive sampling of potential participants was undertaken as an appropriate approach for exploratory research (213). Potential participants were identified through the membership of the British Association of Prosthetists and Orthotists (BAPO). As the national professional body for orthotists within the UK, they hold the largest database for registered orthotic professionals in the country. They

agreed to circulate the eDelphi invitation to members following pilot and review by the BAPO Research Committee. In addition, an email invitation was circulated to all members of the National Orthotic Managers Group (NOMaG) which was then cascaded to clinical teams by their NOMaG manager. As the largest single employer of orthotists within the UK, a circulation via the NHS through the NOMaG was done to encourage a wider circulation to orthotists who may not be members of BAPO. Unfortunately, the exact figure of how many the invitation was sent to through this route is not known as that data could not be recorded.

Orthotic intervention after stroke is only one aspect of post-stroke rehabilitation with a wide multi-disciplinary clinical team working together. As such, the expert opinions of other clinicians, especially those who act as 'gatekeepers' to orthotic involvement such as physiotherapists and occupational therapists, could be considered as valuable additions to the voices captured within the development of best practice statements. However, their perspectives have already been explored during the MDT preparatory survey presented in Chapter Two, and the stakeholder focus groups presented in Chapter Five. The findings from which informed the developed statements of best practice. A diverse eDelphi panel helps to provide a broader perspective and therefore generalisation of consensus findings. However, a homogenous expert group can be considered to be more reliable in a focused Delphi objective (214). With the statements to be refined and agreed upon, relating specifically to the delivery of orthotic interventions after stroke, and a lack of professional consistency on the form and mechanisms of orthotic intervention currently, it was felt important to first establish best practice consensus amongst orthotists.

Sample size

There is no agreed standard sample size for an eDelphi expert panel. However, between 30-50 participants is considered optimum in reaching consensus for a homogenous group allowing for adequate saturation of expert knowledge whilst also ensuring data management is practicable (214). Studies have also indicated

that recruiting eDelphi participants from a homogenous group of experts allows for a smaller sample size to produce the same validity of results (215,216).

To take into account attrition and ensuring meaningful conclusions could still be drawn from the data, a proposed sample size of 30 participants was agreed upon with the aim of at least 20 participants completing all rounds. A 70% response rate between rounds was aimed for to maintain statistical rigour (217) and a smaller sample size, has been shown to reduce drop-out rate (218).

Eligibility criteria

Eligible participants were qualified orthotists with at least 2 years post-qualification experience of working within stroke rehabilitation. Orthotist colleagues do not routinely specialise in one field, which is in contrast to other therapy professions. It was therefore not possible to limit the specification to neurological specialist orthotists. Two years practicing within stroke rehabilitation post-qualification was determined the minimum that could be expected to consider them an expert. Eligibility was self-determined, and the eDelphi questionnaire was built to require participants to confirm their eligibility before being able to advance through to the questions.

Inclusion criteria

- Be HCPC registered prosthetist/orthotist,
- Have >2 years post qualification experience in stroke rehabilitation,
- English reading comprehension and writing ability.

International

Initially the protocol for the eDelphi was drafted to include international participants and ethical approval was gained to undertake this. The aim was to gain consensus collectively on more general statements and then complete sub-analysis of UK specific statements. Approvals were gained to circulate the eDelphi to members of the International Society of Prosthetists and Orthotists (ISPO), the largest network of qualified orthotists internationally. However, upon

request of this, administration and electronic errors resulted in the eDelphi link not being circulated. This was followed up with the circulation team without success. With the national link live and participants responding, supervisors were consulted to discuss the best option to move forward. Alternative means of eDelphi circulation were explored such as social media platforms like Twitter and Facebook. However, ethical approvals to use these had not been gained in the original ethical application. The FMHS ethical review panel were approached to consider an ethical amendment to allow this, but the time scales were such that it would have left too great a gap between rounds one and two. Not leaving too long between rounds is an important characteristic of eDelphi which encourages buy-in by participants and reduces drop-out rate (205). Other international organisations were considered as potential means of circulation of the invite such as the World Health Organisation Global Cooperation on Assistive Technology (GATE) but unlike BAPO and ISPO there is no requirement to be a registered orthotist to join their mailing list and the number of orthotists would likely be low. Ultimately it was decided that the most pragmatic approach for the study would be to concentrate on the UK responses and proceed as a national eDelphi. This element of the eDelphi was the most important to be able to answer the research question outlined and achieve the goal of developing national statements of best practice.

7.3.5 Data analysis

Participant responses after each round were exported from the JISC application and entered into a password protected Excel spreadsheet. They were then analysed to determine consensus percentage by calculating the mean average for each statement before converting to a percentage. Any statement which did not reach 75% consensus agreement was reviewed by the lead researcher and study clinical lead and revised. Any statement below 70% consensus agreement was radically edited or removed. Any statement with over 85% consensus agreement were reviewed and some edited to use stronger wording, for example: *“1.1 The orthotist is an important member of the stroke rehabilitation*

clinical team” was revised to “1.1 The orthotist is an integral member of the stroke rehabilitation clinical team”. Statements that had three or more comments attached to it were reviewed using a simplified thematic analysis (188), to determine commonality across the comments. This was then used to inform the revision of the statement. After 75% consensus agreement was reached on all the statements, the eDelphi was considered complete. The statements were then presented to the PPI study lead and the Nottingham Stroke Rehabilitation Partnership Group for their feedback.

7.4 Findings

Round one of the eDelphi was open for responses between April-May 2023. Invitation emails were shared with BAPO members (n=415) and NOMaG members (n=21) (to cascade to their clinical teams, n=unknown) twice, with a reminder included in the weekly BAPO newsletter. An example of the invitation email is presented in Appendix U. Round one was closed on 31/05/2023 with 32 participants returning responses. In March 2023 there were 1187 HCPC dual registered prosthetist/orthotists in the UK (219). Thirty-two responses therefore represent 2.7% of the registered workforce. The time since qualification is not recorded on the HCPC register and so it was not possible to determine more precisely the percentage of HCPC registrants who were deemed eligible with 2 years or more experience. However, as a dual registered workforce, approximately half of those on the HCPC register report as practicing orthotists thus indicating a response rate of 5% of registered orthotists in the UK.

All participants were found to be eligible following self-determination of meeting the inclusion criteria. Demographic characteristics of the 32 participants are presented in Table 18.

Table 18. eDelphi Participant demographics

Gender	n (%)
Male	12 (37.5)

Female	20 (62.5)
Transgender	0
Other/self-define	0
Prefer not to say	0
Age	n (%)
25-34 years	17 (53.1)
35-44 years	10 (31.2)
45-54 years	3 (9.4)
55-64 years	2 2 (6.3)
65 years and over	0
Prefer not to say	0
Ethnic origin	n (%)
Asian or Asian British	2
Black, Black British, Caribbean, or African	0
Mixed or multiple ethnic groups	0
White	29
Other ethnic group	1
Prefer not to say	0
Geographic region of UK currently practicing in	n (%)
East of England	0
East Midlands	8 (25)
London and surrounding area	4 (12.5)
North-West England	1 (3)
Northern Ireland	2 (6.25)
North-West England	5 (15.5)
Scotland	2 (6.5)
South-East England	1 (3)
South-West England	1 (3)
Wales	0
West Midlands	2 (6.5)
Yorkshire and The Humber	6 (18.75)
Prefer not to say	0
Length of time qualified as an Orthotist	n (%)
2-5 years	3 (9.5)
6-10 years	16 (50)
11-20 years	9 (28)
21 years or more	4 (12.5)
Primary employer	n (%)
Public/national health service provider	26 (81.25)

Private contractor for public/national health service	3 (9.5)
Private health service provider	2 (6.25)
Self-employed/locum	0
Higher educational institute	1 (3)
Charity/social enterprise	0
Non-governmental organisation (NGO)	0
Other (please state)	0
Predominant clinical setting	n (%)
Large/Acute hospital setting	27 (84.5)
Small district hospital setting	3 (9.5)
Private clinical site not within a hospital	1 (3)
Community team treating patients at their usual place of residence (home, care home, school etc.)	0
Research or University site	1 (3)
Charity/NGO site	0
Other (please state)	0
Stroke patient clinical caseload	n (%)
More than 5 patients a day	0
Between 2-5 patients a day	11 (34.5)
1 patient a day	9 (28.125)
1 patient a week	9 (28.125)
1 patient a month	2 (6.25)
Less frequently than one patient a month	1 (3)
Time of first assessment after stroke	n (%)
Within 48 hours	0
Within 7 days	6 (18.75)
Within 3 months	18 (56.25)
Within 6 months	4 (12.5)
More than 6 months	4 (12.5)

7.4.1 Participant demographic characteristics

Participants responded as practicing across all regions of the United Kingdom apart from the East of England and Wales. Participants were qualified orthotists practicing between 2 –21 years+, with over 90% qualified for six years or more. Eighty-one percent of participants reported their predominant employer as a public/national health service provider, namely the NHS. Participants were predominantly based within large/acute hospital settings (n=27) with three in

small district hospitals, one in a private clinical site not within a hospital and one based at a university or research site. Thirty-five percent (approx. one third) of participants reported assessing and treating between 2-5 stroke patients every day in their clinical caseloads. A further nine participants reported seeing at least one stroke patient a day. The mean reported time for first assessment after stroke was within three months.

7.4.1 Round one

In round one, the participants were asked to rate 65 statements divided into five over-arching themes. The consensus level percentage for each statement after round one is presented in Table 19. Any statements which did not reach 75% agreement are highlighted in orange and any statements which had more than three feedback comments from participants are highlighted in yellow. Detailed consensus statistics for round one are presented in Appendix V.

Table 19. eDelphi round one statement consensus percentage

Theme One - The Orthotist	Consensus percentage
1. The orthotist is an important member of the stroke rehabilitation clinical team	97%
2. All patients who have experienced a stroke affecting motor control would benefit from having an orthotist assessment	94%
3. Where an orthotist is not embedded within the stroke clinical unit, regular orthotist contact is important to facilitate timely assessment and treatment	97%
4. Regular orthotist contact with the stroke unit is important to facilitate knowledge exchange, advice giving and provide training	96%
5. The orthotist should lead the orthotics assessment and any subsequent orthotics provision for stroke survivors	96%
6. When not embedded within a stroke clinical unit, please select how regularly you think the orthotist should be in attendance to assess and treat patients*	No consensus

7. Consistency of approach between orthotists in their assessment and treatment is important to ensure equitable treatment for stroke survivors	86%
8. Where an orthosis has been prescribed it should be the same orthotist who fits and trials that device with the stroke survivor	79%
9. The stroke survivor should be reviewed by the same orthotist that prescribed and fitted the orthotic device for consistency and continuity of care	79%
10. Orthotists should have the opportunity to specialise in specific conditions such as neurological rehabilitation	88%
11. There should be stroke specific training available to pre-registration and post-registration orthotists to establish an agreed pathway of treatment for stroke survivors to encourage conformity across settings	92%
12. The orthotist should be involved in the planning, commissioning and provision of stroke rehabilitation services	90%
*Different answer option to other statements. Participants invited to select from: Every day, 2-3 days a week, Once a week (weekly), Every other week (bi-weekly), Once a month (monthly), Less than once a month.	
Theme Two - The Orthoses	
1. Orthotic principals such as biomechanics are important considerations when deciding on a stroke survivors rehabilitation treatment plan	98%
2. Ankle Foot Orthoses (AFOs) should be considered for stroke survivors with mobility problems	94%
3. Any orthotic provision following stroke should be assessed for and prescribed with the intent of 'right first time'	88%
4. Orthoses prescribed for stroke survivors should be considered a rehabilitation tool in their toolbox	93%
5. The time between assessment and provision of any orthoses for an early rehabilitation stroke survivor should be less than 14 days	88%
6. Appropriate orthotic provision for stroke survivors can positively influence stance phase and swing phase limb alignment during mobilising	99%

7. Orthoses in early post stroke rehabilitation can be used to increase dosage of therapeutic alignment and intervention when hands on therapist time is limited or unavailable	95%
8. Orthotic intervention in early post stroke treatment can contribute to a 24-hour therapy model of rehabilitation	88%
9. Early orthotic use ensuring correct alignment and normal movement can assist with neuroplasticity retraining of mobility	93%
10. Following provision of an orthoses, all stroke survivors should have the option of tuning to ensure the best functionality and usability	94%
11. Availability of orthoses type (custom, prefabricated, material etc.) should be equitable for all stroke survivors regardless of location	99%
12. Availability of any orthoses for stroke survivors should not be determined by cost and its prescription should be driven by functional need	94%
13. Custom and personalised orthosis prescriptions should be considered at the first instance over prefabricated orthoses for stroke survivors	62%
14. Prefabricated orthoses have a valid place within orthotic provision post stroke but should be managed carefully for appropriateness for each individual	91%
15. Provision of prefabricated orthoses should be overseen by an orthotist or appropriately trained healthcare professional	92%
16. Information regarding any provided orthoses should be given in both verbal and written formats to stroke survivors	96%
Theme Three - The Stroke Survivor	
1. All stroke survivors with mobility problems should be assessed by an orthotist in a timely and equitable manner	96%
2. Orthotic provision should be considered as a first line rehabilitation intervention for stroke survivors with lower limb tone and/or spasticity	92%
3. Orthotic assessment should be considered for any stroke survivor with secondary complication risk factors such as contracture, even if they are non-mobile	96%

4. Timely and effective orthotist assessment and orthotic provision can enable a stroke survivors independence and improve their mental health	98%
5. For stroke survivors who are prescribed an orthosis, a routine 6-week follow-up appointment should be made to review progress and on-going need	83%
6. Any orthoses prescribed to a stroke survivor should be reviewed at appropriate time periods within the first 12 months of rehabilitation to assess changing need	90%
7. An orthotic assessment should be available at any stage of a stroke survivors' rehabilitation, even if no need was identified early after stroke	94%
8. Difficulties with speech and/or cognition following stroke should be accommodated in any orthotic assessment and provision	94%
9. Where present, carers should be included in orthotic assessment and provision appointments	97%
10. An orthosis prescribed for a stroke survivor should be the most cosmetic and unobtrusive in design that is possible, whilst still meeting the individual functional requirements	86%
11. Appropriate accommodations should be made to enhance compliance of orthoses use when designing an orthotic prescription such as fitting into footwear etc.	93%
Theme Four – The Orthotic Service	
1. Orthotics assessment and provision is an integral part of stroke rehabilitation but not a necessity	52%
2. There should be equity of access to orthotist assessment and orthotic provision across clinical settings (acute hospital, community hospital and community)	91%
3. Orthotic assessment and provision for stroke survivors should be prioritised in orthotic service delivery and referrals actioned with urgency	82%
4. For long-term orthotic users after stroke, a patient or carer should be able to self-refer for further orthotic assessment and review	90%
5. Relationships between the core orthotic service and the stroke rehabilitation service should be established and nurtured to enhance stroke survivor's rehabilitation	94%

6. Orthotic services should be planned, commissioned and run to provide specialist individualised assessment and treatment for stroke survivors	95%
7. The core orthotic service should be invested in to facilitate the orthotic delivery and treatment for stroke survivors	95%
Theme Five – Ways of Working	
1. An orthotist should be included as a member of the core stroke multi-disciplinary rehabilitation (MDT) team	94%
2. The orthotist should be included in MDT assessments of stroke survivors with motor control problems and contribute to agreed rehabilitation goals and treatments	92%
3. An orthotic assessment should be conducted as a joint exercise with the specialist skills of the orthotist and therapy staff working together	93%
4. The use of technology to facilitate joint orthotist assessment such as video evidence or pressure plate technology should be utilised within early stroke rehabilitation	76%
5. Inclusion of the orthotist within the stroke rehabilitation MDT enhances knowledge exchange and leads to better professional relationships	96%
6. Orthoses prescription should be undertaken by the orthotist and decided upon using biomechanical principals	95%
7. Orthotist assessment and provision following a stroke should take a holistic approach seeking to enable tasks of daily living, promote independence and mental health	98%
8. Access to orthotist led orthotic assessment and/or provision should be equitable regardless of where the stroke survivor is located geographically	98%
9. Scope of practice is an important consideration when an orthotic device is prescribed or fitted by a healthcare professional that is not an orthotist	97%
10. Assessment by an orthotist for patients presenting with mobility difficulties after a stroke should be conducted within the 'early' rehabilitation phase (48 hours in line with early mobilising recommendations) ¹	69%
11. Assessment by an orthotist for patients presenting with mobility difficulties after a stroke should be conducted within the 'acute' rehabilitation phase (7 days) ²	83%

12. Assessment by an orthotist for patients presenting with mobility difficulties after a stroke should be conducted within the 'early sub-acute' rehabilitation phase (3 months) ²	90%
13. Orthotist assessment and appropriate provision within early gait rehabilitation is an essential mechanism to avoid compensatory patterns being developed such as over extension at the knee or hip-hiking	93%
14. Screening tools can be used by other healthcare professionals to help identify if a stroke survivor will benefit from an orthotic assessment and/or provision	89%
15. Outcome measures should be used to determine effect of orthotic provision following stroke	95%
16. Requests from other health care professionals for orthotic assessment and/or provision should take the form of referral for assessment rather than a prescription with specified orthoses	98%
17. Referral for orthotic assessment should be considered for stroke survivors who present with severe impairment where an orthoses may aid in comfort, enable transfer and assist in care delivery	98%
18. Stroke services should have a specific referral pathway for orthotic assessment and provision for patients once discharged from the acute hospital setting	95%
19. There should be training for non-therapy acute and sub-acute clinical staff such as nurses and health care assistants on how to correctly put on, remove and use common types of orthotic device such Ankle-Foot Orthoses	95%
1.Langhorne P, Wu O, Rodgers H, Ashburn A, Bernhardt J. A very early rehabilitation trial after stroke (AVERT): a Phase III, multicentre, randomised controlled trial. Health Technol Assess (Rockv). 2017;21(54):1-119. doi:10.3310/hta21540 2.Bernhardt J, Hayward KS, Kwakkel G, et al. Agreed Definitions and a Shared Vision for New Standards in Stroke Recovery Research: The Stroke Recovery and Rehabilitation Roundtable Taskforce. Neurorehabil Neural Repair. 2017;31(9):793-799	

Sixty-two statements reached consensus after round one with only three of those rated below 80%. No statements had above 75% disagreement. Four statements did not meet 75% consensus agreement. These four statements are presented below.

Theme One, Statement 6: *When not embedded within a stroke clinical unit, please select how regularly you think the orthotist should be in attendance to assess and treat patients.* This statement was the only statement to have different answer options to the others. Rather than the 7-point Likert scale, participants were asked to select which option they felt was most suitable. As is shown below, participants gave a spectrum of responses and so it was agreed to help reach consensus in subsequent rounds any option with less than 5 responses would be removed. The options removed before round two are highlighted in red.

1.6 When not embedded within a stroke clinical unit, please select how regularly you think the orthotist should be in attendance to assess and treat patients Please select only one option					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?*
32	0	Every day	2	6%	Mean consensus not reached
		2-3 days a week	6	19%	
		Once a week (weekly)	15	47%	
		Every other week (bi-weekly)	6	19%	
		Once a month (monthly)	2	6%	
		Less than once a month	1	3%	
* Any option with less than 5 responses was removed for the next round					

Theme Two, Statement 13: *Custom and personalised orthoses prescriptions should be considered at the first instance over prefabricated orthoses for stroke survivors.* As shown below, this statement also has a wide spectrum of responses indicating a split in professional opinion. This statement also had more than three comments indicating the further refinement was required. Participant 109422221 stated, "In the early stages of a stroke I think an off the shelf device can be very useful to give support there and then while the presentation is changing. If more rigid control to prevent contracture is required a custom AFO would be needed but the turnaround time for this needs to be within a couple of weeks to ensure the presentation doesn't change following assessment." A simple analysis was completed on the five comments made for these statements to determine commonality (68). This was then used to inform the revision of the statement.

2.13 Custom and personalised orthoses prescriptions should be considered at the first instance over prefabricated orthoses for stroke survivors					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree	3	9%	61.61%
		Somewhat disagree	4	13%	
		Disagree	5	16%	
		Neither disagree or agree	6	19%	
		Agree	3	9%	
		Somewhat agree	4	13%	
		Strongly agree	7	21%	

Theme Four, Statement one: *Orthotics assessment and provision is an integral part of stroke rehabilitation but not a necessity*. The development of this statement was influenced strongly by the perspective of other stroke rehabilitation therapists in the earlier PhD studies and came through during the triangulation exercise. As shown below, after round one of the eDelphi it was the statement with the lowest percentage of agreement indicating that orthotists themselves do not consider this statement an accurate description. Thematic analysis of the 11 comments indicated very similar observations from participants. Participant 109408746 stated simply: “I think orthotic assessment is a necessity of an effective stroke service.”

4.1 Orthotics assessment and provision is an integral part of stroke rehabilitation but not a necessity					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree	2	6%	52.23%
		Somewhat disagree	12	38%	
		Disagree	4	13%	
		Neither disagree or agree	3	9%	
		Agree	2	6%	
		Somewhat agree	6	19%	
		Strongly agree	3	9%	

Theme Five, Statement 10: *Assessment by an orthotist for patients presenting with mobility difficulties after a stroke should be conducted within the ‘early’ rehabilitation phase (48 hours in line with early mobilisation recommendations)*. This statement was presented as one of three to try and gain perspective on the perceived optimum timing of first orthotic assessment after stroke. Evidence of therapy input to determine optimum mobilisation were used to decide the

different time options (8). Mobilising following stroke was used as it is the primary reason for orthotic intervention in this population. This statement was the only one out of the three different statements which has suggested timings for intervention (Theme Five - statements 10,11,12), that was ranked below 75% agreement and so was removed before the next round.

5.10 Assessment by an orthotist for patients presenting with mobility difficulties after a stroke should be conducted within the 'early' rehabilitation phase (48 hours in line with early mobilising recommendations) ¹					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree	1	3%	69.20%
		Somewhat disagree	2	6%	
		Disagree	4	13%	
		Neither disagree or agree	6	19%	
		Agree	5	16%	
		Somewhat agree	9	28%	
		Strongly agree	5	16%	
1. Langhorne P, Wu O, Rodgers H, Ashburn A, Bernhardt J. A very early rehabilitation trial after stroke (AVERT): a Phase III, multicentre, randomised controlled trial. Health Technol Assess (Rockv). 2017;21(54):1-119. doi:10.3310/hta21540					

To help reach consensus in subsequent rounds, it was agreed to combine the other two statements which had reached consensus into a single statement inviting participants to pick just one time option. A third option of entering a 'other' time point was given also. The rehabilitation phases which were used to determine the time points presented are as defined by The Stroke Roundtable Consortium in recognition that recovery-related processes post-stroke are time-dependent (149).

Twenty-four of the statement which did reach consensus had more than three comments made by participants. These comments were analysed thematically to determine themes and use commonality to further refine the statements before the second round (188).

7.4.2 Round two

The revised statements for round two are presented along with the original statements in Appendix W. Sixty-four statements were circulated for round two of the eDelphi on 28/06/2023. An invitation to complete the second round was

sent to the 32 expert participants from round one with a three-week deadline to complete. A final reminder was circulated to nine participants who had yet to complete the second round one week before the eDelphi was closed. Twenty-eight of the original 32 expert participants responded to the second round meaning an 87.5% retention rate between rounds ensuring the findings maintained statistical rigour (217). All but one of the 64 statements reached the pre-defined consensus level of 75% or more with an overall consensus level of 94.31% indicating a high level of consensus across all the statements when considered in totality. Detailed consensus statistics for round two are presented in Appendix X.

As all but one of the statements reached the required consensus level it was agreed no third round was required. The only statement that did not reach expert consensus was Theme Five, Statement 10: *Assessment by an orthotist for patients presenting with mobility difficulties after a stroke should be conducted within: The 'acute' rehabilitation phase (7 days), The 'early sub-acute' rehabilitation phase (3 months), Other (please state)*. As shown below, the expert participants were split almost 50:50. With this result, the clinical and PPI lead for the study were consulted and it was agreed that the statement should be adjusted to incorporate both time options to allow for a degree of interpretation. The revised statement is presented in Table 19.

5.10 Assessment by an orthotist for patients presenting with mobility difficulties after a stroke should be conducted within the 'early' rehabilitation phase (48 hours in line with early mobilising recommendations)					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	The 'acute' rehabilitation phase (7 days)	14	50%	Mean consensus not reached
		The 'early sub-acute' rehabilitation phase (3 months)	12	43%	
		Other defined time period, please specify:	2	7%	

Any statements which were revised between round one and two of the eDelphi were reviewed and the statement format which held the highest consensus

response was included. The full list of statements that reached expert consensus agreement are presented below in Table 20.

Table 20. eDelphi consensus statements included in the statements of best practice

Theme One - The Orthotist	Consensus percentage
1. The orthotist is an important member of the stroke rehabilitation clinical team	97%
2. All patients who have experienced a stroke affecting motor control would benefit from having an orthotist assessment	94%
3. Where an orthotist is not embedded within the stroke clinical unit, regular orthotist contact is important to facilitate timely assessment and treatment	97%
4. Regular orthotist contact with the stroke unit is important to facilitate knowledge exchange, advice giving and provide training	96%
5. The orthotist should lead the orthotics assessment and any subsequent orthotics provision for stroke survivors	96%
6. When not embedded within a stroke rehabilitation unit or community team, the orthotist should attend to assess and treat patients at a minimum of once weekly	79%
7. Consistency of approach between orthotists in their assessment and treatment is important to ensure equitable treatment for stroke survivors	90%
8. Orthotist continuity of care when an orthosis has been prescribed following stroke is the ideal	93%
9. The prescribed orthosis should be reviewed by either the same orthotist or another orthotist from the same team to facilitate collective learning and development of practices	92%
10. Orthotists should have the opportunity to specialise in specific conditions such as neurological rehabilitation	92%
11. There should be stroke specific training available to pre-registration and post-registration orthotists to establish an agreed pathway of treatment for stroke survivors to encourage conformity across settings	95%

12. The orthotist should be involved in the planning, commissioning and provision of stroke rehabilitation services	91%
Theme Two - The Orthoses	Consensus percentage
1. Orthotic principals such as biomechanics are important considerations when deciding on a stroke survivors rehabilitation treatment plan	98%
2. Ankle Foot Orthoses (AFOs) should be considered for stroke survivors with mobility problems	94%
3. Any orthosis provided following stroke should be done so with the intent of 'right first time', to include adjustments and new provision if indicated to address changes in clinical need	92%
4. Orthoses prescribed for stroke survivors should be considered a rehabilitation tool in their toolbox	93%
5. For new users of an early rehabilitation stroke orthosis, the time between assessment and first provision should be less than 14 days	93%
6. Appropriate orthotic provision for stroke survivors can positively influence stance phase and swing phase limb alignment during mobilising	99%
7. Orthoses in early post stroke rehabilitation can be used to increase dosage of therapeutic alignment and intervention when hands on therapist time is limited or unavailable	95%
8. Orthotic intervention early post stroke can contribute to a 24-hour therapy model of rehabilitation	91%
9. Early orthotic use ensuring correct alignment and normal movement can assist with neuroplasticity retraining of mobility	93%
10. Following provision of an orthosis post stroke; tuning should be optimised to ensure the best functionality and usability for the patient	96%
11. Availability of orthosis type (custom, prefabricated, material etc.) should be equitable for all stroke survivors regardless of location	99%
12. Availability of any orthosis for stroke survivors should not be determined by cost and its prescription should be driven by functional need	94%

13. Custom and personalised orthoses are a preferable prescription in patients with complex gait abnormalities or deformities	87%
14. Prefabricated orthoses are a valid and useful orthotic provision post stroke but should be managed carefully for appropriateness for each individual	95%
15. Provision of prefabricated orthoses should be overseen by an orthotist or appropriately trained healthcare professional with suitable competencies	95%
16. Information regarding any provided orthosis should be given in both verbal and written formats to stroke survivors and their carer	97%
Theme Three - The Stroke Survivor	
1. All stroke survivors with mobility problems should be assessed by an orthotist in a timely and equitable manner	96%
2. Orthotic provision should be considered as a first line rehabilitation intervention for stroke survivors with lower limb tone and/or spasticity	92%
3. Orthotic assessment should be considered for any stroke survivor with secondary complication risk factors such as contracture, even if they are non-mobile	96%
4. Orthotic assessment and provision should be considered in early gait rehabilitation to avoid compensatory patterns being developed such as over extension at the knee or hip-hiking	97%
5. Timely and effective orthotist assessment and orthotic provision can enable a stroke survivors independence and improve their mental health	96%
6. For stroke survivors who are prescribed an orthosis, a routine follow-up appointment should be made to review progress and on-going need	92%
7. Any orthoses prescribed to a stroke survivor should be reviewed at appropriate time periods within the first 12 months of rehabilitation to assess changing need	92%
8. An orthotic assessment should be available at any stage of a stroke survivors' rehabilitation, even if no need was identified early after stroke	95%

9. Difficulties with speech and/or cognition following stroke should be accommodated in any orthotic assessment and provision	95%
10. Where present, carers should be included in orthotic assessment and provision appointments	97%
11. An orthosis prescribed for a stroke survivor should be the most cosmetic and unobtrusive in design that is possible, whilst still meeting the individual functional requirements and being cost-effective	88%
12. Appropriate accommodations should be made to enhance compliance of orthoses use when designing an orthotic prescription such as fitting into footwear etc	94%
13. Appropriate orthotic provision for stroke survivors should positively influence mobility and independence	97%
Theme Four – The Orthotic Service	
1. Orthotics assessment and provision should be an integral part of a stroke rehabilitation service	95%
2. There should be equity of access to orthotist assessment and orthotic provision across clinical settings (acute hospital, community hospital and community)	96%
3. Orthotic assessment and provision for stroke survivors should have a degree of priority alongside other more complex patient groups in orthotic service delivery and referrals	92%
4. For long-term orthotic users after stroke, a patient or carer should be able to self-refer for further orthotic assessment and review	93%
5. Relationships between the core orthotic service and the stroke rehabilitation service should be established and nurtured to enhance stroke survivor's rehabilitation	95%
6. Orthotic services should be planned, commissioned and run to provide specialist individualised assessment and treatment for stroke survivors	97%
7. The core orthotic service should be invested in to facilitate the orthotic delivery and treatment for stroke survivors	96%
Theme Five – Ways of Working	
1. An orthotist should be included as a member of the core stroke multi-disciplinary rehabilitation (MDT) team	94%

2. The orthotist should be included in MDT assessments of stroke survivors with motor control problems and contribute to agreed rehabilitation goals and treatments	93%
3. An orthotic assessment should be conducted as a joint exercise with the specialist skills of the orthotist and therapy staff working together	95%
4. The use of technology to facilitate joint orthotist assessment such as video evidence or pressure plate technology can be helpful within early stroke rehabilitation	86%
5. Inclusion of the orthotist within the stroke rehabilitation MDT enhances knowledge exchange and leads to better professional relationships	96%
6. Orthoses prescription should be decided upon using biomechanical principals and lead by the orthotist	97%
7. Orthotist assessment and provision following a stroke should take a holistic approach seeking to enable tasks of daily living, promote independence and mental health	99%
8. Access to orthotist led orthotic assessment and/or provision should be equitable regardless of where the stroke survivor is located geographically	98%
9. Scope of practice is an important consideration when an orthotic device is prescribed or fitted by a healthcare professional that is not an orthotist and appropriate competencies must be met	97%
10. Assessment by an orthotist for patients presenting with mobility difficulties after a stroke should be conducted within the 'acute' (7 days) and 'early sub-acute' (3 months) rehabilitation phase after stroke	93%
11. Screening tools can be used by other healthcare professionals to help identify if a stroke survivor will benefit from an orthotic assessment and/or provision	89%
12. Outcome measures should be used to determine effect of orthotic provision following stroke	96%
13. Requests from other health care professionals for orthotic assessment and/or provision should take the form of referral for assessment with goal/objective rather than a prescription with specified orthoses	98%
14. Referral for orthotic assessment should be considered for stroke survivors who present with severe impairment where	98%

an orthosis may aid in comfort, enable transfer and assist in care delivery	
15. Stroke services should have a specific referral pathway for orthotic assessment and provision for patients once discharged from the acute hospital setting	96%
16. There should be training for non-therapy acute and sub-acute clinical staff such as nurses and health care assistants on how to correctly put on, remove and use common types of orthotic device such Ankle-Foot Orthoses	98%
Total consensus percentage	94.31%

7.5 Discussion

The aim of this study was to refine and finalise statements of best practice through professional consensus on the optimal ways of working when delivering orthotic interventions after stroke.

A national eDelphi study was completed with 64 statements reaching consensus agreement of over 75% across two rounds. By triangulating previous study findings to formulate proposed statements, the final statements are embedded in the evidence and based on the perspectives and experiences of different stakeholders including expert orthotists, other healthcare professionals, and stroke survivors and carers. Additionally, this process of data gathering, and synthesis meant that the traditional first step of a Delphi to generate initial statements was superfluous in this instance. As a homogenous clinical group but heterogenous in geographic location and experience, this modified eDelphi enabled expert participants to reach consensus with consistent high levels of agreement. Combined with a high retention rate between rounds, the findings and subsequent statements of best practice have a high level of professional confidence and support.

In round one participants were asked to provide their demographic characteristics in order to align this work with other research. Every region of the four nations of the UK were represented apart from two: Wales and the East

of England. Unlike the previous statement produced on AFO use after stroke, which were developed within Scotland alone (29), these statements can be considered the first expert agreed guidance produced with cross nation input. The experts who participated in this eDelphi were defined as orthotists with more than two years post-qualification experience of working with stroke survivors. There is no agreed definition of expert within Delphi literature (220), however Jünger et al. (209), reported that experts in Delphi studies were mostly identified through membership of a professional or stakeholder group, or having specific clinical or academic expertise. Baker et al. (220) expands further on this by stating experts are “characterised as those with knowledge, experience, and the ability to influence policy”. For the expert participants in this eDelphi, namely orthotists, they are required to have an accredited qualification and register with the HCPC in order to practice in the UK which demonstrates knowledge. Experience within clinical fields is usually determined by the length of time since qualification and having practiced in a field. Within the orthotic profession, it is generally considered that an orthotist is experienced beyond ‘junior’ level after 2 years. Ninety percent of the participants were qualified for six years or more, satisfying the requirement for participants of the eDelphi to be considered experts in the field.

A high percentage of participants reported working directly for the NHS as their predominant employer. This was not unexpected as one method of recruitment which was undertaken was through the NHS Orthotic Managers network. However, workforce data reports 57% orthotists in the UK were working for private employers compared to the NHS (180). This potential bias should therefore be noted when considering the generalisability of the study findings as working experiences and practices may be different for direct NHS employees. As stated earlier, there was only 12.5% attrition rate between rounds, adding to the statistical rigour (217), and reliability of the conclusions.

7.5.1 Study strengths and limitations

This eDelphi used pre-defined consensus criteria in line with other research and has been reported using CREDES guidance to increase the reliability and transparency of the findings (209). All the expert participants were UK registered orthotists creating a professionally homogenous group adding to accuracy of the findings in this type of focused Delphi objective (214). It has been discussed previously in the Methodology section of this chapter, that a diverse panel of clinical experts would have provided a broader perspective and could have addressed any professional biases present. For example, it is likely that orthotists will say they are important members of the stroke MDT. However, with the developed standards of best practice directly applicable to the orthotic workforce, an important consideration was ownership and so it was determined that orthotist expert perspective alone should be sought. The influence of the wider stroke professional community was apparent within the statements as they were critical to their development. However, it is worth noting that it was the statement that was most heavily influenced by the wider stroke team that was the only one to be removed due to very low consensus amongst orthotists. This should be considered against the backdrop which the cross-sectional professional survey and stakeholder focus groups presented, that MDT working is very limited and not common practice nationally within orthotic provision after stroke. This could indicate why there was apparent disagreement in approach between orthotists and the wider stroke rehabilitation workforce in this statement. It also supports further evaluation of the statements, including perspectives from the wider stroke rehabilitation members, in the future. This would be beneficial for the statements which have been included that relate to scope of practice of orthotists and other professional groups which through this eDelphi have been agreed by orthotists alone. Without further engagement and agreement with other members of the stroke rehabilitation team, implementing these statements should be approached with caution.

The recruitment of expert participants relied heavily on the invitation circulation to British Association of Prosthetists and Orthotists (BAPO) members and the NHS Orthotic Managers Group (NOMaG). Whilst BAPO is the national professional body for orthotists, their members only make up 54% of HCPC registered practitioners and so the recruitment strategy for the Delphi could have been more targeted at orthotists working outside of the reach of BAPO and NOMaG. Moreover, the invitation to a methodology like this is self-selective and is reliant on participants willingness to engage with this kind of research activity. As such, participants are likely motivated to be involved due to interest in this specific area which could skew the generalisability of the findings. However, this study and the development of the statements of best practice were directed by the GRADE approach (51), with pragmatic underpinnings aimed at by those who practice within this specialised clinical area. A potential further bias was noted within the expert participants as they were predominantly white and female, however this is aligned with the HCPC workforce data from March 2023 (219).

The use of an online data collection program was an efficient methodology, and necessary during the Covid-19 pandemic. It also facilitated participation from a wide geographic area including all nations of the UK except Wales. Whilst it is considered that an online system is more inclusive, the PPI lead noted that it can be exclusive for some groups who are not digitally literate. However, as this eDelphi was targeted at clinical professionals, a degree of digital literacy and access to computers is a requirement of the role.

With the traditional first stage of Delphi data generation replaced by the previous studies within the PhD, the eDelphi participants were deprived of the opportunity to input on the statement development directly. However, due to the small professional numbers within the UK (180), and the previous use of BAPO mailing list circulation for recruitment to the cross-sectional survey (Chapter Four) and multi-disciplinary focus groups (Chapter Five), it is likely there were eDelphi participants who participated in those studies also. Moreover, there was the opportunity to add comments throughout the two rounds of the

eDelphi and these were reviewed and incorporated through statement revision using a thematic analysis process (188).

As discussed in the Methodology section of this chapter, there was an original aim to provide an international perspective within this eDelphi. This was unfortunately not possible due technical errors with the distribution of the international invite and a need to progress to the next stage of the eDelphi for UK participants. The international comparison would have added an additional perspective to the findings but the lack of this does not reduce the validity of the statements as a UK centric document. Future research including an international viewpoint, other stroke rehabilitation professions and stroke survivors would provide a broader perspective and applicability of the statements. Working with colleagues within the International Stroke Rehabilitation and Recovery Alliance (ISRRRA), adapting the statements of best practice to test their applicability in other international settings within a future study is being explored. Each element of this PhD programme of work has a national focus and so the eDelphi findings continue that trend.

The findings from this eDelphi are consistent with other international guidance on orthotic provision after stroke (221,222), and reflect similar themes to those identified within the AFO specific Scottish guidance produced by Bowers and Ross (29). More widely within stroke rehabilitation, consensus methods as an approach to developing recommendations as a foundation for future evaluative studies are also being promoted internationally (53,223,224). The statements of best practice that have been refined and agreed within this study, can therefore be assessed in comparison to others produced in this area.

7.4 Conclusion

This chapter presents an eDelphi study designed to determine expert consensus agreement on statements of best practice for delivering orthotic interventions after stroke. This is the first-time expert consensus has been established and

statements produced in this area. The statements encompass the different influencing factors which effect the efficient and effective delivery of this orthotic intervention after stroke. In contrast to the inconsistencies in approach and practice discussed in the cross-sectional professional survey in Chapter Four, and stakeholder focus group findings in Chapter Five, the expert workforce returned high levels of agreement on what constitutes good practice in this area and have a clear idea as to how to deliver it.

The primary purpose of a Delphi is to generate a reliable consensus opinion from a panel of topic experts via an iterative process of data collection and controlled feedback (214). The statements produced, can be considered only representative of the experience and views of the specific expert participants at a precise snapshot in time. Therefore, further review and evaluation of the statements to confirm their applicability and acceptability would be beneficial. Finally, it must be acknowledged that despite the limitations of this methodology, this study was conducted in the midst of the Covid-19 pandemic and as such an eDelphi provided a platform to connect and gather data from clinicians who were geographically disparate to form consensus on an important topic.

The summary of the findings and from each study described within this PhD, along with the developed statements of best practice, are presented in Chapter Eight which concludes the research completed for this PhD thesis.

Chapter Eight: The development of national statements of best practice on delivering orthotic interventions after stroke: Discussion and Conclusions

In this chapter, the findings from the individual studies within this PhD will be brought together and the finalised statements of best practice on delivering orthotic interventions after stroke will be presented. Within this chapter, the mixed methods approach and the strengths and limitations of the methodology in totality will be considered. The influence of collaboration with PPI and clinical experts will also be discussed. A synthesis of the collective findings and the impact of the position of the researcher will then be presented, and the context within which these statements have been developed will be discussed alongside other relevant literature. Finally, an interpretation of the statements' implications for clinical practice and future research will be offered.

8.1 Summary of methodology

Inclusive of the two preparatory and five substantive studies, seven separate studies have been undertaken within this PhD programme to inform the development of the resulting statements of best practice. A mixed methods approach was chosen for this PhD programme of work, with methodologies used including: an MDT survey and clinical observations (Chapter Two); a systematic review (Chapter Three); a national cross-sectional professional survey (Chapter Four); stakeholder focus groups (Chapter Five); a triangulation exercise (Chapter Six); and a national eDelphi (Chapter Seven). All the individual methods have been described in detail in the respective chapters, and the strengths and limitations of each study have been discussed. However, the strengths and

limitations of the methods used in totality is important to consider and is instructive when reflecting on the collective findings from each study.

8.1.1 Mixed methods

Mixed methods are recommended within the GRADE approach (104), to strengthen the study and its findings. The use of mixed methods within this PhD was particularly valuable in addressing an under researched area within a complex health system (225). Orthotics as an intervention and has a myriad of elements which effects its provision within the UK, such as the commissioning of NHS services to private companies (139). As such, it was paramount to take as inclusive an approach to data collection as possible to try and capture the effects of these influencing factors. By mixing qualitative and quantitative research methodologies, a greater understanding of the underlying issues was achieved which couldn't have been realised using a singular method (110).

Whilst the individual findings from each study add to the evidence base within this field, the combined findings from a mixed methods approach also facilitated an output from this PhD which is arguably greater than the sum of its parts. The different datasets were analysed separately before being converged via the triangulation exercise which reinforces their independent and then collective conclusions (54). However, any bias present or limitation of an individual method can then be augmented as its findings are included within further summative analysis (226). Whilst the strengths and limitations of the individual methodologies have been discussed earlier in the thesis, it is important to consider them as a whole and contemplate how this effects the overall trustworthiness and transferability of the resultant statements of best practice.

8.1.2 Methodology strengths and limitations

The methods undertaken throughout this PhD programme of work have added to the evidence base of this important aspect of stroke rehabilitation treatment, but they do not indicate any degree of effectiveness or how they will be operationalised. Many of the statements were developed wholly from clinician

experience and perception using qualitative data collection methods. This means the statements of best practice do not present evidence of effectiveness when considered independently from the PhD work package as a whole. This lack of primary evidence is believed to be the key reason the multi-disciplinary guidelines for stroke rehabilitation do not include more specific details relating to orthotic intervention (7,52). Whilst there is some evidence of positive effect of orthotic interventions after stroke as identified in the systematic review, it is limited (158). As a profession therefore, orthotists should concentrate their efforts on establishing more higher-grade research outputs to consolidate the published evidence with the anecdotal. It is a limitation of this PhD that more higher-grade quantitative research methods of enquiry were not used. In part this is due to the need for feasibility data to first be established before any evaluative study could take place. Additionally, the restrictions imposed during this PhD due to Covid-19 meant that any non-covid trials were de-prioritised and usual evaluative methods of inquiry were halted. Given these restrictions, the findings from this PhD offer the best grade evidence possible within this field at the time due to the combination of qualitative and quantitative methods.

Recruitment

Whilst rich in themselves, the findings from each of the PhD studies were enhanced through their synthesis. However, the similarity in how the participants of the individual research studies were recruited raises risk of potential bias. Circulation of research invitations through professional body mailing lists and personal networks was deemed the most appropriate and efficient method to reach potential participants with experience of this niche clinical topic. This approach will have likely resulted in a similar cohort of potential participants being reached for each study. Where possible, other methods of approach were used such as social media which has been found to be a good opportunity to engage with prospective participants in a nonconventional way (227). However, as this research was focused primarily on gathering clinical professional participants, routes of invitation through their

employer, professional body or interest group are likely considered more acceptable. Taking into account the constraints of the Covid-19 pandemic restrictions, it is felt the research and recruitment methods were the most reliable available to achieve the aims of the PhD.

Stakeholders

Involving key stakeholders both as collaborators and research participants throughout the PhD has been an important aspect which has shaped the outputs. The expertise of orthotists themselves as well as the wider stroke rehabilitation team has been incorporated, with different professions and experience levels represented in the initial MDT survey as well as the MDT focus groups. A spectrum of orthotists were included in the cross-sectional professional survey and national eDelphi studies. As mentioned throughout this thesis, the Nottingham Stroke Research Partnership Group alongside the study PPI lead have collaborated on the project from start to finish. Through refining the research question, the development of the survey questions and topic guides used, feeding into the statement production process and review of the finalised statements. Further inclusion of stroke survivors and carers as participants of the research studies, as has been highlighted previously, would likely serve to enhance the findings further. This is planned for future studies testing the statement effectiveness and suitability for implementation within different settings.

The study clinical lead has offered guidance throughout the delivery of the individual studies ensuring the findings are grounded in real practice. Working with the British Association of Prosthetists and Orthotists (BAPO) on the preparatory MDT survey, cross-sectional professional survey, and stakeholder focus groups has facilitated wider participation of clinical voices from geographically disparate regions. However, a limitation is that only those who are members of BAPO will have been engaged with through that channel. Wider engagement with other clinicians outside of BAPO could have been beneficial

but unlikely practical within the scope of this PhD. Moreover, the way in which other therapist voices were identified for the different studies was reliant on membership of specific interest groups and professional networks thus likely limiting the spectrum of participants views and experience relating to orthotics captured. The involvement of stakeholders as collaborators and participants as described by Beck et al. (228), within the PhD, has enriched the interventions effectiveness, acceptance, and application to real-world clinical settings.

The voice of the lived experience

Involving the voice of lived experience within this PhD programme of work can be considered one of its key strengths (229). Both as research participants and collaborators from its development to its conclusion, the research has been influenced by the people this area impacts most. The voice of lived experience was instrumental in devising the original and revised research questions and methods used within the PhD. With the outbreak of the Covid-19 pandemic, specific input from the Nottingham Stroke Research Partnership Group helped re-direct the focus of the PhD and ensure onward participation of stroke survivors, carers and the clinicians tasked with their care. Throughout the completion of each study the study PPI and clinical leads have directed the research and ensured the patient and clinician relationship has been at the heart of the investigations. The voice of professional lived experience both from orthotists and other key clinical colleagues, has been included in recognition of the important role they play in determining orthotic need and onward therapeutic rehabilitation. In particular, their collaboration within the triangulation and convergence of the data had a significant impact on the development of the proposed statements. Wider participation of clinical and PPI perspective may have been beneficial to diversify their representation. However, relying on a dedicated and core group ensured the reliable support of trusted and valued collaborators. Through continual collaboration and review of the emerging findings from each study which makes up this PhD, the voice of the

PPI and clinical lived experience can be found within the resultant statements of best practice.

Grading of Recommendations Assessment, Development and Evaluation (GRADE)

Each statement of best practice produced within this PhD was developed following the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach (51). Specific consideration was given to the guidance on rating the quality of evidence (64–67,69,70,76,104), to help determine how to operationalise the GRADE guidance in drafting definitive clinical guidance or statements of best practice.

Following the GRADE handbook (104), a determination was made to produce statements of best practice on the best available evidence currently. Statements were drafted against the five criteria for Good Practice Statements (GPS) as described by Dewidar et al (105). This method is thought to enhance confidence when assessing the net consequences of implementing a statement and ensures its relevance within an evidence-decision criterion. As such, the use of the GRADE approach has been influential in directing the kinds of studies that were completed within this PhD and the form of the resultant output. The GRADE approach has become the international standard of best practice guideline development and has been adopted by the World Health Organization (WHO), the Cochrane Collaboration, and the National Institute for Health and Care Excellence (103). Within this PhD it has ensured comprehensive development and description of the methods used for statement generation, informed the data collection, data synthesis, and added transparency to the decisions made. Whilst a determination of the quality of evidence can be made using the GRADE domains, no formal checklist is available to assess the process and findings from this PhD against. To address this limitation, the findings as a complex intervention have been considered within the MRC framework for the development and complex interventions (230). Orthotics is a multifaceted

healthcare provision with influencing elements which require due consideration in the development of any intervention or recommendations. Using such a widely recognised framework promotes confidence in the resulting statements suitability to be further evaluated and implemented within real-world contexts. To evidence the process undertaken in starting to prepare the statements of best practice for the next stages of the development cycle, a checklist from the MRC framework is presented below in Table 21. with the work completed within this PhD considered the first steps towards intervention development.

Table 21. MRC framework checklist (108)

Item	If NO, please justify. If YES, briefly describe how this has been addressed	Reported in Chapter/section
Addressing uncertainties		
1. Have you determined the aim(s)/purpose(s) of the intervention?	Determined through clinical experience, prior research completed and Patient Public Involvement (PPI).	Chapter One, section 1.4
2. Have you identified the key uncertainties given existing evidence about the intervention and the context in which it will be tested or implemented?	Identified through the initial stages of the PhD: MDT survey and clinical observation, as well as the systematic review.	Chapters Two and Three
3. Do the research questions and methods address the key uncertainties?	Use of MRC framework for complex interventions.	Chapter One, section 1.5

4. Does the choice of research perspective (efficacy, effectiveness, theory-based, systems) reflect the key uncertainties that have been identified?	Uncertainties relate to 'ways of working', hence the research question and focus on developing the BPRs to inform the ways of working.	Chapter One, sections 1.2, 1.5 & 1.6
Engaging stakeholders		
1. Have you engaged stakeholders in the design/identification of the intervention and the development of the research protocol?	Clinical and PPI members engaged with during identification of the research question and study design.	Throughout the thesis, specific reference in Chapter One, section 1.5
2. Have you engaged stakeholders in the conduct of the research and the dissemination of findings?	Clinical and PPI members engaged with during data collection, research process and drafting of research outputs.	Chapter Five, sections 5.3, 5.4; Chapter Six, sections 6.3, 6.4; Chapter Seven, section 7.3, 7.4, 7.5
3. Have all stakeholders declared any potential conflicts of interest?	Yes, no conflicts of interest have been declared.	
Considering context		
1. Have you identified all the dimensions of context that may influence how the intervention achieves its effects?	Identified through the cross-sectional survey and focus groups.	Chapters Four and Five
2. Have you considered how context may affect	Considered throughout in using the MRC framework for	Chapter One, section 1.5, Chapter Five, sections 5.4 & 5.5,

the scaling up or scaling out of the intervention?	complex interventions, further work planned outside scope of PhD.	Chapter Eight, section 8.2
Developing and refining programme theory		
1. Have you developed a programme theory for your intervention that describes the key components and mechanisms of the intervention and how it interacts with the context in which it will be implemented?	N/A	Not explicitly included within the PhD.
2. Have you updated the programme theory to incorporate the new evidence gathered by the study?	N/A	Not explicitly included within the PhD.
Refining the intervention		
1. Have you refined the intervention so that it is optimised for the context in which it will be implemented?	With the collaboration of the clinical and PPI lead as well as wider professional refinement within the eDelphi.	Chapter Seven, sections 7.3 & 7.4
2. Have you specified how far and in what ways the intervention can be refined during implementation without undermining the programme theory?	This has not been covered within the scope of the PhD, a further implementation study is planned.	

Economic considerations		
1. Have you considered whether or not the value of the evidence, in terms of informing future decision-making, justifies the cost of the research?	Considered through the efficient use of funds and development of much needed evidence within orthotic practice.	Not explicitly included within the PhD.
2. Have you identified an economic evaluation framework that is appropriate to the expected outcomes of the intervention?	This has not been covered within the scope of the PhD, determining cost-effectiveness is part of the planned future work.	
Phase-specific considerations – This predominantly are beyond the scope of the PhD but will be considered in future research design		
Developing interventions – have you used a formal framework (such as INDEX) to guide development of the intervention? Identifying interventions – for policy and practice interventions, have you performed an evaluability assessment to determine whether or not and how an evaluation should be undertaken? Feasibility – have you defined and used clear progression criteria to guide decisions about whether to proceed to an evaluation study?	As well as MRC framework, GRADE approach used. Further assessment of evaluability, feasibility and evaluation were not conducted as they are beyond the scope of this PhD. Implementation is specifically considered in the future project being developed.	Chapter One, sections 1.3 & 1.4, Chapter Six, sections 6.2 & 6.4

Evaluation – have you chosen an appropriate study design to answer the research questions and provide robust evidence to inform decision-making about further intervention refinement, evaluation or implementation? Implementation – have constraints and enablers of implementation been considered at all phases, from intervention development, through feasibility and effectiveness testing, to large-scale roll-out?		

Within the programme of work for this PhD there are further findings from the combined results of each of the individual studies and these will now be discussed.

8.2 Synthesis of results

The aim of this PhD programme of work was to answer the research question:

What are the optimal ways of working in delivering orthotic interventions to enhance rehabilitation outcomes and reduce complications for stroke survivors?

There were five aims and objectives:

1. To identify, synthesise, and appraise the existing evidence on orthotic interventions targeted at improving or maintaining functional mobility in the lower limb early after stroke.

To achieve this, a systematic review of the literature was undertaken to provide a comprehensive synthesis of relevant evidence and a detailed foundation of existing knowledge before undertaking further work.

2. To establish a cross-section of perspectives from the expert orthotic workforce on current practice and optimum orthotic intervention in early gait rehabilitation following stroke in the UK.

To achieve this, a national cross-sectional professional survey was conducted with orthotists as experts in orthotic intervention following stroke. This survey had a targeted focus of data collection to benchmark current practice in a post-covid landscape and to identify the perceived role of the orthotist in early gait rehabilitation. It also explored the confidence, frustrations, and ambitions of the expert workforce to begin forming a foundation of what optimum orthotic intervention following stroke 'looks like'.

3. To determine stakeholder perspectives on the role of orthotics in stroke rehabilitation, exploring the similarities and differences in their perception to those identified by orthotists.

To achieve this, three focus groups were conducted. Two with clinical members of the wider stroke rehabilitation team and one with stroke survivors and carers. Using a topic guide informed by the findings of the systematic review and cross-sectional professional survey, these focus groups gathered stakeholder perspectives on the role of orthotics within stroke rehabilitation focusing on early gait.

4. To converge data from the previous studies to develop proposed statements of best practice on delivering orthotic interventions after stroke.

To achieve this, a healthcare specific triangulation method described by Farmer et al (54), was used to combine the systematic review, professional cross-sectional survey, and stakeholder focus group data. This method provided a comprehensive way to highlight concurrence, recognise contradictions and note silences within the source data to inform proposed statements of best practice.

5. To refine and finalise statements of best practice through professional consensus on the optimal ways of working when delivering orthotic interventions after stroke.

To achieve this, a national eDelphi was conducted to gain orthotist consensus on the content and composition of statements of best practice on delivering orthotic interventions after stroke. Expert agreement was obtained through a two-round exercise to produce professionally ratified statements of best practice. These detail the optimal ways of working when delivering orthotic interventions to enhance rehabilitation outcomes and minimise complications for stroke survivors, as agreed by orthotic experts.

Further to the aims and objectives completed through this PhD programme of work, further collective findings have been uncovered as part of the synthesis. Specific themes have been repeated throughout each individual study and so impacted on the overall findings from this PhD. Relationships; Access;

Knowledge and understanding of orthotics; Professional consensus; Stakeholder consultation; Context and future implementation; Building the evidence base; The GRADE method; Lived experience; and the Statements of best practice on delivering orthotic interventions after stroke. These discussion themes are presented below.

8.2.1 Relationships

Relationships were found to be of critical influence to orthotic interventions after stroke, acting as the foundation to many aspects of its delivery. Initially identified in the preparatory studies, the effect of localised relationships between clinicians on the likelihood of receiving orthotic intervention is an important finding of this PhD. This has onward impacts on whether a referral is made, ease of access to the orthotist assessment, and then the ease of any subsequent provision. A reliance on individualised relationships between orthotists and physiotherapists as an enabler to orthotic delivery was found. Whilst resulting in perceived successful outcomes, this cannot be recommended as a model to replicate due to vast differences in clinical set-up and the individual nature of relationship building between clinical professionals (231). Services should not establish their pathways and provisions to be reliant on individual clinicians to facilitate them; this would likely become problematic if that person is away either temporarily or moves permanently. A more robust method of establishing team relationships should be encouraged to ensure consistency in approach regardless of who is present within the team on any given day (232). The formation of established ways of working within inter-professional relations impacts not only the access to orthotics for stroke survivors but can influence their longer-term experiences and expected outcomes too. A personalised knowledge of the orthotics service or the orthotists can act to legitimise it as an intervention to the stroke survivor and empower them in their decision making regarding their treatment (233). Stroke survivors spoke about how they were not aware of orthotics as a treatment option and had they been informed of it then they would have likely been receptive to the orthotist assessing them and

being involved in their rehabilitation. This relationship between stroke survivor and orthotist can be long-standing beyond that of other therapists as the patient moves to new settings and has changing needs through their rehabilitation (16). It can be argued therefore that the findings from this PhD indicate the importance of a solid foundation of interprofessional relationships, to inform the service provision between professions and lead to a more successful patient-professional relationship.

8.2.2 Access

This PhD proposes that formulaic relationship building could be considered beneficial both in localised settings and in orthotic service provision within stroke rehabilitation more widely. As identified within the cross-sectional professional survey and the stakeholder focus groups, irregularity in access and approach is unfortunately common across the UK (171). In attempting to address this however, the multifaceted and intricate way health services are organised cannot be ignored. A specific aspect of orthotics services which has a large influence on its delivery is the commissioning of NHS services to private companies. A recent orthotic/prosthetic workforce study found 42% (76 out of 181) of UK NHS trusts/health boards reported their orthotic/prosthetic services had been contracted out to an external supplier for the last five years (180). This undoubtedly has an impact on the access to services with degree of separation from in-house NHS provision. Moreover, focus group respondents spoke of how this model has an impact on their ability to build relationships, a key factor in successful delivery of orthotic intervention as presented in the previous discussion theme. A fuller appreciation for these types of factors is required before any future model of delivery can be recommended and therefore the statements of best practice do not attempt to make specific process recommendations.

8.2.3 Knowledge and understanding of orthotics

Integral to establishing authentic relationships with longevity, is shared knowledge and understanding of orthotics after stroke (234). This finding came

through in several of the studies within the PhD as a barrier to its efficient and optimal delivery. Non-orthotist practitioner focus group participants spoke of the limited teaching related to orthotics in their training and how this carried through into their clinical settings. Clinicians, stroke survivors, and carers highlighted how they weren't aware of orthotic provision for stroke rehabilitation and so were unable to seek it out. Only those considered 'lucky' spoke of working with or being treated by an orthotist.

As a small profession (180), it is understandable that there is not the saturation of orthotic understanding and familiarity within professional and patient circles. However, orthotists have a significant role to play in their self-promotion and knowledge distribution. By integrating themselves more readily within local services and national leadership bodies they could have more opportunities to highlight their important role as autonomous practitioners (235). A profession in its relative infancy, it is the smallest of all the 14 Allied Health Profession workforces within the NHS (180). Their low numbers mean they have limited opportunities to embed themselves within clinical services, a fact which was reflected in the findings of several of the studies within this PhD. Low numbers practicing in patient facing roles translates to poor representation in hospital trust management, Integrated Care Boards (ICBs), and on national governing bodies (180). A lack of advocacy and understanding of a profession at that level can lead to reduced knowledge and de-prioritisation in patient facing clinical settings creating a cycle of poor awareness (236). It was raised that this lack of awareness contributes to stroke survivors and carers being unable to advocate for their care relating to orthotics within the patient and carer focus group. The statements of best practice produced in this PhD act as blueprint for indicating optimum ways of working and detailing ideal mechanisms for delivering orthotics after stroke. They therefore represent a useful resource for orthotists to promote their value, for other clinicians to learn about orthotics, commissioners to direct service provision, and patients to advocate for their own care.

8.2.4 Professional consensus

An important tool for orthotists, it is hoped the statements of best practice will work to address the incongruence within the orthotic workforce. The lack of unity of approach is a significant finding within this PhD which should be addressed as a priority. This influenced the decision to include the expert voices of the orthotists alone within the national eDelphi rather than seeking consensus more widely (204). The findings from the earlier studies have shown a discourse between professional approach and whilst the technical skill of the orthotist is key to the success of the intervention, it was apparent that a degree of consistency is required to establish what their role should, and could, be (37,171). If orthotists themselves cannot agree on their role, it is not surprising that other clinicians and members of the public do not have clarity either. This disparity can possibly be explained through individualised clinical experiences as orthotists are trained at only four universities in the UK with consistency across the courses (237). The differences in clinical approach likely arise once orthotists are practicing, with localised historical ways of working, that were captured in the PhD studies, having a strong influence. A workforce agreed approach is therefore much needed, especially in a profession where condition specialism is uncommon and therefore with less opportunities for learning from other clinical settings. The development of these best practice recommendations, produced through a professional consensus exercise, goes some way to establishing a professionally agreed approach (214). It was purposeful to invite the eDelphi expert participants from orthotists alone to encourage consensus amongst the profession before moving to wider consultation. This also served to prevent dilution of the findings at this early stage and encourage conviction and 'buy-in' for their future evaluation.

8.2.5 Stakeholder consultation

Whilst the collective learning from the PhD is heavily based on the orthotist perspective, other voices are included within the different studies. It is possible that inclusion of other stakeholders within the eDelphi could have produced

more widely accepted statements of best practice (238). The perspectives of other clinicians within the stroke rehabilitation team could have been included and the voice of stroke survivors and carers could have been amplified. However, the objective of the PhD was to explore the optimal ways of working when delivering orthotic interventions after stroke. In doing so the primary output has been to establish a blueprint for professional best practice. This can then be further scrutinised and refined through extended peer-review including other stakeholders more readily (239). It is arguably not surprising that orthotists have advocated for easier access, closer working with the stroke rehabilitation team and greater recognition for the role they play in stroke rehabilitation, so it is important to consult with a wider perspective and consider any counter arguments to these recommendations. Nevertheless, the development of this guidance is an important step forward for the orthotic profession in reaching agreement on where they see themselves within the landscape of stroke rehabilitation. The statements can now be taken forward into wider consultation with other stroke rehabilitation practitioners and stroke survivors.

8.2.6 Context and future implementation

Further findings from the PhD have indicated the factors which can be expected when the statements of best practice are tested in real world situations to determine effectiveness and instruct implementation. Due consideration for the context and mechanisms which influence future testing is important to produce actionable statements which offer real potential for positive change (71). Within the context of the PhD programme, changes that were made due to the Covid-19 pandemic steered the project to studying these important aspects which would have been missed within the original PhD programme. Whilst there was justification in testing feasibility of an intervention within orthotics after stroke, it is likely the factors which have been emphasised throughout the subsequent work packages would have created great challenges. As is recommended within the MRC guidance on the development and evaluation of complex interventions (108), adequate consideration for the context and implementation of a potential

intervention is as important as the evaluation of its effectiveness. The changes made to the PhD ensured such consideration was given over to influencing factors that might have been missed without the change to research methodology. The work completed as part of this PhD therefore stands as a better foundation to understand the factors which influence orthotic provision after stroke, changing the primary focus of the PhD question from 'when' to 'how'. This PhD programme of work has provided the lead researcher with the opportunity to assess the landscape within which the statements of best practice are hoped to operate within, allowing them to be developed with this context in mind. It is accepted practice that this will lead to better adapted interventions to real world clinical contexts and encourage more accurate and ultimately useful future evaluation and implementation.

8.2.7 Building the evidence base

As a rehabilitation intervention orthotics is not unique in its complexity, with elements of professional expertise, inter-disciplinary working, service provision as well as the orthotic device itself (126). However, unlike other rehabilitation interventions, the findings from the systematic review reiterate that orthotics does not have a wealth of evidence as a foundation to direct its efficient and consistent delivery (158). The statements of best practice act as recommendations to guide clinical practice and are actionable statements where effects of an intervention clearly outweigh its undesirable effects or any undesirable effects of not implementing the intervention (105). This is an important outcome from the PhD programme to add to the evidence base which informs an important area of clinical practice. The collective study findings not only produce new insights but also highlight the work and importance of an under-represented and under-researched profession and clinical area.

8.2.8 The GRADE method

The use of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach (51), to develop the statements of best practice has brought reliability and applicability to their recommendations. GRADE

directs that there is an assessment of the certainty of evidence and depending on this outcome either comprehensive clinical guidelines or statements of best practice should be drafted (104,105). By its design, the GRADE method incorporates a significant amount of subjectivity in each decision, but it does provide a reproducible and transparent framework for grading certainty in evidence (105). With the majority of the PhD study findings being perception based it was decided to proceed to develop statements of best practice before more outcomes-based research could be conducted to inform comprehensive clinical guidelines. The GRADE method states that statements of best practice should undergo peer review, be published, and disseminated, and when appropriate, updated (105). The developed statements of best practice produced within this PhD have undergone a degree of peer review through the eDelphi exercise as described in Chapter Seven, but further peer-review is planned through onward consultation with other stakeholders and their presentation at national and international professional and multi-disciplinary conferences. Two abstracts have already been submitted and accepted.

8.2.9 Lived experience

Whilst the PhD has had instructive and consistent input from the PPI and clinical collaborators, a key finding is that further involvement with stroke survivors and carers from a more diverse ethnic, social background, and geographical areas would be desirable (240). It was challenging to include more of these voices within the PhD studies as their focus was mainly on professional perception. Furthermore, within the stakeholder focus groups it was difficult to identify patients with lived experience of orthotics. This echoes the findings from the focus group that many stroke survivors and carers are not aware of orthotics provision within stroke rehabilitation. However, with more time and a wider net of recruitment, more voices of lived experience of stroke can be included. This will be an important aspect of the statement's further review and refinement to ensure applicability in real world settings and that they are grounded in matters which are of importance to those whom they are designed to help. For now, the

voices of lived experience are present within the statements, but efforts will be made to amplify them in future work.

8.2.10 Statements of best practice: Delivering orthotic interventions after stroke

A synthesis of the findings from each of the studies within this PhD, has led to the main output from this programme of work. This is guidance on the optimum delivery of orthotic interventions after stroke within the UK in the form of the first recommendations for best practice. The results from each of the individual studies within this PhD offer insight and data relating to orthotics delivery as a complex intervention which has had very little investigation into previously. The best practice statements present original findings on the mechanisms and facilitators to effective and optimum ways of working as agreed through professional consensus, having brought together the perspectives of different stakeholders on the delivery of orthotic intervention after stroke. The finalised statements of best practice are presented below.

Figure 15. Statements of Best Practice: Delivering Orthotic Intervention After Stroke



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CONTENTS

Authors	1
Introduction	3
Best Practice Themes	3
Theme One - The Orthotist	4
Theme Two - The Orthoses	6
Theme Three - The Patient	9
Theme Four - The Orthotic Service	11
Theme Five - Ways of Working	12
Glossary	15
References	16
Acknowledgements	22

INTRODUCTION

Whilst orthotic intervention following stroke is often considered an important element of rehabilitation for motor deficit, the optimum content, timing and method of intervention is not agreed. The UK's National clinical guidelines for stroke re-published in 2023 recommend 'access to' orthotic intervention as part stroke rehabilitation services [1], but the mechanisms to facilitate this are unspecified.

We have developed the first professionally agreed statements of best practice for delivering orthotic interventions to support motor recovery after stroke in the UK.

These best practice statements have been developed following the internationally agreed Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach [2]. Each statement was developed against the five criterion for Good Practice Statements [3] and are underpinned by 3 key principles:

- They are intended to guide practice and promote a consistent, cohesive and achievable approach to care. Their aims are realistic but challenging.
- They are primarily intended for use by orthotists and other allied health professions, but will also be of relevance to the wider clinical team and the patients they treat.
- They are developed where variation in practice exists and seek to establish an agreed approach for practitioners.

These best practice statements will be periodically reviewed, and if necessary, updated in order to ensure they continue to reflect current evidence and professional opinion with regard to best practice.

The statements of best practice themes are divided within this resource into five themes:

 THE ORTHOTIST • The specialist skills of the orthotist are an integral aspect of orthotic intervention success after stroke	 THE ORTHOSES • The appropriate orthosis is critical to fast and effective rehabilitation following orthotic intervention after stroke	 THE STROKE SURVIVOR • A patient centred approach should be the primary consideration for any orthotic intervention after stroke	 THE ORTHOTIC SERVICE • An appropriately funded and staffed orthotic service is essential for timely and efficient orthotic intervention after stroke	 WAYS OF WORKING • Collaborative and innovative working will lead to the best outcomes for patients requiring orthotic intervention after stroke
Page 4	Page 6	Page 9	Page 11	Page 12

THE ORTHOTIST



1

The orthotist is an important member of the stroke rehabilitation clinical team

2

All patients who have experienced a stroke affecting motor control would benefit from having an orthotist assessment

3

Where an orthotist is not embedded within the stroke clinical unit, regular orthotist contact is important to facilitate timely assessment and treatment

4

Regular orthotist contact with the stroke unit is important to facilitate knowledge exchange, advice giving and provide training

5

The orthotist should lead the orthotics assessment and any subsequent orthotics provision for stroke survivors

6

When not embedded within a stroke rehabilitation unit or community team, the orthotist should attend to assess and treat patients at a minimum of once weekly

7

Consistency of approach between orthotists in their assessment and treatment is important to ensure equitable treatment for stroke survivors

THE ORTHOTIST



8

Orthotist continuity of care when an orthosis has been prescribed following stroke is the ideal

9

The prescribed orthosis should be reviewed by either the same orthotist or another orthotist from the same team to facilitate collective learning and development of practices

10

Orthotists should have the opportunity to specialise in specific conditions such as neurological rehabilitation

11

There should be stroke specific training available to pre-registration and post-registration orthotists to establish an agreed pathway of treatment for stroke survivors to encourage conformity across settings

12

The orthotist should be involved in the planning, commissioning and provision of stroke rehabilitation services

THE ORTHOSES



1

Orthotic principals such as biomechanics are important considerations when deciding on a stroke survivors rehabilitation treatment plan

2

Ankle Foot Orthoses (AFOs) should be considered for stroke survivors with mobility problems

3

Any orthosis provided following stroke should be done so with the intent of 'right first time', to include adjustments and new provision if indicated to address changes in clinical need

4

Orthoses prescribed for stroke survivors should be considered a rehabilitation tool in their tool box

5

For new users of an early rehabilitation stroke orthosis, the time between assessment and first provision should be less than 14 days

6

Appropriate orthotic provision for stroke survivors can positively influence stance phase and swing phase limb alignment during mobilising

7

Orthoses in early post stroke rehabilitation can be used to increase dosage of therapeutic alignment and intervention when hands on therapist time is limited or unavailable

THE ORTHOSES



8

Orthotic intervention early post stroke can contribute to a 24 hour therapy model of rehabilitation

9

Early orthotic use ensuring correct alignment and normal movement can assist with neuroplasticity retraining of mobility

10

Following provision of an orthosis post stroke; tuning should be optimised to ensure the best functionality and usability for the patient

11

Availability of orthosis type (custom, prefabricated, material etc.) should be equitable for all stroke survivors regardless of location

12

Availability of any orthosis for stroke survivors should not be determined by cost and its prescription should be driven by functional need

13

Custom and personalised orthoses are a preferable prescription in patients with complex gait abnormalities or deformities

14

Prefabricated orthoses are a valid and useful orthotic provision post stroke but should be managed carefully for appropriateness for each individual

THE ORTHOSES



15

Provision of prefabricated orthoses should be overseen by an orthotist or appropriately trained healthcare professional with suitable competencies

Information regarding any provided orthoses should be given in both verbal and written formats to stroke survivors and their carer

16

THE STROKE SURVIVOR



1

All stroke survivors with mobility problems should be assessed by an orthotist in a timely and equitable manner

2

Orthotic provision should be considered as a first line rehabilitation intervention for stroke survivors with lower limb tone and/or spasticity

3

Orthotic assessment should be considered for any stroke survivor with secondary complication risk factors such as contracture, even if they are non-mobile

4

Orthotic assessment and provision should be considered in early gait rehabilitation to avoid compensatory patterns being developed such as over extension at the knee or hip-hiking

5

Timely and effective orthotist assessment and orthotic provision can enable a stroke survivors independence and improve their mental health

6

For stroke survivors who are prescribed an orthosis, a routine follow-up appointment should be made to review progress and on-going need

7

Any orthoses prescribed to a stroke survivor should be reviewed at appropriate time periods within the first 12 months of rehabilitation to assess changing need



8

An orthotic assessment should be available at any stage of a stroke survivors' rehabilitation, even if no need was identified early after stroke

9

Difficulties with speech and/or cognition following stroke should be accommodated in any orthotic assessment and provision

10

Where present, carers should be included in orthotic assessment and provision appointments

11

An orthosis prescribed for a stroke survivor should be the most cosmetic and unobtrusive in design that is possible, whilst still meeting the individual functional requirements and being cost-effective

12

Appropriate accommodations should be made to enhance compliance of orthoses use when designing an orthotic prescription such as fitting into footwear etc.

13

Appropriate orthotic provision for stroke survivors should positively influence mobility and independence

THE ORTHOTIC SERVICE



1

Orthotics assessment and provision should be an integral part of a stroke rehabilitation service

2

There should be equity of access to orthotist assessment and orthotic provision across clinical settings (acute hospital, community hospital and community)

3

Orthotic assessment and provision for stroke survivors should have a degree of priority alongside other more complex patient groups in orthotic service delivery and referrals

4

For long-term orthotic users after stroke, a patient or carer should be able to self-refer for further orthotic assessment and review

5

Relationships between the core orthotic service and the stroke rehabilitation service should be established and nurtured to enhance stroke survivor's rehabilitation

6

Orthotic services should be planned, commissioned and run to provide specialist individualised assessment and treatment for stroke survivors

7

The core orthotic service should be invested in to facilitate the orthotic delivery and treatment for stroke survivors

WAYS OF WORKING



1

An orthotist should be included as a member of the core stroke multi-disciplinary rehabilitation (MDT) team

2

The orthotist should be included in MDT assessments of stroke survivors with motor control problems and contribute to agreed rehabilitation goals and treatments

3

An orthotic assessment should be conducted as a joint exercise with the specialist skills of the orthotist and therapy staff working together

4

The use of technology to facilitate joint orthotist assessment such as video evidence or pressure plate technology can be helpful within early stroke rehabilitation

5

Inclusion of the orthotist within the stroke rehabilitation MDT enhances knowledge exchange and leads to better professional relationships

6

Orthoses prescription should be decided upon using biomechanical principals and led by the orthotist

7

Orthotist assessment and provision following a stroke should take a holistic approach seeking to enable tasks of daily living, promote independence and mental health

WAYS OF WORKING



8

Access to orthotist led orthotic assessment and/or provision should be equitable regardless of where the stroke survivor is located geographically

9

Scope of practice is an important consideration when an orthotic device is prescribed or fitted by a healthcare professional that is not an orthotist and appropriate competencies must be met

10

Assessment by an orthotist for patients presenting with mobility difficulties after a stroke should be conducted within the 'acute' (7 days) and 'early sub-acute' (3 months) rehabilitation phase after stroke

11

Screening tools can be used by other healthcare professionals to help identify if a stroke survivor will benefit from an orthotic assessment and/or provision

12

Outcome measures should be used to determine effect of orthotic provision following stroke

13

Requests from other health care professionals for orthotic assessment and/or provision should take the form of referral for assessment rather than a prescription with specified orthoses

14

Referral for orthotic assessment should be considered for stroke survivors who present with severe impairment where an orthosis may aid in comfort, enable transfer and assist in care delivery

WAYS OF
WORKING



15

Stroke services should have a specific referral pathway for orthotic assessment and provision for patients once discharged from the acute hospital setting

16

There should be training for non-therapy acute and sub-acute stroke clinical staff such as nurses and health care assistants on how to correctly put on, remove and use common types of orthotic device such AFOs

GLOSSARY

Acute setting	A location where healthcare interventions are provided that is within a hospital trust site.
Ankle Foot Orthoses (AFO)	An external brace or splint that fits next to the foot and ankle to control its range of motion and helps to stabilise its position. Patients who have weakness in the ankle dorsiflexor or plantar flexor muscles due to stroke may benefit from the support this device offers in standing and walking. By securing an anatomically correct position, this device can prevent muscle shortening or contracture where muscle imbalance is present after stroke.
Community setting	Any geographical location where healthcare interventions are provided that is not within an acute hospital site.
Contracture	A permanent shortening of a muscle or joint due to loss of motion over time due to abnormal shortening of the soft tissue structures spanning one or more joints. Damage to the brain can result in weakness, decreased motor control, sensation, and spasticity. Through disuse, an affected joint becomes less elastic and stiff and eventually contracted.
Custom orthoses	An orthotic splint or brace that has been made specifically for an individual usually by taking a mould. These usually take longer to provide patients as they have to be manufactured individually and are usually more costly than stock devices.
Orthotist	Orthotists are autonomous registered practitioners who provide gait analysis and engineering solutions to patients with problems of the neuro, muscular and skeletal systems. They are extensively trained at undergraduate level in mechanics, biomechanics and material science along with anatomy, physiology and pathophysiology. It is a protected title within the UK regulated by the Health Care and Professions Council.
Stock orthoses	An orthotic splint or brace that is available 'off-the-shelf' and usually kept in stock at orthotic departments which allows immediate provision. These devices are manufactured to 'normal' size dimensions and are usually less expensive than custom devices. They can be used as a long-term prescription, as a temporary device whilst waiting for more the permanent device to be made, or to test the suitability of a certain kind of support before deciding on a longer-term prescription.

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The views and recommendations expressed in these Statements of Best Practice are those of the author(s) and not necessarily those of the Stroke Association, National Health Service, National Institute for Health Research, the Department of Health and social care.

8.3 Reflexivity

Important to recognise within this PhD is the position of the lead researcher as an orthotist and the impact and influence this may have had on its completion

and findings. Reflexivity is a reflection on the ways in which the researchers' values may have impacted on the research process and is particularly relevant to qualitative interpretative research. The lead researcher is an orthotist with professional experience of working within stroke rehabilitation. This PhD programme of work was designed and developed by the lead researcher to answer questions raised during her clinical practice. With so few HCPC registered and practicing orthotists in the UK (180), any research into orthotic practice is valuable and much needed. Specific interest in how orthotic values and ways of working can influence outcomes for stroke survivors was devised as an area to investigate following anecdotal experiences within this field. The research questions were designed to address the lack of guidance currently within this area, which appears at odds to the experiences of clinicians in practice (158). It was believed that mechanisms optimising orthotic intervention after stroke could be of merit with potential detriment to clinical outcomes when it is not. Through discussion with orthotic colleagues, it became clear that further investigation into the wider perceptions of the orthotists role and ways of working were needed. There was therefore already an understanding in relation to the broad content and structure of the programme of work which was outlined in the application to secure funding to complete this PhD. Moreover, the lead researcher intended the development of some clinical guidance as the main output from this PhD, to address the paucity of guidance currently available in this field. The statements of best practice therefore must be considered in this context and should undergo further peer review to enhance their value.

In conducting each of the studies which make up the programme of work within this PhD, the values and beliefs of the lead researcher will be evident (241). These can apply a positive effect in that the researcher's prior knowledge of a phenomena can lead to more accurate interpretation of findings. It can also act as a bias where the findings can be shaped by those pre-existing understandings (241). Nevertheless, the views of the lead researcher in embarking on this PhD

were reflected in the respondents to the preparatory MDT survey, the cross-sectional professional survey and the stakeholder focus groups. Mixed methods research such as that undertaken through the course of this PhD benefits from an experienced knowledge base of the topic at hand to direct discussion especially within interviews and focus groups (225). Similarly, it can ensure the relevance of survey questions, thus capturing the attention and encouraging the subsequent engagement of the potential participants. The lead researcher disclosed their professional role to the focus group participants and the eDelphi and survey participants were also informed of the background of the researcher on the landing page of the survey. Due to the professional numbers of orthotists within the UK being so low (180), it is likely that the lead researcher was personally known to some of the respondents which may have influenced their readiness to participate and their responses. A degree of distance from the delivery of the research may have acted to reverse this potential bias to separate any pre-conceived ideas of the lead researcher from the findings. However, that approach would not have been appropriate within the context of this PhD, where the work needs to be led and conducted by the student. Future evaluative work exploring effectiveness and cost effectiveness would benefit from an MDT research team led by an orthotist.

The process of reflexivity was undertaken throughout the PhD programme of work and continuously returned to with the support of the supervisory team (242). Any pre-conceived ideas were challenged through continual discussion and engagement with the PPI and clinical study collaborators who grounded the research within professional and personal lived experiences.

8.4 Context and consideration of other literature

When considering any orthotic intervention whether after stroke or within the treatment pathway of another condition, it is important to acknowledge the landscape of orthotic provision within the United Kingdom.

Prosthetist/orthotists are the smallest of the 14 Allied Health Professions (180). Currently, there are 1187 registered prosthetist/orthotists in the UK (174) and as a dual qualified profession approximately half of that number are expected to be practicing in orthotics nationally. This context is important as it offers clarification on the paucity of evidence directing orthotic interventions currently and elucidates on some of the difficulties orthotists have in advocating for their specialist input as has been highlighted throughout the PhD.

Within orthotic practice a further element which is unique is the commissioning of NHS services to be provided by private clinical partners. A recent workforce survey, the largest and most comprehensive of its kind, reported 60% of the workforce were employed by private companies (178). This creates a different dynamic to other therapy interventions that needs due consideration. Highlighted within the findings of this PhD was the importance of relationship building between the orthotist and the wider stroke rehabilitation team. This is made increasingly difficult with the five-year cycle of service contracting which can result in a change in provider and staff. This also means that any progress made with pathway development and efficiency of referral can be lost. In Scotland, where the majority of orthotic services are provided directly by the NHS, they have been able to establish best practice guidelines for AFO use after stroke specifically (29), which may suggest that less flux in the way services are commissioned allows for best practice to be determined and agreed upon more easily.

As mentioned throughout this PhD, current recommendations for orthotic provision after stroke are vague and open to interpretation (7,52). It is felt this contributes to the inconsistencies and dissatisfaction described within these studies by orthotists and other stakeholders on provision of orthotic intervention after stroke. The only internationally produced report on orthotic management of stroke patients was published in 2004 and details the professional consensus agreed upon by conference attendees (28). A follow-up event of this kind where participants could review the statements of best

practice produced through this PhD as well as the others identified from international authors would be beneficial (30,221,222). Further peer review from other stakeholders and international perspectives is planned within the next stage of the research programme starting with a symposium at the International Society of Prosthetics and Orthotics (ISPO) world congress in 2025.

As discussed in the systematic review findings, there are reviews which analyse the effect of AFO use specifically but there are none outside of the one conducted for this PhD which consider timing, mechanism of delivery, and differing types of orthotic intervention. The importance of the role of the orthotists themselves is an area which requires further investigation as highlighted through scoping of other literature sources (16,28,243). Orthotists' place within the wider stroke rehabilitation team is also important as many components of the statements of best practice rely on closer MDT working. This way of working is in line with wider thinking on the benefits of MDT clinical provision (190). The bringing together of a group of healthcare professionals from different fields to determine a patients' treatment plan has been shown to be beneficial to the patients' outcomes and encourage knowledge exchange and professional development of the individual clinicians.

8.5 Interpretation and implications

8.4.1 Implications for clinical practice

The outputs from this PhD study add to the evidence base for delivering orthotic interventions after stroke. The individual studies each highlight a different aspect which effects the delivery of orthotic treatment and have produced new evidence from which clinical practice can be influenced. The work completed within this PhD has produced an aspirational blueprint for orthotic ways of working and optimum delivery after stroke. However, as discussed previously, the studies contained within this PhD have not undertaken comprehensive assessment of the practicalities of future implementation. An aspect to consider when viewing these statements is the low number of practicing orthotists within

the UK (180). The statements serve to rationalise existing orthotic services for stroke rehabilitation, and advocate for a more embedded way of working. This model, whilst serving to support the optimum rehabilitation of stroke survivors, would likely put additional pressures on orthotics services in other areas and therefore should be a consideration when exploring implementation. The statements of best practice in their current format are designed to be used by clinicians, commissioners, and patients alike to aid in clinical decision making and advocating for optimum service provision (105). Whilst they have not yet been evaluated within a trial and do not make up conclusive guidelines, the statements of best practice go some way to addressing the lack of any professional agreed guidance on how orthotists should be working and how to start to standardise practice in this area. Designed to promote best treatment and outcomes for a vulnerable population group, the statements have been developed using the GRADE approach (51), and with consideration for the MRC guidelines for intervention development (108), so are rigorous and comprehensive in their intention. This process of development has been transparent and described in detail throughout this thesis in order to offer a much-needed direction to future clinical practice and research in this area.

8.4.2 Implications for further research

Future research exploring orthotic intervention after stroke should focus on the implementation of interventions within different clinical settings and seek to identify the effect of the orthotist beyond just the orthotic device (108). The next stage for this programme of work is two-fold. Firstly, to consult more widely with other stakeholders to further refine and adapt the statements of best practice to clinical settings. Secondly, to determine the suitability and acceptability of implementing such an orthotic intervention. Further research into the different components that make up the statements of best practice would be beneficial with further professional and patient, national and international, review and refinement, of the guidance. This will be important to strengthen the generalisability of the statements and applicability to different settings, as well

as seeking to address the underlying discourse between the approach of orthotists and the wider stroke rehabilitation team (169).

Following on from this, the statements will be better positioned to be evaluated for effectiveness and cost-effectiveness working within the MRC framework for developing and evaluating complex interventions (108). First the feasibility of conducting such a trial should be tested with due consideration for the acceptability of the intervention, the ability to recruit to such a study and the barriers and facilitators to future implementation (244). Following the MRC framework, this would take the form of feasibility assessment and design evaluation, followed by intervention and implementation evaluation using differing methods of data collection to reduce any repetition of weakness or bias (108).

This PhD programme has used a broad spectrum of methodologies. These included both quantitative and qualitative data collections methods offering varied and rich datasets to draw conclusions from. This is a strength of this PhD in incorporating the voices of clinical and patient lived experience from its conception, through the changes, and to its completion. However, to build the higher-grade evidence base in this area there should be a focus on more quantitative outcomes-based research which can be used to direct future service delivery and guidelines development.

8.6 Conclusion

This thesis forms an original programme of work informing an under researched and poorly evidenced area of stroke rehabilitation. It has produced the first national statements of best practice on delivering orthotic interventions after stroke. The preparatory MDT survey laid a foundation for the PhD and indicated the perceived importance of timing and means of orthotic delivery after stroke. The clinical observation inquiry provided context for which the subsequent studies were developed and delivered, and first highlighted the importance of

the inter-professional relationships within stroke rehabilitation. The systematic review found that there are very few evaluative studies which assess the impact of timing of lower limb orthotic delivery on the rehabilitation outcomes for stroke survivors, and that no studies have been conducted exploring the specific role of the orthotist. The national cross-sectional professional survey provided a baseline of data in the post-covid landscape of how orthotists perceive their role and confidence to inform stroke rehabilitation outcomes. The stakeholder focus groups enabled a wider consultation with stroke rehabilitation clinicians, stroke survivors, and carers on their perspective of optimum orthotic intervention after stroke. This was the first study of its kind where views of different stakeholder groups were combined to inform proposed guidance on orthotic practice. A triangulation exercise synthesised the findings of the previous studies systematically allowing quantitative and qualitative data to be combined to form proposed statements of best practice. Finalised statements of best practice were then agreed through professional consensus via an eDelphi exercise with expert orthotists from across the UK. The statements of best practice developed through this PhD programme of work encompass the different elements which inform optimum ways of working when delivering orthotic intervention for stroke survivors, going beyond previously produced device or locality specific guidance.

This is the first research programme exploring the optimal ways of working when delivering orthotic interventions to enhance rehabilitation outcomes and reduce complications for stroke survivors. The combined findings have produced the first national statements of best practice on delivering orthotic interventions after stroke.

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Appendices

Appendix A. Original methodology

Study One: Nominal Group Technique

Study one was to undertake a focus group using a Nominal Group Technique (NGT) with the aim of reaching an expert consensus on the content of an early orthotic intervention for the lower limb after stroke. Up to 12 research and clinical expert participants were to be invited with potential participants identified through local clinical and research networks. Following consultation with the PPI member (CS) it was agreed that patient experts would be consulted in a separate meeting so to encourage free speech.

Inclusion criteria were:

- Clinicians and researchers who have significant experience (>5 years) of either working clinically or conducting research with stroke survivors.
- Clinical experts should have experience of the use of orthotics following stroke.
- Research experts should have experience of conducting research into stroke rehabilitation evidenced through publication.

Feasibility Randomised Controlled Trial

The primary study within the PhD was to undertake a single centre feasibility randomised controlled trial to determine if it is possible to evaluate the effectiveness of an early orthotic intervention for the lower limb after stroke. As this was a feasibility study no formal sample size calculation was required. However, we were guided by Lancaster et al. [19], and planned to recruit 15 participants to each arm of the trial to test ability to recruit, conduct the randomisation process, and deliver the treatment intervention. The trial was timed to recruit for up to twelve months and all eligible patients under the care

of a single clinical stroke service with confirmed stroke were to be screened to take part.

Inclusion criteria were:

- Adult (≥ 18) stroke patients who have a confirmed clinical diagnosis of stroke occurring within the 6 months prior.
- Patients who score ≥ 5 National Institutes of Health Stroke Scale (NIHSS), presenting as having a moderate – severe stroke
- Patients who score ≤ 4 Oxford muscle strength scale for the lower limb, presenting as having reduced muscle strength.
- Patients who have capacity to consent or have a relative or friend who is willing to consent as a consultee on behalf of the patient.

Exclusion criteria were:

- Patients who are already participating in other research involving rehabilitation mobilisation strategies over and above usual care post-stroke.

Recruited participants were to be randomised to either the control or intervention group using the web-based randomisation system 'Sealed Envelope', stratified using participants Modified Rankin Scale score.

Usual care – standard clinical pathway and waiting time for orthotic assessment and prescription if required. Usual follow-up schedule.

Intervention – early orthotic assessment conducted in conjunction with the referring clinician. Early orthotic prescription if required and scheduled follow-up assessments.

Completion of outcome measures was planned with all participants at three time points (baseline, 2 months and 6 months). The primary outcome measures pertained to the feasibility aims of the study seeking to identify our ability to recruit to the trial, and the feasibility, tolerability and acceptability of delivering

the intervention. Further details of the outcome measures to be used and other specifics of this study can be found in the protocol below.

Qualitative Interviews

The final phase of the PhD was to complete qualitative interviews with stroke survivors and clinicians to explore their experiences and perceptions of the early orthotic intervention for the lower limb after stroke. Up to 12 participants were to be invited to participate including up to 8 trial participants and 4 clinicians involved with delivering the study. Sampling was to be purposive to include stroke survivors from each arm of the trial and of different stroke severity. Clinicians from both the orthotic department and stroke clinical team would be invited to participate in the interviews to ensure a spectrum of opinion and experiences.

Inclusion criteria were:

- Participants of the feasibility RCT from either the intervention or control arm who have consented to further follow up.
- Clinicians involved with the trial either through intervention delivery or participant identification.

Exclusion criteria were:

- Patients who are unable to give informed consent.

The qualitative findings would be used to add context to the feasibility RCT results and inform a future definitive trial by allowing the patient and clinical perceptions to be captured.

Further details on the changes made to the research question and methodology used due to the covid-19 pandemic are presented in Section 3.6 of Chapter Three.

Appendix B. Checklist for reporting survey studies (CROSS)(117)

Section/topic	Item	Item description	Reported on page #
Title and abstract			
Title and abstract	1a	State the word “survey” along with a commonly used term in title or abstract to introduce the study’s design.	
	1b	Provide an informative summary in the abstract, covering background, objectives, methods, findings/results, interpretation/discussion, and conclusions.	
Introduction			
Background	2	Provide a background about the rationale of study, what has been previously done, and why this survey is needed.	
Purpose/aim	3	Identify specific purposes, aims, goals, or objectives of the study.	
Methods			
Study design	4	Specify the study design in the methods section with a commonly used term (e.g., cross-sectional or longitudinal).	
	5a	Describe the questionnaire (e.g., number of sections, number of questions, number and names of instruments used).	
Data collection methods	5b	Describe all questionnaire instruments that were used in the survey to measure particular concepts. Report target population, reported validity and reliability information, scoring/classification procedure, and reference links (if any).	
	5c	Provide information on pretesting of the questionnaire, if performed (in the article or in an online supplement). Report the method of pretesting, number of times questionnaire was pre-tested, number and demographics of participants used for pretesting, and the level of similarity of demographics between pre-testing participants and sample population.	
	5d	Questionnaire if possible, should be fully provided (in the article, or as appendices or as an online supplement).	

Sample characteristics	6a	Describe the study population (i.e., background, locations, eligibility criteria for participant inclusion in survey, exclusion criteria).	
	6b	Describe the sampling techniques used (e.g., single stage or multistage sampling, simple random sampling, stratified sampling, cluster sampling, convenience sampling). Specify the locations of sample participants whenever clustered sampling was applied.	
	6c	Provide information on sample size, along with details of sample size calculation.	
	6d	Describe how representative the sample is of the study population (or target population if possible), particularly for population-based surveys.	
Survey administration	7a	Provide information on modes of questionnaire administration, including the type and number of contacts, the location where the survey was conducted (e.g., outpatient room or by use of online tools, such as SurveyMonkey).	
	7b	Provide information of survey's time frame, such as periods of recruitment, exposure, and follow-up days.	
	7c	Provide information on the entry process: →For non-web-based surveys, provide approaches to minimize human error in data entry. →For web-based surveys, provide approaches to prevent "multiple participation" of participants.	
Study preparation	8	Describe any preparation process before conducting the survey (e.g., interviewers' training process, advertising the survey).	
Ethical considerations	9a	Provide information on ethical approval for the survey if obtained, including informed consent, institutional review board [IRB] approval, Helsinki declaration, and good clinical practice [GCP] declaration (as appropriate).	
	9b	Provide information about survey anonymity and confidentiality and describe what mechanisms were used to protect unauthorized access.	

Statistical analysis	10a	Describe statistical methods and analytical approach. Report the statistical software that was used for data analysis.	
	10b	Report any modification of variables used in the analysis, along with reference (if available).	
	10c	Report details about how missing data was handled. Include rate of missing items, missing data mechanism (i.e., missing completely at random [MCAR], missing at random [MAR] or missing not at random [MNAR]) and methods used to deal with missing data (e.g., multiple imputation).	
	10d	State how non-response error was addressed.	
	10e	For longitudinal surveys, state how loss to follow-up was addressed.	
	10f	Indicate whether any methods such as weighting of items or propensity scores have been used to adjust for non-representativeness of the sample.	
	10g	Describe any sensitivity analysis conducted.	
Results			
Respondent characteristics	11a	Report numbers of individuals at each stage of the study. Consider using a flow diagram, if possible.	
	11b	Provide reasons for non-participation at each stage, if possible.	
	11c	Report response rate, present the definition of response rate or the formula used to calculate response rate.	
	11d	Provide information to define how unique visitors are determined. Report number of unique visitors along with relevant proportions (e.g., view proportion, participation proportion, completion proportion).	
Descriptive results	12	Provide characteristics of study participants, as well as information on potential confounders and assessed outcomes.	
Main findings	13a	Give unadjusted estimates and, if applicable, confounder-adjusted estimates along with 95% confidence intervals and p-values.	

	13b	For multivariable analysis, provide information on the model building process, model fit statistics, and model assumptions (as appropriate).	
	13c	Provide details about any sensitivity analysis performed. If there are considerable amount of missing data, report sensitivity analyses comparing the results of complete cases with that of the imputed dataset (if possible).	
Discussion			
Limitations	14	Discuss the limitations of the study, considering sources of potential biases and imprecisions, such as non-representativeness of sample, study design, important uncontrolled confounders.	
Interpretations	15	Give a cautious overall interpretation of results, based on potential biases and imprecisions and suggest areas for future research.	
Generalizability	16	Discuss the external validity of the results.	
Other sections			
Role of funding source	17	State whether any funding organization has had any roles in the survey's design, implementation, and analysis.	
Conflict of interest	18	Declare any potential conflict of interest.	
Acknowledgements	19	Provide names of organizations/persons that are acknowledged along with their contribution to the research.	

Appendix C. Text version of multi-disciplinary survey questions

Orthotic Intervention following stroke: A survey of physiotherapist, occupational therapist and orthotist practice and views in the UK

Section 1

1. What is your clinical role/title?

2. How long have you been qualified?

3. Which of these options most accurately describes your predominant employer?

- NHS
- Private company providing NHS clinics
- Private company providing private clinics
- Self-employed/Locum
- Other

4. What kind of clinical setting do you predominantly work in?

Select all that apply

- Hospital setting – Ward
- Hospital setting – Outpatients
- NHS clinic in building away from hospital site
- Community clinic
- Other

Section 2

5. Do you ever see stroke patients in your clinical caseload?

- Yes
- No

Participants who reply 'No' will be directed to Section 10

6. How regularly do you see stroke patients in your normal clinical caseload?

- More than one a day
- About once a day
- Several times a week
- About once a month
- Several times a year
- Other _____

7. How soon after the stroke event would you normally see the stroke patient?

Select all that apply

- First 24 hours
- First week
- First month
- Between 2-6 months
- Between 6-12 months
- Later in rehabilitation due to secondary complication
- Established patient with long term use of orthotic device

Section 3

8. Where do your stroke patient referrals usually come from for each of these clinical settings?

Select all that apply

In-patient/on the ward

- Consultant
- Doctor/Nurse
- Physio
- OT
- Patient self-referral
- Other _____

Outpatient clinic

- Consultant
- Doctor/Nurse
- Physio
- OT
- Patient self-referral

- Other _____

Community based

- Consultant
- Doctor/Nurse
- Physio
- OT
- Patient self-referral
- Other _____

Section 4

9. Please rate how often you would see the following clinical presentations in the stroke patients under your care:

Foot drop (flaccid)	1 <i>Never</i>	2	3	4	5 <i>Very often</i>

Foot drop (spastic)	1 <i>Never</i>	2	3	4	5 <i>Very often</i>

Muscle Paralysis (Upper or lower limb)	1 <i>Never</i>	2	3	4	5 <i>Very often</i>

Walking fatigue/difficulty	1 <i>Never</i>	2	3	4	5 <i>Very often</i>

Positional management/ contracture prevention	1 <i>Never</i>	2	3	4	5 <i>Very often</i>

Shoulder/upper limb (weakness)	1 <i>Never</i>	2	3	4	5 <i>Very often</i>

Shoulder/upper limb (spasticity)	1 <i>Never</i>	2	3	4	5 <i>Very often</i>

Pain management	1 <i>Never</i>	2	3	4	5 <i>Very often</i>

Cognitive or perceptual issues	1 <i>Never</i>	2	3	4	5 <i>Very often</i>

Speech and Language difficulties	1 <i>Never</i>	2	3	4	5 <i>Very often</i>

If there are any factors or conditions you think we have missed or would like to tell us more about, please say here:

Section 5

10. Please rate how commonly you would consider prescribing the following orthoses for the stroke patients under your care:

AFO (Stock)	1 <i>Never</i>	2	3	4	5 <i>Very often</i>

AFO (Custom)	1 <i>Never</i>	2	3	4	5 <i>Very often</i>

Resting splint lower limb (PRAFO etc.)	1 <i>Never</i>	2	3	4	5 <i>Very often</i>

Insoles/Heel raises	1 <i>Never</i>	2	3	4	5 <i>Very often</i>

Shoulder brace	1 <i>Never</i>	2	3	4	5 <i>Very often</i>

Hand/wrist brace	1 <i>Never</i>	2	3	4	5 <i>Very often</i>

Knee brace	1 <i>Never</i>	2	3	4	5 <i>Very often</i>

Hip brace	1 <i>Never</i>	2	3	4	5 <i>Very often</i>

Abdominal support	1 <i>Never</i>	2	3	4	5 <i>Very often</i>

Spinal support	1 <i>Never</i>	2	3	4	5 <i>Very often</i>

If you think we have missed a commonly used orthotic prescription for stroke patients or would like to tell us more about any mentioned, then please say here:

10a. When prescribing an orthosis for a stroke patient, what **percentage** of your orders would you say are Off-the-shelf, Modular, or Custom items?*

**Off-the-shelf/stock items are considered to be pre-made orthoses and non-customisable, modular items are pre-made but have the option to personalise the prescription for a patient, a custom item is a made-to-measure device for a specific patient.*

Off-the-shelf (stock)

- 0% - 100%

Modular

- 0% - 100%

Custom

- 0% - 100%

11. Do you ever prescribe/order an orthosis without needing to see the stroke patient?

- Yes
- No

Participants who reply 'No' will be directed to Section 6

12. Please describe how these non-assessment requests are made, by whom and for what kind of orthotic item:

Section 6

13. In your experience, at what stage following stroke do you think appropriate patients might benefit from an initial orthotist assessment/fitting with an orthosis?

- First 24 hours
- First few days/before discharge (acute or rehab ward)
- At discharge to the community
- Later on in recovery, possible due to secondary complications
- Never/Rarely

14. In your experience, at what stage following stroke do you find appropriate patients are actually normally seen by an orthotist/fitting with an orthosis?

- First 24 hours
- First few days/before discharge (acute or rehab ward)
- At discharge to the community
- Later on in recovery, possible due to secondary complications
- Never/ Rarely

If there is a discrepancy between your two previous answers, what do you feel are the reasons behind this?

Section 7

15. In your experience, what are the normal referral pathways/waiting times for a stroke patient to be seen by an Orthotist **on the ward**?

16. In your experience, what are the normal referral pathways/waiting times for a stroke patient to be seen by an Orthotist **in an outpatient clinic/ in the community**?

Section 8

17. What do you think are the most important **overall** rehabilitation goals or outcome measures for someone who has suffered a stroke?

(examples might include: to improve quality of life, to be able to perform daily activities unaided)

18. What do you think are the most important **orthotic specific** rehabilitation goals or outcome measures for someone who has suffered a stroke? *

(examples might include: contracture prevention, ability to stand/walk unaided, reduction of pain)

Section 9

19. Do you feel the current system of provision of orthotic devices is sufficient to meet the needs of stroke patients, for both in and out-patients?

20. Are there any other comments you would like to make about orthotics and its place in the stroke rehabilitation pathway?

Section 10

21. Do you have any suggestions for areas, specifically in relation to orthotics, which require further research?

Appendix D. Preparatory MDT survey letter of favourable ethical approval



University of
Nottingham
UK | CHINA | MALAYSIA

Queen's Medical Centre Campus

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A handwritten signature in black ink, appearing to read "Dr. S. Chakraborty".

Appendix E. Multi-disciplinary survey participant information sheet and consent form

Orthotic intervention following stroke: A survey of stroke therapist's practice and views

Division of Rehabilitation and Ageing, School of Medicine, The University of Nottingham, Queens Medical Centre, Nottingham NG7 2UH

Research Ethics Ref: FMHS-287-1803

You are being invited to participate in a research study titled '*Orthotic intervention following stroke: A survey of stroke therapist's practice and views*' as a clinician who works with stroke patients during their rehabilitation. This study is being done by Miriam Golding-Day – Research Associate from the University of Nottingham.

The purpose of this study is help direct future research into orthotics, and its place in the stroke rehabilitation pathway. It will take you approximately 10 minutes to complete with a total of 38 questions. Your participation in this study is entirely voluntary and you can withdraw at any time by clicking the browser exit button. The data will only be uploaded on completion of the questionnaire by clicking the SUBMIT button. You are free to omit any question.

We believe there are no known risks associated with this research study. All of your answers are confidential and will not be traced back to you or your clinical setting.

The results of the study may be published in scientific journals and presented at scientific conferences. The data will be reported anonymously, with any identifying information removed.

If you have any questions about this project, or if you have any concerns about any aspect of this study please contact the Lead Researcher Miriam Golding-Day Miriam.golding-Day@nottingham.ac.uk If you remain unhappy, you should then contact the FMHS Research Ethics Committee Administrator, c/o The University of Nottingham, Faculty PVC Office, B Floor, Medical School, Queen's Medical Centre Campus, Nottingham University Hospitals, Nottingham, NG7 2UH. E-mail: FMHS-ResearchEthics@nottingham.ac.uk

This study has been reviewed and given a favourable opinion by the University of Nottingham, Faculty of Medicine & Health Sciences Research Ethics Committee (FMHS-287-1803).

I have read and understood the above information and consent form, I confirm that I am 18 years old or older and by clicking the NEXT button to begin the online questionnaire, I indicate my willingness to voluntarily take part in the study.

NEXT – I consent to take part

EXIT - I do not give consent

Consent form (on a separate page) including Title, names of researchers, School
and division address + Ethics ref no

Thank you for participating!

Please, tick each box to continue:

- ☐ I confirm that I have read and understood the information on the previous page
 - ☐ I understand that my participation is voluntary and I can end the study at any time and withdraw my data by clicking the EXIT button.
 - ☐ I understand that my answers will be anonymous.
 - ☐ I understand the overall anonymized data from this study may be used in the future for research (with research ethics approval) and teaching purposes.
- NEXT – to be taken to the survey.

Appendix F. Multi-disciplinary survey results tables

Table i: Participant clinical role characteristics

	Orthotist	Physio	OT	All
Clinical Role/ Title	(n=64)	(n=131)	(n=110)	(n=305)
Orthotist	35			35 (11%)
Physiotherapist		37		37 (12%)
Occupational Therapist			49	49 (16%)
Junior	2			2 (0.7%)
Senior	10	22	19	51 (17%)
Advanced/Specialist	4	47	32	83 (27%)
Clinical Lead/Principal	10	15	9	34 (11%)
Consultant therapist		4		4 (1%)
Clinical services manager	1	1		2 (0.7%)
Deputy Head/Head of service	1	1	1	3 (1%)
Clinical Engineer	1			1 (0.3%)
Lecturer/researcher		3		3 (1%)
Retired		1		1 (0.3%)
Length of time qualified in years Mean (SD)	13.33 (11.6)	17.4 (8.8)	15.5 (9.5)	15.88 (9.8)
Predominant clinical setting				
Hospital setting – Inpatient	3 (4%)	61 (47%)	42 (38%)	106 (35%)
Hospital setting – Outpatient	44 (69%)	9 (8%)	12 (11%)	65 (21%)
Clinical building away from hospital	7 (11%)			7 (2%)
Community (general)	5 (8%)	22 (17%)	6 (5%)	33 (11%)
Community (stroke/neuro specific)		37 (28%)	49 (45%)	86 (28%)
Research		1(<1%)	1 (1%)	2 (0.7%)
Retired		1(<1%)		1 (0.3%)
Other	5 (8%)			5 (2%)

Table ii: Clinician stroke patient caseload

	Orthotist	Physio	OT	All
How regularly do you see stroke patients in your clinical caseload?	(n=63)	(n=129)	(n=107)	(n=299)
More than one a day	9 (14%)	90 (70%)	66 (61%)	165 (55%)
About once a day	10 (16%)	14 (11%)	17 (16%)	41 (14%)
About once a week	12 (19%)	1 (1%)	0 (0%)	13 (4%)
Several times a week	23 (36%)	17 (13%)	18 (17%)	58 (19%)
About once a month	6 (10%)	4 (3%)	4 (4%)	14 (5%)
Several times a year	3 (5%)	3 (2%)	2 (2%)	8 (3%)
How soon after the stroke event do you normally see the stroke patient? <i>(multiple answers possible)</i>				
First 24 hours	0	35	25	60
First week	11	51	40	102
First month	31	55	49	135
Between 2-6 months	46	76	55	177
Between 6-12 months	37	35	37	109
Later in rehabilitation	47	34	27	108

Table iii: Orthotic referral practices

	Physio	OT	All
How common is it you think your stroke patients <i>might</i> benefit from orthotics? <i>(percentage of time)</i>	(n=128)	(n=105)	(n=233)
Never (0%)	0	1	1 (0.5%)
Occasional (20%)	16	14	30 (13%)
Sometimes (40%)	29	33	62 (27%)
Quite frequent (60%)	54	35	89 (38%)
Very common (80%)	29	21	50 (21%)
Every patient (100%)	0	1	1 (0.5%)
How common is it for those patients to <i>actually</i> be referred for orthotics? <i>(percentage of time)</i>	(n=128)	(n=104)	(n=232)
Never (0%)	1	3	4 (2%)
Occasional (20%)	18	17	35 (15%)
Sometimes (40%)	24	15	39 (17%)
Quite frequent (60%)	21	22	43 (18%)

Very common (80%)	43	31	74 (32%)
Every patient (100%)	21	16	37 (16%)

Table iV: Area of the body most commonly referred for orthotic intervention in stroke patients

	Physio	OT	All
Which area of the body would you refer for orthotics most commonly in your stroke patients?	(n=127)	(n=102)	(n=229)
Lower limb (foot/ankle)	91	33	124 (54%)
Lower limb (knee)	2	0	2 (1%)
Upper limb (wrist/hand/elbow)	19	54	73 (32%)
Upper limb (shoulder)	15	15	30 (13%)

Table V: Stage following stroke perceived benefit Vs actually received orthotics

	Orthotist	Physio	OT	All
At what stage following stroke do you think appropriate patients might benefit from an initial orthotic assessment/orthoses?	(n=63)	(n=120)	(n=98)	(n=281)
First 24 hrs	11	12	14	37 (13%)
First few days/ before hospital discharge	46	63	44	153 (54%)
At discharge to the community	6	17	18	41 (15%)
Whilst under community care / Later on in rehabilitation	0	28	22	50 (18%)
Never/ Rarely	0	0	0	0 (0%)
What stage following stroke would appropriate patients actually be seen by an orthotist/fitted with an orthoses?	(n=63)	(n=120)	(n=98)	(n=281)
First 24 hrs	0	0	2	2 (<1%)
First few days/ before hospital discharge	22	35	24	81 (29%)
At discharge to the community	22	19	17	58 (21%)
Whilst under community care / Later on in rehabilitation	19	61	47	127 (45%)
Never/ Rarely	0	5	8	13 (5%)

Appendix G. Systematic review data extraction form

<u>Study reference</u> Authors: Year: Title:

Study Aim/Objective:

1. Study Characteristics

Study Design		Notes
RCT		
CCT		
CBA		
ITS		

Study inclusion criteria

Study exclusion criteria

Description of randomization

Description of intervention

	Intervention (n=)	Control (n=)
Age		
Gender (male/female)		

Ethnicity		
Weight (kg)		
Time since stroke at inclusion (days)		
Affected body side (left/right)		
Type of stroke (ischemic/haemorrhagic)		
Type of AFO (flexible/semi-rigid/rigid)		

Do above figures relate to:

- Number eligible
- Number enrolled
- Number randomised
- Number available for follow-up

1. Who received the intervention?

- Individual
- Individual + Caregiver
- Group
- Other (specify)
- NOT CLEAR

2. Who delivered the intervention?

- Individual (state) Orthotist
- MDT (state)
- NOT CLEAR

Timing of intervention

Setting of intervention

Description of any co-interventions

Number of participants enrolled

Number of participants included in analysis

Intervention	Control

3. Analysis by:

- Intention to Treat
- Per-protocol
- Other (state)

Primary outcome

1. Was this outcome included?

- YES
- NO

Outcome 1:

2. Timing of follow-up measurements

Additional Outcomes – Indicate whether each outcome has been reported

a) Reduced complications

- YES
- NO

b) Health related quality of life

- YES
- NO

c) Functional mobility (eg. Timed Up and Go Test)

- YES
- NO

d) Activity limitations: (eg. Barthel Index and Functional Independence Measure)

- YES
- NO

e) Number of falls

- YES
- NO

f) Compliance with the orthosis or duration of use of the orthosis

- YES
- NO

g) Adverse events such as pain, discomfort and skin damage

- YES
- NO

h) Health economic outcomes

- YES
- NO

i) Participant and carer satisfaction with service

- YES
- NO

j) Health care provider satisfaction with service

- YES
- NO

Appendix H. Risk of bias quality assessment form (157)

a) Was the allocation sequence adequately generated?

- Low risk (yes)
- High Risk (no)
- Unclear Risk

b) Was the allocation sequence adequately concealed?

- Low risk (yes)
- High Risk (no)
- Unclear Risk

c) Were baseline outcome measurements similar?

- Low risk (yes)
- High Risk (no)
- Unclear Risk

d) Were baseline characteristics similar?

- Low risk (yes)
- High Risk (no)
- Unclear Risk

e) Were incomplete outcome data adequately addressed?

- Low risk (yes)
- High Risk (no)
- Unclear Risk

f) Was knowledge of the allocated interventions adequately prevented during the study?

- Low risk (yes)
- High Risk (no)
- Unclear Risk

g) Was the study adequately protected against contamination?

- Low risk (yes)

- High Risk (no)
- Unclear Risk

h) Was the study free from selective outcome reporting?

- Low risk (yes)
- High Risk (no)
- Unclear Risk

i) Was the study free from other biases?

- Low risk (yes)
- High Risk (no)
- Unclear Risk

Appendix I. Checklist for Reporting Results of Internet E-surveys
(CHERRIES) (172)

Item Category	Checklist Item	Explanation	Reported on page #
Design	Describe survey design	Describe target population, sample frame. Is the sample a convenience sample? (In “open” surveys this is most likely.)	
IRB (Institutional Review Board) approval and informed consent process	IRB approval	Mention whether the study has been approved by an IRB.	
	Informed consent	Describe the informed consent process. Where were the participants told the length of time of the survey, which data were stored and where and for how long, who the investigator was, and the purpose of the study?	
	Data protection	If any personal information was collected or stored, describe what mechanisms were used to protect unauthorized access.	
Development and pretesting	Development and testing	State how the survey was developed, including whether the usability and technical functionality of the electronic questionnaire had been tested before fielding the questionnaire.	
Recruitment process and description of the sample having access to the questionnaire	Open survey versus closed survey	An “open survey” is a survey open for each visitor of a site, while a closed survey is only open to a sample which the investigator knows (password-protected survey).	
	Contact mode	Indicate whether or not the initial contact with the potential participants was made on the internet. (Investigators may also send out questionnaires by mail and allow for web-based data entry.)	
	Advertising the survey	How/where was the survey announced or advertised? Some examples are offline media	

		(newspapers), or online (mailing lists – If yes, which ones?) or banner ads (Where were these banner ads posted and what did they look like?). It is important to know the wording of the announcement as it will heavily influence who chooses to participate. Ideally the survey announcement should be published as an appendix.	
Survey administration	Web/E-mail	State the type of e-survey (eg. one posted on a website, or one sent out through e-mail). If it is an e-mail survey, were the responses entered manually into a database, or was there an automatic method for capturing responses?	
	Context	Describe the Website (for mailing list/newsgroup) in which the survey was posted. What is the website about, who is visiting it, what are visitors normally looking for? Discuss to what degree the content of the Web site could pre-select the sample or influence the results. For example, a survey about vaccination on an anti-immunization website will have different results from a web survey conducted on a government website.	
	Mandatory/voluntary	Was it a mandatory survey to be filled in by every visitor who wanted to enter the Web site, or was it a voluntary survey?	
	Incentives	Were any incentives offered (eg. monetary, prizes, or non-monetary incentives such as an offer to provide the survey results)?	
	Time/Date	In what timeframe were the data collected?	
	Randomization of items or questionnaires	To prevent biases items can be randomized or alternated.	

	Adaptive questioning	Use adaptive questioning (certain items, or only conditionally displayed based on responses to other items) to reduce number and complexity of the questions.	
	Number of Items	What was the number of questionnaire items per page? The number of items is an important factor for the completion rate.	
	Number of screens (pages)	Over how many pages was the questionnaire distributed? The number of items is an important factor for the completion rate.	
	Completeness check	It is technically possible to do consistency or completeness checks before the questionnaire is submitted. Was this done, and if “yes”, how (usually JavaScript) An alternative is to check for completeness after the questionnaire has been submitted (and highlight mandatory items). If this has been done, it should be reported. All items should provide a non-response option such as “not applicable” or “rather not say”, and selection of one response option should be enforced.	
	Review step	State whether respondents were able to review and change their answers (eg. through a Back button or a Review step which displays a summary of the responses and asks the respondents if they are correct).	
Response rates	Unique site visitor	If you provide view rates or participation rates, you need to define how you determined a unique visitor. There are different techniques available, based on IP addresses or cookies or both.	
	View rate (Ratio of unique survey visitors/unique site visitors)	Requires counting unique visitors to the first page of the survey, divided by the number of unique site visitors (not page views!). It is not unusual to have view rates of less than 0.1 % if the survey is voluntary.	

	Participation rate (Ratio of unique visitors who agreed to participate/unique first survey page visitors)	Count the unique number of people who filled in the first survey page (or agreed to participate, for example by checking a checkbox), divided by participate/unique first survey visitors who visit the first page of the survey (or the informed consents page, if present). This can also be called “recruitment” rate.	
	Completion rate (Ratio of users who finished the survey/users who agreed to participate)	The number of people submitting the last questionnaire page, divided by the number of people who agreed to participate (or submitted the first survey page). This is only relevant if there is a separate “informed consent” page or if the survey goes over several pages. This is a measure for attrition. Note that “completion” can involve leaving questionnaire items blank. This is not a measure for how completely questionnaires were filled in. (If you need a measure for this, use the word “completeness rate”.)	
Preventing multiple entries from the same individual	Cookies used	Indicate whether cookies were used to assign a unique user identifier to each client computer. If so, mention the page on which the cookie was set and read, and how long the cookie was valid. Were duplicate entries avoided by preventing users access to the survey twice; or were duplicate database entries having the same user ID eliminated before analysis? In the latter case, which entries were kept for analysis (eg, the first entry or the most recent)?	
	IP check	Indicate whether the IP address of the client computer was used to identify potential duplicate entries from the same user. If so, mention the period of time for which no two	

		entries from the same IP address were allowed (eg, 24 hours). Were duplicate entries avoided by preventing users with the same IP address access to the survey twice; or were duplicate database entries having the same IP address within a given period of time eliminated before analysis? If the latter, which entries were kept for analysis (eg, the first entry or the most recent)?	
	Log file analysis	Indicate whether other techniques to analyse the log file for identification of multiple entries were used. If so, please describe.	
	Registration	Indicate whether other techniques to analyse the log file for identification of multiple entries were used. If so, please describe.	
Analysis	Handling of incomplete questionnaires	Were only completed questionnaires analysed? Were questionnaires which terminated early (where, for example, users did not go through all questionnaire pages) also analysed?	
	Questionnaires submitted with an atypical timestamp	Some investigators may measure the time people needed to fill in a questionnaire and exclude questionnaires that were submitted too soon. Specify the timeframe that was used as a cut-off point and describe how this point was determined.	
	Statistical correction	Indicate whether any methods such as weighting of items or propensity scores have been used to adjust for the non-representative sample; if so, please describe the methods.	

Appendix J. National cross-sectional professional survey questions

Orthotist involvement in early gait rehabilitation following stroke: a cross sectional survey of orthotists in the United Kingdom

Consent

I have read and understood the information sheet/letter explaining this study

☐ Yes

I understand that I can ask any further questions I may have at any time during the study (if I decide to participate)

☐ Yes

I understand that my participation in this study is entirely voluntary and that I may withdraw from the study at any time, without giving any reason, should I choose to do so. *Please note that we can't withdraw data once it is submitted unless an email address is provided.

☐ Yes

I understand that the results of the study may be published and that my identity will be protected at all times. If I choose to provide an email address my identify will be protected.

☐ Yes

I understand my e-mail address, if provided, will be stored securely and only used for the purpose of the study

☐ Yes

I hereby freely consent to take part in this study

☐ Yes

Part I

1. Please indicate your current status
 - ☐ I confirm I am a registered orthotist (health and care professionals' council HCPC)
 - ☐ I confirm I am a non-practicing orthotist
 - ☐ I confirm I am a retired orthotist
2. What is the highest degree or level of education you have completed?
 - ☐ Diploma
 - ☐ Degree (BSc)
 - ☐ Masters (MSc)
 - ☐ PhD
 - ☐ Other (please state)

3. How long have you been qualified as an orthotist?
 - ☐ 0-2 years
 - ☐ 3-5 years
 - ☐ 6-10 years
 - ☐ More than 10 years
4. Which of these options most accurately describes your primary employer?
 - ☐ National health service provider
 - ☐ Private company delivering national health service provision
 - ☐ Private company delivering private health service provision
 - ☐ Self-employed/locum
 - ☐ Higher educational institute
 - ☐ Charity/social enterprise
 - ☐ Other (please state)

Part II

5. What kind of clinical setting do you predominantly work in?
 - ☐ Hospital setting (in-patient)

- ☐ Hospital setting (out-patient)
 - ☐ Private clinical site not within a hospital
 - ☐ Community team treating patients at their usual place of residence (home, care home, school etc.)
 - ☐ Other (please state)
-

6. How regularly do you see adult stroke patients in your normal clinical caseload?

- ☐ More than once a day
- ☐ Once a day
- ☐ Several times a week
- ☐ Once a week
- ☐ Several times a month
- ☐ 1 patient a month
- ☐ Less frequently than once a month

7. What kind of clinical setting do you normally see stroke patients in? (Please identify all that apply)

- ☐ I see stroke patients as out-patients in a general orthotic clinic
- ☐ I see stroke patients as out-patients in a dedicated neurological clinic
- ☐ I see stroke patients as in-patients on a stroke or general ward within the acute hospital site
- ☐ I see stroke patients within a dedicated in-patient stroke service in a Multi-Disciplinary Team (MDT) setting
- ☐ I see stroke patients within a dedicated out-patient stroke service in a MDT setting
- ☐ I see stroke patients within a dedicated community stroke service in a MDT setting

8. How regularly do you assess and treat stroke patients within an MDT setting (defined as: at least 2 different professions treating the patient in the same clinic, including orthotist)

- ☐ Never
- ☐ Rarely
- ☐ Some of the time
- ☐ Often
- ☐ All of the time

9. How long after the stroke event do you usually see patients?

- ☐ 1-2 weeks post stroke
- ☐ 3-6 weeks post stroke
- ☐ 7-12 weeks post stroke
- ☐ 4-6 months post stroke
- ☐ 7-12 months post stroke
- ☐ >12 months post stroke

10. How involved are you in the early gait rehabilitation decisions being made for stroke patients?

- ☐ I am not involved at all
- ☐ I am involved but only when a specific referral for orthotic assessment is made by another MDT member
- ☐ I am routinely involved without a specific referral for orthotic assessment being made (e.g. I join the MDT meetings or routine assessment clinic)

11. When involved with early gait rehabilitation for stroke patients, how do you make your assessment and detailed prescription decisions?

- ☐ Other members of the MDT or the referrer formulates the orthotic prescription. am not involved at all
- ☐ I work with the MDT to formulate the orthotic prescription
- ☐ I formulate the orthotic prescription independently

12. After assessment and prescription, how is the use of the orthosis determined?

- ☐ Other members of the MDT or the referrer will determine and advise the patient how the orthosis should be best used
- ☐ I work with the MDT to determine and advise the patient how the orthosis should be best used
- ☐ I independently determine and advise the patient how the orthosis should be best used

Would you like to repeat questions 5-12 to register responses for another service that you are employed within?

Part III

13. How involved do you think Orthotists should be in the early gait rehabilitation decisions being made for stroke patients? *For the purposes of this study, we are identifying early stroke as within six weeks of onset*

- ☐ I don't think Orthotists should be involved at all
- ☐ I think Orthotists should be involved but only when a specific referral for orthotic assessment is made by another MDT member
- ☐ I think Orthotists should be routinely involved without a specific referral for orthotic assessment being made (e.g. join the MDT meetings or routine assessment clinic)

14. I am confident in recommending a comprehensive orthotic treatment plan to the MDT. *A comprehensive plan might include when and when not to use the orthosis and recommending complimentary treatment such as strengthening, facilitation, stretching, casting*

- ☐ Strongly agree
- ☐ Agree
- ☐ Neutral
- ☐ Disagree
- ☐ Strongly disagree

15. Orthotic assessment should be an essential element of gait re-education as part of recovery

- ☐ Strongly agree
- ☐ Agree
- ☐ Neutral
- ☐ Disagree
- ☐ Strongly disagree

16. I am confident in recommending a lower limb orthotic treatment plan within early stroke rehabilitation

- ☐ Strongly agree
- ☐ Agree
- ☐ Neutral
- ☐ Disagree
- ☐ Strongly disagree

17. I am confident advising on use of the orthosis within an MDT including duration of use both daily and longer term

- ☐ Strongly agree
- ☐ Agree

- ☐ Neutral
- ☐ Disagree
- ☐ Strongly disagree

18. I am confident advising therapy and activity to progress potential recovery (as a lead member of the therapy team)?

- ☐ Strongly agree
- ☐ Agree
- ☐ Neutral
- ☐ Disagree
- ☐ Strongly disagree

19. I am satisfied with the frequency of involvement I have with early stroke rehabilitation patients

- ☐ Strongly agree
- ☐ Agree
- ☐ Neutral
- ☐ Disagree
- ☐ Strongly disagree

If there is anything further you wish to mention regarding Orthotist involvement in early gait rehabilitation for stroke patients please state it here:

Appendix K. Cross-sectional survey letter of favourable ethical approval



Confirmation of research ethics Clearance

Dear Brian Houston

Re: Project Title: A survey of Orthotists' practice and views on early gait rehabilitation following Stroke ; **Review Reference:** 2021 Feb 1723 Houston

Your application has been reviewed and I can confirm that **this study has received research ethics Clearance** and can proceed as soon as you receive this confirmation.

This document can be used as evidence of authorisation.

Please note that if you need, in the future, to make any amendments to your study details now that it has been approved, you should contact the Chair Dr Darren Flynn to notify the Committee and then forward the required amendments as a document to ERMHelp@tees.ac.uk so that the amendments can be added to your approved application.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'D. Flynn', on a light blue background.

Dr Darren Flynn

on behalf of

Health Research Ethics sub-Committee

Appendix L. National cross-sectional survey Participant Information Sheet

You are being invited to take part in an online survey as part of a research study. Before you decide whether you wish to take part it is important for you to read the below information so you understand why the study is being conducted and what it will involve. Reading this leaflet, discussing it with others, or asking any questions you might have will help you decide whether or not you would like to take part.

What is the Purpose of the Study

We want to find out the views of orthotists as to their role in early stroke gait rehabilitation. We hope to capture current views in order to try and measure change as we introduce new ideas in the near future.

It will take you approximately 10 minutes to complete the survey, which has a total of 20 questions.

Why have I been invited?

You have been invited to participate as you are a qualified orthotist in the UK. We are interested to know your perceptions of orthotist involvement in early stroke gait rehabilitation.

Do I have to take part?

No. It is up to you whether you would like to take part in this study. You can ask the researchers involved if you have any further questions that are not answered by this information sheet. If you do decide to take part you will be asked to indicate consent on the first page of the online survey. Even if you do give your consent, you can withdraw from the study at any time, without giving a reason. If you withdraw after you have submitted the survey the data provided cannot be erased and will still be used in the project analysis.

Will my taking part in this study be kept confidential and anonymous?

Yes. The researchers will be adhering to Good Clinical Practice (GCP) guidelines following ethical and legal practice and all information provided will be handled in strictest confidence. Your name or personal details will not be stored. All data provided will be kept anonymous and stored on a secure spreadsheet.

There is an option to provide your e-mail address should you wish to be involved in future related surveys. This will be stored securely and used only for that purpose.

What will happen with the results of the study?

It is intended that the results of the research will be published formally in scientific journals and/or BAPO Connect. We may use anonymized quotations from any free text responses you provide as part of these reports. You will not be identified in any report or publication. We will be able to provide you with a summary of the study findings on request.

There is the possibility that the data collected in this study may be used for future research, in this situation data will remain anonymized and stored securely.

Who has reviewed this study?

The BAPO Research and Executive Committees have reviewed and piloted the survey to ensure suitability of the research questions to BAPO membership.

Ethical approval granted

All data and its use meets with General Data Protection Regulations (GDPR)

For further information please contact:

Mr Paul Charlton (Paul.Charlton@peacocks.net) Tel 07976002194

Mrs Miriam Golding-Day (Miriam.Golding-Day@nottingham.ac.uk)

Mr Joshua Young (joshua.young@johnflorence.com)

Appendix M. National cross-sectional professional survey consent

1. I have read and understood the information sheet/letter explaining this study
2. I understand that I can ask any further questions I may have at any time during the study (if I decide to participate)
3. I understand that my participation in this study is entirely voluntary and that I may withdraw from the study at any time, without giving any reason, should I choose to do so. *Please note that we can't withdraw data once it is submitted unless an email address is provided
4. I understand that the results of the study may be published and that my identity will be protected at all times. If I choose to provide an email address my identify will be protected
5. I understand my e-mail address, if provided, will be stored securely and only used for the purpose of the study
6. I hereby freely consent to take part in this study

Can Early Specialist OrThotic Assessment Lead to Improved Rehabilitation Outcomes and Reduced Complications for Patients Following a Stroke?

Final Version 1.0

9th December 2020

Short title: Early specialist orthotic assessment after stroke

Acronym: OTIS

Trial Sponsor: University of Nottingham

Sponsor reference: *FMHS 156-0121*

Funding Source: The Stroke Association & ARC East Midlands

TRIAL / STUDY PERSONNEL AND CONTACT DETAILS

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SYNOPSIS

Title	Can Early Specialist Orthotic Assessment Lead to Improved Rehabilitation Outcomes and Reduced Complications for Patients Following a Stroke?

Acronym	OTIS
Short title	Early specialist orthotic assessment after stroke
Chief Investigator	Mrs Miriam Golding-Day
Objectives	To undertake remote focus groups with local and national clinical teams in order to gather participants perceptions and opinions on the optimum orthotic intervention for the lower limb after stroke, and to inform the questions and consensus statements for the eDelphi study. To undertake an eDelphi in order to test consensus statements and reach international expert agreement on what optimum early orthotic intervention following stroke consists of.
Trial Configuration	Remote local and national focus groups International remote eDelphi
Setting	Academic setting, International remote
Sample size estimate	Remote focus Group sample size: It is intended to recruit between six and eight participants for each focus group as suggested by Krueger & Casey¹, with the aim of achieving a purposive sample. Patient experts will be consulted in a separate focus group meeting as recommended by the PPI study expert. International eDelphi To take into account attrition of participants over the two rounds, it is intended to recruit 30 participants for the eDelphi to result in a sample of at least 20 as suggested

	by Mullen ² . Ensuring meaningful conclusions can be drawn, a 70% response rate between iterations will be aimed for to maintain statistical rigor ³ .
Number of participants	Remote focus group participants: Up to five focus groups will be facilitated by the CI using a remote platform. Expert panels will be made up of Health and Care Professions Council (HCPC) registered prosthetist/orthotists based within the UK. The separate PPI focus group panel will be made up of PPI experts recruited from the Nottingham Stroke Research Partnership Group (NSRPG). It is intended to recruit between six and eight participants for each focus group. International eDelphi Exact numbers are uncertain as an open invite will be circulated to potential participants identified through international professional and clinical networks. It is intended to recruit 30 participants.
Eligibility criteria	Remote focus group Inclusion criteria: - HCPC registered prosthetist/orthotists who have at least 1 year of clinical experience of working with stroke survivors. Participants should have specific experience of the use of orthotics following stroke. <i>Potential participants will be identified through local and national clinical and professional networks.</i> - PPI expert members of the Nottingham Stroke Research Partnership Group (NSRPG) who are

	either stroke survivors or carers of stroke survivors. . <i>Potential participants will be identified through the membership of the NSRPG.</i> International eDelphi Inclusion criteria: - Cat 1 registered prosthetic/orthotic clinicians based anywhere in the world who have at least 1 year of experience of working with stroke survivors. Participants should have experience of the use of orthotics following stroke. - English reading comprehension and writing ability. <i>Potential participants will be identified through international professional networks. Professional contacts have also been made with research academics in the United States of America, Sweden and Australia who will facilitate circulation of the invitation.</i>
Description of interventions	No intervention is defined for this study.
Duration of study	The planned start date is 01/01/2021 and the duration of the whole process is 36 months. Expert panellists involved with the remote focus groups will be involved for one session of up to 2 hours. Participants involved with the International eDelphi will be involved for two survey rounds which will take approximately 10 minutes each to complete.

Randomisation and blinding	No randomisation will be undertaken.
Outcome measures	Outcome measures will not be used for this study.
Statistical methods	Responses will be quantitatively analysed with descriptive statistics. Normality of data will be checked using histograms and if the data is normal it will be presented as means and standard deviations for each response. If the data is non-normative medians and interquartile ranges will be presented. Qualitative data from each domain will be analysed and presented as coded themes.

ABBREVIATIONS

BAPO British Association of Prosthetists and Orthotists

CI Chief Investigator

GCP Good Clinical Practice

HCPC Health and Care Professions Council

ISPO International Society for Prosthetics and Orthotics

NHS National Health Service

NSRPG Nottingham Stroke Research Partnership Group

PPI Patient and Public Involvement

PIS Participant Information Sheet

R&D Research and Development department

STUDY BACKGROUND INFORMATION AND RATIONALE

Stroke is the leading cause of adult disability in the UK⁴. Of the 1.2 million stroke survivors, almost two thirds leave hospital with some form of physical impairment⁴, up to 60% develop secondary contractures^{5,6} and up to half live with disability long-term^{7,8}. Reduced mobility and gait dysfunction are amongst the most commonly reported symptoms affecting survivors of stroke, frequently persisting long-term⁴. Hemiparesis, hemiplegia, and muscle spasticity can all contribute to difficulties affecting a patient's ability to stand, walk and perform daily activities. Where muscle imbalance and abnormal tone are present, orthotic splints can aid stroke survivors in their rehabilitation and recovery, assisting weakened muscles and helping to prevent or reduce the extent to which contractures develop. Leg orthoses are external supports in the form of a brace or splint and for many stroke survivors they are a crucial aid in their rehabilitation and recovery, enabling them to get back to daily life.

Orthotic splints and braces can help to address physical difficulties often experienced by stroke patients by aiding mobility, reducing discomfort, making performing daily tasks easier, and reducing the risk of complications^{9–12}. Anecdotal evidence suggests that orthotic intervention complements and enhances other therapy effects, optimising alignment as an adjunct to physiotherapy input, reducing the number of hands required in early treatment, and ensuring consistent repeatable alignment essential for motor learning¹³.

Orthotists are expert clinicians who specialise in the assessment and fitting of orthotic devices as well as the management and monitoring of patients as their orthotic needs change through their rehabilitation. However, in current clinical guidelines they are not named members of the stroke rehabilitation Multi-Disciplinary Team (MDT)¹⁴, and as a result, access to orthotic assessment and provision following a stroke can often be restricted or delayed¹⁵. The stroke rehabilitation MDT is made up of AHPs who are usually physically based together on a stroke unit or in the community and meet regularly to discuss input and direction of a patient's care. Clinicians who make up this team are often the gatekeepers to orthotic referral and intervention and as such it is unusual for orthotist involvement post-stroke without their requesting it¹⁵.

It remains unknown what the optimum timing for specialist orthotic intervention is and there is little evidence for what this intervention should look like in the context of the wider stroke MDT. There is also no clarity of the effect delayed orthotic and orthotist led intervention has on the early stages of rehabilitation after stroke. However, the evidence is clear for the benefit of early stage mobility rehabilitation¹⁶, and orthotics often forms an integral part of enabling stroke survivors through their rehabilitation. With the burden of disability caused by stroke set to double worldwide by 2035¹⁷, stroke rehabilitation research is vital in determining how best to treat and support people both immediately after their stroke and in the long-term. The greatest opportunity for recovery falls within the first days and weeks after stroke⁴. Therefore effective rehabilitation, inclusive of orthotic intervention, starting early after diagnosis may be key to gaining optimal physical recovery for stroke survivors.

A national survey of orthotists, physiotherapists and occupational therapists highlighted that current orthotic intervention following stroke is often delayed, sporadic, and delivered with significant disparity across the UK¹⁵. It has been specifically noted how this can lead to deferred or degraded rehabilitation, especially where other therapy interventions are reliant on orthotic provision. The survey also emphasized that orthotists, are not currently included in the stroke specialist MDT, despite recommendations for this^{9,10}. This can mean that their specialist expertise is not sought or available until later in a stroke survivor's rehabilitation, often once problems have developed or worsened¹⁵. Previous consensus work has also stressed that timing of assessment and orthotic implementation is of importance and the belief that orthotic intervention is often occurring too late in a patient's rehabilitation¹⁰. It has been suggested that delayed orthotic intervention negatively impacts on the effectiveness of other therapy inputs, reduces the patient's rehabilitation potential and misses the prophylactic opportunity to prevent secondary complications^{10,15}. Stroke survivors interviewed at the Nottingham Stroke Research Partnership Group (NSRPG) have described the impact of either good or inadequate orthotic provision on the acute stages of their rehabilitation and the longer-term effects they consider this to have had. Many described how the timing of orthotic assessment and provision made a significant difference on their level of physical independence in the early stages post-stroke with those who received devices in the first few weeks reporting greater

levels of activity and independence. Continuous orthotist re-assessment and management following stroke was also found to be beneficial so any orthotic prescription could be tailored to the patients changing functional ability as they recovered.

Research is needed to explore the potential benefits of early specialist orthotic involvement and increase understanding of the potential risks of delay. In line with the MRC framework for the development of complex interventions, the focus groups and eDelphi will constitute the pre-trial development work¹⁸ intended to inform the design of a large definitive trial of early orthotic intervention for the lower limb following stroke. The proposed project will use remote focus groups of registered prosthetist/orthotist clinicians to explore their opinions, experiences and understanding of early orthotic intervention after stroke. This method allows participants to express their opinions and experiences in their own language and form consensus statements that will be used in the next stage. Employing an iterative process of questionnaire completion and controlled feedback, the international eDelphi will then seek expert agreement on these consensus statements related to the potential benefits of early specialist orthotic intervention.

STUDY OBJECTIVES AND PURPOSE

PURPOSE

The aim of the research is to determine a consensus on optimum orthotic intervention after stroke, establishing the potential impact of early and orthotist led orthotic intervention. Ultimately, we wish to evaluate the effectiveness of an early orthotic intervention after stroke but prior to completing a definitive randomised controlled trial we need to gather further information to inform the design and determine the optimum perceived intervention.

We propose to determine the expert perceptions of early orthotic intervention via means of remote focus groups. Results will then inform consensus statements to be tested on the international stage via an eDelphi survey, the findings of which will inform future work in determining the benefits of such an intervention and contribute to clinical guidelines.

PRIMARY OBJECTIVE

The primary objective is to develop consensus statements on the perceived optimum early orthotic intervention.

STUDY DESIGN

STUDY CONFIGURATION

This study will constitute a two phase design of remote focus groups and eDelphi survey.

Primary endpoint

The primary endpoint will be the collection of the data from the remote focus groups and eDelphi survey.

Stopping rules and discontinuation

The study is a low risk focus group and eDelphi questionnaire. The Chief Investigator along with the co-investigators will supervise the data collection and analysis of the data.

RANDOMIZATION AND BLINDING

No randomization will be undertaken.

STUDY MANAGEMENT

The study will be conducted using Microsoft Teams video conferencing platform which participants will opt-in to joining. The study will be managed from the Division of Rehabilitation, Ageing and Wellbeing within the School of Medicine at the University of Nottingham by Miriam Golding-Day (Chief-Investigator). The research team of co-applicants will meet monthly to ensure the study is on track and no concerns have been raised.

The Chief Investigator has overall responsibility for the study and with the supervision of the co-applicants shall oversee all study management.

The data custodian will be the Chief Investigator.

DURATION OF THE STUDY AND PARTICIPANT INVOLVEMENT

Study Duration: 36 months

Participant Duration for Phase 1, Remote Focus Group: Up to 2 hours.

Participant Duration for Phase 2, eDelphi: up to 10 minutes (x2)

End of the Study

The end of the study will be the end of data collection for the whole protocol.

This will be when the last round of the eDelphi has been completed.

SELECTION AND WITHDRAWAL OF PARTICIPANTS

Recruitment

Remote Focus Group: Participants for phase 1 of the study will be identified through national professional and local clinical networks. An email invitation will be distributed to the members of the British Association of Prosthetists and Orthotists (BAPO) giving an introduction to the study and containing a link to access the digital Participant Information Sheet (PIS) and details of how to become involved. Practicing members of BAPO must be registered with the HCPC. We will also distribute email invitations via the BAPO research group to circulate to local clinical networks and reach clinicians who are not members of BAPO. We aim to recruit between six and eight participants, as suggested by Krueger & Casey¹, for each focus group (up to five) with the aim of achieving a purposive sample. At least 24 hours will be allowed between receiving the email invitation and participation in the focus group. Digital consent forms will be accessed and signed using Microsoft Office Forms online platform prior to the focus group beginning.

Patient experts will be consulted in a separate focus group meeting as recommended by the PPI study expert. Potential participants will be identified through their membership of the Nottingham Stroke Research Partnership Group, a group of stroke survivors and carers who work with researchers to guide, co-produce and participate in research impacting on the management and treatment of stroke. A Participant Information Sheet (PIS) will be distributed to members at a scheduled NSRPG meeting with details on the proposed focus group and how to become involved. Digital consent forms will be accessed and

signed using Microsoft Office Forms online platform prior to the focus group beginning.

International eDelphi: Participants for Phase 2 of the study will be identified through international professional networks. It is intended to recruit 30 Cat 1 registered prosthetist/orthotist clinicians, who have at least 1 year of experience of working with stroke survivors, with the aim of acquiring a sample of at least 20 participants across both rounds as suggested by Mullen². An email invitation will be distributed to members of the International Society of Prosthetists and Orthotists and personal professional networks for colleagues based in the United States of America, Sweden, and Australia. The email will contain an introduction to the study and a link which will take potential participants to a digital PIS, consent form and the eDelphi survey page. At the end of the first round of questions, participants will be asked to provide their email address so they may be contacted for the second round of questions.

Eligibility criteria/ Inclusion criteria

Remote Focus Group: To be eligible to participate persons will:

- Be HCPC registered prosthetist/orthotists who have at least 1 year of clinical experience of working with stroke survivors. Participants should have specific experience of the use of orthotics following stroke.

Potential participants will be identified through local and national clinical and professional networks.

- PPI expert members of the Nottingham Stroke Research Partnership Group who are either stroke survivors or carers of stroke survivors.

Potential participants will be identified through the membership of the NSRPG

International eDelphi: To be eligible to participate persons will:

- Cat 1 registered prosthetic/orthotic clinicians based anywhere in the world who have at least 1 year of experience of working with stroke survivors. Participants should have experience of the use of orthotics following stroke.
- English reading comprehension and writing ability.

Potential participants will be identified through international professional networks. Professional contacts have also been made with research academics in the United States of America, Sweden and Australia who will facilitate circulation of the invite.

Exclusion criteria

Remote Focus Group:

- Participants who do not speak English

International eDelphi:

- Participants without comprehensive English reading and writing ability.

Expected duration of participant participation

Participants recruited into the Remote Focus Groups will be involved for an expected duration of up to 2 hours. Participants recruited into Phase 2 International eDelphi will be involved for an expected duration of 10 minutes for two time periods.

Participant Withdrawal

Participants of both the remote focus groups and eDelphi survey may choose to withdraw at any point during their involvement. Participants will be made aware (via the Participant Information Sheet and consent form) that should they withdraw, the data collected to date cannot be erased and may still be used in the final analysis.

Consent will be gained immediately prior to the planned interactions and so withdrawal is unlikely.

Informed consent

It will be explained to all potential participants that entry into each phase of the study is entirely voluntary and that their employment or status within their professional body will not be affected in any way.

Informed consent will be gained by the researcher before each remote focus group which will be at least 24 hours after the initial approach has been made

through email invitation with link to Patient Information Sheet (PIS). This time delay ensures participants have appropriate opportunity to consider if they wish to participate. The researcher obtaining consent has completed Good Clinical Practice (GCP) training and so understands the informed consent process.

All participants will provide informed consent on a standardised digital consent form which has been drafted to meet the host institutions requirements. The researcher will be available to contact and answer any questions that the participants have prior to them taking part. The digitally signed consent form will be kept and stored securely in password protected data file on the University secure server.

STUDY TREATMENT AND REGIMEN

Remote Focus Group

Participants for phase 1 of the study will be identified through national professional and local clinical networks. An email invitation will be distributed to the members of the British Association of Prosthetists and Orthotists (BAPO) and via the BAPO research group to local clinical networks.

The aim of the focus groups is to explore the opinions, experiences and understanding of specialist prosthetic/orthotic clinicians on the perceived optimum early orthotic intervention following stroke. Each focus group will have between 6-8 participants and constitute an informal one off meeting with participants talking to each other and to the researcher about their experiences. The focus groups will be facilitated by the CI and discussion will be guided by quick fire survey questions which will also generate some quantitative data from the participant's responses. The focus group will last for approximately one to two hours and be recorded using the remote platform. Attempts will be made to recruit participants from different geographical regions and diverse backgrounds to ensure we explore experiences outside of just one system of working.

Before the focus group commences, participants will be asked to digitally consent before completing an initial set of questions in order to confirm eligibility and collect participant professional demographics. Questions will be on a Microsoft Office Forms and include:

- Sex
- Ethnicity
- Geographic location (area)
- Number of years qualified
- Number of years experience working with stroke patients (must be >1 year to take part)

Patient experts will be consulted in a separate focus group meeting as recommended by the PPI study expert. Potential participants will be identified through their membership of the Nottingham Stroke Research Partnership Group and be approached to participate at a scheduled meeting. A Participant Information Sheet will be distributed to members and then interested members will be asked to sign a digital consent form before the focus group commences.

Data for all focus groups will be digitally recorded and stored in a password protected file on the University of Nottingham's secure server in keeping with established protocols for information governance and data protection. Research team members will endeavor to protect the rights of the participants to privacy and confidentiality by adhering to the Good Research Practice Guidelines. All data will be anonymized.

International eDelphi:

Participants for phase 2 of the study will be identified through international professional networks. An email invitation will be distributed to members of the International Society of Prosthetists and Orthotists and through personal professional networks of clinical academic colleagues based in the United States of America, Sweden, and Australia. The email will contain an introduction to the study and a link which will take potential participants to a digital PIS, consent form and the eDelphi survey page. Prospective participants can choose whether they firstly follow the link contained in the email, and then whether they wish to take part in the eDelphi survey after reading the digital participant information sheet.

Participants will be asked to digitally consent before completing an initial set of questions in order to confirm eligibility and collect participant professional demographics. Questions will include:

- Sex
- Ethnicity
- Geographic location (country)
- Institution where qualification Cat 1 prosthetist/orthotist status achieved
- Number of years qualified
- Number of years experience working with stroke patients (must be >1 year to proceed)

Participants will then be shown a series of questions and consensus statements to respond to. As previously explained in the PIS, at the end of the questions they will be asked to provide their email address so that they may be contacted directly for the second stage. The responses from the first round will be collated and used to determine a smaller set of consensus statements for the participants to respond to.

All response data will be stored securely on the University file storage system and saved with a participant ID number. Any email addresses will be stored on a separate password protected file.

Compliance

Due to the nature of the study we do not anticipate any major problems with compliance from participants. Participation is voluntary and to encourage compliance, researchers will be available to answer any questions the participants may have via email or telephone contact.

Sample size and justification

Remote Focus Group:

Between six and eight participants will be recruited for each group with the aim of achieving a purposive sample¹. This number of participants has been

shown to foster in-depth discussions amongst participants from a variety of clinical viewpoints and experiences.

International eDelphi

To take into account attrition of participants over the two rounds and ensuring that meaningful conclusions can be drawn from the data, 30 participants will be recruited with the aim of a sample of at least 20 participants completing both rounds. A 70% response rate between iterations will be aimed for to maintain statistical rigor³ A smaller panel size has been shown to reduce drop-out rate², and is also more appropriate with a homogenous group of participants. Future exercises will seek to take into account the wider perspectives from other health care professionals, stroke survivors and their carers.

Procedures for missing, unused and spurious data

The eDelphi survey questionnaire will be built to encourage data completion for all questions. For key questions participants will be required to select/enter an answer before progress is permitted. The data will be collected using an online survey platform and checks made to ensure completeness of data as the survey is on-going.

ADVERSE EVENTS

This is a low risk study and the occurrence of adverse events as a result of participation within this study is not expected. However in the incidence of an adverse event arising from participation we will withdraw the participant from the study where appropriate.

Reporting of adverse events

All adverse events will be recorded and closely monitored until resolution, stabilisation, or until it has been shown that the study is not the cause. The Chief Investigator shall be informed immediately of any adverse events and shall determine seriousness and causality. In circumstances where an external perspective is necessary, due to the CI facilitating the focus group for example, another member of the research team will be available for consultation and shall determine and facilitate appropriate action.

ETHICAL AND REGULATORY ASPECTS

ETHICS COMMITTEE AND REGULATORY APPROVALS

The study will not be initiated before the protocol, consent forms, and participant information sheets have received approval / favourable ethical opinion.

INFORMED CONSENT AND PARTICIPANT INFORMATION

Remote Focus Group:

Participants will receive a Participant Information Sheet in advance of the session and then be asked to indicate their consent digitally before the session commences. The decision to participate in the focus group is entirely voluntary.

eDelphi:

Participants will be shown a Participant Information Sheet on a holding page before they start the survey. They will then be required to indicate their consent to participation before they can proceed to seeing the survey questions. The decision to participate in the eDelphi survey is entirely voluntary.

RECORDS

Each participant will be assigned a study identity code, allocated at random for use in the electronic database.

Focus group and eDelphi responses will be treated confidentially and held securely in accordance with regulations. The investigator will make a separate confidential record of the participant's email address so they may be contacted as appropriate. This record will not be used for any other purpose than for the study.

Source documents

As all data collection will be remote, no source documents will be produced through the course of the study.

DATA PROTECTION

All research team members will endeavour to protect the rights of the study participants to privacy and informed consent, and will adhere to the Data Protection Act, 2018 which is recognised internationally. We will only collect the minimum required information for the purposes of the study. Computer held data

including the eDelphi survey database will be held securely and be password protected. Access will be restricted by user identifiers and passwords (encrypted using a one way encryption method). Electronic data will be backed up every 24 hours to both local and remote media in encrypted format.

QUALITY ASSURANCE & AUDIT

STUDY DATA

Monitoring of study data shall include confirmation of informed consent; data storage and data transfer procedures; local quality control checks and procedures, back-up and disaster recovery of any local databases and validation of data manipulation. The Academic Supervisor, or where required, a nominated designee of the Sponsor, shall carry out monitoring of study data as an ongoing activity.

Study data and evidence of monitoring and systems audits will be made available for inspection by as required.

RECORD RETENTION AND ARCHIVING

In compliance with the GCP guidelines, regulations and in accordance with the University of Nottingham Research Code of Conduct and Research Ethics, the Chief Investigator will maintain all records and documents regarding the conduct of the study. These will be retained for at least 7 years or for longer if required. If the responsible investigator is no longer able to maintain the study records, a second person will be nominated to take over this responsibility.

STATEMENT OF CONFIDENTIALITY

Individual participant information obtained as a result of this study are considered confidential and disclosure to third parties is prohibited with the exceptions noted above.

Participant confidentiality will be further ensured by utilising identification code numbers.

Data generated as a result of this study will be available for inspection on request by University of Nottingham representatives, the ethics committee, local R&D Departments and the regulatory authorities.

PUBLICATION AND DISSEMINATION POLICY

Findings from the research will be disseminated via national and international clinical and research networks. We intend to publish the findings from this study in peer-reviewed journals and present findings at appropriate local and national conferences. Dissemination via the funder (Stroke Association and NIHR ARC) networks will also be undertaken. No personal identifiable information will be included in either publications or presentations.

We will invite all people interested or involved in the study to the yearly patient led stroke research conference to present the findings of the study. This will include the service user group Nottingham Stroke Research Partnership Group who have collaborated with the project, academics, practitioners, service commissioners and family members.

The PPI member of the research team will be involved in preparing a lay summary of the key research findings.

All the findings and publications will form the basis of the PhD thesis for the Chief Investigator.

USER AND PUBLIC INVOLVEMENT

The proposed study has been built upon previous work carried out in partnership with stroke survivors and the research project has been designed in response to their expressed need for more research in this area.

The Nottinghamshire Stroke Research Partnership Group are a service user group who have been actively involved in the design of the research. A named PPI expert member with specific interest in this topic has informed the design of the study and will be involved in the development of participant information resources, contribute to the study report, and the dissemination of research findings.

The PPI expert member who is a stroke survivor and orthotic user herself is part of the research team and is involved with the study on-going. By actively involving patients in the research process we are looking to ensure that the research is driven by patient need.

Patient members of the Nottingham Stroke Research Partnership Group will help add to the validity and resonance of findings and will be actively involved in the translation of research findings.

STUDY FINANCES

Funding source

This study is funded by The Stroke Association and the ARC East Midlands programmes via a joint funded doctoral fellowship.

Participant stipends and payments

Participants will not be paid to participate in the study.

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Appendix O. Focus group discussion topic guide

Kick off statement:

“Orthotics is an integral aspect of successful post-stroke rehabilitation” could I pick on xxx to perhaps kick us off with a response to that statement and then invite everyone else to give their perspective?

How key do we consider ‘Orthotist’ involvement is as appose to just ‘orthotics’ provision which may be provided by other members of the stroke rehab team?

How involved is the orthotist in the early gait rehabilitation decisions being made for stroke patients?

Within the UK, audit shows that early-stage gait rehabilitation tends to be driven by Physiotherapists, how influential do we consider their approach to be to the inclusion of orthotics within post-stroke rehabilitation?

Conference – Bobath concepts fitting in with orthotics? When is orthotics considered for post-stroke gait re-education within BOBATH remit?

Something we are looking to explore is the patients perspective in all this, do you have any anecdotes or experiences from your own patients?

Joint decision making or isolated assessment for orthotics? What kind of follow up is ideal as stroke patients needs can change rapidly over the first year post-stroke.

What do you consider the barriers to efficient orthotic intervention in post-stroke rehabilitation?

What do you consider the facilitators to efficient orthotics intervention in post stroke rehabilitation?

What do you consider the potential negatives to early orthotic intervention?

In previous research, access to orthotics and orthotist assessment has been found to be a barrier to intervention, do you consider this to be the case in your experience and how does it impact specifically in post-stroke rehabilitation?

What about Early supported discharge? We all know interventions should be delivered at the same degree and intensity as if still on the ward, do you find orthotics is easier or harder to access when patient is in the community?

Something that's been highlighted in the UK is that, unlike Physiotherapists and OT, Orthotists are not named members of the stroke rehab MDT with guidance just stating services should have 'easy access'. Do you think this makes a difference in patients experiences?

At the FORTH conference a lot of concepts were covered but something that came up in the break out rooms was the idea that AFO use is considered only in swing phase – to prevent foot drop. Do you consider orthotics have a place in stance phase control as well?

Key aspect of our research is the 'early' stage of post-stroke rehab and by that we mean the first 6 weeks. Clear evidence Early mobilising leads to better outcomes. So do we consider early or earlier orthotic consideration would be beneficial for our patients?

Are there any aspects of this topic that we haven't covered today that you have a specific perspective on that you would like to share?

Any final comments?

Appendix P. Focus group and eDelphi letter of favourable ethical approval



University of
Nottingham
UK | CHINA | MALAYSIA

Queen's Medical Centre Campus

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Appendix Q. Remote focus group Participant Information Sheet



University of
Nottingham
UK | CHINA | MALAYSIA

Final version 1.0: 09.12.20

Project ID: FMHS 156-0121

Title of Study: Can Early Specialist Orthotic Assessment Lead to Improved Rehabilitation Outcomes and Reduced Complications for Patients Following a Stroke?

Name of Chief Investigator: Miriam Golding-Day

Local Researcher(s): Prof Marion Walker, Dr Shirley Thomas, Dr Jane Horne

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will be available to go through the information sheet with you should you wish and answer any questions you have.

What is the purpose of the study?

We want to find out what prosthetist/orthotist clinicians consider to be the means of optimum orthotic intervention for patients after they have had a stroke. Specifically, we want to look at their perceptions on the potential impact of early and orthotist led orthotic intervention.

Why have I been invited?

You are being invited to take part because you are practicing prosthetist/orthotist registered with the HCPC. We are interested to know your opinions and experiences on orthotic intervention following stroke and are inviting up to 8 participants like you to take part in each focus group.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be asked to sign a digital consent form prior to the focus group

commencing. If you decide to take part you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights, employment or your status within a professional body (such as BAPO). Should you choose to withdraw, the data collected to that point cannot be erased and may still be used in the final analysis.

What will happen to me if I take part?

A researcher, who is also a prosthetist/orthotist, will arrange a time to conduct a remote focus group session with up to 8 prosthetist/orthotist colleagues using a video conferencing platform such as Zoom or Teams. They will try and do this at a time that is convenient for everyone. At the beginning of the focus group, the researcher will send you a link to a digital consent form which you will need to sign before the focus group can begin. The researcher will then ask the group some questions relating to orthotic intervention after stroke and encourage you and the other participants to discuss and provide feedback. During the session, you will be asked to complete quick poll questions within the video conferencing platform so we can gather anonymous data from you on some closed questions. The whole focus group session likely to last between 1-2 hours but this will be tailored to each groups requirements. The remote focus group session will be recorded using the video conferencing platform recorder with your consent.

Expenses and payments

Due to the remote nature of the focus group, participants will not be paid expenses to participate in the study.

What are the possible disadvantages and risks of taking part?

We do not anticipate any disadvantages in taking part in the study other than the time taken to participate in the remote focus group. Some of the questions will focus on your experiences with your local clinical setting and whilst you are not required to answer these, if you choose to do so then your responses would be kept completely confidential.

What are the possible benefits of taking part?

There may be no direct benefit to you in taking part in the study but the information we collect will help to inform future research in this area and seeking to establish optimum orthotic intervention for patients following stroke.

What happens when the research study stops?

All information which has been collected from you during the remote focus groups including the recording of the session will be stored on the University of Nottingham secure server in a drive which is password protected. All data will be stored in accordance with the University guidelines and the Data Protection Act 2018.

Any data collected from the study will be stored for 7 years from the completion of the study and then destroyed.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers' contact details are given at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this by contacting Professor Neil Coulson Head of the Division of Rehabilitation, Ageing and Wellbeing at the University of Nottingham by telephone on: 0115 8466642 or by email at: neil.coulson@nottingham.ac.uk.

Will my taking part in the study be kept confidential?

If you join the study, we will use information collected from you during the course of the research. This information will be kept strictly confidential, stored in a password protected database at the University of Nottingham. Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (named above) is the Data Custodian (manages access to the data). This means we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your rights we will use the minimum personally – identifiable information possible.

You can find out more about how we use your information and to read our privacy notice at: <https://www.nottingham.ac.uk/utilities/privacy.aspx>.

The data collected for the study will be looked at and stored by authorised persons from the University of Nottingham who are organising the research.

They may also be looked at by authorised people from regulatory organisations to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

Your contact information will be kept by the University of Nottingham for 1 year after the end of the study so that we are able to contact you about the findings of the study and possible follow-up studies (unless you advise us that you do not wish to be contacted). This information will be kept separately from the research data collected and only those who need to will have access to it. All other research data will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team given permission by the data custodian will have access to your personal data.

In accordance with the University of Nottingham's, the Government's and our funders' policies we may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is usually anonymised (so that you could not be identified) but if we need to share identifiable information we will seek your consent for this and ensure it is secure. You will be made aware then if the data is to be shared with countries whose data protection laws differ to those of the UK and how we will protect your confidentiality.

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw we will no longer collect any information about you or from you but we will keep the information about you that we have already obtained as we are not allowed to tamper with study records and this information may have already been used in some analyses and may still be used in the final study analyses. To safeguard your rights, we will use the minimum personally identifiable information possible.

What will happen to the results of the research study?

The results of this study may be published in the scientific literature and may also be presented at scientific meetings. All such data will be presented anonymously, that is with no personal details that could identify any of the participants.

Who is organising and funding the research?

This research is being organised by the University of Nottingham and is being funded by The Stroke Association and ARC East Midlands in a joint funded PhD fellowship held by the CI.

Who has reviewed the study?

All research is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by The University of Nottingham Faculty for Medicine and Health Sciences Research Ethics Committee (FMHS 156-0121).

Further information and contact details

Please contact the chief investigator: Miriam Golding-Day (0115 8230323) at the Division of Rehabilitation, Ageing & Wellbeing, Queens Medical Centre, Nottingham NG7 2UH for more information.

Appendix R. Remote focus group consent form

(Final version 1.0 date 09.12.2020)

Title of Study: Can Early Specialist Orthotic Assessment Lead to Improved Rehabilitation Outcomes and Reduced Complications for Patients Following a Stroke?

Project ID: FMHS 156-0121

Name of Researcher:

Name of Participant:

Please initial each statement

1. I confirm that I have read and understand the participant information sheet version number XX dated XX 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. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis.
3. I understand that the remote focus group will be recorded and that anonymous direct quotes from the focus group may be used in the study reports.
4. I understand that the information collected about me may be used to support other research in the future and may be shared anonymously with other researchers.
5. I agree to take part in the above study.

Name of participant

Date

Signature

Name of person taking consent

Date

Signature

Appendix S. Convergence coding matrix

Theme	The Patient
Number of systematic review studies that mentioned theme	6 out of 6
Number of national survey respondents that mentioned theme	56 out of 56
Number of focus group participants that mentioned theme	15 out of 18
Convergence, complementarity, contradiction, and silence	Convergence: The patient as a theme was clearly important across all the data sets, important to both clinician and stroke survivors within the focus groups. Example quote from the national professional survey: • <i>"Often see stroke patients too late and so they will have contractures etc making it harder to achieve good outcomes."</i> (Respondent 9) Example descriptive statistic from the national professional survey: • <i>61% of respondents disagreeing or strongly disagreeing with the statement 'I am satisfied with the frequency of involvement I have with early stroke rehabilitation patients.' A further 23% described being neutral and only 16% were satisfied with their involvement.</i> Complementarity: The patient was referred to across all the data sets in a similar format relating to their journey or pathway from point of stroke throughout their rehabilitation and recovery. By keeping the patient at the centre of intervention there is significant impact on other themes identified such as the way an AFO is provided and their longer-term follow-up and outcomes. Example quotes from the focus groups:

	• <i>"You know you're dealing with all the cognitive stuff, whether they'll tolerate it, whether they'll wear it. You know, longer term whether anyone is going to be able to help them put it on, it's all that kind of stuff."</i> (Participant 004) • <i>"I had my stroke 13 years ago and I know within a year and a half, because my foot pattern of walking wasn't corrected with orthotics, I had to have a complete hip replacement...I found that a real trouble, almost as bad as the stroke you know, having to have a left hip replacement only a year after having my stroke, which was a major ordeal to me as a stroke survivor...if they had given my orthotics I might not have gone through that."</i> (Participant 013)
	Contradiction: Within the systematic review data sets, the concept of the patient was less defined with more focus on their outcomes as appose to the person themselves and how they impact on the intervention being delivered. Example quote from the systematic review: • <i>"We found positive effects of providing ankle-foot orthoses in (sub)acute stroke subjects that had not used these orthoses before."</i> (Nikamp, Buurke et al. 2017)
	Silence: [No evidence]
Themes that have been derived from this synthesis	9. Patient compliance 10. Secondary complications 11. Carers 12. Importance of home 13. Orthotic influence on post stroke rehabilitation goals 14. Incidence of secondary complications connected with lack or delayed orthotic provision 15. Longer-term impacts of AFO use on patient rehabilitation outcomes 16. Earlier provision of AFO benefits patient rehabilitation outcomes

Appendix T. National eDelphi Participant Information Sheet, Consent form, Title and Final page



eDelphi PIS Version 0.2_14/03/2023

What is the purpose of the study?

We want to define expert consensus on what is considered the optimum orthotic intervention after stroke to promote patients rehabilitation outcomes. We are asking you as an expert clinician in this area, as well as other orthotists from around the globe, to help agree on consensus statements. It is hoped these can then be used to inform future research and practice in this area.

Why have I been invited?

You are being invited to take part because you are a registered orthotist with experience of working with stroke patients. We are interested to know your perspective on consensus statements which have been drafted on orthotic intervention for patients following stroke. We are inviting participants from around the globe to take part.

Do I have to take part?

It is up to you. If you do decide to take part you will need to confirm your consent to do so at the bottom of this page and provide your email address so that we may contact you to invite you to the second round of the eDelphi. You are free to withdraw at any time and without giving a reason and this would not affect your legal rights, employment or your status within a professional body. Should you choose to withdraw, the data collected to that point cannot be erased and may still be used in the final analysis.

What will happen to me if I take part?

Your participation will constitute a 2 round eDelphi survey. You will be required to sign the consent form and confirm your eligibility to take part before accessing the eDelphi survey. You will then be presented with a series of questions which you will respond to indicating how strongly you agree or disagree with them. Your email address will only be available to the Chief Investigator of the study. After collating the responses from the first

round of questions, the Chief Investigator will use your email address to send you a link to complete a shorter more focused second round of questions to determine a more concise set of consensus statements. Once you have completed the second round of the Delphi your contact information will be deleted.

What are the possible disadvantages and risks of taking part?

We do not anticipate any disadvantages in taking part in the study other than the time taken to complete the survey which we anticipate to be 10 minutes. Some of the questions will focus on your working and clinical experiences and your responses would be kept completely confidential.

What are the possible benefits of taking part?

There may be no direct benefit to you in taking part in the study but the information we collect will help to inform future research and practice in this area seeking to establish guidelines on optimum orthotic intervention for patients following stroke.

What happens when the research study stops?

All information which has been collected from you during the eDelphi will be stored anonymously on the University of Nottingham secure server in a drive which is password protected. All data will be stored in accordance with the University guidelines and the Data Protection Act 2018.

Any data collected from the study will be stored for 7 years from the completion of the study and then destroyed.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the Chief Investigator who will do their best to answer your questions. Contact details are given at the bottom of this information sheet.

Will my taking part in the study be kept confidential?

If you choose to take part in the eDelphi survey your answers to the questions will be collected to help form the consensus statements to be agreed. This information will be kept strictly confidential, stored in a password protected database at the University of Nottingham. Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (named above) is the Data Custodian (manages access to the data). This means we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard

your rights we will use the minimum personally – identifiable information possible.

You can find out more about how we use your information and to read our privacy notice at:

<https://www.nottingham.ac.uk/utilities/privacy.aspx>

The data collected for the study will be looked at and stored by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people from regulatory organisations to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

In accordance with the University of Nottingham's, the Government's and our funders' policies we may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is usually anonymised (so that you could not be identified) but if we need to share identifiable information we will seek your consent for this and ensure it is secure. You will be made aware then if the data is to be shared with countries whose data protection laws differ to those of the UK and how we will protect your confidentiality.

What will happen if I don't want to carry on with the study?

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What will happen to the results of the research study?

The results of this eDelphi study may be published in the scientific literature and may also be presented at scientific meetings. Any data will be presented anonymously, that is with no personal details that could identify any of the participants.

Who is organising and funding the research?

This research is being organised by the University of Nottingham UK and is being funded by The Stroke Association and ARC East Midlands in a joint funded PhD fellowship held by the Chief Investigator.

Who has reviewed the study?

All research is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by The University of Nottingham Faculty for Medicine and Health Sciences Research Ethics Committee (FMHS 156-0121).

This eDelphi study has also been reviewed by The British Association of Prosthetists and Orthotists Research committee and they have given their approval for its distribution.

Thank you in advance for agreeing to take part in this research, it is essential and so valuable that we are able to gather your expert opinion on this important area of orthotic practice.

For further information and contact details:

Miriam Golding-Day (+44 115 8230323)

miriam.golding-day@nottingham.ac.uk

Consent

I confirm that I have read and understand the participant information sheet above for the eDelphi study and I will need to provide a contact email in order that I can be notified about the second round of eDelphi questions

☐ Yes

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis.

☐ Yes

I understand that the information collected about me may be used anonymously to support other research in the future

☐ Yes

I agree to take part in the eDelphi study

☐ Yes

Please enter an email address so you may notified about the second round of eDelphi questions

Title Page

Title of Study: Can Early Specialist Orthotic Assessment Lead to Improved Rehabilitation Outcomes and Reduced Complications for Patients Following a Stroke?

Name of Chief Investigator: Miriam Golding-Day

Researcher(s): Dr Shirley Thomas, Prof Marion Walker, Dr Jane Horne

We would like to invite you to take part in an international eDelphi exercise to help develop a set of best practice statements. These will focus on the role of the orthotist and the use of orthotic devices in early gait rehabilitation following stroke. Before you continue you will need to read the following information sheet and provide consent to take part.

Final Page

Thank you for taking part in this eDelphi exploring ***Can Early Specialist Orthotic Assessment Lead to Improved Rehabilitation Outcomes and Reduced Complications for Patients Following a Stroke?***

You will be contacted by the researchers via the email you provided at the beginning of the survey in approximately 6 weeks time with the link to complete the second round of eDelphi questions. The second round of questions will be very similar to the questions completed in this round but with a more specific focus. We anticipate it will only take 5-10 minutes to complete.

Thank you again for taking the time to be part of this important research. If you have any queries or questions about this study then please contact the Chief Investigator on Miriam.golding-day@nottingham.ac.uk

Appendix U. eDelphi email advert



We would like to invite you to take part in our study: "Can Early Specialist Orthotic Assessment Lead to Improved Rehabilitation Outcomes and Reduced Complications for Patients Following a Stroke?"

Are you an orthotist experienced in treating stroke patients at different stages of their rehabilitation? We want to hear from you! A research team based in the United Kingdom is undertaking a national eDelphi exercise to gather the experiences and opinions of orthotists across the country. We want to agree an expert consensus from orthotists on what they think constitutes the best orthotic treatment for patients that have had a stroke. As a member of BAPO, we would like to invite you to take part.

The eDelphi survey will be conducted across up to 3 rounds and will take 10 minutes to complete each round. You will be asked to provide your email address at the beginning of the first round so we may contact you to take part in round two. We encourage you to read through the information sheet which can be found by clicking the below link, a PDF downloadable version is also available. Please feel free to make contact with the research team should you have any further questions about the eDelphi or the wider study and thank you for taking the time to be part of this important research!

Please follow the below link to find the information sheets and to complete the eDelphi survey questions.



Appendix V. eDelphi round one detailed consensus statistics

Key:	
Statement consensus reached (>75%)	Statement consensus not reached (<75%)

Theme One – The Orthotist

1.1 The orthotist is an important member of the stroke rehabilitation clinical team					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			96.9%
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree	1	3%	
		Somewhat agree	5	16%	
		Strongly agree	26	81%	

1.2 All patients who have experienced a stroke affecting motor control would benefit from having an orthotist assessment					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			93.75%
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree	2	6%	
		Somewhat agree	10	31%	
		Strongly agree	20	63%	

1.3 Where an orthotist is not embedded within the stroke clinical unit, regular orthotist contact is important to facilitate timely assessment and treatment					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			97.32%
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree			
		Somewhat agree	6	19%	
		Strongly agree	26	81%	

1.4 Regular orthotist contact with the stroke unit is important to facilitate knowledge exchange, advice giving and provide training					

# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			95.53%
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree	1	3%	
		Somewhat agree	8	25%	
		Strongly agree	23	72%	

1.5 The orthotist should lead the orthotics assessment and any subsequent orthotics provision for stroke survivors					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			95.98%
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree			
		Somewhat agree	9	28%	
		Strongly agree	23	72%	

1.6 When not embedded within a stroke clinical unit, please select how regularly you think the orthotist should be in attendance to assess and treat patients Please select only one option					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?*
32	0	Every day	2	6%	Mean consensus not reached
		2-3 days a week	6	19%	
		Once a week (weekly)	15	47%	
		Every other week (bi-weekly)	6	19%	
		Once a month (monthly)	2	6%	
		Less than once a month	1	3%	
* Any option with less than 5 responses was removed for the next round					

1.7 Consistency of approach between orthotists in their assessment and treatment is important to ensure equitable treatment for stroke survivors					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			85.71%
		Somewhat disagree			
		Disagree			
		Neither disagree or agree	2	6%	
		Agree	7	22%	
		Somewhat agree	12	38%	
		Strongly agree	11	34%	

1.8 Where an orthoses has been prescribed it should be the same orthotist who fits and trials that device with the stroke survivor					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?

32	0	Strongly disagree			79.46%
		Somewhat disagree	1	3%	
		Disagree	1	3%	
		Neither disagree or agree			
		Agree	14	44%	
		Somewhat agree	9	28%	
		Strongly agree	7	22%	

1.9 The stroke survivor should be reviewed by the same orthotist that prescribed and fitted the orthotic device for consistency and continuity of care					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			79.02%
		Somewhat disagree	1	3%	
		Disagree	2	6%	
		Neither disagree or agree	1	3%	
		Agree	11	34%	
		Somewhat agree	9	28%	
		Strongly agree	8	25%	

1.10 Orthotists should have the opportunity to specialise in specific conditions such as neurological rehabilitation					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			88.39%
		Somewhat disagree			
		Disagree	1	3%	
		Neither disagree or agree			
		Agree	6	19%	
		Somewhat agree	10	31%	
		Strongly agree	15	47%	

1.11 There should be stroke specific training available to pre-registration and post-registration orthotists to establish an agreed pathway of treatment for stroke survivors to encourage conformity across settings					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			91.52%
		Somewhat disagree			
		Disagree			
		Neither disagree or agree	2	6%	
		Agree	1	3%	
		Somewhat agree	11	34%	
		Strongly agree	18	56%	

1.12 The orthotist should be involved in the planning, commissioning and provision of stroke rehabilitation services					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			90.18%
		Somewhat disagree			
		Disagree			

		Neither disagree or agree	1	3%	
		Agree	5	16%	
		Somewhat agree	9	28%	
		Strongly agree	17	53%	

Theme Two – The Orthoses

2.1 Orthotic principals such as biomechanics are important considerations when deciding on a stroke survivors rehabilitation treatment plan					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			98.21%
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree			
		Somewhat agree	4	12%	
		Strongly agree	28	88%	

2.2 Ankle Foot Orthoses (AFOs) should be considered for stroke survivors with mobility problems					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			93.75%
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree	2	6%	
		Somewhat agree	10	31%	
		Strongly agree	20	63%	

2.3 Any orthotic provision following stroke should be assessed for and prescribed with the intent of 'right first time'					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			88.39%
		Somewhat disagree			
		Disagree	1	3%	
		Neither disagree or agree	1	3%	
		Agree	5	16%	
		Somewhat agree	9	28%	
		Strongly agree	16	50%	

2.4 Orthoses prescribed for stroke survivors should be considered a rehabilitation tool in their tool box					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			92.86%
		Somewhat disagree	1	3%	
		Disagree			
		Neither disagree or agree			
		Agree	2	6%	
		Somewhat agree	7	22%	
		Strongly agree	22	69%	

2.5 The time between assessment and provision of any orthoses for an early rehabilitation stroke survivor should be less than 14 days					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree	1	3%	87.5%
		Somewhat disagree			
		Disagree	1	3%	
		Neither disagree or agree	2	6%	
		Agree	3	9%	
		Somewhat agree	6	19%	
		Strongly agree	19	60%	

2.6 Appropriate orthotic provision for stroke survivors can positively influence stance phase and swing phase limb alignment during mobilising					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			99.12%
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree			
		Somewhat agree	2	6%	
		Strongly agree	30	94%	

2.7 Orthoses in early post stroke rehabilitation can be used to increase dosage of therapeutic alignment and intervention when hands on therapist time is limited or unavailable					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			95.10%
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree			
		Somewhat agree	11	34%	
		Strongly agree	21	66%	

2.8 Orthotic intervention in early post stroke treatment can contribute to a 24 hour therapy model of rehabilitation					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			87.95%
		Somewhat disagree			
		Disagree			
		Neither disagree or agree	4	13%	
		Agree	2	6%	
		Somewhat agree	11	34%	
		Strongly agree	15	47%	

2.9 Early orthotic use ensuring correct alignment and normal movement can assist with neuroplasticity retraining of mobility					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			93.30%
		Somewhat disagree			
		Disagree			
		Neither disagree or agree	1	3%	
		Agree	2	6%	
		Somewhat agree	8	25%	
		Strongly agree	21	66%	

2.10 Following provision of an orthoses, all stroke survivors should have the option of tuning to ensure the best functionality and usability					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			94.20%
		Somewhat disagree			
		Disagree			
		Neither disagree or agree	1	3%	
		Agree	1	3%	
		Somewhat agree	6	19%	
		Strongly agree	24	75%	

2.11 Availability of orthoses type (custom, prefabricated, material etc.) should be equitable for all stroke survivors regardless of location					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			98.70%
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree			
		Somewhat agree	3	9%	
		Strongly agree	29	91%	

2.12 Availability of any orthoses for stroke survivors should not be determined by cost and its prescription should be driven by functional need					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree	1	3%	94.20%
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree	2	6%	
		Somewhat agree	3	9%	
		Strongly agree	26	82%	

2.13 Custom and personalised orthoses prescriptions should be considered at the first instance over prefabricated orthoses for stroke survivors					

# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree	3	9%	61.61%
		Somewhat disagree	4	13%	
		Disagree	5	16%	
		Neither disagree or agree	6	19%	
		Agree	3	9%	
		Somewhat agree	4	13%	
		Strongly agree	7	21%	

2.14 Pre-fabricated orthoses have a valid place within orthotic provision post stroke but should be managed carefully for appropriateness for each individual

# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree	1	3%	90.63%
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree	3	9%	
		Somewhat agree	9	28%	
		Strongly agree	19	60%	

2.15 Provision of pre-fabricated orthoses should be overseen by an orthotist or appropriately trained healthcare professional

# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			92.41%
		Somewhat disagree			
		Disagree			
		Neither disagree or agree	1	3%	
		Agree	4	13%	
		Somewhat agree	6	19%	
		Strongly agree	21	66%	

2.16 Information regarding any provided orthoses should be given in both verbal and written formats to stroke survivors

# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			95.98%
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree	1	3%	
		Somewhat agree	7	22%	
		Strongly agree	24	75%	

Theme Three – The Patient

3.1 All stroke survivors with mobility problems should be assessed by an orthotist in a timely and equitable manner

# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?

32	0	Strongly disagree	1	3%	95.98%
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree			
		Somewhat agree	3	9%	
		Strongly agree	28	88%	

3.2 Orthotic provision should be considered as a first line rehabilitation intervention for stroke survivors with lower limb tone and/or spasticity					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			91.52%
		Somewhat disagree			
		Disagree	1	3%	
		Neither disagree or agree	1	3%	
		Agree	2	6%	
		Somewhat agree	8	25%	
		Strongly agree	20	63%	

3.3 Orthotic assessment should be considered for any stroke survivor with secondary complication risk factors such as contracture, even if they are non-mobile					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			95.54%
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree	3	9%	
		Somewhat agree	4	13%	
		Strongly agree	25	78%	

3.4 Timely and effective orthotist assessment and orthotic provision can enable a stroke survivors independence and improve their mental health					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			97.77%
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree			
		Somewhat agree	5	16%	
		Strongly agree	27	84%	

3.5 For stroke survivors who are prescribed an orthoses, a routine 6 weeks follow-up appointment should be made to review progress and on-going need					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree	1	3%	83.48%
		Somewhat disagree			
		Disagree	1	3%	
		Neither disagree or agree	1	3%	

		Agree	7	22%	
		Somewhat agree	10	31%	
		Strongly agree	12	38%	

3.6 Any orthoses prescribed to a stroke survivor should be reviewed at appropriate time periods within the first 12 months of rehabilitation to assess changing need					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree	1	3%	90.18%
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree	1	3%	
		Somewhat agree	14	44%	
		Strongly agree	16	50%	

3.7 An orthotic assessment should be available at any stage of a stroke survivors rehabilitation, even if no need was identified early after stroke					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			93.75%
		Somewhat disagree			
		Disagree			
		Neither disagree or agree	4	13%	
		Agree			
		Somewhat agree	11	34%	
		Strongly agree	20	63%	

3.8 Difficulties with speech and/or cognition following stroke should be accommodated in any orthotic assessment and provision					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			93.75%
		Somewhat disagree	1	3%	
		Disagree			
		Neither disagree or agree			
		Agree	2	6%	
		Somewhat agree	5	16%	
		Strongly agree	24	75%	

3.9 Where present, carers should be included in orthotic assessment and provision appointments					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			97.32%
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree	1	3%	
		Somewhat agree	4	13%	
		Strongly agree	27	84%	

3.10 An orthoses prescribed for a stroke survivor should be the most cosmetic and unobtrusive in design that is possible, whilst still meeting the individual functional requirements					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			86.16%
		Somewhat disagree	1	3%	
		Disagree	1	3%	
		Neither disagree or agree	1	3%	
		Agree	5	16%	
		Somewhat agree	9	28%	
		Strongly agree	15	47%	

3.11 Appropriate accommodations should be made to enhance compliance of orthoses use when designing an orthotic prescription such as fitting into footwear etc.					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			92.86%
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree	3	9%	
		Somewhat agree	10	31%	
		Strongly agree	19	60%	

Theme Four – The Orthotic Service

4.1 Orthotics assessment and provision is an integral part of stroke rehabilitation but not a necessity					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree	2	6%	52.23%
		Somewhat disagree	12	38%	
		Disagree	4	13%	
		Neither disagree or agree	3	9%	
		Agree	2	6%	
		Somewhat agree	6	19%	
		Strongly agree	3	9%	

4.2 There should be equity of access to orthotist assessment and orthotic provision across clinical settings (acute hospital, community hospital and community)					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			91.10%
		Somewhat disagree			
		Disagree	1	3%	
		Neither disagree or agree			
		Agree	2	6%	
		Somewhat agree	12	38%	
		Strongly agree	17	53%	

4.3 Orthotic assessment and provision for stroke survivors should be prioritised in orthotic service delivery and referrals actioned with urgency					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			82.14%
		Somewhat disagree			
		Disagree			
		Neither disagree or agree	2	6%	
		Agree	11	34%	
		Somewhat agree	12	38%	
		Strongly agree	7	22%	

4.4 For long-term orthotic users after stroke, a patient or carer should be able to self-refer for further orthotic assessment and review					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			90.63%
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree	2	6%	
		Somewhat agree	17	53%	
		Strongly agree	13	41%	

4.5 Relationships between the core orthotic service and the stroke rehabilitation service should be established and nurtured to enhance stroke survivor's rehabilitation					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			93.75%
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree			
		Somewhat agree	14	44%	
		Strongly agree	18	56%	

4.6 Orthotic services should be planned, commissioned and run to provide specialist individualised assessment and treatment for stroke survivors					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			94.64%
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree	1	3%	
		Somewhat agree	10	31%	
		Strongly agree	21	66%	

4.7 The core orthotic service should be invested in to facilitate the orthotic delivery and treatment for stroke survivors					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?

32	0	Strongly disagree			95.10%
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree	1	3%	
		Somewhat agree	9	28%	
		Strongly agree	22	67%	

Theme Five – Ways of Working

5.1 An orthotist should be included as a member of the core stroke multi-disciplinary rehabilitation (MDT) team					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			93.75%
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree	1	3%	
		Somewhat agree	12	38%	
		Strongly agree	19	59%	

5.2 The orthotist should be included in MDT assessments of stroke survivors with motor control problems and contribute to agreed rehabilitation goals and treatments					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			91.96%
		Somewhat disagree			
		Disagree			
		Neither disagree or agree	1	3%	
		Agree	1	3%	
		Somewhat agree	13	41%	
		Strongly agree	17	53%	

5.3 An orthotic assessment should be conducted as a joint exercise with the specialist skills of the orthotist and therapy staff working together					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			93.30%
		Somewhat disagree			
		Disagree			
		Neither disagree or agree	1	3%	
		Agree	1	3%	
		Somewhat agree	10	31%	
		Strongly agree	20	63%	

5.4 The use of technology to facilitate joint orthotist assessment such as video evidence or pressure plate technology should be utilised within early stroke rehabilitation					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?

32	0	Strongly disagree			75.89%
		Somewhat disagree			
		Disagree	3	9%	
		Neither disagree or agree	6	19%	
		Agree	9	28%	
		Somewhat agree	6	19%	
		Strongly agree	8	25%	

5.5 Inclusion of the orthotist within the stroke rehabilitation MDT enhances knowledge exchange and leads to better professional relationships					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			95.98%
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree			
		Somewhat agree	9	28%	
		Strongly agree	23	72%	

5.6 Orthoses prescription should be undertaken by the orthotist and decided upon using biomechanical principals					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			94.64%
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree	1	3%	
		Somewhat agree	6	19%	
		Strongly agree	25	78%	

5.7 Orthotist assessment and provision following a stroke should take a holistic approach seeking to enable tasks of daily living, promote independence and mental health					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			98.21%
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree			
		Somewhat agree	4	13%	
		Strongly agree	28	87%	

5.8 Access to orthotist led orthotic assessment and/or provision should be equitable regardless of where the stroke survivor is located geographically					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			98.21%
		Somewhat disagree			
		Disagree			

		Neither disagree or agree			
		Agree			
		Somewhat agree	4	13%	
		Strongly agree	28	87%	

5.9 Scope of practice is an important consideration when an orthotic device is prescribed or fitted by a healthcare professional that is not an orthotist					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			96.88
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree	1	3%	
		Somewhat agree	5	16%	
		Strongly agree	26	81%	

5.10 Assessment by an orthotist for patients presenting with mobility difficulties after a stroke should be conducted within the ‘early’ rehabilitation phase (48 hours in line with early mobilising recommendations) ¹					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree	1	3%	69.20%
		Somewhat disagree	2	6%	
		Disagree	4	13%	
		Neither disagree or agree	6	19%	
		Agree	5	16%	
		Somewhat agree	9	28%	
		Strongly agree	5	16%	
1. Langhorne P, Wu O, Rodgers H, Ashburn A, Bernhardt J. A very early rehabilitation trial after stroke (AVERT): a Phase III, multicentre, randomised controlled trial. Health Technol Assess (Rockv). 2017;21(54):1-119. doi:10.3310/hta21540					

5.11 Assessment by an orthotist for patients presenting with mobility difficulties after a stroke should be conducted within the ‘acute’ rehabilitation phase (7 days) ²					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			82.59%
		Somewhat disagree	2	6%	
		Disagree	1	3%	
		Neither disagree or agree	1	3%	
		Agree	6	19%	
		Somewhat agree	10	31%	
		Strongly agree	12	38%	
2. Bernhardt J, Hayward KS, Kwakkel G, et al. Agreed definitions and a shared vision for new standards in stroke recovery research: The Stroke Recovery and Rehabilitation Roundtable taskforce. Int J Stroke. 2017;12(5):444-450.					

5.12 Assessment by an orthotist for patients presenting with mobility difficulties after a stroke should be conducted within the 'early sub-acute' rehabilitation phase (3 months) ²					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?

32	0	Strongly disagree			90.18%
		Somewhat disagree			
		Disagree	2	6%	
		Neither disagree or agree	1	3%	
		Agree	2	6%	
		Somewhat agree	4	13%	
		Strongly agree	23	72%	
2. Bernhardt J, Hayward KS, Kwakkel G, et al. Agreed definitions and a shared vision for new standards in stroke recovery research: The Stroke Recovery and Rehabilitation Roundtable taskforce. Int J Stroke. 2017;12(5):444-450.					

5.13 Orthotist assessment and appropriate provision within early gait rehabilitation is an essential mechanism to avoid compensatory patterns being developed such as over extension at the knee or hip-hiking					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			93.30%
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree	3	9%	
		Somewhat agree	9	28%	
		Strongly agree	20	63%	

5.14 Screening tools can be used by other healthcare professionals to help identify if a stroke survivor will benefit from an orthotic assessment and/or provision					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			89.29%
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree	4	13%	
		Somewhat agree	16	50%	
		Strongly agree	12	37%	

5.15 Outcome measures should be used to determine effect of orthotic provision following stroke					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			95.10%
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree	1	3%	
		Somewhat agree	9	28%	
		Strongly agree	22	69%	

5.16 Requests from other health care professionals for orthotic assessment and/or provision should take the form of referral for assessment rather than a prescription with specified orthoses					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			98.21%

		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree			
		Somewhat agree	4	13%	
		Strongly agree	28	87%	

5.17 Referral for orthotic assessment should be considered for stroke survivors who present with severe impairment where an orthoses may aid in comfort, enable transfer and assist in care delivery					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			97.77%
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree	1	3%	
		Somewhat agree	3	9%	
		Strongly agree	28	87%	

5.18 Stroke services should have a specific referral pathway for orthotic assessment and provision for patients once discharged from the acute hospital setting					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			94.64%
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree	3	9%	
		Somewhat agree	6	19%	
		Strongly agree	23	72%	

5.19 There should be training for non-therapy acute and sub-acute clinical staff such as nurses and health care assistants on how to correctly put on, remove and use common types of orthotic device such Ankle-Foot Orthoses					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
32	0	Strongly disagree			95.10%
		Somewhat disagree			
		Disagree			
		Neither disagree or agree	1	3%	
		Agree	1	3%	
		Somewhat agree	6	19%	
		Strongly agree	24	75%	

Appendix W. Original and revised eDelphi statements

Theme One – The Orthotist	
Original statement (round 1)	1. The orthotist is an important member of the stroke rehabilitation clinical team
Revised statement (round 2)	1. The orthotist is an integral member of the stroke rehabilitation clinical team
Original statement (round 1)	2. All patients who have experienced a stroke affecting motor control would benefit from having an orthotist assessment
Revised statement (round 2)	2. All patients who have experienced a stroke affecting motor control should have an orthotist assessment
Original statement (round 1)	5. The orthotist should lead the orthotics assessment and any subsequent orthotics provision for stroke survivors
Revised statement (round 2)	5. The orthotist should lead the orthotics assessment and any subsequent orthotics provision for stroke survivors who require it
Original statement (round 1)	6. When not embedded within a stroke clinical unit, please select how regularly you think the orthotist should be in attendance to assess and treat patients: - Every day - 2-3 days a week - Once a week (weekly) - Every other week (bi-weekly) - Once a month (monthly) - Less than once a month
Revised statement (round 2)	6. When not embedded within a stroke rehabilitation unit or community team , the orthotist should attend to assess and treat patients at a minimum of : - 2-3 days a week - Once a week (weekly) - Every other week (bi-weekly)
Original statement (round 1)	8. Where an orthoses has been prescribed it should be the same orthotist who fits and trials that device with the stroke survivor

Revised statement (round 2)	8. Orthotist continuity of care when an orthoses has been prescribed following stroke is the ideal
Original statement (round 1)	9. The stroke survivor should be reviewed by the same orthotist that prescribed and fitted the orthotic device for consistency and continuity of care
Revised statement (round 2)	9. The prescribed orthoses should be reviewed by either the same orthotist or another orthotist from the same team to facilitate collective learning and development of practices
Theme Two – The Orthoses	
Original statement (round 1)	3. Any orthotic provision following stroke should be assessed for and prescribed with the intent of 'right first time'
Revised statement (round 2)	3. Any orthoses provided following stroke should be done so with the intent of 'right first time', to include adjustments and new provision if indicated to address changes in clinical need.
Original statement (round 1)	5. The time between assessment and provision of any orthoses for an early rehabilitation stroke survivor should be less than 14 days
Revised statement (round 2)	5. For new users of an early rehabilitation stroke orthoses, the time between assessment and first provision should be less than 14 days
Original statement (round 1)	8. Orthotic intervention in early post stroke treatment can contribute to a 24 hour therapy model of rehabilitation
Revised statement (round 2)	8. Orthotic intervention early post stroke can contribute to a 24 hour therapy model of rehabilitation
Original statement (round 1)	10. Following provision of an orthoses all stroke survivors should have the option of tuning to ensure the best functionality and usability
Revised statement (round 2)	10. Following provision of an orthoses post stroke, tuning should be optimised to ensure the best functionality and usability for the patient
Original statement (round 1)	12. Availability of any orthoses for stroke survivors should not be determined by cost and its prescription should be driven by functional need
Revised statement (round 2)	12. Provision of any orthoses for stroke survivors should not be determined by cost or convenience and its prescription should be driven by functional need
Original statement (round 1)	13. Custom and personalised orthoses prescriptions should be considered at the first instance over prefabricated orthoses for stroke survivors

Revised statement (round 2)	13. Custom and personalised orthoses are a preferable prescription in patients with complex gait abnormalities or deformities
Original statement (round 1)	14. Pre-fabricated orthoses have a valid place within orthotic provision post stroke but should be managed carefully for appropriateness for each individual
Revised statement (round 2)	14. Pre-fabricated orthoses are a valid and useful orthotic provision post stroke especially as temporary or an assessment devices but should be managed carefully
Original statement (round 1)	15. Provision of pre-fabricated orthoses should be overseen by an orthotist or appropriately trained healthcare professional
Revised statement (round 2)	15. Provision of pre-fabricated orthoses should be overseen by an orthotist or appropriately trained healthcare professional with suitable competencies
Original statement (round 1)	16. Information regarding any provided orthoses should be given in both verbal and written formats to stroke survivors
Revised statement (round 2)	16. Information regarding any provided orthoses should be given in both verbal and written formats to stroke survivors and their carers
Theme Three – The Patient	
Original statement (round 1)	3. Orthotic assessment should be considered for any stroke survivor with secondary complication risk factors such as contracture, even if they are non-mobile
Revised statement (round 2)	3. Orthotic assessment should be offered for any stroke survivor with secondary complication risk factors such as contracture, even if they are non-mobile
Original statement (round 1)	Originally placed within Theme Five – Ways of Working
Revised statement (round 2)	4. Orthotic assessment and provision should be considered in early gait rehabilitation to avoid compensatory patterns being developed such as over extension at the knee or hip-hiking
Original statement (round 1)	4. Timely and effective orthotist assessment and orthotic provision can enable a stroke survivors independence and improve their mental health
Revised statement (round 2)	5. Timely and effective orthotist assessment and orthotic provision can enable a stroke survivors independence, quality of life and improve their mental health

Original statement (round 1)	5. For stroke survivors who are prescribed an orthoses, a routine 6 weeks follow-up appointment should be made to review progress and on-going need
Revised statement (round 2)	6. For stroke survivors who are prescribed an orthoses, a routine follow-up appointment should be made to review progress and on-going need
Original statement (round 1)	10. An orthoses prescribed for a stroke survivor should be the most cosmetic and unobtrusive in design that is possible, whilst still meeting the individual functional requirements
Revised statement (round 2)	11. An orthoses prescribed for a stroke survivor should be the most cosmetic and unobtrusive in design that is possible, whilst still meeting the individual functional requirements and being cost-effective
Original statement (round 1)	New statement developed by splitting previous statements and following thematic review of participant feedback
Revised statement (round 2)	13. Appropriate orthotic provision for stroke survivors should positively influence mobility and independence
Theme Four – The Orthotic Service	
Original statement (round 1)	1. Orthotics assessment and provision is an integral part of stroke rehabilitation service but not a necessity
Revised statement (round 2)	1. Orthotics assessment and provision should be an integral part of a stroke rehabilitation service
Original statement (round 1)	3. Orthotic assessment and provision for stroke survivors should be prioritised in orthotic service delivery and referrals actioned with urgency
Revised statement (round 2)	3. Orthotic assessment and provision for stroke survivors should have a degree of priority alongside other more complex patient groups in orthotic service delivery and referrals
Theme Five – Ways of Working	
Original statement (round 1)	4. The use of technology to facilitate joint orthotist assessment such as video evidence or pressure plate technology should be utilised within early stroke rehabilitation
Revised statement (round 2)	4. The use of technology to facilitate joint orthotist assessment such as video evidence or pressure plate technology can be helpful within early stroke rehabilitation
Original statement (round 1)	6. Orthoses prescription should be undertaken by the orthotist and decided upon using biomechanical principals

Revised statement (round 2)	6. Orthoses prescription should be decided upon using biomechanical principals and lead by the orthotist
Original statement (round 1)	9. Scope of practice is an important consideration when an orthotic device is prescribed or fitted by a healthcare professional that is not an orthotist
Revised statement (round 2)	9. Scope of practice is an important consideration when an orthotic device is prescribed or fitted by a healthcare professional that is not an orthotist and appropriate competencies must be met
Original statement (round 1)	(Three separate statements) 10./11./12. Assessment by an orthotist for patients presenting with mobility difficulties after a stroke should be conducted within the 'early rehabilitation phase (48 hours)'/ acute rehabilitation phase (7 days)'/ 'early sub-acute rehabilitation phase (3 months)'
Revised statement (round 2)	10. Assessment by an orthotist for patients presenting with mobility difficulties after a stroke should be conducted within: - The 'acute' rehabilitation phase (7 days) - The 'early sub-acute' rehabilitation phase (3 months) - Other defined time period, please specify:
Original statement (round 1)	14. Screening tools can be used by other healthcare professionals to help identify if a stroke survivor will benefit from an orthotic assessment and/or provision
Revised statement (round 2)	11. Standardised screening tools are a useful method for other healthcare professionals to help identify if a stroke survivor will benefit from an orthotic assessment and/or provision
Original statement (round 1)	16. Requests from other health care professionals for orthotic assessment and/or provision should take the form of referral for assessment rather than a prescription with specified orthoses
Revised statement (round 2)	13. Requests from other health care professionals for orthotic assessment and/or provision should take the form of referral for assessment with goal/objective rather than a prescription with specified orthoses

Appendix X. eDelphi round two detailed consensus statistics

Theme One – The Orthotist

Key:	
Statement consensus reached (>75%)	Statement consensus not reached (<75%)

1.1 The orthotist is an integral member of the stroke rehabilitation clinical team					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			91.84% <i>Include Round one statement</i>
		Somewhat disagree			
		Disagree	1	3.5%	
		Neither disagree or agree			
		Agree	1	3.5%	
		Somewhat agree	10	36%	
		Strongly agree	16	57%	

1.2 All patients who have experienced a stroke affecting motor control should have an orthotist assessment					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			83.67% <i>Include Round one statement</i>
		Somewhat disagree			
		Disagree			
		Neither disagree or agree	2	7%	
		Agree	6	21%	
		Somewhat agree	14	50%	
		Strongly agree	6	21%	

1.3 Where an orthotist is not embedded within the stroke clinical unit, regular orthotist contact is important to facilitate timely assessment and treatment					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			91.84% <i>Include Round one statement</i>
		Somewhat disagree			
		Disagree			
		Neither disagree or agree	1	4%	
		Agree	2	7%	
		Somewhat agree	9	32%	
		Strongly agree	16	57%	

1.4 Regular orthotist contact with the stroke unit is important to facilitate knowledge exchange, advice giving and provide training					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			94.39% <i>Include Round one statement</i>
		Somewhat disagree			
		Disagree			
		Neither disagree or agree	1	4%	

		Agree			
		Somewhat agree	8	28%	
		Strongly agree	19	68%	

1.5 The orthotist should lead the orthotics assessment and any subsequent orthotics provision for stroke survivors who require it					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			94.90% <i>Include Round one statement</i>
		Somewhat disagree			
		Disagree	1	4%	
		Neither disagree or agree			
		Agree			
		Somewhat agree	6	21%	
		Strongly agree	21	75%	

1.6 When not embedded within a stroke rehabilitation unit or community team, the orthotist should attend to assess and treat patients at a minimum of:					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	2-3 days a week	6	21%	75% minimum of once weekly or more frequently
		Once a week (weekly)	15	54%	
		Every other week (bi-weekly)	7	25%	

1.7 Consistency of approach between orthotists in their assessment and treatment is important to ensure equitable treatment for stroke survivors					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			90.31% <i>Include Round two statement</i>
		Somewhat disagree			
		Disagree	1	4%	
		Neither disagree or agree			
		Agree	4	14%	
		Somewhat agree	7	25%	
		Strongly agree	16	57%	

1.8 Orthotist continuity of care when an orthoses has been prescribed following stroke is the ideal					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			93.37% <i>Include Round two statement</i>
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree	3	11%	
		Somewhat agree	7	25%	
		Strongly agree	18	64%	

1.9 The prescribed orthoses should be reviewed by either the same orthotist or another orthotist from the same team to facilitate collective learning and development of practices					

# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			91.84% <i>Include Round two statement</i>
		Somewhat disagree			
		Disagree			
		Neither disagree or agree	1	4%	
		Agree	3	11%	
		Somewhat agree	7	25%	
		Strongly agree	17	60%	

1.10 Orthotists should have the opportunity to specialise in specific conditions such as neurological rehabilitation					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			91.84% <i>Include Round two statement</i>
		Somewhat disagree			
		Disagree			
		Neither disagree or agree	1	4%	
		Agree	2	7%	
		Somewhat agree	9	32%	
		Strongly agree	16	57%	

1.11 There should be stroke specific training available to pre-registration and post-registration orthotists to establish an agreed pathway of treatment for stroke survivors to encourage conformity across settings					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			94.90% <i>Include Round two statement</i>
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree	1	4%	
		Somewhat agree	8	28%	
		Strongly agree	19	68%	

1.12 The orthotist should be involved in the planning, commissioning and provision of stroke rehabilitation services					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			90.82% <i>Include Round two statement</i>
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree	3	11%	
		Somewhat agree	12	43%	
		Strongly agree	13	46%	

Theme Two – The Orthoses

2.1 Orthotic principals such as biomechanics are important considerations when deciding on a stroke survivors rehabilitation treatment plan					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			96.43%

		Somewhat disagree			Include Round one statement
		Disagree			
		Neither disagree or agree			
		Agree			
		Somewhat agree	7	25%	
		Strongly agree	21	75%	

2.2 Ankle Foot Orthoses (AFOs) should be considered for stroke survivors with mobility problems					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			92.86% Include Round one statement
		Somewhat disagree			
		Disagree			
		Neither disagree or agree	1	4%	
		Agree	2	7%	
		Somewhat agree	7	25%	
		Strongly agree	18	64%	

2.3 Any orthoses provided following stroke should be done so with the intent of 'right first time', to include adjustments and new provision if indicated to address changes in clinical need					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			91.84% Include Round two statement
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree	2	7%	
		Somewhat agree	12	43%	
		Strongly agree	14	50%	

2.4 Orthoses prescribed for stroke survivors should be considered a rehabilitation tool in their tool box					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			93.37% Include Round two statement
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree	1	4%	
		Somewhat agree	11	39%	
		Strongly agree	16	57%	

2.5 For new users of an early rehabilitation stroke orthoses, the time between assessment and first provision should be less than 14 days					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			92.86% Include Round two statement
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree	2	7%	
		Somewhat agree	10	36%	

		Strongly agree	16	57%	

2.6 Appropriate orthotic provision for stroke survivors can positively influence stance phase and swing phase limb alignment during mobilising					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			97.96% <i>Include Round one statement</i>
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree			
		Somewhat agree	4	14%	
		Strongly agree	24	86%	

2.7 Orthoses in early post stroke rehabilitation can be used to increase dosage of therapeutic alignment and intervention when hands on therapist time is limited or unavailable					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			92.86% <i>Include Round one statement</i>
		Somewhat disagree			
		Disagree	1	3.5%	
		Neither disagree or agree			
		Agree	1	3.5%	
		Somewhat agree	8	29%	
		Strongly agree	18	64%	

2.8 Orthotic intervention early post stroke can contribute to a 24 hour therapy model of rehabilitation					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			91.33% <i>Include Round two statement</i>
		Somewhat disagree			
		Disagree			
		Neither disagree or agree	1	4%	
		Agree	2	7%	
		Somewhat agree	10	36%	
		Strongly agree	15	53%	

2.9 Early orthotic use ensuring correct alignment and normal movement can assist with neuroplasticity retraining of mobility					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			93.37% <i>Include Round two statement</i>
		Somewhat disagree			
		Disagree			
		Neither disagree or agree	1	3.5%	
		Agree	1	3.5%	
		Somewhat agree	8	29%	
		Strongly agree	18	64%	

2.10 Following provision of an orthoses post stroke, tuning should be optimised to ensure the best functionality and usability for the patient					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			96.43% <i>Include Round two statement</i>
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree			
		Somewhat agree	7	25%	
		Strongly agree	21	75%	

2.11 Availability of orthoses type (custom, prefabricated, material etc.) should be equitable for all stroke survivors regardless of location					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			97.96% <i>Include Round one statement</i>
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree			
		Somewhat agree	4	14%	
		Strongly agree	24	86%	

2.12 Provision of any orthoses for stroke survivors should not be determined by cost or convenience and its prescription should be driven by functional need					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree	1	4%	93.37% <i>Include Round one statement</i>
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree	2	7%	
		Somewhat agree	3	11%	
		Strongly agree	22	78%	

2.13 Custom and personalised orthoses are a preferable prescription in patients with complex gait abnormalities or deformities					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			86.73% <i>Include Round two statement</i>
		Somewhat disagree			
		Disagree			
		Neither disagree or agree	2	7%	
		Agree	8	29%	
		Somewhat agree	4	14%	
		Strongly agree	14	50%	

2.14 Pre-fabricated orthoses are a valid and useful orthotic provision post stroke but should be managed carefully for appropriateness for each individual					

# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			95.41% <i>Include Round two statement</i>
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree	2	7%	
		Somewhat agree	5	18%	
		Strongly agree	21	75%	

2.15 Provision of pre-fabricated orthoses should be overseen by an orthotist or appropriately trained healthcare professional with suitable competencies					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			95.41% <i>Include Round two statement</i>
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree	1	4%	
		Somewhat agree	7	25%	
		Strongly agree	20	71%	

2.16 Information regarding any provided orthoses should be given in both verbal and written formats to stroke survivors and their carers					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			97.45% <i>Include Round two statement</i>
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree			
		Somewhat agree	5	18%	
		Strongly agree	23	82%	

Theme Three – The Patient

3.1 All stroke survivors with mobility problems should be assessed by an orthotist in a timely and equitable manner					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree	1	3.5%	90.31% <i>Include Round one statement</i>
		Somewhat disagree			
		Disagree			
		Neither disagree or agree	1	3.5%	
		Agree			
		Somewhat agree	10	36%	
		Strongly agree	16	57%	

3.2 Orthotic provision should be considered as a first line rehabilitation intervention for stroke survivors with lower limb tone and/or spasticity					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?

28	0	Strongly disagree			90.82% <i>Include Round one statement</i>
		Somewhat disagree			
		Disagree			
		Neither disagree or agree	1	4%	
		Agree	3	11%	
		Somewhat agree	9	32%	
		Strongly agree	15	54%	

3.3 Orthotic assessment should be offered for any stroke survivor with secondary complication risk factors such as contracture, even if they are non-mobile					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			94.39% <i>Include Round one statement</i>
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree	2	7%	
		Somewhat agree	7	25%	
		Strongly agree	19	68%	

3.4 Orthotic assessment and provision should be considered in early gait rehabilitation to avoid compensatory patterns being developed such as over extension at the knee or hip-hiking					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			96.94% <i>Include Round two statement</i>
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree			
		Somewhat agree	6	21%	
		Strongly agree	22	79%	

3.5 Timely and effective orthotist assessment and orthotic provision can enable a stroke survivors independence, quality of life and improve their mental health					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			96.43% <i>Include Round one statement</i>
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree			
		Somewhat agree	7	25%	
		Strongly agree	21	75%	

3.6 For stroke survivors who are prescribed an orthosis, a routine follow-up appointment should be made to review progress and on-going need					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			91.84% <i>Include Round two statement</i>
		Somewhat disagree			
		Disagree			

		Neither disagree or agree	1	4%	
		Agree	3	11%	
		Somewhat agree	7	25%	
		Strongly agree	17	60%	

3.7. Any orthoses prescribed to a stroke survivor should be reviewed at appropriate time periods within the first 12 months of rehabilitation to assess changing need					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			92.35% <i>Include Round two statement</i>
		Somewhat disagree			
		Disagree	1	3.5%	
		Neither disagree or agree			
		Agree	1	3.5%	
		Somewhat agree	9	32%	
		Strongly agree	17	61%	

3.8 An orthotic assessment should be available at any stage of a stroke survivors' rehabilitation, even if no need was identified early after stroke					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			94.90% <i>Include Round two statement</i>
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree	3	11%	
		Somewhat agree	4	14%	
		Strongly agree	21	75%	

3.9 Difficulties with speech and/or cognition following stroke should be accommodated in any orthotic assessment and provision					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			93.88% <i>Include Round two statement</i>
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree	1	4%	
		Somewhat agree	10	35%	
		Strongly agree	17	61%	

3.10 Where present, carers should be included in orthotic assessment and provision appointments					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			94.90% <i>Include Round one statement</i>
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree			
		Somewhat agree	10	35%	
		Strongly agree	18	65%	

3.11 An orthoses prescribed for a stroke survivor should be the most cosmetic and unobtrusive in design that is possible, whilst still meeting the individual functional requirements and being cost-effective					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			87.76% <i>Include Round two statement</i>
		Somewhat disagree	1	3.5%	
		Disagree			
		Neither disagree or agree	1	3.5%	
		Agree	3	11%	
		Somewhat agree	10	35%	
		Strongly agree	13	47%	

3.12 Appropriate accommodations should be made to enhance compliance of orthoses use when designing an orthotic prescription such as fitting into footwear etc.					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			93.88% <i>Include Round two statement</i>
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree			
		Somewhat agree	12	53%	
		Strongly agree	16	57%	

3.13 Appropriate orthotic provision for stroke survivors should positively influence mobility and independence					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			97.45% <i>Include Round two statement</i>
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree			
		Somewhat agree	5	18%	
		Strongly agree	23	82%	

Theme Four – The Orthotic Service

4.1 Orthotics assessment and provision should be an integral part of a stroke rehabilitation service					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			95.41% <i>Include Round two statement</i>
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree	1	4%	
		Somewhat agree	7	25%	
		Strongly agree	20	71%	

4.2 There should be equity of access to orthotist assessment and orthotic provision across clinical settings (acute hospital, community hospital and community)					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			95.92% <i>Include Round two statement</i>
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree	2	7%	
		Somewhat agree	4	14%	
		Strongly agree	22	79%	

4.3 Orthotic assessment and provision for stroke survivors should have a degree of priority alongside other more complex patient groups in orthotic service delivery and referrals					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			91.84% <i>Include Round two statement</i>
		Somewhat disagree			
		Disagree	1	3.5%	
		Neither disagree or agree			
		Agree	1	3.5%	
		Somewhat agree	10	36%	
		Strongly agree	16	57%	

4.4 For long-term orthotic users after stroke, a patient or carer should be able to self-refer for further orthotic assessment and review					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			92.86% <i>Include Round two statement</i>
		Somewhat disagree			
		Disagree			
		Neither disagree or agree	2	7%	
		Agree	1	4%	
		Somewhat agree	6	21%	
		Strongly agree	19	68%	

4.5 Relationships between the core orthotic service and the stroke rehabilitation service should be established and nurtured to enhance stroke survivor's rehabilitation					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			95.41% <i>Include Round two statement</i>
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree			
		Somewhat agree	9	32%	
		Strongly agree	19	68%	

4.6 Orthotic services should be planned, commissioned and run to provide specialist individualised assessment and treatment for stroke survivors					

# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			96.94% <i>Include Round two statement</i>
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree			
		Somewhat agree	6	21%	
		Strongly agree	22	79%	

4.7 The core orthotic service should be invested in to facilitate the orthotic delivery and treatment for stroke survivors					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			96.43% <i>Include Round two statement</i>
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree			
		Somewhat agree	7	25%	
		Strongly agree	21	75%	

Theme Five – Ways of Working

5.1 An orthotist should be included as a member of the core stroke multi-disciplinary rehabilitation (MDT) team					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			93.37% <i>Include Round one statement</i>
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree	2	7%	
		Somewhat agree	9	32%	
		Strongly agree	17	61%	

5.2 The orthotist should be included in MDT assessments of stroke survivors with motor control problems and contribute to agreed rehabilitation goals and treatments					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			93.37% <i>Include Round two statement</i>
		Somewhat disagree			
		Disagree			
		Neither disagree or agree	1	3.5%	
		Agree	1	3.5%	
		Somewhat agree	8	29%	
		Strongly agree	18	64%	

5.3 An orthotic assessment should be conducted as a joint exercise with the specialist skills of the orthotist and therapy staff working together					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			94.90%

		Somewhat disagree			Include Round two statement
		Disagree			
		Neither disagree or agree			
		Agree	1	4%	
		Somewhat agree	8	29%	
		Strongly agree	19	67%	

5.4 The use of technology to facilitate joint orthotist assessment such as video evidence or pressure plate technology can be helpful within early stroke rehabilitation					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			85.71% Include Round two statement
		Somewhat disagree			
		Disagree			
		Neither disagree or agree	2	7%	
		Agree	7	25%	
		Somewhat agree	8	29%	
		Strongly agree	11	39%	

5.5 Inclusion of the orthotist within the stroke rehabilitation MDT enhances knowledge exchange and leads to better professional relationships					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			96.43% Include Round two statement
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree			
		Somewhat agree	7	25%	
		Strongly agree	21	75%	

5.6 Orthoses prescription should be decided upon using biomechanical principals and led by the orthotist					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			96.94% Include Round two statement
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree			
		Somewhat agree	6	21%	
		Strongly agree	22	79%	

5.7 Orthotist assessment and provision following a stroke should take a holistic approach seeking to enable tasks of daily living, promote independence and mental health					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			98.98% Include Round two statement
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree			

		Somewhat agree	2	7%	
		Strongly agree	26	93%	

5.8 Access to orthotist led orthotic assessment and/or provision should be equitable regardless of where the stroke survivor is located geographically					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree	1	4%	95.41% <i>Include Round one statement</i>
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree			
		Somewhat agree	3	11%	
		Strongly agree	24	85%	

5.9 Scope of practice is an important consideration when an orthotic device is prescribed or fitted by a healthcare professional that is not an orthotist and appropriate competencies must be met					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			97.45% <i>Include Round two statement</i>
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree			
		Somewhat agree	5	18%	
		Strongly agree	23	82%	

5.10 Assessment by an orthotist for patients presenting with mobility difficulties after a stroke should be conducted within:					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	The 'acute' rehabilitation phase (7 days)	14	50%	93% within the 'acute' (7 days) and 'early sub-acute' (3 months) rehabilitation phase after stroke
		The 'early sub-acute' rehabilitation phase (3 months)	12	43%	
		Other defined time period, please specify:	2	7%	

5.11 Standardised screening tools are a useful method for other healthcare professionals to help identify if a stroke survivor will benefit from an orthotic assessment and/or provision					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			85.71% <i>Include Round one statement</i>
		Somewhat disagree	1	4%	
		Disagree			
		Neither disagree or agree	2	7%	
		Agree	4	14%	
		Somewhat agree	9	32%	
		Strongly agree	12	43%	

5.12 Outcome measures should be used to determine effect of orthotic provision following stroke					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			95.92% <i>Include Round two statement</i>
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree	1	4%	
		Somewhat agree	6	21%	
		Strongly agree	21	75%	

5.13 Requests from other health care professionals for orthotic assessment and/or provision should take the form of referral for assessment with goal/objective rather than a prescription with specified orthoses					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			97.96% <i>Include Round one statement</i>
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree	1	4%	
		Somewhat agree	2	7%	
		Strongly agree	25	89%	

5.14 Referral for orthotic assessment should be considered for stroke survivors who present with severe impairment where an orthoses may aid in comfort, enable transfer and assist in care delivery					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			96.94% <i>Include Round one statement</i>
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree	1	4%	
		Somewhat agree	4	14%	
		Strongly agree	23	82%	

5.15 Stroke services should have a specific referral pathway for orthotic assessment and provision for patients once discharged from the acute hospital setting					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?
28	0	Strongly disagree			96.43% <i>Include Round two statement</i>
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree			
		Somewhat agree	7	25%	
		Strongly agree	21	75%	

5.16 There should be training for non-therapy acute and sub-acute stroke clinical staff such as nurses and health care assistants on how to correctly put on, remove and use common types of orthotic device such Ankle-Foot Orthoses					
# of responses	# of comments	Ranking	Frequency	Percentage	Consensus reached?

28	0	Strongly disagree			97.96% <i>Include Round two statement</i>
		Somewhat disagree			
		Disagree			
		Neither disagree or agree			
		Agree			
		Somewhat agree	4	14%	
		Strongly agree	24	86%	