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<https://doi.org/10.3310/hta20550>

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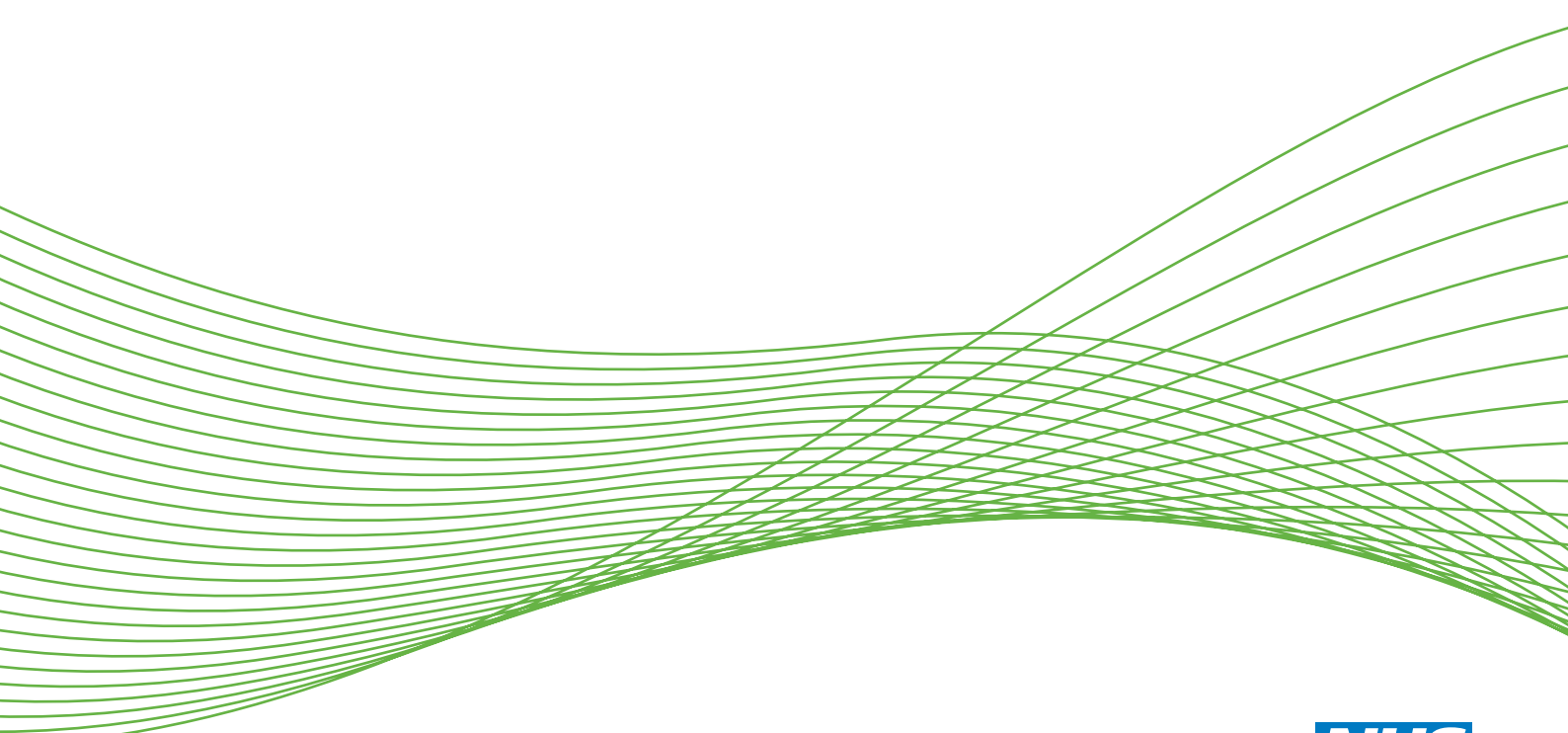
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## Orthotic management of instability of the knee related to neuromuscular and central nervous system disorders: systematic review, qualitative study, survey and costing analysis

*Joanne O'Connor, Dorothy McCaughan, Catriona McDaid, Alison Booth, Debra Fayter, Rocio Rodriguez-Lopez, Roy Bowers, Lisa Dyson, Cynthia P Iglesias, Simon Lalor, Rory J O'Connor, Margaret Phillips and Gita Ramdharry*



**National Institute for  
Health Research**



# Orthotic management of instability of the knee related to neuromuscular and central nervous system disorders: systematic review, qualitative study, survey and costing analysis

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**Declared competing interests of authors:** During this study Simon Lalor was an employee of Opcare, a company that provides orthotic and prosthetic services to the UK NHS. This company does not manufacture orthotic devices, although a sister company ORTHO C FAB does. Cynthia Iglesias is a member of the National Institute for Health and Care Excellence Medical Technologies Assessment Committee and member of the European Clinical Research Infrastructure Network.

Published July 2016

DOI: 10.3310/hta20550





This report should be referenced as follows:

O'Connor J, McCaughan D, McDaid C, Booth A, Fayter D, Rodriguez-Lopez R, *et al.* Orthotic management of instability of the knee related to neuromuscular and central nervous system disorders: systematic review, qualitative study, survey and costing analysis. *Health Technol Assess* 2016;**20**(55).

*Health Technology Assessment* is indexed and abstracted in *Index Medicus/MEDLINE*, *Excerpta Medica/EMBASE*, *Science Citation Index Expanded (SciSearch®)* and *Current Contents®/Clinical Medicine*.



ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 4.058

*Health Technology Assessment* is indexed in MEDLINE, CINAHL, EMBASE, The Cochrane Library and the ISI Science Citation Index.

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) ([www.publicationethics.org/](http://www.publicationethics.org/)).

Editorial contact: [nhredit@southampton.ac.uk](mailto:nhredit@southampton.ac.uk)

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## This report

The research reported in this issue of the journal was funded by the HTA programme as project number 13/30/02. The contractual start date was in April 2014. The draft report began editorial review in July 2015 and was accepted for publication in November 2015. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

This report presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health.

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# Abstract

## Orthotic management of instability of the knee related to neuromuscular and central nervous system disorders: systematic review, qualitative study, survey and costing analysis

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**Background:** Patients who have knee instability that is associated with neuromuscular disease (NMD) and central nervous system (CNS) conditions can be treated using orthoses, such as knee–ankle–foot orthoses (KAFOs).

**Objectives:** To assess existing evidence on the effectiveness of orthoses; patient perspectives; types of orthotic devices prescribed in the UK NHS; and associated costs.

**Methods:** Qualitative study of views of orthoses users – a qualitative in-depth interview study was undertaken. Data were analysed for thematic content. A coding scheme was developed and an inductive approach was used to identify themes. Systematic review – 18 databases were searched up to November 2014: MEDLINE, MEDLINE In-Process & Other Non-Indexed Citations, Cumulative Index to Nursing and Allied Health, EMBASE, PASCAL, Scopus, Science Citation Index, BIOSIS Previews, Physiotherapy Evidence Database, Recal Legacy, Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects, Health Technology Assessment database, Cochrane Central Register of Controlled Trials, Conference Proceedings Citation Index: Science, Health Management Consortium, ClinicalTrials.gov, International Clinical Trials Registry Platform and National Technical Information Service. Studies of adults using an orthosis for instability of the knee related to NMD or a CNS disorder were included. Data were extracted and quality was assessed by two researchers. Narrative synthesis was undertaken. Survey and costing analysis – a web survey of orthotists, physiotherapists and rehabilitation medicine physicians was undertaken. Telephone interviews with orthotists informed a costing analysis.

**Results:** Qualitative study – a total of 24 people participated. Potential for engagement in daily activities was of vital importance to patients; the extent to which their device enabled this was the yardstick by which it was measured. Patients' prime desired outcome was a reduction in pain, falls or trips, with improved balance and stability. Effectiveness, reliability, comfort and durability were the most valued features of orthoses. Many expressed frustration with perceived deficiencies in service provision relating to appointment and administrative systems and referral pathways. Systematic review – a total of 21 studies (478 participants) were included of people who had post-polio syndrome, inclusion body myositis, were post stroke or had spinal cord injury. The studies evaluated KAFOs (mainly carbon fibre), stance control KAFO and hip KAFOs. All of the studies were at risk of bias and, in general, were poorly reported. Survey and costing analysis – in total, 238 health-care professionals responded. A range of orthoses is prescribed for knee instability that is related to NMD or CNS conditions, approximately half being custom-made. At least 50% of respondents thought that comfort and confidence in mobility were extremely important treatment outcomes. The cost of individual KAFOs was highly variable, ranging from £73 to £3553.

**Conclusions:** Various types of orthoses are used in the NHS to manage patients with NMD/CNS conditions and knee instability, both custom-made and prefabricated, of variable cost. Evidence on the effectiveness of the orthoses is limited, especially in relation to the outcomes that are important to orthoses users.

**Limitations:** The population included was broad, limiting any in-depth consideration of specific conditions. The response rate to the survey was low, and the costing analysis was based on some assumptions that may not reflect the true costs of providing KAFOs.

**Future work:** Future work should include high-quality research on the effectiveness and cost-effectiveness of orthoses; development of a core set of outcome measures; further exploration of the views and experiences of patients; and the best models of service delivery.

**Study registration:** This study is registered as PROSPERO CRD42014010180. The qualitative study is registered as Current Controlled Trials ISRCTN65240228.

**Funding:** The National Institute for Health Research Health Technology Assessment programme.

# Contents

<b>List of tables</b>	<b>xv</b>
<b>List of figures</b>	<b>xix</b>
<b>List of abbreviations</b>	<b>xxi</b>
<b>Plain English summary</b>	<b>xxiii</b>
<b>Scientific summary</b>	<b>xxv</b>
<b>Chapter 1 Background</b>	<b>1</b>
Introduction	1
Neuromuscular disease	1
Knee instability in neuromuscular disease	1
Orthotic devices for knee instability	2
Provision of orthoses	4
Patient perspective	4
Previous research on effectiveness	5
Aims and objectives	6
<b>Chapter 2 Methods</b>	<b>7</b>
Overview	7
Systematic review	7
<i>Selection criteria and searching</i>	7
<i>Search strategy</i>	8
<i>Data extraction</i>	9
<i>Assessment of risk of bias</i>	9
<i>Analysis and synthesis</i>	9
Qualitative study of patient views	10
<i>Ethics considerations</i>	10
<i>Study design</i>	10
<i>Conduct of qualitative interviews</i>	10
<i>Data sources</i>	11
<i>Modes of analysis/interpretation</i>	12
Survey of health-care professionals	13
<i>Survey</i>	13
<i>Questionnaire development</i>	14
<i>Survey distribution</i>	15
Costing analysis	15
<i>Identification of resource-use estimates</i>	15
<i>Identification of cost estimates</i>	16
Patient and public involvement	17
<b>Chapter 3 Results of systematic review</b>	<b>19</b>
Study selection	19
Characteristics of included studies	20
Study quality	22



Results from studies of patients with post-polio syndrome	26
<i>Patient-reported outcomes</i>	28
<i>Objective assessments</i>	30
<i>Resource utilisation</i>	31
<i>Adverse effects</i>	31
Results from studies of patients with inclusion body myositis	31
<i>Patient-reported outcomes</i>	31
<i>Objective outcomes</i>	33
Results from studies of post-stroke patients	33
<i>Patient-reported outcome</i>	33
<i>Objective assessments</i>	35
Results from studies of patients with spinal cord injury	35
<i>Hip guidance orthosis: ParaWalker</i>	37
<i>Hip guidance orthosis: Walkabout orthosis</i>	39
<b>Chapter 4 Results of qualitative study of orthoses users' perspectives</b>	<b>43</b>
Sample characteristics	43
Impact of neuromuscular disease and central nervous system conditions on walking and mobility	43
Use of orthotic devices	46
Wearing orthotic devices	47
Use of mobility aids	48
Fitting/acquisition of orthotic devices	50
<i>Fitting/acquisition of knee–ankle–foot orthoses</i>	50
<i>Fitting/acquisition of ankle–foot orthoses</i>	52
<i>Acquisition of knee braces</i>	53
How use of orthotic devices (knee–ankle–foot orthosis, ankle–foot orthosis, knee brace) may impact on skin	54
Positive and negative aspects of orthotic devices	55
<i>Positive aspects of devices</i>	55
<i>Negative aspects of devices</i>	56
Appearance connected to orthoses	60
Footwear	63
Desired treatment goals and outcomes	67
Care pathway and factors that impact on experiences of care	69
<i>Factor 1: referral pathways</i>	69
<i>Factor 2: appointment systems</i>	69
<i>Factor 3: poor record-keeping and inadequate transfer of information</i>	71
<i>Factor 4: lack of coordination between services</i>	71
<i>Factor 5: perceived 'busyness' of orthotics services</i>	72
<i>Factor 6: complex care</i>	72
<i>Factor 7: provision of 'in-house' facilities for fitting, adjustment and repair of orthotic devices</i>	73
<i>Factor 8: NHS funding</i>	73
<i>Factor 9: perceived lack of business ethos within NHS services, resulting in treatment delays and hold-ups and lack of innovation</i>	74
<i>Factor 10: use of private sector services</i>	74
Interactions with health-care professionals	75
<i>Interactions with orthotists</i>	75
<i>Interactions with consultants in rehabilitation medicine</i>	78
<i>Interactions with physiotherapists</i>	79
<i>Interactions with general practitioners</i>	80
<i>Interactions with podiatrists</i>	81

<b>Chapter 5 Results of survey of health-care professionals</b>	<b>83</b>
Response and completion rates	83
Demographic characteristics	84
Patient demographics	86
Patient referrals	87
Initial assessment	91
Prescription and fitting of orthotic devices	93
Types of devices	95
<i>Patient factors</i>	96
<i>Device factors</i>	97
Provision of orthoses	98
<i>Typical time frame between appointments</i>	98
Typical length of appointments	101
Patient information at fitting appointments	103
Long-term review appointments	104
Quantifying the success of an orthotic device	105
Device breakages	106
Treatment outcomes and acceptability factors	108
<i>Treatment outcomes</i>	108
Patient preferences	111
<i>Device factors</i>	111
<i>Patient factors</i>	111
Effectiveness of device	113
<i>Patient factors</i>	115
<i>Device factors</i>	115
<i>Other factors</i>	115
Outcome measures	115
Acceptability of device to patients	116
<i>Patient factors</i>	116
<i>Device factors</i>	116
<i>Other factors</i>	117
Care pathway of patients	118
<i>Patients with a neuromuscular disease</i>	118
<i>Patients with central nervous system conditions</i>	118
<b>Chapter 6 Costing analysis</b>	<b>121</b>
Materials	121
<i>Conventional knee–ankle–foot orthoses</i>	121
<i>Cosmetic knee–ankle–foot orthoses</i>	121
<i>Hybrid knee–ankle–foot orthosis</i>	121
<i>Other materials required</i>	122
<i>Where the materials are sourced and the knee–ankle–foot orthoses constructed</i>	122
<i>Deciding factors of which material to use and the quantity of material to use</i>	122
<i>Materials required for shape capture</i>	122
Staff requirements to prescribe/fit a knee–ankle–foot orthosis	123
Overheads	123
Spending caps	124
Opportunity cost	124
Unit cost estimates	124
Cost estimates for knee–ankle–foot orthoses	126
<i>Cost of custom-made devices</i>	126
<i>Cost of prefabricated (off-the-shelf) devices</i>	128

<b>Chapter 7 Dissemination and engagement</b>	<b>131</b>
Strategy development	131
Tools for engagement	131
Engaging with target audiences	132
Blog and Twitter activity	133
<b>Chapter 8 Discussion</b>	<b>137</b>
Principal findings	137
<i>Perspective of orthoses users</i>	137
<i>Clinical effectiveness evidence</i>	140
<i>Survey of health-care professionals</i>	142
<i>Costing analysis</i>	144
<i>Dissemination and engagement</i>	145
Strengths and limitations of the research	146
<i>Definition of knee instability</i>	146
<i>Systematic review</i>	147
<i>Qualitative study</i>	147
<i>Survey</i>	147
<i>Costing analysis</i>	148
Improving the evidence	148
<i>Population</i>	148
<i>Intervention and comparator</i>	149
<i>Outcomes</i>	149
<i>Patient perspective</i>	149
<i>Summary</i>	150
<b>Chapter 9 Conclusions</b>	<b>151</b>
Implications for service provision	151
Suggested research priorities	151
<b>Acknowledgements</b>	<b>153</b>
<b>References</b>	<b>155</b>
<b>Appendix 1 Search strategies for the systematic review</b>	<b>161</b>
<b>Appendix 2 Quality assessment criteria</b>	<b>169</b>
<b>Appendix 3 Invitation e-mail for health-care professional focus groups/telephone interviews</b>	<b>171</b>
<b>Appendix 4 Participant information sheet for health-care professional focus groups/telephone interviews</b>	<b>173</b>
<b>Appendix 5 Consent form for health-care professional focus groups/telephone interviews</b>	<b>177</b>
<b>Appendix 6 Patient interview and orthotist telephone interview topic guides</b>	<b>179</b>
<b>Appendix 7 Survey questionnaire</b>	<b>183</b>
<b>Appendix 8 Invitation e-mail for survey of health-care professionals</b>	<b>203</b>

<b>Appendix 9</b> Advertisement of survey for health-care professionals	<b>205</b>
<b>Appendix 10</b> Ongoing studies	<b>207</b>
<b>Appendix 11</b> Excluded studies	<b>209</b>
<b>Appendix 12</b> Data extraction tables	<b>233</b>
<b>Appendix 13</b> Demographic characteristics of participants in qualitative study	<b>259</b>
<b>Appendix 14</b> Orthotics for Knee Instability blog post timeline	<b>261</b>



# List of tables

<b>TABLE 1</b> Overview of included studies	<b>20</b>
<b>TABLE 2</b> Risk-of-bias assessment of RCTs	<b>22</b>
<b>TABLE 3</b> Quality assessment of non-randomised controlled studies	<b>23</b>
<b>TABLE 4</b> Quality assessment of case series	<b>24</b>
<b>TABLE 5</b> Post-polio syndrome study characteristics	<b>27</b>
<b>TABLE 6</b> Outcomes evaluated in post-polio syndrome studies	<b>29</b>
<b>TABLE 7</b> Inclusion body myositis study characteristics	<b>32</b>
<b>TABLE 8</b> Outcomes assessed in inclusion body myositis studies	<b>32</b>
<b>TABLE 9</b> Post-stroke study characteristics	<b>34</b>
<b>TABLE 10</b> Outcomes assessed in post-stroke studies	<b>34</b>
<b>TABLE 11</b> Spinal cord injury study characteristics	<b>36</b>
<b>TABLE 12</b> Outcomes assessed in spinal cord studies	<b>38</b>
<b>TABLE 13</b> Study participants' reports of devices and mobility aids	<b>47</b>
<b>TABLE 14</b> How are orthotic services provided in your clinical setting?, number (%) of responses	<b>84</b>
<b>TABLE 15</b> Health-care professionals in MDTs, number (%) of responses	<b>85</b>
<b>TABLE 16</b> Types of CNS conditions and/or NMD seen most frequently, number (%) of responses	<b>86</b>
<b>TABLE 17</b> Referral of patients with NMD to HCPs, number (%) of responses	<b>87</b>
<b>TABLE 18</b> Referral of patients with CNS conditions to HCPs, number (%) of responses	<b>88</b>
<b>TABLE 19</b> Information provided on referral, number (%) of responses	<b>89</b>
<b>TABLE 20</b> Symptoms that trigger referral, number (%) of responses	<b>89</b>
<b>TABLE 21</b> Which HCPs assess these patients?, number (%) of responses	<b>90</b>
<b>TABLE 22</b> Respondents' perception of barriers to patients' referrals, number (%) of responses	<b>90</b>

<b>TABLE 23</b> Average waiting time for a patient with NMD between referral and initial assessment, number (%) of respondents	<b>92</b>
<b>TABLE 24</b> Average waiting time for a patient with a CNS condition between referral and initial assessment, number (%) of respondents	<b>92</b>
<b>TABLE 25</b> Assessments routinely undertaken, number (%) of responses	<b>93</b>
<b>TABLE 26</b> Do you prescribe or fit orthotic devices?, number (%) of responses	<b>94</b>
<b>TABLE 27</b> Patients with CNS conditions: referrals for prescription/fitting of orthotic devices, number (%) of responses	<b>94</b>
<b>TABLE 28</b> Patient with NMDs: referrals for prescription/fitting of orthotic devices destination, number (%) of responses	<b>94</b>
<b>TABLE 29</b> Orthotic devices prescribed, number (%) of responses	<b>95</b>
<b>TABLE 30</b> Orthotic devices fitted, number (%) of responses	<b>96</b>
<b>TABLE 31</b> Proportion (%) of devices that are custom-made	<b>96</b>
<b>TABLE 32</b> Where custom-made devices are manufactured, number (%) of responses	<b>97</b>
<b>TABLE 33</b> Number of visits required to provide a device to a patient with NMD and knee instability	<b>98</b>
<b>TABLE 34</b> Number of visits required to provide a device to a patient with CNS conditions and knee instability	<b>99</b>
<b>TABLE 35</b> Average waiting time from initial visit to fitting devices (weeks)	<b>99</b>
<b>TABLE 36</b> How often do HCPs see patients with NMD and/or CNS conditions with knee instability?, number (%) of responses	<b>100</b>
<b>TABLE 37</b> Typical time frame from fitting of a device to first review (weeks)	<b>101</b>
<b>TABLE 38</b> Length of initial assessment appointment (minutes)	<b>101</b>
<b>TABLE 39</b> Duration of appointment for casting and measure (minutes)	<b>102</b>
<b>TABLE 40</b> Duration of review visit (minutes)	<b>102</b>
<b>TABLE 41</b> Information provided to patients at fitting appointments, number (%) of responses	<b>103</b>
<b>TABLE 42</b> Form of information provided to patients at fitting appointments, number (%) of responses	<b>104</b>
<b>TABLE 43</b> Are long-term review appointments provided?, number (%) of responses	<b>104</b>
<b>TABLE 44</b> Does your practice have a 'review on request' option for patients?, number (%) of responses	<b>104</b>

<b>TABLE 45</b> How the HCP quantifies the success of an orthosis when fitting/reviewing the device, number (%) of responses	<b>105</b>
<b>TABLE 46</b> Procedures in place if a custom-made device breaks, number (%) of responses	<b>106</b>
<b>TABLE 47</b> Procedures in place if an off-the-shelf device breaks, number (%) of responses	<b>107</b>
<b>TABLE 48</b> Who repairs the device when it breaks?, number (%) of responses	<b>107</b>
<b>TABLE 49</b> Factors influencing prescription decisions (all responses)	<b>108</b>
<b>TABLE 50</b> Factors influencing prescription decisions (orthotists)	<b>109</b>
<b>TABLE 51</b> Factors influencing prescription decisions (physiotherapists)	<b>109</b>
<b>TABLE 52</b> Factors influencing prescription decisions (rehabilitation medicine physicians)	<b>109</b>
<b>TABLE 53</b> What HCPs are trying to achieve when treating patients, number (%) of responses	<b>110</b>
<b>TABLE 54</b> Patients expressing a preference for particular devices, number (%) of responses	<b>111</b>
<b>TABLE 55</b> Health-care professionals views on outcomes important to patients (all respondents)	<b>112</b>
<b>TABLE 56</b> Orthotists' views on outcomes that are important to patients	<b>112</b>
<b>TABLE 57</b> Physiotherapists' views on outcomes that are important to patients	<b>112</b>
<b>TABLE 58</b> Rehabilitation medicine physicians' views on outcomes important to patients	<b>113</b>
<b>TABLE 59</b> Factors influencing the effectiveness of the orthosis (all respondents)	<b>113</b>
<b>TABLE 60</b> Factors influencing the effectiveness of the orthosis (orthotists)	<b>114</b>
<b>TABLE 61</b> Factors influencing the effectiveness of the orthosis (physiotherapists)	<b>114</b>
<b>TABLE 62</b> Factors influencing the effectiveness of the orthosis (rehabilitation medicine physicians)	<b>114</b>
<b>TABLE 63</b> Formal outcome measures used, number (%) of responses	<b>116</b>
<b>TABLE 64</b> Cosmetic appearance of the device and acceptability to patients, number (%) of responses	<b>117</b>
<b>TABLE 65</b> Average cost of devices	<b>125</b>
<b>TABLE 66</b> Unit (and component) costs for KAFOs	<b>125</b>



<b>TABLE 67</b> Staff costs	<b>125</b>
<b>TABLE 68</b> Information used to inform costing analysis	<b>126</b>
<b>TABLE 69</b> Cost estimate for a custom-made KAFO	<b>127</b>
<b>TABLE 70</b> Cost estimate of off-the-shelf KAFO	<b>129</b>
<b>TABLE 71</b> Relevant audiences	<b>133</b>
<b>TABLE 72</b> Top 10 blog posts	<b>134</b>

# List of figures

<b>FIGURE 1</b> Flow of studies through the review process	<b>19</b>
<b>FIGURE 2</b> Study participants' perceptions of positive and negative aspects of their orthoses	<b>61</b>
<b>FIGURE 3</b> Study participants' perceptions of positive and negative aspects of footwear	<b>64</b>
<b>FIGURE 4</b> Project logo	<b>131</b>
<b>FIGURE 5</b> Project favicon	<b>131</b>
<b>FIGURE 6</b> Orthotics for Knee Instability QR code	<b>132</b>



## List of abbreviations

ACPIN	Association of Chartered Physiotherapists Interested in Neurology	HCP	health-care professional
AFO	ankle-foot orthosis	HGO	hip guidance orthosis
AGO	alternative gait orthosis	HKAFO	hip-knee-ankle-foot orthosis
AHP	allied health professional	HTA	Health Technology Assessment
ARGO	advanced reciprocating gait orthosis	IRGO	isocentric reciprocating gait orthosis
BAPO	British Association of Prosthetists and Orthotists	KAFO	knee-ankle-foot orthosis
BSRM	British Society of Rehabilitation Medicine	KO	knee orthosis
CCG	Clinical Commissioning Group	MDT	multidisciplinary team
CDSR	Cochrane Database of Systematic Reviews	MHRA	Medicines and Healthcare products Regulatory Agency
CE	Conformité Européenne	NIHR	National Institute for Health Research
CENTRAL	Cochrane Central Register of Controlled Trials	NMD	neuromuscular disease
CIDP	chronic inflammatory demyelinating polyradiculoneuropathy	NTIS	National Technical Information Service
CMT	Charcot-Marie-Tooth	OKIS	Orthotics for Knee Instability
CNS	central nervous system	PASA	Purchasing and Supply Agency
DARE	Database of Abstracts of Reviews of Effects	QR	Quick Response
FES	functional electrical stimulation	RCT	randomised controlled trial
FIM	functional independence measure	RGO	reciprocating gait orthosis
FO	foot orthosis	ROM	range of movement
FSH	facioscapulohumeral muscular dystrophy	SCKAFO	stance control knee-ankle-foot orthosis
GP	general practitioner	SCO	stance control orthosis
GRAFO	ground reaction ankle-foot orthosis	SD	standard deviation
		SF-36	Short Form questionnaire-36 items
		WHOQOL-BREF	The World Health Organization Quality of Life-BREF
		WO	Walkabout orthosis



## Plain English summary

People with neuromuscular and central nervous system conditions can experience knee instability, which may be treated using callipers or splints, known as 'orthotic devices'. Very little is known about the effectiveness of these devices, how often they are used, how much they cost the UK NHS or what patients think about them. This study aimed to investigate these knowledge gaps. Previous research was examined to find out what is already known about the effectiveness of these devices. Health-care professionals were asked to take part in a survey and interviews to identify the types of devices currently being provided by the NHS, how often they are used, their cost and professionals' views about the use of devices. Patients using devices were invited to talk to a researcher in a face-to-face interview about their views and experiences. Study results suggest that a number of different devices are provided in the NHS. However, we cannot tell from existing literature how effective they are, as very few studies examined the extent to which the devices help patients when they were used in real-life settings. Patients highlighted how important their device can be in helping them to work, support their family and take part in social and community activities. However, they were unhappy about some aspects of their treatment. Treatment outcomes considered important by patients are not being routinely measured. Further research is needed to identify how to best deliver cost-effective care concerning supply of devices to patients, which takes account of their concerns.



# Scientific summary

## Background

There are several mechanisms that may lead to knee instability in neuromuscular disease (NMD) and central nervous system (CNS) conditions, which can cause several problems for the individual, including pain, falls and a range of mobility issues. Knee instability may be treated using orthoses. A knee–ankle–foot orthosis (KAFO) is usually prescribed when other forms of bracing, such as an ankle–foot orthosis (AFO) or knee orthosis (KO), are insufficient to adequately control knee instability due to weakness or joint laxity. Modern KAFOs made from thermoplastics or carbon fibre composites are lighter and fit more closely, potentially affording better control of the limb compared with ‘conventional’ KAFOs made of metal and leather. Historically, KAFOs were either entirely locked or entirely unlocked at the knee; the locked-knee type requires the individual to alter his/her gait to allow their foot to clear the ground in the swing phase of walking. Recent years have seen the introduction of stance control KAFOs (SCKAFOs), whereby mechanical or microprocessor-controlled knee joints allow the knee to flex during the swing phase of walking but lock when the knee is extended during the stance phase of walking and when weight is borne through the leg to provide stability to the knee in order to allow a more normal walking pattern. Hip KAFOs (HKAFOs) extend across the hip joint connecting to a pelvic band or lumbar or thoracic spinal support. Hip guidance orthoses (HGOs) and reciprocating gait orthoses (RGOs) are examples of HKAFOs with different locking/unlocking mechanisms. There is uncertainty about the acceptability of these devices to patients, the extent to which prescribed devices are used, and factors that determine their usage.

## Objectives

To:

- assess the evidence base for the effectiveness of orthotic devices for management of instability of the knee in adults who have NMD or a CNS disorder
- identify the most important outcomes for patients
- identify the types of orthotic devices currently being provided by the NHS for these conditions, the frequency of their use and their cost
- identify any implications for clinical practice, any gaps in the evidence and future research needs.

## Methods

We undertook (1) a systematic review of the effectiveness of orthotic devices for management of instability of the knee in adults with NMD or CNS disorders; (2) a qualitative study of the perspective of users of orthotic devices; and (3) a survey of health-care professionals (HCPs) and a costing analysis of KAFOs.

### Systematic review

We searched MEDLINE, MEDLINE In-Process & Other Non-Indexed Citations, Cumulative Index to Nursing and Allied Health, EMBASE, PASCAL, Scopus, Science Citation Index, BIOSIS Previews, Physiotherapy Evidence Database, Recal Legacy, Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects, Health Technology Assessment database and Cochrane Central Register of Controlled Trials in May 2014, and updated in November 2014. Studies in progress, unpublished research or research reported in the grey literature were identified by searching multiple other electronic databases and websites. There were no language restrictions. Studies of adults using an orthosis to manage impaired walking ability due to instability of the knee related to NMD or a CNS disorder were included, provided



that the orthosis had been used in a real-life setting. Randomised controlled trials (RCTs) and other study designs, with and without a comparator group, were eligible. Key study characteristics and results were extracted and quality assessed. The findings were discussed in a narrative synthesis, grouped by clinical condition, type of orthosis evaluated and outcome.

### *Qualitative study of views of orthoses users*

A qualitative in-depth interview study of people with a NMD or CNS condition who had been offered an orthotic device for knee instability was undertaken. The interviews elicited views and experiences of using an orthosis, their perceptions of the treatment they have received, and views of treatment goals and outcomes. A topic guide was used and interviews were audio-recorded, fully transcribed and a sample checked for accuracy. Data were analysed for thematic content following sequential steps of familiarisation with the data; development of a coding scheme and attribution of data to individual codes; collating codes into themes; and interpretation through seeking meaning, salience and connections. Coding procedures were cross-checked in a sample of early transcripts. Data handling and retrieval was assisted by the use of the computer software package NVivo (version 10, QSR International, Warrington, UK). The analytic approach used was both systematic and iterative. An inductive approach was undertaken in order to identify themes in a 'bottom-up' way.

### *Survey of health-care professionals*

We undertook a web survey of orthotists, physiotherapists and rehabilitation medicine physicians. The questionnaire was distributed using Qualtric® (Qualtrics LLC, Provo, UT, USA) software as an open survey, via an e-mail from the relevant professional bodies, which included an invitation letter and a link to the questionnaire. Reminder e-mails were sent 2 weeks and 4 weeks later. The results were downloaded into Microsoft Excel® (2010, Microsoft Corporation, Redmond, WA, USA). Responses collected for each question were analysed and the response rate for each question calculated.

The cost of KAFOs was estimated using information collected from four telephone interviews undertaken with orthotists, the overall survey, and unit costs estimates collected from NHS sources and expert opinion.

### *Engagement and dissemination*

We planned and implemented a combined engagement and dissemination strategy from the early stages of the project. We used a project blog, Twitter (Twitter, Inc., San Francisco, CA, USA; [www.twitter.com](http://www.twitter.com)) feed and articles in newsletters to raise awareness of the project, explain the research methods being used and promote involvement by HCPs in the survey.

## **Results**

### *Qualitative study*

We interviewed 19 users of orthotic devices across three geographically dispersed NHS sites and five from outside the NHS across different areas of England ( $n = 24$ ). Half of the sample had been diagnosed as having poliomyelitis; other participants had multiple sclerosis, Charcot–Marie–Tooth (CMT) disease, spinal injury or spina bifida, or had experienced stroke. The median age was 64.5 years (range 36–80 years). Half were engaged in either full- or part-time paid employment; half were retired.

Participants relied on orthotic devices to enable them to engage, as far as possible, in 'normal' daily activities, such as working, driving, using public transport, outdoor activities and taking part in social events and gatherings. They used a range of orthoses (KAFO, AFOs and KOs) and mobility aids (sticks, crutches, wheelchairs, mobility scooters), 'mixing and matching' these according to differing circumstances and contexts, in order to achieve maximum comfort and independence. Of major importance was whether or not they had a 'spare' device in case the currently used device required adjustment or repair or failed unexpectedly. Participants also spoke at length about the footwear associated with their orthosis, and expressed a range of views relating to desirable and undesirable characteristics.

The prime desired outcomes were a reduction in pain, falls or trips, with improved balance and stability. Effectiveness, reliability, comfort and durability were the most valued features of orthoses, and were related to reported use of orthotic devices. Goals for mobility were defined in terms of what they wished to achieve in their daily lives, according to their individual circumstances. They did not discuss treatment outcomes by how far or how fast they could walk. Rather, they focused on different activities that they wished to pursue and judged the success of treatment in terms of how far it enabled them to participate in these activities. The extent to which their orthosis enabled participants to engage in paid employment, outdoor activities (such as gardening), family visits and social events was the yardstick used to assess the effectiveness of treatment. Being able to take part in these activities was regarded as important by participants for both their physical and mental well-being.

Participants expressed frustration with referral routes into orthotic services, channelled through general practitioners and orthopaedic services, which resulted in delays in obtaining effective treatment. People under the care of a consultant in rehabilitation medicine appreciated the consultant's role in coordinating their care and monitoring their condition, while making proactive and timely decisions to refer them to orthotics and other specialist services, such as to neurophysiotherapy. Many of those interviewed expressed a degree of frustration with deficiencies in the appointment systems in operation in orthotic services. They reported delays in receiving treatment, as well as inconvenience and, sometimes, financial consequences when they had to take time off from work to attend appointments. A particular aspect of orthotic service provision that generated a great deal of commentary among participants related to provision of 'in-house' workshops within orthotics departments for the manufacture, adjustment and repair of orthoses. Availability of this facility was associated with delivery of timely, good-quality orthotic care, particularly for minor or emergency repairs to devices.

### Systematic review

Twenty-one studies ( $n = 478$  patients) were included: two RCTs (one with a crossover design); two non-randomised studies with a control group (one with a crossover design); one cohort study; and 16 case series. Sample sizes were small (range 5–67 participants). Eight studies reported knee instability as a result of NMD (153 patients), seven patients with post-polio syndrome and one patient with inclusion body myositis; 13 studies reported knee instability resulting from CNS causes (325 patients), either post stroke or spinal cord injury. The devices evaluated were KAFOs (mainly carbon fibre), SCKAFO and HKAFOs (RGO and HGO designs).

There were three key findings from the review. First, all of the studies were at risk of bias, in particular in how participants were selected for inclusion or allocated to treatments (in controlled studies) and in how outcomes were assessed. In general reporting was poor. Second, there was a mismatch between the outcomes that were assessed in the studies and the outcomes that were identified in the qualitative study as important to users. The most systematically assessed outcomes were mechanical outcomes, such as gait analysis and energy consumption. In contrast, participants in the qualitative study wanted their orthosis to reduce pain, falls or trips; improve balance and stability; and allow participation in work and a range of other family and social activities. Third, the focus of the effectiveness studies tended to be on the device in isolation. Few studies reported the orthosis 'dose' given to the patient, that is, the amount of time per day/week that they were advised to use their orthosis; reporting of fitting and training in use of the device and ongoing review was limited. A strong theme emerging from the qualitative study was that users did not see the device itself in isolation from how they were assessed for provision of the device, measured and fitted, how it functions with footwear, ongoing adjustment of the device and review. Provision of an orthosis is essentially a complex intervention, and this was generally not reflected in the effectiveness literature.

### **Health-care professional survey**

Two hundred and thirty-eight HCPs responded to the survey. Of the 229 who responded to the question on their occupation, there were 80 orthotists, 94 physiotherapists and 50 rehabilitation medicine physicians (five were from other professions). No single group dominated provision among NMD conditions: between 65% and 76% of respondents who managed patients with NMD reported managing patients with poliomyelitis, post-polio syndrome, muscular dystrophy, CMT disease, motor neurone disease and Guillain–Barré Syndrome. Similarly, no single group dominated provision among CNS conditions, although HCPs most commonly reported managing patients who had experienced a stroke (100%) and multiple sclerosis (83%). A range of orthoses are prescribed for knee instability that is related to NMD or CNS conditions: KAFOs (75%), AFOs (94%) and knee brace (89%). A substantial proportion also prescribed shoe adaptations (66%) and insoles (70%). Approximately half of the devices prescribed or fitted were reported to be custom-made (range 0–100%). At least 50% of HCPs thought that comfort and confidence in mobility were extremely important outcomes from treatment. Just over one-quarter of respondents reported that no formal outcome measure was used to assess the effectiveness of the devices provided. No single outcome measure was used by the remaining respondents: the most commonly used measures were the visual analogue scale, the 10-m Walk Test and the Timed Up and Go Test. One-third formally assessed patient satisfaction.

The cost of individual KAFOs was highly variable, ranging from £73 to £3553.

## **Conclusions**

Several different orthoses, both custom-made and prefabricated, are provided in the NHS to manage knee instability that is related to NMD and CNS disorders. Orthoses can play a crucial role in maintaining, promoting and enhancing physical and psychological health and well-being by enabling patients to pursue paid employment, thereby financially supporting their family and facilitating involvement in social and community activities. There is a large gap in the evidence on the effectiveness of KAFOs, AFOs and other orthotic devices for managing knee instability that is related to NMD and CNS conditions. In particular, the outcomes that are important to orthoses users are not being systematically assessed in studies of effectiveness.

### **Implications for health care**

Given the paucity of evidence, it is not appropriate to make conclusions about the effectiveness of specific orthotic devices for knee instability that is related to NMD or CNS disorders.

Better understanding of models of delivery that ensure maximum benefit for patients and best value for money is required.

Use of a core set of patient-reported outcome measures in the clinical setting would facilitate assessment of the impact of any change in device or management strategy on individual patients and would also facilitate audit.

### **Recommendations for research**

Research is required on the effectiveness of orthoses in managing knee instability that is related to NMD and CNS conditions and using outcome measures relevant to patients' everyday lives. Owing to challenges identified during this research, it is suggested that any future trial be informed by a feasibility study. Given the relative rarity of some of the populations and the personalised nature of the intervention, particularly for custom-made devices, a national registry may be an appropriate way forward.

Development of a core set of outcome measures would be beneficial. Reduction in pain, falls and trips, improved balance and stability, as well as participation in paid employment, outdoor activities (such as gardening), family visits and social events, were all identified as important to patients.

To date there is scant evidence about the views and experiences of people who are given orthoses for knee instability, and further studies are required to investigate further some of the issues raised in our exploratory study.

It is suggested that future research should explore different models of delivery of orthotic service for people with NMD and CNS conditions to identify best practice in terms of greatest benefit to patients and value for money.

## Study registration

This study is registered as PROSPERO CRD42014010180. The qualitative study is registered as ISRCTN65240228.

## Funding

Funding for this study was provided by the Health Technology Assessment programme of the National Institute for Health Research.



# Chapter 1 Background

## Introduction

This project was undertaken in response to a commissioning brief from the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) to address the question of which devices are in use in the UK NHS for instability of the knee in adults with neuromuscular disease (NMD), which conditions these devices are used for, and what further research is needed. The purpose of the commissioned research was to inform development of a future substantive research question to assess the clinical effectiveness and cost-effectiveness of different types of orthotic management of the knee in people with neuromuscular and central nervous system (CNS) diseases.

## Neuromuscular disease

The term 'NMD' encompasses a heterogeneous group of conditions, and terminology can vary. Neurology practice in the UK recognises NMDs as conditions that primarily affect the peripheral nerve, muscle and/or neuromuscular junction. Hilton-Jones *et al.*<sup>1</sup> describe the term as covering any condition caused by dysfunction of the motor unit (the motor nerve and the muscle it controls). They identify four anatomical sites: the anterior horn cell/motor neuron (e.g. poliomyelitis and motor neurone disease); the peripheral nerve [e.g. Charcot–Marie–Tooth (CMT) disease]; the neuromuscular junction (e.g. myasthenia gravis) and the muscle (e.g. muscular dystrophy).<sup>1</sup> There is a wide variety of pathologies, motor impairments and comorbidities across these neuromuscular disorders, for instance peripheral nerve conditions, which may be sensory as well as motor; neuromuscular junction conditions, for which there may be a large element of variability and physiological fatigue; and muscle conditions, which will vary in comorbidities such as cardiomyopathy and respiratory impairment. The exact muscle groups affected will vary both between and within individual conditions. However, there are common factors, particularly muscle weakness and fatigue, which affect mobility and lower limb function.

The term NMD is sometimes used in a more inclusive way, encompassing upper motor neuron conditions that have a common end point of affecting muscle function. This definition would therefore include CNS disorders, such as multiple sclerosis and stroke. Clinical management of people with primarily CNS conditions will often differ from the conditions described above because of the effect of upper motor neuron features on lower limb function. For example, spasticity will influence the prescription of orthoses in conditions such as multiple sclerosis. Likewise, in patients who have experienced a stroke, issues such as spasticity, neglect and spatial awareness will have an impact, plus there is acute onset usually with improvement and plateau. At the request of the commissioners, the term NMD is used inclusively to also encompass knee instability that related to CNS conditions, and both groups of conditions are included in this research.

## Knee instability in neuromuscular disease

There are several mechanisms that may lead to knee instability in NMD. The knee is a polycentric hinge joint that also has a rotatory action, with articular surfaces between the femur and the tibia, and the patella and femur. The muscle groups that have a direct effect on the knee are the knee extensors, comprising the quadriceps femoris and tensor fasciae latae, and the knee flexors that include the hamstring group – sartorius, gracilis and gastrocnemius. Weakness in any of these muscles is one mechanism that may lead to knee instability. This would be particularly common in muscle conditions that are predominantly limb girdle in origin; peripheral nerve conditions that affect these muscles, such as

diabetic amyotrophy or poliomyelitis; or in upper motor neuron conditions that affect the lower limb. This could be unilateral or bilateral, according to condition. Weakness in these muscle groups, or in more remote muscle groups, might also lead to secondary impairment of the tendons, ligaments and cartilage, such as laxity and contracture, associated with the knee due to altered alignment and redistribution of force across the joints and soft tissue. Muscle weakness, or overactivity remote from the muscles directly affecting the knee, may also cause knee instability due to the secondary effects on posture, such as excessive plantar flexion leading to abnormal anterior progression of the ground reaction force under the foot.

Sensory impairment can affect joint control where proprioceptive loss may reduce awareness of the knee position. Reduced pain or pressure perception may also increase skin vulnerability to excessive pressure or friction, for example from an orthosis. Knee instability itself may be in any of the planes in which the knee can move, that is, anteroposterior, medial–lateral and rotational (transverse plane).

In the case of CNS conditions, spasticity in the muscles acting around the knee can also cause knee instability. For example, spasticity in the gastrocnemius, which causes the foot to plantarflex in stance, shifts the ground reaction force anterior to the knee. Over time, this overstretches the posterior capsule of the knee joint, causing the knee to hyperextend. Similarly, spasticity in the hamstring muscles causes the knee to be flexed in stance phase, inducing knee flexion and associated joint instability.

## Orthotic devices for knee instability

Knee instability due to muscle weakness or ligamentous laxity is often treated using orthoses. The commonly stated goals of lower limb orthoses are to improve the ability and quality of walking, protect, stabilise and improve function.<sup>2</sup>

A knee–ankle–foot orthosis (KAFO) is usually prescribed when other forms of bracing, such as an ankle–foot orthosis (AFO) or knee orthosis (KO), are insufficient to adequately control knee instability due to weakness or joint laxity.<sup>2</sup> KAFOs span the knee, ankle and foot to stabilise the joints and assist safe ambulation. There are many types of KAFO designs. ‘Conventional’ KAFOs, made of metal and leather, have been used for centuries. Modern KAFOs, made from thermoplastics or carbon fibre composites, are lighter and fit more closely, potentially affording better control of the limb. Modern KAFOs tend to combine plastic and metal components, commonly polypropylene for calf and thigh shells and shoe inserts; aluminium, magnesium, titanium or steel for uprights; and steel for joints.<sup>3</sup> Devices can also vary in the type of knee joint, type of knee locking mechanism, types of knee pads and bands and whether or not there is frontal plane control.<sup>3</sup>

Historically, KAFOs were either entirely locked or entirely unlocked at the knee.<sup>4</sup> Most KAFOs incorporate knee joints that lock the knee straight during walking and unlock only when the user sits. Using a KAFO with a locked knee requires the individual to alter their gait to allow their foot to clear the ground in the swing phase of walking. Polycentric knee joints can be locked or unlocked and allow a more natural knee motion, although they have more moving parts, require more maintenance and are therefore more expensive.<sup>3</sup> They can also be heavier and bulkier, require the wearer to have voluntary hip extension and can be problematic when walking on uneven surfaces. Recent years have seen the introduction of stance control knee joint technology, through which mechanical or microprocessor controlled knee joints allow the knee to flex during the swing phase of walking but lock when the knee is extended during stance phase of walking and when weight is borne through the leg to provide stability to the knee in order to allow a more normal walking pattern. These are generally known as stance control KAFOs (SCKAFOs). KAFOs can be worn unilaterally or bilaterally as required.

Hip KAFOs (HKAFOs) are KAFOs that extend across the hip joint connecting to a pelvic band or lumbar/thoracic spinal support.<sup>4</sup> Bilateral KAFOs are linked via hip joints with flexion stops and a release mechanism for sitting.<sup>4</sup> Hip guidance orthoses (HGOs) and reciprocating gait orthoses (RGOs) are examples of HKAFOs with different locking/unlocking mechanisms. Ambulation with these devices by individuals with extensive paresis or paralysis of the lower limbs usually requires additional walking aids, such as crutches or walking frames.<sup>4</sup> These devices were originally designed for patients with higher-level spinal cord dysfunction, who might otherwise not have been able to walk.<sup>5</sup> Modifications of RGOs include the advanced RGO (ARGO) and the isocentric RGO (IRGO).<sup>5</sup>

Knee stability can also be improved by the use of knee braces or KOs, or in some cases by a type of AFO known as a ground reaction AFO (GRAFO). An AFO provides direct control of the ankle and foot, and is used to support mobility in people who experience joint instability, muscle weakness or muscle spasticity at the ankle joint. However, it can also provide indirect control of the knee and hip, and may be of benefit for knee instability. Quality Improvement Scotland has issued a Best Practice Statement on the use of AFOs following stroke.<sup>6</sup> The statement recommends that assessment for the orthotic device should be undertaken jointly by a specialist orthotist and specialist physiotherapist, and that the design specification should be based on biomechanical principles and desired functional outcomes of the patient.

The above devices can be prefabricated/off-the-shelf or fully custom-made. Some off-the-shelf devices may be customised to the individual. The clinical effectiveness of the various orthotic options for knee instability related to NMD is unclear. Diagnosis is thought to be a poor predictor of the type of orthosis that will be most effective. Orthosis design should be driven by the specific biomechanical impairments of each individual patient, the rehabilitation goals of the multidisciplinary team (MDT) and the patient's own goals. In addition to technical and structural considerations to ensure stability and safety, the clinician who is fitting the device needs to understand the goals of the orthosis within a patient's living and working circumstances.<sup>7</sup> Devices are generally fitted for the individual patient, and the correct supply and fitting of orthotic devices is important to allow a patient to manage his or her condition or prevent future problems.

Factors to be considered when prescribing and fitting a device are the type of deformity or instability present, the biomechanical deficit to be addressed, patient weight and activity level, and lifestyle issues. Patients with significant fixed deformity may benefit from a weight-relieving brim in the orthosis, so that some of the patient's weight can be offloaded from the affected leg. The biomechanical deficit will influence the way that forces are applied to the limb by the orthosis, the trimlines of the orthosis and the type of materials chosen. Weight and activity level will influence material choice, including the type of side bars and joints used. An important consideration when prescribing and fitting a device is whether off-the-shelf orthoses will meet the needs of the patient or a bespoke device is required. This decision will be influenced by the size and body habitus of the patient, the need to control certain movements as a result of the weakness in the limb, and the experience and skill of the orthotist in fabricating a device.

Most orthotic devices are classified as class 1 (lowest level of risk) with a Conformité Européenne (CE) mark.<sup>8</sup> There is a legal requirement for class 1 devices to meet the requirements of the European Union Medical Device Directive. Following registration with the Medicines and Healthcare products Regulatory Agency (MHRA) and self-declaration, the CE mark (which declares conformity with the Medical Devices Directive) can then be put on the product. A CE mark is not required for custom-made orthoses, although they must meet the requirements of the relevant sections of the Medical Devices Regulations.<sup>9</sup> A custom-made device is defined by MHRA as being 'manufactured specifically in accordance with a written prescription of a registered medical practitioner, or other authorised person . . . which gives under his responsibility, specific characteristics as to its design; and intended for the sole use of a particular patient'.<sup>9</sup> The prescription can take the form of a letter or a moulded impression of the shape of device required, with a request to 'make as pattern'.<sup>9</sup>



## Provision of orthoses

Orthotists in the NHS work closely with several clinical specialties, ranging from orthopaedics to diabetes care to rheumatology, and they provide services to people with a range of other conditions as well as NMD. There are an estimated 1.2 million people using orthotic services in the NHS.<sup>10</sup> An Audit Commission report in 2000 found that in most hospital trusts, orthotics services were small-scale, with an annual expenditure of < £500,000, although there were also a small number of trusts with an expenditure of > £2M.<sup>11</sup> The Audit Commission report<sup>11</sup> estimated that in the study sites, 8% of orthotic expenditure was on KAFOs, 9% on HKAFOs and 1% on AFOs. Lower limb orthosis repair accounted for 2% of expenditure. They found a wide variation in the prices quoted by different suppliers for identical products: across four suppliers the cost of a KAFO ranged from £390 to £650 and the cost of an AFO ranged from £40 to £130 (approximate values read from graph).<sup>11</sup>

Orthotics services are normally provided in secondary care using a number of different models of provision: in-house service employing a NHS orthotist; employing a NHS orthotist in conjunction with neighbouring trusts; outsourcing the service to a commercial supplier; or a mix of public and private provision.<sup>11</sup> Based on a survey of 150 orthotics managers in acute trusts, the Audit Commission found that 20% employed their own orthotist.<sup>11</sup>

Physiotherapists, neurologists and rehabilitation medicine physicians are also involved in the prescription of orthoses for people with NMD. Physiotherapists are often the first professionals who may prescribe orthoses. These tend to be off-the-shelf devices. For more complex situations, the physiotherapist will refer to, and liaise with, an orthotics clinic. Some clinics have a specialist physiotherapist as part of the team but this is not universal. A survey, in 2004–5, of clinicians running specialist clinics for adults with NMD found that the availability of specialist orthotics in the form of an orthotist with experience in NMDs was low in the 32 clinics surveyed.<sup>12</sup>

## Patient perspective

There is uncertainty about the acceptability of these devices to patients, the extent to which prescribed devices are used, and the factors that determine their usage. Information on acceptability and use has not been collated systematically in relation to people with neuromuscular conditions that lead to knee instability. The lack of a consistent and reliable method of reporting on the daily use of KAFOs after the patient leaves the clinic or laboratory setting has been highlighted.<sup>2</sup>

Phillips *et al.*<sup>13</sup> explored perceptions and experiences of the disadvantages and benefits associated with use of AFO in 15 people with CMT disease, using individual interviews and nominal group technique. Barriers to use that were identified related to the functional use of the AFO (such as lack of mobility in tight spaces); discomfort when wearing the device, including rubbing and digging into the skin; concerns about the appearance of the device and its potential for drawing attention to disability; and problems with finding suitable footwear. The main perceived advantages of wearing the AFO were linked to improvements in walking. Vinci and Gargiulo<sup>14</sup> explored acceptability of AFOs to a study sample of 8 male and 17 female participants with CMT disease, who had severe bilateral foot drop, and who had been prescribed AFOs at least 4 months before the start of the study. Results from this qualitative interview study indicated that adherence to the prescribed AFOs was poor, with only five people (20% of the sample) wearing the devices. Reasons for not wearing AFOs were that patients preferred to manage without them because they felt that the AFOs highlighted their disability, the AFOs were uncomfortable, and they had difficulty finding footwear to accommodate the devices. A third study<sup>15</sup> explored the differences in presentation and gait function of people with CMT disease who wore AFOs for daily mobility ( $n = 11$ ) and a group who did not ( $n = 21$ ).

Six of the non-users had been prescribed AFOs but chose not to wear them. Their physical characteristics resembled the non-AFO group more than the AFO group for measures of muscle strength and disease severity. The authors of this study<sup>15</sup> concluded that severity of presentation seems to determine whether or not people with CMT disease will use AFOs, and the timing of prescription may accordingly assist with acceptability of the devices.

Garralda *et al.*<sup>16</sup> explored the views and adjustment of families with a child with Duchenne muscular dystrophy in relation to use of KAFOs. The authors conducted interviews with 17 parents and 9 children (all boys aged 8–18 years) seeking views about the use of KAFOs. Findings from the study revealed the emotional significance for parents of the introduction of KAFOs as an indicator of illness deterioration and re-affirmation of the severity and life-limiting nature of the disorder. Most parents expressed satisfaction with the use of KAFOs, but some wished to have had more discussion about practical aspects beforehand.

In a trial of AFOs,<sup>17</sup> only 50% of stroke patients actually wore their orthoses. Long-term rejection rates of KAFOs have been found to be high in people with paraplegia and with spinal cord lesions.<sup>7</sup> One study suggested that a patient selection and training programme could help target the orthoses at those who were more likely to have successful outcomes.<sup>18</sup> The importance of appropriate training with the orthosis and associated assistive devices has been previously emphasised.<sup>19</sup> It has been suggested that rejection might, in some instances, be due solely to lack of appropriate gait training.<sup>2</sup> The need for training for orthosis users in the care of the orthosis and care of the skin to avoid adverse effects has also been recommended.<sup>19</sup>

Other problems that have been cited include auditory distraction, memory of old leather and steel orthoses for patients with poliomyelitis, and damage to clothing.<sup>20</sup> If a patient has unrealistic and unfulfilled expectations then this may lead to abandoning the orthosis.<sup>2</sup> A patient's prior history with orthoses and any reasons for previous failure may be important.<sup>2</sup>

In summary, the existing research literature relating to patients' perceptions and experiences of using orthoses for knee instability is limited in several respects. Studies that have been conducted to date are mainly small-scale; some do not include in-depth exploratory techniques, such as face-to-face interviews, and existing studies are not fully representative of the diverse populations with NMD and CNS conditions for whom prescription of an orthosis may be an appropriate measure.

## Previous research on effectiveness

Scoping searches were undertaken prior to commencing the current review to establish whether or not a systematic review had been previously undertaken. No previous systematic reviews were identified that assessed the effectiveness of orthotic devices in the specific population of interest: knee instability in adults with NMD and CNS disorders. A systematic review conducted in 2013 (searches to November 2011) found that an AFO fitted in patients following stroke had a statistically significant effect on ankle kinematics, knee kinematics in stance phase, kinetics and energy cost, although not on knee kinematics in swing phase, hip kinematics or energy expenditure. However, the focus was on gait biomechanics, and the effects and acceptability of long-term usage have not been evaluated.<sup>21</sup> A Cochrane review<sup>22</sup> has investigated any intervention for CMT disease and identified a single controlled study of foot orthoses (FOs); however, the device was not being used for knee instability – although FOs can influence the alignment of the knee on the coronal plane, they do not correct sagittal plane knee instability. A review of non-surgical interventions for people with CMT disease did not identify any studies evaluating an orthotic device.<sup>23</sup> The literature searches for these reviews were undertaken in 2007 and 2006, respectively, and therefore need to be updated.

An overview of the evidence on KAFOs and HKAFOS for all conditions in 2006<sup>4</sup> concluded that the level of evidence was generally low and consisted mainly of small study sample sizes and inadequate study design, although these aspects were not addressed in any detail. Two Cochrane reviews<sup>24,25</sup> were identified which assessed interventions for ankle instability or reduced range of motion in the ankle in people with NMD, but did not investigate knee instability. A review published in 2012 (searching to 8 November 2010) of stance control orthoses (SCOs) for any condition found benefits of SCOs in comparison with locked KAFOs but these studies had methodological limitations.<sup>26</sup>

## Aims and objectives

The project aimed to address the commissioned research question of which orthoses are in use in the NHS for instability of the knee, for which NMD and CNS disorders, and what further research is needed. There were four objectives.

1. *Assess the evidence base for the effectiveness of orthotic devices for management of instability of the knee in adults who have NMD or a CNS disorder* To meet this objective, we undertook a systematic review of the best available evidence on the effectiveness of orthotic devices in this population.
2. *Identify the types of orthotic devices currently being provided by the NHS for the management of instability of the knee in adults with NMD or a CNS disorder, the frequency of their use and their cost* To meet this objective, we conducted a survey of orthotists and physiotherapists, and undertook a costing analysis of orthoses for knee instability.
3. *Identify the most important outcomes for patients* To meet this objective, we used qualitative research methods to collate the views of people with NMD or a CNS disorder, who have been fitted with an orthotic device for knee instability.
4. *Identify any implications for clinical practice, any gaps in the evidence and future research needs* To meet this objective, we interrogated and integrated the three sources of evidence: health-care professionals (HCPs), patients and the systematic review.

# Chapter 2 Methods

## Overview

To address the research objectives we undertook (1) a systematic review of the effectiveness of orthotic devices for management of instability of the knee in adults with NMD or CNS disorders; (2) a survey of orthotists and physiotherapists and a costing analysis; and (3) a qualitative study of the perspective of users of orthotic devices. Details of the methods used for each component are outlined below.

## Systematic review

The systematic review was designed to identify and evaluate the best available evidence on orthotic devices for the management of instability of the knee in adults with NMD or CNS disorders. We undertook it following the principles recommended by CRD guidance<sup>27</sup> and we have reported the review following PRISMA guidelines.<sup>28</sup> The protocol was registered with PROSPERO, registration number CRD42014010180.

### Selection criteria and searching

In order to identify all relevant evidence, we formulated the following selection criteria.

*Population* Adults ( $\geq 16$  years) with a neuromuscular disorder, who have impaired walking ability due to instability of the knee. Neuromuscular disorders included conditions that primarily affect the peripheral nerve, muscle and neuromuscular junction, for example motor neurone disease, muscular dystrophy, myasthenia gravis, spinal muscular atrophy, CMT disease, poliomyelitis, myopathies and inclusion body myositis. Knee instability related to CNS conditions was also included, for example spinal cord injury and stroke.

*Intervention* Orthoses with the clinical aim of controlling knee instability, for example KAFOs, AFOs and KOs or mixed designs. Orthoses of any design or material, custom or prefabricated; locked knee joint, eccentric knee joint or stance control design (KAFO), with and without an electronic component, were eligible. Studies evaluating the use of functional electrical stimulation (FES) were excluded.

*Comparator* Studies using any of the above orthoses as a comparator, including studies comparing different designs of the same orthosis, or no intervention.

*Outcomes* Studies reporting any of the following outcomes were eligible for the review:

- condition-specific or generic patient-reported outcomes measures assessing function, disability, independence, activities of daily living, quality of life or psychosocial outcomes
- pain
- walking ability
- other functional ability, for example sit to stand, short turns in confined spaces
- biomechanical analysis
- adverse effects, for example tissue damage, falls
- usage
- patient satisfaction and the acceptability of a device
- resource utilisation data, such as number of follow-up appointments, device malfunction or other problems.

*Study design* Randomised controlled trials (RCTs) and other study designs, with and without a comparator group, were eligible for the review such as non-randomised controlled studies, before-and-after studies and case series. There was no minimum study size. Owing to the risk of bias, non-RCTs have limitations in providing robust evidence about the effectiveness of interventions; however, there are relatively few RCTs undertaken in this field. In addition, a key focus of our research was to inform future research. Therefore, a broad range of study designs was included to provide a comprehensive overview of the research available.

Studies were eligible provided that the orthosis had been used in a real-life setting (i.e. not solely in a laboratory/experimental setting). Outcomes could be assessed in a laboratory or clinic setting; however, participants had to have had the opportunity to have used the device outside that setting. Studies entirely in the laboratory setting focusing on biomechanical outcomes have an important role in identifying effective devices; however, they are at an earlier stage of development. Although the clinical trial phases for pharmaceuticals do not directly translate across to devices, the entirely laboratory-based studies are closer to a Phase II pharmaceutical trial than a Phase III trial investigating efficacy or effectiveness.

Published and unpublished studies from any country and reported in any language were eligible for inclusion in the review.

### **Search strategy**

We developed a comprehensive search strategy to ensure that all of the relevant sources of data were located. For full details of the search strategies used see *Appendix 1*. Searches were designed in conjunction with an experienced information specialist.

We searched MEDLINE, MEDLINE In-Process & Other Non-Indexed Citations, Cumulative Index to Nursing and Allied Health, EMBASE, PASCAL, Scopus, Science Citation Index, BIOSIS Previews, Physiotherapy Evidence Database, Recal Legacy, Cochrane Database of Systematic Reviews (CDSR), Database of Abstracts of Reviews of Effects (DARE), HTA database and the Cochrane Central Register of Controlled Trials (CENTRAL) from inception.

Information on studies in progress, unpublished research or research reported in the grey literature was identified by searching the Conference Proceedings Citation Index: Science, Health Management Information Consortium, ClinicalTrials.gov, International Clinical Trials Registry Platform and the National Technical Information Service (NTIS). Selected websites were also searched: the International Society for Prosthetics and Orthotics, British Association of Prosthetists & Orthotists (BAPO), American Orthotic & Prosthetic Association and the American Academy of Orthotists and Prosthetists, and the associated *Journal of Prosthetics and Orthotics*.

Searches were run in May 2014 by the information specialist. No limits on date, language or study design were applied in any of the searches. We carried out an update of the searches in November 2014 in all the above databases, with the exception of BIOSIS, PASCAL, Recal Legacy and NTIS. The same procedures as above were followed.

The reference lists of all included studies, any related systematic reviews and key background papers were checked to identify any further relevant studies. The results of all searches were imported into EndNote bibliographic software (version XVII, Thomson Reuters, CA, USA) and deduplicated.

Two researchers independently screened the bibliographic references in EndNote for relevance, based on the inclusion criteria. The full texts of any potentially relevant papers were ordered. Full papers were loaded into EPPI-Reviewer 4 software (version 4.6.0.1, EPPI-Centre, Social Science Research Unit, Institute of Education, University of London) and read to determine relevance. Reasons for exclusion of studies were documented in EPPI-Reviewer. Disagreements were resolved through discussion and consultation with

another member of the project team if necessary. Authors were contacted if eligibility was uncertain from the information provided in the publication.

### Data extraction

A data extraction form was developed in EPPI-Reviewer. This was piloted on a small number of studies and adjusted as necessary. Guidelines on its use were produced to enhance consistency among the team. Data from multiple publications of the same study (linked papers) were extracted and reported as a single study. Data extracted included details of the study methods, country, patient characteristics, intervention, comparators, analysis methods and results. Data were extracted as stated by authors and not transformed in any way. Between-group differences were extracted from studies with a comparator. For studies without a comparator, pre- and post-intervention data were extracted.

Data were extracted by one researcher and checked by a second researcher. Studies in languages other than English were extracted by a native speaker who was also a researcher. These were checked by a second researcher for consistency only. We planned to extract data to allow calculation of between-group differences and confidence intervals; however, as a result of the generally poor reporting of data, it was not possible to consistently do this across studies. When data were available, these were extracted; when the appropriate data were not reported, the description of the results provided in the paper was extracted and the lack of summary data was noted.

### Assessment of risk of bias

The Cochrane risk-of-bias criteria were used to assess included RCTs.<sup>29</sup> There is a lack of consensus about how risk of bias should be assessed in non-randomised studies, and there is no gold-standard tool for assessing risk of bias of case series or other observational designs.<sup>30,31</sup> However, there is a broad consensus in the methodological literature that selection bias and confounding are key sources of bias in observational study designs.<sup>30,31</sup> We used a similar approach to Siegfried *et al.*<sup>32</sup> for non-randomised studies with a control group. These studies were assessed for external validity, performance bias, detection bias and selection bias/control of confounding based on eight criteria (gender, age, cause of muscle weakness, presence of sensory disturbance, whether or not the orthosis was used for proximal or distal muscle weakness, previous use of an orthosis, acclimatisation time and type of orthosis used) (see *Appendix 2*). There are no consensus criteria for assessment of case series. The criteria used were adapted from the assessment of controlled studies and criteria used in a previous systematic review.<sup>33</sup> Assessment of risk of bias was undertaken independently by two researchers (except for non-English-language studies). Discrepancies were resolved by discussion.

### Analysis and synthesis

Data extracted from the studies were tabulated and discussed in a narrative synthesis grouped by condition then by type of orthosis and outcome, in conjunction with an assessment of the quality of the studies. Given the diversity of the studies and the insufficient data, neither a meta-analysis nor planned subgroup analyses on the presence of proximal or distal weakness and the presence of sensory disturbance could be undertaken.

Outcomes have been grouped under categories: patient-reported outcomes included measures of satisfaction, measures of functionality and usage of the orthotic device. Objective assessments were those conducted in a laboratory or clinic setting and usually involved gait analysis, including walking ability, energy consumption and muscle activity. Resource utilisation included measures of device function including breakages and cost. Adverse event data were also recorded.

## Qualitative study of patient views

This exploratory qualitative study aimed to:

1. explore perceptions relating to acceptability, effectiveness and usage of orthoses
2. identify important outcomes among people who have been fitted with an orthotic device for knee instability across a broad range of diverse NMDs
3. explore the factors influencing the perceived likelihood of achieving the outcomes for those individuals within the context of their condition and care pathway.

### *Ethics considerations*

The study received research ethics (REC reference 14/LO/1132) and governance approvals to recruit patients through NHS sites. Research governance approval was sought and obtained from the University of York's Department of Health Sciences' Research Governance Committee in order to recruit study participants via patient support groups. The study was also registered with the ISRCTN registry (ISRCTN 65240228). All study participants were given verbal and written information relating to the study aims and their involvement. Written consent was obtained prior to interviews and participants were given assurances concerning the confidentiality and anonymity of their responses. Participants were also reassured that their care would not be affected in any way whether or not they decided to take part in an interview, and it was made clear that they could withdraw from the study at any time.

### *Study design*

A qualitative in-depth interview study was carried out to elicit peoples' views and experiences of using an orthotic device, perceptions of the treatment they had received and views of treatment goals and outcomes.

Twenty-four people were recruited for interview from both in and outside the NHS, using a topic guide that was planned to reflect the research aims and objectives. A patient adviser was consulted to assist with design of the interview topic guide. This adviser helped to guide the development of the interview schedule by commenting on the relevance of content, comprehensiveness, the 'flow' of questioning and language used. The aim was to develop an instrument sufficiently structured to ensure consistency in information gathering but flexible enough to allow participants to recount their individual experiences.<sup>34</sup>

The study protocol included a proposal to undertake a small number of focus groups (2–4) with a sample of participants experiencing a particular neuromuscular condition with instability of the knee (poliomyelitis was identified as a condition of interest). Focus groups were not undertaken for two main reasons. First, half of the study sample (12 participants) had a diagnosis of poliomyelitis and it was therefore not clear that focus groups would have added to the information obtained from the individual interviews. Second, study participants indicated a strong preference to be interviewed in their own home, as attending a focus group could pose problems related to their personal mobility or family or work commitments. Analysis of the data from the 12 in-depth interviews with participants with poliomyelitis suggests that data saturation was achieved in the categories of interest; that is to say, no new findings emerged from the later interviews.<sup>35</sup> We are, therefore, reassured that it is unlikely that focus groups would have yielded new insights.

### *Conduct of qualitative interviews*

Most ( $n = 21$ ) interviews with participants were conducted by the researchers (DM) and (CJ) in participants' homes or workplace; three interviews were conducted by telephone when this was more convenient for the participant and/or researcher. The majority of interviews lasted around 1 hour, although some were shorter or longer, and all were audio-recorded. In a number of cases, the participant's spouse was present during the interview and participated to a greater or lesser extent.



## Data sources

### Study sites

NHS patients and members of patient support groups were purposively sampled to include people with different types of NMD, including CNS conditions. Participants were recruited from three different regions in England: one to the north, one in the middle of the country, and one to the south, referred to as sites 1, 2 and 3, respectively. Regional variations exist between the nature and organisation of orthotic services offered in the three different sites, ranging from large, specialist units with a high throughput of patients, to services provided through smaller units based in local hospitals or attached to rehabilitation centres.

The orthotic service in research site 1 is a large department operating out of six hospital sites across an urban and suburban area serving a population of 800,000 people. Approximately 10,000 items are dispensed each year from a range of appointments from single-handed orthotist-led clinics through to multidisciplinary clinics run in combination with orthopaedic or rehabilitation medicine consultants. The service also provides in-reach to the inpatient wards as well as domiciliary visits. The service is commissioned by a consortium of Clinical Commissioning Groups (CCGs) in the region and is hosted by the acute hospital Trust, although provided by an independent company. The company has an orthotic manufacturing unit in the city. A parallel orthotic service, located in general practitioner (GP) surgeries, also exists in the city and is commissioned by each CCG independently. This latter service tends to see patients with less complicated needs that can be met by a single-handed orthotist.

Research site 2 offers orthotic services across a range of clinical settings, commissioned by the local CCG. Approximately 7000 items are dispensed each year, which range from KAFOs for patients who are new to the service, and include AFOs, insoles and footwear, including footwear adaptations, repeat orders and repairs. Around 10,000 appointments are offered annually – a mix of new patients and review appointments – as well as those including supply of an orthosis. Appointments vary from 15 to 60 minutes, depending on complexity. The team of orthotists deliver care through hospital sites, as well as outreach clinics. An in-house manufacturing workshop is available at one of the sites, and specialises in plastics (AFO and KAFO) and insoles. Referrals are via GPs and consultants within the local Trust, with some specialist pathways to enable podiatry and physiotherapy referral as part of the MDT.

Research site 3 is located within the boundaries of a major city in the south of England, where specialist orthotic services are provided across a range of locations, including a local hospital and a number of clinics. Patients included in the study accessed orthotic care via a team of orthotists specialising in complex rehabilitation problems, many of which require a multidisciplinary approach. Orthotists work closely with a MDT, including physiotherapists, consultants and podiatrists, to enhance care pathways and treatment programmes and promote the best outcomes and patient experience. Referrals to the service are accepted from GPs, consultants and members of the allied health team. This specialist service benefits from an on-site workshop for the manufacture, maintenance and adaptation of orthotic products.

### Sampling and recruitment of participants

Participants were recruited from a range of sources to ensure that a wide range of views was captured, namely through the charities, such as the British Polio Fellowship and Charcot–Marie–Tooth UK, as well as through NHS orthotics clinics. Purposive sampling<sup>36</sup> was used to select participants for interview, to reflect a range of conditions: age, sex, length of time fitted with an orthosis, high and low usage, and living in different regions in England.

Inclusion criteria for the study were adults ( $\geq 16$  years for NHS participants;  $> 18$  years of age for non-NHS participants) with a neuromuscular disorder who have impaired walking ability primarily due to instability of the knee. Neuromuscular disorder included conditions that primarily affect the peripheral nerve, muscle and neuromuscular junction, for example motor neurone disease, muscular dystrophy, myasthenia gravis, spinal muscular atrophy, CMT disease, poliomyelitis, myopathies and inclusion body myositis. People with knee instability that was related to CNS conditions were also included, for example spinal cord injury,



spina bifida and stroke. Participants were people who were able to give informed consent. Principal exclusion criteria were aged < 16 years, people with neuromuscular disorders other than those described above, and people who were unable to give informed consent because of cognitive impairment or for other reasons.

Two methods of recruitment were used, one in and one outside the NHS.

1. *NHS recruitment* Clinicians were requested to approach patients with NMD who have been fitted with an orthosis to ask if they might be interested in taking part in the study. If a patient expressed an interest, the clinician partner requested written permission to pass his or her telephone number to the qualitative researcher using a confidential, password-protected 'drop-off' system in operation at the University of York. The clinician gave the patient a copy of the participant information sheet containing further details of the study. The patient information sheet explained why the interviews were being conducted and what was involved in taking part in the study. After a period of no shorter than 5 days, patients were contacted by the researcher to provide further details and to find out if they would like to be involved in the study. If so, a mutually convenient date and location were arranged for an interview to take place. Nineteen patients were recruited in this way. Two patients contacted declined to take part: one expressed no further interest in being involved; the second patient's general condition had suddenly deteriorated so he or she was unable to participate.

The study protocol included a proposal of a second method of recruitment by NHS HCPs, by sending out letters of invitation to patients they considered eligible to take part in the study, along with a participant information sheet. However, we did not resort to this method of recruitment, as we were able to obtain an adequately sized study sample using our (preferred) method whereby the clinician approached the patient in person. Moreover, identifying suitable patients for the study through searching clinical records would have been very difficult, as record systems are based on a record of the patient's clinical condition rather than on causes underlying difficulties with walking, such as knee instability.

2. *Non-NHS recruitment* Information about the Orthotics for Knee Instability (OKIS) study was provided to the chairpersons/lead representatives of the British Polio Fellowship, Charcot–Marie–Tooth UK, the FSH (facioscapulohumeral muscular dystrophy) Support Group UK and the Muscular Dystrophy Campaign, with a request to forward this to their members, who were invited to contact the qualitative researcher directly. The response to this method of recruitment was lower than anticipated; of the six people who contacted the researcher seeking further information, five agreed to take part in an interview.

### **Modes of analysis/interpretation**

Audio-recordings of interviews were fully transcribed. A random sample of six transcripts was checked by three researchers (LD, CJ and DM) for accuracy. Data were analysed for thematic content following sequential steps of familiarisation with the data by reading and rereading transcripts; development of a coding scheme and attribution of data to individual codes; collating codes into potential themes; and interpretation through seeking meaning, salience and connections.<sup>37</sup> Data handling and retrieval was assisted by the use of the computer software package NVivo, which also enabled *intra* (within an individual's responses) and *inter* (across the whole data set) case comparison.<sup>38</sup> To promote rigour in analysis, the three qualitative researchers involved in the study (LD, CJ and DM) cross-checked coding procedures in a sample (6) of the early transcripts, followed by discussion and modification of the coding framework where necessary, during the initial phases of data analysis. The coding frame, therefore, evolved and expanded to include relevant categories of interest.

The analytic approach used was both systematic and iterative.<sup>35</sup> An inductive approach was undertaken in order to identify themes in a 'bottom-up' way as opposed to a theoretical or 'top-down' manner.<sup>37</sup> Deviant cases (those that appear to contradict emerging themes) were actively sought throughout the analysis to ensure full interrogation of the data.<sup>35</sup> The Braun and Clarke<sup>37</sup> checklist of criteria for a good thematic analysis provided a guide during the analytic and interpretative processes.

The study protocol suggested that, if appropriate, data from the in-depth interviews would also be examined on a case-by-case basis using phenomenological research methods to examine the perspective and experience of the individual in relation to their own condition and care experience.<sup>39,40</sup> These methods have not been used in this final report, although they may be incorporated into future publications arising from the study, in order to capture the 'lived experience' of individuals using orthoses in day-to-day life. The aim of this report is rather to present a more general overview of the data, which broadly represents the perspectives of all study participants, although data from particular individuals will be presented in more depth when this seems warranted.

## Survey of health-care professionals

We undertook a web survey of orthotists, physiotherapists and doctors in rehabilitation medicine in order to address the second aim of the project, to identify the types of orthoses currently being used by the NHS for the management of instability of the knee in adults with NMD and CNS disorders, the frequency of their use, the resources required to provide them and the care pathways of these patients. To obtain data for costing orthotic devices, telephone interviews with orthotists were also undertaken.

### Survey

The target population was orthotists, physiotherapists and doctors in rehabilitation medicine, within the UK, who provide care to NMD and/or CNS patients with knee instability. The sample frame was membership lists of the following:

- Association of Chartered Physiotherapists Interested in Neurology (ACPIN)
- BAPO
- the British Society of Rehabilitation Medicine (BSRM).

This may be an incomplete sampling frame, as the relevant health professionals may not all be members of these organisations. Conversely, not all members of these organisations will be treating the patient population of interest. Because of the way orthotic services are arranged in the NHS, with orthotists in some hospitals employed by private organisations and others by the NHS, as well as variations in which directorate orthotic services come under in different hospitals, any other approach to identifying these professionals would be very resource intensive. Based on previous work in this area, and the knowledge of the steering group members, regional variations are expected in the types of orthotic devices being prescribed and the care pathways of patients. Therefore, a web survey of membership of the relevant professional organisations was chosen to obtain as wide a geographical coverage as possible.

Response rates in surveys of HCPs vary greatly. A recent systematic review and meta-analysis estimated a mean response rate of 38% by health professional to online surveys.<sup>41</sup> An earlier systematic review reported response rates ranging from 9% to 94%. We have taken a conservative estimate of 30% to estimate what an appropriately powered sample would be.<sup>42</sup> The primary purpose of the survey was to provide descriptive information on current NHS practice and the sample size was calculated on that basis.<sup>43</sup> Based on a 95% confidence level and a 10% margin of error (which would seem reasonable, given the exploratory nature of the survey) the estimated minimum sample size required was 96 and, assuming a more ideal 5% margin of error, the sample size required was 384.

Ethical approval for the web survey, the telephone interviews and focus group used to inform development of the questionnaire and follow-up interviews for costing devices was sought from and granted by the University of York's Department of Health Sciences' Research Governance Committee. As per this approval, the personal information collected from these sessions was stored securely, accessible only to the research team and will be securely destroyed after 5 years.

### Questionnaire development

To inform the survey questionnaire, two focus groups were planned, to include orthotists, physiotherapists and doctors in rehabilitation medicine. Two focus groups were planned in two separate geographical locations. Recruitment to the focus groups was facilitated by members of the steering group. An invitation e-mail, provided in *Appendix 3*, was sent to potential focus group members. Potential participants who expressed an interest were subsequently e-mailed an information sheet, provided in *Appendix 4*, detailing the length of the session, and data protection and storage information.

The focus group for the first geographical location took place with 11 HCPs in attendance. Unfortunately, a suitable date for all participants could not be reached for the second location, so approval for telephone interviews was obtained from the Research Governance Committee. Four telephone interviews were subsequently undertaken. Informed consent was sought from all participants for the focus group and the telephone interviews (see *Appendix 5*). Both the focus group and the telephone interviews followed the topic guide presented in *Appendix 6*. Orthotists, physiotherapists, doctors in rehabilitation medicine and a gait scientist participated in these discussions. Participants were asked to discuss orthoses provision to patients with a NMD or a CNS condition with knee instability, around the following:

- types of orthoses
- referral and care pathways
- patient and treatment
- factors influencing effectiveness and acceptability.

During these discussions, it became clear that patients with a NMD or CNS condition and knee instability are a diverse group. This introduces variation in the types of orthoses being prescribed, referral mechanisms, care pathways and HCPs involved in the care of these patients. The barriers to referral for orthotics services were also raised as an issue. Discussion highlighted the substantial level of individualised care and the personalised nature of the devices that is required for optimal treatment.

The data collected from this consultation, and feedback from the Advisory Group and research team, were used to develop and enhance the planned survey. The questionnaire is presented in *Appendix 7*, with the following section headings:

- demographic characteristics of respondents
- patient demographic
- patient referrals
- initial assessment
- prescription and fitting of orthotic devices
- types of devices
- treatment outcomes and acceptability factors
- additional requests (which included a request for any audit, service evaluation or other type of data and an invitation to the orthotists to take part in telephone interviews focusing on the cost of orthotic devices).

Qualtrics® software (Qualtrics LLC, Provo, UT, USA) was used to distribute the survey. The questions were ordered to follow a typical care pathway for a patient and distributed over 78 screen pages – one question per page. In an attempt to reduce the number of questions, adaptive questioning was used throughout the questionnaire – details are available in *Appendix 7*. Respondents had to answer each question, in turn, in order to progress; some questions included a non-response option such as ‘not applicable’. No consistency or completion checks were undertaken before the questionnaire was submitted (this was not possible with the software used). Respondents were able to review and change their answers using a ‘previous’ and ‘next’ button, and monitor their progress through the questionnaire on a ‘% completed’ bar.

The survey was piloted on HCPs and the Advisory Group members: usability and technical functionality was tested by project team members and colleagues.

### Survey distribution

The survey was distributed to respondents as an open survey link, via an e-mail invitation from their relevant organisation. The information necessary to make informed consent was included in the invitation e-mail (see *Appendix 8*) and participation was taken as implied consent. Participation was voluntary and no incentives were offered or passwords required for completion of the questionnaire. The first distribution letter was e-mailed in November 2014; reminder e-mails were sent at 2 and 4 weeks after distribution and the survey was closed in January 2015.

The survey was advertised on the NHS Orthotics Network forum and the NHS Orthotics Manager Network forum (see *Appendix 9*) and blogs posted on the project blog site, encouraging HCPs to complete the survey when they received the link.

The results collated in the Qualtrics software were downloaded into Microsoft Excel® (2010 version, Microsoft Corporation, Redmond, WA, USA). All responses that were collected for each question were analysed, with the response rate for each question calculated. The length of time taken by respondents to answer questions was not collected and therefore no cut-off points were used. No adjustments were made to adjust for the non-representativeness of our sample. To help compensate for the incomplete sampling frame, those respondents who stated that they did not treat patients with a NMD or CNS condition and knee instability skipped to the end of the survey, and provided only their demographic profile to the survey results.

We have followed the Checklist for Reporting Results of Internet E-Surveys.<sup>44</sup>

### Costing analysis

Following on from the survey of HCPs, an analysis to estimate the cost of orthotic devices currently being used by the NHS for the management of instability of the knee in adults with NMD and CNS disorders was undertaken. As per the study protocol, the costing analysis involved estimating two components:

1. the resources (e.g. staff and materials) required to provide orthotic devices to patients with NMD and CNS conditions with knee instability
2. the unit costs associated with these resource-use estimates.

### Identification of resource-use estimates

The target population to estimate the resources required to provide orthotic devices to patients with NMD and CNS conditions with knee instability were orthotists. Therefore, the information gathered from the survey of HCPs, which included orthotists, was used, where appropriate. This was supplemented by telephone interviews with orthotists, looking specifically at the resources required to provide orthotic devices. These orthotists were recruited through the survey of HCPs. At the end of the questionnaire, orthotists were asked if they would be willing to take part in a telephone interview at a later date (Q65). Respondents were also asked if they had any audit, service evaluation or other type of data, which could be shared with the project team (Q63, Q64). This question elicited some contact with HCPs but did not result in any data being obtained.

Ethical approval for the telephone interviews to estimate the resource-use requirements for costing devices was sought from, and granted by, the University of York's Department of Health Sciences' Research Governance Committee. As per this approval, the personal information collected from these sessions was stored securely, accessible only to the research team and will be destroyed after 5 years. Five orthotists e-mailed the research team, were sent a participant information sheet and consent form, and agreed to take part in these interviews. Four telephone interviews were subsequently undertaken. Informed consent was sought from the four participants. The telephone interviews followed the topic guide presented in *Appendix 6*. The four telephone interviewees were all male, and all worked in a hospital setting. Two interviewees were based in the south of England, one interviewee was based in the north of England, and one interviewee worked as a locum.

The original project protocol stated that the semistructured interviews would be structured around a series of patient profiles and would cover the key types of orthotics used for knee instability in our patient population. However, the patients' interviews and the HCPs' focus groups, telephone interviews and survey, highlighted not only that patients with NMD and/or CNS conditions with knee instability are a diverse group of patients, but that the devices being prescribed to them are also diverse and the prescription process undertaken to provide this patient population with the appropriate device is relatively complex. Custom-made devices could be considered to be a personalised medicine, in that although the components of the various devices (e.g. KAFOs) available may be fairly similar, there is the potential for a KAFO to be unique to each patient for whom it is prescribed. Therefore, in the same way that the survey became more detailed, the telephone interviews for the costing analysis became more focused and the scope of the discussions was reduced.

Given the complexity of the prescription process and the number of variables that need to be taken into account to accurately cost orthotic devices for this patient population, a more detailed costing exercise was undertaken. To begin quantifying the cost of a personalised device, the materials required and the determinants of the quantity of these materials required needed to be estimated. Given these additional information requirements, the interviewees were asked to provide estimates only for a KAFO. The KAFO was chosen as the orthotic device of most interest because of the project's original commissioning brief; the KAFO is also one of the commonly prescribed orthotic devices for this patient population according to our survey. Respondents were asked to consider the following KAFOs:

1. '*conventional*', which are made from conventional materials, such as metal and leather
2. '*cosmetic*', which are made from materials such as carbon fibre and thermoplastic
3. '*hybrid*', which are a combination of the materials used in conventional and cosmetic KAFOs.

Given the volume of information required from these telephone interviews, it was not possible to discuss the resources required to provide KAFOs to particular groups and so patient profiles were not used.

As per the topic guide, the orthotists were asked to discuss orthotic provision to patients with NMD and CNS conditions with knee instability around the following:

- materials required to manufacture KAFOs
- staff required to provide KAFOs
- overheads and types of orthotic service provision in the UK
- opportunity cost of not prescribing a KAFO to our patient population of interest.

The orthotists were asked to consider costs and resource-use estimates from a NHS perspective only, as per the topic guide.

### **Identification of cost estimates**

As stated in the project protocol, up until 2010, the NHS Purchasing and Supply Agency (PASA) was the main health service purchasing organisation and would have provided estimates for the device costs under consideration in this report. Enquiries were made to NHS Supply Chain, the organisation into which NHS PASA was subsumed. Enquiries were also made to private manufacturer/suppliers of orthotic devices. However, the replies received indicated that price lists could not be made available because of commercial confidentiality agreements. Expert opinion was also sought, for unit cost estimates. The expert opinion provided to the project, was from a senior orthotist, who worked in a large hospital setting where orthotic devices are manufactured on site.

## Patient and public involvement

We developed an advert and role description (available from authors) to recruit two patients with NMD or CNS conditions with experience of using orthoses for knee problems to join the project Advisory Group. We approached several voluntary organisations to disseminate the opportunity among members: Charcot–Marie–Tooth UK, the Stroke Association, the Spinal Injuries Association, Muscular Dystrophy UK, and the British Polio Fellowship. One individual joined our Advisory Group. At the outset our view was that it was important that we had input from individuals with specific experience of using the devices of interest, as there was very little information available to us about patient perspectives. This limited the pool of people available to us locally, and distance, as well as daytime meetings for people who worked, was a barrier. However, the expertise our public member brought about orthotic devices and how services operate was essential; in particular, their views were sought on the qualitative study and the survey questionnaire. At their suggestion they joined the meeting by Skype™ (Microsoft Corporation, Redmond, WA, USA) and we undertook some work by e-mail. In future projects we would be clearer in advertisements about the possibility of communicating in various ways in addition to, or instead of, face to face. We also undertook various public engagement activities (see *Chapter 7*), which created the opportunity to speak with individuals from the Yorkshire and Humber Muscle Group and the Polio Survivors Network in the early stages of the project.

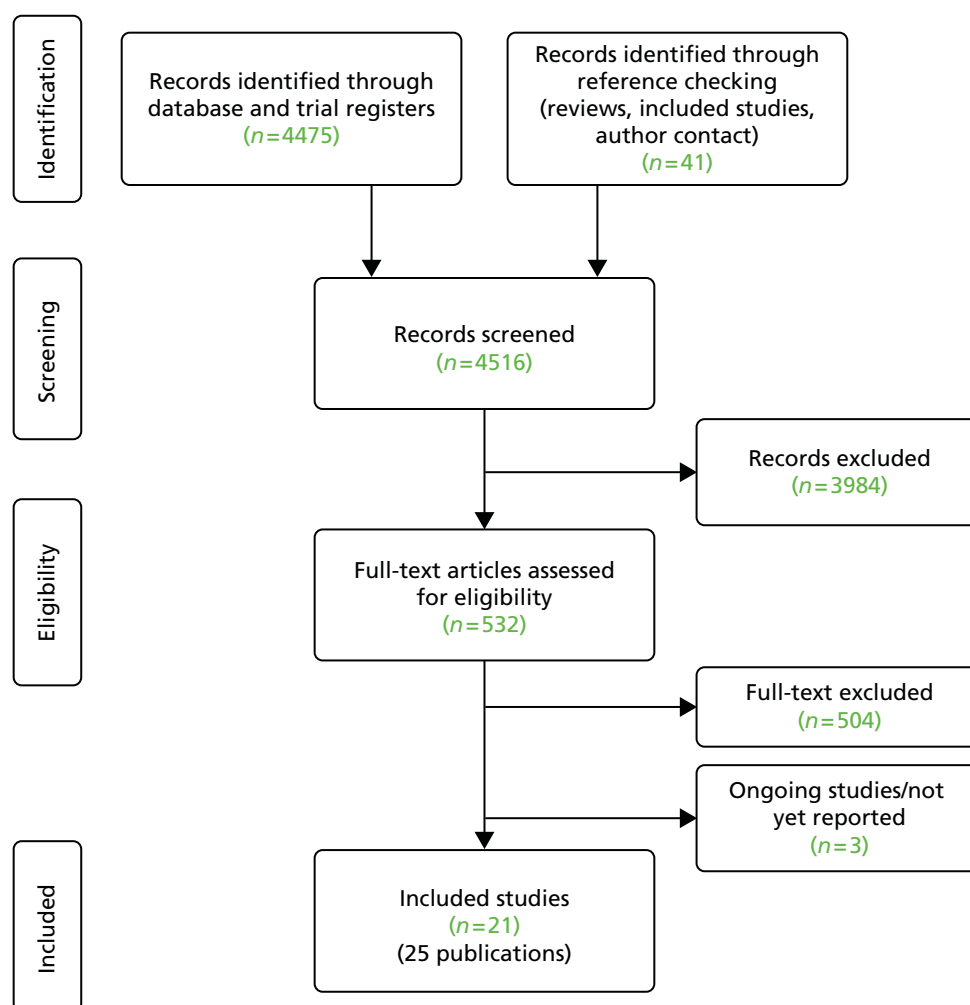


## Chapter 3 Results of systematic review

### Study selection

The search strategies and allied searching identified 4516 references (including update searches). Titles and abstracts were screened and full copies of 532 papers were obtained and assessed for inclusion in the review. *Figure 1* shows the flow of studies through the review process and the numbers excluded at each stage. Overall, we included 21 studies reported in 25 publications.<sup>45–69</sup> Three ongoing studies were identified and further details of these are provided in *Appendix 10*.

Determining eligibility was quite tricky for some studies, as it was sometimes difficult to definitively determine whether or not the problem being managed was knee instability. This was partly because of poor reporting but also because knee instability was sometimes part of a more complex problem with stability and mobility. Seventy-six studies were identified that took place in laboratory or clinical settings without the patient using the orthosis in the community. These were excluded as participants had not had the opportunity to use the orthosis in everyday life. Other reasons for exclusion were that participants did not have a relevant CNS disorder or NMD ( $n = 80$ ); they were aged  $< 16$  years or the results for adults and children were not reported separately ( $n = 41$ ); they did not have knee instability ( $n = 73$ ); they were not using an orthosis ( $n = 71$ );



**FIGURE 1** Flow of studies through the review process.



no outcomes were reported ( $n = 38$ ); an inappropriate comparator ( $n = 1$ ); not a primary study ( $n = 109$ ); unavailable ( $n = 18$ ); and background only ( $n = 25$ ) (some studies had more than one reason for exclusion). A list of the 504 full papers excluded and reason(s) for exclusion is provided in *Appendix 11*.

## Characteristics of included studies

Twenty-one studies were included in the review.<sup>45,47–50,52,53,56–69</sup> An overview of the included studies is presented in *Table 1*. Full data extraction tables are provided in *Appendix 12*.

The included studies were published between 1982<sup>60</sup> and 2013.<sup>48</sup> All were reported as full papers. There were two RCTs (one with a crossover design); two non-randomised studies with a control group

**TABLE 1** Overview of included studies

Main publication (associated papers)	Study design	Country	Number of participants in study	Number of participants in analysis	Device evaluated
<b>Post-polio syndrome</b>					
Bocker 2013 <sup>47</sup> (Bocker 2011 <sup>46</sup> )	Case series	Germany	10	6	I: carbon fibre KAFO C: no comparator
Brehm 2007 <sup>49</sup>	Case series	Netherlands	23	20	I: carbon fibre KAFO (locked knee joint) C: leather/metal or plastic/metal KAFO used previously by same participants
Davis 2010 <sup>50</sup>	Case series	Australia	10	10	I: carbon fibre SCKAFO in stance control mode C: KAFO in locked-knee mode used by same participants
Hachisuka 2006 <sup>52</sup> (Hachisuka 2007 <sup>51</sup> )	Case series	Japan	11	8 to 11 <sup>a</sup>	I: carbon fibre KAFO C: traditional non-carbon KAFO used by same participants
Heim 1997 <sup>56</sup>	Case series	Israel	30	27	I: carbon fibre KAFO C: no comparator
Peethambaran 2000 <sup>61</sup>	Case series	USA	5	5	I: carbon titanium KAFO (anterior approach design) C: plastic KAFO (posterior approach design) used previously by the same participants
Steinfeldt 2003 <sup>63</sup>	Case series	Germany	55	55	I: carbon fibre KAFO C: no comparator
<b>Inclusion body myositis</b>					
Bernhardt 2011 <sup>45</sup>	Case series	USA	9	6	I: SCKAFO C: no comparator
<b>Post stroke</b>					
Boudharam 2013 <sup>48</sup>	Case series	France	11	Unclear	I: carbon fibre KAFO C: no comparator

TABLE 1 Overview of included studies (continued)

Main publication (associated papers)	Study design	Country	Number of participants in study	Number of participants in analysis	Device evaluated
Kakurai and Akai 1996 <sup>58</sup>	Case series	Japan	28	28	I: plastic convertible KAFO (to AFO) C: participants who changed to AFO compared with those remaining on KAFO
Morinaka 1982 <sup>60</sup>	Cohort study	Japan	25	25	I: plastic KAFO C: 50 participants fitted with AFOs and a group of 30 healthy adult males
Yang 2005 <sup>69</sup>	RCT	China	67	67	I: KAFO or AFO C: 'conventional rehabilitation'
<b>Spinal cord injury</b>					
Harvey 1997 <sup>53</sup> (Harvey 1997, <sup>54</sup> 1998 <sup>55</sup> )	RCT (crossover)	Australia	10	5–10 <sup>b</sup>	I: HKAFO (WO) C: HKAFO (IRGO)
Jaspers 1997 <sup>57</sup>	Case series	Belgium	14	14	I: HKAFO (ARGO) C: no comparator
Middleton 1997 <sup>59</sup>	Case series	Australia	25	21	I: HKAFO (WO) C: no comparator
Scivoletto 2000 <sup>62</sup>	Case series	Italy	24	24 <sup>c</sup>	I: HKAFO (RGO) C: no comparator (internal comparison of non-users with users)
Summers 1988 <sup>64</sup>	Case series	UK	20	20	I: HKAFO (HGO ParaWalker; The Orthotic Research & Locomotor Assessment Unit, Robert Jones & Agnes Hunt Orthopaedic Hospital NHS Foundation Trust, Oswestry) C: no comparator
Sun 2007 <sup>65</sup>	Case series	China	20	15	I: HKAFO (RGO) C: no comparator
Tang 2009 <sup>66</sup>	Controlled study	China	58	Unclear	I: AGO, RGO, KAFO C: rehabilitation training
Whittle 1991 <sup>67</sup>	Controlled study (crossover)	UK	22	Unclear <sup>d</sup>	I: HKAFO (HGO ParaWalker) C: HKAFO (RGO)
Wu 2003 <sup>68</sup>	Case series	China	6	6	I: HKAFO (WO) C: no comparator group

AGO, alternative gait orthosis; I, intervention; C, comparator; WO, Walkabout® (Polymedic, QLD, Australia) orthosis.

a Eight completed assessment of non-carbon fibre KAFO and walking without an orthosis and 11 completed assessment of carbon fibre KAFO.

b Appears to be 10 for all analyses except for speed of walking on flat surface ( $n=8$ ) and speed of walking on ramp ( $n=5$ ).

c A total of 24 for the single outcome eligible for the review, although unclear for other analyses in the study.

d Appears to be 22 for analysis of final choice of orthosis, although one left the trial without trying either, and three participants tried only one. It was unclear how many participants were included in other analyses.

(one with a crossover design); one cohort study; and 16 case series (see *Table 1*). The case series made predominantly before-and-after comparisons either with a previously used device or no device (see *Table 1*).

The literature is international with studies in China, Japan, Australia, UK, Germany, USA, the Netherlands, France, Belgium, Italy and Israel. Seventeen studies were published in English,<sup>45,47–50,52,53,56–62,64,67,68</sup> three in Chinese<sup>65,66,69</sup> and one in German.<sup>63</sup> The studies in languages other than English were extracted by a native speaker who was also a researcher with experience of undertaking systematic reviews. These were checked by a second researcher for consistency only.

Overall, 478 patients were included in the review. Sample sizes were small, ranging from 5<sup>61</sup> to 67<sup>69</sup> participants with 11 studies having 20 or fewer participants (see *Table 1*). Eight of the studies reported knee instability as a result of NMD (153 patients)<sup>45,47,49,50,52,56,61,63</sup> (all except one study<sup>45</sup> being of patients with post-polio syndrome) and 13 reported knee instability resulting from CNS causes (325 patients),<sup>48,53,57–60,62,64–69</sup> either post stroke or spinal cord injury.

Follow-up time was generally short, ranging from 6 weeks<sup>61</sup> to 30 months.<sup>56</sup>

## Study quality

The quality assessments are reported for RCTs (*Table 2*), non-randomised controlled studies (*Table 3*) and case series (*Table 4*). Overall, both RCTs<sup>53,69</sup> had a high risk of bias (see *Table 2*). Owing to poor reporting it was not possible to determine whether or not they were truly randomised studies or to determine whether or not a robust method of allocation concealment had been used. It is not possible to blind participants or clinicians treating them to an orthotic device. Independent outcome assessment would have protected against detection bias; however, there was no evidence of this in either study.

**TABLE 2** Risk-of-bias assessment of RCTs

Study	Selection bias		Performance bias: blinding of participants and personnel	Detection bias: blinding of HCP-assessed outcomes	Attrition bias	Selective outcome reporting	Other
	Random sequence generation	Allocation concealment					
Yang <sup>69</sup>	Unclear risk	Unclear risk	High risk  Not possible due to nature of intervention	High risk of bias  Treating clinician-assessed outcome, which is likely to be influenced by lack of blinding	Low risk of bias	Unclear	
Harvey <sup>53</sup>	Unclear risk	Unclear risk	High risk  Not possible due to nature of intervention	High risk of bias  Treating clinicians appeared to be involved in gathering data on outcomes that were likely to be influenced by lack of blinding	High risk of bias for ambulatory outcomes	Unclear	Only a small number of patients wore their second device, suggesting that a crossover design was not appropriate

**TABLE 3** Quality assessment of non-randomised controlled studies

Study	Selection criteria adequately reported?	Representative sample?	Participation rate $\geq$ 80%?	Performance bias?	Independent outcome assessment?	Follow-up $\geq$ 80%?	Selection bias?							
							1	2	3	4	5	6	7	8
Morinaka <sup>60</sup>	N	U	N	U	N	NA <sup>a</sup>	Y	Y	U	U	U	U	N <sup>b</sup>	U
Tang <sup>66</sup>	Y	Y	Y	U	N	U	U	U	U	U	U	U	U	U
Whittle <sup>67</sup>	N	U	U	U	N	Y	U	U	U	U	U	U	U	U

N, no; NA, not applicable; U, unclear; Y, yes.

a Appears to be retrospective.

b The average time post-stroke was 20 months for the KAFO group and 40 months for the AFO group, suggesting probable differences in functioning and time using an orthotic device.

**Note**

1, gender; 2, age; 3, cause of muscle weakness; 4, presence of sensory disturbance; 5, purpose of orthosis (proximal/distal muscle weakness); 6, previous use of orthosis; 7, acclimatisation time; 8, type of orthosis used.

TABLE 4 Quality assessment of case series

Study	Selection criteria adequately reported?	Representative simple?	Participation rate $\geq 80\%$ ?	Prospective?	Independent outcome assessment?	Follow-up $\geq 80\%$ ?	Prognostic variables reported?	Cointerventions?	Measure of variability?	Other important limitations
Bernhardt <sup>45</sup>	N	U	U	Y	N	N	Y	N	P	Reporting of results
Bocker <sup>47</sup>	Y	Y	U	Y	N	N	N	Y	Y	Reporting of results
Boudarham <sup>48</sup>	Y	U	U	Y	N	U	Y	N	Y	
Brehm <sup>49</sup>	Y	U	U	Y	N	Y	Y	N	P	Reporting of results
Davis <sup>50</sup>	Y	U	U	Y	N	Y	Y	Y	Y	Generalisability of assessing two different modes of using orthosis in clinic
Hachisuka <sup>52</sup>	U	Y	U	Y	N	N	Y	Y	P	Reporting of results
Heim <sup>56</sup>	N	U	U	Y	N	Y	N	N	N	Reporting of results
Jaspers <sup>57</sup>	N	U	N	N	Y	N	Y	Y	NA	
Kakurai and Akai <sup>58</sup>	N	U	U	Y	N	Y	Y	N	Y	Ability to actively control knee a confounder for KAFO and AFO comparisons
Middleton <sup>59</sup>	Y	U	U	U	N	Y <sup>a</sup>	Y	Y	Y	Only patients who had successfully completed gait training and continued to used the orthosis were administered a questionnaire

TABLE 4 Quality assessment of case series (continued)

Study	Selection criteria adequately reported?	Representative sample?	Participation rate $\geq 80\%$ ?	Prospective?	Independent outcome assessment?	Follow-up $\geq 80\%$ ?	Prognostic variables reported?	Cointerventions?	Measure of variability?	Other important limitations
Peethambaran <sup>61</sup>	Y	U	U	Y	N	Y	Y	N	Y	Generalisability due to small sample
Scivoletto <sup>62</sup>	U	U	U	Y	N	Y <sup>a</sup>	Y	N	Y	
Steinfeldt <sup>63</sup>	N	U	U	N	N	Y	N	N	N	
Summers <sup>64</sup>	Y	U	U	N	N	NA <sup>b</sup>	N	Y	NA	Lack of information on interview questionnaire
Sun <sup>65</sup>	N	U	U	U	N	N	N	U	N	
Wu <sup>68</sup>	Y	U	U	U	N	Y	Y	Y	Y	Generalisability due to small sample

N, no; NA, not applicable; P, partial; U, unclear; Y, yes.

<sup>a</sup> For outcome/s included in review.

<sup>b</sup> Retrospective study.

Poor reporting was also an issue for assessing risk of bias in the non-randomised controlled studies and case series. Overall, only one of the non-randomised control studies met all of the three criteria that were related to selection of participants into the study; however, it was unclear if the groups were balanced appropriately for key clinical criteria and it was not possible to assess how complete the follow-up was.<sup>66</sup> As with the RCTs, none reported independent outcome assessment (see *Table 3*).

Ten of the case series were prospective, three were retrospective and for three there was insufficient information to determine the design (see *Table 4*). There was a risk of selection bias across all of the case series: eight described their inclusion criteria (see *Table 4*);<sup>47-50,59,61,64,68</sup> for two of the studies<sup>52,62</sup> it was not possible to determine if the criteria presented were a priori inclusion criteria or a description of who was included in the study; and the remaining studies did not clearly specify the inclusion criteria. Two case series used a method that suggested that they were likely to have a representative sample, such as a consecutive sample of patients from a clinic, although it was unclear whether or not the participation rate was > 80% and, therefore, selection bias may have been introduced here.<sup>47,52</sup> One study<sup>57</sup> reported using independent outcome assessment.

Most studies did not have a comparator group of patients. In just one comparative study<sup>62</sup> was it possible to determine that performance bias was not present (i.e. treatment groups were not treated differently). One study<sup>57</sup> had an independent assessor, with the remainder assessing follow-up through treating health professionals (i.e. the individuals delivering the intervention also assessed the effectiveness of the intervention) thereby introducing the risk of bias in outcome assessment.

Poor reporting was in evidence across the studies in this review; this was in relation to both study methods and results. In terms of methods, 15 studies<sup>45,48,49,52,56-60,62-64,67-69</sup> gave no indication of the orthosis 'dose' given to patients (i.e. the time per day/week for which they were advised to use their orthosis). Actual use of the orthoses was not provided in 12 studies.<sup>47-50,52,61,63,65-69</sup> Other study aspects that could also impact on results were under-reported. Participants' previous use of orthoses was not reported in six studies<sup>48,62,63,65-67</sup> and co-interventions were not well reported. In general, results were poorly reported. Studies, in the results section, often made statements that were not backed up with numerical data. When no data have been provided to support statements, this has been highlighted in the relevant results sections that follow. Adverse effects were not investigated or not reported in 17 studies.<sup>45,47-50,52,53,59-63,65-69</sup>

We planned to extract data to allow calculation of between-group differences and confidence intervals. However, because of the generally poor reporting of data, it was not possible to consistently do this across studies. When data were available, these were extracted; when the appropriate data were not reported, the description of the results provided in the paper was extracted and the lack of summary data was noted.

## Results from studies of patients with post-polio syndrome

Seven studies<sup>47,49,50,52,56,61,63</sup> (*Table 5*) assessed the effects of orthoses on patients with knee instability following poliomyelitis (143 patients). None of the studies was conducted in the UK. All were case series, with four studies having  $\leq 11$  patients.<sup>47,50,52,61</sup>

Four studies<sup>49,50,52,61</sup> compared different types of orthoses used by the same participants, three of these were effectively comparisons before and after provision of a new device; in the fourth study,<sup>50</sup> participants were provided with a new stance control device and the comparison was between using the device in stance control mode and using it in locked mode (with the aim of replicating a traditional KAFO design). Comparisons were made before and after use of the orthosis in two studies:<sup>47,63</sup> and post-intervention only in one study.<sup>56</sup> All orthoses investigated were types of carbon fibre KAFO.

TABLE 5 Post-polio syndrome study characteristics

Author	Population		Intervention					
	Total n, % male, mean age (SD) years	Previous orthotic use	Type of device	Material, manufacture	Orthosis dose	Co-interventions	Comparison	Follow-up
Bocker <sup>47</sup>	n = 10, 30%, 64.5	No	KAFO, 'type eight', mechanical lockable knee joint plus Glenzack joints to lift foot	Carbon fibre, prefabricated	Used over the whole day	Gait training, physical pain therapy and exercises, (both twice per week for 3 months)	Before-and-after provision of orthosis	3 months
Brehm <sup>49</sup>	n = 23, 61%, 55 (9.2)	Yes <sup>a</sup>	KAFO, locked knee joint	Carbon fibre (weight ranged from 0.9 to 2.1 kg), custom-made	Not reported	Walking aids were used by some participants	Leather and metal or plastic and metal KAFO previously used by same patients (weight ranged from 0.9 to 2.1 kg)	26 weeks
Davis <sup>50</sup>	n = 10 <sup>b</sup> , 40%, 61.9 (7.7)	Yes <sup>c</sup>	SCKAFO	Carbon fibre, prefabricated using Horton Stance Control knee joint	Regular use for > 4 hours/day	Walking aids	Same KAFO used in locked-knee mode	Mean duration of use at time of evaluation 6.2 (SD 5.2) months
Hachisuka <sup>52</sup>	n = 11, 18%, 53.9 (9.8)	Yes <sup>d</sup>	KAFO	Carbon fibre (mean weight 0.992 kg, SD 0.168 kg), custom-made	Not reported	Walking aids	Traditional non-carbon fibre KAFO and no orthosis in same participants (mean weight 1.403 kg, SD 0.157 kg)	Not reported
Heim <sup>56</sup>	n = 30, 33%, 44	Yes, all	KAFO	Carbon fibre (on average weighed 1.150 kg), prefabricated	Not reported	Not reported	After provision of orthosis only	30 months
Peethambaran <sup>61</sup>	n = 5, 40%, 61.4 (12.4)	Yes, all	KAFO, anterior approach, cable control locking mechanism	Carbon titanium, custom-made	Not reported	Not reported	Plastic KAFO used by same patients, posterior approach	6 weeks
Steinfeldt <sup>63</sup>	n = 55, 44%, 58	Not reported	KAFO	Carbon fibre, prefabricated	Not reported	Not reported	Before-and-after provision of orthosis	> 3 months

SD, standard deviation.

a All patients previously used a conventional locked knee joint KAFO made of leather/metal or plastic/metal with no technical deficits for < 2 years.

b One patient with motor neurone disease.

c Solid GRAFO 4, LKAFO ('LKAFO' used in original paper but not explained) 1, posterior offset KAFO 1, knee brace 1, none 3.

d Eight had used KAFO with double-metal uprights for > 10 years.



The outcomes were sparsely reported. Five<sup>49,52,56,61,63</sup> of seven studies<sup>47,49,50,52,56,61,63</sup> reported measures of patient satisfaction, although not in sufficient detail to assess the robustness of the evaluation. Few of the studies reported assessing device functionality, device usage and quality of life (*Table 6*). Three studies<sup>49,50,52</sup> made a formal assessment of walking ability and four studies<sup>47,49,50,52</sup> assessed either energy consumption or particular muscle activity. Resource utilisation data were limited to assessment of device malfunction in four studies<sup>49,52,56,61</sup> and cost in one study.<sup>52</sup> Five studies<sup>47,49,50,52,63</sup> failed to report adverse effects data or to mention that no adverse effects were identified, therefore, it was unclear if adverse effects had been formally assessed or not reported.

### Patient-reported outcomes

#### Satisfaction

Five studies assessed patient satisfaction.<sup>49,52,56,61,63</sup> Steinfeldt *et al.*<sup>63</sup> considered patient satisfaction before and after using a carbon fibre KAFO for 3 months. However, this was undertaken retrospectively and it was not clear if participants had previously used an orthosis. Additionally, the views were sought from only 55 of the 78 people who had received a device over the relevant time period; it was unclear why this was the case. Satisfaction was measured in terms of a range of activities measured on a 10-point numerical rating scale, with a higher score indicating better functioning.<sup>63</sup> Satisfaction was greater post device (pre-walking mean 3.8, post-orthosis mean 8.3; sitting pre 4.8, post 8.9; driving a car pre 5.8, post 9.1; comfort pre 4, post 8.8; putting the device on/taking it off pre 4.7, post 8.6). Statistical significance of these data and standard deviations (SDs) were not reported.<sup>63</sup> The authors combined the post-intervention Likert scores and reported that 63% of patients were very satisfied (45–50 points), 32% were satisfied (35–44 points), 3% were neither satisfied nor unsatisfied (20–34 points) and 2% were unsatisfied.<sup>63</sup>

Four further studies<sup>49,52,56,61</sup> assessed patient satisfaction by comparison with a previously worn device. All four studies<sup>49,52,56,61</sup> had improved satisfaction scores for carbon fibre devices compared with older devices. Brehm *et al.*,<sup>49</sup> in their study of 23 patients, state that mean patient satisfaction scores were 48% higher with the carbon fibre KAFO than with the leather/metal or plastic/metal device previously used by the same participants. However, baseline and follow-up scores were not reported in full, meaning that it was not possible to verify this finding or establish how satisfied participants were with the new device, other than that they were more satisfied.<sup>49</sup> Hachisuka *et al.*<sup>52</sup> reported that participants were more satisfied with their carbon fibre KAFO than with their previous (unspecified) KAFO especially relating to fatigue during walking, safety during walking and appearance (six patients); however, full details of these results were not provided. Heim *et al.*<sup>56</sup> reported that 19 out of 27 patients said that they would like to have a permanent carbon fibre orthosis because of it being lighter, better fitting and more aesthetic. Details of the patient structured questionnaire were not provided. In a very small sample of five patients, Peethambaran<sup>61</sup> reported that patients were statistically significantly more satisfied with a new carbon fibre anterior approach design KAFO than a conventional posterior approach design plastic KAFO for selected aspects (comfort, gait, appearance, effort, support, putting on/taking off, not catching on clothes and not rubbing on skin), with mean scores ranging from 4.4 to 4.8 on a 5-point scale, but not others (hours of wearing, loss of function, wearing an orthosis, device weight, device soiling clothes and device encouraging perspiration).

#### Functionality

Two studies considered patient-reported functionality.<sup>61,63</sup> Peethambaran<sup>61</sup> assessed patient functionality using a 5-point questionnaire and found that results were statistically significantly in favour of the carbon fibre anterior approach KAFO for ease of putting on and removal, and interference with sitting, but not for strap application, shoe application, maintenance and cleaning, balance, stability in level and uneven ground walking and adequacy for sports compared with a conventional plastic posterior approach KAFO.<sup>61</sup> However, the sample size in this study was very small ( $n = 5$ ). Steinfeldt *et al.*<sup>63</sup> reported that two-thirds of patients did not need orthopaedic shoes with the new carbon fibre KAFO (no comparator).

TABLE 6 Outcomes evaluated in post-polio syndrome studies

Study	Patient-reported outcomes			Objective assessments			Resource utilisation			
	Satisfaction with device	Functionality of device	Usage of device	Quality of life	Walking ability	Energy consumption	Muscle activity	Device malfunction	Cost	Adverse effects
Bocker <sup>47</sup>				✓			✓			
Brehm <sup>49</sup>	✓				✓	✓		✓		
Davis <sup>50</sup>					✓	✓				
Hachisuka <sup>52</sup>	✓				✓	✓		✓	✓	
Heim <sup>56</sup>	✓		✓					✓		✓
Peethambaran <sup>61</sup>	✓									✓
Steinfeldt <sup>63</sup>	✓	✓						✓		

## Usage

It was unclear in all studies, except one,<sup>56</sup> if patients had actually worn their orthosis as advised. Heim *et al.*<sup>56</sup> stated that 21 out of 27 patients wore their orthosis 'throughout the day', but did not provide further detail on how this was elicited and the precise duration of use. Two further studies<sup>47,50</sup> specified an amount of time that the orthosis should be worn, and one study<sup>61</sup> specified that patients wore the orthosis for a period of 6 weeks, but it was unclear in either study if participants had used the orthotic device as advised.

## Quality of life

At 3-month follow-up of six patients, Bocker *et al.*<sup>47</sup> noted no significant changes in patient quality of life as measured by the Short Form questionnaire-36 items (SF-36) compared with baseline (no orthosis). SF-36 data were reported in a figure only and it was not possible to extrapolate the data because of the scale. At 26-week follow-up Brehm *et al.*<sup>49</sup> reported no significant difference in physical function subscale of the SF-36 with a carbon fibre KAFO compared with the leather/metal or plastic/metal device previously worn. Again, the actual data were not reported.

## Objective assessments

Four studies<sup>47,49,50,52</sup> conducted a gait assessment. Two studies<sup>49,52</sup> evaluated walking ability and energy consumption between an older and newer design of orthosis; one study<sup>50</sup> assessed these outcomes using a SCKAFO in stance control mode and locked-knee mode. One study<sup>47</sup> focused on muscle activity before, and 3 months after, use of the orthosis.

## Walking ability

Hachisuka *et al.*<sup>52</sup> ( $n = 11$  participants) found that walking speed with a custom-made carbon KAFO was significantly faster than walking without an orthosis: 39.5 (SD 9.8) m/minute compared with 31.0 (SD 8.6) m/minute, and walking with an 'ordinary' KAFO 42.6 (SD 7.8) m/minute compared with 38.5 (SD 7.0) m/minute; both  $p < 0.05$  (not all patients completed each condition). Based on 10 participants, Davis *et al.*<sup>50</sup> stated that walking velocity was significantly increased in the stance control condition of the Horton Stance Control orthosis compared with the locked mode [locked mode mean 65.0 cm/second (SD 24.5), SCKAFO mean 72.9 (SD 95.7) cm/second;  $p = 0.000107$ ]. This was reported to be a result of significantly increased cadence and increased step length on the sound limb.<sup>50</sup> Brehm *et al.*<sup>49</sup> reported that walking speed remained unchanged between the carbon fibre locked KO and previous plastic or leather KAFO (23 participants): 1.8 m/minute (95% CI  $-4.35$  to  $0.57$  m/minute) (data as reported in original paper, effect lies outside confidence interval).

## Energy consumption

Two studies<sup>49,52</sup> found that energy costs were lower for the newer device than the older one. Brehm *et al.*<sup>49</sup> found that the gross and net energy cost of walking were both significantly lower for the new carbon fibre KAFO than the plastic or leather KAFO previously used. Gross energy consumption: mean difference  $-0.42$  (95% CI  $-0.63$  to  $-0.21$ ) J/kg/minute; 7% reduction. Net energy consumption: mean difference  $-0.36$  (95% CI  $-0.54$  to  $-0.18$ ) J/kg/minute; 8% reduction.<sup>49</sup> Hachisuka *et al.*<sup>52</sup> reported that oxygen consumption per body weight (ml/kg/minute), oxygen cost and physiological cost index while walking with a carbon KAFO were significantly lower than while walking without an orthosis ( $-16\%$ ,  $-35\%$  and  $-33\%$ , respectively) and with an ordinary KAFO ( $-9\%$ ,  $-14\%$  and  $-15\%$ , respectively); all  $p < 0.05$ . Davis *et al.*<sup>50</sup> found no difference in the oxygen cost of walking between the two conditions (nine participants): locked condition 0.213 (SD 0.081) ml/kg/minute, stance control 0.224 (SD 0.069) ml/kg/minute;  $p = 0.515$ .

## Functionality

One study<sup>47</sup> assessed muscle function. Bocker *et al.*<sup>47</sup> reported an increased stance duration of 24% from baseline to 3 months' follow-up ( $p = 0.029$ ) in the leg with the carbon fibre KAFO. They reported that there were no statistically significant differences in the opposite leg during the intervention. Muscle activity was reported in some detail and a summary can be found in the data extraction tables (see *Appendix 12*).

## Resource utilisation

### Device malfunction

Four studies<sup>49,52,56,63</sup> reported on device problems. Data were provided in the text of the papers, but it was unclear how systematically this information had been gathered. Brehm *et al.*<sup>49</sup> stated that 7 out of 23 patients reported technical deficits relating to the hinge at the ankle or knee, which could be easily repaired (no details of repair procedures provided). Seven patients reported wear to the cloth upholstery inside the KAFO. One patient needed a replacement of the orthosis as a result of a break of the KAFO. In the study by Hachisuka *et al.*,<sup>52</sup> follow-up data were available for at least 2 years for this outcome, and the carbon fibre KAFO remained undamaged. Heim *et al.*<sup>56</sup> noted that within 30 months 19 out of 30 braces had undergone minor repair in the workshop. Steinfeldt *et al.*<sup>63</sup> commented that 'patient reports of the need for repairs did not show substantial problems' (no further details provided). However, none of these studies reported full details of usage of the orthosis, so it is unclear how reliable and generalisable these data are.

### Cost

One study undertaken in Japan (published in 2006) by Hachisuka *et al.*<sup>52</sup> reported that the price of a standard carbon fibre KAFO was 180,000 Japanese yen (US\$1700), 50% more expensive than the ordinary KAFO.

### Adverse effects

Data on any adverse effects were sparse: the majority of studies did not appear to systematically collect these data. Two studies<sup>56,61</sup> (35 participants) reported adverse effects in a limited way. Peethambaran<sup>61</sup> stated that the new carbon fibre KAFO was statistically significantly favoured for comfort compared with conventional KAFO in ankle, thigh (back), knee (back) and lower leg (back), but not for thigh (front), knee (front) or lower leg (front). However, this may simply relate to the fit of the device rather than the construction per se. It was an improvement on the previous device in terms of rubbing on skin and catching on clothes, but no difference was noted for the device soiling clothes or causing perspiration (five patients).<sup>61</sup> Heim *et al.*<sup>56</sup> reported that, at the end of the study, 8 out of 30 patients chose a metal orthosis rather than the carbon fibre brace as a result of skin irritation from the material, excessive sweating due to proximity of orthosis to skin, and inability to alter the shape in accordance with circumferential limb changes. The remaining studies did not report adverse effects or stated that none had occurred.

## Results from studies of patients with inclusion body myositis

One case series study<sup>45</sup> (*Table 7*) assessed the effects of orthoses on patients with knee instability as a result of inclusion body myositis (nine patients). This small study of a rare condition was conducted in the USA. Patient selection criteria for the study were not reported in full and it is unclear if the patients are fully representative of those seen in practice.

A comparison was made between patient gait with and without the SCO after 6 months' use of the device. Patient feedback on the device was also sought. The study<sup>45</sup> did not appear to use an independent outcome assessor and follow-up was incomplete (six of nine had outcome data). A gait assessment was conducted to assess walking ability. An author-designed questionnaire was used to elicit patient outcomes but results were not reported in full, just as textual summaries. No data were reported on resource utilisation or adverse effects (*Table 8*).

### Patient-reported outcomes

These were reported by the authors as a narrative summary only; data were not presented. Follow-up was available for six out of nine participants. In terms of functionality of the device, the authors reported that participants felt that the SCKAFO was helpful for protecting against falls and providing stability. The authors further explained that, in relation to patient satisfaction, all participants had complaints regarding size, bulk,

**TABLE 7** Inclusion body myositis study characteristics

Author	Population		Intervention					
	Total <i>n</i> , % male, mean age (SD) years	Previous orthoses use	Type of device	Material, manufacture	Orthoses dose	Co-interventions	Comparison	Follow-up
Bernhardt <sup>45</sup>	<i>n</i> =9, 78%, 61 (9)	No	SCKAFO	Not reported  Prefabricated, Sensor Walk™ (Otto Bock Health Care, Minneapolis, MN, USA)	Not reported	Not reported	With and without the orthosis	6 months

**TABLE 8** Outcomes assessed in inclusion body myositis studies

Study	Patient-reported outcomes				Objective assessments			Resource utilisation		Adverse effects
	Satisfaction with device	Functionality of device	Usage of device	Quality of life	Walking ability	Energy consumption	Muscle activity	Device malfunction	Cost	
Bernhardt <sup>45</sup>	✓	✓	✓		✓					

cosmesis and noise of the device. They cited difficulty in putting on/taking off the brace. Most participants stated that they would prefer a less-intrusive assistive device. The authors identified that participants with less weakness tended to have positive feedback on the device. This was found to be regardless of the amount of time spent using it. Use of the brace ranged from about 2 hours per day to all day every day.<sup>45</sup>

### Objective outcomes

Data for most of these outcome measures were available in small-scale graphs only and summary statistics were not presented. At 6-month follow-up participants walked more slowly ( $p = 0.025$ ) and with a lower cadence ( $p = 0.0007$ ) with the SCKAFO than when walking without the device. Stride length with the SCKAFO was not significantly different between the two conditions. Participants had a wider step width with the brace (0.035). When wearing the device the weaker participants walked more slowly ( $p = 0.022$ ) and had a lower cadence ( $p = 0.019$ ) and a shorter stride length ( $p = 0.048$ ) than participants with less weakness. Peak knee flexion during swing significantly decreased when using the device [from mean 74.7 (SD 2.9) degrees to mean 62.9 (SD 10.8) degrees;  $p = 0.021$ ]. There was no significant difference in peak hip flexion during swing when using the device [from mean 41.4 (4.6) degrees to mean 39.7 (6.5) degrees;  $p = 0.355$ ].<sup>45</sup> No further outcomes were reported.

## Results from studies of post-stroke patients

Four studies<sup>48,58,60,69</sup> (Table 9) assessed the effects of orthoses on patients with knee instability following stroke (131 patients). None of the studies was conducted in the UK. There was one RCT<sup>69</sup> that was limited in its reporting, a cohort study<sup>60</sup> and two case series<sup>48,58</sup> (one of which had only 11 patients).

The studies made varying comparisons. Boudharam *et al.*<sup>48</sup> undertook gait analysis with and without a carbon fibre KAFO. Kakurai and Akai<sup>58</sup> compared patients who had changed to a plastic AFO with those who continued to use a plastic KAFO. This study<sup>58</sup> was not comparing two types of devices: the comparison was between those who had recovered sufficient control of knee activity to switch to an AFO device and those who had not. Morinaka *et al.*<sup>60</sup> compared a plastic KAFO to AFO and to normal adult gait. Yang *et al.*<sup>69</sup> undertook a RCT comparing AFO or KAFO to conventional rehabilitation (not reported in detail). In one study,<sup>48</sup> orthoses were made of carbon fibre, two used plastic orthoses,<sup>58,60</sup> and the RCT by Yang *et al.*<sup>69</sup> did not report the material.

None of the studies reported using an independent outcome assessor to assess outcomes. Duration of follow-up was not reported in two studies,<sup>58,69</sup> although the RCT by Yang *et al.*<sup>69</sup> appeared to conduct an assessment of patients two to three months after treatment. In one study, the device had to have been prescribed in the previous 6 months<sup>48</sup> and in the fourth study<sup>60</sup> the follow-up was 14.6 months, but in the study with the longer follow-up such follow-up was incomplete (< 80%).<sup>60</sup> Outcomes were sparsely reported (Table 10). No studies assessed patient-reported outcomes, with the exception of Morinaka *et al.*,<sup>60</sup> who reported solely on the usage of the orthotic device. Three studies<sup>48,58,60</sup> made a formal assessment of walking ability and two studies<sup>58,69</sup> assessed other functional abilities. No studies reported on resource utilisation data. None reported any adverse effects data or mentioned that no adverse effects were identified.

### Patient-reported outcome

#### Usage

Morinaka *et al.*<sup>60</sup> reported that 25 patients continued to wear the orthosis without rejection at the end of the study, but did not provide results for all 36 patients who were fitted with an orthosis during the study period. It is not explained why only a subset of those fitted with a device was evaluated.

**TABLE 9** Post-stroke study characteristics

Author	Population		Intervention						Follow-up
	Total <i>n</i> , % male, mean age (SD) years	Previous orthoses use	Type of device	Material, manufacture	Orthoses dose	Co-interventions	Comparison		
Boudharam <sup>48</sup>	11, 64%, 51 (15)	Not reported	KAFO	Carbon fibre, custom-made	Required to have worn device daily > 1 month	Not reported	With and without KAFO	Device prescribed within past 6 months	
Kakurai and Akai <sup>58</sup>	28, 50%, 54.5	No	KAFO, which was convertible to an AFO	Plastic, custom-made	Not reported	Not reported	Patients changed to AFO vs. those who continued using KAFO	Not reported	
Morinaka <sup>60</sup>	25, 64%, 56	Yes, AFO (3)	KAFO	Plastic	Not reported	Not reported	AFO ( <i>n</i> = 50), adults who have not had a stroke ( <i>n</i> = 30)	Mean 14.6 months (range 1–35)	
Yang <sup>69</sup>	67, 84%, 58	No	KAFO/AFO	Not reported	Not reported	Not reported	Conventional rehabilitation	Not reported	

**TABLE 10** Outcomes assessed in post-stroke studies

Study	Patient-reported outcomes				Objective assessments			Resource utilisation		
	Satisfaction with device	Functionality of device	Usage of device	Quality of life	Walking ability	Energy consumption	Functional ability	Device malfunction	Cost	Adverse effects
Boudharam <sup>48</sup>					✓					
Kakurai and Akai <sup>58</sup>					✓		✓			
Morinaka <sup>60</sup>			✓		✓					
Yang <sup>69</sup>							✓			

## Objective assessments

### Walking ability

Walking ability was assessed in three studies,<sup>48,58,60</sup> two<sup>48,60</sup> of which conducted a formal gait assessment. Morinaka *et al.*<sup>60</sup> reported that 25 patients were able to walk smoothly after fitting of the KAFO (data not reported). The authors<sup>60</sup> state that follow-up results were more favourable for the KAFO users than for the AFO users for 8 out of 12 gait characteristics (data available only as small scale graph). The authors<sup>60</sup> state that knee flexion was better in AFO users and that KAFO users were about half to one-third faster than AFO users; again, outcomes were not reported in full (only qualitatively and in figures). It is unlikely that the AFO and KAFO groups were clinically similar, as the average time post stroke was 40 months in the AFO group and 20 months in the KAFO group; therefore, aside from inadequate reporting, there is undoubtedly confounding. Boudharam *et al.*<sup>48</sup> also conducted a formal gait assessment and found that gait velocity was significantly greater with the KAFO than without (21%;  $p = 0.025$ ). Stride length and cadence were also significantly greater in the KAFO condition (15%,  $p = 0.030$ ; 11%,  $p = 0.049$ ). Symmetry between the paretic and non-paretic limbs increased with the KAFO. There was no significant difference between the two conditions for step width ( $p = 0.384$ ). More details of gait measurements can be found in the data extraction tables in the appendices.<sup>48</sup>

In the study by Kakurai and Akai,<sup>58</sup> 11 out of 28 patients could control their knee actively at between 1.5 and 10 months (average 4 months) after initial prescription of the convertible plastic KAFO. The 11 patients had their KAFOs changed to AFOs (AFO group). The 17 remaining patients were unchanged and continued to use their KAFO (KAFO group). In the AFO group, three were classified as outdoor independent, one as indoor independent and seven as indoor dependent. In the KAFO group, two patients were classified as indoor independent, 11 were classed as indoor dependent and four were classed as non-ambulant.<sup>58</sup>

### Functional ability

Functional ability was reported in the RCT by Yang *et al.*<sup>69</sup> and in the case series by Kakurai and Akai.<sup>58</sup> Yang's reporting<sup>69</sup> suggested that, after 2–3 months of treatment, 97% of those in the orthoses group experienced improved motor function recovery, whereas in the conventional rehabilitation group 81% experienced such improvement. The detail of how this was ascertained was unclear. The difference was statistically significant ( $p < 0.01$ ). Kakurai and Akai<sup>58</sup> measured functionality using the Barthel Index. Those wearing an AFO had a higher (better) Barthel Index score (mean 72.8, SD 7.2) than the KAFO group (mean 43.1, SD 4.6);  $p < 0.01$ .<sup>58</sup> However, this study<sup>58</sup> was not comparing two types of devices: the comparison was between those who had recovered sufficient control of knee activity to switch to an AFO device and those who had not. No further outcomes were reported in relation to resource utilisation and adverse effects.

## Results from studies of patients with spinal cord injury

Nine studies<sup>53,57,59,62,64–68</sup> (Table 11) assessed the effects of orthoses on patients with knee instability following spinal cord injury (194 patients). Two of the studies<sup>64,67</sup> were conducted in the UK. There was one RCT of 10 participants<sup>53</sup> and two controlled trials<sup>66,67</sup> and the remainder were case series.<sup>57,59,62,64,65,68</sup> Five studies<sup>53,57,64,65,68</sup> had 20 or fewer patients. In five studies<sup>57,64,65,67,68</sup> it was unclear if the sample was representative of patients seen in practice. In one study<sup>53</sup> patients were chosen based on their motivation to walk.

All the studies investigated types of HKAFO. Three studies<sup>53,59,68</sup> investigated the Walkabout® (Polymedic, QLD, Australia) orthosis (WO), a HGO. Harvey *et al.*<sup>53</sup> compared the WO with an ISOCENTRIC® RGO (Centre for Orthotics Design, Campbell, CA, USA) used by the same patients. A randomised crossover design was used with a 3-month home trial period and a 2-month washout period of no orthoses use, although the data were analysed as though from a parallel trial. Two studies<sup>59,68</sup> had no comparator group.



**TABLE 11** Spinal cord injury study characteristics

Author	Population		Intervention					
	Total n, % male, mean age (SD) years	Previous orthoses use	Type of device	Material, manufacture	Orthoses dose	Co-interventions	Comparison	Follow-up
Harvey <sup>53</sup>	10, 90%, 37 (8.4)	Yes, all had KAFO standing experience	HGO (WO)	Not reported	Yes <sup>a</sup>	Gait training (30–54 hours per orthosis), crutches	IRGO worn by same patients	28 weeks
Jaspers <sup>57</sup>	14, 86%, 33.6	Yes, long leg brace (4 patients)	ARGO	Not reported	Not reported	Walker (12), crutches (2)	After provision of orthosis only	> 1 year
Middleton <sup>59</sup>	25, 76%, 35 (13)	Yes, KAFOs plus backslabs (22)	HGO (WO)	Not reported	Not reported	Parallel bars, forearm crutches or frames	After orthosis only	≥ 18 months
Scivoletto <sup>62</sup>	24, 79%, 33.6 (3.2)	Not reported	RGO	Not reported	Not reported	Not reported	RGO non-users	1 year
Summers <sup>64</sup>	20, 100%, 28	Yes, long leg callipers <sup>b</sup> (11)	HGO ParaWalker	Not reported	Not reported	Crutches used as decided by patient	After orthosis only	Mean 20 months
Sun <sup>65</sup>	15, 67%, 33.7	Not reported	RGO	Not reported	1 hour, twice per day for 2 months	Not reported	After orthosis only	Not reported
Tang <sup>66</sup>	58, 83%, 32.4	Not reported	KAFO, ARGO, AGO	Not reported	50 minutes, twice per day for 6–8 weeks	Rehabilitation training	Rehabilitation training	4 months <sup>c</sup>
Whittle <sup>67</sup>	22, 82%, 34	Not reported	HGO (ParaWalker)	Metal foot section	Not reported	Rollator or crutches <sup>d</sup>	RGO (plastic foot section)	4 months for each orthoses
Wu <sup>68</sup>	6, 67%, 27.6	No	HGO (WO)	Plastic	Not reported	Gait training including balance plus walking exercises	Before and after orthosis	Unclear

AGO, alternative gait orthosis.

a Patients used each orthosis as they wished, but had to complete a brief summary sheet each time the orthosis was worn.

b Ten of the 11 had abandoned use of the callipers at the time of assessment for the study.

c Eight weeks after fitting of device.

d Predominantly crutches with HGO and rollator with RGO.

Two UK studies<sup>64,67</sup> investigated the ParaWalker, a HGO. Summers *et al.*<sup>64</sup> had no comparator group and Whittle *et al.*<sup>67</sup> compared the HGO to a custom-made RGO worn by the same patients in a crossover study.

The remaining four studies<sup>57,62,65,66</sup> investigated types of RGO. Two of these studies<sup>57,65</sup> had no comparator group. Scivoletto *et al.*<sup>62</sup> compared patients using a RGO to those patients not using it, and Tang *et al.*<sup>66</sup> compared three different types of orthoses (plus rehabilitation training) to rehabilitation training.

All nine studies<sup>53,57,59,62,64–68</sup> used patient-reported outcomes, specifically functionality of the device (*Table 12*). Five<sup>53,57,59,64,67</sup> studies reported measures of patient satisfaction, one study<sup>66</sup> reported quality of life and five studies<sup>53,57,59,62,64</sup> reported usage of the device. There were fewer objective assessments across the studies. Four studies<sup>53,65,67,68</sup> made a formal assessment of walking ability. Resource utilisation data were limited to assessment of device malfunction in four studies<sup>57,59,64,67</sup> and cost in one study.<sup>67</sup> Six studies<sup>53,59,62,66–68</sup> failed to report adverse effects data or to mention that no adverse effects were identified. This section is grouped by orthotic device.

### **Hip guidance orthosis: ParaWalker**

Two UK studies investigated a HGO (ParaWalker).<sup>64,67</sup> Whittle *et al.*<sup>67</sup> compared a HGO to a RGO in 22 people. Participants tried one of the devices for 4 months and then switched to the other type. The order in which the device was tried was not randomly allocated. Summers *et al.*<sup>64</sup> evaluated 20 patients after at least 6 months of home use of the ParaWalker.

## **Patient-reported outcomes**

### **Satisfaction**

Both studies<sup>64,67</sup> evaluated patient satisfaction and both found a range of opinions, although details of precisely how satisfaction was assessed were limited. Following patient interviews at a mean follow-up of 20 months, Summers *et al.*<sup>64</sup> reported that, overall, five patients were highly pleased with the device, 10 were pleased, three were non-committal and two disliked it. Two of 20 patients complained that the HGO was unsightly to wear.<sup>64</sup> Whittle *et al.*<sup>67</sup> reported that, at the end of the study, 12 of the 22 participants chose to keep the RGO, four chose to keep the HGO and six chose to keep neither orthotic device. The main reasons given for the final choice (no numerical data provided) of the HGO was ease of putting on and taking off, and, for the RGO, cosmesis and ease of standing with hands free. For those who chose neither, fear of developing pressure sores and difficulty using either orthosis were concerns.<sup>67</sup>

### **Functionality**

Whittle *et al.*<sup>67</sup> reported that 17 patients had successfully used the HGO, three did not and two left the study. No details on what constituted 'successful use' were provided. Other statements on functionality were not backed up with numerical data.<sup>67</sup> Summers *et al.*<sup>64</sup> reported that eight patients used the HGO outdoors independently for therapeutic purposes, nine used the HGO independently for therapeutic purposes indoors only, and three abandoned the device. The reasons for abandoning the device were that it was too tiring to use ( $n = 2$ ) and one patient with an unrelated arm injury (crutches needed to be used with the device) hoped to return to using it.<sup>64</sup> All three patients were dependent therapeutic indoor walkers. In total, 17 of 20 patients achieved independent putting on/taking off of the device, and standing from, and sitting in, a wheelchair. The three individuals who could not manage these functions stopped using the device. Ten patients were able to get into the passenger seat of a car, with some difficulty. Two patients had driven a car with the HGO on but found it difficult and did not often repeat this task.<sup>64</sup>

### **Usage**

One study<sup>64</sup> reported on usage of the device as determined by patient interview: four patients used the HGO > 3 times a week, 11 patients used it 1–3 times a week, two patients used it < 1 times a week, and three patients abandoned it.<sup>64</sup> Of the 17 users, two used the device for > 3 hours on each occasion, 13 users for 1–3 hours, and two users for < 1 hour per occasion.<sup>64</sup>

**TABLE 12** Outcomes assessed in spinal cord studies

Study	Patient-reported outcomes				Objective assessments			Resource utilisation		Adverse effects
	Satisfaction with device	Functionality of device	Usage of device	Quality of life	Walking ability	Energy consumption	Functional ability	Device malfunction	Cost	
Harvey <sup>53</sup>	✓	✓	✓		✓	✓	✓			
Jaspers <sup>57</sup>	✓	✓	✓					✓		✓
Middleton <sup>59</sup>	✓	✓	✓					✓		
Scivoletto <sup>62</sup>		✓	✓							
Summers <sup>64</sup>	✓	✓	✓					✓		✓
Sun <sup>65</sup>		✓			✓					✓
Tang <sup>66</sup>		✓		✓						
Whittle <sup>67</sup>	✓	✓		✓	✓			✓	✓	
Wu <sup>68</sup>		✓			✓		✓			

## Objective assessments

### *Walking ability*

One study<sup>67</sup> reported making an objective assessment of walking ability; however, no data were provided: the authors stated that there were no significant differences between the HGO and RGO in gait parameters of cadence, stride length and velocity after 4 months (no data provided). The average walking velocity was about 0.24 m/s.<sup>67</sup>

### *Energy consumption*

One study<sup>67</sup> reported measuring energy consumption but no data were provided: the authors stated that the effort involved in walking estimated by changes in pulse rate and oxygen consumption was similar for the HGO and RGO.<sup>67</sup>

## Resource utilisation

### *Device malfunction*

Summers *et al.*<sup>64</sup> stated that minor repairs of the HGO were usually required at 6-monthly follow-up sessions but there were no breakages. Whittle *et al.*<sup>67</sup> reported that frequent adjustments were needed initially for both the HGO and RGO and this was undertaken by the on-site orthotist. No major failures occurred with the HGO. The RGO was damaged in two cases as a result of overstressing. In 4 months of use for both orthoses, the authors stated that about one-third of participants' devices needed minor repairs, replacements or adjustments.<sup>67</sup>

### *Cost*

One study<sup>67</sup> reported on cost. Whittle *et al.*<sup>67</sup> stated that fabrication of the RGO was £1772, compared with £1116 for the HGO (paper published in 1991). Training and out-of-pocket expenses were reported to be similar between the orthoses.<sup>67</sup> The combined cost of training and 4 months' maintenance was about £330 for each device.<sup>67</sup> Patients and their carers had an average of 8 days off work and out-of-pocket expenses of £160–200.<sup>67</sup>

### *Adverse effects*

One study<sup>64</sup> reported adverse effects. Summers *et al.*<sup>64</sup> reported that there were no pressure sores in the study. The authors stated that the RGO particularly required attention to ensure that patients did not get pressure sores (no data provided), although this relates to fitting of the device. They stated that 'most' patients had one or two falls during early use and one patient sustained a significant injury (fractured distal end of radius) (unclear how data were ascertained).<sup>64</sup>

### *Hip guidance orthosis: Walkabout orthosis*

Three studies evaluated the WO, a HGO.<sup>53,59,68</sup> Harvey *et al.*<sup>53</sup> used a crossover design comparing the WO with an IRGO in 10 people. This was described as a RCT; however, details of the method of randomisation or allocation concealment were not reported. Middleton *et al.*<sup>59</sup> assessed 25 patients after provision of the device, and Wu *et al.*<sup>68</sup> undertook a before-and-after assessment of six orthoses users.

## Patient-reported outcomes

### *Satisfaction*

Two studies<sup>53,59</sup> evaluated patient satisfaction. Harvey *et al.*<sup>53</sup> found that seven participants preferred the IRGO at completion of the study and three participants preferred the WO ( $p = 0.17$ ). Middleton *et al.*<sup>59</sup> stated that > 90% of patients reported physical benefits, around 50% reported psychological benefits, around 40% reported exercise benefits and < 10% reported functional benefits (approximate percentages read from small-scale graph) at the follow-up review after 18 months of use.

### Functionality

All three studies reported functional outcomes, although in a limited way. Harvey *et al.*<sup>53</sup> stated that all participants could sit in a wheelchair with the WO on but no participants could do so with the IRGO. Middleton *et al.*<sup>59</sup> reported that 24 out of 25 patients were able to apply the WO independently and transfer themselves between standing and sitting while wearing it, although three patients could not be successfully trained in using the device and 'several' preferred to have assistance for taking the device on and off. The authors<sup>59</sup> state that improved standing stability was reported by all patients after using the orthosis.<sup>59</sup> The authors gave several examples of improved functionality in household tasks but stated that overall indoor accessibility was not improved and was often hampered by the accompanying walking aid. Numerical data were not provided. Wu *et al.*<sup>68</sup> found a functional improvement after use of the orthoses (length of follow-up not specified) as measured by the Barthel Index [pre-treatment mean 26 (SD 8), post-treatment mean 47 (SD 7);  $p < 0.01$ ].

### Usage

Two studies<sup>53,59</sup> reported on usage of the orthosis. Harvey *et al.*<sup>53</sup> stated that there was no significant difference in the number of times that the WO and IRGO orthoses were used over the course of the 28-week study. During the home trial period no participant wore either orthosis for > 2 hours at any one time. The most common reasons for using either orthosis were for exercise, practice or for the long-term benefits.<sup>53</sup> Based on information provided in a graph, it appears as though the device provided at crossover (i.e. the second device) was not worn at all by 6 of the 10 participants. Six participants used the WO at home, with one of these participants requiring assistance. Four of seven participants using the IRGO needed assistance, mainly for sitting and standing. Three participants wore the WO under clothes but no participants wore the IRGO under clothes.<sup>53</sup> Participants could sit in their wheelchair wearing the WO but not the IRGO. When participants were asked why they did not make more use of their orthoses, the most common response was being 'too busy'. Additionally, participants stated that using the orthoses (type not specified) prevented them from undertaking certain activities in the home, as their hands were unavailable due to holding elbow crutches.<sup>53</sup>

Middleton *et al.*<sup>59</sup> found that 16 of 25 patients still used the WO at follow-up with 15 of these having continued for > 18 months. The mean intensity of WO usage was 150 (SD 24) minutes/week at the first review at 7–12 months and 169 (SD 36) minutes/week at the second review 12 months later. The median at both time points was 120 minutes.<sup>59</sup> Five patients discontinued usage of the WO device between 7 and 20 months, three patients were unsuccessfully trained because of spinal immobility and one patient was lost to follow-up. Four of five who discontinued usage reported a lack of functional enhancement over the orthosis that they had previously used (KAFO, RGO) or a wheelchair.<sup>59</sup> One of these patients had problems with ankle contractures. The fifth patient was satisfied with the device but was forced to withdraw after 11 months because of previous surgery-related back pain.<sup>59</sup>

## Objective assessments

### Walking ability

Two studies<sup>53,68</sup> evaluated walking ability after use of the WO. Harvey *et al.*<sup>53</sup> found that after 8 weeks' training the participants walked significantly faster with the IRGO than with the WO on the flat surface (eight participants) [IRGO mean = 0.34 (SD 0.18) m/second; WO mean = 0.14 (SD 0.12) m/second;  $p = 0.002$ ]. Participants also walked significantly faster with the IRGO than with the WO up and down ramps (five participants) [IRGO mean = 0.25 (SD 0.09) m/second; WO mean = 0.1 (SD 0.06) m/second;  $p = 0.02$ ].<sup>53</sup> Wu *et al.*<sup>68</sup> reported that 1 week after use of the orthosis all six patients could stand or walk better between parallel bars (no data provided). After 2 weeks of exercises with the orthoses, Wu *et al.*<sup>68</sup> state that patients could continuously walk for 40 m and complete therapeutic walking.

### Energy consumption

Harvey *et al.*<sup>53</sup> found that there were no differences in heart rate or oxygen uptake between the WO and IRGO for any surface. When heart rate and oxygen uptake were expressed relative to walking speed (method of calculation not reported), physical cost index and oxygen cost of gait were significantly greater with WO than IRGO on all surfaces. Participants' physical cost index (beats/minute) ranged from 8.4–10.3 beats/minute with WO compared with 4.3–7.0 beats/minute with IRGO;  $p < 0.05$ . Oxygen cost during WO gait was 3.95–4.91 ml/kg/minute compared with 1.65–1.80 ml/kg/minute for IRGO gait;  $p < 0.05$ .<sup>53</sup>

### Functionality

Harvey *et al.*<sup>53</sup> reported that there was no significant difference between WO and IRGO in the extent of assistance required to put on/take off their orthoses; get up and down stairs and kerbs; and walk on the flat. Participants required significantly more assistance when using the WO to walk over inclined surfaces ( $p = 0.03$ ) compared with the IRGO.

### Resource utilisation

#### Device malfunction

Middleton *et al.*<sup>59</sup> reported that all devices required adaptation to the patient at the fitting stage; however, once set up, few devices required any adjustment, maintenance or repairs (no data provided).<sup>59</sup>

#### Adverse effects

None of the studies reported on adverse effects.

### Reciprocating gait orthoses

Four studies<sup>57,62,65,66</sup> evaluated RGOs. Jasper *et al.*<sup>57</sup> undertook the assessment of the ARGO (ARGO, developed by Steeper) after patients had been using their device for at least 12 months (range 19–56 months). It was possible to contact only 14 of the 23 patients who had received a device during the study period.<sup>57</sup> Scivoletto *et al.*<sup>62</sup> primarily focused on the differences between people who used and did not use their RGO, and there was limited information on the outcomes of interest to this review. Tang *et al.*<sup>66</sup> compared RGO, KAFO and what they described as an alternative gait orthosis (AGO) plus rehabilitation to rehabilitation only. It is unclear how participants were allocated to the different management strategies. Sun *et al.*<sup>65</sup> evaluated functioning of 20 patients following fitting of a RGO and up to 30 days' rehabilitation; there was no comparator.

### Patient-reported outcomes

#### Satisfaction

One<sup>57</sup> of the studies evaluating ARGO assessed patient satisfaction using a telephone interview. Jaspers *et al.*<sup>57</sup> reported that all 14 patients stated that they had been well informed about the possibilities of walking with the ARGO prior to fitting, and two patients said that they were disappointed in their expectations. Of the 12 active ARGO users, two found it 'very good', six 'good', three did not state their opinion and one found it 'bad'. Of the two non-users, one rated the device 'good' and one did not answer.<sup>57</sup>

#### Functionality

All four studies<sup>57,62,65,66</sup> reported on functionality. Jaspers *et al.*<sup>57</sup> stated that all patients used the ARGO mainly to stand and walk, based on responses to the telephone interview. A few (unspecified) tried to use it at work but did not continue, as they considered the ARGO to be too heavy and cumbersome for use in a really functional way.<sup>57</sup> They also found the walking speed to be too slow.<sup>57</sup> One user could make a transfer into a car without much difficulty; two others were able to transfer but found it too difficult to do on a regular basis. The other participants had never tried this.<sup>57</sup>

In the study by Sun *et al.*,<sup>65</sup> 12 patients achieved household ambulation, five patients achieved community ambulation and three patients achieved therapeutic ambulation at the end of the study.<sup>65</sup> Tang *et al.*<sup>66</sup>

assessed functionality using the Barthel Index and functional independence measure (FIM); however, because of lack of clarity in the analysis and reporting, it is unclear whether or not there were any between group differences 8 weeks after the devices were fitted.

### **Usage**

Two studies<sup>57,62</sup> reported on usage. Jaspers *et al.*<sup>57</sup> stated that 12 out of 14 users were still using the ARGO on a regular basis at least 1 year following provision. Principal reasons for abandoning ARGO use were mechanical problems with the ARGO and lack of time owing to employment or preoccupation because of various interests.<sup>57</sup> The frequency of using the ARGO ranged from daily to twice a month, with an average of three times a week. On each occasion, the ARGO was used for 1–2 hours.<sup>57</sup> However, Scivoletto *et al.*<sup>62</sup> reported in their study that 11 out of 24 patients (46%) no longer used the RGO at 1-year follow-up. This included one patient with a fractured femur and several patients (number unspecified) finding the orthosis uncomfortable or too difficult to put on/take off, too slow or too hard to use, or poor fitting.<sup>62</sup>

### **Quality of life**

Tang *et al.*<sup>66</sup> assessed quality of life using the World Health Organization Quality of Life-BREF (WHOQOL-BREF; a subset of 26 questions from the WHOQOL-100, which measures the following broad domains – physical health, psychological health, social relationships, and environment). However, because of lack of clarity in the analysis and reporting it is unclear whether there were any between group differences 8 weeks after the devices were fitted.

## **Objective assessments**

### **Walking ability**

Sun *et al.*<sup>65</sup> investigated walking ability after provision of ARGO. Across the 15 cases, mean step length was 37.6 cm, mean walking distance within 6 minutes was 75.3 m, and mean walking time for 10 m was 54.9 seconds.<sup>65</sup>

## **Resource utilisation**

### **Device malfunction**

One study by Jaspers *et al.*<sup>57</sup> found that most complaints, according to the patient telephone interview, were related to the functioning of the knee-locking cables and the knee-locking mechanism when rising and sitting down (numbers unclear). Further complaints about the ARGO were its weight, the fact that it was too big to use in an active wheelchair and the discomfort while sitting due to the back tube.

### **Adverse effects**

Two studies<sup>57,65</sup> reported on adverse effects. Jaspers *et al.*<sup>57</sup> found that there were no complications of a physiological nature according to patient report. Two patients had fallen but without serious injury.<sup>57</sup> Sun *et al.*<sup>65</sup> reported that there were no adverse effects but it was unclear how this was ascertained.

## Chapter 4 Results of qualitative study of orthoses users' perspectives

### Sample characteristics

Twenty-four people were recruited into the study. Nineteen patients were recruited across the three NHS sites; five patients were recruited in site 1 (P1, P2, P4, P13, P17); five in site 2 (P10, P11, P12, P20, P21); and nine patients were recruited in site 3 (P3, P5, P6, P7, P8, P9, P19, P23, P24). The five people recruited outwith the NHS (P14, P15, P16, P18, P22) were located across different areas of England. Of the total sample, 12 people had been diagnosed as having poliomyelitis; five people said they had multiple sclerosis; two people had CMT disease; three people had experienced spinal injury; one person had a diagnosis of spina bifida; and one participant had experienced a stroke. Participants' ages ranged from 36 years to 80 years, and the median age was 64.5 years. Half of the study participants were engaged in either full- or part-time paid employment, whereas the other half described themselves as retired. Three-quarters of those interviewed said that they lived with their spouse and/or other family members. Details of the study sample are given in *Appendix 13*.

Findings from the qualitative study are reported under the following subheadings:

1. impact of NMD and CNS conditions on walking and mobility
2. use of orthotic devices
3. wearing orthotic devices
4. use of mobility aids
5. fitting/acquisition of orthotic devices
6. how use of orthotic devices (KAFOs, AFOs, knee braces) may impact on skin
7. positive and negative aspects of orthotic devices
8. appearance connected to orthoses
9. footwear
10. desired treatment goals and outcomes
11. care pathways and factors that impact on experiences of care
12. interactions with HCPs.

### Impact of neuromuscular disease and central nervous system conditions on walking and mobility

Study participants reported a range of symptoms and sequelae associated with neuromuscular and CNS conditions that limited their ability to walk and mobilise as they might wish. They described experiencing pain (sometimes severe) in the knee or ankle joints; hyperextension of the knee joint; muscle weakness in the lower limb and/or of the muscles supporting joints; limbs of unequal length; having feet that are 'frozen' in an abnormal position; varying degrees of paralysis in lower limbs and feet; toes that are 'curling' inwards; and drop foot. Participants described resultant difficulties associated with walking and mobility: frequent falls, often preceded by a feeling that their leg was about to 'give way' under them; loss of sense of balance and stability; a 'lop-sided' gait; dragging their feet; constantly tripping, especially on uneven surfaces; difficulty standing for any length of time or walking for any but short distances; and fatigue, as well as wear and tear in their 'good' or unaffected limb due to transfer of weight and effort in walking.



*I went, I am in pain, and then he examined me and goes, of course, it's not normal, your body is lop-sided.*

P1

*I am very good at falling over . . . it's because my muscles are so bad [weak] and you need lots of muscles to hold you up straight.*

P18

*I fall all the time because my knee can give way . . . sometimes it's very serious falls and sometimes it's minor falls.*

P1

*My knee giving way, like the muscles suddenly weakened . . . as I was picking up heavy things, my legs felt weak . . . I am used to them crumbling underneath me and sometimes I catch myself from falling.*

P7

*I started to take some heavy falls because my one leg kept giving way underneath me and it was then that they decided, well hang on a minute, you know, you've got some form of instability of not walking properly and I was forever going over on my ankles because I've got weak ankles and it was then that I started to go see somebody about getting some orthotics fitted.*

P22

*I wouldn't be picking my feet up properly and I would trip and go full length.*

P2

*I can walk about but I have to keep sitting down and have a bit of a rest and I can't, you know, stand talking to somebody, you think, oh, I've got to sit down.*

P11

*It was just my right knee that got a lot of wear and tear because the right leg is less straight than the left, and that's the one that's been bearing the brunt of not walking very well.*

P2

Participants also commented on psychosocial impacts arising from their experiences of chronic pain and impaired ability to walk and be fully mobile. They expressed feelings of fearfulness and anxiety about falling which, in turn, led to diminished self-confidence and independence.

*The last time I was on the tube I got pushed, literally, and I lack confidence and get scared, so if I haven't got somebody with me, I won't use the tube.*

P23

*Usually when I go out of the house always my partner has walked at the back of me, always, and he needs a medal.*

P4

A number of participants expressed concerns about their future ability to carry on driving, or working, with implications for becoming dependent on others. Deterioration of their neuromuscular condition, leading to possible further impairment in the future, was a pre-occupying concern of almost everyone interviewed.

*I used to be able to go there quite quickly . . . I used to work for this mobile crèche and I used to get on trains confidently . . . but I can't do that now.*

P7

*I was . . . in a very well paid job and of course one of the main things of Charcot–Marie–Tooth does, not only does it affect your walking but it also affects your hands and it affects your dexterity. Well as an electronics engineer that was the one thing that I actually depended on was my hands and my dexterity and of course I had to stop work . . . and so what am I going to do now for the rest of my life because, you know, I've still got a long working career in front of me . . . my condition has got worse as I've got older.*

P22

*I am concerned that the knee is going to get worse. I'm 64, not desperately old yet. You know in 10 years' time, it's not going to be good. I can feel that it's changing, my leg is changing shape. My foot now sticks out at an angle and my knee goes it, so it is all sort of collapsing a bit really. The knee definitely needs support.*

P14

A few respondents revealed feeling socially isolated from friends while others expressed feelings of regret that they were unable to pursue activities they once enjoyed.

*Because obviously I walk slower so I am on my own quite a bit because I have got good friends who will walk with me but a lot of people [won't] . . . so it does actually make you an alone sort of person because society doesn't really accommodate, it's intolerant of people who have a lot of weaknesses . . . people who have never had that problem just don't understand.*

P2

*We used to go to [place name] a lot but the last couple of years we haven't because you have to go up the side steps . . . when it started to get a bit difficult for walking.*

Husband of P13

Many of the people interviewed indicated that they were proactive in pursuing preventative measures to postpone and/or abate the impact of future deterioration related to their neuromuscular condition on their ability to mobilise independently. These measures included keeping their weight under control; exercising to maintain or enhance general levels of fitness through, for example, regular walking or swimming; and undertaking exercise regimens recommended by NHS or private physiotherapists.

*I am going to have problems later on and I want to keep independent, if I could prolong independence . . .*

P15

*I saw how much I deteriorated in the last 5 years you know . . . I try to help myself, I am trying, like with my weight for example, I have to work on that and my exercise . . . I am active.*

P22

*I've been referred to a physio . . . I was also sent for some hydrotherapy treatments . . . but I mean I used to go swimming anyway but I don't any more because I find it's too difficult to get in and out of the pool and I've lost a lot of upper body strength as well over the last 2 years, so swimming I now find very difficult . . . basically it's down to me to monitor my condition and then if I think I need to do something about it then I'll go and see my GP and then my GP points me in the area of where I need to go.*

P22

None of the 19 study participants recruited via the NHS reported belonging to a patient support group, whereas four out of the five participants recruited outside the NHS were recruited via patient support groups, including British Polio Fellowship and Charcot–Marie–Tooth UK. (The fifth non-NHS recruited participant had read about the study on the dedicated web page and made contact with the study team.) The benefits of support groups cited were related to obtaining information and gaining mutual support from people with similar experiences.

*People say, oh, I've tried this and I've done that and you can get information from people and it's just being around people with the same condition because when I first got diagnosed with this [CMT] I felt very isolated . . . the reaction from medical staff was 'what the hell is that?'*

P22

Of the 12 participants who had a diagnosis of poliomyelitis, four (P15, P16, P18 and P23) spoke (unprompted) about their concerns about future deterioration linked to post-polio syndrome, although P15 and P18 commented that they had encountered scepticism among HCPs about this diagnosis. These four interviewees were anxious about muscle wasting in their upper body, arms and hands, and associated potential impacts on their functional ability. P16 revealed his reservations about advice from physiotherapists because of his perception that non-expert advice could result in further damage.

*Somebody told me that there's a neurological physiotherapy department at [name of hospital] you know, sort of cut above the rest as it were and my quack referred me and I went along really quite apprehensive to talk to them about what they were planning on doing because I didn't really want to be damaged and the problem with multiplex polio is exercise makes it worse rather than better. Exercise will improve your suppleness and what have you but if you start working the muscles too hard, you further damage the validity and quite a few people with polio ended up sort of worse off through having physiotherapy.*

P16

Obtaining the 'right' orthotic device(s) to help with current and future mobility was, understandably, a central concern of all those interviewed for the study. Participants' perceptions of the desirable features of a suitable orthotic device (or devices) will be discussed in the body of the report below.

## Use of orthotic devices

The orthotic devices that patients reported that they had received varied according to their diagnosis and their individual needs. Generally speaking, patients who had been diagnosed with poliomyelitis had received KAFOs, which they frequently referred to as 'callipers'; these had mainly been obtained through NHS orthotic services, although two people had sought devices through private suppliers, and others were considering doing so. Most of these people had more than one device. Some were in the process of being fitted for a new KAFO and were also using their 'old' device while they were, in their words, 'breaking the new one in'.

Some differentiated between KAFOs that they used for indoor and outdoor wear; most people were very keen to retain at least one 'spare' KAFO that they could fall back on in the event of breakage or need for repair of a newer device. Three people with a diagnosis of multiple sclerosis reported having been given an AFO, as did the two respondents with CMT disease. The study participants with spinal injury and the one patient with a diagnosis of stroke reported using knee braces and inserts in their shoes, which had been fitted and provided through NHS orthotics services. We also asked patients about other aids to mobility that they use, and participants reported using these aids in combination with, or sometimes, instead of, the orthotic device with which they had been issued. *Table 13* lists the devices and/or aids that they said they had received or were using at time of their interview.

**TABLE 13** Study participants' reports of devices and mobility aids

Participant	Diagnosis	KAFO	AFO	Crutches/stick	Wheelchair/ mobility scooter	Brace or splint	Insert in shoe	'FlopStop' <sup>a</sup>
P1	Poliomyelitis	✓	✓	✓				
P2	Spinal injury			✓			✓	
P3	Poliomyelitis	✓		✓				
P4	Stroke				✓	✓		
P5	Poliomyelitis	✓			✓			
P6	Poliomyelitis	✓		✓				
P7	Multiple sclerosis		✓		✓		✓	
P8	Poliomyelitis	✓	✓	✓				
P9	Poliomyelitis	✓						
P10	Multiple sclerosis		✓		✓		✓	
P11	Multiple sclerosis		✓					
P12	Multiple sclerosis		✓	✓	✓			✓
P13	Multiple sclerosis				✓	✓		✓
P14	Poliomyelitis	✓						
P15	Poliomyelitis	✓						
P16	Poliomyelitis	✓		✓	✓	✓		
P17	Spinal injury		✓	✓	✓			
P18	Poliomyelitis	✓		✓	✓			
P19	Spina bifida/ amputation	✓		✓	✓			
P20	Spinal injury				✓	✓		
P21	CMT disease		✓					
P22	CMT disease		✓	✓				
P23	Poliomyelitis	✓					✓	
P24	Poliomyelitis	✓	✓					

<sup>a</sup> 'FlopStop' is a commercially available device which aims to correct foot drop ([dropfootorthotics.com](http://dropfootorthotics.com), Kelowna, BC, Canada).

## Wearing orthotic devices

Participants' reports of the wearing of their orthotic devices ranged along a continuum from 'full-time' (daytime) use to non-use of issued devices. Some people (P3, P5, P6, P7, P19 and P23) reported that their device is essential for them to be able to mobilise independently and, consequently, they said that they would wear it for all daily activities, including at work, using public transport, and participating in social events and gatherings.

Other participants reported partial use of their device for a variety of reasons: some (e.g. P21) said that they might use their device(s) outdoors, but that they could manage to move around inside their own home without it, sometimes by holding on to furniture, as reported by P13. Other participants reported wearing their device only intermittently because they were 'breaking in' a new device (P6, P14); because they felt that they did not always need the support of the device, only on 'bad' days (P20); or because of discomfort (P18). P18, for example, commented that she benefited from using her KAFO for walking, but found it uncomfortable when she was seated as it 'stops the circulation'.

Participant 13, with a diagnosis of multiple sclerosis, commented on a (KAFO) device that had been proposed to her in the past; she had given it a week-long trial but had rejected it because she could not operate the locking mechanism because of a lack of muscle power in her hands. Her husband appeared angry and frustrated that she had not been offered a more suitable alternative.

*She [orthotist] told us to try it . . . it didn't work because that's what you've got to do, lock and unlock it . . . we had our hopes for that calliper thing . . . until we found out what we had to do with it.*

*P13's husband*

Participant 1 was the only person interviewed who responded that she was not wearing the provided orthoses at all; during her interview, she retrieved her KAFO from another room in the house, still in its plastic wrapper, and said that she preferred to rely on a stick for assistance with mobilising.

Most people who relied on a KAFO indicated that they viewed it as essential to hang on to their 'old' device during and after fitting of a new one, and some people appeared reluctant to make the transition to a new device, which could pose challenges to them in having to work through a period of teething troubles and possibly have to adjust their gait to some extent. They revealed that they would choose to wear the 'old' device for specific activities. For example, P15 had purchased a new, high-tech device from a private supplier and was trying to become accustomed to it at the time of interview; she commented that although she was endeavouring to use her new device for increasing periods of time, she relied on her 'old' calliper for her daily walking, which was extensive (up to 8 miles per day) and which she regarded as essential for her physical and mental health.

Interestingly, some participants commented that they did not use their devices all the time because they wanted to try to remain as mobile as possible without it and feared becoming totally reliant on their device.

*I feel that if I completely rely on it I won't be able to do without it.*

*P18*

## Use of mobility aids

Most of the people interviewed indicated that in addition to (or sometimes instead of) their orthotic device, they made use of mobility aids, such as sticks and crutches, wheelchairs and mobility scooters.

People commented that using one or two sticks afforded them extra confidence with balance and stability, particularly when walking outdoors, and more so if the ground is icy or slippery. Participants also commented that a stick could help with transfer and distribution of body weight, a strategy that they used to assist with pain management in their knee joint. P23, like many of those interviewed, had purchased a stick himself, without any form of assessment or measurement, and he commented that he was experiencing pain in his arm on the side that he used the stick; he thought that he should really be using two sticks all of the time to achieve a more even transfer of body weight, but was reluctant to have to rely on two sticks for walking, in addition to his KAFO, because he would have to recognise and come to terms with the continuing deterioration in his condition.

*I'm at the stage now where I need two sticks to walk. If I want to go for a walk in the park, I take the two sticks with me and it's so much easier, so much easier because I compensate a lot for my balance and I don't realise how much effort I am putting, how much pressure I am putting . . .*

*P23*

Some participants (P8, P16 and P17) stated that they needed to use crutches in addition to their orthotic device for walking even short distances. Crutches were also reported as being used for getting up in the night to go to the toilet, or when relaxing at home after work, after taking off the KAFO device, or for 'popping' out to local shops, when the sustained support from the KAFO was not needed. However, one participant commented that she had found it difficult to obtain comfortably fitting crutches.

*I mean even my elbow crutches, they don't make these elbow crutches to fit me any more, so I spent another two or three years chasing round the services to get these commissioned because the Health Service en masse provide the adjustable ones but they're too long for me here. They don't come small enough here for me because of my physique.*

P19

Views about wheelchair use were polarised across the sample. For some people, combining the use of a wheelchair along with wearing of their orthotic device represented freedom and independence, for example to cover long distances, much further than they could walk, to travel abroad for work or leisure and to carry out activities (such as visiting shopping malls or supermarkets, or a Christmas fair) that would otherwise be denied them. P5 described 'whizzing around' in his electrically powered wheelchair, which he had purchased through an Access to Work scheme.

Qualities sought in a wheelchair were that it should be light (for easy transfer in and out of a car) and preferably not too large, so that it could easily be accommodated in the home. Some study participants who relied heavily on a wheelchair, such as P16, commented that they had one wheelchair for indoor use and one for outdoors, one of which had been supplied by the NHS and the other purchased privately. P19, who owned a manually operated wheelchair, commented that she has bought a hoist, at her own expense, in order to be able to load it into and out of her car without assistance.

Two study participants (P4 and P10) described their reluctance to use a wheelchair, although both felt that the benefits outweighed the drawbacks. P4 did not like the stares she attracted when out in her wheelchair. P10 said that she had avoided using a wheelchair for as long as possible but, as her condition deteriorated, she had had to accept that she could benefit from using one; when interviewed, she was planning to take her wheelchair with her on an overseas trip to see a close family member, and she also recounted how using her wheelchair enabled her to go out on day trips with friends.

Participants 1 and 2 viewed wheelchairs as anathema: P2 described having to use a wheelchair as her 'worst fear', whereas P1 said that she felt pity for people in wheelchairs because 'they're like thrown away, lost causes'.

The advantages of disability scooters cited by participants were similar to those of wheelchairs; P18 said that she had a disability scooter for 'getting around' and a 'luggie', a small disability scooter that was useful for travel as it could be folded up for taking on an aeroplane. P12 said that he had resisted buying a mobility scooter for a long time, but then saw one in action at a festival and realised how useful a scooter could be; for instance, it facilitated independent mobility without the need to have someone else to push the scooter.

## Fitting/acquisition of orthotic devices

### *Fitting/acquisition of knee–ankle–foot orthoses*

Study participants reported a range of issues relating to the fitting of their orthotic devices. The fitting of devices appeared to be perceived as potentially particularly fraught with problems by patients who had a diagnosis of poliomyelitis and who had been fitted for KAFOs. Problems cited included the protracted length of time it could take to achieve a well-fitting and comfortable device, and frustration at the number of appointments that this could necessitate, and a perception that when appointments were delayed or cancelled no progress was being made; the need to have a reliable and comfortable spare device while being fitted for a new one, and during the period of 'breaking in' the new device; measurements being taken and lost before transfer to manufacturers; and participants feeling removed and remote from the manufacturers of devices. Quotations from individuals are reproduced here to illustrate the above points.

*The latest device has been in progress for the last 3 years . . . the last two and a half years of my life I've really struggled to mobilise.*

P19

*So it was nearly 3 years before I got the brace completely right and then I wanted another one as back-up.*

P15

*If you're not getting the appointments, you're not getting the work done.*

P19

*They took a total of four casts of my leg because they kept losing the casts.*

P9

*I think there is a factor of distance and anonymity . . . it is exacerbated in our system by the remoteness of the patient from the manufacturers who are actually doing something bespoke.*

P8

*The thing that is upsetting me is that you get measured for these callipers, they keep sending them away, I never actually see the people who make the calliper or who do the adjustments.*

P18

*It takes the clerks weeks to send the order out and I managed to get them to agree to let me go over there [to the manufacturers] and do the trial fitting there and then I went back a few days later and they'd finished and I got the callipers in about 8 days.*

P16

A minority of people reported that, after a lengthy period of fittings, they were disappointed to receive a device so ill-fitting that it was unwearable.

*It was too big, too high, so it was going right into my buttocks, it was too wide, so I wasn't getting support at the knee and it was like it wasn't made for me.*

P15

*It wasn't a question of being uncomfortable, it didn't fit. It just did not fit, it didn't fit and they took it away – I didn't even leave with it.*

P8



Participants expressed mixed views about the length of time that was available for fitting during appointments. Some people mentioned being allocated double appointments, allowing for more time, whereas others commented that the time available was not sufficient for them to identify problems with devices, which are really recognised only once the patient returns home, and then they had to wait for further appointments to follow-up with questions, comments and suggestions.

*You know you don't really sort of pick up that sort of a problem when you're having a short appointment. You try it on and you think, oh these are a bit odd, I don't know how this is going to be. But you're only there for 20 minutes, half an hour and then you take it home with you in a bag. You only think about the questions afterwards.*

P14

*In clinic time you don't really have time to try it out properly, you don't necessarily have enough time to adjust how it's feeling and what's pulling and what's feeling uncomfortable and what's feeling stiff . . . you can only do that if you've tried it on at home . . . then you might have to wait three to six weeks to report back on it.*

P19

Three participants, two with a diagnosis of poliomyelitis (P5 and P14) and one with a diagnosis of spina bifida (P19), considered themselves to be 'complex' cases, posing particular challenges to those fitting them with an orthosis, because they are not 'standard' cases. P5, for example, reported that his foot had been 'fused' to assist with walking; he commented that he had undergone a long and fruitless period of fitting and re-fitting for a new device before being seen by an orthotist who adopted a different approach. During his interview, he suggested that perhaps it would be beneficial to have case conferences for complex cases, involving more than one clinician, to focus on specific problems from different perspectives, so that lessons could be learnt.

*It was not a standard case, it made it much harder and I think for those first 2 or 3 years where it seemed I was going backwards and forwards to [place] and I felt that no real progress was being made and I think it was almost when someone else came on who looked at it with different eyes and thought of a different type of solution, that's when it clicked really I would say,*

P5

*When things are taking that length of time, what I would have assumed is that they would have had some form of case meeting with all the orthotists and say, look this is atypical let's get our brains altogether around it, rather than just allowing one person to struggle with it . . . because at the moment the system is that you turn up for, let's say an hour's appointment and that's it really. So each clinician has their patients . . . which is fine in the normal run of things but when you've got an atypical case like myself where you'd have thought that someone managing the clinician side would say, oh for the last year we've had no progress really, can we have a look at this or could we collectively look at this and then also let's even write it up to help future clinicians with an atypical cases so there is a resource there to say, oh this is what we, at the time, thought what the issues were. This is what we thought the options were. This is what we tried. This is what worked and what didn't work and then there'd be some form of learning within that profession as well.*

P5

The need for people to be fitted for and receive appropriate footwear at the same time as being fitted for a new KAFO, was highlighted by P23, among others:

*When you do a new calliper you need new boots okay, because no matter what, no matter how accurate the measurements are, they can't get it spot on. So every calliper kind of needs a new boot to kind of fit it, so I was wearing the old calliper and had to wear it with these boots which didn't kind of work with the calliper.*

P23



Three participants (P8, P15 and P24) included in the study described seeking devices through private suppliers. P8 commented that he was motivated to do this because of poorly fitting devices that he had received through NHS services. He referred to a KAFO that he had recently received via the NHS as 'a disaster' and described how he had made contact with a specialist orthotics unit located outside the UK, saying that he was impressed by the thorough assessment and fitting processes that were being proposed.

*Then he [specialist clinician] said, what we would normally now do with you is take you to our gait room where we have cameras linked into a computer programme where we get you to walk and up and down stairs and for and back, side to side and we work out your gait. So I've had none of that in UK . . . and then he said, once we've done that, we will then draw up a specification, a CadCam model and then we will take a close plaster fit of it and then we will work with that and then we will make a, this wasn't the word he used but it describes it, we will make a unique prototype for you which will be nowhere near the finished but it will be the fit and then you will come back and then we will go through the whole process again and then when you're satisfied and we're satisfied, we will then finish it.*

P8

In the case of P15 and P24, their prime motivation for purchasing a device from a private company was the desire to explore new options for technologically advanced devices that might not be available to them through NHS services.

*I came to realise that there were new devices out there that could enable me to have the height of my left leg adjusted to the same as my right leg so that I'd have bendy knees so that I could develop a more normal [gait].*

P15

*[Name of company] are . . . brilliant . . . it's amazing what they do there . . . it's unbelievable the technology!*

P24

In the study sample, one person (P2) said that she was waiting to take up an appointment at a gait clinic for gait analysis to be carried out; P19 reported having had her gait assessed on two occasions during the past 3–4 years; and P8 commented that he was told that if he chose to pursue the acquisition of a KAFO via a private clinic he would undergo a thorough gait analysis. Other participants did not mention having had gait analysis carried out.

### **Fitting/acquisition of ankle-foot orthoses**

Participants with an AFO commented that either they had been fitted with their device after a plaster cast had been taken, or they had received an 'off-the-shelf' device from an orthotics unit; overall, most people were satisfied with the fit of their device.

*I had a casting like a cast put on my feet, quite a nice warm feeling.*

P7

*They had a look and tried one or two, they'd got various ones that fit right, and we went from there, and this one is quite adjustable . . . you can lengthen it or shorten it.*

P11

However, being measured for an AFO did not seem to guarantee satisfaction with the finished device. P21, with a diagnosis of CMT disease, described having a plaster cast and mould taken prior to be given new 'splints', but she reported that they were uncomfortable and painful to wear, and expressed fears about developing sores on her leg and foot.

*I've just had a new pair . . . at the moment I've been bedding them in but something is not quite right with them . . . I've worn them for about a month but my foot has started to hurt again and I think the padding is not quite in the right place . . .*

P21

This participant commented on how important it was to keep her 'old splints' for wear until the problem with the fit of her new ones was resolved. Like many of the people interviewed, she appeared to have a disinclination to let go of the device that she had grown accustomed to over a long period of time, in exchange for a new one, which she perceived as not being an exact replica of the old one. P21 appreciated having an 'open appointment' to attend her local orthotic services, which meant that she could return at any point during the coming year with any problems relating to her device(s) without having to be referred by her GP.

### **Acquisition of knee braces**

During their interviews, two participants (P4 and P13) focused on how they had acquired their knee braces, one of which (belonging to P4) was described as a 'Swiss knee brace'. The devices issued to these two patients were said to be 'off-the-shelf' items; in neither case were measurements taken nor did the devices fit properly, with the result that the recipients were reluctant to wear them.

Participant 4 commented that she had received a device that was too small for her, having been told 'they only do small and large' and the one she was issued with apparently 'dug in' when she walked, resulting in pain and bruising, and affecting her mood adversely. This patient indicated that she would have liked to have been measured for her brace and felt she was offered a restricted range of options.

*I just couldn't bear it. When I walked it just dug in, you can see the bruising . . . I got, not tearful, but sad . . .*

P4

*They said there's nothing else, only these . . . but there are about a dozen on the internet . . . I would have preferred a bespoke one right from the start.*

P4

Participant 13's husband commented that the brace his wife had recently been sent was 'too big, they've sent us the wrong one . . . any time we need a new one we just phone up and they send us one out but they've sent the wrong one out, they've sent a large one out'.

One-quarter of the sample participants mentioned making adaptations to their devices themselves to improve the fit of their device, to protect their skin or improve the function of the device.

*I have to like pad out the knee to keep my knee really straight and they've tried making the straps tighter fitting and stronger but I still at the moment have a sock wedged in the strap because if my leg is not completely straight . . .*

P15

## How use of orthotic devices (knee–ankle–foot orthosis, ankle–foot orthosis, knee brace) may impact on skin

Most of those interviewed said that they were not experiencing ill effects on their skin due to wearing a KAFO or AFO, in part seemingly due to measures that they themselves took to prevent skin damage, such as wearing tights or leggings or pyjamas under the device to protect the skin, adding extra padding at 'pressure points' or, in one case, (P9) buying his own ankle straps, made of softer leather than those that were supplied. One participant (P16) stated that he had worn devices made from plastic in the past, which had resulted in skin rashes, and he expressed a preference for callipers that were made from metal and leather because he thought that devices made from carbon fibre would cause problems similar to those made of plastic.

Wearing the device in summer if the weather is warm was associated with discomfort and some participants referred to the pleasure of being able to take the device off at the end of the day, to allow their skin to 'breathe'.

*During the summer I quite often wear pyjama bottoms underneath the straps and leather of the calliper . . . they have to be cotton and easily washable.*

P9

*One year I was on holiday and it was very hot, very hot and I didn't have any tights on and, oh, it just rubs your skin, you can't wear it against the skin. I had blisters . . .*

P18

*It's a bit like taking your shoes off . . . when I take the calliper off the skin can breathe a bit more.*

P3

Skin damage was mainly associated with newly acquired and/or ill-fitting devices, when some people said that they might expect some 'marking' or 'bruising' at pressure points, such as where the knee is in close proximity to the joint on the KAFO. P4 commented that she had received an ill-fitting knee brace after her stroke, and suggested that this had caused her to develop bruising. P21 reported padding out her AFO to protect the skin on her shin after receiving a new device, and expressed concern about wearing her newly issued device, specifically because of her anxiety about possible skin damage. In the past, she had suffered an open sore associated with her device, for which she had needed to seek treatment from podiatry services. P16 was the only person interviewed who described experiencing a long-standing leg ulcer during the time that he has been wearing a KAFO. The cause of his leg ulcer had apparently not been established, but P16 described a difficult period of non-healing of the ulcer, with frequent recurrence, despite intensive treatment in a specialist clinic. He suggested that non-healing of the ulcer may have been protracted by friction from his device.

*They [ulcers] kept forming and they thought they'd cleared but all they were doing was getting them to heal over but there was still rot inside, the thing seemed to be caused by either pressure or something on the side of the ankle from my boots, so the orthotist built the boots out and then put different types of pads in . . . foam pads on and things like this. None of them stopped the reoccurrence and I guessed that what was happening was we were getting sheer forces from the action of the calliper and the boot because as you stand and put weight on one leg with a calliper, inevitably you get a sort of piston effect of your leg within the calliper . . .*

P16

## Positive and negative aspects of orthotic devices

### Positive aspects of devices

Participants' perceptions of positive aspects of their orthoses were closely linked to perceived effectiveness of the device to control pain and offer support for the knee or ankle and/or assist with lifting the foot; reliability and durability; and capacity of the device(s) to promote self-confidence and independence through enabling mobility and participation in work and social activities. People who were satisfied with their orthoses talked about the 'transformative' effect that they had made on their lives, as illustrated in the quotations, below, from one person who wears a KAFO and one using an AFO on each lower limb.

*Oh transformative really . . . before the brace I would say that as soon as I got into the pub, I'd have to sit down because of the pain. I couldn't necessarily stand up at the bar and talk to people at the same level because of intense knee pain really, so in that way it's really transformed my life also from here to [place name] may not appear sort of a long distance but for me I don't think I could have done it beforehand, now I can which is a major sort of step forward . . . it's made me much more mobile than I ever was before really.*

P5

*. . . the best thing I've ever had. I've got to say it, they are because I was walking I was frightened to go out . . . It's just like, they just give me a new lease, you know, they give me my independence to go out on my own which without them I haven't got, you know. As I say walking around the house is different. I've always got something to hold on. It's when I get out there, I need the confidence to and I feel with these splints I've got that my independence. I can go out without my husband, I can go out with my friends, you know.*

P21

Study participants commented in detail on the physical properties of their devices that they liked and appreciated, which were mainly associated with comfort, durability, cosmesis and 'user-friendliness'. Properties cited included ease of getting the device on and off; light weight; fastenings that are easy to manage and reliable [some people preferred Velcro (Velcro Ltd, Cheshire, UK), whereas others preferred leather fastenings]; ease of use with preferred clothing, for example, 'normal' trousers; 'breathability' of materials used, and, of central importance, a device that can be relied upon to withstand wear and tear without sudden failure to function. A quotation from P3, who wears a carbon fibre KAFO every day in his job as a teacher, serves to illustrate a number of these points, alongside a series of briefer quotations.

*It has carbon fibre, so it's lighter and it's meant to be better. So I think it was made in [European country] and personally as someone deeply in favour of getting the latest technology . . . the benefit is to have one joint so it's not as wide, I can use most trousers. The other one [previous device] is a lot wider underneath, so then if I go to Primark as I don't have any trousers that fit, so it's better to be lighter, looks better design which is better and the issue I have with it is the joint because I use the calliper quite a lot, with teaching, you know, go up and down a lot of the stairs. There's a lot of wear and tear . . .*

P3

*I like it . . . it feels comfortable, I quite like all the Velcro bits. In the old days, it was a sort of buckles system.*

P5

*It's speedy . . . you can put it on quickly.*

P6

*It's a full 5 minutes job [to put her KAFO on].*

P19

*It's more comfortable than the old one, than the plastic ordinary one . . . it's fibre, not like the older ones . . .*

P7

*He said, we want to make you a carbon fibre and he showed me one at the time, which looked pretty cool . . . it just looked really, really good.*

P8

*Modern day materials are absolutely fabulous . . . there is no weight in them and they are very strong.*

P22

### **Negative aspects of devices**

Negative aspects of devices highlighted by study participants included devices that they judged to be ineffective; ill-fitting (causing pain, discomfort or skin damage); unreliable; uncomfortable; heavy, bulky or cumbersome; aesthetically displeasing; damaging to clothing and/or footwear; difficult to put on or take off; susceptible to breakage; and/or requiring high maintenance in the form of frequent repairs and readjustments (see *Figure 2*). When negative aspects of a device were perceived to outweigh positive ones, participants indicated limited or non-wearing of the device.

Of the total 24 participants interviewed, P1, with a diagnosis of poliomyelitis, expressed the most extreme negative feelings towards the orthotic devices that she had received. P1 reported that she was not wearing the KAFO and AFO that had been supplied for her, preferring to mobilise with the use of a stick. This participant, a woman in her thirties, works to support her family in an occupation requiring her to be physically mobile and able to stand for long periods of time during the working day. Her disappointment with the devices she had received became very apparent as the interview proceeded. The Velcro fastenings on her KAFO did not hold it in place, making it unwearable. She felt the devices supplied for her were a 'complete waste of NHS money' and that the orthotist had not listened to her when she was describing her problems and needs. P1 said that she had stopped attending appointments with local orthotics services, although was waiting to be referred to a different orthotist after a visit to a rehabilitation consultant. P1's disappointment and frustration are reflected in the following quotations.

### **Ankle-foot orthosis**

#### ***Perceived as ineffective***

*It's supposed to help my ankle.*

#### ***Causing pain and discomfort***

*It was cutting me and the shoe . . .*

#### ***Damage to footwear***

*The ankle one, I've given up on it because to be honest, it's ruined my shoes.*

*I put it inside my boot, which it has ripped my boot and damaged them.*

## Knee–ankle–foot orthosis

### Perceived as not secure

*This [brace] is for my knee . . . this doesn't stay on my knee, as I am walking it falls right to the bottom . . . it doesn't even stay on my leg.*

*Can you imagine, as I am walking it's slipping down.*

### Perceived as ineffective

*If it worked, it would be OK . . . there's no benefit in it.*

*It just doesn't do nothing . . . I swear, I feel completely hopeless.*

### Difficulty in putting devices on

*These items are becoming like a toy . . . like a jigsaw puzzle that I'm having to deal with. I have to put my knee on, then I have to put my leg on before I can put my shoe on, and I still have to use my walking stick by the way with these on.*

### Non-wearing of device

*I'm not going to lie or say I wear it, it's just sat in the bag looking pretty.*

### Frustration with orthotic service

*The last appointment I didn't even know, because I didn't go, because I was just like, I'm wasting my time . . . I just cancelled it.*

*Doctor [name] took a picture of them . . . he put them up on his table and took a picture of them and laughed, he couldn't believe it . . . the device they gave me.*

Male and female participants reported having to restrict their choice of clothing and/or footwear to accommodate their devices, as well as damage to clothing that caused inconvenience and expense. In particular, it was reported that fabric would be damaged when it comes into contact with the joint of a device. Male participants commented that they were restricted in their choice of trousers, which could prevent them from being able to appear smartly dressed on formal business or social occasions.

*All callipers are not great in terms of heat in summer and in hot weather you've got plastic and metal against your skin, and you have to wear socks and boots in August . . .*

*P6, female*

*You get ladders quite a lot [in tights] . . . my tights aren't 50 pence a pack . . . you're going through them very rapidly . . . Velcro snags very easily . . .*

*P19, female*

*The other thing that callipers do, if you get quite expensive trousers, they tear them up and just rip, you know, even linen or wool trousers, they will just tear . . .*

*P6, female*

*Two wears and the trousers are gone . . . it's really annoying, I can't buy decent trousers.*

*P23, male*

*I don't wear super tight jeans!*

P9, male

*It's difficult to get trousers that are really wide . . . so I buy women's jeans . . . from second-hand shops, the charity shops . . . callipers damage them, I can't pay £50–70.*

P16, male

*It's really annoying, I can't buy decent trousers.*

P23, male

Issues concerning footwear were commonly reported by participants in relation to their orthotic devices, and will be discussed in more depth below. Some participants experienced difficulties and discomfort when trying to accommodate a new device with their existing footwear; some said the orthosis caused shoes to wear out more quickly, whereas others appeared reluctant to exchange their usual footwear for new footwear that would more easily accommodate a new device.

*Getting a shoe on with my [new] calliper is very difficult . . . I mean it's not very comfortable in the shoes that I've got because they're not purpose built for the device.*

P14

*You just can't get in most of the shoes and it's very bulky because of this strap going round your ankle . . . you've got to be wearing the right shoes . . . you couldn't really wear the shoes I've got on now, or my work shoes. You've really got to wear outdoor shoes that are very wide . . . in fact we only managed to get it in one very, very big pair of trainers . . . and I just said straightaway, I'm never going to be able to wear this, it was just horrible, very, very impractical.*

*P12, discussing an AFO supplied to him but which was not used*

*I buy [brand name] shoes because they are a bit more sturdy but even then they might only last 6 months. Most of them really should last 2–3 years, so that is a cost.*

P3

The look and feel of the orthotic device appeared important to both male and female participants, with the ideal suggested being a lightweight, sleek, discreet device. However, some participants reported having devices which they found heavy and cumbersome.

*It was a big clunky piece of machinery . . . the whole thing was just too clunky. It was substantially heavier and almost cruder.*

P9

*I'm not really getting on with it [new KAFO] . . . it is such a cumbersome, difficult thing.*

P14

Several participants expressed a wish to obtain devices that are more technologically advanced than the ones they currently had.

*I don't know if they've got electronic knee devices now that I can stand up without having to hand lock it . . . I've been wearing this for years and years. Technology has been zero on it, absolutely zero . . . I mean there are so many new materials available, I am sure they could use titanium, all kinds of other materials.*

P23



A dislike of Velcro fastenings was expressed by number of those interviewed, the main reasons cited being that Velcro did not hold the device securely in place, or that it 'snags' on tights, and collects fabric fibres and fluff, making it ineffective; one participant (P16) said he disliked Velcro fastenings because they could not be quietly adjusted, for instance, during a meeting.

*I have buckles, I hate Velcro . . . you can't adjust it quietly so if you're in a meeting or something and it's too tight . . .*

P16

The aspects of devices that were considered highly negative by participants, and significantly concerning, were the likelihood of a device to fail in some way and a need for frequent repair and/or readjustment. Both had the potential to have a hugely negative impact on patients' confidence, ability to be mobile and get on with their daily lives. The breakage of a device was viewed as a crisis. Participants suggested that there might be a potential trade-off between the lightness and elegance of a device, and its durability. Some people questioned the quality of various components used in the manufacture of devices, suggesting that, for reasons of cost, the most effective or enduring components might not be routinely used. Comments on the functioning of rivets and hinges in KAFO devices were frequent. Participants provided vivid accounts of specific incidents when a device malfunctioned in some way, especially concerning if it happened when they were travelling abroad. Fear of failure of a device seemed to be the major underlying reason for participants repeatedly commenting on the importance of having a spare device that could be used as a replacement while the new model was being repaired.

*if it breaks, you're kind of thrown really . . . I came out of work, it was about half past six, and I got across the road and the calliper just went, it just snapped, it was one of those carbon fibres . . .*

P6

*As soon as this thing breaks down, I'm in silly street . . . that's not a place I want to go.*

P19

*I would say the source of failure now, as opposed to the wear and tear, is the hinges, you need reliability in the hinges . . . this is one of the problems with this kit [device] . . . one of the hinges just failed without warning. So that's an immediate demobilisation . . . so in the normal course of circumstances if you didn't have a spare to hand, which I didn't when I was away . . . one of the problems is how do you get that emergency repair effected immediately?*

P8

*Let's assume that the strongest rivets are stainless steel rivets, well I was saying, well why don't you use the stronger rivets to begin with. It's almost as if they've got three levels of rivet, a bronze, silver and gold and you start with the bronze and they say, oh they're not surprised that went and then they take you to silver and you almost say, well let's assume that the gold variety of rivets was stainless steel, let's assume, it may cost a few quid extra but it would make a huge difference because it holds the whole thing together really.*

P5

*When I had this one, I found that the rivets on it broke but these have been replaced but I always worry that these will go as well because they've been going and I've been told that there are two or three different types of rivets and I think it's more when you're twisting on the leg, it creates a torsion whereby the rivets after one or two pop it creates almost like a quick mechanism for the rest of them to go really. So that's been an issue really.*

P5



*I get the knee joints failing which is terrifying because you go flying across the room on a good day and hit the floor on a bad day and you've completely lost confidence in that calliper then.*

P16

*Last year we went to [American city] and literally, literally we'd just landed at [ ] airport and I'm walking to get my suitcase and I fell flat on my face . . . what happened this, the thingy here, see there, it just went. Really is this screw holding me, I mean can't you think of something stronger than that! That's what I'm saying . . . the whole thing is very basic. All these should have been tightened up. Another time, the same thing here, the thing that they solder in the middle, the solder went, so that slipped out and again . . . the most unhelpful place on earth, [ ] airport, but yeah the holiday was ruined because I could walk but I had to do everything by hand and I sort of held it with thread and things. I couldn't relax, you know, it was a short trip.*

P23

Even a seemingly relatively simple procedure, such as having leather straps replaced when they wear out, could cause difficulties and inconvenience for device users.

*The knee strap by virtue of the fact that it's made of leather will after a while stretch, there's no getting around that. So last time I had one replaced, I took it in and it got replaced and it was sent back out to me, but actually someone had put it on back to front . . . so I had to take it back.*

P19

Participant 15 reported on negative aspects of the device that she had procured from a private supplier (a stance control model) including that it is adapted for walking only on level ground, which left her feeling frightened of walking downhill with it on. She said that she had to concentrate hard on thinking about walking while wearing it, as it seemed to require different walking patterns from her usual ones; she added that she had experienced a bad fall while wearing the device, resulting in damage to ligaments.

Participants' perceptions of the negative and positive aspects of their orthoses are summarised in *Figure 2*.

## Appearance connected to orthoses

For many people, appearance of their device seemed less important than other aspects, such as reliability and comfort, which they said they valued more.

*Given the choice of a bad-looking orthotic appliance compared to one that is snazzy, obviously everybody would like a smart looking one but to me that's not the be all and end all. I'm looking for reliability that's the most important thing to me and one that doesn't need a lot of repair.*

P3

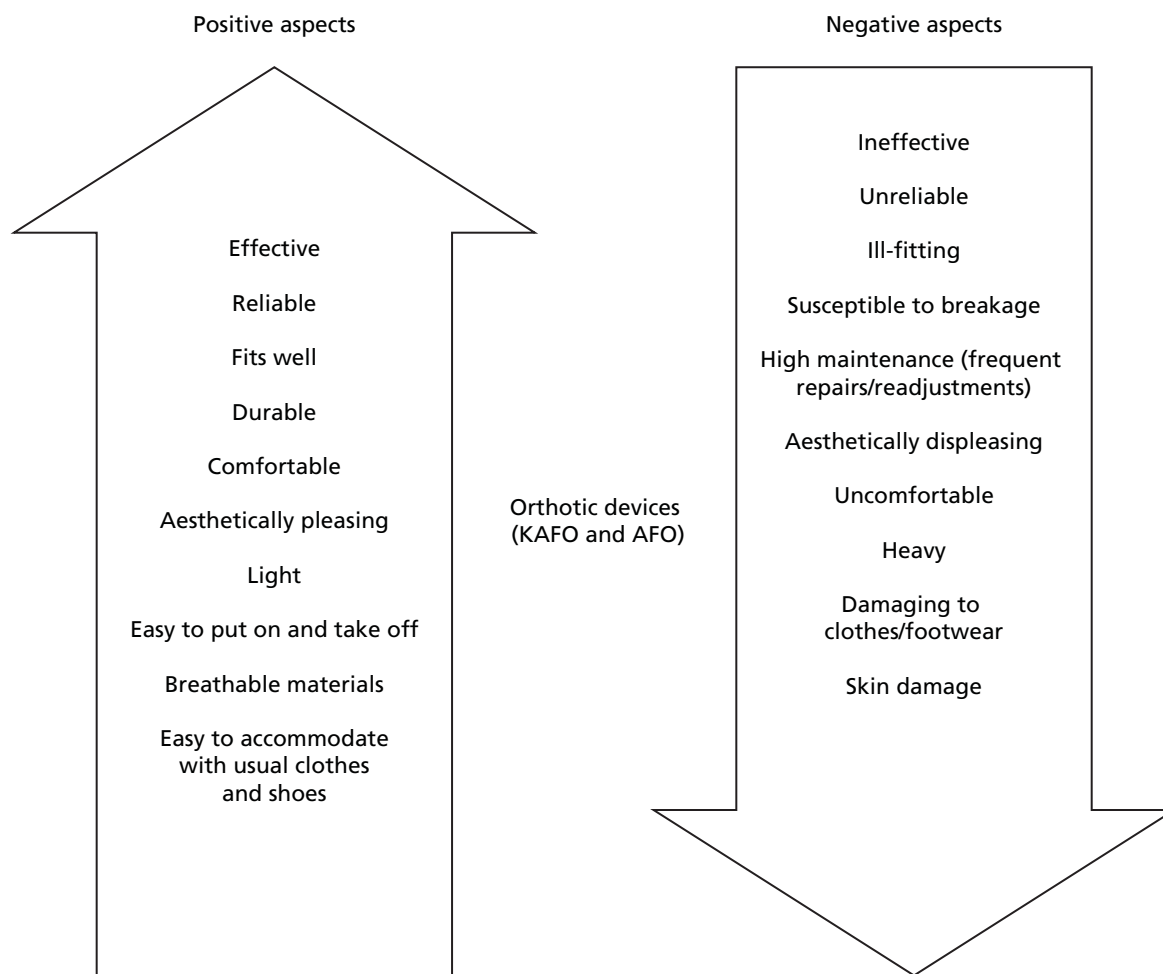
*I've got to an age now accepting that I've got to be comfortable.*

P2

Most of the women included in the study commented that they tended to choose to wear trousers, in part to conceal their device, as well as for more practical reasons. P18, a woman in her early seventies, commented that she 'detests' wearing her device, always wearing long skirts or trousers to hide it.

*It's a little bit of vanity as regards wearing something on top.*

P4



**FIGURE 2** Study participants' perceptions of positive and negative aspects of their orthoses.

*It is horrible, really horrible to wear. I hate it. I detest it with a passion. When I wear it I always wear really long skirts to hide it or trousers.*

P18

The desire to appear as 'normal' as possible when wearing an orthosis was expressed by both male and female participants. Among the men included in the study, P12 displayed strongly felt views on the importance of appearance in relation to wearing a device and he suggested that clinicians ought to pay it more attention. P12 commented that he did not want to have a device that made him look or feel 'trussed up like a turkey'.

*I think the appearance, I would always want to look normal as possible . . . and maybe other people don't notice that you've got it on sort of thing.*

P12

*Orthotics a long, long time ago said that I ought to look at having something and it was something that went right down to my toes and virtually up to just below my knee and . . . you needed two or three sizes bigger shoe. In fact I think we only managed to get it in one pair of shoes and that was a very big pair of trainers and I said straightaway, well I'm never actually going to be able to ever wear this. It was just horrible, very, very impractical. I'm not even sure why they actually gave it me at the time.*

P12

*If it was left to them you'd be trussed up with, you know, yes things that make you walk absolutely great but you'd look like a clown in the street sort of thing rather than thinking now what would make you look normal, that's really what I mean. They work on thinking they've got to make device as effective as possible to get over the disability and blow the what it looks like whereas I think you've got to have a bit of a compromise at times, that's what I would say.*

P12

A number of participants expressed the wish for uniform colouring of their KAFO, and for the last few inches of a device (towards the ankle) to be in a colour which matched their skin tone. This was underlined by P5 (male) and P19 (female) who pointed out that they regarded their device as an extension of themselves, integral to their identity. P19 stated that 'the cosmesis is really important to me otherwise we are back in the dark ages'.

*Why have we got the blue leather with the flesh colour . . . I don't get it . . . why have we got flesh colour leather if we're going to put the blue/grey round the outside? . . . actually this is how I present to the world and it's very important to me . . . I refuse to be Polly Patchwork . . .*

P19

*So I was thinking, oh I've seen prostheses with various skin colour and they do whatever it is the fibreglass with different colours and I'm thinking why isn't that given as a possibility in terms of different types of skin colour when you're sort of wearing it and things, just where you feel, it's an extension of your own leg but sort of it's part of you in a way.*

P5

Participants reported that they could feel conspicuous when their orthosis was visible to other people because of the stares they could attract; some people mentioned feeling discouraged from going to the gym or swimming pool because they could feel people looking at them, or because they sensed the discomfort of the people around them. Other participants commented that they did not want to evoke feelings of pity in others, nor to feel stigmatised or concerned about their personal safety if they could be identified as 'disabled'.

*If I go to the gym, there is only one piece of equipment I can actually use but people don't seem comfortable even about advising you . . .*

P6

*When I go on holiday there's a pool and I can swim, you know, without an audience.*

P23

*You walk into a restaurant, and where are the eyes?*

P4

*I'm not trying to make people feel sorry for me . . . I don't want nobody to pity me. I don't want them to feel sorry for me. I want to get on with my life. I know I have got a disability but do I have to let the whole world know that I am disabled?*

P1

*Sometimes I wear shorts in summer but when people see me they act different to me . . . the fact they can see my calliper.*

P3

*People can come up to you and you never know when, any kind of disability can trigger you know, nice and not so nice behaviour and so I suppose in a way even though like covering it up, you know, you are identified as disabled, it feels a bit more safer . . .*

P6

A few male participants downplayed the importance of the visibility of their orthotic device. P8 suggested that he was quite uninhibited about wearing his device with shorts and a tee shirt when on holiday abroad. By way of contrast, he recounted how the 'invisibility' of a device was important to a business man who, he had heard, had sought a discreet, high-tech device that he could conceal from view.

*It's easy for a man, you just stick [the orthosis] in your trousers and nobody notices it when you are walking about.*

P11

*I'm in my Bermuda shorts . . . so I wear my undercarriage [device], training shoes and a tee shirt, so there was good visibility of the undercarriage and I went for a walk through town, I was comfortable, I wasn't the slightest bit bothered at all.*

P8

*This Aston Martin carbon fibre device built for this business man, he wanted its actual existence to be invisible . . . he had a strap that came into his pocket in his bespoke design suits and he just puts his hands in his pockets and click it and sit down as if it was a normal leg . . . he doesn't want people to know.*

P8

## Footwear

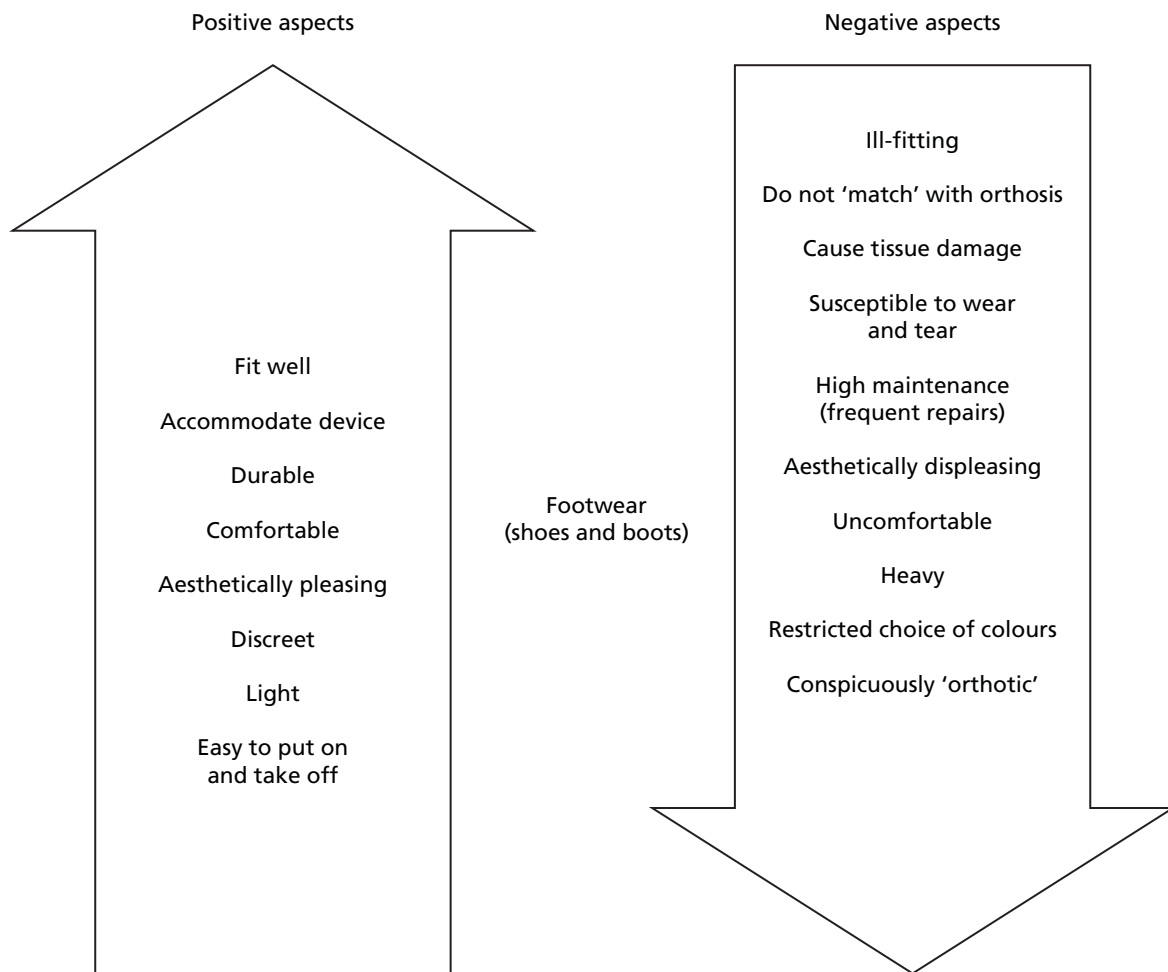
People interviewed for the study referred to the footwear that they used with their orthoses by various terms, including shoes, boots, orthopaedic shoes and surgical shoes. People who used KAFOs and/or AFOs stated that they might be fitted for new shoes at the same time as being fitted for their orthosis in order to accommodate that particular device, whereas others said that they used their device with 'normal' shoes that they purchased themselves. Many respondents mentioned using orthotic devices, such as insoles and inserts, in their shoes; others described how each shoe of a pair might need to be of different width or height, depending on their individual needs.

Participants whose first preference was to wear 'normal' shoes seemed to accept that they might, or would, have to move to having their shoes supplied through orthotic services at some point in the future. A number of issues connected to footwear emerged as important to participants, namely the fit of the shoes; damage to skin/and or deeper tissue; repairs; number of pairs of shoes supplied to individuals; choice of colour or material; weight of shoes; level of comfort; absence of 'grip'; and appearance (Figure 3).

A major priority identified by everyone spoken to was that shoes should fit well. Participants with a diagnosis of poliomyelitis commented that they can require shoes of different width and height for each of their feet. Some people commented that they needed to receive shoes via orthotic services to accommodate their orthotic devices. P14 had recently received her first KAFO device but was not wearing it because she was facing difficulties using the device with her 'normal' shoes, although she reported that the orthotist had advised her to try to manage with her usual footwear, at least initially.

*Since I took possession of it [orthotic device] I've been back to see the orthotist twice and he said, well do try and get on with it, but he said, if you really can't we'll think about getting some shoes made. My foot is stuck in the equinus position so the calliper means I have trouble with shoes . . . my shoes don't fit . . . I can't get it in my shoes, it's uncomfortable and it just seems easier not to use it, which is terrible really because I should be using it.*

P14



**FIGURE 3** Study participants' perceptions of positive and negative aspects of footwear.

The importance of having feet assessed and measured frequently, to detect any possible changes, was highlighted. For example, P5 stated that recently his toes had started to curl under his foot, rubbing against the leather on one of shoes, causing pain, and he said his shoe had started to feel too small; he thought he would require new shoes, as well as a possible intervention through podiatry services. Only two of the people interviewed mentioned experiencing difficulties in getting their feet measured. P9 commented that he had been 'wearing the same type of shoe without a refit since 1970' and his wife suggested he needed to have a new mould of his feet taken. P15, who said she had not had her feet measured for > 10 years, found that the shoes she was receiving were becoming increasingly ill-fitting, and that recently she had 'insisted' on having a review and having her feet measured:

*I had to insist and say, look none of your shoes is fitting me properly . . . I haven't had them reviewed since the 90s and I'm a lot older . . . every time I come, something is wrong.*

P15

Almost all participants who wore shoes that were provided through orthotic services suggested that they were 'entitled' to a certain number of pairs of shoes a year, and most people thought that they could have up to two pairs of shoes at any one time, which allowed for one pair to be undergoing repairs while the other pair was being worn. Individuals reported different time frames for shoes to be provided and repairs to be effected.

Participants said that shoes required repair frequently, as heels and soles wore out quickly as a result of their particular gait. Long waiting times were said to be frustrating, and people could feel anxious having only one pair of shoes for everyday use. Some people reported that they had been told to expect shoes to be delivered by a particular date, and feeling disappointed when they were not available when promised. P23 said that he had hoped to pick up a pair of boots on the day before a job interview but they did not arrive, and he added that he had been waiting > 3 months to receive a new pair of boots. He suggested that provision of footwear would be improved if the people making the shoes were on the same site as those involved in provision of orthoses, so that their particular expertise is readily available.

*I think personally, if the shoemakers were on-site it would make a big difference because [name of orthotist] has to relay to that person and that person has to relay to that person, it's like too much. Well that thing could have been resolved in a second, you know.*

P23

The convenience of delivery of new or repaired shoes to a home address was appreciated. P3, who works full-time, said that a pair of new shoes were waiting for him to collect, but that he would be unable to pick them up until his half-term holiday, whereas extended opening hours of the orthotics department would enable him to pick them up sooner.

Choice of colour, fastening (Velcro or lace-up), material (leather or suede) and style of shoes were deemed more or less important by everyone interviewed. Several people mentioned that they tended to choose black or brown shoes as they 'go with anything' and are particularly suitable for work or business, and a few people seemed to think these colours were the only ones on offer. One individual (P5) made a strong case for having a choice of brighter colours, saying that wearing brightly coloured shoes is one of the ways in which he expresses his personality.

*Because of my personality, I like bright shoes, for example, I always wore bright green shoes . . . these are quite bright red really, you can only go for one of the five colours that are provided really . . . I would be happy to pay for it, it is part of your identity.*

P5

Participant 16 said that, in his view, choices concerning durability, appearance and comfort of shoes would vary according to the purpose or occasion for which the shoes were wanted, and he stated that people should not feel 'pressurised' into having black or brown shoes.

*If you want some boots for everyday work, durability and comfort are important things, and appearance comes lower down the list. If you are the bride's mother, appearance is number 1, durability is zero because you are only going to wear them once and comfort doesn't come into it either, but without that information, they [manufacturers] are not able to match what they are producing to the requests, demands, or expectations of the customer.*

P16

Participants 1 and 2 suggested that comfort was more important than appearance, although they said they would prefer footwear that was discreet.

*There is no point in weeping over kitten heels because I am never going to wear those. But something reasonably presentable, that is not too intrusive, because you've got enough to be getting on in life with without having some people staring at things you might be wearing because obviously I am a bit conscious of the way I do walk . . . and people do stare a bit, so something that can be quite discreet is important.*

P2

*A normal shoe, but built inside, so it's normal . . . so you can't tell no difference, but build inside . . . if you don't want somebody to notice that you are wearing something or that you're disabled.*

P1

Many people expressed a dislike of 'heavy, clumpy' orthotic shoes because heavy shoes compromised the ease with which they could walk. P22 felt that features of orthotics shoes have improved substantially in recent years to great benefit, but he was less happy about having to be referred to the orthotic service each time by his GP when he required a new pair of shoes.

*Well compared to the original ones, they're a lot more comfortable, modern day orthotics now have come a long way especially in the last sort of five years you know. My shoes that they make me are sort of a quarter of the weight that they was when I first started having orthotics . . . it's all right having these things to help you to walk but it's the weight aspect. Because obviously the more weight you've got on, that causes problems in itself because of the weakness in your legs, you know.*

P22

*. . . each time I have to go back to my GP surgery for them to refer me back to orthotics . . . it's quite a long-winded process . . . I can't go straight to orthotics.*

P22

Choice of fastening for shoes (Velcro or laces) was important to some people, whether to accommodate a particular device or for ease of use.

*I always wore lace-ups because I always thought Velcro was for old ladies . . . and he's a lovely orthotist, he actually ordered me a pair of lace-ups and Velcro so I could choose between them and when I actually used the Velcro I could see that if I look like an old lady, tough, that is what I wanted.*

P10

*I just choose something that's easy for me to bend down and put on . . . just a Velcro to get on in a morning.*

P7

*She'd like to wear something different but she can't.*

Husband of P13

*I can't . . . I wear laces all the time . . . with ankle boots.*

P13

Several participants mentioned that the grip on the soles of shoes supplied to them was often not very good, making them anxious about walking on muddy, icy or uneven surfaces, and it was suggested that a walking shoe type of sole could improve confidence with walking outdoors. Two female participants (P18 and P21) who were purchasing their own shoes, favoured a particular make of shoes for their width, allowing accommodation of their device, and their suppleness and comfort. P21 mentioned that she was advised by the orthotist to try this particular brand.

*Well, I have [brand name] shoes . . . the [brand name] shoe is flexible enough, it's got room enough and the [brand name] has an insole which can be taken out and then the calliper fits in.*

P18

*She told me to try [brand name] shoes because they do really wide fittings . . . I like my tie-ups because I can lift the tongue and slide my feet in . . .*

P21



## Desired treatment goals and outcomes

During their interviews, study participants were asked to identify their desired treatment goals and outcomes and their responses related to a range of physical and psychosocial factors that were deemed important.

Orthotic treatment that achieved effective support for the affected joint (the knee or ankle joint) was identified as the prime desired outcome, along with a reduction in the number of falls and/or trips experienced. Participants highly valued gaining, or maintaining, the ability to mobilise as independently as possible. Reduction of joint pain was identified as an important enabler of increased mobility. Freedom from having to worry that their joint might 'give way' was cited as an important treatment goal.

People associated an ability to mobilise confidently and safely with numerous benefits for their physical and mental health: increased self-esteem; possibilities for employment and assurance about financial security for themselves and their family; enjoyment of 'ordinary' family and social life; opportunities for travel; maintaining an interest in daily activities (e.g. gardening, days out with friends and family); and prevention of deterioration of their physical health or mental outlook, through being able to undertake regular exercise, such as swimming and walking.

Most of those interviewed seemed to have accepted that they were unlikely to ever be able to walk very fast or for very far, without a degree of fatigue, and they showed little interest in increasing the speed of their walking, or distance covered, as treatment goals per se.

Participants defined their own goals for mobility in terms of what they needed to achieve to enable them to lead their lives in the way that they wanted, as far as realistically possible, based on their own knowledge of themselves as individuals and the circumstances of their lives. P16 vividly described his own treatment goals in terms of being able to take just a few steps from his wheelchair, which allows him to engage in family life, something that was clearly of great importance to him.

*My walking is so limited. If I can stand and get something out of a cupboard and walk a few steps and get back to the wheelchair or whatever, that's what I can do, and that's what I need to do. For example in [name] mother's house I can't get the wheelchair in . . . because of the threshold, so I have to get out, walk a couple of steps over the threshold and then get back in the wheelchair and to be able to just walk those few steps to stand is an enormous advantage. If I was paraplegic and couldn't get out of the wheelchair, there is no way I could get into their house. Same as my son's house in [place], they've just moved actually to one where hopefully we will be able to get in but that just been able to walk, you know, four or five steps is fantastic . . . There's a bigger difference between me and a paraplegic than there is between [name] and I, you know, if you are paraplegic and cannot stand at all that is an incredibly limiting thing. The fact that I can't walk more than a couple of steps isn't that bad because I can zoom over in a wheelchair, so that is a tremendous advantage to me and I would be very reluctant to lose that ability . . . you can't imagine how useful that is . . .*

P16

Participants associated different activities with the prime treatment goal of enhanced independent mobility and attached varying degrees of importance to them.

*I think the key outcome is independence actually . . . for me, it's just having that freedom not having to worry that my leg is going to give way and I know it is stable and that I can stand for long periods of time . . .*

P5

*They [her orthoses] just give me a new lease, they give me my independence to go out on my own.*

P21



*I just do not want to become housebound, so that primarily is the objective of my orthotics.*

P22

*I need my surgical appliance to get on with my life . . . it needs to be effective and reliable . . . I want to be in the real world. I love it . . . I'm in a working world and I just want to get on with it . . .*

P2

*It's just enabling me to keep going as long as possible which is really important to me.*

P10

*Walking is essential to him . . . to keep active as much as possible.*

Wife of P9

Most respondents were prepared to accept and use mobility aids, in conjunction with their orthoses, in pursuit of independence.

*In the last 3 or 4 months I've been to [name of place], [name of place] and on a family holiday to [name of place], so with the brace and wheelchair combined, it gives me total and utter freedom to do what I want really.*

P5

*If my legs get a bit funny sometimes, like I'm putting the washing on the line, I just sit in the self-propelling one [wheelchair] because I can move it myself.*

P7

*I've got a [brand name] mobility scooter and I've got a luggie which is a small mobility scooter which can be folded up and it can go in an aeroplane and I can go on holidays with that.*

P18

Retaining the ability to carry on driving was regarded as vital to the majority of respondents as it allowed patients to pursue opportunities for to work and socialise, both identified as important for their mental well-being.

*It's very important having a car, I couldn't do my job without a car . . . I try to go by train but by the time I get there, I am exhausted.*

P3

*I want to drive down and pick my mum up and bring her here.*

P10

*I've got an automatic car . . . I've got a mobility car with a hoist in the back which can pick up my scooter.*

P18

Participant 2, like others, identified close monitoring of her condition with a view to preventing future deterioration as an important short and long-term treatment goal:

*it is sort of critical . . . to know that I am under someone's care and that I will be looked at and monitored and not just left until it flares up again, I want somebody keeping an eye on it now.*

P2

## Care pathway and factors that impact on experiences of care

The majority of factors cited by participants as impacting on their care pathway were mentioned by individuals across all three research sites, as well as by people recruited via non-NHS support groups. These generalised perceptions will be discussed with reference to specific research sites where warranted. Details of the research site will be included in attribution of quotation to specific individuals.

### Factor 1: referral pathways

The referral pathway into orthotic services was regarded as problematical by around half of those interviewed. Some people described having followed a very circuitous route: they went to their GP (often said to know very little about their particular NMD or condition), who then said that referral to an orthopaedic surgeon was needed, who would then make an assessment before referring to orthotic services. This was perceived as a lengthy process, which negatively impacted on patients through delays in waiting for appointments; waiting periods of up to 1 year to access orthotic services were reported.

*I waited to see this GP again, another three to four weeks down the track, to establish that if I want to find out more about spina bifida I can go on-line and find a forum.*

P19, site 3

*I went to my GP and he said, no the proper way to do it is for him to refer me to an orthopaedic surgeon. But I said, I don't want an operation on my right knee and he said, no, no, that's all right, you just need to go . . . so I went . . . and saw Dr [orthopaedic surgeon] and he said, yes, I needed a calliper for my right knee, and he then he recommended me [to orthotic services].*

P18, site 3

*About once every 12 months I need to go back for a pair of shoes made but each time I want to go back I have to go to my GP to refer me back to the orthotics . . . it's quite a long-winded process.*

P22, non-NHS recruitment

The people who appeared most satisfied with their referral pathway were those who were under the care of a consultant in rehabilitation medicine, whom they saw at regular intervals for review and monitoring. These patients reported that their consultant was alerted to changes and deterioration in their condition during review visits, and could make a direct referral to orthotic and other specialist services, such as specialist neurophysiotherapy or gait assessment clinics. Patients with CMT disease and multiple sclerosis were more likely to report having experienced this more direct referral pathway than those with a diagnosis of poliomyelitis. It was suggested by one participant (P15) that patients with poliomyelitis could gain significantly from this kind of regular review, from a senior clinician, who could initiate appropriate referrals and who might pick up early warning signs of development of post-polio syndrome.

Reported routes for referral to specialist services varied between individuals within the different research sites. Some people suggested that non-specialist physiotherapists could refer directly to specialist physiotherapists, or that orthotists could refer patients to podiatry services, and vice versa, whereas others said that all referrals had to be carried out through their GP.

### Factor 2: appointment systems

A majority of respondents made comments relating to their views and experiences of the appointment system in operation within the orthotic departments they attend. There were discernible differences between participants recruited in the different research sites. Participants in research site 2 seemed generally more satisfied with the appointment system than people in sites 1 and 3. Within sites 1 and 3, individual participants often drew a sharp contrast between perceived good clinical care and the administrative system, which, in one case, was described as 'totally useless'.

*My perception is that the clinical side is relatively good. The administrative side is totally useless . . . I have experienced numerous occasions . . . where the administration side have made appointments for me without ever telling me or where they have told me, I've turned up and the appointment has been cancelled . . .*

*P5, site 3*

*They keep changing the appointments and stretching the time plans, and actually the time plans are important.*

*P19, site 3*

*I got delayed for a month because I never got the appointment letter and they said they'd sent it to me but I never got it.*

*P2, site 1*

Problems experienced by participants, which were perceived as affecting them negatively, included delays in waiting for appointments to access services or between appointments; the need to attend multiple appointments over long periods of time, sometimes with little sense of progress (e.g. for fitting or repair of devices); errors in administration of appointments (last-minute cancellations, letters arriving after the appointment date); appointment slots that were considered too short to ask questions or for information or explanation; and the possibility of 'dropping off' an appointment list if one or more appointments were missed (which could be due to administrative errors). In general, respondents felt that those who were involved in running the administration and appointment systems had little appreciation or understanding of the detrimental implications and effect of inefficiencies on individuals' treatment.

*The appointment system and the filing system were so wrong and just seemed to be so inefficient . . . you'd get a letter to say you've missed your appointment on a date that we never had an appointment or you've an appointment on such and such a date when you'd already been.*

*P9*

*So actually I got delayed for a month because I never got the appointment letter and they said they'd sent it to me but I never got it.*

*P2*

*The thing is they are just so busy . . . they're just focusing on the leg . . . you feel guilty if you want to ask something . . . you're just happy to get the calliper.*

*P23*

Participants also mentioned difficulties that they sometimes faced when attending appointments: lack of private transport, yet using public transport was not a viable or preferred alternative; expense of using taxis; need for someone to be free to accompany them to appointments; difficulties of taking time off work (two participants who work full-time suggested extended opening hours would be helpful); orthotic units situated at a distance from their home, sometimes requiring long drives through traffic; and orthotic departments sometimes located a long walk from parking facilities.

One appointment facility (in research site 2) was identified as particularly beneficial by P21. This patient mentioned having been allocated an 'open appointment' to her local orthotics service for the duration of 1 year after being fitted with new orthotic devices. This meant she could return at any time during that period without the need for referral from a clinician. Participants in other sites had commented that more frequent and shorter-spaced appointments would be beneficial during the early period of being fitted with a new device.

### Factor 3: poor record-keeping and inadequate transfer of information

Record-keeping and sharing and transfer of information across orthotic and other NHS services were viewed as deficient by a minority of respondents. P19 highlighted lack of time as the reason preventing clinicians from completing written records of consultations. Some participants described having to recount their history to different clinicians within a single service, whereas others indicated that information about them was not being shared across services.

*He [registrar] had just transferred from another department . . . he had a blank file because he didn't even have the physiotherapy letters in it as far as I could see and [name of doctor] had written letters back to the GP . . .*

P2, site 1

*The orthotics person, she always really listens but she never writes anything down . . . I feel as though it is Chinese whispers . . . I don't think what she has to say gets through to the right people.*

P15

*I do find I have to remind the guys at times about things we have spoken of . . . if they're not written effectively in the notes . . . they're not getting the time to write the notes up either and details are being lost . . . they don't have time to read the notes even if it's in the notes.*

P19, site 3

Interview accounts also included patients relating many instances of seemingly minor, but frequently occurring, incidents that resulted in treatment delays. For example, the measurements for their devices or shoes were often said to have been 'lost' in the system, and had to be taken again, and participants recalled occasions when instructions for repairs were not relayed or correctly followed out, leading to delays in them receiving the finished orthosis.

### Factor 4: lack of coordination between services

People in the study described accessing care from a wide range of sources in connection with their knee instability or as a result of other health problems that were related to their neuromuscular condition. Lack of coordination between these services was identified as hampering patients' progress in achieving the outcomes for which they had hoped. People under the care of a consultant in rehabilitation medicine seemed to have a stronger sense of themselves as at the centre of an integrated health-care service than others. For example, P5 described being shuttled between services while trying to access care for corns on his foot, which associated with his orthotic shoes.

*I went to my GP and said, look, I've got these corns . . . went to the podiatrist . . . finally they put me in touch with a consultant podiatrist who can operate on things but they can't deal with corns . . . so they say, you've got to go back to podiatry . . . and they say, it's a recurring thing, you need to go back to [orthotic service] and they say, oh, no, that's not our thing, it's more the podiatrist needs to sort that bit out.*

P5

*My doctor [GP] suggested I go and see [consultant] because that [CMT] is one of her fields . . . and I know if I've got any problems she'll sort it out and try and help . . . I always know that all I've got to do is ring her up and either go to see [consultant] or one of her colleagues and they're pretty good at getting me to see someone.*

P21

**Factor 5: perceived 'busyness' of orthotics services**

In general, participants were satisfied with the time available to them for appointments with an orthotist, although some people suggested that they would benefit from having longer or more frequent appointments in the initial period following acquisition of a new device, especially if receiving a KAFO for the first time. Two participants (P9, P16) thought that it would be useful for people receiving a device for the first time to be shown photographs or a video of the kind of device being proposed in order to help prepare them to receive the orthosis.

Individual participants mentioned instances of clinicians booking them double or even triple appointments in one block of time at certain time points, which they appreciated as beneficial, but this practice was not reported as uniform. Participants in site 2 expressed higher overall satisfaction with the number and length of appointments made available to them than respondents in the other two research sites. Reorganisation of services into new configurations was viewed by one participant (P19) as 'diluting' service provision in site 3. This long-term service user commented that orthotic services in her area seemed to be increasingly stretched across hospital Trust-wide sites, with the result that 'her' orthotist might be required to work across several sites, with increased pressures on the individual clinician. She also suggested that, increasingly, when orthotists were ill or on holiday, there might be no replacement available, resulting in disruption to continuity of care and further delays in treatment.

*It's part of the [name of trust] . . . it means they have kind of stretched the services even further and that means people like [orthotist] have to work from [Trust] on certain days of the week . . . so he's physically not at [name] as much as he was so that's even less options for appointments . . . the level of complexity I have doesn't make it useful for me to see someone who doesn't know enough about my work . . . they are more pushed and trying to see more people.*

P19

**Factor 6: complex care**

Three participants in the study (P5, site 3; P14, non-NHS; P19, site 3) suggested that they might be viewed as having 'complex' care needs, requiring particularly intensive input from orthotic services at various crucial junctures in their care trajectory. P5 would have liked to have been the focus of a 'case conference' to help identify and resolve difficulties in his case that were impeding progress with treatment. P5 said he had waited for > 2 years for the 'breakthrough' that came when he was seen by a different orthotist. P14 described some of the problems she was experiencing with a new KAFO (she had not had one before) and feeling she would prefer not to have to wait the 3-month period until her next appointment. P19 expressed the view that she 'selfishly' felt that there should be a system for prioritising people with complex care needs.

*[Orthotist] saying, why don't we give that a go and see if it works . . . the difficulty that there was initially I think I spent about two or three years trying to explore different options and it was just because of the complexity of having my foot fused which meant the dynamics of the whole walking thing had changed . . . I was mindful that when you are an atypical case there is a sense of oh, we are out of our depth here.*

P5

*My foot is in the equinus position so the calliper means I am having trouble with shoes . . . I can't get it in the shoe and it is uncomfortable and it just seems easier not to use it . . .*

P14

*People such as myself with what I do understand are complex or multiple needs are sat in the same clinic with people who have got fallen arches and bunions being dealt with . . . I'm not suggesting they don't have a need . . . what I am suggesting is that there are different ends of the scale and you know, actually selfishly I feel I have priority over something like that but the reality is that the health service pushes you together, that's part of the outcome we've got now with people charging into services that are actually specialised for a good reason.*

P19

### Factor 7: provision of 'in-house' facilities for fitting, adjustment and repair of orthotic devices

Availability of an 'in-house' workshop, located within the orthotic services department, was viewed by participants as significantly promoting and enhancing the delivery of timely and well-integrated orthotic care. Several participants in site 2 commented favourably on a fast response and turnaround when they had needed 'emergency' attention for their orthotic device. Study participants who used an orthotic service provider through which devices had to be sent away to manufacturers (sometimes abroad) expressed the negative impact that this could have on them. They recalled feelings of anxiety about having to relinquish their device, having to attend multiple appointments as the device went back and forth between the orthotic department and the workshop, and experiencing sometimes long delays before they were reunited with their device(s).

*I used to go to [name] and they really didn't have a good or should I say big orthotic department and they used to send my device to [place name] for repair, so even if it was a small thing they had to send it off . . . in [name] they have a special orthotic department where people work on surgical appliances . . . they can do quite a few repairs and sort it out an hour or two later, which makes a big difference.*

P3

*One of the places I was attached to, I went there and they'd got me a new one [device] and it was slightly out, just needed to be bent, the pins on one side kept popping out of my shoe with every step I took. So I went down there and said, look, can we just, you know, and they said, we haven't got a workshop here. I said, well if you give me the tool I can do this. He said, no, you've got to leave it here and we've got to send it to the [place name] and it will be back in two weeks. Now that is just madness. So I went to [name of orthotics department] and they've got a fantastic workshop there and by the way it took about two and a half minutes to do . . . the guys there are fantastic.*

P24

*I just went in and said look I've got a bit of a crisis, it's the only brace I've got any chance I'm happy to come first thing in the morning and wait all day to get the rivets sorted so I waited and they did do it there and then.*

P5

### Factor 8: NHS funding

Issues relating to NHS funding were mentioned by participants, in all three research sites, as seemingly impacting on patient care within orthotic services. Some participants referred to funding decisions relating to orthotic services being made at commissioning level, and sometimes they had appealed against the outcome of these decisions; others referred to 'cut backs' in funding, which they linked to restrictions in the number or type of orthotic device (or footwear) available to them; and some people referred to the apparent existence of a postcode lottery, whereby they thought that some people were more likely to receive specialist services (such as neurophysiotherapy) than others.

*They would only give me two pairs of shoes . . . for someone who is walking you go out and get one pair wet . . . and one's being repaired . . . you can be left without any shoes at all and I was saying, I needed three [pairs] and I had to go to [name] and put this complaint in to say I needed three pairs of shoes.*

P15

*He wouldn't agree to me having a second calliper, he said no, they couldn't afford it.*

P18

*One thing that does concern me is how the budgets are organised and spent, you know, certain things might be available to people in one area that are not available in another and vice versa . . . people in a far worse position than I am that do need these specialist services . . .*

P22



### **Factor 9: perceived lack of business ethos within NHS services, resulting in treatment delays and hold-ups and lack of innovation**

One participant (P16, non-NHS) highlighted a lack of 'business ethos' within the NHS as a barrier to patients receiving timely treatment through orthotic services. His views of NHS services in general, including provision of orthotic services, were that there is a lack of urgency in meeting contract deadlines, and no repercussions for suppliers or manufacturers if deadlines are not met; a lack of focus on customer service and satisfaction; and inefficiencies that would not be tolerated in a private company, resulting in wastage of clinicians' and patients' time. To illustrate his views, he cited the appointment system used by local services, commenting that it would be cheaper and quicker for patients to be texted or telephoned with details of appointments, rather than sending out letters to patients with second-class stamps, which could reach their destination after the date for the appointment had elapsed.

*The whole NHS is not like industry or anything else . . . it's what I call sheltered employment where people always do things the way they've done them before, they've not thought about the end product . . . the contracts the NHS writes are obviously very slack because the contractors take months in many cases. There's no penalty clauses in for not returning them within a set period . . . you know, if the customer is waiting you'd say this needs to be returned within 21 days and we'll deduct 15% for every 7 days you're over that . . . sometimes months go by without anything happening . . . there is no sense of urgency, no sense of customer service, and I regard myself as a customer, not a patient . . . people are sitting around waiting for things . . . you've got people ringing up, chasing things . . . no private company could afford the wastage that the health service has . . .*

P16

Participant 24 suggested that constraints within NHS budgets and work pressures resulted in lack of innovation in the technology of orthotic devices. He himself was using a 'state of the art' device supplied by specific company with a price label of around £40,000 and he contrasted his feelings about the different approaches of the NHS and the private sector to development of orthotic devices.

*I've found sometimes through the NHS because of a number of financial constraints and lack of investment sometimes in new materials . . . I think the only change in 30–40 years was in the Velcro . . . no-one used to say to me, look, we've got this new idea, what about it . . . it's almost like, if it works, just leave it . . . I think it's the pressure they're under . . . it's all finances and pressure of work and budgets . . .*

P24

*[Name of company] are probably one of the best prosthetic leg makers in the world, they're brilliant . . . they bring new models out . . . unbelievable technology . . . what I love about [name of company] is the way that, you know, like cars, you know the engineering and quality that's gone into the design and that gives you huge confidence knowing what they've done in prosthetics and how good and safe these things are and I think that's a big positive for going forward.*

P24

### **Factor 10: use of private sector services**

Respondents in the study who had contemplated or accessed private orthotic and physiotherapy services cited a number of reasons for doing so: to bypass long waiting times or receive what they considered would be a better-quality or more convenient service, for example by paying privately for a neurophysiotherapist to visit them at home for a longer period than would be available through the NHS; to purchase 'cutting-edge' technological devices that they thought would not be funded or available through NHS channels; or because they felt let down by NHS services (not satisfied with the fit and/or performance of KAFOs supplied to them) and were seeking a more personalised service.

*She's a private physio [therapist] . . . she's does lots of talks and lectures, so I think she is quite well thought of in the area . . . I pay for that privately, my second mortgage!*

P11

*Maybe I need to speak to people who make non-NHS callipers to find out if there are better devices but I don't really know where to start because you'll be going to a commercial organisation.*

P14

*In 2011 I contacted [name of company] and they checked my legs out and muscle strength and he said, yes, you'll be an ideal candidate for a new brace that they've just started promoting.*

P15

*They said there's nothing else they only have these . . . but there are about a dozen on the internet that you can have . . .*

P4

*The National Health Service probably hasn't got the money to do something like that.*

P13

*So he said what we would normally do with you is take you to our gait room where we have cameras linked to a computer programme to work out your gait . . . so I've had none of that on the NHS . . . and we will take a close plaster fit of it and then we will make a unique prototype for you . . . and when you're satisfied and we're satisfied . . .*

P8

## Interactions with health-care professionals

### Interactions with orthotists

Study participants commented on a range of aspects of their interactions with orthotists that were important to them, such as orthotists' levels of knowledge and expertise.

*The guys there [orthotics department] are excellent you know, I think [name] and [name] are extremely passionate about what they do . . . very professional and they're always on the cutting edge and improving things.*

P24

The two major factors recurring across the data set, which were highlighted consistently and by a majority of participants, related to perception (1) about ease of access to orthotists and (2) concerning orthotists' communication skills. Specifically, participants focused on orthotists' willingness and ability to invite and listen to patients describe the issues and problems that they were experiencing, and to engage them in making choices and decisions about available treatment options.

### Perceived accessibility of orthotists

Ease of obtaining an appointment with an orthotist when they felt they required one was important to study participants, as was the amount of time available for discussion during appointments. Participants described experiencing varying levels of frustration when they were not able to access input from an orthotist at a particular juncture in their care, when they felt that they needed contact; or because the time available to discuss their needs seemed curtailed; or if the particular clinician they wanted to see was unavailable for whatever reason. Longer-term users of orthotic services (mainly respondents with a diagnosis of poliomyelitis) suggested that seeing the same clinician at consecutive appointments, and building up a relationship of trust with that person over time, were important factors, which affected their views of the quality of care they received. Contrastingly, a few patients commented that it was only when they were seen by an orthotist who was 'new' to them that they felt that substantive progress had been made. Study participants in full-time paid employment commented that extending the availability of appointments with orthotists beyond 'nine-to-five' hours on weekdays would lead to an improvement in continuity of care for them.



*I was wondering whether I need a bit more support rather than an appointment every 3 months in the initial stages just to get me up and running with it [her new orthosis].*

P14

*When I'm seeing [name of orthotist] on a regular basis things tick over very well. The trouble is we get gaps . . . there were reasons why I couldn't see him, blah, blah, blah . . . so I'm getting a bit disconnected with him, and that's not OK . . .*

P19

*If anything, it was a junior orthotist who came in and provided just 'fresh eyes'.*

P5

*I am a teacher, I have to schedule my appointments on the holidays . . . if they opened on a Saturday I could just see somebody on a Saturday.*

P3

### Perceptions concerning communication skills of individual orthotists and their willingness to engage in patient-centred care

The perceived presence or absence of listening skills in an individual orthotist appeared to have a profound impact on patients' perceptions of their quality of care. Listening skills seemed to be valued more highly than the clinician's apparent knowledge and expertise about orthoses. Participants indicated that they wanted orthotists to listen to their specific problems, so that they would gain an understanding of how their condition was affecting them as an individual at a particular point in time. People with poliomyelitis especially commented on the need for orthotists to take time to elicit the wide range of issues that might be affecting them, and how these could be impacting on their lives. Those who felt that their concerns were not listened to perceived clinicians as 'dismissive' or 'arrogant', provoking feelings of disappointment and/or anger in patients.

*Each person is an individual, has an individual problem, polio leaves people with so many different problems . . .*

P9

*It goes in one ear and out of that one and he [orthotist] gives me what he wants to give me. He gives me stuff, the latest thing, and it's really good, but it's no good for me . . . he's not listening to me . . . it's like I don't know what I'm talking about . . .*

P1

*I'm sure he knows his stuff but . . . he didn't feel quite so empathetic, that he had a lot of empathy . . . a bit unsympathetic in as much as I was trying to get my head around it . . . almost a bit dismissive.*

P2

*I've not been listened to one iota!*

P4

Judgements about clinicians' listening skills were closely linked to perceptions about the orthotist's willingness and/or ability to engage with the patient, and include them in the decision-making process about treatment options. Some participants described interactions that they judged as highly satisfactory. During such encounters, the orthotist was said to listen to the patient's concerns, give information and explanation, discuss treatment options and offer choice where feasible. Study participants frequently drew a contrast between orthotists whom they had encountered whom they thought were 'good' or 'bad' listeners, revealing the extent of the potential for positive or negative impact on the patient by the orthotist during consultations. P16, with long-term experience as an orthotic services user, suggested that

the younger (female) orthotists he has come into contact with more recently tend to be skilled communicators, possibly as a result of improvements in training.

*He is very nice, very easy going. He really wants you to be comfortable but he knows that, it's not that I know better than him, it's like he knows that I've been wearing it [orthosis] for so long, so he sort of listens to what I am telling him . . .*

P23

*He always listens to what I have to say, he gives me a choice to have a new style or old style calliper. I explained to him my concerns . . . and we had a long discussion and he said to me, the design of this is better . . . so he gave me a choice and he also listened to me if I explained to him as a user what issues are important to me . . . most of the time people have listened to me, but he listens a little bit more.*

P3

*I go back to before they called themselves orthotics because they just used to be appliance fitters . . . I remember getting an adjustment, you know, spinal brace back after it had been modified and they just sort of strapped it on me and said, oh that's better isn't it, and I said, hang on a minute, you have to allow me to tell you whether it's better or not. I mean that's the sort of arrogance that you used to get and that was very common. Also they were not receptive to almost listening to what difficulties you were having, you know, they would make the decision with what was wrong with something rather than even if it was completely, you know, you were trying to correct them and say no, that's not the problem. The problem is hurting here or something like that. Now about eight years ago I noticed a significant change and now again, all the orthotists that I'd seen up to that point have been blokes. Eight years ago I had the first girl, she's much younger, so I don't know whether the difference was because she was younger and therefore had a different attitude or she was just forward than the others but she was very good.*

P16

**Interviewer:** *So what was good about her? What did you like about her?*

**P16:** *She listened. She always asked before she touched me because people can hurt me touching me, you know, they don't know what hurts and what doesn't. Very gentle but more to the point listened to the problem, thought about solutions, proposed solutions and worked with me to say we could do this or do that and what have you, so that was a very big difference. It was an enormous difference. I can't describe what a shock it was. Now she left after a couple of years and they got another orthotist who is the current one and I've been with her for about 6 years and she's very good as well, excellent, and again she's much younger. So whether the difference is age, whether the difference is training, whether it's – I mean the whole attitude is different. That's the biggest difference. So the results tend to be better because they're listening to the problem and solving the problem rather than not really interested in your input just making their own assessment and what the problem is and going off on their own to do that.*

Although communication with orthotists was described as sometimes suboptimal, only one participant (P1) in the sample mentioned the occurrence of a complete breakdown in communication relating to issues concerning supply of a device.

*I had [an orthotist] build me a calliper and I couldn't stand up in it and she told me to take it home . . . and I said to her, I'm not happy. So when I told her, I'd seen her about eight times in between building the calliper and she said 'well, I've had enough, I'm going to send you to somebody else' . . . they haven't done me wrong, but if you can't listen to what I'm telling you about my leg, and what I need for my leg . . .*

P1

**Interactions with consultants in rehabilitation medicine**

Comments on interactions with consultants in rehabilitation medicine came mainly from study participants who were located in research sites 1 and 2. These comments were highly favourable; participants were very pleased with the way that consultants could refer them directly to a variety of services and facilities (e.g. to orthotic services, for specialist neurophysiotherapy, and for specialist assessment at gait clinic). They also valued consultants' in-depth knowledge of their condition and highly developed interpersonal skills; some people reported that they felt they had been fully understood for the first time when they spoke to the consultants about the issues and problems that they were encountering and trying to deal with. GPs were said to frequently lack knowledge or interest in (relatively) rare conditions, such as CMT disease. Patients appreciated having a consultant to coordinate their care, and felt reassured by regular reviews and monitoring.

*I got in a bit quicker [to orthotic services] with going through [consultant] than my GP.*

P21

*I was very impressed by [consultant]. [Consultant] pulled up a chair and sat down and said, now tell me . . . and [consultant] sat there and listened without putting anything on to me. Just listened to what I was saying . . . somebody you go in and you've got confidence.*

P2

*The registrar had said, oh, we'll get a brace for your knee, and [consultant] said, no we won't that's not what you need. We'll send you to the walking gait clinic and we'll get you fixed up with neuro-physiotherapy, and that was that.*

P2

*[Consultant] actually listens to what you are talking about and [consultant] visualises himself in that situation for [consultant] to understand what you are talking about.*

P1

*I think it was when I went back to [consultant] and I was saying, this is what I've got, and then [consultant] put me in touch with orthotics and they supplied me with the extra bits.*

P12

*I see [consultant] every 12 months . . . I know if I've got any problems [consultant]'ll sort it out and try and help . . .*

P21

In contrast, P15, with a diagnosis of poliomyelitis, did not feel that she was being treated as a 'joined-up person' and she thought that she would benefit from someone taking a more holistic approach to her overall health and well-being.

*I think they're just not treating me as a joined-up person. They're not looking at me as a polio person. They are looking at me as someone who has got a weak leg. No-one has been proactive about anything and I think if you had a person overseeing things as you got older, people tend to get osteoporosis where it could be worse for me . . . I think things could be a lot better for people with polio if they did have someone in overall charge of their care and who made sure that at different stages of my life that people came in and said things, like a review of gait education . . .*

P15

### Interactions with physiotherapists

Participants reported accessing physiotherapist services via GP referrals, referral from consultants in rehabilitation medicine, and through orthotic services. Referral via a consultant was considered the fastest route, although some participants nonetheless mentioned experiencing long waiting times for their initial appointment which caused them anxiety, and/or that the service was pressurised.

*I'm still waiting for neuro-physiotherapy . . . if there is only one person who does this specialist physiotherapy you can understand she can only see so many people.*

P2

*They were having a bit of a crisis because one of their physiotherapists was off ill, so they were really pushed for time and I felt a bit, 'you're done'.*

P12

*I am quite anxious that I am going to get worse and I really want to talk to some more specialist people [neuro-physiotherapists] to know what we could be doing over the next few years.*

P2

Many respondents indicated that they were aware of the difference between an 'ordinary' physiotherapist and a specialist neurophysiotherapist, and a number of people (mainly, but not entirely, limited to those in research site 2) mentioned paying privately for the services of neurophysiotherapists, sometimes using the money that they received through their disability allowance. There was a widespread perception among participants with poliomyelitis that non-specialist physiotherapy could result in damage to muscles.

*The normal one, I did go there but it didn't do anything.*

*P21, research site 2, who had been referred for neurophysiotherapy by a consultant*

*She's a great physiotherapist but she is not a neurophysiotherapist . . . I know of a very good neurophysio [therapist] in [place name] and I've asked to see her.*

P10, research site 2

*I've been having physio [therapy] for 5 or 6 years at least and she has helped me a lot . . . it's a private one . . . she was with the NHS but she said they don't give you long enough for your patients, anyway she's set up on her own . . .*

P11, research site 2

*I went along really quite apprehensive to talk to them about what they were planning because I didn't want to be damaged . . . if you start working the muscles too hard, you [can cause] further damage . . . quite a few people with polio end up worse off through having physiotherapy.*

P16, non-NHS

Participants who felt assured that they were receiving good advice and treatment from (neuro) physiotherapists were keen to carry out recommended exercises in an attempt to prevent potential future deterioration.

*I've been giving various exercises by the physiotherapy department . . . I've been given a lot of information to manage my condition so really it's up to me to manage it.*

P22

Only 3 of the 24 participants who were interviewed mentioned being given an orthotic device by a physiotherapist; a device to assist with foot drop to P12, and a knee brace to each of P4 and P13.

*She [physiotherapist] said, what about splints? . . . so she went and got a splint but a large one, so they put the large one on and although when I stood up it dropped down, still it had that support at the back of my knee . . . nothing digging in anywhere . . . so then I got referred to orthotics, I got referred for a small one.*

P4

Some degree of multidisciplinary working between physiotherapists and orthotists was reflected in the comments of P2 and P19. P2 recounted her referral to orthotic services by a physiotherapist, whereas P19 remarked that her orthotist was able to make a direct referral for her to see a physiotherapist with quicker access than she would have achieved if she had needed to go through a GP referral.

*I saw the physiotherapist and she put a towel under my foot . . . I was feeling very lopsided . . . and she said, right, I'll refer you to orthotics because it looks like you might need some help with raising that heel to give you better balance.*

P2

*It was quite straightforward . . . I guess some kind of consultation between [orthotist] and physio [therapist] . . . physio [therapist] agreed to see me . . . I went and we sorted it out. It wasn't one of those elongated things where I had to get a consultant involved and a GP and all that nonsense because my GP is hopeless.*

P19

### **Interactions with general practitioners**

With few exceptions, study participants viewed GPs' role in their care as primarily one of referral to specialist services, including orthotic services and physiotherapy. GPs' involvement in referral decisions was perceived as partly linked to mechanisms for funding, and partly because of GPs lacking the expertise to manage patients with needs for specialist services. Participants reported varying levels of frustration at having to contact their GP when they wanted access to particular services, including orthotic services.

*Somebody told me there is a neurological physiotherapy department at [name] and my [GP] referred me.*

P16

*About probably once every 12 months when I need to go back and have a pair of shoes made . . . I have to go through the GP surgery for them to refer me to the orthotics for them to make me an appointment to go, so it's quite a long-winded process. I can't just go straight to the orthotics. You have to go through your GP. It's all to do with the way funding is allocated.*

P22

Less than one-quarter of those interviewed felt that their GP(s) were interested in their condition, or finding out more about it, and a majority reported that their GP lacked both knowledge about and interest in the condition that was their primary diagnosis (poliomyelitis, CMT disease, multiple sclerosis and spina bifida).

*I went to my GP who knew absolutely nothing about the condition [CMT] but it was really good and both of us sort of researched it and sort of swapped notes. My first doctor got really involved to try because there wasn't and there still isn't a lot of knowledge within the medical community about this condition.*

P22

*I feel there is almost a black hole with GPs really.*

P5

*Mostly GPs don't know very much about it [polio].*

P18

*Nobody knows anything about me in the surgery now and it hacks me off something chronic . . . I did enquire if I could see someone who was a bit more knowledgeable about the spina bifida side of things. . . I waited to see this GP, another 3 or 4 weeks . . . to establish that if I want to find out more about spina bifida I can go on-line and find a forum.*

P19

A few patients reported a lack of response or encountering active resistance from GPs when they had requested particular investigations or services. P2 felt that her GP made referrals for her only when she was 'at crisis point' rather than making proactive, preventative referrals on her behalf, whereas P15 had to 'push' to be tested for post-polio syndrome when she felt that her condition was deteriorating.

*Not referring until I got to crisis point because I had to go to the doctors to get physio [therapy] for my knee. Nobody ever said, it's starting to give you problems, I think we should . . . if they'd had the knowledge they might have said, I think it would be better if we referred you for some advice.*

P2

*I went to my doctor about my pins and needles in my left leg and also about weakness in my arms . . . I said I want to be referred to someone . . . so she [GP] said to me, you're very proactive, she wasn't terribly happy about it but she did do it and about 3 months later I got an appointment with [name] who did loads of tests.*

P15

### **Interactions with podiatrists**

Only three (P5, P7 and P21) of the 24 participants interviewed referred to having any contact with podiatry services. P7 stated that she had been referred for regular review at podiatry services through her contact with a specialist (multiple sclerosis) nurse. P21 described attending a podiatry clinic for treatment of an open sore, over a long period after wearing an ill-fitting AFO. She thought the sore had occurred due to pressure from the device:

*I was going to the foot clinic every week and it took them ages and ages to get it right.*

P21

Participant 5 had had recent contact with podiatry services because of corns that had developed when wearing his orthotic footwear. He described being passed back and forth between orthotic and podiatry services, with a lack of clarity about who should take responsibility for dealing with his problem:

*You need to go back to [orthotic services] to sort this out, and [orthotic services] say, oh, no, it's not our thing it's more the podiatrists need to sort that bit out.*

P5



## Chapter 5 Results of survey of health-care professionals

### Response and completion rates

The survey was circulated to members of BAPO ( $n = 700$ ), ACPIN ( $n = 2700$ ) and BSRM ( $n = 300$ ). A total of 238 HCPs agreed to participate in the survey, that is, they clicked into the survey questionnaire via the link in the invitation letter. Based on the sampling frame described above, this equates to a response rate of 6.43%. The response rate by organisation was 12% for BAPO, 3.48% for ACPIN and 16.67% for BSRM. These response rates are an underestimate as a result of the imprecise sampling frame. For example, information supplied by BAPO suggests that approximately three-quarters of their membership are orthotists, not all of whom manage patients with NMD or CNS conditions, leaving a more likely sampling frame of  $< 400$ . Similarly, not all participants in the sampling frame for ACPIN and BAPO manage the populations of interest.

The overall completion rate [the number of participants who finished the survey ( $n = 138$ )/the number who agreed to participate ( $n = 238$ )] was 57.98%; 68% for orthotists, 62.8% for physiotherapists and 54% for doctors in rehabilitation medicine.

The response rate was also calculated for each question in the survey. The denominator used was the number eligible to complete a specific question. As the survey hid certain questions from certain respondents (e.g. all questions that are specifically related to patients with a CNS condition were not asked of respondents who indicated that they did not treat patients with a CNS condition), the denominator varies across questions and across professions. The denominator used ranged from a maximum of 238 for the questions that all participants were eligible to complete to a minimum of 115 when only respondents who fitted devices could respond to a specific question.

The total number of respondents was well above the estimated minimum sample size required, based on a 95% confidence level and a 10% margin of error ( $n = 96$ ), but insufficient for the more ideal 5% margin of error ( $n = 384$ ). It was, therefore, not appropriate to undertake subgroup analyses. Descriptive results are presented by HCP as well as the total group; however, any apparent differences should be interpreted with caution.

For each question, the number of responses to each answer option is reported, and the proportion is calculated using the number of respondents who answered that particular question as the denominator. For completeness, the number of non-responders for each question was also reported. This ensured that the proportions of the responses presented were not overestimated. In the tables the total number in the all respondents column is greater than the sum of the three professional groups owing to data not being reported separately for 'other' types of health-care professionals and also to missing data on profession. The full questionnaire is provided in *Appendix 7*.



## Demographic characteristics

Although 238 HCPs clicked into the survey via the invitation letter and consented to undertake the survey, only 229 respondents answered the first question. Respondents were asked their occupation (question 1, Q1) and their years of post-qualification experience (Q2). The response rate for Q1 was 96.22% ( $n = 229$ ) and for Q2 was 95.38% ( $n = 227$ ).

The respondents included 80 orthotists (34.93% of responders), 94 physiotherapists (41.05% of responders), 50 doctors in rehabilitation medicine (21.83% of responders) and five other types of HCP (one prosthetist/orthotist, two prothetists, one orthotic technician and one podiatrist). Responses for the last group are provided in the overall responses, but not as an individual group, in the tables below.

Most commonly respondents had  $\geq 16$  years of post-qualification experience (44.49%,  $n = 101$ ). Similar proportions had up to 5 years' (19.38%,  $n = 44$ ), 6–10 years' (19.38%,  $n = 44$ ) and 11–15 years' (16.74%,  $n = 38$ ) experience. This trend of years of experience held for the physiotherapists and the doctors in rehabilitation medicine, a larger proportion (40%,  $n = 32$ ) of orthotists who had 0–5 years' of post-qualification experience, and a small proportion (30%,  $n = 24$ ) had  $\geq 16$  years' experience.

Respondents were asked where their clinical setting was located (Q3). The response rate was 92.44% ( $n = 220$ ): 96.25% of orthotists, 100% of physiotherapists and 88% of rehabilitation medicine physicians. The vast majority (82.27%,  $n = 181$ ) of respondents' clinical setting was in England, 10.45% ( $n = 23$ ) were based in Scotland, 3.18% ( $n = 7$ ) in Wales and 3.64% ( $n = 8$ ) in Northern Ireland.

When asked about the type of clinical setting(s) in which they work (Q4), the question response rate was 92.44% ( $n = 220$ ); 96.25% of orthotists, 98.94% of physiotherapists and 88% of rehabilitation medicine physicians. The majority of respondents (65.91%,  $n = 145$ ) were from a NHS setting, 9.09% ( $n = 20$ ) a private company setting, and both NHS and private settings (18.18%,  $n = 40$ ). Fifteen respondents (6.82%) chose 'other' settings, 11 of whom described their clinical setting, which included private domiciliary ( $n = 1$ ); a subcontracted private company within the NHS ( $n = 1$ ); a university setting ( $n = 3$ ); private community ( $n = 1$ ); Ministry of Defence ( $n = 1$ ); self-employed ( $n = 1$ ) and retired ( $n = 1$ ).

Respondents were asked how orthotic services in their clinical setting are provided (Q5). No single model predominated: 38.89% ( $n = 84$ ) reported that orthotic services are provided as an integrated part of a MDT service and 46.76% ( $n = 101$ ) within a stand-alone prescribing/fitting orthotic service. Thirty-one respondents (14.35%) chose the 'other' option (Table 14).

**TABLE 14** How are orthotic services provided in your clinical setting?, number (%) of responses

Service provision	All respondents	Orthotists	Physiotherapists	Rehabilitation medicine physicians
Response rate	$n = 216$ (90.76%)	$n = 77$ (96.25%)	$n = 92$ (97.87%)	$n = 43$ (86%)
As an integrated part of a multidisciplinary service	84 (38.89)	31 (40.26)	27 (29.35)	24 (55.81)
Stand-alone prescribing/fitting orthotic service	101 (46.76)	33 (42.86)	50 (54.35)	17 (39.53)
Other	31 (14.35)	13 (16.88)	15 (16.30)	2 (4.65)
No response	22	3	2	7

Thirteen orthotists chose the 'other' option and their responses indicated that the orthotic services in their setting are a combination of both MDTs and stand-alone services. This was also the case for both doctors in rehabilitation medicine who chose 'other'. There was a variety of responses from the 15 physiotherapists who chose the 'other' option: one physiotherapist worked with a podiatrist to access FOs but other orthotic devices prescribed are provided through a stand-alone orthotic service. Five physiotherapists stated that they source orthoses themselves directly from orthotics companies. One physiotherapist stated that their orthotic service was provided as part of a therapy team, which was not a wider MDT. One physiotherapist is part of a privately run rehabilitation service, and patients are referred to the NHS for orthotic devices. Two respondents stated a mix of both stand-alone and MDTs; one respondent stated provision varies depending on whether it is available through the NHS or privately.

The respondents who stated that the orthotic services in their clinical setting are provided by a MDT were asked what HCPs make up their MDT (Q6).

The majority of respondents' MDTs include a physiotherapist (96.43%), an orthotist (79.76%), occupational therapists (69.05%) and doctors in rehabilitation medicine (60.71%) (Table 15). A smaller proportion reported a gait scientist as part of the MDT (10.71%). Nineteen (22.62%) respondents' MDTs included HCPs other than those listed.

Six orthotists chose 'other' HCPs. Five orthotists stated that their MDTs also included a podiatrist, and one stated they also include community therapists. Eight physiotherapists chose 'other' HCPs. Their responses included podiatrists, speech and language therapists, psychologists/neuropsychologists, rehabilitation assistants, inpatient nursing team, geriatricians, social workers, dietitians and one respondent stated 'patient and family'. Four doctors in rehabilitation medicine chose 'other' HCPs. Among the HCPs stated were speech and language therapists, clinical psychologists, dietitians, plastic surgeons, psychologist/neuropsychologist and prosthetists.

**TABLE 15** Health-care professionals in MDTs, number (%) of responses

HCP	All respondents n = 84 (78.5%)	Orthotists n = 32 (91.14%)	Physiotherapists n = 28 (93.33%)	Rehabilitation medicine physicians n = 24 (77.42%)
Response rate	n = 84 (78.5%)	n = 32 (91.14%)	n = 28 (93.33%)	n = 24 (77.42%)
Physiotherapist	81 (96.43)	29 (90.63)	27 (96.43)	23 (95.83)
Orthopaedic surgeon	32 (38.10)	21 (65.63)	2 (7.14)	6 (25.00)
Doctor in rehabilitation medicine	51 (60.71)	16 (50.00)	12 (42.86)	22 (91.67)
Occupational therapist	58 (69.05)	16 (50.00)	22 (78.57)	18 (75.00)
Gait scientist	9 (10.71)	4 (12.50)	1 (3.57)	4 (16.67)
Neurologist	14 (16.67)	6 (18.75)	6 (21.43)	2 (8.33)
Orthotist	67 (79.76)	27 (84.38)	18 (64.29)	21 (87.50)
Clinical nurse specialist	30 (35.71)	9 (28.13)	11 (39.29)	9 (37.50)
Other HCP	19 (22.62)	6 (18.75)	8 (28.57)	4 (16.67)
No response	23	3	2	7

## Patient demographics

A series of questions was asked to ensure that the respondents for the survey are currently treating, or have recently treated, adult patients with NMD and/or CNS with knee instability (Q7–10).

In relation to adult patients with NMD with knee instability, 66.34% ( $n = 136$ ) of respondents reported that they treat, or have recently treated, this population: 33.66% ( $n = 69$ ) had not and 33 respondents did not answer this question (response rate to question 86.13%,  $n = 205$ ).

In relation to adult patients with CNS disorders with knee instability, 83.82% ( $n = 171$ ) of respondents reported that they treat, or have recently treated, this population, 16.18% ( $n = 33$ ) had not and 34 respondents did not answer this question (response rate to question 85.71%,  $n = 204$ ).

The respondents who stated that they currently treat, or have recently treated, these patients were then asked about the types of CNS conditions and/or NMD that they see most frequently. Responses are presented in *Table 16*.

**TABLE 16** Types of CNS conditions and/or NMD seen most frequently, number (%) of responses

Disease/condition	Total respondents	Orthotists	Physiotherapists	Rehabilitation medicine physicians
<b>NMD</b>				
<i>Response rate</i>	$n = 136$ (76.47%)	$n = 55$ (91.67%)	$n = 48$ (88.89%)	$n = 25$ (71.43%)
Poliomyelitis	73 (70.19)	50 (90.91)	6 (12.50)	8 (32.00)
Muscular dystrophy	61 (58.65)	21 (38.18)	22 (45.83)	10 (40.00)
Post-polio syndrome	80 (76.92)	45 (81.82)	12 (25.00)	15 (60.00)
Motor neurone disease	71 (68.27)	23 (41.82)	29 (60.42)	9 (36.00)
Inclusion body myositis	23 (22.12)	3 (5.45)	11 (22.92)	6 (24.00)
CMT disease	71 (68.27)	40 (72.73)	9 (18.75)	14 (56.00)
Guillain–Barré syndrome	68 (65.38)	14 (25.45)	31 (64.58)	18 (72.00)
CIDP	48 (46.15)	7 (12.73)	21 (43.75)	17 (68.00)
Other	10 (9.62)	4 (7.27)	1 (2.08)	4 (16.00)
No response	32	5	6	10
<b>CNS conditions</b>				
<i>Response rate</i>	$n = 171$ (91.81%)	$n = 64$ (92.75%)	$n = 72$ (90%)	$n = 34$ (77.27%)
Adult cerebral palsy	79 (50.32)	43 (67.19)	15 (20.83)	21 (61.76)
Multiple sclerosis	130 (82.80)	54 (84.38)	51 (70.83)	25 (73.53)
Traumatic brain injury	110 (70.06)	39 (60.94)	43 (59.72)	28 (82.35)
Stroke	157 (100.00)	60 (93.75)	66 (91.67)	30 (88.24)
Acquired brain injury	102 (64.97)	37 (57.81)	37 (51.39)	28 (82.35)
Spinal cord disorders	98 (62.42)	32 (50.00)	37 (51.39)	29 (85.29)
Other	4 (2.55)	1 (1.56)	3 (4.17)	0 (0.00)
No response	14	5	8	10

CIDP, chronic inflammatory demyelinating polyradiculoneuropathy.

The most common type of NMD disorder being treated was post-polio syndrome (76.92%), followed by poliomyelitis (70.19%), motor neurone disease (68.27%), CMT disease (68.27%), Guillain–Barré Syndrome (65.38%), muscular dystrophy (58.65%), chronic inflammatory demyelinating polyradiculoneuropathy (CIDP; 46.15%) and inclusion body myositis (22.12%).

The most common type of CNS condition being treated was stroke (100%), followed by multiple sclerosis (82.80%), traumatic brain injury (70.06%), acquired brain injury (64.97%), spinal cord disorders (62.42%) and adult cerebral palsy (50.32%).

The respondents who stated that they do not currently treat, and have not recently treated, patients with a NMD or a CNS condition with knee instability  $n = 23$  (9.66%,  $n = 238$  total) were directed to the end of the survey.

From this section onwards, some questions were asked specifically about NMD/CNS patients with knee instability. Therefore, only the questions relevant to the respondents, based on Q7 and Q9 were displayed to the respondents.

## Patient referrals

Those respondents who stated that they treat, or have recently treated, patients with NMD were asked how these patients would routinely be referred to them (Q11). Referrals were from a wide range of sources (*Table 17*).

**TABLE 17** Referral of patients with NMD to HCPs, number (%) of responses

HCP	All respondents	Orthotists	Physiotherapists	Rehabilitation medicine physicians
<i>Response rate</i>	$n = 137$ (82.04%)	$n = 64$ (92.75%)	$n = 45$ (85.19%)	$n = 25$ (71.43%)
GP	82 (59.85)	38 (59.38)	27 (58.70)	17 (68.00)
Physiotherapist	86 (62.77)	54 (84.38)	18 (39.13)	14 (56.00)
Orthopaedic surgeon	52 (37.96)	40 (62.50)	5 (10.87)	7 (28.00)
Doctor in rehabilitation medicine	56 (40.88)	30 (46.88)	20 (43.48)	6 (24.00)
Occupational therapist	17 (12.41)	4 (6.25)	9 (19.57)	5 (20.00)
Gait scientist	5 (3.65)	4 (6.25)	1 (2.17)	0 (0.00)
Neurologist	87 (63.50)	40 (62.50)	33 (71.74)	14 (56.00)
Orthotist	9 (6.57)	3 (4.69)	1 (2.17)	5 (20.00)
Clinical nurse specialist	18 (13.14)	6 (9.38)	7 (15.22)	5 (20.00)
Other	23 (16.79)	5 (7.81)	14 (30.43)	3 (12.00)
No response	30	5	8	10

A substantial proportion of referrals are from GPs (59.85%), physiotherapists (62.77%) and neurologists (63.50%), with orthopaedic surgeons (37.96%) and doctors in rehabilitation medicine (40.88%) also being significant sources of referrals. A total of 23 respondents chose 'other' as the HCPs that refers patients with NMD to them; this included 14 (30.43%) of the physiotherapists. The responses provided by these respondents indicated that there can be self-referrals and referrals through inpatient systems. Orthotists can receive referrals from podiatrists, community physiotherapists, the MDT team and self-referrals from patients. Physiotherapists also receive referrals from the inpatient ward, self-referrals from patients, and referrals from oncologists, stroke doctors and case managers. Rehabilitation medicine physicians can receive referrals from community stroke rehabilitation teams.

Those respondents who stated that they treat, or have recently treated, patients with CNS conditions were asked how these patients would routinely be referred to them (Q12).

As for patients with NMD, a substantial proportion of referrals are from GPs (59.64%), physiotherapists (65.66%) and neurologists (55.42%), with doctors in rehabilitation medicine (43.98%) also a significant source of referral (*Table 18*). A total of 37 respondents chose 'other' as the HCPs that refer patients with CNS conditions to them; this included 31 (44.29%) of the physiotherapists. The responses provided by these respondents indicated that referrals can also be self-referrals (by the patients themselves) and referrals through inpatient systems (particularly stroke patients).

Orthotists can also receive referrals from medicolegal sources, community physiotherapists and self-referral from patients. Physiotherapists can also receive referrals from the inpatient ward, stroke units, a MDT member, oncologists, case managers, nursing homes, stroke doctors and self-referral from patients. Doctors in rehabilitation medicine can also receive referrals from the inpatient ward, spinal surgeons and neurologists. One rehabilitation medicine physician stated that he/she would never receive a direct referral for these conditions.

Respondents were asked what information is usually provided on referral of patients with NMD and/or CNS conditions (Q13).

**TABLE 18** Referral of patients with CNS conditions to HCPs, number (%) of responses

HCP	All respondents	Orthotists	Physiotherapists	Rehabilitation medicine physicians
<i>Response rate</i>	n = 166 (80.98%)	n = 64 (92.75%)	n = 70 (87.5%)	n = 31 (70.45%)
GP	99 (59.64)	42 (65.63)	34 (48.57)	23 (74.19)
Physiotherapist	109 (65.66)	54 (84.38)	32 (45.71)	22 (70.97)
Orthopaedic surgeon	44 (26.51)	33 (51.56)	3 (4.29)	8 (25.81)
Rehabilitation medicine physician	73 (43.98)	35 (54.69)	29 (41.43)	9 (29.03)
Occupational therapist	30 (18.07)	8 (12.50)	17 (24.29)	5 (16.13)
Gait scientist	6 (3.61)	4 (6.25)	1 (1.43)	1 (3.23)
Neurologist	92 (55.42)	32 (50.00)	41 (58.57)	19 (61.29)
Orthotist	11 (6.63)	4 (6.25)	2 (2.86)	5 (16.13)
Clinical nurse specialist	39 (23.49)	8 (12.50)	22 (31.43)	9 (29.03)
Other	37 (22.29)	2 (3.13)	31 (44.29)	4 (12.90)
No response	39	5	10	13

Almost all respondents stated that they are provided with the patient diagnosis (94.64%) and two-thirds are provided with the patient's medical details (Table 19). Smaller proportions reported being provided with physical assessment details (33.93%), with the aims and goals of the orthotic intervention (32.14%), with the type of orthoses provided (20.24%) and with a gait analysis report (1.79%). Twenty-two respondents chose 'other' and some provided further details. The orthotists are also sometimes provided with a suggestion of the orthoses required, what is required from them and medical details from medicolegal reports. Five orthotists also essentially stated that the aims/goals of the intervention would be provided. Physiotherapists are also provided with the reason for referral and care needs reports.

Respondents were asked what symptoms in patients with NMD and/or CNS conditions would trigger a referral to them for assessment (Q14).

The three options available appear to all trigger a substantial number of referrals and this was the case across the types of HCPs (Table 20). A number of respondents (20.12%) chose the 'other' option. Symptoms that would trigger a referral to an orthotist also include the patient having gait problems, the patient having poor function, and normal service provision not having worked for the patient. Symptoms that would trigger a referral to a physiotherapist also include the patient having gait problems, the patient having poor balance and a recent change in the patient's comorbidities. Five physiotherapists stated that they see all patients. A doctor in rehabilitation medicine could also be referred a patient having gait problems.

**TABLE 19** Information provided on referral, number (%) of responses

Information	All respondents	Orthotists	Physiotherapists	Rehabilitation medicine physicians
<i>Response rate</i>	n = 168 (79.25%)	n = 69 (93.24%)	n = 67 (81.71%)	n = 32 (71.11%)
Medical details	112 (66.67)	37 (53.62)	50 (74.63)	24 (75.00)
Diagnosis	159 (94.64)	65 (94.20)	62 (92.54)	32 (100.00)
Physical assessment details	57 (33.93)	17 (24.64)	20 (29.85)	19 (59.38)
Gait analysis report	3 (1.79)	2 (2.90)	1 (1.49)	0 (0.00)
The aims/goals of the orthosis (if an orthosis has already been prescribed)	54 (32.14)	32 (46.38)	15 (22.39)	7 (21.88)
Type of orthosis provided (if an orthosis has already been prescribed)	34 (20.24)	16 (23.19)	12 (17.91)	6 (18.75)
Other	22 (13.10)	11 (15.94)	11 (16.42)	0 (0.00)
No response	44	5	15	13

**TABLE 20** Symptoms that trigger referral, number (%) of responses

Symptoms	All respondents	Orthotists	Physiotherapists	Rehabilitation medicine physicians
<i>Response rate</i>	n = 169 (79.34%)	n = 69 (93.24%)	n = 62 (81.71%)	n = 32 (71.11%)
Patient has reported falls	131 (77.51)	59 (85.51)	48 (71.64)	24 (75.00)
Patient-reported pain in knee or lower limb	110 (65.09)	51 (73.91)	39 (58.21)	19 (59.38)
Patient-reported weakness in knee or lower limb	137 (81.07)	61 (88.41)	52 (77.61)	24 (75.00)
Other	34 (20.12)	11 (15.94)	11 (16.42)	3 (9.38)
No response	44	5	15	13

The respondents were asked what other HCPs would assess the patients that are referred to them (Q17). *Table 21* shows that physiotherapists would most commonly assess these patients (75.63%), followed by GPs (55%), neurologists (55%), doctors in rehabilitation medicine (50.63%), orthopaedic surgeons (43.75%), orthotists (41.25%), occupational therapists (37.50%), clinical nurse specialists (21.88%) and gait scientists (12.50%).

Fifteen respondents (9.38%) chose the 'other' option. One orthotist stated that any of the HCPs listed and any MDT member could potentially also assess these patients. Another orthotist stated that this information would not be available to them on referral. The physiotherapists stated that a consultant, a neurosurgeon and a podiatrist could also assess these patients. Two physiotherapists stated that any of the HCPs listed and any MDT member could potentially also assess these patients, and one physiotherapist stated that his/her patients would not be seen by any other HCP.

Respondents were asked if they thought that there were any barriers to patients being referred to them (Q15). Results are presented in *Table 22*. The most commonly reported response was that there were 'sometimes' barriers to patients being referred (47.85%), followed by 'rarely' (30.67%). Although the trend was similar for orthotists and rehabilitation medicine doctors, a higher proportion of physiotherapists felt that there were 'rarely' or 'never' barriers. This may be explained by the fact that physiotherapist respondents received more referrals from inpatient wards than the other groups; however, the difference is small.

**TABLE 21** Which HCPs assess these patients?, number (%) of responses

HCP	All respondents	Orthotists	Physiotherapists	Rehabilitation medicine physicians
<i>Response rate</i>	n = 160 (75.12%)	n = 65 (87.84%)	n = 64 (78.05%)	n = 30 (66.67%)
GP	88 (55.00)	42 (64.62)	32 (50.00)	14 (46.67)
Physiotherapist	121 (75.63)	63 (96.92)	29 (45.31)	29 (96.67)
Orthopaedic surgeon	70 (43.75)	44 (67.69)	13 (20.31)	13 (43.33)
Rehabilitation medicine physician	81 (50.63)	36 (55.38)	35 (54.69)	10 (33.33)
Occupational therapist	60 (37.50)	17 (26.15)	36 (56.25)	7 (23.33)
Gait scientist	20 (12.50)	9 (13.85)	5 (7.81)	6 (20.00)
Neurologist	88 (55.00)	39 (60.00)	35 (54.69)	13 (43.33)
Orthotist	66 (41.25)	18 (27.69)	31 (48.44)	17 (56.67)
Clinical nurse specialist	35 (21.88)	8 (12.31)	21 (32.81)	6 (20.00)
Other	15 (9.38)	2 (3.08)	13 (20.31)	0 (0.00)
No response	53	9	18	15

**TABLE 22** Respondents' perception of barriers to patients' referrals, number (%) of responses

Perception of barriers	All respondents	Orthotists	Physiotherapists	Doctors in rehabilitation medicine
<i>Response rate</i>	n = 163 (76.53%)	n = 66 (89.19%)	n = 65 (79.27%)	n = 31 (69.89%)
Never	20 (12.27)	5 (7.58)	12 (18.46)	3 (9.68)
Rarely	50 (30.67)	12 (18.18)	28 (43.08)	10 (32.26)
Sometimes	78 (47.85)	42 (63.64)	22 (33.85)	13 (41.94)
Most of the time	13 (7.98)	6 (9.09)	2 (3.08)	5 (16.13)
Always	2 (1.23)	1 (1.52)	1 (1.54)	0 (0.00)
No response	50	8	17	14



When asked to briefly explain their answers, respondents described both the lack and the presence of barriers to patients being referred to them. Thirty-six of the comments indicated that there were no barriers. It appears that those HCPs with blanket referrals or working in an inpatient setting do not feel that there are barriers to patients being referred to them. However, there were a number of responses for which potential barriers to patient referrals were highlighted.

Lack of awareness and knowledge appear to be the main issues affecting referral of patients to orthotic services. Forty-one comments indicated that a lack of awareness by potential referrers of orthotists' professional expertise was causing barriers to referrals. Two additional comments noted the lack of knowledge of GPs about patient conditions and four additional comments noted the lack of knowledge of the potential of orthotic devices for this patient population as barriers.

The ability to refer also appears to be affecting referrals for this patient population. Six comments referred to the inability of some HCPs to refer directly to orthotic services. For example, one respondent stated that they could only accept internal referrals; another stated that some areas only allow referrals from consultants and another noted the inability of GPs to provide direct referrals. Five comments indicated that there can be a lack of knowledge by potential referrers in the potential pathway for this patient population. Nine comments indicated that in some cases there are difficulties with the referral pathway, such as criteria required for referrals, making the process less than straightforward.

Seven comments detailed the poor access to service in some areas of the country. One respondent noted a 'postcode lottery' and another comment noted the 'non-existent outpatient facility' in their setting. Nineteen comments indicated that the cost was a barrier. Cost appears to be a factor both in terms of providing an orthotic service and the cost of referral for GPs. The financial status of the patient themselves was also highlighted, presumably if the cost needs to be borne by the patient. Eighteen comments indicated that long waiting times were causing barriers to referral. Ten comments noted late referrals, from both lack of awareness and long waiting times, as a barrier to treatment. It seems that patients are presenting at orthotic services when their condition has deteriorated to the point at which orthotic provision may no longer be beneficial.

Two comments noted that some settings accept referrals from large geographical areas (one respondent stated that referrals were accepted from all over the country), which provides a barrier as a result of patients having difficulty attending appointments. One comment noted the lack of hospital transport. Two comments also noted that sometimes patients do not seek help, which creates a barrier to referral.

## Initial assessment

Respondents were asked the average waiting time for adult patients with NMD-related knee instability between referral of the patient to them and their initial assessment (Q19).

The majority of respondents reported that, on average, patients were seen within 12 weeks of referral (*Table 23*). Physiotherapists reported the shortest waiting times for referral (86.48% of physiotherapists said that referral occurred within 8 weeks).

Respondents were asked about the average waiting time for adult patients with CNS conditions with knee instability between referral of the patient to them and their initial assessment (Q20).

As for patients with NMD, the majority of respondents reported an average time from referral to initial assessment of up to 12 weeks (*Table 24*). A higher proportion of physiotherapists reported an average waiting time of up to 4 weeks than the other two groups.



**TABLE 23** Average waiting time for a patient with NMD between referral and initial assessment, number (%) of respondents

Average waiting time	All respondents	Orthotists	Physiotherapists	Rehabilitation medicine physicians
Response rate	n = 115 (68.45%)	n = 57 (82.61%)	n = 37 (69.81%)	n = 21 (60%)
Up to 4 weeks	41 (35.65)	11 (19.30)	23 (62.16)	7 (33.33)
5–8 weeks	40 (34.78)	26 (45.61)	9 (24.32)	5 (23.81)
9–12 weeks	19 (16.52)	12 (21.05)	0 (0.00)	7 (33.33)
13–16 weeks	9 (7.83)	5 (8.77)	3 (8.11)	1 (4.76)
17–20 weeks	1 (0.87)	0 (0.00)	1 (2.70)	0 (0.00)
21–24 weeks	3 (2.61)	2 (3.51)	1 (2.70)	0 (0.00)
≥ 24 weeks	2 (1.74)	1 (1.75)	0 (0.00)	1 (4.76)
No response	53	12	16	14

**TABLE 24** Average waiting time for a patient with a CNS condition between referral and initial assessment, number (%) of respondents

Average waiting time	All respondents	Orthotists	Physiotherapists	Rehabilitation medicine physicians
Response rate	n = 143 (69.76%)	n = 59 (85.51%)	n = 58 (72.5%)	n = 26 (59.1%)
Up to 4 weeks	62 (43.36)	16 (27.12)	39 (67.24)	7 (26.92)
5–8 weeks	43 (30.07)	23 (38.98)	13 (22.41)	7 (26.92)
9–12 weeks	22 (15.38)	11 (18.64)	2 (3.45)	9 (34.62)
13–16 weeks	9 (6.29)	6 (10.17)	2 (3.45)	1 (3.85)
17–20 weeks	3 (2.10)	1 (1.69)	1 (1.72)	1 (3.85)
21–24 weeks	3 (2.10)	2 (3.39)	1 (1.72)	0 (0.00)
≥ 24 weeks	1 (0.70)	0 (0.00)	0 (0.00)	1 (3.85)
No response	62	10	22	18

Respondents were asked what assessments they would routinely undertake as part of their initial assessment of patients with NMD and/or CNS with knee instability (Q18). Results are presented in *Table 25*.

Respondents reported using a variety of combinations of initial assessments in their clinical practice. The majority of respondents routinely assess a patient's muscle strength (95.42%), joint range of movement (ROM) and the quality of that movement (95.42%), the presence of spasticity (92.81%), patient expectations (89.54%); observe gait (88.89%); take history of pain/falls/walking ability (87.58%); and assess previous treatments (83.66%), sensation (83.01%), activity limitations (79.74%), ligament laxity (69.82%), proprioception (66.01%), aggravating factors (64.05%) and balance tests (57.52%). Smaller proportions reported using timed walking tests (33.33%) and imaging (18.95%).

It appears that formal gait analysis is rarely used as part of the initial assessment of patients with NMD and/or CNS conditions. Nine respondents chose the 'other' option. These respondents stated that they also routinely undertake the following assessments: functional movement tests, such as sit-to-stand or stairs; assessment of psychological limitations and social inclusion; ability/inability to stand; and lifestyle

**TABLE 25** Assessments routinely undertaken, number (%) of responses

Assessment	All respondents	Orthotists	Physiotherapists	Rehabilitation medicine physicians
<i>Response rate</i>	n = 153 (71.83%)	n = 63 (85.14%)	n = 60 (73.17%)	n = 28 (62.22%)
Ligament laxity	106 (69.28)	58 (92.06)	28 (46.67)	20 (71.43)
Muscle strength	146 (95.42)	61 (96.83)	58 (96.67)	26 (92.86)
Joint ROM and quality of ROM	146 (95.42)	62 (98.41)	58 (96.67)	25 (89.29)
Presence of spasticity (if appropriate)	142 (92.81)	59 (93.65)	57 (95.00)	25 (89.29)
Previous treatments	128 (83.66)	55 (87.30)	48 (80.00)	25 (89.29)
Previous history of pain/falls/walking ability	134 (87.58)	58 (92.06)	52 (86.67)	24 (85.71)
Sensation	127 (83.01)	50 (79.37)	53 (88.33)	24 (85.71)
Observational gait analysis	136 (88.89)	59 (93.65)	55 (91.67)	22 (78.57)
Video recording gait	16 (10.46)	5 (7.94)	10 (16.67)	1 (3.57)
Three-dimensional/video vector gait analysis	1 (0.65)	1 (1.59)	0 (0.00)	0 (0.00)
Balance tests	88 (57.52)	18 (28.57)	55 (91.67)	15 (53.57)
Timed walking tests	51 (33.33)	6 (9.52)	37 (61.67)	8 (28.57)
Patient expectations	137 (89.54)	58 (92.06)	57 (95.00)	22 (78.57)
Activity limitations	122 (79.74)	46 (73.02)	54 (90.00)	22 (78.57)
Aggravating factors	98 (64.05)	35 (55.56)	43 (71.67)	20 (71.43)
Proprioception	101 (66.01)	27 (42.86)	54 (90.00)	20 (71.43)
Imaging (e.g. radiography, MRI or ultrasound)	29 (18.95)	6 (9.52)	6 (10.00)	17 (60.71)
Other	9 (5.88)	3 (4.76)	4 (6.67)	2 (6.67)
No response	60	11	22	17

MRI, magnetic resonance imaging.

assessments. Respondents stated that they would also undertake the following: review of any imaging or related reports as part of assessment; assessment of pain, balance and confidence in walking with numeric rating scales; assessment of current orthosis; and assessment of patient's expectations and understanding of the limitations of treatment.

## Prescription and fitting of orthotic devices

This section of the survey began by asking our respondents if, in their routine work, they *prescribe or fit* orthotic devices for adult patients with NMD and/or CNS conditions, with knee instability (Q24).

The majority of respondents (70.21%) prescribe or fit orthotic devices for patients with NMD/CNS conditions, with knee instability (*Table 26*). All but two orthotists prescribe/fit orthotic devices for this patient group (96.72%). Slightly more of our respondents who were physiotherapists and doctors in rehabilitation medicine do not prescribe/fit orthotic devices for this patient group (50% and 52%, respectively).

**TABLE 26** Do you prescribe or fit orthotic devices?, number (%) of responses

Response	All respondents	Orthotists	Physiotherapists	Rehabilitation medicine physicians
<i>Response rate</i>	n = 141 (66.51%)	n = 61 (82.43%)	n = 55 (68.29%)	n = 25 (55.56%)
Yes	99 (70.21)	59 (96.72)	28 (50.00)	12 (48.00)
No	42 (29.79)	2 (3.28)	28 (50.00)	13 (52.00)
No response	71	13	26	20

In order to reduce the burden on respondents, those who answered no to this question subsequently skipped all of the questions that assumed that the respondent prescribed or fitted orthotic devices. Those respondents who stated that they did not prescribe or fit devices to this patient group were asked to which HCP they would refer patients requiring prescription and fitting of orthotic devices (Q25). The results of this question are presented in *Tables 27* and *28*, and indicated that the most common referrals for prescribing or fitting an orthosis was to an orthotist.

**TABLE 27** Patients with CNS conditions: referrals for prescription/fitting of orthotic devices, number (%) of responses

HCP	All respondents	Orthotists	Physiotherapists	Rehabilitation medicine physicians
<i>Response rate</i>	n = 43 (37.39%)	n = 2 (12.25%)	n = 28 (51.85%)	n = 13 (39.4%)
Orthotist	36 (83.72)	1 (50.00)	24 (85.71)	11 (84.62)
Physiotherapist	2 (4.65)	0 (0.00)	0 (0.00)	2 (15.38)
Doctor in rehabilitation medicine	1 (2.33)	0 (0.00)	1 (3.57)	0 (0.00)
Other	2 (4.65)	0 (0.00)	2 (7.14)	0 (0.00)
NA	2 (4.65)	1 (50.00)	1 (3.57)	0 (0.00)
No response	72	14	26	20

NA, not applicable.

**TABLE 28** Patient with NMDs: referrals for prescription/fitting of orthotic devices destination, number (%) of responses

HCP	All respondents	Orthotists	Physiotherapists	Doctors in rehabilitation medicine
<i>Response rate</i>	n = 43 (37.39%)	n = 2 (12.25%)	n = 28 (51.85%)	n = 13 (39.4%)
Orthotist	31 (72.09)	1 (50.00)	20 (71.43)	10 (76.92)
Physiotherapist	2 (4.65)	0 (0.00)	0 (0.00)	2 (15.38)
Doctor in rehabilitation medicine	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Other	2 (4.65)	0 (0.00)	2 (7.14)	2 (15.38)
NA	8 (18.60)	1 (50.00)	6 (21.43)	1 (7.69)
No response	72	14	26	20

NA, not applicable.

## Types of devices

The respondents were asked about what types of orthotic devices they prescribe for patients with NMD and/or CNS conditions with knee instability (Q26). The results for this question are presented in *Table 29*.

Ankle-foot orthoses appear to be the device prescribed by most respondents (93.94%), followed closely by knee braces (88.89%) and KAFOs (74.75%). Eighteen respondents (18.18%) chose 'other' for the type of orthotic device prescribed. Patients with NMD and CNS conditions with knee instability are also prescribed 'FOOT-UP'<sup>®</sup> Orthoses (Össur, Reykjavik, Iceland), Lycra, 'heel raises', ankle supports, GRAFOs, taping and anti-hyperextension cages.

Respondents were also asked about what types of orthotic devices they fit for patients with CNS conditions and/or NMD with knee instability (Q27). Only 14 respondents (8.24%) stated that they do not fit any devices, indicating that the majority of respondents both prescribe and fit orthotic devices for patients with CNS conditions and/or NMD with knee instability (*Table 30*). The responses to this question were very similar to the responses to the previous question on prescribing. The most commonly fitted devices overall were AFOs (89.90%), knee braces (87.88%) and KAFOs (65.66%). Fourteen respondents (14.14%) chose 'other' for the type of orthotic device prescribed. Seven orthotists chose 'other' and stated that spinal supports, heel raises and Lycra supports could also be fitted. Four physiotherapists chose 'other' and stated that FOOT-UPS, taping, GRAFOs and sensory dynamic orthoses could also be fitted. Four doctors in rehabilitation chose 'other'; responses stated that the orthoses that they prescribe would be fitted by an orthotist.

Respondents were asked what proportion (approximately) of the devices that they prescribe/fit for patients with CNS conditions and/or NMD is custom-made (Q28).

**TABLE 29** Orthotic devices prescribed, number (%) of responses

Orthotic device	All respondents	Orthotists	Physiotherapists	Rehabilitation medicine physicians
<i>Response rate</i>	n = 99 (58.24%)	n = 60 (82.19%)	n = 27 (51.85%)	n = 12 (37.5%)
KAFO	74 (74.75)	55 (91.67)	8 (28.57)	11 (91.67)
AFO	93 (93.94)	56 (93.33)	26 (92.86)	11 (91.67)
Knee brace	88 (88.89)	58 (96.67)	19 (67.86)	11 (91.67)
Shoe adaptations	65 (65.66)	44 (73.33)	11 (39.29)	10 (83.33)
Insoles	69 (69.70)	46 (76.67)	13 (46.43)	10 (83.33)
Other	18 (18.18)	7 (11.67)	11 (39.29)	0 (0.00)
None	0 (0.00)	1 (1.67)	0 (0.00)	0 (0.00)
NA	0 (0.00)	0 (0.00)	1 (3.57)	0 (0.00)
No response	71	13	26	20

NA, not applicable.

**TABLE 30** Orthotic devices fitted, number (%) of responses

Orthotic device	All respondents	Orthotists	Physiotherapists	Rehabilitation medicine physicians
Response rate	n = 99 (58.24%)	n = 59 (81.94%)	n = 28 (52.83%)	n = 12 (37.5%)
KAFO	65 (65.66)	54(91.53)	6 (21.43)	5 (41.67)
AFO	89 (89.90)	57 (96.61)	26 (92.86)	6 (50.00)
Knee brace	87 (87.88)	58 (98.31)	23 (82.14)	6 (50.00)
Shoe adaptations	61 (61.62)	45 (76.27)	10 (35.71)	6 (50.00)
Insoles	67 (67.68)	46 (77.97)	16 (57.14)	5 (41.67)
Other	14 (14.14)	6 (10.17)	4 (14.29)	4 (33.33)
None	13 (13.13)	7 (11.86)	4 (14.29)	2 (16.67)
NA	1 (1.01)	0 (0.00)	0 (0.00)	1 (8.33)
No response	71	13	25	20

NA, not applicable.

The results indicated that approximately half of all devices prescribed/fitted by our respondents were reported to be custom-made devices (*Table 31*). This is the case for both orthotists and doctors in rehabilitation medicine; however, physiotherapists indicated that approximately one-third of the devices that they prescribe are custom-made devices. Respondents were then asked what influences their decision to prescribe a custom-made or an off-the-shelf device (Q29). The question response rate was 55.03% ( $n = 93$ ). The comments indicate that there are patient and device factors that influence the HCPs' decision.

### Patient factors

Forty-one comments stated that the clinical condition of the patients on presentation will influence the decision of what device to prescribe. For example, one comment stated that:

*The individual's functional deficit will dictate the mechanical/biomechanical requirements of the orthosis/orthotic device. Typically custom devices have the potential to exert much greater external moments to the knee and other joints.*

Twenty-three comments also discussed the anatomy of the patient and how that influences the decision. For example, one comment stated that '... often if thigh is atrophied, a custom brace may be more appropriate'. The 'other' factors highlighted as influencing the decision were eight comments indicating that patient preference needs should be taken into account; seven comments noting patients' past experiences with orthoses; five comments stating the patient's ability to put the orthosis on and take it off; four comments highlighting patient compliance; and one comment noting the patient's ability to self-fund.

**TABLE 31** Proportion (%) of devices that are custom-made

HCP	Response rate	Mean (SD)	Median	Minimum, maximum	No response
All respondents	57.06% (n = 97)	50.16 (27.33)	50	0, 100	73
Orthotists	81.94% (n = 59)	56.75 (21.70)	60	6, 100	13
Physiotherapists	48.15% (n = 25)	35.62 (33.92)	33	0, 100	28
Rehabilitation medicine physicians	37.5% (n = 12)	49.33 (26.21)	44.5	3, 94	20

### Device factors

Thirty-one comments highlighted that the decision about the type of device will be influenced by the desired features required by the patients, for example flexibility, control, fit and durability. Eleven comments noted that the availability of devices will influence the decision of which device to prescribe, and 10 comments noted the time to acquire the device. Ten comments stated that the type of device would influence the decision. For example, one respondent wrote: 'If it is an AFO or KAFO or insole it would be custom-made. Most knee braces are off the shelf unless the knee is a very unusual shape.' Nine comments stated that an off-the-shelf device may be trialled first on a patient while considering whether or not a custom-made device is needed. Six comments stated that cost influences the decision: 'If none of these basic items are appropriate, a sound clinical reasoned request is put to manager (budget holder) for the need for alternate item not on the list.' Two comments stated that off-the-shelf devices are used for assessment. Two comments also noted that someone else would decide whether a custom-made or off-the-shelf device is prescribed.

Respondents were asked where the prescribed custom-made devices are manufactured (Q30). The response rate to this question is particularly low as, although it was set up so that eligible respondents could not skip this question, the function failed.

A higher proportion of respondents reported that custom-made devices (73.58%) are manufactured by a central fabrication manufacturer outside the hospital compared with an on-site workshop (16.98%) (Table 32). Two doctors chose 'other' and stated that some are manufactured 'off-site' and in an 'other NHS facility'.

**TABLE 32** Where custom-made devices are manufactured, number (%) of responses

Site	All respondents	Orthotists	Physiotherapists	Rehabilitation medicine physicians
Response rate	n = 53 (24.88%)	n = 25 (33.78%)	n = 1 (1.06%)	n = 25 (55.56%)
On-site workshop in clinical setting	9 (16.98)	1 (4.00)	0 (0.00)	8 (32.00)
Central fabrication manufacturer outside hospital	39 (73.58)	24 (96.00)	1 (100.00)	14 (56.00)
Other	2 (5.66)	0 (0.00)	0 (0.00)	2 (8.00)
NA	2 (3.77)	0 (0.00)	0 (0.00)	1 (4.00)
No response	160	49	93	20

NA, not applicable.

## Provision of orthoses

In order to get an indication of how many visits were required to provide orthotic devices, respondents were asked how many visits would be needed depending on whether it was a patient with NMD or CNS condition, and what device they were prescribing (Q34, Q36). Respondents were asked how many visits are normally required to provide orthotic devices for patients with NMD. The results of this question and response rates are presented in *Table 33*. These underestimate the question response rate, as this is the number of respondents who responded to each element of the answer rather than those who supplied an answer for Q34 and Q36.

Respondents were also asked how many visits are normally required to provide orthotic devices for patients with CNS conditions. The results of this question are presented in *Table 34* (Q35, Q37). As with the previous table, the response rates are an underestimate, as this is the number of respondents who responded to each element of the answer rather than those who supplied an answer for Q35 and Q37.

For all devices and for both patients with NMD and CNS conditions, custom-made devices were found to require additional visits to HCPs compared with off-the-shelf devices in order for the patients to be provided with orthotic devices.

For patients with both NMD and CNS conditions, the custom-made KAFO required the most visits, with an average of three visits to HCPs in order to be fitted with a KAFO; off-the-shelf insoles required the least number of visits (average of 1.62 visits for patient with NMDs and 1.54 for those with CNS conditions).

### Typical time frame between appointments

Respondents who stated that they prescribe or fit orthotic devices for patients with NMD and/or CNS conditions were asked a series of questions regarding the typical time frame between particular appointments. The questions were asked for both off-the-shelf devices and for custom-made devices as these times may differ.

**TABLE 33** Number of visits required to provide a device to a patient with NMD and knee instability

Device	Mean (SD)	Median	Minimum, maximum	Response rate, % (n)	No response
Custom-made orthoses					
KAFO	3 (0.55)	3	2, 4	34.18 (n = 54)	104
AFO	2.05 (0.58)	2	1, 4	37.35 (n = 62)	104
Knee brace	2.02 (0.56)	2	1, 4	36.97 (n = 61)	104
Shoe adaptations	1.78 (0.47)	2	1, 3	30.20 (n = 45)	104
Insoles	1.84 (0.55)	2	1, 4	32.03 (n = 49)	104
Off-the-shelf orthoses					
KAFO	2.64 (0.67)	3	2, 4	19.35 (n = 24)	100
AFO	1.71 (0.73)	2	1, 4	38.27 (n = 62)	100
Knee brace	1.80 (0.69)	2	1, 4	38.65 (n = 63)	100
Shoe adaptation	1.68 (0.47)	2	1, 2	25.37 (n = 34)	100
Insoles	1.62 (0.61)	2	1, 4	31.97 (n = 47)	100

**TABLE 34** Number of visits required to provide a device to a patient with CNS conditions and knee instability

Device	Mean (SD)	Median	Minimum, maximum	Response rate, % (n)	No response
Custom-made orthoses					
KAFO	3.03 (0.56)	3	2, 4	31.55 (n = 59)	128
AFO	2.07 (0.50)	2	1, 4	34.36 (n = 67)	128
Knee brace	2.09 (0.61)	2	1, 4	33.33 (n = 64)	128
Shoe adaptation	1.90 (0.47)	2	1, 3	33.33 (n = 64)	128
Insoles	1.91 (0.53)	2	1, 4	29.28 (n = 53)	128
Off-the-shelf orthoses					
KAFO	1.96 (0.71)	2	1, 4	18.24 (n = 27)	121
AFO	1.66 (0.65)	2	1, 4	36.98 (n = 71)	121
Knee brace	1.75 (0.63)	2	1, 4	36.32 (n = 69)	121
Shoe adaptation	1.73 (0.45)	2	1, 2	25.31 (n = 41)	121
Insoles	1.54 (0.54)	2	0, 2	30.86 (n = 54)	121

Respondents were asked the typical time frame between an initial appointment and the time at which the device is fitted on the patient (Q31). The response rate was 54.12% (n = 92). 76.39% of the orthotists, 54.9% of the physiotherapists and 34.38% of the doctors in rehabilitation medicine responded to the question. The results of this question are presented in *Table 35*.

The average typical waiting time from initial visit to fitting a custom-made device is longer than the waiting time to fitting an off-the-shelf device (3.45 vs. 5.72 weeks).

Respondents were asked how often they see patients with NMD and/or CNS conditions with knee instability for review (Q22).

**TABLE 35** Average waiting time from initial visit to fitting devices (weeks)

Device	Mean (SD)	Median	Minimum, maximum	No response
Custom-made orthoses				
All respondents	5.72 (3.51)	5	0, 20	78
Orthotists	5.89 (3.25)	5	2, 20	17
Physiotherapists	3.71 (2.90)	4	0, 10	28
Rehabilitation medicine physicians	8.73 (3.69)	11	3, 12	21
Off-the-shelf orthoses				
All respondents	3.45 (2.61)	3	0, 12	78
Orthotists	4.09 (2.56)	4	0, 12	17
Physiotherapists	1.91 (2.39)	1	0, 8	28
Rehabilitation medicine physicians	3.45 (2.07)	4	0, 6	21



The results from this question were quite interesting in that the majority of respondents chose the 'other' option (Table 36). It appears from the narrative responses that reviews do not follow a distinctive pattern, do not continue cyclically and are not always available to patients. Eleven physiotherapists stated that the timing of review visit 'varies' and eight physiotherapists stated review visits were provided 'as required' or 'as needed'. Twelve respondents (including two orthotists, seven physiotherapists and three doctors in rehabilitation medicine) stated that the frequency of review visits would depend on the patient's condition. An orthotist also stated that review visits depend on the orthotic device. Six orthotists suggested that review visits depend on the patient's request.

Some alternative timelines were provided. One orthotist stated that review visits happen 'regularly', one physiotherapist's review visits were weekly for 6 weeks, and another physiotherapist's review visits were fortnightly. Review visits can be daily (according to seven physiotherapists) if the patient is an inpatient. One physiotherapist wrote that review visits are initially every 4 weeks and then every 6 months if the patient is doing well. Another physiotherapist wrote that review visits are quarterly until the patient is discharged. Finally, a doctor in rehabilitation medicine wrote that the initial review visit would be after 1–2 months after which review visits are biannual or annual when the patient is established.

Several respondents (four orthotists and two physiotherapists) found that rather than after a certain time period, review visits take place at specific time points in a patient pathway.

Respondents who stated that they provide review appointments were asked for the typical time frame from fitting of a device to the first review appointment (Q41).

The average time from fitting the device to the first review appointment was 8.28 weeks (Table 37). This was substantially less for physiotherapists, whose average time frame was 1.70 weeks. This may be explained by the larger proportion of physiotherapists who regularly see patients within an inpatient setting.

**TABLE 36** How often do HCPs see patients with NMD and/or CNS conditions with knee instability?, number (%) of responses

Time period	All respondents	Orthotists	Physiotherapists	Rehabilitation medicine physicians
Response rate	n = 144 (67.61%)	n = 61 (82.43%)	n = 57 (71.25%)	n = 26 (59.1%)
Weekly	6 (4.17)	1 (1.64)	5 (8.77)	0 (0.00)
Monthly	7 (4.86)	2 (3.28)	4 (7.02)	1 (3.85)
Quarterly	12 (8.33)	4 (6.56)	2 (3.51)	6 (23.08)
Biannually	21 (14.58)	10 (16.39)	1 (1.75)	10 (38.46)
Annually	5 (3.47)	5 (8.20)	0 (0.00)	0 (0.00)
No follow-up	11 (7.64)	3 (4.92)	3 (5.26)	5 (19.23)
Other	82 (56.94)	36 (59.02)	42 (73.68)	4 (15.38)
No response	69	13	23	19

**TABLE 37** Typical time frame from fitting of a device to first review (weeks)

HCP	Mean (SD)	Median	Minimum, maximum	No response
All respondents	8.28 (6.74)	6	1, 32	87
<i>Response rate 30.95% (n = 39)</i>				
Orthotists	8.68 (6.74)	7	2, 32	20
<i>Response rate 55.56% (n = 25)</i>				
Physiotherapists	3.71 (1.70)	4	1, 6	24
<i>Response rate 17.95% (n = 7)</i>				
Rehabilitation medicine physicians	11.43 (8.24)	8	4, 27	23
<i>Response rate 23.33% (n = 7)</i>				

## Typical length of appointments

Respondents who stated that they prescribe or fit orthotic devices for patients with NMD and/or CNS conditions were also asked a series of questions regarding the typical duration of particular appointments discussed. Respondents moved a slider within the range of 0–60 minutes.

The length of appointment required for an initial assessment (Q21) is presented in *Table 38*.

The responses indicate that it takes on average 38 minutes for an initial assessment appointment, with orthotists taking slightly less time than the other HCPs at 28 minutes. These appointments can vary in length, from 0 minutes to 60 minutes.

The length of appointment required for the casting and measuring of orthotic devices (Q32) is presented in *Table 39*. The response rate was 50.29% ( $n = 86$ ): 76.39% of the orthotists, 36.54% of the physiotherapists and 28.13% of the doctors in rehabilitation medicine responded to the question.

**TABLE 38** Length of initial assessment appointment (minutes)

HCP	Mean (SD)	Median	Minimum, maximum	No response
All respondents	38 (15.75)	40	0, 60	65
<i>Response rate 69.48% (n = 148)</i>				
Orthotists	28 (10.59)	29	14, 60	12
<i>Response rate 83.78% (n = 62)</i>				
Physiotherapists	48 (13.56)	48	0, 60	23
<i>Response rate 71.95% (n = 59)</i>				
Rehabilitation medicine physicians	39 (16.09)	40	1, 60	18
<i>Response rate 60% (n = 27)</i>				

**TABLE 39** Duration of appointment for casting and measure (minutes)

HCP	Mean (SD)	Median	Minimum, maximum	No response
Custom-made orthoses				
All respondents	38.31 (13.27)	40	5, 60	85
Orthotists	36.85 (11.18)	40	15, 60	17
Physiotherapists	42.88 (17.44)	43.5	5, 60	33
Rehabilitation medicine physicians	39.11 (16.37)	41	8, 60	23
Off-the-shelf orthoses				
All respondents	25.57 (12.83)	20	0, 60	85
Orthotists	24.31 (10.42)	20	10, 60	17
Physiotherapists	30.79 (17.73)	30	0, 60	33
Rehabilitation medicine physicians	22.11 (12.30)	20	3, 41	23

The respondents required slightly more time to cast and measure custom-made devices than for an off-the-shelf device. On average, for custom-made devices the appointment length was 38.31 minutes compared with 25.57 minutes for off-the-shelf devices. The mean duration for physiotherapists was slightly longer for both custom-made and off-the-shelf devices.

The respondents who stated that they do provide a review appointment were asked how long a review visit lasts, on average (Q23). The mean duration of review appointments was 27 minutes. This ranged from 1 minute to 45 minutes (*Table 40*). Physiotherapists' review visits lasted slightly longer on average than those of the other HCPs.

**TABLE 40** Duration of review visit (minutes)

HCP	Mean (SD)	Median	Minimum, maximum	No response
All respondents	27 (10.62)	21	1, 45	65
<i>Response rate 69.48% (n = 148)</i>				
Orthotists	22 (7.66)	20	14, 45	13
<i>Response rate 81.69% (n = 58)</i>				
Physiotherapists	34 (10.99)	30	1, 45	26
<i>Response rate 67.09% (n = 53)</i>				
Rehabilitation medicine physicians	22 (8.29)	20	22, 45	19
<i>Response rate 52.5% (n = 21)</i>				

## Patient information at fitting appointments

Respondents were asked what information they provided to patients at fitting appointments (Q38). The majority of the respondents indicated that they relay all of the information in the options provided (*Table 41*).

Almost all respondents reported providing instructions on taking the device on and off (95.29%); instructions on use of the orthosis (94.12%); when to wear the orthosis (92.94%); when to seek a review appointment (89.41%); and how to monitor the fit of the orthosis (88.24%). Fifteen respondents choose the 'other' option.

The response from the orthotists stated that information on the following would also be provided to patients: safety checks, instructions on lifespan and replacement of the orthosis, instructions on adjustment of the orthosis, a review of the goal of the orthosis, instructions on weaning procedure, skin care, and instructions on suitable footwear if an AFO or KAFO is being provided. One doctor in rehabilitation medicine stated that their patient would be provided with the phone number of the rehabilitation consultant's secretary.

Respondents were asked in what form they provide information to patient at fitting appointments (Q39).

The majority of respondents reported providing information to patients verbally (91.95%), through short leaflets (70.11%) and, to a lesser extent, instruction booklets (44.83%) (*Table 42*). A small number of respondents (four orthotists and three physiotherapists) direct patients to a website; none provided information on CDs.

Six respondents chose the 'other' option. The orthotists stated a safety agreement is signed and returned from the patient and retained in the patient's notes. The physiotherapists stated they used written notes and within discharge reports, and one physiotherapist stated that this would not be their role.

**TABLE 41** Information provided to patients at fitting appointments, number (%) of responses

Information provided	All respondents	Orthotists	Physiotherapists	Rehabilitation medicine physicians
<i>Response rate</i>	n = 85 (50%)	n = 52 (72.22%)	n = 24 (44.44%)	n = 9 (28.13%)
Instructions on taking the device on and off	81 (95.29)	50 (96.15)	23 (95.83)	8 (88.89)
Instructions on care of the orthosis	80 (94.12)	50 (69.15)	22 (91.67)	8 (88.89)
Instructions on how to monitor the fit of the orthosis	75 (88.24)	47 (90.38)	21 (87.50)	7 (77.78)
Instructions on when to wear the orthosis	79 (92.94)	49 (94.23)	22 (91.67)	8 (88.89)
Instructions on when to seek a review appointment	76 (89.41)	51 (98.08)	18 (75.00)	7 (77.78)
Other	15 (17.65)	11 (21.15)	2 (8.33)	2 (22.22)
None of the above	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
No response	85	20	30	23

**TABLE 42** Form of information provided to patients at fitting appointments, number (%) of responses

Form of information	All respondents	Orthotists	Physiotherapists	Rehabilitation medicine physicians
<i>Response rate</i>	n = 87 (51.18%)	n = 54 (75%)	n = 24 (44.44%)	n = 9 (28.13%)
Verbally	80 (91.95)	51 (94.44)	22 (91.67)	7 (77.78)
Short leaflets	61 (70.11)	44 (81.48)	10 (41.67)	7 (77.78)
Instruction booklets	39 (44.83)	20 (37.04)	14 (58.33)	5 (55.56)
CD	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Direct patient to a website	7 (8.05)	4 (7.41)	3 (12.50)	0 (0.00)
Other	6 (6.90)	1 (1.85)	3 (12.50)	0 (0.00)
None of above	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
No response	83	18	24	23

### Long-term review appointments

Respondents were asked whether or not they routinely offer long-term review appointments (Q40).

A slightly higher proportion of respondents (54.12%) do not routinely provide long-term review appointments than those who do (45.88%), and this is particularly noticeable in the physiotherapist group (*Table 43*). Slightly more doctors in rehabilitation medicine do provide long-term review appointments than those who do not.

In a separate question, respondents were asked if their practice has a 'review on request' option for patients (Q46).

The results show that a substantial majority of respondents operate 'review on request' appointments within their clinical setting (88.24%) compared with those who do not (11.76%) (*Table 44*). The results from both questions on long-term review appointments indicate that instead of prespecified review appointments, review appointments can be instigated by patients.

**TABLE 43** Are long-term review appointments provided?, number (%) of responses

Response	All respondents	Orthotists	Physiotherapists	Rehabilitation medicine physicians
<i>Response rate</i>	n = 85 (50%)	n = 52 (72.22%)	n = 24 (44.44%)	n = 9 (28.13%)
Yes	39 (45.88)	25 (48.08)	7 (29.17)	7 (77.78)
No	46 (54.12)	27 (51.92)	17 (70.83)	2 (22.22)
None	85	20	30	23

**TABLE 44** Does your practice have a 'review on request' option for patients?, number (%) of responses

Response	All respondents	Orthotists	Physiotherapists	Rehabilitation medicine physicians
<i>Response rate</i>	n = 85 (49.71%)	n = 52 (72.22%)	n = 24 (44.44%)	n = 9 (28.13%)
Yes	75 (88.24)	51 (98.08)	16 (66.67)	8 (88.89)
No	10 (11.76)	1 (1.92)	8 (33.33)	1 (11.11)
None	86	20	31	23

## Quantifying the success of an orthotic device

Following on from the questions on fitting and reviewing the orthotic devices, respondents were asked how they would normally quantify the success of an orthosis when fitting/reviewing the device (Q42).

Respondents rely on patient feedback (94.87%), family/carer feedback (84.62%), and observational gait analysis (87.18%) a significant proportion of the time to quantify the success of the device (Table 45). Formal gait analysis via video gait analysis or video vector gait analysis appears to be used to a lesser extent (17.95% and 2.56%, respectively). One respondent stated that they used none of the above measures to quantify the success of the device. Two respondents chose the 'other' option. Only one respondent provided a text response and stated they were unable to comment as the 'orthotist would provide this response'.

**TABLE 45** How the HCP quantifies the success of an orthosis when fitting/reviewing the device, number (%) of responses

Quantifying success	All respondents	Orthotists	Physiotherapists	Rehabilitation medicine physicians
<i>Response rate</i>	n = 39 (30.95%)	n = 25 (55.56%)	n = 7 (17.95%)	n = 7 (23.33%)
Patient feedback	37 (94.87)	24 (96.00)	6 (85.71)	7 (100.00)
Family/carer feedback	33 (84.62)	24 (96.00)	4 (57.14)	5 (71.43)
Another clinician or therapist's feedback	22 (56.41)	14 (56.00)	3 (42.86)	5 (71.43)
Observational gait analysis	34 (87.18)	24 (96.00)	4 (57.14)	6 (85.71)
Video gait analysis	7 (17.95)	2 (8.00)	4 (57.14)	1 (14.29)
Video vector gait analysis	1 (2.56)	0 (0.00)	0 (0.00)	1 (14.29)
Patient-reported outcome measures	27 (69.23)	18 (72.00)	5 (71.43)	4 (57.14)
Clinician-reported outcome measures	20 (51.28)	12 (48.00)	5 (71.43)	3 (42.86)
Other	2 (5.13)	0 (0.00)	1 (14.29)	1 (14.29)
None of the above	1 (2.56)	0 (0.00)	0 (0.00)	0 (0.00)
No response	87	20	32	23

## Device breakages

The respondents were asked several questions about what happens when orthotic devices break. Respondents were asked separately what procedures are in place in their setting if custom-made or off-the-shelf devices break or are damaged (Q43, Q44).

The most commonly used options in the event of breakage of a custom-made device were provision of a spare orthosis to the patients at the same time as they receive the original device (36.47%); provision of an off-the-shelf device until the prescribed device is repaired (32.94%); and use of on-the-spot repair at an on-site workshop (37.65%) (Table 46). Provision of a wheelchair until the device is repaired was reported by 7.06% of respondents. Twenty-two respondents chose the 'other' option (13 orthotists, 8 physiotherapists and 1 doctor in rehabilitation medicine). In the responses provided, the orthotists stated the following: a spare device is provided after first satisfactory review ( $n = 3$ ); this would depend on the device ( $n = 3$ ); the patient would have to wait ( $n = 1$ ); no procedures are in place ( $n = 1$ ); this is dependent on patient funding ( $n = 1$ ) or dependent on NHS trust protocol ( $n = 1$ ); and this is also dependent on whether or not the patient can travel to an off-site workshop ( $n = 1$ ). The physiotherapists stated that patients are referred to the orthotist for review and/or replacement ( $n = 6$ ); the patient has to wait ( $n = 1$ ); and no procedures are in place ( $n = 1$ ). One doctor in rehabilitation medicine stated that he or she would call the company.

The most commonly used options in the event of breakage of an off-the-shelf device were use of on-the-spot repair at an on-site workshop (37.65%) and provision of a spare orthosis to the patient at the same time as they receive the original device (30.59%) (Table 47). Provision of a wheelchair until the device is repaired was reported by 3.53% of respondents. Forty respondents chose the 'other' option (22 orthotists, 16 physiotherapists and 2 doctors in rehabilitation medicine). Several respondents (four orthotists, four physiotherapists and one doctor in rehabilitation medicine) stated that a replacement is provided on the day if stock is available or soon as possible otherwise. A further six orthotists and two physiotherapists stated that a replacement device is ordered. One orthotist can provide emergency appointments to fit a new device. Four orthotists provide a spare device after the first satisfactory review.

**TABLE 46** Procedures in place if a custom-made device breaks, number (%) of responses

Procedure	All respondents	Orthotists	Physiotherapists	Rehabilitation medicine physicians
<i>Response rate</i>	$n = 85$ (50%)	$n = 52$ (72.22%)	$n = 24$ (44.44%)	$n = 9$ (28.13%)
A spare orthosis is provided in conjunction with the original device	31 (36.47)	29 (55.77)	1 (4.17)	1 (11.11)
An off-the-shelf orthosis is provided until the prescribed orthosis is fixed	28 (32.94)	11 (21.15)	10 (41.67)	7 (77.78)
Patient is given a wheelchair until their orthosis is fixed	6 (7.06)	1 (1.92)	0 (0.00)	0 (0.00)
Patient comes to an on-site workshop for an on-the-spot repair	32 (37.65)	26 (50.00)	2 (8.33)	4 (44.44)
Other	22 (25.88)	13 (25.00)	8 (33.33)	1 (11.11)
NA	9 (10.59)	1 (1.92)	7 (29.17)	1 (11.11)
No response	85	20	30	23
NA, not applicable.				

**TABLE 47** Procedures in place if an off-the-shelf device breaks, number (%) of responses

Procedure	All respondents	Orthotists	Physiotherapists	Rehabilitation medicine physicians
<i>Response rate</i>	n = 85 (50%)	n = 52 (72.22%)	n = 24 (44.44%)	n = 9 (28.13%)
A spare orthosis is provided in conjunction with the original device	26 (30.59)	22 (42.31)	2 (8.33)	2 (22.22)
Patient is given a wheelchair until their orthosis is fixed	3 (3.53)	1 (1.92)	0 (0.00)	2 (22.22)
Patient comes to an on-site workshop for an on-the-spot repair	32 (37.65)	24 (46.15)	2 (8.33)	6 (66.67)
Other	40 (47.06)	22 (42.31)	16 (66.67)	2 (22.22)
NA	8 (9.41)	1 (1.92)	6 (25.00)	1 (11.11)
No response	85	20	30	23
NA, not applicable.				

Similar to the procedure for custom-made devices, patients sometimes have to wait (two orthotists) and no procedures are currently in place in some settings (two orthotists and one physiotherapist). Four physiotherapists refer the patient to the orthotist for review and/or replacement. Once again, one doctor in rehabilitation medicine stated that he/she would call the company.

Respondents were also asked who repairs the device when it breaks (Q45). The results for this question indicated that off-site technicians most commonly repair broken devices (56.32%) (Table 48). However, given the high response rate of the orthotists in comparison with the other HCPs for this question, this may not be the case for all clinical settings and for all HCPs prescribing and fitting orthotic devices.

Fourteen respondents selected the 'other' option. This included two orthotists, 11 physiotherapists and one doctor in rehabilitation medicine. The orthotists responses stated that this depends on the site and the required repair. The physiotherapists stated the following: the device is replaced and not repaired ( $n = 3$ ); the orthotist repairs the device ( $n = 2$ ); this depends on the device ( $n = 1$ ); and they do not know who repairs the device when it breaks ( $n = 4$ ); one did not elaborate.

**TABLE 48** Who repairs the device when it breaks?, number (%) of responses

Device repair	All respondents	Orthotists	Physiotherapists	Rehabilitation medicine physicians
<i>Response rate</i>	n = 87 (59.58%)	n = 52 (72.22%)	n = 25 (46.3%)	n = 9 (27.27%)
On-site				
Clinician	36 (41.38)	27 (51.92)	5 (20.00)	4 (44.44)
Technician	31 (35.63)	21 (40.38)	6 (24.00)	4 (44.44)
Off-site				
Clinician	6 (6.90)	1 (1.92)	5 (20.00)	0 (0.00)
Technician	49 (56.32)	40 (76.92)	6 (24.00)	3 (33.33)
Other	14 (16.09)	2 (3.84)	11 (44.00)	1 (11.11)
No response	85	20	29	24



## Treatment outcomes and acceptability factors

Respondents were asked a series of questions exploring treatment outcomes, acceptability factors and patient expectations.

### Treatment outcomes

First, respondents were asked to what extent, when trying to manage the expectations of patients, do the following factors influence their decision of what device to prescribe (Q47).

The question response rate was 57.75% ( $n = 123$ ): 70.27% of the orthotists, 59.26% of the physiotherapists and 48.89% of the doctors in rehabilitation medicine responded to the question. Ninety respondents did not answer this question (which included, where known, 22 orthotists, 33 physiotherapists and 23 doctors in rehabilitation medicine). The responses to this question are presented in *Table 49*.

The highest proportion of respondents (45.53%) chose 'sometimes' when asked about the cosmetic aspects of the device; 'most of the time' when asked about the weight of the device (42.28%); 'sometimes' when asked about the material of the device (31.71%); and 'most of the time' when asked about the types of shoes or clothing that the devices can be worn (36.59%). The majority of respondents (61.79%) chose 'always' when asked about patients' ability to take the device on and off; when asked about the reliability of the device (52.85%); and when asked about the comfort of the device (71.54%). The 'other' option was chosen by 69 (56.09%) respondents. The responses are presented in *Tables 50–52*, grouped by profession.

The highest proportion of orthotists chose 'sometimes', when asked about the cosmetic aspects of the device (46.15%); 'most of the time' when asked about the weight of the device (40.38%); 'always' when asked about the material of the device (44.23%); and 'most of the time' when asked about the types of shoes or clothing that the devices can be worn (34.62%). The majority of orthotists chose 'always' when asked about patient's ability to take the device on and off (78.85%); 'always' when asked about the reliability of the device (69.23%); and 'always' when asked about the comfort of the device (80.77%). The 'other' option was chosen by 34 (65.39%), some of whom provided further information.

The orthotists who chose the 'other' option stated that the following factors also influence their decision: the cost of the device and the funding available ( $n = 2$ ); the function of the device ( $n = 2$ ); the likely benefit to the patient ( $n = 2$ ); patient acceptability ( $n = 3$ ); the mental health of the patient ( $n = 1$ ); and the durability of the device ( $n = 1$ ).

**TABLE 49** Factors influencing prescription decisions (all responses)

Factor	Responses, $n$ (%)				
	Never	Rarely	Sometimes	Most of the time	Always
Cosmetic aspect of the device	2 (1.63)	12 (9.76)	56 (45.53)	32 (26.02)	17 (13.82)
Weight of the device	0 (0.00)	1 (0.81)	33 (26.83)	52 (42.28)	34 (27.64)
Material of the device	1 (0.81)	12 (9.76)	39 (31.71)	34 (27.64)	34 (27.64)
Types of shoes/clothing that can be worn with the device	0 (0.00)	9 (7.32)	38 (30.89)	45 (36.59)	28 (22.76)
Patients ability to take device on and off	0 (0.00)	0 (0.00)	15 (12.20)	29 (23.58)	76 (61.79)
Reliability of the device	0 (0.00)	3 (2.44)	12 (9.76)	40 (32.52)	65 (52.85)
Comfort of the device	0 (0.00)	0 (0.00)	8 (6.50)	24 (19.51)	88 (71.54)
Other	34 (27.64)	1 (0.81)	11 (8.94)	5 (4.07)	18 (14.63)

**TABLE 50** Factors influencing prescription decisions (orthotists)

Factor	Responses, <i>n</i> (%)				
	Never	Rarely	Sometimes	Most of the time	Always
The cosmetic aspects of the device	0 (0.00)	3 (5.77)	24 (46.15)	12 (23.08)	13 (25.00)
The weight of the device	0 (0.00)	0 (0.00)	11 (21.15)	21 (40.38)	20 (38.46)
The material of the device	0 (0.00)	4 (7.69)	8 (15.38)	17 (32.69)	23 (44.23)
Types of shoes or clothing with which the device can be worn	0 (0.00)	2 (3.85)	14 (26.92)	18 (34.62)	15 (28.85)
Patient's ability to take the device on and off	0 (0.00)	0 (0.00)	3 (5.77)	8 (15.38)	41 (78.85)
The reliability of the device	0 (0.00)	0 (0.00)	3 (5.77)	10 (19.23)	36 (69.23)
The comfort of the device	0 (0.00)	0 (0.00)	4 (7.69)	6 (11.54)	42 (80.77)
Other	18 (34.62)	1 (1.92)	5 (9.62)	3 (5.77)	7 (13.46)

**TABLE 51** Factors influencing prescription decisions (physiotherapists)

Factor	Responses, <i>n</i> (%)				
	Never	Rarely	Sometimes	Most of the time	Always
The cosmetic aspects of the device	2 (4.17)	6 (12.50)	21 (43.75)	14 (29.17)	2 (4.17)
The weight of the device	0 (0.00)	1 (2.08)	13 (27.08)	20 (41.67)	11 (22.92)
The material of the device	0 (0.00)	2 (4.17)	22 (45.83)	11 (22.92)	9 (18.75)
Types of shoes or clothing with which the device can be worn	0 (0.00)	1 (2.08)	15 (31.25)	19 (39.58)	10 (20.83)
Patient's ability to take the device on and off	0 (0.00)	0 (0.00)	8 (16.67)	12 (25.00)	25 (52.08)
The reliability of the device	0 (0.00)	3 (6.25)	2 (4.17)	20 (41.67)	19 (39.58)
The comfort of the device	0 (0.00)	0 (0.00)	2 (4.17)	9 (18.75)	34 (70.83)
Other	8 (16.67)	0 (0.00)	3 (6.25)	2 (4.17)	9 (18.75)

**TABLE 52** Factors influencing prescription decisions (rehabilitation medicine physicians)

Factor	Responses, <i>n</i> (%)				
	Never	Rarely	Sometimes	Most of the time	Always
The cosmetic aspects of the device	0 (0.00)	3 (13.64)	11 (50.00)	6 (27.27)	2 (9.09)
The weight of the device	0 (0.00)	0 (0.00)	8 (36.36)	11 (50.00)	3 (13.64)
The material of the device	1 (4.55)	4 (18.18)	9 (40.91)	6 (27.27)	2 (9.09)
Types of shoes or clothing with which the device can be worn	0 (0.00)	3 (13.64)	9 (40.91)	7 (31.82)	3 (13.64)
Patient's ability to take the device on and off	0 (0.00)	0 (0.00)	4 (18.18)	8 (36.36)	10 (45.45)
The reliability of the device	0 (0.00)	0 (0.00)	2 (9.09)	10 (45.45)	10 (45.45)
The comfort of the device	0 (0.00)	0 (0.00)	2 (9.09)	8 (36.36)	12 (54.55)
Other	8 (36.36)	0 (0.00)	3 (13.64)	0 (0.00)	2 (9.09)

The highest proportion of physiotherapists chose 'sometimes' when asked about the cosmetic aspects of the device (43.75%); 'most of the time' when asked about the weight of the device (41.67%); 'sometimes' when asked about the material of the device (45.85%); 'most of the time' when asked about the types of shoes or clothing with which the devices can be worn (39.58%); 'always' when asked about patient's ability to take the device on and off (52.08%); and 'most of the time' when asked about the reliability of the device (41.67%). The majority of physiotherapists (70.83%) chose 'always' when asked about the comfort of the device. The 'other' option was chosen by 22 physiotherapists (45.84%), some of whom provided further details.

The physiotherapists who chose the 'other' option stated that the following factors also influence their decision: the function and effectiveness of the device ( $n = 3$ ); the availability of the device ( $n = 1$ ); patient acceptability ( $n = 1$ ); patient compliance ( $n = 1$ ); patient prognosis ( $n = 1$ ); social support available to the patient ( $n = 1$ ); the fit of the device ( $n = 1$ ); and advice from the orthotist ( $n = 1$ ).

The highest proportion of doctors in rehabilitation chose 'sometimes' when asked about the cosmetic aspects of the device (50%); 'most of the time' when asked about the weight of the device (50%); 'sometimes' when asked about the material of the device (40.91%); 'sometimes' when asked about the types of shoes or clothing with which the devices can be worn (40.91%); 'always' when asked about patient's ability to take the device on and off (45.45%); 'always' or 'most of the time' when asked about the reliability of the device (45.45%); and 'always' when asked about the comfort of the device (54.55%). The 'other' option was chosen by 13 (41.36%) and some provided further details.

The doctors in rehabilitation medicine who chose the 'other' option stated that the following factors also influence their decision: the cost to the NHS ( $n = 1$ ) and the likely benefit and/or discomfort to the patient ( $n = 1$ ).

Respondents were then asked about what treatment outcomes that they are personally trying to achieve when treating patients with NMD and CNS conditions with knee instability (Q50) (Table 53).

The majority of the outcomes that were presented had a positive response from > 80% of respondents, apart from contracture management and increased walking speed, for which 62.10% and 55.65%, respectively chose these outcomes. Nineteen chose 'other'. Respondents are also trying to achieve the following treatment outcomes: improved independence (two orthotists and two physiotherapists); improved quality of life (three orthotists); improved mobility (one orthotist and two physiotherapists); improved confidence (two physiotherapists); improved symmetry and reduced deterioration in the other leg

**TABLE 53** What HCPs are trying to achieve when treating patients, number (%) of responses

Aim	All respondents	Orthotists	Physiotherapists	Rehabilitation medicine physicians
<i>Response rate</i>	$n = 124$ (58.22%)	$n = 52$ (70.27%)	$n = 50$ (60.98%)	$n = 22$ (48.89%)
Control joint movement	108 (87.10)	49 (94.23)	45 (90.00)	14 (63.64)
Reducing the number of falls	110 (88.71)	48 (92.31)	42 (84.00)	20 (90.91)
Less pain	114 (91.94)	50 (96.15)	45 (90.00)	19 (86.36)
Increased walking distance	100 (80.65)	46 (88.46)	37 (74.00)	17 (77.27)
Increased walking speed	69 (55.65)	31 (59.62)	26 (52.00)	12 (54.55)
Contracture management	77 (62.10)	36 (69.23)	30 (60.00)	11 (50.00)
Avoid further deterioration	105 (84.68)	46 (88.46)	40 (80.00)	19 (86.36)
Other	19 (15.32)	7 (13.46)	11 (22.00)	1 (4.55)
No response	89	22	32	23

(two physiotherapists); support of ligamentous and tendinous structures (one orthotist); improved function (one orthotist); increased social/work integration (one physiotherapist); management of fatigue by reducing effort (one physiotherapist); and prevention of secondary arthritis (one doctor in rehabilitation medicine). One physiotherapist also stated that this would depend on the patient.

## Patient preferences

Respondents were asked about the extent to which they agreed that their patients are expressing a preference for particular devices (Q48).

Most commonly respondents stated that they neither agreed nor disagreed that their patients are expressing a preference for particular devices (46.40%) (*Table 54*). The respondents who chose 'strongly agree' or 'agree' were asked about what types of devices their patients were expressing a preference for. The responses to this question can be categorised into device factors and patient factors.

### Device factors

Nineteen comments stated that patients are expressing a preference for lightweight devices; nine stated that respondents are expressing a preference for discreet devices; seven stated that patients are expressing a preference for particular devices (e.g. SCKAFOs) and one stated that patients are expressing a preference for FES devices. Patients are also expressing a preference for comfortable devices (four comments), custom-made devices (three comments), cosmetically appealing devices (three comments), functional devices (two comments), durable devices (one comment) and devices that are easy to take on and off (two comments).

### Patient factors

Six comments noted that patients may express a preference for devices that they have heard about: 'Brand they have seen on internet or advised by another MDT member' or which they have previous experience of using. Two comments also noted that the age of the patient affects their preferences. For example, 'older patients – callipers/young ones – that fit in nice shoes, and don't hurt'.

Respondents were also asked the extent to which they thought six individual outcomes were important to patients who have been fitted with an orthotic device (Q51). The question response rate was 58.69% ( $n = 125$ ): orthotists 70.27%, physiotherapists 60.98% and rehabilitation medicine physicians 48.89%. Eighty-eight respondents did not answer this question (22 orthotists, 31 physiotherapists and 23 doctors in rehabilitation medicine). *Table 55* presents the results for all respondents.

**TABLE 54** Patients expressing a preference for particular devices, number (%) of responses

Preference	All respondents	Orthotists	Physiotherapists	Rehabilitation medicine physicians
<i>Response rate</i>	$n = 125$ (58.69%)	$n = 52$ (70.27%)	$n = 51$ (62.2%)	$n = 22$ (48.89%)
Strongly agree	11 (8.80)	3 (5.77)	6 (11.76)	2 (9.09)
Agree	35 (28.00)	17 (32.69)	14 (27.45)	4 (18.18)
Neither agree not disagree	58 (46.40)	25 (48.08)	20 (39.22)	13 (59.09)
Disagree	18 (14.40)	7 (13.46)	10 (19.61)	1 (4.55)
Strongly disagree	3 (2.40)	0 (0.00)	1 (1.96)	2 (9.09)
No response	88	22	31	23

**TABLE 55** Health-care professionals views on outcomes important to patients (all respondents)

Outcome	Response, <i>n</i> (%)				
	Not at all important	Somewhat important	Important	Very important	Extremely important
Comfort	0 (0.00)	1 (0.80)	11 (8.80)	36 (28.80)	76 (60.80)
Confidence in mobility	0 (0.00)	0 (0.00)	5 (4.00)	47 (37.60)	72 (57.60)
Increased stability	0 (0.00)	2 (1.60)	19 (15.20)	59 (47.20)	45 (36.00)
Less energy expenditure	1 (0.80)	24 (19.20)	35 (28.00)	39 (31.20)	24 (19.20)
Cosmetic aspect of device	1 (0.80)	23 (18.40)	45 (36.00)	40 (32.00)	17 (13.60)
Other	30 (24.00)	4 (3.20)	6 (4.80)	3 (2.40)	5 (4.00)

Overall, the vast majority of respondents stated that these outcomes are at least somewhat important. Over 80% of respondents chose 'extremely important' or 'very important' for comfort, confidence in mobility and increased stability. Less energy expenditure was rated as very or extremely important by 50.4% of respondents and the cosmetic aspects of device by 45.6% of respondents. *Tables 56–58* present the results for each profession. These followed a similar trend to the overall results.

**TABLE 56** Orthotists' views on outcomes that are important to patients

Outcome	Responses, <i>n</i> (%)				
	Not at all important	Somewhat important	Important	Very important	Extremely important
Comfort	0 (0.00)	1 (1.92)	4 (7.69)	10 (19.23)	37 (71.15)
Confidence in mobility	0 (0.00)	0 (0.00)	2 (3.85)	18 (34.62)	32 (61.54)
Increased stability	0 (0.00)	0 (0.00)	6 (11.54)	18 (34.62)	28 (53.85)
Less energy expenditure	0 (0.00)	8 (15.38)	13 (25.00)	19 (36.54)	11 (21.15)
Cosmetic aspect of device	0 (0.00)	11 (21.15)	19 (36.54)	16 (30.77)	7 (13.46)
Other	14 (26.92)	1 (1.92)	3 (5.77)	1 (1.92)	2 (3.85)

**TABLE 57** Physiotherapists' views on outcomes that are important to patients

Outcome	Responses, <i>n</i> (%)				
	Not at all important	Somewhat important	Important	Very important	Extremely important
Comfort	0 (0.00)	0 (0.00)	5 (9.80)	16 (31.37)	29 (56.86)
Confidence in mobility	0 (0.00)	0 (0.00)	2 (3.92)	18 (35.29)	30 (58.82)
Increased stability	0 (0.00)	2 (3.92)	10 (19.61)	28 (54.90)	11 (21.57)
Less energy expenditure	1 (1.96)	11 (21.57)	13 (25.49)	16 (31.37)	9 (17.65)
Cosmetic aspect of device	1 (1.96)	6 (11.76)	17 (33.33)	19 (37.25)	8 (15.69)
Other	10 (19.61)	0 (0.00)	1 (1.96)	2 (3.92)	3 (5.88)

**TABLE 58** Rehabilitation medicine physicians' views on outcomes important to patients

Outcome	Responses, <i>n</i> (%)				
	Not at all important	Somewhat important	Important	Very important	Extremely important
Comfort	0 (0.00)	0 (0.00)	2 (9.09)	10 (45.45)	10 (45.45)
Confidence in mobility	0 (0.00)	0 (0.00)	1 (4.55)	11 (50.00)	10 (45.45)
Increased stability	0 (0.00)	0 (0.00)	3 (13.64)	13 (59.09)	6 (27.27)
Less energy expenditure	0 (0.00)	5 (22.73)	9 (40.91)	4 (18.18)	4 (18.18)
Cosmetic aspect of device	0 (0.00)	6 (27.27)	9 (40.91)	5 (22.73)	2 (9.09)
Other	6 (27.27)	3 (13.64)	2 (9.09)	0 (0.00)	0 (0.00)

Overall, 18 respondents (14.4%) stated that 'other' factors were at least somewhat important. Two orthotists and three physiotherapists also stated that the ease of taking the device on and off was important to patients. The ability to participate in activities of daily living (one orthotist) and improved function (another orthotist) were also important factors. A doctor in rehabilitation medicine stated that cost was also an important treatment outcome for patients. A physiotherapist stated that the weight of the device, lead-in time to fitting, goal achievement and compliance were all important treatment outcomes to patients.

## Effectiveness of device

Respondents were asked about the extent to which the following factors affect the effectiveness of the device (Q52). The question response rate (based on the number who completed all the questions) was 38.50% ( $n = 82$ ) (67.57% of the orthotists, 28.05% of the physiotherapists and 20% of the doctors in rehabilitation medicine). The overall responses to this question are presented in *Table 59*. A total of 131 respondents did not answer this question (who included 24 orthotists, 59 physiotherapists and 36 doctors in rehabilitation medicine).

The majority of respondents chose 'always' for pain due to the device (70.73%), pressure areas due to the device (62.2%), acceptability of the device to patient (59.76%), patient adherence (59.76%) and for fit of the device (64.63%). The most popular response was 'most of the time' for therapy back-up (43.90%), for medical back-up (46.34%) and 'rarely' for surgical back-up (42.68%). *Tables 60–62* present the results by profession; the results were broadly similar across professions.

**TABLE 59** Factors influencing the effectiveness of the orthosis (all respondents)

Factor	Responses, <i>n</i> (%)				
	Never	Rarely	Sometimes	Most of the time	Always
Acceptability of the device to patient	0 (0.00)	0 (0.00)	7 (8.54)	26 (31.71)	49 (59.76)
Patient adherence	0 (0.00)	0 (0.00)	4 (4.88)	29 (35.37)	49 (59.76)
Fit of the device	0 (0.00)	1 (1.22)	1 (1.22)	27 (32.93)	53 (64.63)
Therapy back-up	0 (0.00)	3 (3.66)	33 (40.24)	36 (43.90)	10 (12.20)
Medical back-up	6 (7.32)	26 (31.71)	38 (46.34)	12 (14.63)	1 (1.22)
Surgical back-up	8 (9.76)	35 (42.68)	29 (35.37)	9 (10.98)	1 (1.22)
Pain due to the device	0 (0.00)	0 (0.00)	14 (17.07)	11 (13.41)	58 (70.73)
Pressure areas due to the device	0 (0.00)	0 (0.00)	16 (19.51)	15 (18.29)	51 (62.20)

**TABLE 60** Factors influencing the effectiveness of the orthosis (orthotists)

Factor	Responses: <i>n</i> , (%)				
	Never	Rarely	Sometimes	Most of the time	Always
Acceptability of the device to patient	0 (0.00)	0 (0.00)	3 (6.00)	15 (30.00)	32 (64.00)
Patient adherence	0 (0.00)	0 (0.00)	3 (6.00)	19 (38.00)	28 (56.00)
Fit of the device	0 (0.00)	1 (2.00)	1 (2.00)	17 (34.00)	31 (62.00)
Therapy back-up	0 (0.00)	2 (4.00)	22 (44.00)	21 (42.00)	5 (10.00)
Medical back-up	1 (2.00)	13 (26.00)	28 (56.00)	8 (16.00)	1 (2.00)
Surgical back-up	2 (4.00)	18 (36.00)	23 (46.00)	6 (12.00)	1 (2.00)
Pain due to the device	0 (0.00)	0 (0.00)	10 (20.00)	6 (12.00)	35 (70.00)
Pressure areas due to the device	0 (0.00)	0 (0.00)	12 (24.00)	10 (20.00)	28 (56.00)

**TABLE 61** Factors influencing the effectiveness of the orthosis (physiotherapists)

Factor	Responses: <i>n</i> , (%)				
	Never	Rarely	Sometimes	Most of the time	Always
Acceptability of the device to patient	0 (0.00)	0 (0.00)	3 (13.04)	9 (39.13)	11 (47.83)
Patient adherence	0 (0.00)	0 (0.00)	1 (4.35)	6 (26.09)	16 (69.57)
Fit of the device	0 (0.00)	0 (0.00)	0 (0.00)	7 (30.43)	16 (69.57)
Therapy back-up	0 (0.00)	1 (4.35)	9 (39.13)	9 (39.13)	4 (17.39)
Medical back-up	5 (21.74)	10 (43.48)	7 (30.43)	1 (4.35)	0 (0.00)
Surgical back-up	6 (26.09)	12 (52.17)	4 (17.39)	1 (4.35)	0 (0.00)
Pain due to the device	0 (0.00)	0 (0.00)	4 (17.39)	2 (8.70)	17 (73.91)
Pressure areas due to the device	0 (0.00)	0 (0.00)	4 (17.39)	2 (8.70)	17 (73.91)

**TABLE 62** Factors influencing the effectiveness of the orthosis (rehabilitation medicine physicians)

Factor	Responses: <i>n</i> , (%)				
	Never	Rarely	Sometimes	Most of the time	Always
Acceptability of the device to patient	0 (0.00)	0 (0.00)	1 (11.11)	2 (22.22)	6 (66.67)
Patient adherence	0 (0.00)	0 (0.00)	0 (0.00)	4 (44.44)	5 (55.56)
Fit of the device	0 (0.00)	0 (0.00)	0 (0.00)	3 (33.33)	6 (66.67)
Therapy back-up	0 (0.00)	0 (0.00)	2 (22.22)	6 (66.67)	1 (11.11)
Medical back-up	0 (0.00)	3 (33.33)	3 (33.33)	3 (33.33)	0 (0.00)
Surgical back-up	0 (0.00)	5 (55.56)	2 (22.22)	2 (22.22)	0 (0.00)
Pain due to the device	0 (0.00)	0 (0.00)	0 (0.00)	3 (33.33)	6 (66.67)
Pressure areas due to the device	0 (0.00)	0 (0.00)	0 (0.00)	3 (33.33)	6 (66.67)



Respondents were asked if they thought that there were other factors that affected the effectiveness of the device (Q53). The question response rate was 58.22% ( $n = 124$ ): 70.27% of the orthotists, 60.98% of the physiotherapists and 48.89% of the doctors in rehabilitation medicine responded to the question. Eighty-six respondents (69.35%) stated that there were no other factors that they thought affected the effectiveness of the device, while 38 respondents (30.65%) stated that there were other factors. Eight-nine respondents did not answer this question. The 38 respondents who thought there were other factors were asked to specify these, and the responses to this question are presented below, categorised into patient factors, device factors and other factors.

### Patient factors

Eight comments referred to the patients' expectations. For example, one respondent stated that 'they are sometimes referred having been told about a "magical thing" that will solve their ills and so start the process with us already disappointed'. Eight comments also referred to psychological factors affecting the effectiveness of the device. For example, respondents referred to the patients' motivation, their ability to encompass change, their cognitive ability and how well they feel that they can use the devices. Seven comments noted patient compliance affecting the effectiveness of the device. Six comments described how support from family and friends can have an effect. Five comments described how the patient's clinical condition can have an effect, in terms of how well the device can work with the patients' abilities and the progressive nature of some conditions. Finally, four comments noted that the level of involvement of the patient in the decision of what device to prescribe can affect the effectiveness of the device. One respondent stated:

*Ensuring the patient is involved in the assessment and understands that there isn't a magic answer, and the orthosis won't solve their problem; giving them as much choice as possible; so that they take ownership of how the problem is managed.*

### Device factors

The device factors that were noted in the comments, which can affect the effectiveness of the device, included ease of use ( $n = 8$ ), effectiveness ( $n = 4$ ), cost ( $n = 3$ ) and comfort ( $n = 1$ ).

### Other factors

Two respondents stated that there needs to be an appropriate time given for assessment, explanation and review. One respondent stated:

*I think that available time for orthotic assessment – to achieve an appropriate prescription, and for review – to conduct outcome measures and necessary device fine tuning, will have an impact on orthotic treatment success.*

## Outcome measures

Respondents were asked what, if any, formal outcome measures they use to assess the effectiveness of orthotic devices (Q55).

There was no single outcome measure that was commonly in use across the sample (Table 63). Thirty-six respondents (29.03%) stated that they do not use a formal outcome measure. The most commonly used measures were a visual analogue scale (50.81%), the 10-m Walk Test (41.13%), the Timed Up and Go Test (35.48%), patient satisfaction questionnaire (33.87%) and the Goal Attainment Scale (27.42%). Twenty (16.13%) respondents stated that they use a formal outcome measure that was not listed in the response options.

Three orthotists chose 'other' and stated that patient feedback at review appointment and 'measures against named goals' were also used. Fifteen physiotherapists chose 'other'. They reported using the Berg balance scale ( $n = 5$ ); the 'timed and videoed functional movement test' ( $n = 1$ ); the 'timed 360 degree



**TABLE 63** Formal outcome measures used, number (%) of responses

Outcome measure	All respondents	Orthotists	Physiotherapists	Rehabilitation medicine physicians
<i>Response rate</i>	n = 124 (58.22%)	n = 52 (70.27%)	n = 50 (60.98%)	n = 22 (48.89%)
Timed Up and Go Test	44 (35.48)	9 (17.31)	24 (48.00)	11 (50.00)
10-Walk Test	51 (41.13)	6 (11.54)	34 (68.00)	11 (50.00)
2-Minute Walk Test	14 (11.29)	8 (15.38)	4 (8.00)	2 (9.09)
6-Minute Timed Walk Test	19 (15.32)	3 (5.77)	12 (24.00)	4 (18.18)
Visual analogue scale	63 (50.81)	21 (40.38)	32 (64.00)	10 (45.45)
Goal Attainment Scale	34 (27.42)	11 (21.15)	17 (34.00)	6 (27.27)
Patient satisfaction questionnaire	42 (33.87)	16 (30.77)	17 (34.00)	9 (40.91)
Activities Balance Confidence Scale	6 (4.84)	0 (0.00)	4 (8.00)	2 (9.09)
OPUS	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Manchester Oxford Knee Score	5 (4.03)	3 (5.77)	2 (4.00)	0 (0.00)
Do not use a formal outcome measure	36 (29.03)	23 (44.23)	5 (10.00)	8 (36.36)
Other	20 (16.13)	3 (5.77)	15 (30.00)	2 (9.09)
No response	89	22	32	23

OPUS, the Orthotic and Prosthetic Users Survey.

test' ( $n = 1$ ); the 'Tinetti Test' ( $n = 1$ ); the 'Leeds Movement Performance Index' ( $n = 1$ ); the 'Walk 12 Scale' ( $n = 1$ ); the '6-Minute Walk Test' ( $n = 1$ ); the 'Modified Rivermead Mobility Index' ( $n = 1$ ); 'Functional SMART goals' ( $n = 1$ ); and 'TUSS' (presumably in reference to the Timed Unsupported Steady Stand) ( $n = 1$ ). One physiotherapist also stated 'usually being seen by other therapists if having treatment so I will goal set and they will use formal outcome measures'. Two doctors in rehabilitation medicine chose 'other'. One stated that patient satisfaction measurement by the hospital can also be used.

## Acceptability of device to patients

Respondents were asked what factors they think affect the acceptability of devices to patients (Q56). Again, these responses can be divided into patient factors, device factors and 'other' factors.

### Patient factors

It appears that patients need to perceive a benefit from using the device, and 32 respondents felt that this can affect the acceptability of devices to patients. Previous experience of the device (one comment), seeing others benefit from orthotic devices (two comments) and psychological factors (three comments) can also affect the acceptability of devices to patients. Nine comments noted that pain relief potential of the devices can affect acceptability. One respondent noted that support from family and friends can also affect acceptability.

### Device factors

Sixty-one respondents commented that the comfort, or lack of, affected the acceptability of devices to patients. Appearance of device (52 comments), ease of use (45 comments) and effectiveness of device (40 comments) all appear to be common factors affecting the acceptability of devices to patients. The devices weight (28 comments), size/bulk (12 comments) and fit (seven comments) were also noted by respondents as potential

factors. Finally, 11 respondents commented that patients' ability to wear the device under clothing and/or with a range of footwear were also factors that may affect the acceptability of devices to patients.

### Other factors

One respondent felt that MDT provision can affect the acceptability of devices to patients.

Respondents were then asked about the cosmetic aspect of the device, and to what extent the cosmetic look of the device affects acceptability to the patient and whether or not he/she wears the device (Q57). The results of this question are presented in *Table 64*. Additional comments made by respondents are summarised in the text.

The majority of respondents stated that the cosmetic look of the device often affects the acceptability of the device to the patient (51.22%). Very few respondents ( $n = 9$ ) stated that the cosmetic look never or rarely affected the acceptability of the device to the patient and whether or not the patient wears the device.

Respondents were asked to provide details for their answer. Fifty-five respondents expanded on why they responded 'often'. They stated that patients want discretion, so the device fitting under their clothes and the impact of the device on their choice of footwear available to them is important. Twenty-two respondents stated it depends on the attitude of the patient. For example, one respondent wrote: 'some patients are more self-conscious than others and struggle to compromise with the device once away from the clinic.'

In terms of the patients most likely to be affected by the cosmetic look of the device, 19 respondents stated that the cosmetic look can sometimes be more important to their female patients. For example, 'Female patients are more bothered about this as they often wear a skirt. Males can cover it up with trousers'. Seven respondents stated that the cosmetic look is more important for young people.

In contrast, five respondents commented that the cosmetic look of the device did not, or rarely, affect the acceptability of the device. Seventeen respondents felt that function is more important to patients. One respondent wrote: 'Many patients however see function as more important and would not want to compromise this over cosmesis as sometimes the two just can't go hand in hand.' Three respondents stated that the cosmetic look is less important if the patient's condition is severe and/or painful. Six respondents noted that the degree to which the cosmesis affects the acceptability of the device to patients often depends on the device in question.

**TABLE 64** Cosmetic appearance of the device and acceptability to patients, number (%) of responses

Cosmetic appearance	All respondents	Orthotists	Physiotherapists	Rehabilitation medicine physician
<i>Response rate</i>	$n = 123$ (57.75%)	$n = 51$ (68.92%)	$n = 50$ (60.98%)	$n = 22$ (48.89%)
Never	1 (0.81)	1 (1.96)	0 (0.00)	0 (0.00)
Rarely	8 (6.50)	1 (1.96)	5 (10.00)	2 (9.09)
Sometimes	42 (34.15)	20 (39.22)	13 (26.00)	9 (40.91)
Often	63 (51.22)	24 (47.06)	29 (58.00)	10 (45.45)
All of the time	9 (7.32)	5 (9.80)	3 (6.00)	1 (4.55)
No response	90	23	32	23

## Care pathway of patients

Respondents were asked their opinion on the care pathways for these patients. Separate questions were asked for patient with NMDs (Q59, Q60) and patients with CNS conditions (Q61, Q62).

### *Patients with a neuromuscular disease*

Respondents treating patients with NMDs were asked if they felt that there are any aspects of the care pathway for patient with NMDs with knee instability that could be improved. The question response rate was 54.44% ( $n = 92$ ). A total of 77 respondents did not answer the question. Overall, 78.26% ( $n = 72$ ) of respondents felt that improvement could be made to the care pathway, compared with 21.74% ( $n = 20$ ) of respondents who felt that improvement could not be made. The majority of orthotists (41 respondents compared with six respondents), physiotherapists (19 respondents compared with 10 respondents) and doctors in rehabilitation medicine (12 respondents compared with four respondents) felt that improvements could be made. Respondents were asked to provide details for their answer to this question.

Twenty-six respondents felt that improved communication and teamworking across professions would improve the care pathway. Twenty-two respondents felt that reducing the waiting time for appointments with the orthotics service would also improve the pathway. Ten respondents felt that improving awareness of orthotic services in potential referrers would be beneficial. Six respondents believed that making earlier referrals to orthotics services would improve the overall care pathway. Six respondents felt that the removal of budget barriers would improve the care pathway. One respondent suggested that community-based clinics would improve the care pathway. Three respondents felt that the pathway would be improved if differences in the quality of orthotic services were eliminated. Three respondents believed that the pathway would be improved if there was a reduction in the waiting time from orthotic assessment to fitting and delivery of devices. Two respondents felt that improvements could be made through the increase of the time available for orthotic treatment. Four respondents highlighted that improvements in the assessment of patients could lead to improvements in the pathway. For example, one respondent wrote 'improving the pre/post device with gait assessment would give some form of validated measure of outcome'. Finally, five respondents felt that the care pathway could be improved if improvements were made to patient care in clinic and post device.

In the further information provided, eight respondents reiterated that they did not feel that there any aspects of the care pathway could be improved for patients with NMDs and knee instability. Seven respondents stated that they did not know and one respondent felt that there is no pathway in place for patients with NMDs and knee instability.

### *Patients with central nervous system conditions*

Respondents treating patients with CNS conditions were asked if they felt that any aspects of the care pathway could be improved for patients with CNS conditions and knee instability. The question response rate was 56.59% ( $n = 116$ ). A total of 89 respondents did not answer the question. Overall, 77.59% ( $n = 90$ ) of respondents felt that improvement could be made to the care pathway, compared with 22.41% ( $n = 26$ ) of respondents who felt that improvement could not be made. The majority of orthotists (41 respondents compared with seven respondents), physiotherapists (34 respondents compared with 13 respondents) and doctors in rehabilitation medicine (15 respondents compared with six respondents) felt that improvements could be made. Once again, respondents were asked to provide details for their answer to this question. The responses to this question were very similar to those given for patients with NMDs.

Thirty-five respondents felt that improved communication and team working across professions would improve the care pathway. Twenty-seven respondents felt that reducing the waiting time for appointments with the orthotic service would also improve the pathway. Seven respondents felt that improving awareness of orthotic services in potential referrers would be beneficial. Nine respondents believed that making earlier referrals to orthotics services would improve the overall care pathway. Four respondents felt that the removal of budget barriers would improve the care pathway. Eight respondents felt that the care pathway could be improved if improvements were made to patient care in clinic and post device.

Five respondents believed that the pathway would be improved if there was a reduction in the waiting time from orthotic assessment to fitting and delivery of devices. Five respondents highlighted that improvements in the assessment of patients could lead to improvements in the pathway. Three respondents felt that the pathway would be improved if there was an increase in the number of orthotists available. Two respondents felt the pathway would be improved if differences in the quality of orthotic services were eliminated. Finally, one respondent felt that improvements could be made through the increase of the time available for orthotic treatment.

An additional improvement noted by eight respondents, which seems to be specific to patients with CNS conditions in particular, is that an increase in the availability of orthoses would improve the pathway. One respondent noted that 'stroke patients benefit from strong carbon [fibre] light weight'. Two respondents also stated that changing the referral pathway would improve the overall care pathway. For example, one respondent stated that 'all of the health professions should be able to refer directly to orthotists without having to send patient to orthopaedic clinic to see a medic first'.

In the further information provided, 11 respondents reiterated that they did not feel that there are any aspects of the care pathway that could be improved for patients with CNS conditions and knee instability. Five respondents stated that they did not know, and three respondents felt that there is no pathway in place for patients with CNS conditions and knee instability.



## Chapter 6 Costing analysis

The telephone interviews provided a fairly comprehensive list of the variables that would need to be taken into account to cost custom-made KAFOs. At the beginning of each telephone interview, the orthotists were told to consider only the costs that were associated with providing KAFOs to adult patients with NMD or CNS disorders, and to consider only the costs that would be incurred by the NHS. The results from the telephone interviews are presented below.

### Materials

Interviewees were asked about what materials would be used for each component of the KAFO, and they were presented with tables within the topic guide to facilitate the discussion around the materials that would be required to produce a completed KAFO. Tables were provided separately for conventional KAFOs, cosmetic KAFOs and hybrid KAFOs.

#### *Conventional knee–ankle–foot orthoses*

All components of a conventional KAFO could potentially be made from metal. Typically, the thigh, calf and foot sections would be the sections that were most likely to be made of leather, although the knee joint and ankle joints could have leather components, which would be used to influence the position of the joint. Foam lining may be used to increase patient comfort.

#### *Cosmetic knee–ankle–foot orthoses*

All components of a cosmetic KAFO could potentially be made from thermoplastic. Carbon fibre would typically be used for the thigh, calf and foot sections, that is, not used for the joints. Thermoplastic and carbon fibre would not be used together in the one KAFO. The knee and ankle joints would typically be made from metal. Other materials that could potentially be used within a cosmetic KAFO were leather and, in rare circumstances, a laminate material for the ankle or thigh sections. Lining or padding may also be used to increase patient comfort.

#### *Hybrid knee–ankle–foot orthosis*

All of the components of a hybrid KAFO could potentially be made from metal. It appears that titanium is more frequently used than steel or aluminium. The decision regarding which metal to use would depend on the patient's weight and activity levels. Leather, thermoplastic or carbon fibre could be used for the thigh, calf and foot sections. As with the cosmetic KAFO, either thermoplastic or carbon fibre would be used in the KAFO, but they would not be used together. Additional materials that would be used include fabric, which may be used to cover sections of the device if needed, and foam lining, which may be used to increase patient comfort.

Preliminary discussions indicated that the cosmetic and hybrid KAFOs were more commonly prescribed than the conventional KAFO. One orthotist stated that the vast majority of the KAFOs prescribed in their setting would be carbon fibre KAFOs with titanium joints. Another orthotist stated that they would prescribe a conventional KAFO only if it was a repeat prescription and they would rarely prescribe a conventional KAFO to a new patient.

Discussions also indicated that the main cost driver for KAFOs is the joint elements. Depending on the joint element required, this can significantly increase the cost of manufacturing a KAFO. These joints all appear to require being ordered from a private manufacturer.

One orthotist stated that in his/her clinical setting, the aim was to provide two KAFOs to the patient. This is an important additional cost to take into consideration.

***Other materials required***

Another associated cost of providing KAFOs is footwear and footwear adaptations. Discussions with one orthotist indicated that the patient population of interest often need adapted footwear or tailor-made footwear in order for the patient to be able to wear the KAFO. It is unclear if this associated cost is necessary for all KAFO prescriptions as another orthotist stated that this may be more common for conventional KAFOs, although the qualitative interviews with orthoses users support the importance of taking footwear into consideration in estimating costs.

Tailor-made shoes or adapted shoes can be an expensive addition that would need to be taken into account in a future cost-effectiveness analysis. The orthotist stated that the policy in their clinical setting was to issue two pairs of tailor-made shoes or up to three adapted shoes. If this policy is widespread then this is an important cost consideration to take into account.

***Where the materials are sourced and the knee–ankle–foot orthoses constructed***

The consensus from the orthotists interviewed is that the joint sections of the KAFOs are ordered from manufacturing companies. Some orthotists order all of the components individually. One orthotist orders each component apart from leather and plastic, as these are bulk bought for their on-site workshop. The KAFOs can be constructed in an on-site workshop or off-site from the clinical setting.

***Deciding factors of which material to use and the quantity of material to use***

All of the orthotists stated that patient's height, weight and activity levels determine the quantity of raw materials that are needed for KAFOs. The patient's ability, and muscle strength in particular, seems to be the deciding factor on what knee and ankle joint to prescribe. One orthotist stated that their manufacturer provides a matrix to which the patient's weight and activity levels can be imputed to help with the decision-making process. The patient's ability to apply the device independently may also affect the prescription.

When deciding what materials to use within the KAFO, the patient's health condition is taken into consideration. For example, generally speaking, KAFOs being prescribed for patients with diabetes would not include plastic in order to avoid skin contact. Patients with reduced sensation need to be prescribed a KAFO that does not touch the skin as they may not feel the device rubbing on their skin. The weight of the device also appears to be an important consideration that is taken into account by orthotists.

***Materials required for shape capture***

For the majority of cases, plaster seems to be used to capture the shape of the patient when fitting their KAFO. Tracing the leg and the use of transparent adhesive tape are also options that appear to be used frequently. Computer scanners appear to be used only occasionally and are not always an option available to orthotists. In general, orthotists use one technique to shape capture per patient, that is to say they would not use different techniques for different sections of the patient, although one orthotist stated that the cast of the foot may be taken with plaster and then a trace is taken of the upper leg. Foam shape capture boxes can be used to capture the shape of the underneath of the foot. One orthotist stated that an alignment tool can also be used, which assesses how a patient spreads their weight across both legs, in the prescription of KAFOs.

## Staff requirements to prescribe/fit a knee–ankle–foot orthosis

The interviews indicated that, although a multidisciplinary approach would be ideal, in the majority of cases only the orthotist and an orthotic technician are required to prescribe and fit a KAFO. Orthotists require between three and five appointments to prescribe, fit and review a KAFO. The first appointment would be 40–60 minutes long, with the following visits lasting 20–40 minutes. The time required for an orthotic technician to assemble a KAFO varies, depending on the complexity of the device. It was estimated that conventional or more straightforward devices would require 6–8 hours of a technician's time; more complex devices can require up to 12 hours of a technician's time.

The following HCPs may also be required:

- A physiotherapist may be included in the fitting if the patient is a first-time wearer of a KAFO or if it is a complicated prescription. The physiotherapist's role would be to provide gait training in the new device.
- An occupational therapist may be required.
- A gait scientist may walk the patient through a gait laboratory, both wearing and not wearing the KAFO, to get an objective benefit measure of the device and to assess the appropriateness of the device. This would be a 2-hour appointment and for one particular orthotist this would be standard practice for new patients.
- Rehabilitation medicine physicians may also be involved, given the patient population, but they may not be directly involved in the prescription of the device.

One orthotist stated that they would not be able to refer patients into other services. If the orthotist felt that a patient required, for example, an appointment with a physiotherapist, then the orthotist would need to advise the patient to seek referral through their GP. The neurologist and/or the rehabilitation medicine physicians are 'often the conductors of the allied health professionals (AHPs)', who all work separately.

## Overheads

During the telephone interviews, it became clear that the overheads, that is, the costs associated with providing the service (not including staff and device costs), vary significantly across clinical settings. The following types of service provision appear to be in place:

- Some settings have a fully managed service or a block contract. In this scenario, the orthotic services are provided by private companies, subcontracted to the NHS. In this scenario, the company is paid a single fee to cover the entire service, including staff and device costs.
- Some trusts pay sessional fees: the orthotists are paid sessional fees, such as a daily fee, and then the trust also pays for an item that is prescribed on top of this sessional fee.
- CCG funding usually is used to cover GP referrals to orthotic services. The CCG would pay a fixed amount per appointment and then pay for items prescribed on top of this. In comparison, a referral from a consultant can come out of the orthotics budget.
- Finally, some orthotics services are paid per appointment, with the hardware cost included in this fee.



## Spending caps

The orthotists were asked whether or not there were any spending restrictions in place in their own clinical settings. It appears that there are no formal restrictions in place apart from high-end items for which approval would need to be requested, but it was not unusual for these requests to be granted if the case for prescribing the device was substantiated. One orthotist stated that a KAFO costing > £2000 would need to be justified, and another stated that approval is needed for some of the more expensive joints such as electronic joints. Approval to prescribe electronic joints often has to go to managerial meetings or be discussed at clinical meetings, at which a consensus would be required that this is necessary for a patient. One specific example of a spending restriction provided was for specialist SCKAFOs. To prescribe these devices would require an application for specialist funding to a board within the Trust.

An orthotic manager stated that although there is no explicit spending cap in place, orthotists need to be mindful of budgets and waiting lists. In their setting, which is a fully managed service, the NHS has its own managers in place whose primary concerns are often budgets and waiting lists and the orthotists are expected to see patients in a timely manner.

It appears that apart from high-cost items, there are very few restrictions in place on what types of KAFOs can be funded, and it is the orthotist's clinical decision of what orthotic device to prescribe to a patient.

## Opportunity cost

The standard care, in terms of either a KAFO or a treatment provided to our patient group, was not clear. Therefore, the orthotists were asked to discuss the cost and effects of not being able to prescribe a KAFO to patients with a NMD or CNS condition with knee instability.

Almost unanimously, the orthotists concluded that if the patient's condition was severe enough to warrant a KAFO, in these conditions, then their only alternative treatment pathway would be to be given a wheelchair. It seems that an AFO or a knee brace may be of some use for mild knee instability, but if the knee instability is moderate to severe then there is no orthotic alternative to a KAFO. One orthotist stated that, for the conditions in which we are interested for this study, the knee instability would most likely be moderate to severe.

The effects on a patient's health due to being confined to a wheelchair were discussed with the orthotists, and all agreed that these can have a detrimental effect on a patient's health compared with using a KAFO regularly.

## Unit cost estimates

The orthotists stated during the telephone interviews that conventional KAFOs cost in the region of £1400–1500, and more complex devices can start at £2500; however, these were estimates and may not be generalisable for all clinical settings and for all KAFOs prescribed. Previous literature has used the NHS PASA prices to cost orthotic devices in the UK. Following some investigation, these costs were elicited from NHS Supply Chain Product and Transaction Database; however, these were available for prefabricated (off-the-shelf devices) and for FOs and AFOs only. The average costs for these devices are presented in *Table 65*.

An expert opinion provided the unit costs for a KAFO and its individual components. These are presented in *Table 66*. It was estimated the 'standard' locked-knee conventional finished product and the 'standard' locked-knee cosmetic finished product would require at least 20 hours of labour to be manufactured.

Staff costs were estimated from NHS reference costs.<sup>70</sup> The unit costs for staff used are presented in *Table 67*.

**TABLE 65** Average cost of devices

Device	Unit cost (£)		
	Minimum	Mean	Maximum
FO	5.35	14.65	27.79
AFO	9.24	28.89	220.54

**TABLE 66** Unit (and component) costs for KAFOs

Component	Cost (£)	Total (£)
'Standard' locked-knee conventional finished product		
Joints and uprights (steel)	143.50	
Straps	6	
Buckles	4	
Leather	27.84	
Aluminium square	8.50	189.94
'Standard' locked-knee cosmetic finished product		
Joints (steel)	120	
Uprights (steel)	20	
Plastic	20	
Carbon reinforcements	25	
Straps	6	191
'Standard' carbon fibre locked-knee KAFO		
SCKAFO		2500
Off-the-shelf KAFO		2187
		900

**TABLE 67** Staff costs

Type of visit	Cost per hour (£)
Hospital physiotherapist	33
First visit with orthotist	106.56
Subsequent visits with orthotist	97.27
Occupational therapist	33
Doctor in rehabilitation medicine	259

## Cost estimates for knee–ankle–foot orthoses

Using the information collected in *Tables 65–67*, combined with the relevant results from the survey of HCPs undertaken, the cost of four different types of KAFOs are estimated. The information taken from the survey to inform this costing analysis is presented in *Table 68*.

The methodology used below follows that of Simoens *et al.*<sup>71</sup> The aim of this paper<sup>71</sup> was to develop a model that calculates the cost of production and distribution of orthotic braces. The paper began by estimating the cost of production of knee and neck braces and overheads. However, this was beyond the scope of the present exercise and so the cost of production and overheads were assumed to have been included in the unit costs collected.

The device costs are estimated using three scenarios:

1. *low-cost scenario*, for which the lowest resource-use estimate and minimum values are used
2. *average-cost scenario*, for which the mean value for all estimates are used
3. *high-cost scenario*, for which the highest resource-use estimates and maximum values are used.

These scenarios will enable a cost range to be presented.

### Cost of custom-made devices

The staff requirements were estimated using the guidelines provided by the orthotists in the telephone interviews and from the survey results. The staff requirements were estimated as follows:

- *Low-cost scenario* Patient has appointments with orthotist only. This includes:
  - (a) an initial assessment appointment lasting 14 minutes
  - (b) a casting/measuring appointment lasting 10 minutes
  - (c) a review appointment lasting 14 minutes.

**TABLE 68** Information used to inform costing analysis

Information	HCP	Minimum (minutes)	Mean (minutes)	Maximum (minutes)	
Length of initial assessment appointment	Orthotist	14	28	60	
	Physiotherapist	0	48	60	
	Doctor in rehabilitation medicine	1	39	60	
Length of casting/measuring appointment	Custom-made	Orthotist	15	37	60
		Physiotherapist	5	43	60
		Doctor in rehabilitation medicine	8	39	60
	Off the shelf	Orthotist	10	24	60
		Physiotherapist	0	31	60
		Doctor in rehabilitation medicine	3	22	41
Length of review appointment	Orthotist	14	22	45	
	Physiotherapist	1	34	45	
	Doctor in rehabilitation medicine	9	22	45	

- *Average-cost scenario* Patient has appointments with orthotist, physiotherapist and rehabilitation medicine physician. This includes:
  - (a) initial assessment appointments (28 minutes with an orthotist; 48 minutes with physiotherapists; and 39 minutes with a doctor in rehabilitation medicine)
  - (b) casting/measuring appointments (24 minutes with an orthotist; 31 minutes with physiotherapists; and 22 minutes with a doctor in rehabilitation medicine)
  - (c) review appointments (22 minutes with an orthotist; 34 minutes with physiotherapists; and 22 minutes with a doctor in rehabilitation medicine).
  
- *High-cost scenario*:
  - (a) initial assessment appointments (60 minutes with an orthotist; 60 minutes with physiotherapists; and 60 minutes with a doctor in rehabilitation medicine)
  - (b) casting/measuring appointments (60 minutes with an orthotist; 60 minutes with physiotherapists; and 41 minutes with a doctor in rehabilitation medicine)
  - (c) an additional 40 minute appointment with orthotist
  - (d) review appointments (45 minutes with an orthotist; 45 minutes with physiotherapists; and 45 minutes with a doctor in rehabilitation medicine)
  - (e) 40-minute appointment with an occupational therapist
  - (f) 1-hour appointment with a gait scientist.

The unit costs for KAFOs provided by expert opinion were used to provide the cost estimate for a custom-made KAFO. As stated earlier, it was estimated that the 'standard' locked-knee conventional finished product and the 'standard' locked-knee cosmetic finished product would require at least 20 hours of labour to be manufactured. In the absence of the appropriate unit cost, orthotic technician time was assumed to be equivalent to the cost of orthotist's time. This cost is presented in *Table 69*.

**TABLE 69** Cost estimate for a custom-made KAFO

Estimate	Cost scenario (£)		
	Low cost	Average	High cost
<i>'Standard' locked-knee conventional finished product</i>			
Device	189.94	189.94	189.94
Staff	2009	2589	2998
Total	2198.94	2778.94	3187.94
<i>'Standard' locked-knee cosmetic finished product</i>			
Device	191	191	191
Staff	2009	2589	2998
Total	2200	2780	3189
<i>'Standard' carbon fibre locked-knee KAFO</i>			
Device	2500	2500	2500
Staff	64	644	1053
Total	2564	3144	3553
<i>SCKAFO</i>			
Device	2187	2187	2187
Staff	64	644	1053
Total	2251	2831	3240

Our analysis estimates that the cost of a custom-made KAFO could range from £2198 to £3553. However, these estimates are based on some assumptions and may not be reflective of the true cost of providing a KAFO to patients with a NMD or CNS condition with knee instability and, therefore, should be interpreted with caution.

### **Cost of prefabricated (off-the-shelf) devices**

The staff requirements for off-the-shelf devices were estimated from the survey of HCPs and are presented below:

- *Low-cost scenario* Patient has appointments with orthotist only. This includes:
  - (a) an initial assessment appointment lasting 14 minutes
  - (b) a casting/measuring appointment lasting 10 minutes
  - (c) a review appointment lasting 14 minutes.
  
- *Average cost scenario* Patient has appointments with orthotist, physiotherapist and doctor in rehabilitation medicine. This includes:
  - (a) initial assessment appointments (28 minutes with an orthotist; 48 minutes with physiotherapists; 39 minutes with a doctor in rehabilitation medicine)
  - (b) casting/measuring appointments (24 minutes with an orthotist; 31 minutes with physiotherapists; 22 minutes with a doctor in rehabilitation medicine)
  - (c) review appointments (22 minutes with an orthotist; 34 minutes with physiotherapists; 22 minutes with a doctor in rehabilitation medicine).
  
- *High-cost scenario*
  - (a) initial assessment appointments (60 minutes with an orthotist; 60 minutes with physiotherapists; 60 minutes with a doctor in rehabilitation medicine)
  - (b) casting/measuring appointments (60 minutes with an orthotist; 60 minutes with physiotherapists; 41 minutes with a doctor in rehabilitation medicine)
  - (c) review appointments (45 minutes with an orthotist; 45 minutes with physiotherapists; 45 minutes with a doctor in rehabilitation medicine).

The unit costs for AFOs provided by the NHS Supply Chain were assumed to be equivalent to the cost of KAFOs and these along with the expert opinion estimate were used to provide the cost estimate for off-the-shelf KAFO. It was assumed that the off-the-shelf devices did not require any labour time for assembly. This cost is presented in *Table 70*.

Our analysis estimates that the cost of an off-the-shelf KAFO could range from £73.24 to £1898. However, these estimates are based on some assumptions and may not be reflective of the true cost of providing a KAFO to patients with a NMD or CNS condition with knee instability and, therefore, should be interpreted with caution. In addition, the upper range may be an overestimate, as respondents of the survey were considering off-the-shelf and custom-made devices when giving their answers.

**TABLE 70** Cost estimate of off-the-shelf KAFO

Estimate	Low-cost scenario (£)	Average cost (£)	High-cost scenario (£)
Using NHS Supply Chain unit costs			
Device	9.24	28.89	220.54
Staff	64	455	998
Total	73.24	483.89	1218.54
Using expert opinion cost			
Device	900	900	900
Staff	64	455	998
Total	964	1355	1898



# Chapter 7 Dissemination and engagement

## Strategy development

The project was likely to be of relevance and interest in varying degrees to a wide range of parties. The identified audiences included those involved in the prescribing, supplying and training in the use of orthoses; those using orthoses, carers, and support organisations; and those making policy and commissioning decisions. For some groups (e.g. policy-makers and commissioners), their interests would be served through dissemination of the findings of the project.

However, those using orthotics, carers and support charities were likely to have varying levels of understanding of the research methods to be used in the project. The health professionals on the Advisory Group made us aware that orthotics, in general, is an underdeveloped area of research. This meant that when thinking about the eventual impact of the project results we were unsure of how well developed the channels for dissemination and implementation were to these groups. We decided therefore to undertake some engagement activities from the beginning of the project to help facilitate the planned dissemination of the results on completion of the project. The aim of engagement was to raise awareness within the relevant diverse audiences of the purpose, content and methods of the project, as a whole and within the different elements. Engagement is a two-way process, so we looked at mechanisms that would facilitate a dialogue in order to create a channel for the dissemination of the findings.

## Tools for engagement

The key vehicle for engagement was a project-specific blog, which anyone could access and read, and sign up to receive e-mail or Twitter (Twitter, Inc., San Francisco, CA, USA, [www.twitter.com](http://www.twitter.com)) alerts to new content. The link to the blog is <http://kneeorthotics.blogspot.co.uk/> (accessed 12 July 2015). The free Google 'Blogger' software (Google Inc., Mountain View, CA, USA) was used, and Google Analytics (Google Inc.) was set up to collect statistics on use and users. A project logo (Figure 4) and favicon (Figure 5) (a 'favourite icon' that appears next to a webpage title on the tab) were devised in house and the NIHR acknowledgement and disclaimer added to the site.



FIGURE 4 Project logo.



FIGURE 5 Project favicon.



The project-specific Twitter account was set up as Orthotics for Knees @OKIS\_York, and automated tweets were sent to followers each time a new blog was posted using twitterfeed.com. Users also had the option of following the blog by receiving e-mails via Google FeedBurner (Google Inc.).

A 'QR' (Quick Response) code for the blog site was generated for use in articles and on posters (*Figure 6*). QR codes are a type of bar code that smartphones and tablets can read and decode. When users scanned the OKIS QR code the embedded link took them to a mobile phone-friendly version of the OKIS blog. QR codes are frequently used when space or display time is limited, such as on posters. A 'digital' link can be acquired by those who are interested, as an alternative to paper handouts.

Fixed pages on the blog site were created for a lay overview of the whole project and biographical details of the research team and Advisory Group members. The site was created and coordinated by the project's dissemination lead and the blogs were written by various members of the research team. All blogs were edited by the dissemination lead. The posts provided information about the different elements of the project as they progressed and ultimately summaries of the findings. Some additional related topics were included such as a report on AHPs, the NIHR OK to Ask campaign, and the Testing Treatment site. These related topics aimed to raise awareness more generally about the need for high-quality research to support good health-care practice.

A moderated comments facility was made available with each blog post for users to submit their comments and suggestions. A project specific e-mail account was set up with Goglemail (Google Inc.) to facilitate the moderation process, to avoid the risk of a work e-mail account being overloaded.

### Engaging with target audiences

The blog was also used to promote involvement in the project where appropriate, for example to advertise for a Patient and Public Involvement representative for the project; and encourage health professionals to complete the survey. Patients considering taking part in the one-to-one interviews or focus groups were referred to the site for further information.

Details of the blog were sent to relevant networks, organisations and charities (*Table 71*) for general awareness raising. We identified a wide range of diverse groups that were relevant to the broad scope of conditions covered by the project. However, they all had far broader interests than the specific focus of orthotic devices for knee instability. The OKIS Twitter account was set up, with a link to the blog site, and 'followed' relevant individuals and charitable and professional organisations to raise visibility and encourage reciprocal links and followers.

The overall project dissemination strategy included a number of activities to make the findings widely available, with many using the blog as a publicity vehicle. The activities include production of a lay summary report on completion of the project. This will give brief background details, information about the quality of evidence, the results and implications to inform all relevant parties. A blog featuring the summary report, and links to this full HTA report for further detail, will be posted and tweeted.



**FIGURE 6** Orthotics for Knee Instability QR code.

**TABLE 71** Relevant audiences

Charities/associations	HCP organisations
Muscular Dystrophy Campaign	BAPO
FSH-MD Support Group UK	ACPIN
Polio Survivors Network	Prosthetics Network (@PROSTHETICSnet)
British Polio Fellowship	NHS Orthotics Network
Charcot–Marie–Tooth UK	Chartered Society of Physiotherapy
The Stroke Association	British Society for Rehabilitation Medicine
Spinal Injuries Association	SRR
Headway	
Neurological Alliance	
The Patients Association	
Brain and Spine Foundation	
Myasthenia Gravis Association	
Multiple Sclerosis Society	
SRR, Society for Research in Rehabilitation.	

The summary report will also be distributed electronically directly to the organisations listed in *Table 71*, with links to the blog, and to other relevant parties, such as the Chief Allied Health Professions Officer, NHS England and the British Orthopaedic Association. The professional bodies for GPs and neurologists will also be included, as the survey of health professionals identified these roles as referral sources.

Additional dissemination activities include the submission of papers for peer-reviewed publication and abstracts for oral and poster presentations at conferences; these will also be featured in the blog.

## Blog and Twitter activity

Presented here are the figures and other details relating to the project blog and Twitter account as of 14 May 2015. Administrator page views have been excluded from the figures.

A total of 36 blogs were posted in the 12 months of the project. The blogs were all written by research team members. Although support and guidance were offered, pressure of work prohibited the health professional members of the steering group and some of the research team from contributing. The majority of the blog posts were about research methods that were related to the particular stage of the project. The rest were on Advisory Group meetings, general research issues or profession-related topics, and avoided any commercial perspectives. A timeline and summary of blogs posted is provided in *Appendix 14*.

The top 10 blog posts with their page views are presented in *Table 72*. The total number of page views was 5777. Page views for *About the OKIS Project* were 331, *The Project Steering Group* 319 and *The Project Team* 315. The page views by country were primarily from the USA ( $n = 2051$ ) and the UK ( $n = 1593$ ), followed by Ukraine ( $n = 409$ ), France ( $n = 326$ ), Taiwan ( $n = 260$ ), Russia ( $n = 186$ ), India ( $n = 70$ ), Poland ( $n = 65$ ), Iran ( $n = 44$ ) and Australia ( $n = 34$ ).

TABLE 72 Top 10 blog posts

Post title	Date published	Page views on last access (12 July 2015)
<i>AHPs: essential but under valued?</i> Based on an independent report on the value of AHPs	20 October 2014	173
<i>Involving patients and the public in research</i> Focus on OK to Ask campaign	23 September 2014	116
<i>Orthotics provision: Survey of health-care professionals launched</i> Announcing launch of survey through professional organisations	5 December 2014	104
<i>Focus on focus groups</i> About focus group methods and use to inform development of the survey	15 August 2014	102
<i>A complex problem</i> The broad inclusion criteria for the systematic review element	28 May 2014	88
<i>What's this blog all about?</i> Introductory explanation of the project	26 Mar 2014	87
<i>Orthotics services: who is delivering what?</i> Project aim to map provision of orthotics services	18 November 2014	84
<i>Survey of health professionals: analysis begins</i> Closure of the survey and explanation of next steps	2 February 2015	76
<i>Needles in Haystacks: Part 2. Which haystacks should we look in?</i> Sources to be searched for the systematic review	5 June 2014	76
<i>How can we know what works?</i> Health information on the internet and 'Testing Treatments'	2 September 2014	75

The OKIS Twitter account gained 59 followers: 16 individuals (specific interest unclear but included some users of orthotic devices); 11 orthotic product manufacturers; 10 HCPs; six charities; five researchers; four professional organisations; three private health-care clinics; two litigation lawyers; one report design company and one research organisation. An additional follower was removed, as it linked inappropriately to material of a sexual nature. The 36 tweets created for the corresponding blogs generated 24 retweets and 12 favourites or mentions.

Although comment boxes were provided with each blog, at moderation the seven comments received were all rejected, as they included advertisements for commercial products or services.

In response to approaches to the charities/patient associations and professional organisations, which included links to the blog, we received requests for articles from the Polio Survivors Network to include in their newsletter; BAPO [article in *BAPOMag*, issue 2, 2014: Seeking health professional experiences: orthotics for knee instability (OKIS)] and the British Polio Fellowship posted a news item on their website ([www.britishpolio.org.uk/latest-news/orthotics-knee-instability/](http://www.britishpolio.org.uk/latest-news/orthotics-knee-instability/) last accessed 12 July 2015) and later tweeted links to the project blog. The Muscular Dystrophy campaign and Post-Polio news tweeted the link to the project blog site. Others expressed an interest in hearing from us once the results are available.

Some sites were not routinely maintained and/or did not feature research, or only the research they funded, and, as anticipated, for others 'knee instability' was too small a subgroup for them to be interested in the project.

Recruitment to the qualitative research element of the project was not carried out through the blog. However, we received e-mails from three members of the public who were interested in sharing their experiences and views, having seen articles through the British Polio Fellowship and the Post Polio Network (now known as Polio Survivors Network). They were contacted and offered the opportunity to take part in the one-to-one interviews (according to our procedures for recruiting outside the NHS, approved by the University of York Department of Health Sciences Research Governance Committee) and all three accepted.

Similarly, the survey of health professionals was distributed through professional organisation mailing lists. A blog post raised awareness that the survey had gone out, with a point of contact should anyone have not received the link. This was followed up with a reminder and message about the value and importance of as many different health professionals as possible responding. Response rates increased slightly following each of these posts. However, there were other peaks in response rates, so it is not possible to know what role the blog posts or tweets played in encouraging responses. A blog post about the next steps explained the analysis phase following closure of the survey.

The blog will remain active as it forms part of the dissemination strategy for the final results. A manuscript on our experience using the blog site will be prepared for peer review publication after dissemination of the summary report in a blog.



## Chapter 8 Discussion

### Principal findings

The project was undertaken in response to a commissioning brief to address the question of what devices are in use in the NHS for instability of the knee in adults with NMD and CNS conditions, for what diseases/conditions, and what further research is needed. We undertook a qualitative study exploring the perspectives of users of orthoses, a systematic review of the effectiveness evidence, a survey of HCPs and a costing analysis. The purpose of the commissioned research was to inform the future research assessing the clinical effectiveness and cost-effectiveness of different types of orthotic management of the knee in people with NMD and CNS conditions. In the sections below we discuss the key findings that are relevant to this purpose and explore areas of agreement and disagreement from the different sources of information.

#### *Perspective of orthoses users*

We undertook qualitative interviews with 24 users of orthotic devices for knee instability. Nineteen patients were recruited across three geographically dispersed NHS sites and five people were recruited from outside the NHS across different areas of England. Half of the sample had been diagnosed as having poliomyelitis. Other participants had multiple sclerosis, CMT disease, spinal injury or spina bifida, or had experienced a stroke. Participants' ages ranged from 36 years to 80 years and the median age was 64.5 years. Half of the study participants were engaged in either full- or part-time paid employment, whereas the other half described themselves as retired.

Study participants reported a range of symptoms and sequelae that were associated with neuromuscular and CNS conditions, which could limit their ability to walk and engage in everyday activities. Participants recounted how fear of falling or of their knee 'giving way' could result in diminished self-confidence and circumscribed independence, leading to feelings of social isolation and low mood.

Study participants relied on orthotic devices to enable them to engage, as far as possible, in 'normal' daily activities, such as working, driving, using public transport, the pursuit of outdoor activities, and taking part in social events and gatherings. People who had used an orthotic device over a long period of time (e.g. individuals with a diagnosis of poliomyelitis) regarded their orthotic device as an extension of their body, essential for daily functioning and integral to their identity.

Potential for future deterioration of their neuromuscular condition and general health was a preoccupation of many of those interviewed, and was a major consideration for them when seeking advice and assistance from orthotic and other specialist services.

Study participants reported using a range of orthoses (KAFOs, AFOs, knee braces) and mobility aids (sticks, crutches, wheelchairs, mobility scooters), 'mixing and matching' these according to differing circumstances and contexts in order to achieve maximum comfort and independence. Views on wheelchair use were polarised: for some, their wheelchair represented possibilities for increased freedom and independence, whereas others said that they dreaded having to use a wheelchair.

Obtaining the 'right' orthosis was, understandably, a central concern of all of those interviewed. The features of orthoses that were important to participants related to the fit of the device and how comfortable it was; whether or not it caused any damage to skin; effectiveness, reliability and durability; weight (which affected how far or easily they could walk); appearance; whether or not it caused any damage to clothing or footwear; and 'user-friendliness' in terms of ease of putting the device on or getting it off.

Of major importance to patients was whether or not they had a 'spare' device in case the currently used device required adjustment or repair, or failed unexpectedly. Participants often appeared reluctant to relinquish an 'old' device, to which they had grown accustomed, in exchange for a new one because they envisaged a difficult period of adjustment, during which they would have to 'break in' the new device.

Participants spoke at length about the footwear associated with their orthotic device, and expressed a range of views relating to desirable and undesirable characteristics. Central concerns related to careful and frequent measuring of the feet; shoe width and height, which should be sufficient to accommodate the device comfortably; durability; light in weight, preferably with good grip; sufficient number of pairs offered for individual need; in a range of styles and colour; aesthetically pleasing; easy to put on and take off; and prompt delivery of new shoes and return of those sent for repair.

During their interview, participants were asked to identify desired treatment goals and outcomes. The prime desired outcome was to receive treatment that offered effective support for their knee, resulting in a reduction in pain and the number of falls or trips experienced, with improved balance and stability. Effectiveness, reliability, comfort and durability were the features of orthoses that were most valued, and were related to reported use of orthotic devices. Participants defined their own goals for mobility in terms of what they wished to achieve in their daily lives, according to their individual circumstances. Respondents did not discuss treatment outcomes as measured by how far or how fast they could walk. Rather, they focused on different activities that they wished to pursue and judged the success of treatment in terms of how far it enabled them to participate in these activities. The extent to which their orthotic device enabled participants to engage in paid employment, outdoor activities (such as gardening), family visits and social events, was the yardstick used to assess the effectiveness of treatment. Being able to take part in these activities was regarded as important by participants for both their physical and mental well-being.

All participants were concerned about receiving treatment that would slow down, as far as possible, further deterioration in the affected knee joint, and which would not cause collateral, 'compensatory' damage to other joints. People with a diagnosis of poliomyelitis revealed concerns about symptoms of post-polio syndrome and were anxious about following advice from physiotherapists who were not specialists in neurophysiotherapy for fear of inadvertent muscle damage.

Respondents in the study commented on a range of factors, related to their care pathway, which they thought impacted on the quality of care they received. The overall picture that emerged was mixed; participants frequently praised individual clinicians (mainly orthotists and consultants in rehabilitation medicine) but were critical of the systems in which they worked.

Participants expressed frustration with referral routes into orthotic services, channelled through GPs and orthopaedic services, which resulted in delays in obtaining effective treatment for their knee instability. People under the care of a consultant in rehabilitation medicine appreciated the consultant's role in coordinating their care and monitoring their condition, while making proactive and timely decisions to refer them to orthotics and other specialist services, such as to neurophysiotherapy. Three people in the study shared the view that 'atypical' or complex cases, who might pose specific challenges related to their orthotic treatment, should be prioritised for a more intensive and in-depth approach; one approach suggested was holding a 'case conference' involving more than one orthotist to explore different ways of tackling a problem.

Many of those interviewed expressed a degree of frustration with deficiencies in the appointment systems in operation in orthotic services. They reported delays in receiving treatment, as well as inconvenience and sometimes financial consequences when they had to take time off from work to attend appointments. Other perceived shortfalls in orthotic services that were reported included work pressures from the 'busyness' of orthotics departments; poor record-keeping and transfer of information between different parts of the service (e.g. information relating to measurements for devices not reaching manufacturers); lack of coordination between services (such as podiatry and orthotic services); and a perceived lack of

'business ethos' in the NHS services, associated with slow production (of orthoses) and toleration of delays, as well as a lack of innovation and investment in new ways of working and technological developments in the field of orthotics.

Several of those sampled said that they had contemplated or had made use of the private sector in relation to acquisition of orthoses. The reasons they gave were mainly related to perceptions about underfunding and investment in NHS orthotic services. These people stated that they were seeking more technologically advanced orthoses than they thought would be available to them through the NHS, and they also hoped to 'buy in' to a more personalised care package, with quicker turnaround times than those they had experienced through NHS services.

A particular aspect of orthotic service provision that generated a great deal of commentary among study participants related to provision of 'in-house' workshops within orthotics departments for the manufacture, adjustment and repair of orthotic devices. Availability of this facility was associated with delivery of timely, good-quality orthotic care, particularly for minor or emergency repairs to devices. Participants were dissatisfied with long delays and having to attend multiple appointments that they associated with manufacturers being located outside the department – for example, some manufacturers are based abroad.

Aspects of their interactions with individual orthotists that were important to study participants: their level of knowledge and expertise, their accessibility and, most importantly, their listening skills and willingness/ability to engage with patients during consultations in decision-making about treatment options and outcomes. Participants rated most highly those clinicians who took time to listen to them describe the problems that they were experiencing in relation to their knee instability and how these impacted on their daily life; offered information and explanation; and explained the benefits and drawbacks of different devices while involving patients in treatment decisions.

### Findings in the context of other studies

Participants in our study described their experiences of lengthy waiting times to access orthotic services, in part because of circuitous referral routes, for example via orthopaedic surgeons. They also reported frequent delays in the provision and repair of custom-made KAFOs and footwear – issues already highlighted elsewhere.<sup>10–12,72</sup>

Our study participants emphasised the need for individually tailored care in relation to provision of orthotic devices. Their comments align with Hutton and Hurry's recommendation<sup>10</sup> [based on findings from the Darzi review (Department of Health)<sup>73</sup>] for a model of service that recognises that 'orthotic products are not commodities, but individually prescribed solutions suited to each patient's personal needs' (p. 10).

Study participants suggested that people receiving an orthotic device for the first time may require intensive support during the initial phases of receiving, adapting to, accepting and using the device, as they adjust to altered self-image. In addition to technical information related to the use of the device, patients may further require psychological support, as found in studies by Vinci and Garguilo<sup>14</sup> and Garralda *et al.*<sup>16</sup> involving people with CMT disease and children with Duchenne muscular dystrophy, and their main carers. In their combined questionnaire and interview study of patient satisfaction with lower limb orthoses, Fisher and McLellan<sup>72</sup> found that patients who were dissatisfied with their lower limb orthosis had usually decided not to wear it within the first 2 weeks.

Participants in our study cited functional independence as their prime desired treatment outcome, which they linked closely to their perceived ability to perform a range of work and leisure activities that promoted and enhanced their psychosocial well-being. A study by Schaffalitzky *et al.*,<sup>74</sup> which included six focus groups with 24 lower limb prosthetic users, highlighted that even small gains in mobility provided by a device may constitute a successful outcome from the patient's perspective, which mirrors our own findings. Interestingly, in Schaffalitzky *et al.*'s study,<sup>74</sup> wheelchair use was regarded as anathema by the participants, whereas in our own study, participants were often positive about using a wheelchair and



other mobility aids, frequently in combination with their orthotic device, as a means of gaining increased mobility and independence.

Findings from our study concur with previous research with regards to patients' views of orthotic footwear. Studies by Williams *et al.*<sup>75</sup> and Fisher and McLellan,<sup>72</sup> with 13 and 28 people interviewed, respectively, indicate that the range of choice available to patients in terms of colour, style and material is important, as are cosmesis and weight of the finished shoes, all factors that appear to be associated with likely wearing of prescribed shoes. Williams *et al.*<sup>75</sup> identify the importance of footwear to people's self-image, self-expression and identity, something that seemed important equally to both male and female participants in our study.

Three studies<sup>13,72,76</sup> have considered the views of patients towards the use of AFOs. These studies,<sup>13,72,76</sup> utilising different research techniques and with varying patient populations, found that orthoses that did not fit properly, which were considered uncomfortable, heavy, cumbersome and unsightly, and which drew attention to disability, were less acceptable to patients, results which match findings from our own study. Phillips *et al.*<sup>13</sup> combined nominal group technique and interviews in her study of people with CMT disease to identify perceived barriers and benefits to the use of AFOs. Results from this study<sup>13</sup> revealed a range of factors that were important to patients in determining the likelihood of their wearing a device. Benefits associated with their orthosis were ranked and included enablement of independent mobility, prevention of falls and stumbles, pain reduction, improved balance and prevention of deterioration, similar to factors cited as significant by participants in our own study. However, Phillips *et al.*'s study<sup>13</sup> revealed marked differences between male and female participants with regard to perceived barriers to using AFOs (e.g. men citing barriers to use of AFOs in the work environment more frequently, and women focusing on difficulties with accessing, and availability of, orthotists and their lack of listening skills).<sup>13</sup> Interview data in our own study did not reveal such marked differentiation of views by gender.

Bernhardt *et al.*<sup>45</sup> administered a questionnaire to nine people with inclusion body myositis (six of whom were followed up after a 6-month period), who had received a SCO to treat quadriceps weakness. Subjectively, all of the participants felt that the SCO was helpful in safeguarding against falls and providing stability; however, there were complaints about size, bulk, cosmesis and noise of the SCO, as well as difficulty putting on/taking off the brace, and most people noted that they would prefer a less intrusive device. In our own study, comfort, durability, effectiveness and reliability of the device were deemed more important than the size or appearance of the device; participants in our study seemed willing to 'trade off' elegance and unobtrusiveness of a device for effectiveness and reliability.

### **Clinical effectiveness evidence**

The systematic review included 21 studies (478 patients) evaluating the effectiveness of orthotic devices for knee instability related to a NMD or CNS condition. The most common CNS conditions were post stroke and spinal cord injury. The NMD studies were of people who had experienced poliomyelitis, with the exception of one study including nine patients with inclusion body myositis. We found that studies were generally small and were not reported in a way to allow confidence that the included patients were representative of patients seen in clinical practice. Only two of the included studies ( $n = 42$  patients) were undertaken in the UK.

Also, the full range of conditions for which devices may be used for knee instability is not reflected in the literature. Although the epidemiology of knee instability in adults, related to NMD or CNS conditions, is unclear, we are aware of other conditions for which a KAFO or AFO may be provided for knee instability. For example, in the qualitative study that we undertook, some of the participants had CMT disease or multiple sclerosis, yet these patients were not represented in the studies included in the review. The survey of HCPs also confirmed that people with a range of other NMD and CNS conditions beyond those found in the studies of effectiveness are users of orthotic devices. This may be related to prevalence. Although some of the NMD and CNS conditions are of relatively high prevalence, the specific problem of knee instability, and being suitable for one of the orthotic devices of relevance, may be relatively small.

For example, people with multiple sclerosis may experience walking problems due to balance impairments, fatigue, muscle weakness or spasticity.<sup>77</sup> In addition to the devices under consideration here, other assistive technologies that may be considered for people with multiple sclerosis include walking sticks, crutches, wheeled walkers, and manual/motorised wheelchairs.<sup>77</sup>

In the studies in which the participants had experienced poliomyelitis, carbon fibre or plastic KAFOs were investigated. One study investigated a SCKAFO. There was either no comparator or another type of KAFO (one used the same KAFO in locked and stance control mode). The studies of patients who had experienced a stroke compared plastic or carbon fibre KAFOs to no comparator or AFO, except for one study, which compared KAFO or AFO to 'conventional rehabilitation'. The studies of patients with spinal cord injury assessed HKAFOs, RGOs and HGOs. Predominantly custom-made devices were evaluated across the conditions.

There were three key findings from the review:

- First, the majority of studies were case series, making before-and-after comparisons and had a substantial risk of bias due to the inherent limitations in this study design to robustly assess the effectiveness of an intervention. In addition, outcomes were not assessed by independent assessors but usually by the treating clinician, and many of the studies were very poorly reported; for example, several made statements about findings without presentation of supporting data.
- Second, there was a mismatch between the outcomes identified in the qualitative study as important to users of orthotic devices, and also identified in the survey of HCPs as important, and the outcomes that were assessed in the studies of device effectiveness. The literature is dominated by laboratory evaluations of orthoses. During our searching for this review we identified 76 studies that were excluded because the evaluation of the orthosis did not include any use of the orthosis by the patient in a non-clinic setting. Laboratory-based studies can provide useful insights about effectiveness, particularly during development of a device. In this review, we included only studies where patients made use of the orthosis in a 'real-life' situation rather than only in a laboratory setting. In this way we hoped to gain the patient perspective of the intervention in addition to objective assessments of gait. However, the most systematically assessed outcomes in the included studies were outcomes such as gait analysis and energy consumption. Although several studies did report patient satisfaction with the device, this was predominantly reported in an anecdotal fashion and it was not possible to assess how robustly the information had been collected. Despite our requirement that participants in studies had used their orthoses outside the clinic there was no assessment of the extent to which the device had been used outside the clinic or use of validated measures of patient function and quality of life. Generally, adverse effects were not systematically reported. It cannot be inferred that there were few adverse events, as authors did not specifically mention that no adverse events were identified. It is apparent from the interviews with orthoses users that concerns (such as falls, avoiding collateral compensatory damage to their other joint, pain, discomfort and skin damage due to an ill-fitting device), and the consequences for them if a device requires frequent repairs and readjustment, were all important. In addition to the mismatch in outcomes that were important to users of devices and those assessed in studies of effectiveness, whereas the majority of studies had follow-up period of < 1 year, users of devices referred to fairly long time frames in terms of adjusting to a new device, with some suggesting > 1 year. Therefore, the studies may not have been long enough in duration to fully capture the effects of using the devices.

The prime desired outcome expressed by participants in the qualitative study was to receive treatment that offered effective support for their knee, resulting in a reduction in pain, the number of falls or trips experienced, improved balance and stability, and participation in work and a range of other family/social activities. Participants defined their own goals for mobility in terms of what they wished to achieve in their daily lives, according to their individual circumstances. Respondents did not discuss treatment outcomes as measured by how far or how fast they could walk. The studies in the systematic review primarily focused on device performance using gait analysis and, in some instances, walking distance and speed, whereas, from a patient perspective, reduction in pain, falls, trips, and improving

balance and stability are potential measures of effectiveness. A factor that might contribute to this discrepancy in outcome measurement is the current requirements for device regulation; only evidence of performance and safety is required for medical devices, which may result in a lack of incentives to conduct primary research on efficacy and/or effectiveness.<sup>78</sup>

- Third, the focus of the effectiveness studies tended to be on the device in isolation. Few studies reported the orthosis 'dose' given to the patient, i.e. the time per day/week for which they were advised to use the orthosis. In addition, reporting of fitting and training in use of the device and ongoing review was limited. A strong theme emerging from the qualitative study is that users do not see the device itself in isolation from how they were assessed for provision of the device, measured and fitted, how it functions with footwear, cointerventions, ongoing adjustment of the device and review. Given that provision of an orthosis may require a reassessment of self-image, some individuals may require psychological support, as well as technical and other information about the device itself. Provision of an orthosis is essentially a complex intervention and this was not reflected in the effectiveness literature.

### Findings in the context of other studies

The broad picture of a very limited evidence base, small single-centre studies and inadequate study design is similar to that identified in other reviews of orthotic devices.<sup>4,17,21</sup> A systematic review of questionnaires that was used to assess patient satisfaction with any limb orthoses found that 63% of the 106 included papers used questionnaires that had been developed for the specific study rather than validated measures, indicating that our findings related to orthoses for knee instability is a broader issue in the field.<sup>79</sup>

### Survey of health-care professionals

A total of 238 HCPs responded to the survey. Of the 229 who responded to the question on their occupation, there were 80 orthotists, 94 physiotherapists and 50 doctors in rehabilitation medicine (5 other). The majority of respondents had  $\geq 16$  years' post-qualification experience. The orthotics services with which they were involved used a number of different models: orthotic provision as part of a MDT, stand-alone services, a combination of both depending on patient group, and other models, such as physiotherapists sourcing orthoses directly. MDTs included physiotherapists, orthopaedic surgeons, specialists in rehabilitation medicine, occupational therapists, neurologists, orthotists, clinical nurse specialists and others. Respondents rarely reported that gait scientists were involved in MDTs. Interestingly, gait analysis is one of the more commonly used outcome measures in the studies that were included in the systematic reviews. There is, therefore, a discrepancy between what is viewed as an important outcome when assessing the effectiveness of a device in a research study and clinical practice. When used in clinical practice, gait analysis may be viewed more as a tool to assess the impact of the orthosis in correcting gait and guiding further intervention rather than a formal measure of outcome. Resources to measure gait may also be a factor here.

The most common NMDs being managed by respondents were poliomyelitis, post-polio syndrome, muscular dystrophy, CMT disease, motor neurone disease and Guillain-Barré syndrome; between 65% and 76% of respondents who managed patients with knee instability that was related to NMDs reported managing these conditions, suggesting that there is no single group that dominates provision. Similarly, no single group dominated provision among CNS conditions, although HCPs most commonly reported managing patients who had experienced a stroke (100%) and multiple sclerosis (83%). Other CNS conditions were adult cerebral palsy, traumatic brain injury, acquired brain injury and spinal cord disorders (50–65%). However, even taking into account the 10% margin of error, there seemed to be a different profile of patient conditions being managed by orthotists and physiotherapists; physiotherapists less commonly reported seeing patients with poliomyelitis, post-polio syndrome and adult cerebral palsy. This is a very tentative suggestion, as the sample size did not permit subgroup analysis; however, it is noted here as it may have implications for how best to recruit specific population groups for future orthotic research.

Falling, experiencing pain or weakness in the lower limb triggered referrals. There were many HCPs involved in assessing the patients in addition to the person referring for an orthosis or providing an orthosis. There is a suggestion in the data that there are some differences between orthotists and physiotherapists in terms of which other HCPs they reported as being involved. This may support that there are differences in the profile of patients they see or may simply suggest differences in how services are organised influencing patterns of referral between HCPs. Again, however, this can be considered as only a very tentative suggestion, but worth investigating further when planning future research.

A range of orthoses are prescribed for knee instability related to NMD or CNS conditions: taking into account the 10% margin of error, broadly similar proportions of respondents reported prescribing KAFOs (75%), AFOs (94%) and knee brace (89%). A substantial proportion also prescribed shoe adaptations (66%) and insoles (70%). Approximately half of the devices prescribed or fitted are custom-made (range 0–100%). There was a range of device and patient factors that influenced the decision to prescribe a custom-made device. Patient factors mainly related to functional deficit and anatomy; device factors mainly related to requirements of patients such as flexibility, control, fit, durability, availability of devices, the type of device (knee braces were rarely custom-made) and, for a small number of respondents, cost. The number of visits that are required to fit a device varied depending on the complexity of the device (least number of visits with insoles and most with a KAFO) and whether or not a device was custom-made. The number of visits was similar across NMD and CNS conditions. For a patient with a NMD the mean number of visits to provide a KAFO was 3 (SD 0.55) and for an insole 1.8 (SD 0.55). The time frame from the initial visit to fitting was shorter for a prefabricated device [mean 3.5 (SD 2.6) weeks; median 3 (range 0–12) weeks] than custom-made [mean 5.7 (SD 3.5) weeks; median 5 (range 0–20) weeks]. The duration of an appointment for casting and fitting a custom-made device was also longer (mean 38 vs. 26 minutes). There was considerable variability in the arrangements for review visits: on average this was 8.3 (SD 6.7) weeks [median 6 (range 1 to 32) weeks]. Respondents were fairly evenly split (taking into account the margin of error) in terms of whether or not they provided long-term review appointments (46% vs. 54%), although 88% reported providing reviews on request.

There was a range of different approaches to dealing with a broken custom device ranging, more commonly, from provision of a spare at the time of receiving the original device (36%), provision of an off-the-shelf device until device is fixed, and on-the-spot repair at an on-site workshop (38%), to rarely that the patient would have to wait for a repair or that there were no procedures in place (single respondents). The picture was broadly similar with off-the-shelf devices. The mechanisms in place to deal with device adjustment, repair or unexpected failure of a device were of major importance to patients. It was beyond the remit of our research to consider whether or not these variations in how repairs are dealt with are associated with variation in the quality of service that patients receive and the extent to which it affects daily functioning.

The majority of respondents were prescribing or fitting an orthotic device in order to achieve the following outcomes: control joint movement, reduce the number of falls, reduce pain, increase walking distance and avoid deterioration. Other treatment goals that were suggested included the broader outcomes of improving quality of life and independence; increasing social and work integration; and management of fatigue, as well as the more focused outcomes of improving symmetry, supporting ligamentous and tendinous structures, and preventing secondary arthritis. The majority of respondents were either neutral or disagreed that patients are expressing a preference for a particular device, although approximately one-third said that patients were expressing preferences for lightweight, discrete and cosmetically appealing orthoses, which are comfortable, functional and durable, easy to take on and off, and specific types of devices, such as SCKAFOs or custom-made devices.

The two treatment outcomes that at least 50% of respondents thought were extremely important were comfort and confidence in mobility. Similarly, a wide range of factors were thought to influence the effectiveness of orthotic devices, reflecting the complexity of the intervention. These ranged from factors related to fit, device-related pain and pressure areas, to acceptability of the device to the patient, each of which the majority of respondents identified as important. Additional factors identified by small proportions of respondents were psychological and cognitive factors, the underlying condition, motivation and expectations, patient involvement in choosing the device and support from family and friends. The majority of respondents (64%) thought that the cosmetic appearance of a device affected the acceptability of the device to patients and whether or not they wore it. They indicated that patients want a discrete device that fits under clothing and that the type of footwear they can use with the device is important to them, although they acknowledged that there was variability in patient views and the factors affecting acceptability depended on the individual patient. The outcomes identified by HCPs and the issues considered to be of concern to patients showed some degree of overlap with those identified by patients themselves in the qualitative interviews. However, what is being evaluated in research is at variance with what is reported as important by both patients and HCPs.

Just over one-quarter of respondents (29%) reported that no formal outcome measure was used to assess the effectiveness of the devices provided. No single outcome measure was used by the remaining respondents. The most commonly used outcome measures were the visual analogue scale (51%), the 10-m Walk Test (41%); and the Timed Up and Go Test (35%). Only 34% reported formally assessing patient satisfaction. Given what patients reported as desired outcomes, it is unlikely that the formal outcome measures used fully capture how useful and effective the devices are for users.

Approximately three-quarters of people who responded to the question on whether or not the care pathway could be improved thought that improvements could be made. There was a wide range of suggestions including improving communication and team working across professions, reducing waiting times, improving awareness of orthotic services, earlier referrals, removal of budget barriers, and improvement of care in clinic, follow-up care and improvements in assessment. Specific to patients with CNS conditions, eight respondents thought that an increase in the availability of orthotic device for stroke patients – such as strong, carbon fibre, lightweight devices – would be beneficial. The concerns of HCPs showed some overlap with the concerns of patients: referral routes, delays and a coordinated approach to care particularly for more complex problems. However, many patients also identified administration-related aspects of orthotics services as an area of concern.

### Costing analysis

The costing analysis attempted to give an overview of the complexity of the service provision of KAFOs, as well as the many variables that would need to be taken into account to provide an accurate estimate of the cost of these devices. The telephone interviews highlighted the huge variations in costs that are possible. The following variables, in particular, may alter the price of a KAFO dramatically: the joint elements chosen for the device; the materials chosen for the device; and the HCPs involved in the prescription and/or fitting of the device. Our analysis estimates that the cost of a custom-made KAFO could range from £2198 to £3553 and an off-the-shelf KAFO could range from £73.24 to £1898. However, these estimates are based on some assumptions, may not be reflective of the true cost of providing a KAFO to patients with NMD or CNS conditions with knee instability, and should be interpreted with caution.

Orthotists perceive that the benefits of walking and weight-bearing for the patient as a result of wearing the KAFO far outweigh the cost of the hardware that is required to provide the device; however, this is an area for which future research is needed. Future research could focus on conducting a microcosting of these devices. Such analysis would need to involve device manufacturers and suppliers of KAFO components/raw materials. Raw material and production costs would need to be estimated in more detail; the methodology used by Simeons *et al.*<sup>71</sup> provides an initial framework to conduct such an analysis.



## Findings in the context of other studies

A costing analysis undertaken by Simeons *et al.*<sup>71</sup> estimated the cost of hard knee and neck braces from a Belgian third-party perspective. This study<sup>71</sup> was able to obtain more detailed manufacturing and production costs. The study estimated neck braces to cost between 55 and 150 euros (€) and knee braces to be between €331 and €694. These smaller ranges of cost estimates highlight that there was less uncertainty in Simeons *et al.*'s analysis,<sup>71</sup> given their increased data on the manufacturing costs of these devices.

## Dissemination and engagement

We planned and implemented a combined engagement and dissemination strategy. The engagement process started at the beginning of the project in order to prepare channels of communication. We used a project blog, Twitter feed and articles in newsletters to raise awareness of the project, explain the research methods being used and promote involvement by health professionals in the survey. This prepared the audiences who were less familiar with the research process to understand the background to the project in advance of disseminating the results. The dissemination activities focus on ensuring that all of those who need to know the results receive them and can make sense of them. This includes targeted circulation of this full HTA report, a summary report and blog articles.

The use of social media for awareness-raising was a pragmatic approach involving minimal costs for a potentially wide exposure. Free software options were selected, so the only cost was researcher time in setting up the various elements and maintaining the dialogue. However, not everyone uses the internet and not all of those who do so use social media. We found that many of the charities are not active on Twitter and have out-of-date websites and/or did not cater for news items or articles and/or published only every 6 months. Several of the most active of the organisations we interacted with had developed their own Facebook account and used that rather than a traditional website. Our concerns about using Facebook or its equivalent were primarily about the advertisements that appear alongside a page and also about ensuring control over the content of comments and postings from external sources.

Having the blog site as a focal point when approaching organisations and individuals proved to be a useful resource, and one that we could control. We were aware of the broad range of conditions to be considered in our research and the different types and styles of orthoses for inclusion. The project was very specifically focused on people with a NMD or CNS condition and who had knee instability as a consequence. We did not want to raise expectations in the large number of people with a NMD or CNS condition who need and/or use orthotic devices for reasons other than knee instability. Likewise, the project would not be of direct relevance to people with orthotic devices for knee instability from other causes, such as injuries or arthritis. This was a concern when agreeing the necessarily short titles for the blog (Orthotics for Knee Instability) and Twitter (Orthotics for Knees) accounts. The limitation on the number of characters in the titles precluded specifying the relevant conditions and, for the Twitter account, even that the project was specifically looking at knee instability. In mitigation, the project parameters were explicitly stated on the front pages of both the blog and Twitter sites in order to be as transparent as possible.

At the start of the project we prepared a list of potential blog topics and attempted to allocate members of the team to produce at least first drafts. It was hoped that guest blogs from members of the steering group could be featured, but time pressures for the health professionals prevented this. The research team had similar problems, although some embraced the opportunity to write a short piece in a 'chatty' style. Getting the pitch right was a challenge but the focus was on patients, and public and health professionals who did not have a research background.

Our original thoughts were to try and post a blog each week or at least once every 2 weeks on the basis that less-frequent posts and the blog would not attract or retain followers. However, as with all types of social media, blogging has evolved in the way it is used and accessed. Instead of signing up to follow the blog, our audiences signed up to receive tweets. These gave the title of the blog so they could then decide whether to click through to the full post or not. We therefore became more comfortable with tailoring blog post content and timing to our project needs rather than our perceived need of interested audiences.

After the research findings have been posted, we plan to do a final blog asking how useful it was to readers, whether or not the content was interesting/boring, pitched at the right level, etc.

It is difficult to assess the success or otherwise of the use of the blog as a medium. Overall it was felt by the team to be most useful as a focal point to refer people to. For example, patients and professionals could easily find out more about the project and who was involved. Anecdotal feedback was positive. For example, prospective health-care professional focus group members and telephone interviewees were directed to information about the project on the blog site. Several participants then mentioned that they had clicked into the blog, seen who was involved and became interested in helping. We also got three valuable contacts from more traditional articles in the magazines of charitable organisations.

Given the increasing simplicity of setting up free websites, this could be a viable alternative to a blog site, as long as there are no advertising issues such as with Facebook. A website may also provide more flexibility in display and content capabilities while achieving the same aims as the blog. However, a cost is usually attached to additional functions, providing little advantage over the simpler blog site.

We will have a full perspective of usefulness of the blog only after the dissemination of the findings, which starts with the publication of this report. It is anticipated that the blog will continue to provide a vehicle for accessing information about the project and all of its outputs, including the summary report, conference presentations and peer-reviewed papers. An assessment after this stage will be included in the planned peer-reviewed journal publication.

If feasible, longer-term news of the impact of this work – for example, any subsequent research commissioned – will also be posted. The blog site has the potential to be linked to, or developed for, use in subsequent related work.

## Strengths and limitations of the research

### *Definition of knee instability*

A key challenge across all of the elements of the research was clearly defining the population of interest, specifically the knee instability element. Knee instability is not an explicit and well-defined clinical diagnosis. This created several challenges as the project progressed. When trying to recruit patients to the Advisory Group we attempted to target people using an orthotic device for knee instability. We had limited success. It became apparent from the qualitative study that people do not really define themselves in this way. Therefore, in hindsight this may have limited the number of people approached for involvement in the Advisory Group. It also had implications for recruitment of patients to the qualitative study. In the three recruitment centres, patients were not classified on clinic databases as to whether or not they had knee instability. This also had implications for the screening of studies for inclusion in the systematic review. It was often difficult to determine whether or not the participants in included studies had knee instability. As it is not a diagnosis as such, we sometimes had to rely on the authors' description of the ambulatory difficulties of the participants and make a judgement. In other instances, knee instability was part of a more complex ambulatory problem and we had to make a judgement as to what the predominant problem was. Therefore, there may be studies included in the systematic review for which it is arguable that knee instability was the main problem and there may be studies that were rejected from the review that do include people with knee instability. However, we would not expect that this would in any way change the overall conclusions of the review about the lack of high-quality evidence or allow conclusions to be made about the effectiveness of specific devices.

### Systematic review

For the systematic review we undertook thorough searches for eligible studies, which included systematic searches of 13 electronic bibliographic databases and numerous sources for unpublished and ongoing studies without any language restrictions. Risk of bias in the included studies was assessed and taken into consideration in the synthesis. Standard methods to reduce error and bias in the review process were used at all stages of the review. Several studies provided a descriptive report of some outcomes with no numerical data. Owing to the paucity of evidence we extracted these reports in order to provide as clear a picture as possible of what information is currently available, especially as many of these data related to patient perspectives. Arguably this inflates the amount of evidence that is available. The key limitation of the review was the lack of high-quality generalisable studies; however, it does provide a comprehensive overview of the gaps in the evidence on orthotic devices for knee instability that is related to NMD or CNS conditions.

### Qualitative study

The qualitative study was designed to elicit people's views and experiences of using orthotic devices for knee instability. It is, as far as we are aware, the largest interview study of its kind. Participants were selected to ensure the inclusion of people with different types of neuromuscular conditions and disease or damage of the CNS, and who had experience of orthotic services in one of three different regions of England. We also recruited from NHS and non-NHS settings. The purposive sample of 24 individuals included people of different age, gender and ethnicity; some people lived alone, whereas others lived with family members, and around half of the sample was in paid employment, whereas the remainder were partially or wholly retired. Significant others who were present when participants were interviewed often contributed to the interview, and added a further dimension to the findings, although we did not specifically set out to recruit significant others into the study.

Our study was strengthened by the inclusion of a patient representative at key stages: the patient representative was requested to assist with development of the participant topic guide used in individual interviews, through suggestions on content, language and phrasing of questions. In addition, the individual was included in study team meetings and provided with the opportunity to comment on draft findings from analysis of interview data, during both early and later phases, as well as on the draft final report. Involvement of a patient representative in this way may be viewed as a means of promoting and enhancing 'trustworthiness' of the study findings.<sup>36</sup>

It might be considered that a weakness of our study was that we did not manage to recruit participants with the full range of pathologies, motor impairments and comorbidity across NMDs. We did not, for example, recruit anyone with a diagnosis of myasthenia gravis or with muscular dystrophy. Nonetheless, we feel reassured that the study included people whose diagnosis (poliomyelitis, stroke, CMT disease, multiple sclerosis, spina bifida and spinal injury) means that they have regular and sustained contact with orthotic services in connection with knee instability.

Owing to the relatively under-researched nature of our research topic, the issue of the generalisability of the qualitative study may be considered less salient here than that of 'sensitising' readers to new information captured in the interviews, and new ways of thinking about patients' perspectives of using orthotic devices and services. These insights can inform our understanding of similar contexts and issues, a form of conceptual generalisability.<sup>35</sup> The small numbers of study participants, with different NMDs, constituting the total study sample urges caution in extrapolating findings in relation to 'parent' populations.

### Survey

A total of 238 HCPs agreed to participate in the survey equating to a response rate of 6.43%. The response rate by organisation was 12% for BAPO, 3.48% for ACPIN and 16.67% for BSRM. This is a low response rate. However, it is an underestimate, as we did not have a precise sampling frame: membership of the three organisations includes an unknown number of individuals who do not manage people with NMD and CNS conditions with knee instability. The total number of respondents was well above the



estimated minimum sample size required based on a 95% confidence level and a 10% margin of error ( $n = 96$ ) but insufficient for the more ideal 5% margin of error ( $n = 384$ ). This was the case for most of the questions, although some had fewer than 96 respondents and this is clearly reported throughout the results section. It was not appropriate to undertake subgroup analyses. Given the exploratory nature of the research, descriptive results are presented by professional group as well as the total sample; however, any apparent differences should be interpreted with caution.

Our preliminary focus group and HCP interviews indicated a high level of variability in practice related to individual patient needs, variation in relation to different conditions, variation in how orthotic services are provided and care pathways. This led to a fairly lengthy questionnaire in an attempt to capture the complexity. The overall completion rate was 58%: 68% for orthotists, 63% for physiotherapists and 54% for doctors in rehabilitation medicine, suggesting that the survey was too long. There would be benefit in any follow-up research with HCPs focusing in more detail on specific conditions and specific elements of the care pathway given the complexity.

### **Costing analysis**

There are several device options available depending on the individual patient. In our study we focused on KAFOs. The costing of orthoses used for knee instability is incredibly complex, as many of the devices are custom-made. The telephone interviews with orthotists and the survey of HCPs did not give a clear indication of the useful life of these devices or when a replacement device would be required. One orthotist stated that KAFOs could potentially last for 15–20 years but a standard useful life is not available. This would need to be elicited for a future cost-effectiveness analysis. In addition, because of the large variation across the UK, the cost estimates do not include overheads, replacement device costs and shoes cost. This costing analysis is a stepping stone towards a future cost-effectiveness analysis and has highlighted the areas that would need careful consideration in future analyses. Any future cost-effectiveness analyses would need to consider carefully the devices being compared, the manufacturing costs of these devices and the care setting being assessed. Further research is needed on the service provision of these orthotic services to fully understand the various models of care available and the implications for costs.

### **Improving the evidence**

There is a large gap in the evidence on the effectiveness of KAFOs, AFOs and other orthotic devices for managing knee instability related to NMD and CNS conditions. Robust research addressing this gap is required; RCTs are the most robust way of assessing effectiveness. However, the feasibility of a trial to assess the effectiveness of orthotic devices for knee instability in these populations would need to be carefully considered, as well as to whom the findings would be generalisable and the most appropriate research question.

### **Population**

How the population for a trial should be defined would need consideration, as applying inclusion criteria that are related to knee instability in the context of a trial would be complex. Given the exploratory nature of our research, we were pragmatic and accepted the clinician and/or orthoses user opinion that they had problems with their knee. However, recruitment to the qualitative study was slow and it took us 9 months (September 2014 to May 2015) to recruit 24 people to the study despite strenuous efforts. This was exacerbated by the fact that people were not classified on the basis of knee instability on clinical databases. In addition, patients with knee instability may have had other interventions to manage their condition such as FES or their knee was so unstable that they used a wheelchair and had never used orthoses. Another factor was that some patients had multiple other lower limb problems.

There is also the question of whether or not people with NMD and CNS conditions are a similar enough population and indeed whether or not within these two groupings the clinical problems are similar enough to be included in the same trial on the effectiveness of orthotic management. Clinical management of people with primarily CNS conditions will often differ from the conditions described above because of the effect of upper motor neuron features on lower limb function. For example, in conditions such as multiple sclerosis, spasticity will influence the prescription of orthoses; in patients who have experienced a stroke, issues such as spasticity and spatial awareness will impact prescription of orthoses, additionally there is acute onset usually with improvement and plateau. The importance of this heterogeneity is likely to vary, depending on the specific research question being addressed and needs to be balanced against the fact that including a broader population will make recruitment to a trial more feasible.

The evidence base would also be improved through future studies providing detailed descriptions of the population under investigation so that judgements can be made about the generalisability.

### **Intervention and comparator**

As illustrated by the qualitative research the goals in terms of functioning vary from patient to patient. Given the individualised nature of orthotic provision in these populations with complex needs, use of customised devices is relatively common. The extent of variation that would be permissible if evaluating the effects of a specific type of device would need to be addressed. Similarly, consideration needs to be given to the appropriate comparator. A KAFO is a substantial and intrusive device and there is a view that this tends to be offered when other devices such as an AFO are not likely to help. Therefore, possible comparators are another type of KAFO, no orthosis or use of wheelchair.

As discussed above, being provided with an orthotic device is a complex intervention and consideration would need to be given to where the boundaries of that intervention lie in terms of other assistive devices used, such as walking sticks and the process of measuring, fitting and reviewing the device provided to an individual. Any intervention should be developed with consideration of guidance available on developing complex interventions.<sup>80</sup>

As with population characteristics, the evidence base would also be improved through future studies providing detailed descriptions of the intervention and comparators under investigation, so that judgements can be made about the generalisability. In addition to the technical specification of the device and any associated shoes or walking aids, this should include details of any training and/or rehabilitation and advice on wearing.

### **Outcomes**

There is inconsistency between studies in the outcome measures being used and a focus on mechanical outcomes at the expense of other outcomes, such as patient functioning and patient experience. Any future research must consider how best to measure the impact of orthotic devices on patient quality of life, daily functioning outside the clinical setting, use of their device and any adverse effects. Important outcomes for patients in the qualitative study were a reduction in pain, falls or trips, improved balance and stability, and participation in paid employment, outdoor activities (such as gardening), family visits and social events. Brehm *et al.*<sup>81</sup> have suggested a core set of outcomes for studies of lower limb orthoses, based on the World Health Organization International Classification of Functioning Disability and Health. However, as far as we are aware, a consensus process has not taken place therefore further work is required to achieve consensus between patients, researchers and health-care providers to ensure the acceptability of the measures that have been identified.<sup>81</sup>

### **Patient perspective**

The evidence base could also be developed through consideration of the priorities of those using the devices. Findings from our study suggest that provision of an effective and acceptable orthosis for knee instability to people with a range of NMD and CNS conditions has a crucial role to play in maintaining, promoting and enhancing their physical and psychosocial health and well-being.

Our study sample included people in their thirties, forties and fifties, as well as those of older age. Younger participants whose 'normal' lives included full-time employment and responsibilities connected to supporting their families, or themselves, in the role of main breadwinner, were reliant on their orthoses to enable them to assume these roles. Older participants frequently described the central importance of their device for their engagement in leisure and family activities, which helped them feel connected to the outside world.

Our findings suggest that acceptability and use of orthoses depend on a range of factors, but that effectiveness, reliability, comfort and durability are the most important considerations for patients in deciding whether or not to use a specific device. Results indicate that people who are receiving their first orthosis (particularly a KAFO), or who are in the initial phases of trialling a new replacement device, may benefit from a period of more frequent appointments than is necessary later on, as they adjust and become accustomed to the device. Participants in the study frequently expressed strong feelings about the appearance of their device and associated footwear, and their individual choices and preferences need to be taken into account as they are likely to be associated with device use.

Results from the study highlight the importance of orthotists (and other HCPs) understanding the 'lived experience' of this patient group, so that they can engage with individual patients to identify acceptable management strategies and treatment outcomes. Establishment of a therapeutic relationship in which patients feel listened to and supported would seem to be a necessary prerequisite to promoting patient acceptance and use of orthotic devices. HCPs require the necessary time during consultations and appropriate skills to enable this to be achieved.

Our study findings reveal that many participants experienced a care pathway prone to disruption and delays, primarily due to circuitous referral routes to the specialist services that they require, and administrative inefficiencies within those services. Respondents suggested that improved communication with orthotists, a smoother care pathway and increased continuity of care would enhance their experience of receiving care. Our results indicate that commercial companies producing orthoses offer an attractive option to some people seeking the most technologically advanced products, but information and advice from these sources may be dominated by commercial interests.

Health-care professionals are faced with multiple and complex challenges in caring for patients with a range of neuromuscular and CNS conditions who require orthoses for knee instability. Assessment and measurement of the physical and psychological impact of orthosis use on patients' quality of life require appropriate, psychometrically valid measurement tools, which may not be currently available or are not in use.

To date there is scant evidence about the views and experiences of people who are given orthoses for knee instability, and other, larger studies are required to investigate further some of the issues raised in our exploratory study. Our study provides preliminary evidence concerning acceptability and use of orthoses for knee instability, alongside patients' views of desired treatment outcomes, useful information for consideration in the design of any future trial of orthoses.

### Summary

There are a number of challenges for any future studies assessing the clinical effectiveness and cost-effectiveness of different types of orthotic management of the knee in NMD and CNS conditions. The challenge in defining the target population, the personalisation of treatment including customisation of devices, the relative rarity of the problem within individual conditions and the potential difficulty in generating generalisable findings suggest that a RCT, although the most robust approach, may not be the most feasible approach to improving knowledge about effectiveness and cost-effectiveness. High-quality observational studies may provide a compromise between robustness and feasibility, and a bridge to designing future trials.

# Chapter 9 Conclusions

## Implications for service provision

- Given the paucity of evidence it is not appropriate to make conclusions about the effectiveness of specific orthotic devices for knee instability that is related to NMD or CNS disorders.
- It is clear from the perspective of orthoses users that these devices can play a crucial role in maintaining, promoting and enhancing physical and psychological health and well-being, as well as enabling participation in paid employment, supporting family, and involvement in social and community activities. Based on the interviews with patients and the survey of HCPs, services are delivered in diverse ways; it is suggested that better understanding of models of delivery that ensure maximum benefit for patients and best value for money would be beneficial, in particular a model of delivery that permits closer integration of orthotics services with other NHS services.
- Use of a core set of patient-reported outcome measures in the clinical setting would facilitate assessment of the impact of any change in device or management strategy on individual patients, and would also facilitate audit.

## Suggested research priorities

- There is a large gap in the evidence on the effectiveness of KAFOs and AFOs for managing knee instability related to NMD and CNS conditions and using outcome measures relevant to patient's everyday lives. Robust research addressing this gap is required. RCTs are the most robust way of assessing effectiveness; however, the feasibility of a trial to assess the effectiveness of these devices for knee instability in these populations would need to be carefully considered as well as to whom the findings would be generalisable. It is suggested that any future trial be informed by a feasibility study. A more feasible strategy for future research may be, in the first instance, to create a national registry for this population to systematically collect data on the ambulatory problem; devices provided; key elements of management of the instability; factors that inform/determine the process of matching patients to orthotic devices; collection of a core set of standardised and validated patient-reported outcome measures; and device and resource use. Although registries do have limitations, this would be a major step from the current evidence base in rigour and generalisability, and would create a population database and an infrastructure from which future RCTs could be undertaken. Any future research regardless of study design should follow reporting standards: [www.equator-network.org/](http://www.equator-network.org/) (accessed 12 July 2015).
- The impact of knee instability on individuals needs to be studied in the context of other aspects of neuromuscular and CNS conditions that affect the structure and function of the lower limb, for example ankle instability or muscle spasticity.
- Development of a core set of outcome measures would be beneficial [[www.comet-initiative.org](http://www.comet-initiative.org) (accessed 12 July 2015)]. Reduction in pain, falls and trips, and improved balance and stability, as well as participation in paid employment, outdoor activities (such as gardening), family visits and social events were identified as important to patients. Consideration will need to be given to the fact that lower limb orthoses use covers a wide range of different conditions and whether or not some consideration needs to be given to whether or not this is too broad for a shared core outcome set. If undertaken by specific conditions there is a risk that development could be piecemeal. This process could also be informed from progress in identification of suitable instruments to measure effectiveness in other related areas, such as chronic pain; falls (osteoporosis) and self-management.

Following consensus on the core outcomes that are relevant, consensus will also be required as to the appropriate measurement instruments, drawing on methods developed as part of the COSMIN initiative [Consensus-based Standards for the selection of health Measurement Instruments: [www.cosmin.nl/COSMIN.html](http://www.cosmin.nl/COSMIN.html) (accessed 12 July 2015)]. These could also be considered for use in the clinical setting to address the gap identified in the survey in the use of standardised outcome measures in the clinical setting.

- To date there is scant evidence about the views and experiences of people who are given orthoses for knee instability, and other larger studies are required to investigate further some of the issues that were raised in our exploratory study.
- Although our research did not set out to explore service provision, the interviews with patients identified that, as well as being concerned with having a device that works for them, aspects of service delivery are an important concern, for example how repairs and breakages are handled, provision of shoes, holistic care and good communication between the different HCPs involved in their care. It is suggested that future research should explore different models of delivery of orthotic service for people with NMD and CNS conditions to identify best practice in terms of greatest benefit to patients and value for money.
- Once a set of core outcome measures has been put in place, a full economic evaluation would be beneficial to assess the cost-effectiveness of these devices. These future economic evaluations would need to be explicit about the devices being compared and the study settings chosen, as these will have large implications on the quality of care and costs.

# Acknowledgements

We thank all of the participants who took part in the study: the patients who took part in qualitative interviews and the clinicians who participated in the survey, focus group and telephone interviews. We also thank everyone who assisted with recruitment for the study and members of the Advisory Group for overseeing its progress.

We would specifically like to thank Ms Samantha Bunting in her role as patient representative. Additionally, thanks are due to Dr Cath Jackson, Valid Research, for undertaking some of the qualitative interviews and the coding of the qualitative data.

We would like to thank Jennifer Brown, Alexis Llewellyn, Nick Meader and Huiqin Yang for help with study selection and data extraction of studies for the systematic review, including non-English language papers. Thanks also to Claire Khouja for compiling the excluded studies table for the systematic review.

## Contributions of authors

**Joanne O'Connor** (Research Associate, health economics) was lead for the HCP survey and costing analysis, and report writing; undertook HCP focus groups/interviews; designed and distributed survey; undertook analysis; contributed to the systematic review (study selection, data extraction, report writing); and contributed to the protocol.

**Dorothy McCaughan** (Research Fellow, qualitative research) was lead for the qualitative study of patient perspective and report writing; designed topic guide and patient information sheets; wrote ethics application; undertook majority of patient interviews, coding, analysis and report writing; undertook HCP focus group; and commented on drafts of survey questionnaire.

**Catriona McDaid** (Senior Research Fellow, health services research) was responsible for writing the protocol and had overall responsibility for coordinating and leading the project; provided advice and input to all elements of the project; and contributed to report writing.

**Alison Booth** (Research Fellow, systematic reviews and dissemination) was lead for dissemination and engagement and report writing; contributed to the systematic review (study selection, quality assessment and report writing); commented on drafts of the survey questionnaire; and contributed to the protocol.

**Debra Fayter** (Research Fellow, systematic reviews) was lead for the systematic review and report writing; undertook study selection, data extraction, quality assessment, data synthesis; and commented on drafts of survey questionnaire.

**Roccio Rodriguez-Lopez** (Research Fellow, information specialist) designed and undertook literature searches and the related sections in the report.

**Roy Bowers** (Senior Teaching Fellow, orthotics) was a member of the Advisory Group, contributed to the protocol, provided clinical and/or methodological advice throughout the project, and commented on drafts of the report.

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### Data sharing statement

Most of the data are available in the main body of the report and the appendices. Any further data can be obtained from the corresponding author.



## References

1. Hilton-Jones D, Freebody J, Stein J. *Neuromuscular Disorders in the Adult*. Oxford: Oxford University Press; 2011. <http://dx.doi.org/10.1093/med/9780199580354.001.0001>
2. Hebert JS. Ambulatory KAFOs: a physiatry perspective. *J Prosthet Orthot* 2006;**18**:169–74. <http://dx.doi.org/10.1097/00008526-200606001-00004>
3. Edelman J, Bruckner J. *Orthotics: A Comprehensive Clinical Approach*. Thorofare, NJ: Slack; 2002.
4. Fatone S. A review of the literature pertaining to KAFOs and HKAFOS for ambulation. *J Prosthet Orthot* 2006;**18**:137–68. <http://dx.doi.org/10.1097/00008526-200606001-00003>
5. Campbell JH. Linked hip-knee-ankle-foot orthoses designed for reciprocal gait. *J Prosthet Orthot* 2006;**18**:204–8. <http://dx.doi.org/10.1097/00008526-200606001-00011>
6. NHS Quality Improvement Scotland. *Use of Ankle Foot Orthoses Following Stroke. Best Practice Statement*. Edinburgh: Healthcare Improvement Scotland; 2009.
7. Michael JW. KAFOs for ambulation: an orthotist's perspective. *J Prosthet Orthot* 2006;**18**:187–91. <http://dx.doi.org/10.1097/00008526-200606001-00007>
8. Medicine and Healthcare products Regulatory Agency. *Medical Devices: Legal Requirements for Specific Medical Products*. London: MHRA; 2014.
9. Medicines and Healthcare products Regulatory Agency. *Custom-made Medical Devices*. London: MHRA; 2013.
10. Hutton J, Hurry M. *Orthotic Service in the NHS: Improving Service Provision*. York: York Health Economics Consortium; 2009.
11. Audit Commission. *Fully Equipped: The Provision of Equipment to Older or Disabled People by the NHS and Social Services in England and Wales*. London: Audit Commission; 2000.
12. Hill ME, Phillips MF. Service provision for adults with long-term disability: a review of services for adults with chronic neuromuscular conditions in the United Kingdom. *Neuromuscul Disord* 2006;**16**:107–12. <http://dx.doi.org/10.1016/j.nmd.2005.11.011>
13. Phillips MF, Radford K, Willis A. Ankle foot orthoses for people with Charcot Marie Tooth disease: views of users and orthotists on important aspects of use. *Disabil Rehabil Assist Technol* 2011;**6**:491–9. <http://dx.doi.org/10.3109/17483107.2010.549899>
14. Vinci P, Gargiulo P. Poor compliance with ankle-foot-orthoses in Charcot-Marie-Tooth disease. *Eur J Phys Rehabil Med* 2008;**44**:27–31.
15. Ramdharry G, Pollard A, Marsden J, Reilly M. Comparing gait performance of people with Charcot-Marie-Tooth disease who do and do not wear ankle foot orthoses. *Physiother Res Int* 2012;**17**:191–9. <http://dx.doi.org/10.1002/pri.531>
16. Garralda ME, Muntoni F, Cunniff A, Caneja AD. Knee-ankle-foot orthosis in children with Duchenne muscular dystrophy: user views and adjustment. *Eur J Paediatr Neurol* 2006;**10**:186–91. <http://dx.doi.org/10.1016/j.ejpn.2006.07.002>
17. Chisholm AE, Perry SD. Ankle-foot orthotic management in neuromuscular disorders: recommendations for future research. *Disability* 2012;**7**:437–49. <http://dx.doi.org/10.3109/17483107.2012.680940>



18. Gatti MA, Sundblad M, Freixes O, Fernández SA, Olmos LE, Rubel IF. Usage follow-up after a knee-ankle-foot orthoses selection and training program in spinal cord injury patients. *J Prosthet Orthot* 2010;**22**:146–9. <http://dx.doi.org/10.1097/JPO.0b013e3181e98c82>
19. Edelstein JE. Ambulatory KAFOs: a physical therapist's perspective. *J Prosthet Orthot* 2006;**7**:183–6. <http://dx.doi.org/10.1097/00008526-200606001-00006>
20. Genet F, Schnitzler A, Mathieu S, Autret K, Thefenne L, Dizien O, *et al.* Orthotic devices and gait in polio patients. *Ann Phys Rehabil Med* 2010;**53**:51–9. <http://dx.doi.org/10.1016/j.rehab.2009.11.005>
21. Tyson SF, Sadeghi-Demneh E, Nester CJ. A systematic review and meta-analysis of the effect of an ankle-foot orthosis on gait biomechanics after stroke. *Clin Rehabil* 2013;**27**:879–91. <http://dx.doi.org/10.1177/0269215513486497>
22. Young P, De Jonghe P, Stogbauer F, Butterfass-Bahloul T. Treatment for Charcot-Marie-Tooth disease. *Cochrane Database Syst Rev* 2008;**1**:CD006052. <http://dx.doi.org/10.1002/14651858.cd006052.pub2>
23. Smith C, Kumar S, Causby R. The effectiveness of non-surgical interventions in the treatment of Charcot foot. *Int J Evid Based Healthc* 2007;**5**:437–49.
24. Rose KJ, Burns J, Wheeler DM, North KN. Interventions for increasing ankle range of motion in patients with neuromuscular disease. *Cochrane Database Syst Rev* 2010;**2**:CD006973. <http://dx.doi.org/10.1002/14651858.cd006973.pub2>
25. Sackley C, Disler PB, Turner-Stokes L, Wade DT, Brittle N, Hoppitt T. Rehabilitation interventions for foot drop in neuromuscular disease. *Cochrane Database Syst Rev* 2009;**3**:CD003908. <http://dx.doi.org/10.1002/14651858.cd003908.pub3>
26. Zacharias B, Kannenberg A. Clinical benefits of stance control orthosis systems: an analysis of the scientific literature. *J Prosthet Orthot* 2012;**24**:2–9. <http://dx.doi.org/10.1097/JPO.0b013e3182435db3>
27. Center for Reviews and Dissemination (CRD). *CRD's Guidance for Undertaking Reviews in Health Care*. York: CRD, University of York; 2009.
28. Moher D, Liberati A, Tetzlaff J, Altman DG. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *BMJ* 2009;**339**:b2535. <http://dx.doi.org/10.1136/bmj.b2535>
29. Higgins J, Altman D, Sterne J. Assessing Risk of Bias in Included Studies. In Higgins J, Green S, editors. *Cochrane Handbook for Systematic Reviews of Interventions*. Version 5.1.0 (updated March 2011). London: The Cochrane Collaboration; 2011.
30. Valentine J, Thompson S. Issues relating to confounding and meta-analysis when including non-randomised studies in systematic reviews of the effects of interventions. *Res Synth Methods* 2013;**4**:26–35. <http://dx.doi.org/10.1002/jrsm.1064>
31. Higgins J, Ramsay C, Reeves B, Deeks J, Shea B, Valentine J. Issues relating to study design and risk of bias when including non-randomised studies in systematic reviews on the effects of interventions. *Res Synth Methods* 2013;**4**:12–25. <http://dx.doi.org/10.1002/jrsm.1056>
32. Siegfried N, Muller M, Deeks J, Volmink J, Egger M, Low N, *et al.* HIV and male circumcision: a systematic review with assessment of the quality of studies. *Lancet Infect Dis* 2005;**5**:165–73. [http://dx.doi.org/10.1016/S1473-3099\(05\)70024-4](http://dx.doi.org/10.1016/S1473-3099(05)70024-4)
33. Llewellyn A, Norman G, Harden M, Coatesworth A, Kimberling D, Schilder A, *et al.* Interventions for adult Eustachian tube dysfunction: a systematic review. *Health Technol Assess* 2014;**18**(46). <http://dx.doi.org/10.3310/hta18460>
34. Hennink M, Hutter I, Bailey AM. *Qualitative Research Methods*. London: Sage; 2011.

35. Green J, Thorogood N. *Qualitative Methods for Health Research*. London: Sage; 2014.
36. Flick U. *An Introduction to Qualitative Research*. 5th edn. London: Sage; 2014.
37. Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol* 2006;**33**:1314–23. <http://dx.doi.org/10.1191/1478088706qp0630a>
38. Richards L. *Handling Qualitative Data: A Practical Guide*. London: Sage; 2005.
39. Moustakas C. *Phenomenological Research Methods*. Thousand Oaks, CA: Sage; 1994.
40. Silverman D. *Interpreting Qualitative Data: Methods for Analysing Talk, Text and Interaction*. London: Sage; 2006.
41. Cho I, Johnson T, Vangeest JB. Enhancing surveys of health care professionals: a meta-analysis of techniques to improve response. *Eval Health Prof* 2013;**36**:382–407. <http://dx.doi.org/10.1177/0163278713496425>
42. Braithwaite D, Emery J, de Lusignan S, Sutton S. Using the internet to conduct surveys of health professionals: a valid alternative? *Fam Pract Manag* 2003;**20**:545–51. <http://dx.doi.org/10.1093/fampra/cm9509>
43. Czaja R, Blair J. *Designing Surveys: A Guide to Decisions and Procedures*. London: Sage; 2005.
44. Eysenbach G. Improving the quality of web surveys: the checklist for reporting results of internet e-surveys (CHERRIES). *J Med Internet Res* 2004;**6**:e34. <http://dx.doi.org/10.2196/jmir.6.3.e34>
45. Bernhardt K, Oh T, Kaufman K. Stance control orthosis trial in patients with inclusion body myositis. *Prosthet Orthot Int* 2011;**35**:39–44. <http://dx.doi.org/10.1177/0309364610389352>
46. Bocker B, Hölig C, Smolenski UC. Orthosis management in patients after poliomyelitis anterior acuta. *J Rehabil Med* 2011;**49**:40.
47. Bocker B, Hoelig C, Smolenski UC. Orthosis management in patients after poliomyelitis anterior acuta. *Phy Med Rehab Kuror* 2013;**23**:16–21. <http://dx.doi.org/10.1055/s-0032-1331218>
48. Boudarham J, Zory R, Genet F, Vigne G, Bensmail D, Roche N, *et al*. Effects of a knee-ankle-foot orthosis on gait biomechanical characteristics of paretic and non-paretic limbs in hemiplegic patients with genu recurvatum. *Clin Biomech* 2013;**28**:73–8. <http://dx.doi.org/10.1016/j.clinbiomech.2012.09.007>
49. Brehm MA, Beelen A, Doorenbosch CA, Harlaar J, Nollet F. Effect of carbon-composite knee-ankle-foot orthoses on walking efficiency and gait in former polio patients. *J Rehabil Med* 2007;**39**:651–7. <http://dx.doi.org/10.2340/16501977-0110>
50. Davis PC, Bach TM, Pereira DM. The effect of stance control orthoses on gait characteristics and energy expenditure in knee-ankle-foot orthosis users. *Prosthet Orthot Int* 2010;**34**:206–15. <http://dx.doi.org/10.3109/03093641003773189>
51. Hachisuka K, Makino K, Wada F, Saeki S, Yoshimoto N. Oxygen consumption, oxygen cost and physiological cost index in polio survivors: a comparison of walking without orthosis, with an ordinary or a carbon-fibre reinforced plastic knee-ankle-foot orthosis. *J Rehabil Med* 2007;**39**:646–50. <http://dx.doi.org/10.2340/16501977-0105>
52. Hachisuka K, Makino K, Wada F, Saeki S, Yoshimoto N, Arai M. Clinical application of carbon fibre reinforced plastic leg orthosis for polio survivors and its advantages and disadvantages. *Prosthet Orthot Int* 2006;**30**:129–35. <http://dx.doi.org/10.1080/03093640600574474>
53. Harvey LA, Newton-John T, Davis GM, Smith MB, Engel S. A comparison of the attitude of paraplegic individuals to the Walkabout Orthosis and the Isocentric Reciprocal Gait Orthosis. *Spinal Cord* 1997;**35**:580–4. <http://dx.doi.org/10.1038/sj.sc.3100470>

54. Harvey LA, Smith MB, Davis GM, Engel S. Functional outcomes attained by T9-12 paraplegic patients with the walkabout and the isocentric reciprocal gait orthoses. *Arch Phys Med Rehabil* 1997;**78**:706–11. [http://dx.doi.org/10.1016/S0003-9993\(97\)90077-0](http://dx.doi.org/10.1016/S0003-9993(97)90077-0)
55. Harvey LA, Davis GM, Smith MB, Engel S. Energy expenditure during gait using the walkabout and isocentric reciprocal gait orthoses in persons with paraplegia. *Arch Phys Med Rehabil* 1998;**79**:945–9. [http://dx.doi.org/10.1016/S0003-9993\(98\)90092-2](http://dx.doi.org/10.1016/S0003-9993(98)90092-2)
56. Heim M, Yaacobi E, Azaria M. A pilot study to determine the efficiency of lightweight carbon fibre orthoses in the management of patients suffering from post-poliomyelitis syndrome. *Clin Rehabil* 1997;**11**:302–5. <http://dx.doi.org/10.1177/026921559701100406>
57. Jaspers P, Peeraer L, Van Petegem W, Van der Perre G. The use of an advanced reciprocating gait orthosis by paraplegic individuals: a follow-up study. *Spinal Cord* 1997;**35**:585–9. <http://dx.doi.org/10.1038/sj.sc.3100462>
58. Kakurai S, Akai M. Clinical experiences with a convertible thermoplastic knee-ankle-foot orthosis for post-stroke hemiplegic patients. *Prosthet Orthot Int* 1996;**20**:191–4.
59. Middleton JW, Yeo JD, Blanch L, Vare V, Peterson K, Brigden K. Clinical evaluation of a new orthosis, the 'walkabout', for restoration of functional standing and short distance mobility in spinal paralysed individuals. *Spinal Cord* 1997;**35**:574–9. <http://dx.doi.org/10.1038/sj.sc.3100459>
60. Morinaka Y, Matsuo Y, Nojima M, Morinaka S. Clinical evaluation of a knee-ankle-foot-orthosis for hemiplegic patients. *Prosthet Orthot Int* 1982;**6**:111–15.
61. Peethambaran A. The relationship between performance, satisfaction, and well being for patients using anterior and posterior design knee-ankle-foot-orthosis. *J Prosthet Orthot* 2000;**12**:33–40. <http://dx.doi.org/10.1097/00008526-200012010-00008>
62. Scivoletto G, Petrelli A, Lucente LD, Giannantoni A, Fuoco U, D'Ambrosio F, et al. One year follow up of spinal cord injury patients using a reciprocating gait orthosis: preliminary report. *Spinal Cord* 2000;**38**:555–8. <http://dx.doi.org/10.1038/sj.sc.3101047>
63. Steinfeldt F, Seifert W, Gunther KP. Modern carbon fibre orthoses in the management of polio patients: a critical evaluation of the functional aspects. *Z Orthop Ihre Grenzgeb* 2003;**141**:357–61.
64. Summers BN, McClelland MR, el Masri WS. A clinical review of the adult hip guidance orthosis (Para Walker) in traumatic paraplegics. *Paraplegia* 1988;**26**:19–26. <http://dx.doi.org/10.1038/sc.1988.6>
65. Sun JL, Tang D, Ouyang YT, Zhong SZ. [Influence of reciprocating gait orthosis on walking function in paraplegic patients after ambulation.] *J Clin Rehabil Tissue Engineering Res* 2007;**11**:2437–40.
66. Tang D, Pei G, Li K. The effects of alternative gait orthosis on activity of daily living and quality of life in patients with spinal cord injury. *Chinese J Rehabil Med* 2009;**24**:985–8.
67. Whittle MW, Cochrane GM, Chase AP, Copping AV, Jefferson RJ, Staples DJ, et al. A comparative trial of two walking systems for paralysed people. *Paraplegia* 1991;**29**:97–102. <http://dx.doi.org/10.1038/sc.1991.13>
68. Wu JX, Zhou XL, Liu HL, Yin Q, Cong L, Feng L, et al. Effect of the new reciprocating gait orthosis (Walkabout orthosis) in improving paraplegic patients' independent living ability. *Chinese J Clin Rehabil* 2003;**7**:2469–70.
69. Yang JL, Xu YL, Wei Y, Sun BJ, Ke YY, Zhan SS. [Effects of lower limb orthosis therapy on the recovery of motor function in the post-stroke hemiplegic patients.] *Chinese J Clin Rehabil* 2005;**9**:6–7.

70. Department of Health. *Reference Costs 2013–14*. London: Department of Health; 2015. URL: [www.gov.uk/government/publications/nhs-reference-costs-2013-to-2014](http://www.gov.uk/government/publications/nhs-reference-costs-2013-to-2014) (accessed 12 July 2015).
71. Simoens S, Debruyne H, Moldenaers I, Guillaume P, De Coster S, Van den Steen D, *et al*. Do tariffs and prices correspond with costs? A case study of orthotic braces. *J Med Econ* 2008;**11**:245–54.
72. Fisher LR, McLellan DL. Questionnaire assessment of patient satisfaction with lower limb orthoses from a district hospital. *J Prosthet Orthot* 1989;**13**:29–35.
73. Department of Health (DH). *High Quality Care for All: NHS Next Stage Review Final Report*. London: DH; 2008.
74. Schaffalitzky E, Gallagher P, Maclachlan M, Ryall N. Understanding the benefits of prosthetic prescription: exploring the experiences of practitioners and lower limb prosthetic users. *Disabil Rehabil* 2011;**33**:1314–23. <http://dx.doi.org/10.3109/09638288.2010.529234>
75. Williams A, Nester C, Ravey M. Rheumatoid arthritis patients' experiences of wearing therapeutic footwear: a qualitative investigation. *BMC Musculoskelet Disord* 2007;**8**:104. <http://dx.doi.org/10.1186/1471-2474-8-104>
76. Bulley C, Shiels J, Wilkie K, Salisbury L. User experiences, preferences and choices relating to functional electric stimulation and ankle foot orthoses for foot drop after stroke. *Physiotherapy* 2011;**97**:226–33. <http://dx.doi.org/10.1016/j.physio.2010.11.001>
77. Souza A, Kelleher A, Cooper R, Cooper R, Iezzoni L, Collins D. Multiple sclerosis and mobility-related assistive technology: systematic review of the literature. *J Rehabil Res Dev* 2010;**47**:213–24. <http://dx.doi.org/10.1682/JRRD.2009.07.0096>
78. Iglesias C. Does assessing the value for money of therapeutic medical devices require a flexible approach. *Pharmacoecon Outcomes Res* 2015;**15**:21–32. <http://dx.doi.org/10.1586/14737167.2015.982098>
79. Bettoni E, Ferriero G, Bakhsh H, Bravini E, Massazza G, Franchignoni F. A systematic review of questionnaires to assess patient satisfaction with limb orthoses. *Prosthet Orthot Int* 2016;**40**:158–69. <http://dx.doi.org/10.1177/0309364614556836>
80. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ* 2008;**337**:a1655. <http://dx.doi.org/10.1136/bmj.a1655>
81. Brehm M, Bus SA, Harlaar J, Nollet F. A candidate core set of outcome measures based on the International Classification of Functioning, Disability and Health for clinical studies on lower limb orthoses. *J Prosthet Orthot* 2011;**35**:269–77. <http://dx.doi.org/10.1177/0309364611413496>
82. ClinicalTrials.gov. *The Use of Brace to Retrain Hemiparetic Gait*. URL: <https://clinicaltrials.gov/ct2/show/study/NCT02082938> (accessed 23 May 2016).
83. Frechtel A, Portnoy S, Raveh E, Schwartz I. Prevention of knee hyperextension in stroke patients using a knee orthosis: 3D computational gait analysis and dynamic EMG. *Gait Posture* 2013;**38**:S85. <http://dx.doi.org/10.1016/j.gaitpost.2013.07.178>
84. Kannenberg A, Probsting E. An orthotronic mobility system improves perceived walking capabilities in traditional leg orthosis users. *PM R* 2014;**1**:S229–30. <http://dx.doi.org/10.1016/j.pmrj.2014.08.525>



# Appendix 1 Search strategies for the systematic review

## Ovid MEDLINE® In-Process & Other Non-Indexed Citations and Ovid MEDLINE®

Date range searched: 1946 to 21 May 2014.

Date of search: 22 May 2014.

### Search strategy

1. Orthotic Devices/ or Braces/ or Splints/ (16,320)
2. Gait/ (17,744)
3. Lower Extremity/ or Leg/ (61,929)
4. Hip/ or Hip Joint/ (28,943)
5. Knee/ or exp Knee Joint/ (51,355)
6. Ankle/ or Ankle Joint/ (16,707)
7. Foot/ or Foot Joints/ (20,388)
8. 1 and (2 or 3 or 4 or 5 or 6 or 7) (2732)
9. Foot Orthoses/ (145)
10. 8 or 9 (2870)
11. ((gait or "lower extremity" or "lower extremities" or "lower limb" or "lower limbs" or leg? or hip? or knee? or ankle? or foot or feet) adj3 (orthos\* or orthot\* or brace? or bracing or support)).ti,ab. (3590)
12. (heel adj2 (pad? or raise?)).ti,ab. (365)
13. ((shoe? and (modification? or insert? or "negative heel" or "negative heels")) or (rocker? or insole?)).ti,ab. (1507)
14. ((HKAFO? or KAFO? or SCKAFO? or AFO? or GRAFO? or RGO? or SWASH? or DAFO? or SAFO?) and (orthos\* or orthot\* or brace? or bracing)).ti,ab. (387)
15. (SMART? and walker).ti,ab. (10)
16. 11 or 12 or 13 or 14 or 15 (5269)
17. 10 or 16 (6735)
18. exp Knee Joint/ or Knee/ (51,355)
19. knee?.af. (11,4312)
20. 18 or 19 (115,529)
21. 17 and 20 (2085)

## EMBASE

Date range searched: 1974 to 21 May 2014.

Date of search: 22 May 2014.

### Search strategy

1. orthotics/ or brace/ or exp splint/ (16,472)
2. gait/ (27,502)
3. leg/ or leg muscle/ or lower leg/ or thigh/ (76,123)
4. hip/ (32,702)

5. knee/ (41,879)
6. ankle/ (19,516)
7. Foot/ (17,901)
8. 1 and (2 or 3 or 4 or 5 or 6 or 7) (1987)
9. exp foot orthosis/ or knee brace/ or leg brace/ (1097)
10. 8 or 9 (3017)
11. ((gait or "lower extremity" or "lower extremities" or "lower limb" or "lower limbs" or leg? or hip? or knee? or ankle? or foot or feet) adj3 (orthos\* or orthot\* or brace? or bracing or support)).ti,ab. (4462)
12. (heel adj2 (pad? or raise?)).ti,ab. (410)
13. ((shoe? and (modification? or insert? or "negative heel" or "negative heels")) or (rocker? or insole?)).ti,ab. (1888)
14. ((HKAFO? or KAFO? or SCKAFO? or AFO? or GRAFO? or RGO? or SWASH? or DAFO? or SAFO?) and (orthos\* or orthot\* or brace? or bracing)).ti,ab. (506)
15. (SMART? and walker).ti,ab. (15)
16. 11 or 12 or 13 or 14 or 15 (6531)
17. 10 or 16 (8134)
18. knee instability/ or knee/ (44,382)
19. knee?.af. (145,743)
20. 18 or 19 (145,743)
21. 17 and 20 (2436)

## Cumulative Index to Nursing and Allied Health Literature Plus

Date of search: 22 May 2014.

### Search strategy

S1 (MH "Orthoses") OR (MH "Orthoses Design") OR (MH "Orthoses Fitting") OR (MH "Slings") OR (MH "Splints") (6577)

S2 (MH "Gait+") (5519)

S3 (MH "Lower Extremity") OR (MH "Leg") OR (MH "Thigh") (12,585)

S4 (MH "Hip") OR (MH "Hip Joint") (8336)

S5 (MH "Knee") OR (MH "Knee Joint") (14,318)

S6 (MH "Ankle") OR (MH "Ankle Joint") (6148)

S7 (MH "Foot") OR (MH "Heel") OR (MH "Toes") (8605)

S8 S1 AND (S2 or S3 or S4 or S5 or S6 or S7) (1315)

S9 (MH "Foot Orthoses") OR (MH "Reciprocating Gait Orthoses") (1615)

S10 S8 OR S9 (2834)

S11 TX (gait OR "lower extremity" OR "lower extremities" OR "lower limb" OR "lower limbs" OR leg? OR hip? OR knee? OR ankle? OR foot OR feet) N3 (orthos\* OR orthot\* OR brace? OR bracing (2751)

S12 TX (heel N2 (pad? OR raise?)) (51)

S13 TX ((shoe? AND (modification? OR insert? OR "negative heel" OR "negative heels")) OR (rocker? OR insole?)) (448)

S14 TX ((HKAFO? OR KAFO? OR SCKAFO? OR AFO? OR GRAFO? OR RGO? OR SWASH? OR DAFO? OR SAFO?) AND (orthos\* OR orthot\* OR brace? OR bracing)) (127)

S15 TX SMART? AND walker (0)

S16 S11 or S12 or S13 or S14 or S15 (3084)

S17 S10 or S16 (3892)

S18 (MH "Knee") OR (MH "Knee Joint") (14,318)

S19 TX knee? OR MW knee? (3121)

S20 S18 or S19 (16,111)

S21 S17 AND S20 (534)

## **The Cochrane Library (includes Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects, Cochrane Central Register of Controlled Trials, Health Technology Assessment and NHS Economic Evaluation Database)**

Date of search: 22 May 2014.

### **Search strategy**

- #1 MeSH descriptor: [Orthotic Devices] this term only (521)
- #2 MeSH descriptor: [Braces] this term only (326)
- #3 MeSH descriptor: [Splints] this term only (377)
- #4 (#1 or #2 or #3) (1192)
- #5 MeSH descriptor: [Lower Extremity] this term only (629)
- #6 MeSH descriptor: [Leg] this term only (2593)
- #7 MeSH descriptor: [Hip] this term only (296)
- #8 MeSH descriptor: [Hip Joint] this term only (814)
- #9 MeSH descriptor: [Knee] this term only (573)
- #10 MeSH descriptor: [Knee Joint] explode all trees (2304)
- #11 MeSH descriptor: [Ankle] this term only (355)
- #12 MeSH descriptor: [Ankle Joint] this term only (463)



- #13 MeSH descriptor: [Foot] explode all trees (1173)
- #14 MeSH descriptor: [Foot Joints] this term only (31)
- #15 #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 (8061)
- #16 #4 and #15 (288)
- #17 MeSH descriptor: [Foot Orthoses] this term only (25)
- #18 #16 or #17 (311)
- #19 ((gait or "lower extremity" or "lower extremities" or "lower limb" or "lower limbs" or leg? or hip? or knee? or ankle? or foot or feet) near/3 (orthos\* or orthot\* or brace? or bracing or support)):ti,ab (379)
- #20 (heel near/2 (pad? or raise?)):ti,ab (16)
- #21 ((shoe? and (modification? or insert? or "negative heel" or "negative heels")) or (rocker? or insole?)):ti,ab (156)
- #22 ((HKAFO? or KAFO? or SCKAFO? or AFO? or GRAFO? or RGO? or SWASH? or DAFO? or SAFO?) and (orthos\* or orthot\* or brace? or bracing)):ti,ab (22)
- #23 (SMART? and walker):ti,ab (0)
- #24 #19 or #20 or #21 or #22 or #23 (522)
- #25 #18 or #24 (700)
- #26 MeSH descriptor: [Knee Joint] explode all trees (2304)
- #27 MeSH descriptor: [Knee] this term only (573)
- #28 knee?:ti,ab,kw (973)
- #29 #26 or #27 or #28 (3445)
- #30 #25 and #29 (104)

Of 104 total results in The Cochrane Library, 2 were from CDSR, 7 from DARE, 94 from CENTRAL, 1 from HTA and 0 from NHS EED.

## PASCAL

Date of search: 22 May 2014.

### Search strategy

S1 ti(((gait or "lower extremity" or "lower extremities" or "lower limb" or "lower limbs" or leg? or hip? or knee? or ankle? or foot or feet) NEAR/3 (orthos\* or orthot\* or brace? or bracing or support))) OR ab(((gait or "lower extremity" or "lower extremities" or "lower limb" or "lower limbs" or leg? or hip? or knee? or ankle? or foot or feet) NEAR/3 (orthos\* or orthot\* or brace? or bracing or support))) (696)

S2 ti((heel NEAR/2 (pad? or raise?))) OR ab((heel NEAR/2 (pad? Or raise?))) (30)

S3 ti(((shoe? and (modification? or insert? or "negative heel" or "negative heels") or (rocker? or insole?))) OR ab(((shoe? And (modification? or insert? or "negative heel" or "negative heels") or (rocker? or insole?))) (175)

S4 ti(((HKAFO? or KAFO? or SCKAFO? or AFO? or GRAFO? or RGO? Or SWASH? or DAFO? or SAFO?) and (orthos\* or orthot\* or brace? Or bracing))) OR ab(((HKAFO? or KAFO? or SCKAFO? or AFO? or GRAFO? or RGO? or SWASH? or DAFO? or SAFO?) and (orthos\* or orthot\* or brace? or bracing))) (36)

S5 ti((SMART? and walker)) OR ab((SMART? and walker)) (0)

S6 S1 OR S2 OR S3 OR S4 OR S5 (883)

S7 \*knee\* (36,128)

S8 S6 AND S7 (178)

## Scopus

Date of search: 23 May 2014.

### Search strategy

((TITLE-ABS-KEY(((gait OR "lower extremity" OR "lower extremities" OR "lower limb" OR "lower limbs" OR leg? OR hip? OR knee? OR ankle? OR foot OR feet) W/3 (orthos\* OR orthot\* OR brace? OR bracing OR support)))) OR (TITLEABS- KEY(heel W/2 (pad? OR raise?))) OR (TITLE-ABS-KEY((shoe? AND (modification? OR insert? OR "negative heel" OR "negative heels")) OR (rocker? OR insole?))) OR (TITLE-ABS-KEY(((hkafo? OR kafo? OR sckafo? OR afo? OR grafo? OR rgo? OR swash? OR dafo? OR safo?) AND (orthos\* OR orthot\* OR brace? OR bracing)))) OR (TITLE-ABS-KEY(smart? AND walker))) AND (TITLE-ABS-KEY(\*knee\*)) (1190)

## Science Citation Index

Date of search 22 May 2014.

### Search strategy

# 8 #7 AND #6 (914)

# 7 TOPIC: (\*knee\*) (96,659)

# 6 #5 OR #4 OR #3 OR #2 OR #1 (3851)

# 5 TOPIC: (((SMART? and walker))) (0)

# 4 TOPIC: (((HKAFO? or KAFO? or SCKAFO? or AFO? or GRAFO? or RGO? or SWASH? or DAFO? or SAFO?) and (orthos\* or orthot\* or brace? or bracing)))) (127)

# 3 TOPIC: (((shoe? and (modification? or insert? or "negative heel" or "negative heels") or (rocker? or insole?)))) (743)

# 2 TOPIC: (((heel NEAR/2 (pad? or raise?)))) (109)

# 1 TOPIC: (((gait or "lower extremity" or "lower extremities" or "lower limb" or "lower limbs" or leg? or hip? or knee? or ankle? or foot or feet) NEAR/3 (orthos\* or orthot\* or brace? Or bracing or support)))) (3151)

## Bioscience Information Service Previews

Date of search: 22 May 2014.

### Search strategy

# 8 #7 AND #6 (306)

# 7 TOPIC: (\*knee\*) (39,826)

# 6 #5 OR #4 OR #3 OR #2 OR #1 (1579)

# 5 TOPIC: (((SMART? and walker))) (0)

# 4 TOPIC: (((HKAFO? or KAFO? or SCKAFO? or AFO? or GRAFO? or RGO? or SWASH? or DAFO? or SAFO?) and (orthos\* or orthot\* or brace? or bracing)))) (28)

# 3 TOPIC: (((shoe? and (modification? or insert? or "negative heel" or "negative heels") or (rocker? Or insole?)))) (183)

# 2 TOPIC: (((heel NEAR/2 (pad? or raise?)))) (53)

# 1 TOPIC: (((gait or "lower extremity" or "lower extremities" or "lower limb" or "lower limbs" or leg? Or hip? or knee? or ankle? or foot or feet) NEAR/3 (orthos\* or orthot\* or brace? or bracing or support)))) (1366)

## Health Management Information Consortium

Date range searched: 1979 to March 2014.

Date of search: 23 May 2014.

### Search strategy

1. orthotic devices/ or braces/ or splints/ (57)
2. lower limbs/ or legs/ (113)
3. hip joints/ (141)
4. knees/ or knee joints/ (59)
5. ankles/ or ankle joints/ (9)
6. feet/ or heels/ or toes/ (37)

7. 1 and (2 or 3 or 4 or 5 or 6) (5)
8. ((gait or "lower extremity" or "lower extremities" or "lower limb" or "lower limbs" or leg? or hip? or knee? or ankle? or foot or feet) adj3 (orthos\* or orthot\* or brace? or bracing or support)).ti,ab. (12)
9. (heel adj2 (pad? or raise?)).ti,ab. (1)
10. ((shoe? and (modification? or insert? or "negative heel" or "negative heels")) or (rocker? or insole?)).ti,ab. (1)
11. ((HKAFO? or KAFO? or SCKAFO? or AFO? or GRAFO? or RGO? or SWASH? or DAFO? or SAFO?) and (orthos\* or orthot\* or brace? or bracing)).ti,ab. (1)
12. (SMART? and walker).ti,ab. (0)
13. 8 or 9 or 10 or 11 or 12 (14)
14. 7 or 13 (15)
15. knees/ or knee joints/ (59)
16. knee?.af. (331)
17. 15 or 16 (331)
18. 14 and 17 (4)

## Physiotherapy Evidence Database

Date of search: 22 May 2014.

### Search strategy

Knee\* ortho\* (32)

Knee\* brace\* (33)

## RECAL Legacy

Date of search: 22 May 2014.

Knee Instability Orthoses in Descriptors (41)

## Conference Proceedings Citation Index – Science

Date of search: 23 May 2014.

### Search strategy

#8 #7 AND #6 (164)

#7 TOPIC: ((\*knee\*)) (11,585)

#6 #5 OR #4 OR #3 OR #2 OR #1 (936)

#5 TOPIC: ((((((shoe? and (modification? or insert? or "negative heel" or "negative heels")) or (rocker? or insole?)))))) (122)

#4 TOPIC: (((((SMART? and walker)))) (0)

#3 TOPIC: ((((((HKAFO? or KAFO? or SCKAFO? or AFO? or GRAFO? or RGO? or SWASH? or DAFO? or SAFO?) and (orthos\* or orthot\* or brace? or bracing)))))) (28)

#2 TOPIC: (((((heel NEAR/2 (pad? or raise?)))))) (6)

# 1 TOPIC: (((((gait or "lower extremity" or "lower extremities" or "lower limb" or "lower limbs" or leg? Or hip? or knee? or ankle? or foot or feet) NEAR/3 (orthos\* or orthot\* or brace? or bracing or support)))) (918)

## ClinicalTrials.gov

Date of search: 23 May 2014.

### Search strategy

(HKAFO OR KAFO OR SCKAFO OR AFO OR GRAFO OR RGO OR SWASH OR DAFO OR SAFO) AND (orthoses OR orthosis OR orthotic OR brace OR bracing) (18)

(gait OR "lower extremity" OR "lower extremities" OR "lower limb" OR "lower limbs" OR leg OR hip OR knee OR ankle OR foot OR feet) AND (orthoses OR orthosis OR orthotic OR brace OR bracing) (158)

## International Clinical Trials Registry Platform Portal – World Health Organization

Date of search: 23 May 2014.

### Search strategy

knee and ((stability or instability) AND (orthosis OR orthoses OR orthotic)) (192)

## National Technical Information Service

Date of search: 23 May 2014.

### Search strategy

Knee AND (orthosis orthoses orthotic) (2)

leg AND (orthosis orthoses orthotic) (10)

ankle AND (orthosis orthoses orthotic) (1)

## Appendix 2 Quality assessment criteria

### Randomised controlled trials

Possible answers for each criterion were low risk of bias, high risk of bias or unclear risk of bias. Cochrane criteria for judgement of low, high and unclear risk of bias were used.<sup>29</sup>

- Selection bias:
  - owing to inadequate generation of a randomised sequence
  - owing to inadequate concealment of allocations prior to assignment.
- Performance bias:
  - owing to participants' knowledge of the allocated intervention during the study
  - owing to personnels' knowledge of the allocated intervention during the study.
- Detection bias:
  - owing to knowledge of the allocated interventions by outcome assessors (for HCP assessed outcomes)
- Attrition bias:
  - owing to number, nature or handling of incomplete outcome data.
- Selective outcome reporting:
  - reporting bias due to selective outcome reporting.
- Other bias:
  - bias due to problems not covered elsewhere.

### Non-randomised controlled studies

- External validity:
  - Were the selection criteria adequately reported? (yes/no)
  - Is the sample likely to be representative? ('yes' if the sample included all eligible patients with a NMD or CNS condition requiring on orthotic over a defined period of time, such as a consecutive sample or a random or systematic sample of that population/'no' if none of above/'unclear' if not reported)
  - Was the participation rate adequate? ('yes' if percentage participation was  $\geq 80\%$ /'no' if  $< 80\%$ ; 'unclear' if not reported)
- Performance bias:
  - Were there differences in the care received by the two groups? (yes/no/unclear)

- Detection bias:
  - Was there independent outcome assessment (for HCP-assessed outcomes)? (yes/'no' if not explicitly stated)
- Attrition bias:
  - Completeness of outcome assessment ('yes' if  $\geq 80\%$  of participants were included in the final analysis; no if  $< 80\%$ ; unclear if not reported)
- Selection bias/control of confounding ('yes' if the group variable was balanced between groups ( $\leq 10\%$  difference) or adjusted for in analysis):
  - gender
  - age
  - cause of muscle weakness
  - presence of sensory disturbance
  - purpose of orthotic (proximal/distal muscle weakness)
  - previous use of orthotic device
  - acclimatisation time
  - type of orthotic device used.

### Uncontrolled studies

- Were the selection criteria adequately reported? (yes/no)
- Is the sample likely to be representative? ('yes' if the sample included all eligible patients with a NMD or CNS condition requiring on orthosis over a defined period of time, such as a consecutive sample or a random or systematic sample of that population/'no' if none of the above/'unclear' if not reported)
- Was the participation rate adequate? ('yes' if percentage participation was  $\geq 80\%$ /'no' if  $< 80\%$ /'unclear' if not reported)
- Was recruitment prospective? (yes/no/unclear)
- Was there independent outcome assessment (for HCP-assessed outcomes)? (yes/'no' if not explicitly stated)
- Completeness of outcome assessment ('yes' if  $\geq 80\%$  of participants were included in the final analysis/'no' if  $< 80\%$ /'unclear' if not reported)
- Were relevant prognostic factors reported? ('yes' for all or some of cause of muscle weakness, presence of sensory disturbance, whether or not the orthosis was used for proximal or distal muscle weakness, previous use of an orthosis, acclimatisation time, other relevant)
- Were other relevant confounding factors reported, such as cointerventions? (yes/no)
- Was an appropriate measure of variability reported? (yes/no/'partial' if reported for some outcomes)
- Were there any other important limitations?

## Appendix 3 Invitation e-mail for health-care professional focus groups/telephone interviews

### **Do you fit orthotic devices to patients with instability of the knee?**

If so, you could help us find out more about what types of devices are being used and what is involved in this process. You are invited to take part in a focus group where you will be asked about your experience, practice and preferences in orthotic devices for the treatment of patients with knee instability due to NMDs or CNS disorders.

There will be between six and eight people in the focus group and two researchers will guide the discussion. We are interested in finding out about the types of orthotic devices being fitted in these patients, and the resources required to provide this service within the NHS.

The focus group will be held on [day date time] in the [location]. The session will last approximately 90 minutes and refreshments will be provided.

This focus group is one element of a larger project which involves researchers and health professionals from the University of York, Nottingham University, University of Strathclyde, Kingston University and Queen Mary's Hospital Roehampton. The research team is based at the University of York. The study has research governance approval from the University of York Health Sciences Research Governance Committee.

If you are interested in taking part or would like to know more please contact [researcher contact details].





# Appendix 4 Participant information sheet for health-care professional focus groups/ telephone interviews



## Participant Information Sheet

### Orthotic management of instability of the knee in neuromuscular disease

I would like to invite you to take part in this study. Before you decide whether to do so it is important for you to understand why it is being done and what it will involve. Please read the following information carefully and discuss it with others if you wish.

#### What is the purpose of this study?

This study will compile information about the types of orthotic devices that are currently being used within the NHS for the management of knee instability due to neuromuscular disease and central nervous system disorders. We are trying to find out what orthotic devices are being used for patients with different conditions, the frequency of their use and the resources required to provide them to patients. This information will be used to inform a survey which we intend to send out to orthotists and physiotherapists who fit orthotic devices.

#### Who is doing the study?

The study, commissioned by the National Institute of Health Research, is being led by Dr Catriona McDaid, a senior researcher at the Department of Health Sciences at the University of York. This focus group and the subsequent survey of health care professionals are being undertaken by Joanne O'Connor, a researcher at the Centre for Reviews and Dissemination at the University of York. A second researcher, experienced in facilitating focus groups will also be involved to assist with the work.

#### Why have I been asked to participate?

You have been invited to participate in this focus group because you are a health care professional who fits or is involved with fitting orthotic devices.

#### Do I have to take part?

The decision to take part in this study is entirely voluntary. You do not have to take part if you do not want to.

#### What will be involved if I take part in this study?

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If you confirm you would like to take part in the study, and you are able to attend on the date and time given, you will be asked to confirm your name, preferred method of contact (email/telephone/post) and to give some brief details about your area of professional expertise. When you attend for the focus group discussion, there will be 5 to 7 other people present and two facilitators. A digital audio recording will be taken of the group discussion for later transcription. The session will last no longer than 90 minutes.

### **What are the advantages and disadvantages of taking part?**

By taking part in the study you will be helping us to understand more about the use of orthotics devices within the NHS. We will use that information to inform the survey of health care professionals as well as inform our study's report on use of orthotic devices within the NHS, and what further research is required.

Participation will involve attending a focus group and giving up approximately 90 minutes of your time.

We will cover reasonable travel expenses and refreshments will be provided.

### **Can I withdraw from the study at any time?**

You are free to withdraw from the study at any time without giving a reason. If you choose to withdraw from the study during the focus group, any information you have already provided during the discussion would still be used.

### **Will the information I give be kept confidential?**

The information that you give us and anything you say in the focus group will be treated in the strictest confidence. Only the research team will have access to your personal data (this will be limited to your name, contact details, your special area of expertise or interest and the focus group you are in).

The focus group transcripts will be stored securely and will not include any of your personal details. With your permission the focus groups will be digitally audio recorded so that they can be accurately transcribed. In the focus group transcripts you will be given a pseudonym so you cannot be identified; any other potentially identifying features will be removed. The digital recordings will be permanently erased once they have been transcribed and the transcripts will be stored securely for five years after which time they will be destroyed.

All data will be stored in a secure and locked location in accordance with data protection requirements and all information collected about you during the study will be stored securely in a locked office and on a password protected computer. The information will be destroyed after five years.

### **What will happen to the results of the study?**

The results of the focus groups will be used to inform the questions asked within a survey of health professionals. The results may be reported in the final report which will be submitted to the funders. The results may also be reported in academic journals and during conference proceedings. No individual will be able to be identified from details in any reports, papers or presentations that come out of the study.

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**Who has reviewed this study?**

This study has been reviewed and approved by the Department of Health Sciences Research Governance Committee (HSRGC), University of York, 19<sup>th</sup> May 2014.

**If you agree to take part, would like more information or have any questions or concerns about the study please contact me;**

*Researcher contact details*

**Thank you for taking the time to read this information sheet.**

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Draft submitted to HTA for peer review 14<sup>th</sup> July 2015



## Appendix 5 Consent form for health-care professional focus groups/telephone interviews



### Participant Consent form

#### Orthotic management of instability of the knee in neuromuscular disease

	Please confirm the statements by putting your initials in the box below
I have read and understood the participant information sheet	
I have had the opportunity to ask questions and discuss this study	
I have received satisfactory answers to all of my questions	
I have received enough information about the study	
I understand that I am free to withdraw from the study:- 1 At any time 2 Without having to give a reason for withdrawing	
I understand that if I choose to withdraw from the study during the focus group any information I have already provided during the discussion would still be used.	
I understand that the focus group will be audio-recorded.	
I understand that any information I provide, including personal details, will be confidential, stored securely and only accessed by those carrying out the study. The focus group transcripts and other personal information will be stored securely for five years then destroyed.	
I understand that any information I give may be included in published documents but my identity will be protected by the use of pseudonyms	
I agree to take part in this study:	
Participant Signature .....	Date
Name of Participant	
Researcher Signature .....	Date
Name of Researcher	

Draft submitted to HTA for peer review 14<sup>th</sup> July 2015



## Appendix 6 Patient interview and orthotist telephone interview topic guides

- Researcher to ask brief details about age, occupation, ethnicity, family member, etc. to frame and contextualise the interview.
- Can you tell me a little bit about yourself and how you came to have your orthotic device(s) (such as brace or callipers)? [*explore important aspects further, such as diagnosis, referral, care pathway, length of time having an orthosis*]
- How has the orthotic device impacted on your daily life?
- [*from answer to above question*] – What factors have affected you most and why? [*explore important aspects further*]
- What do you like, or not like, about your orthotic device? Which factors influence your decisions to use your orthotic device and why are they important?
- How effective do you think your device is in the management of knee instability?
- How do you feel about the treatment you have received in connection with your knee instability? How could this have been improved?
- What are the goals of treatment that matter most to you?
- How do you feel about the interactions you have had with HCPs? How could these have been improved?
- Any other aspects that have not already been discussed or you would like to expand upon?



### Orthotics for knee instability

#### Topic guide for telephone interviews with orthotists

For the purposes of our analysis, we are interested only in:

- the costs associated with providing KAFOs to adult patients with NMD or CNS disorders
- the costs incurred by the NHS only.

Below is a list of all the information that we would like to collate. We understand that this is a very large quantity of information and some aspects of the list are quite detailed. If you cannot answer a particular question – please let us know the reason. This would be just as helpful as filling in an answer.



## 1 MATERIALS

In this section, the materials required to manufacture/shape and capture **conventional, cosmetic and hybrid** KAFOs will be discussed.

### *Components of a conventional KAFO*

	Thigh section	Knee joint (including up-rights)	Calf section	Ankle joint	Foot section	Other elements
Metal						
Leather						
Other						

### *Components of a cosmetic KAFO*

	Thigh section	Knee joint (including up-rights)	Calf section	Ankle joint	Foot section	Other elements
Thermoplastic						
Carbon fibre						
Other						

### *Components of a hybrid KAFO*

	Thigh section	Knee joint (including up-rights)	Calf section	Ankle joint	Foot section	Other elements
Metal						
Leather						
Thermoplastic						
Carbon fibre						
Aluminium						
Titanium						
Steel						
Fabric						
Other						

### *Components used for shape capture*

	Thigh section	Knee joint (including up-rights)	Calf section	Ankle joint	Foot section	Other elements
Computer scanner						
Plaster						
Synthetic casting tape						

- Are there other materials required in the manufacturer/fitting/prescription of KAFOs?
- What decides the quantity of these materials that are used?

	Thigh section	Knee joint (including up-rights)	Calf section	Ankle joint	Foot section	Other elements
Health condition (i.e. disease)						
Primary indication (e.g. support, align, prevent, improve function, etc.)						

- Who decides what materials can be purchased or are available?

Health-Care provider

Clinical Commissioning Groups (CCGs)

## 2 STAFF

Our survey asked you what HCPs routinely referred patients to you. We would now like to know what HCPs are routinely required to provide a KAFO.

	Number of visits required	Length of visit
Physiotherapist		
Doctor in rehabilitation medicine		
Occupational therapist		
Gait scientist		
Neurologist		
Orthotist		
Clinical nurse specialist		
Orthotic technician		
Other		

## 3 OVERHEADS

We understand that orthotics service provision varies across the UK. Provision can vary from a fully managed service by a private company to a solely NHS provided service.

- What type of orthotic provision is in place in your clinical setting?
- How is your orthotic service funded? (e.g. block contract, pay per appointment, pay per item).
- Are spending caps in place?

#### 4 OPPORTUNITY COST

This section looks at the costs that would be accumulated if our patient population of interest were not prescribed an orthotic device (a KAFO in particular).

Disease type	Other devices required (e.g. wheelchairs)	Medical staff requirements	More/less visits with particular staff	Inpatient stays required	Other
<b><i>NMD patients</i></b>					
Poliomyelitis					
Muscular dystrophy					
Post-polio syndrome					
Motor neurone disease					
Inclusion body myositis					
Charcot–Marie–Tooth disease					
Guillain–Barré syndrome					
CIDP					
<b><i>CNS patients</i></b>					
Adult cerebral palsy					
Multiple sclerosis					
Traumatic brain injury					
Stroke					
Acquired brain injury					
Spinal cord disorders					

Thank you very much for taking part in this telephone interview – we do appreciate it.

As a participant, you will receive a summary of the study findings.

If you wish to follow the progress of the study, you can access the study blog on <http://kneeorthotics.blogspot.co.uk>

## Appendix 7 Survey questionnaire

### Demographic characteristics

Q1: What is your occupation?

- Orthotist
- Physiotherapist
- Doctor in rehabilitation medicine
- Other (please specify) \_\_\_\_\_

Q2: How many years of post-qualification experience do you have?

- 0-5 years
- 6-10 years
- 11-15 years
- 16 years +

Q3: Where is your clinical setting located?

- England
- Scotland
- Wales
- Northern Ireland

Q4: In what clinical setting(s) do you work?

- NHS setting
- Private company setting
- Both NHS and private settings
- Other (please specify) \_\_\_\_\_

Q5: How are orthotic services in your clinical setting provided?

- As an integrated part of a multi-disciplinary service
- Stand-alone prescribing/fitting orthotic service
- Other (please specify) \_\_\_\_\_

This question is only displayed if in Q5: How are orthotic services in your clinical setting provided? –

Option: “As an integrated part of a multi-disciplinary team” Is Selected

Q6: What healthcare professionals make up your multidisciplinary team?

- Physiotherapist
- Orthopaedic surgeon

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- Doctor in rehabilitation medicine
- Occupational therapist
- Gait scientist
- Neurologist
- Orthotist
- Clinical nurse specialist
- Other (please specify) \_\_\_\_\_

### **Patient Demographic**

We appreciate that there is variation in terminology across and within disciplines. For the purpose of this survey, we define the patient population as follows:

**Adults** are patients **age 16 years or older**.

**Neuromuscular disease (NMD)** encompasses any condition caused by dysfunction of the motor unit: the anterior horn cell/motor neuron (e.g. polio and motor neuron disease); the peripheral nerve (e.g. Charcot Marie Tooth); the neuromuscular junction (e.g. myasthenia gravis); and the muscle (e.g. muscular dystrophy). Although there may be CNS signs lower motor neuron features of flaccid weakness, loss of reflexes and muscle wasting are predominant.

**Central nervous system conditions (CNS)** encompasses conditions, such as multiple sclerosis and stroke, where upper motor neurone conditions affect muscle function. Knee instability relates to problems with external neuromuscular control of the alignment of the knee leading to muscle weakness, ligament laxity, loss of reflexes or muscle wasting.

Q7: Are you currently treating or have you recently treated adult patients with **neuromuscular disease (NMD) with knee instability**?

- Yes
- No

This question is only displayed if in Q7: Are you currently treating or have you recently treated adult patients with neuromuscular disease (NMD) with knee instability? – Option “Yes” Is Selected

Q8: What type of neuromuscular disease (NMD) do you see most frequently in these adult patients? You can choose more than one.

- Poliomyelitis
- Muscular dystrophy
- Post-polio syndrome
- Motor neurone disease
- Inclusion body myositis
- Charcot Marie Tooth disease
- Guillain Barré syndrome

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- Chronic inflammatory demyelinating polyradiculoneuropathy (CIDP)
- Other (please specify) \_\_\_\_\_

Q9: Are you currently treating or have you recently treated adult patients with **central nervous system (CNS) disorders with knee instability?**

- Yes
- No

This question is only displayed if in Q9: Are you currently treating or have you recently treated adult patients with central nervous system (CNS) disorders with knee instability? – Option “Yes” Is Selected

Q10: What type of central nervous system (CNS) conditions do you see most frequently in these adult patients? You can choose more than one.

- Adult cerebral palsy
- Multiple sclerosis
- Traumatic brain injury
- Stroke
- Acquired brain injury
- Spinal cord disorders
- Other (please specify) \_\_\_\_\_

This statement is only displayed if in Q7: Are you currently treating or have you recently treated adult patients with neuromuscular disease (NMD) with knee instability? – Option “No” Is Selected AND

If in Q9: Are you currently treating or have you recently treated adult patients with central nervous system (CNS) disorders with knee instability? – Option “No” Is Selected

You have now completed the survey

If the statement “You have now completed the survey” displayed, then respondent skips to End of Survey

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**Patient Referrals**

This question is only displayed if in Q7: Are you currently treating or have you recently treated adult patients with neuromuscular disease (NMD) with knee instability? – Option “Yes” Is Selected

Q11: Thinking specifically of **adult NMD** patients **with knee instability**, how are these patients **routinely** referred to you?

Please tick all that apply

- General practitioner
- Physiotherapist
- Orthopaedic surgeon
- Doctor in rehabilitation medicine
- Occupational therapist
- Gait scientist
- Neurologist
- Orthotist
- Clinical nurse specialist
- Other (please specify) \_\_\_\_\_

This question is only displayed if in Q9: Are you currently treating or have you recently treated adult patients with central nervous system (CNS) disorders with knee instability? – Option “Yes” Is Selected

Q12: Thinking specifically of **adult CNS** patients **with knee instability**, how are these patients **routinely** referred to you?

Please tick all that apply

- General practitioner
- Physiotherapist
- Orthopaedic surgeon
- Doctor in rehabilitation medicine
- Occupational therapist
- Gait scientist
- Neurologist
- Orthotist
- Clinical nurse specialist
- Other (please specify) \_\_\_\_\_

Q13: Thinking about **both CNS and/or NMD** adult patients **with knee instability**, what information is usually provided to you on referral?

Please tick all that apply

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- Medical details
- Diagnosis
- Physical assessment details
- Gait analysis report
- The aims/goals of the orthotic intervention (if they have already been prescribed an orthotic)
- Type of orthotic provided (if they have already been prescribed an orthotic)
- Other (please specify) \_\_\_\_\_

Q14: What symptoms in **NMD and/or CNS** patients **with knee instability** would trigger a referral to you for assessment?

Please tick all that apply

- Patient has reported falls
- Patient reported pain in their knee or lower limb
- Patient reported weakness in their knee or lower limb
- Other (please specify) \_\_\_\_\_

Q15: Do you think there are any barriers to patients being referred to you?

- Never
- Rarely
- Sometimes
- Most of the Time
- Always

Q16: Please briefly explain your answer.

Q17: Thinking about **both CNS and/or NMD** adult patients **with knee instability** being referred to you, what other healthcare professionals assess them?

Please tick all that apply

- General practitioner
- Physiotherapist
- Orthopaedic surgeon
- Doctor in rehabilitation medicine
- Occupational therapist
- Gait scientist
- Neurologist
- Orthotist
- Clinical nurse specialist
- Other (please specify) \_\_\_\_\_

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**Initial Assessment**

Q18: What assessments do you routinely undertake as part of your initial assessment of these patients?

This question refers to NMD and/or CNS patients with knee instability.

- Ligament laxity
- Muscle strength
- Joint ROM and quality of ROM
- Presence of spasticity (if appropriate)
- Previous treatments
- Previous history of pain/falls/walking ability
- Sensation
- Observational gait analysis
- Video recording of gait
- Three dimensional/video vector gait analysis performed in a gait laboratory
- Balance tests
- Timed walking tests
- Patient expectations
- Activity limitations
- Aggravating factors
- Proprioception
- Imaging (such as X-ray, MRI or Ultrasound)
- Other (please specify) \_\_\_\_\_

This question is only displayed if in Q7: Are you currently treating or have you recently treated adult patients with neuromuscular disease (NMD) with knee instability? – Option “Yes” Is Selected

Q19: What is the average waiting time for adult NMD patients with knee instability between referral of the patient to you and your initial assessment?

- up to 4 weeks
- 5-8 weeks
- 9-12 weeks
- 13 - 16 weeks
- 17-20 weeks
- 21-24 weeks
- 24 weeks +

This question is only displayed if in Q9: Are you currently treating or have you recently treated adult patients with central nervous system (CNS) disorders with knee instability? – Option “Yes” Is Selected

Q20: What is the average waiting time for adult CNS patients with knee instability between referral of the patient to you and your initial assessment?

- up to 4 weeks
- 5-8 weeks
- 9-12 weeks
- 13-16 weeks
- 17-20 weeks
- 21-24 weeks
- 24 weeks +

Q21: Thinking of adult **NMD and/or CNS** patients **with knee instability**, how long does your initial assessment last, on average?

\_\_\_\_\_ minutes

[A slider is presented to the respondent which ranges from 0-60 minutes]

#### **Prescription and fitting of orthotic devices**

Q22: How often do you see NMD and/or CNS patients with knee instability for review?

- Weekly
- Monthly
- Quarterly
- Biannually
- Annually
- No follow up
- Other (please specify) \_\_\_\_\_

This question is only displayed if in Q22: How often would you see NMD and/or CNS patients with knee instability for review? - Option “No follow up” Is Not Selected

Q23: Thinking of NMD and/or CNS patients with knee instability, on average, how long does a review visit last?

\_\_\_\_\_ minutes

[A slider is presented to the respondent which ranges from 0-45 minutes]

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Q24: In your routine work, do you prescribe or fit orthotic devices for adult NMD and/or CNS patients, with knee instability?

- Yes  
 No

This question is only displayed if in Q24: In your routine work, do you prescribe or fit orthotic devices for adult NMD and/or CNS patients with knee instability for review? – Option “No” Is Selected

Q25: To whom do you refer a patient to for prescription/fitting of orthotic devices?

	Orthotist	Physiotherapist	Doctor in rehabilitation medicine	Other	Not applicable
CNS patients with knee instability	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
NMD patients with knee instability	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

### **Types of devices**

This question is only displayed if in Q24: If In your routine work, would you prescribe or fit orthotic devices for adult NMD and/or CNS patients with knee instability for review? – Option “Yes” Is Selected

Q26: What orthotic devices do you prescribe for patients with CNS and/or NMD with knee instability?

Please tick all that apply.

- Knee ankle foot orthosis (KAFO)  
 Ankle foot orthosis (AFO)  
 Knee brace  
 Shoe adaptations  
 Insoles  
 Others (please specify) \_\_\_\_\_  
 None  
 Not applicable

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Draft submitted to HTA for peer review 14<sup>th</sup> July 2015

This question is only displayed if in Q24: If In your routine work, would you prescribe or fit orthotic devices for adult NMD and/or CNS patients with knee instability for review? – Option “Yes” Is Selected

Q27: What orthotic devices do you fit for patients with CNS and/or NMD with knee instability?

- Knee ankle foot orthosis (KAFO)
- Ankle foot orthosis (AFO)
- Knee brace
- Shoe adaptations
- Insoles
- Others (please specify) \_\_\_\_\_
- None \_\_\_\_\_
- Not applicable

This question is only displayed if in Q24: If In your routine work, would you prescribe or fit orthotic devices for adult NMD and/or CNS patients with knee instability for review? – Option “Yes” Is Selected

Q28: Please indicate on the slider below what proportion (approximately) of the devices you prescribe/ fit for patients with CNS and/or NMD and knee instability are custom-made.

\_\_\_\_\_ The % of custom-made devices that you prescribe or fit

[A slider is presented to the respondent which ranges from 0-100%]

This question is only displayed if in Q24: If In your routine work, would you prescribe or fit orthotic devices for adult NMD and/or CNS patients with knee instability for review? – Option “Yes” Is Selected

Q29: What influences your decision to prescribe a custom-made or an off the shelf device?

This question is only displayed if in Q24: If In your routine work, would you prescribe or fit orthotic devices for adult NMD and/or CNS patients with knee instability for review? – Option “Yes” Is Selected

Q30: Where are the custom-made devices you prescribe manufactured?

- On-site workshop in your clinical setting
- A central fabrication manufacturer outside of your hospital
- Other (please specify) \_\_\_\_\_
- Not applicable

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Draft submitted to HTA for peer review 14<sup>th</sup> July 2015

This question is only displayed if in Q24: If In your routine work, would you prescribe or fit orthotic devices for adult NMD and/or CNS patients with knee instability for review? – Option “Yes” Is Selected

Q31: If a patient is prescribed a device, what is the typical time frame from initial visit to fitting the device? Please consider CNS and/or NMD patients with knee instability.

\_\_\_\_\_ Typical time frame for off-the-shelf devices

\_\_\_\_\_ Typical time frame for custom-made devices

[Two sliders are presented to the respondents ranging from 0-20 weeks. Both sliders include a “Not applicable” option that can be chosen]

This question is only displayed if in Q24: If In your routine work, would you prescribe or fit orthotic devices for adult NMD and/or CNS patients with knee instability for review? – Option “Yes” Is Selected

Q32: How long is a typical patient appointment for casting and measuring of the orthosis? Please consider CNS and/or NMD patients with knee instability.

\_\_\_\_\_ Typical appointment length for off-the-shelf devices

\_\_\_\_\_ Typical appointment length for custom-made devices

[Two sliders are presented to the respondents ranging from 0-60 minutes. Both sliders include a “Not applicable” option that can be chosen]

This question is only displayed if in Q28: Please indicate on the slider below what proportion (approximately) of the devices you prescribe/ fit for patients with CNS and/or NMD and knee instability are custom-made. – Greater than 10 is selected.

Q33: Do you use any of the following methods to capture that shape of custom-made devices?

	Never	Rarely	Sometimes	Most of the time	Always
Tracing/measurements	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Plaster casts	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Synthetic casts	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Shape capture technology	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other (please specify)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

This question is only displayed if in Q24: If In your routine work, would you prescribe or fit orthotic devices for adult NMD and/or CNS patients with knee instability for review? – Option “Yes” Is Selected

AND

If in Q7: Are you currently treating or have you recently treated adult patients with neuromuscular disease (NMD) with knee instability? – Option “Yes” Is Selected

AND

If in Q27: What orthotic devices do you fit for patients with CNS and/or NMD with knee instability? – Options “None” or “Not applicable is Not Selected

Q34: How many visits are normally required to provide a completed custom-made device for a NMD patient with knee instability?

Please give the number of visits depending on the device you prescribe.

- Knee ankle foot orthosis (KAFO)
- Ankle foot orthosis (AFO)
- Knee brace
- Shoe adaptations
- Insoles
- Others (please specify) \_\_\_\_\_

Only the devices selected in Q26: What orthotic devices do you prescribe for patients with CNS and/or NMD with knee instability? are displayed for respondent. A “Not applicable” option is provided for all devices presented.

This question is only displayed if in Q24: If In your routine work, would you prescribe or fit orthotic devices for adult NMD and/or CNS patients with knee instability for review? – Option “Yes” Is Selected

AND

If in Q9: Are you currently treating or have you recently treated adult patients with central nervous system (CNS) disorders with knee instability? – Option “Yes” Is Selected

AND

If in Q27: What orthotic devices do you fit for patients with CNS and/or NMD with knee instability? – Options “None” or “Not applicable is Not Selected

Q35: How many patient visits are normally required to provide a completed custom-made device for a CNS patient with knee instability?

Please give the number of visits depending on the device you prescribe.

- Knee ankle foot orthosis (KAFO)
- Ankle foot orthosis (AFO)
- Knee brace
- Shoe adaptations
- Insoles
- Others (please specify) \_\_\_\_\_

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Draft submitted to HTA for peer review 14<sup>th</sup> July 2015

Only the devices selected in Q26: What orthotic devices do you prescribe for patients with CNS and/or NMD with knee instability? are displayed for respondent. A “Not applicable” option is provided for all devices presented.

This question is only displayed if in Q24: If In your routine work, would you prescribe or fit orthotic devices for adult NMD and/or CNS patients with knee instability for review? – Option “Yes” Is Selected

AND

If in Q7: Are you currently treating or have you recently treated adult patients with neuromuscular disease (NMD) with knee instability? – Option “Yes” Is Selected

AND

If in Q27: What orthotic devices do you fit for patients with CNS and/or NMD with knee instability? – Options “None” or “Not applicable is Not Selected

Q36: How many patient visits are normally required to provide a completed off-the shelf device for a NMD patient with knee instability?

Please give the number of visits depending on the device you prescribe.

- Knee ankle foot orthosis (KAFO)
- Ankle foot orthosis (AFO)
- Knee brace
- Shoe adaptations
- Insoles
- Others (please specify) \_\_\_\_\_

Only the devices selected in Q26: What orthotic devices do you prescribe for patients with CNS and/or NMD with knee instability? are displayed for respondent. A “Not applicable” option is provided for all devices presented.

This question is only displayed if in Q24: If In your routine work, would you prescribe or fit orthotic devices for adult NMD and/or CNS patients with knee instability for review? – Option “Yes” Is Selected

AND

If in Q9: Are you currently treating or have you recently treated adult patients with central nervous system (CNS) disorders with knee instability? – Option “Yes” Is Selected

AND

If in Q27: What orthotic devices do you fit for patients with CNS and/or NMD with knee instability? – Options “None” or “Not applicable is Not Selected

Q37: How many patient visits are normally required to provide a completed off-the shelf device for a CNS patient with knee instability?

Please give the number of visits depending on the device you prescribe.

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Draft submitted to HTA for peer review 14<sup>th</sup> July 2015

- Knee ankle foot orthosis (KAFO)
- Ankle foot orthosis (AFO)
- Knee brace
- Shoe adaptations
- Insoles
- Others (please specify) \_\_\_\_\_

Only the devices selected in Q26: What orthotic devices do you prescribe for patients with CNS and/or NMD with knee instability? are displayed for respondent. A “Not applicable” option is provided for all devices presented.

This question is only displayed if in Q24: If In your routine work, would you prescribe or fit orthotic devices for adult NMD and/or CNS patients with knee instability for review? – Option “Yes” Is Selected

Q38: What information is provided to patients at fitting appointments?

Please tick all that apply

- Instructions on taking the device on and off
- Instructions on care of the orthosis
- Instructions on how to monitor the fit of the orthosis
- Instructions on when to wear the orthosis
- Instructions on when to seek a review appointment
- Instructions on how to seek a review appointment
- Other (please specify) \_\_\_\_\_
- None of above

This question is only displayed if in Q24: If In your routine work, would you prescribe or fit orthotic devices for adult NMD and/or CNS patients with knee instability for review? – Option “Yes” Is Selected

Q39: In what form do you provide information to patients at fitting appointments?

Please tick all that apply

- Verbally
- Short leaflets
- Instruction booklets
- CD
- Direct patient to a website
- Other (please specify) \_\_\_\_\_
- None of the above

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Draft submitted to HTA for peer review 14<sup>th</sup> July 2015



This question is only displayed if in Q24: If In your routine work, would you prescribe or fit orthotic devices for adult NMD and/or CNS patients with knee instability for review? – Option “Yes” Is Selected

Q40: Do you routinely provide long-term review appointments?

- Yes
- No

If Option “No” is selected – Respondents skips to Q43: What procedures are in place, in your setting, if a custom-made device breaks?

This question is only displayed if in Q24: If In your routine work, would you prescribe or fit orthotic devices for adult NMD and/or CNS patients with knee instability for review? – Option “Yes” Is Selected

Q41: What is the usual time frame from fitting of a device to first review visit?

\_\_\_\_\_ Time from fitting to first review visit

[A slider is presented to the respondents ranging from 0-52 weeks.]

This question is only displayed if in Q24: If In your routine work, would you prescribe or fit orthotic devices for adult NMD and/or CNS patients with knee instability for review? – Option “Yes” Is Selected

Q42: How do you normally quantify the success of an orthotic when fitting/reviewing the device?

Please tick all that apply

- Patient feedback
- Family/carer feedback
- Another clinician or therapist's feedback
- Observational gait analysis
- Video gait analysis
- Video vector gait analysis
- Patient reported outcome measures (PROMs)
- Clinician reported outcome measures (CROMs)
- Other (please specify) \_\_\_\_\_
- None of the above

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Draft submitted to HTA for peer review 14<sup>th</sup> July 2015

This question is only displayed if in Q24: If In your routine work, would you prescribe or fit orthotic devices for adult NMD and/or CNS patients with knee instability for review? – Option “Yes” Is Selected

Q43: What procedures are in place, in your setting, if a custom-made device breaks?

Please tick all that apply

- A spare orthotic device is provided to the patient at the time they receive the original device
- An off-the-shelf device is provided to the patient until their prescribed device is fixed
- Patient is given a wheelchair until their device is fixed
- Patient comes to an onsite workshop for on the spot repair
- Other (please specify) \_\_\_\_\_
- Not applicable

This question is only displayed if in Q24: If In your routine work, would you prescribe or fit orthotic devices for adult NMD and/or CNS patients with knee instability for review? – Option “Yes” Is Selected

Q44: What procedures are in place, in your setting, if an off-the-shelf device breaks?

Please tick all that apply

- A spare orthotic device is provided to the patient at the time they receive the original device
- Patient is given a wheelchair until their device is fixed
- Patient comes to an onsite workshop for on the spot repair
- Other (please specify) \_\_\_\_\_
- Not applicable

This question is only displayed if in Q24: If In your routine work, would you prescribe or fit orthotic devices for adult NMD and/or CNS patients with knee instability for review? – Option “Yes” Is Selected

Q45: Who repairs the device when it breaks?

- On-site Clinician
- On-site Technician
- Off-site Clinician
- Off-site Technician
- Other (please specify) \_\_\_\_\_

This question is only displayed if in Q24: If In your routine work, would you prescribe or fit orthotic devices for adult NMD and/or CNS patients with knee instability for review? – Option “Yes” Is Selected

Q46: Does your practice have a "review on request" option for patients?

- Yes
- No

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Draft submitted to HTA for peer review 14<sup>th</sup> July 2015

**Treatment outcomes and acceptability factors**

Q47: When trying to manage the expectations of adult patients with knee instability due to CNS and/or NMD disorders, to what extent do the following factors influence your decision of what device to prescribe?

	Never	Rarely	Sometimes	Most of the time	Always
The cosmetic aspects of the device	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The weight of the device	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The material of the device	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Type of shoes or clothing can be worn with	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Patient's ability to take the device on and off	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The reliability of the device	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The comfort of the device	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other (please specify)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q48: To what extent do you agree that your patients are expressing a preference for particular devices?

- Strongly Agree
- Agree
- Neither Agree nor Disagree
- Disagree
- Strongly Disagree

This question is only displayed if in Q48: To what extent do you agree that your patients are expressing a preference for particular devices? - Options "Strongly Agree" OR "Agree" Is Selected

Q49: For what types of devices are your patients expressing a preference?

Q50: What are the treatment outcomes that you personally are trying to achieve when treating adult patients with knee instability related to NMD or CNS conditions?

Please tick all that apply.

- Control joint movement
- Reducing the number of falls
- Less pain
- Increased walking distance

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Draft submitted to HTA for peer review 14<sup>th</sup> July 2015

- Increased walking speed
- Contracture management
- Avoid further deterioration
- Other (please specify) \_\_\_\_\_

Q51: To what extent do you think the following outcomes are important to patients who have been fitted with these devices?

	Not at all important	Somewhat important	Important	Very important	Extremely important
Comfort	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Confidence in mobility	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Increase stability	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Less energy expenditure	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cosmetic aspect of device	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other (please specify)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

This question is only displayed if in Q24: If In your routine work, would you prescribe or fit orthotic devices for adult NMD and/or CNS patients with knee instability for review? – Option “Yes” Is Selected

Q52: To what extent do the following factors affect the effectiveness of the device? Please rate each factor from never to always.

	Never	Rarely	Sometimes	Most of the time	Always
Acceptability of the device to the patient	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Patient adherence	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Fit of the device	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Therapy back up	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Medical back up	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Surgical back up	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Pain due to the device	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Pressure areas due to the device	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Draft submitted to HTA for peer review 14<sup>th</sup> July 2015

Q53: Are there other factors which you think affect the effectiveness of the device?

- Yes
- No

This question is only displayed if in Q53: Are there other factors which you think affect the effectiveness of the device? - Option "Yes" Is Selected

Q54: Please specify these other factors, and why you think they affect the effectiveness of the device.

Q55: What, if any, formal outcome measure do you use to assess the effectiveness of orthotic devices for treating knee instability in adult patients with CNS and/or NMD? Please tick all that apply.

- Timed up and go test
- Ten metre walk test
- Two minute walk test
- Six minute timed walk test
- Visual Analogue Scale (VAS) e.g. for pain, balance, confidence, quality of walking.
- Goal Attainment Scaling (GAS)
- Patient satisfaction questionnaire
- Activities Balance Confidence Scale
- OPUS (the Orthotic and Prosthetic Users Survey)
- Manchester Oxford Knee Score
- Do not use a formal outcome measure
- Other (please specify) \_\_\_\_\_

Q56: What factors do you think affect the acceptability of the device to patients?

Q57: Does the cosmetic look of the device affect acceptability to the patient and whether they wear the device?

- Never
- Rarely
- Sometimes
- Often
- All of the Time

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Draft submitted to HTA for peer review 14<sup>th</sup> July 2015

Q58: Please give brief details for your answer

This question is only displayed if in Q7: Are you currently treating or have you recently treated adult patients with neuromuscular disease (NMD) with knee instability? – Option “Yes” Is Selected

Q59: Are there any aspects of the care pathway for NMD patients with knee instability that could be improved?

- Yes
- No

Q60: Please give brief details for your answer

This question is only displayed if in Q9: Are you currently treating or have you recently treated adult patients with central nervous system (CNS) disorders with knee instability? – Option “Yes” Is Selected

Q61: Are there any aspects of the care pathway for CNS patients with knee instability that could be improved?

- Yes
- No

This question is only displayed if in Q9: Are you currently treating or have you recently treated adult patients with central nervous system (CNS) disorders with knee instability? – Option “Yes” Is Selected

Q62: Please give brief details for your answer

### **Additional Requests**

Q63: Do you have any audit, service evaluation or other type of data that is or could be anonymized concerning provision of orthotic devices to this patient population?

We are particularly looking for any data relating to whether patients regularly wear the device, patient acceptability, or data on the types of devices that are being provided for knee instability related to NMD and CNS conditions. We are also interested in the costs associated with the providing and maintaining orthotic devices.

- Yes
- No

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Draft submitted to HTA for peer review 14<sup>th</sup> July 2015

This question is only displayed if in Q63: Do you have any audit or service evaluation data that is or could be anonymized concerning provision of orthotic devices to this patient population? – Option “Yes” Is Selected

Q64: Is it possible for you to share these data with us, in accordance with Data Protection regulations?

- Yes
- No

This statement is only displayed if in Q64: Is it possible for you to share these data with us, in accordance with Data Protection regulations? - Option “Yes” Is Selected

We would be very grateful if you could contact *researcher* email address to discuss sharing these data with us.

This question is only displayed if in Q1: What is your occupation? – Option “Orthotist” Is Selected

Q65 As part of our research for NIHR, we are trying to establish the costs of providing different types of orthotic devices for knee instability related to NMD or CNS conditions.

Would you be available for a telephone interview to discuss in more detail the resources required to provide orthotic services in the UK to CNS and NMD patients with knee instability?

- Yes
- No

This statement is only display if in Q65: Would you be available for a telephone interview to discuss in more detail the resources required to provide orthotic services in the UK to CNS and NMD patients with knee instability? – Option “Yes” Is Selected

We would be very grateful if you could contact *researcher email address* to discuss arranging an interview at a time that is convenient for you.

We cannot contact you as the anonymous nature of this survey means that we do not have your contact details.

Thank you for taking the time to complete our survey. Your responses will allow us to assess the orthotic provision in the UK and to identify any further research needed in this area. For more information on our study and to keep informed on our progress, please visit our blog on:

<http://kneeorthotics.blogspot.co.uk/>

## Appendix 8 Invitation e-mail for survey of health-care professionals

### Orthotics for Knee InStability

Dear Participant,

You are invited to take part in a survey where you will be asked about your experience, practice and preferences in providing orthotic devices for the treatment of adult patients (aged 16 and over) with knee instability due to neuromuscular diseases or central nervous system disorders.

We are interested in finding out about the types of orthotic devices being fitted, and the resources required to provide this service within the NHS. This survey is one element of a larger project which involves researchers and health professionals from the Universities of York, Nottingham and Strathclyde, Kingston University and Queen Mary's Hospital Roehampton. The core research team is based at the University of York. The study has been commissioned by the National Institute of Health Research and the findings will inform what further research is needed in this area. The University of York's Department of Health Science Research Governance Committee has granted ethics approval for the survey to proceed.

**I would like to invite you to participate in this on-line survey:**

*Link to survey* You are invited to complete this survey if you are a health care professional who fits orthotic devices for, or are involved in the care of, these patients. If you are not currently providing a service to this population, we would be very grateful if you could complete the first nine questions of our survey.

If you have any questions regarding the survey or this research project in general, please contact *Researcher contact details*

The questionnaire should take 20-30 minutes of your time and all responses are anonymised.

Your participation is greatly appreciated as it is important that we have the views of as many health care professionals as possible.

**For more information on our study and to keep informed on our progress, please visit our blog at:**

<http://kneeorthotics.blogspot.co.uk/>

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Draft submitted to HTA for peer review 14<sup>th</sup> July 2015





## Appendix 9 Advertisement of survey for health-care professionals

### Orthotics for Knee InStability

#### Orthotics for Knee Instability (OKIS): Seeking healthcare professional experiences

OKIS is a research project about orthotics for knee instability in patients with neuromuscular disease or central nervous system (CNS) disorders. A survey of orthotists, physiotherapists and rehabilitation medicine clinicians is currently being undertaken to establish what types of devices are being fitted for these patients within the NHS and the resources required for this. The survey has been distributed to the members of the Association of Chartered Physiotherapists Interested in Neurology (ACPIN), the British Association of Prosthetists and Orthotists (BAPO), and the British Society for Rehabilitation Medicine (BSRM).

You are invited to complete this survey if you are a member of one of these professions and fit orthotic devices for, or are involved in the care of people with neuromuscular disease or CNS condition that have knee instabilities. **If you have not received an invitation to complete this survey and would like to, please contact *researcher contact details***

The study has been commissioned by the National Institute of Health Research and the findings will inform what further research is needed in this area. The University of York's Department of Health Science Research Governance Committee has granted ethics approval for the survey to proceed.

The survey will take 20-30 minutes to complete which is longer than we would like, but we know that many health professionals working in this area are as keen as we are to address this knowledge gap.

We hope you will participate and contribute to this under researched but important area. Your participation would be greatly appreciated as it is important that we have the views of as many health care professionals as possible.

**For more information on our study and to keep informed on our progress, please visit our blog at: <http://kneeorthotics.blogspot.co.uk/>**

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Draft submitted to HTA for peer review 14<sup>th</sup> July 2015



## Appendix 10 Ongoing studies

Study details	Participants	Intervention	Outcomes
<p><b>Cardoso (2014)</b><sup>82</sup></p> <p>Country: Brazil</p> <p>Before-and-after study</p> <p>Study completion date: January 2014</p>	<p>12 post-stroke patients with hemiparesis with genu recurvatum (no participant details provided)</p>	<p>Brace (unspecified) for retraining and control of genu recurvatum</p>	<p><i>Primary outcome:</i> distribution of plantar pressures during walking at 4 weeks</p>
<p><b>Frechtel (2013)</b><sup>83</sup></p> <p>Country: Israel</p> <p>Randomised crossover trial</p> <p>Study completion date: April 2014</p>	<p>60 post-stroke patients 20 evaluated in interim results [16 male, 4 female; mean age 61 (13.5) years]</p>	<p>Genu Neurexa orthosis (Otto Bock, Germany)</p>	<p><i>Gait characteristics:</i> spatiotemporal parameters, symmetry index, paretic knee angle in the sagittal plane</p> <p>Dynamic muscle activity patterns</p> <p><i>Functional measures:</i> 6-Minute Walk Test, 10-Metre Walk Test, Berg Balance Scale, Timed Up and Go Test</p> <p>Satisfaction questionnaire</p>
<p><b>Kannenberg (2014)</b><sup>84</sup></p> <p>Country: USA</p> <p>Case series</p> <p>Study completion date: Unclear</p>	<p>13 participants with various neurological conditions causing paresis/paralysis of lower limb muscles</p>	<p>OBS with microprocessor hydraulic stance and swing-phase control</p>	<p>mPEQ, on perceived difficulty to perform 45 activities of daily living</p> <p>Activities of Daily Living rating scale</p>

mPEQ, prosthesis evaluation questionnaire modified for orthosis use; OBS, orthotronic mobility system.



## Appendix 11 Excluded studies

Reference	Reason for exclusion
Aalam M. [The Kettwig lower-limb orthosis.] <i>Orthopadische Praxis</i> 1984; <b>20</b> :404–8	No outcomes reported
Abe H, Michimata A, Sugawara K, Sugaya N, Izumi S. Improving gait stability in stroke hemiplegic patients with a plastic ankle-foot orthosis. <i>Tohoku J Exp Med</i> 2009; <b>218</b> :193–9	Not instability of the knee
Abe K. Comparison of static balance, walking velocity, and energy consumption with knee-ankle-foot orthosis, walkabout orthosis, and reciprocating gait orthosis in thoracic-level paraplegic patients. <i>J Prosthet Orthot</i> 2006; <b>18</b> :87–91	Not instability of the knee
Abiko T, Shimamura R, Abiko Y, Soma M, Ogawa D, Kamiya A, <i>et al.</i> A case study of a patient with polio and stroke who improved in gait ability by exercise and plastic ankle foot orthosis. <i>Rigakuryoho Kagaku</i> 2011; <b>26</b> :163–7	Not orthotic intervention
Ackermann M, Cozman FG. Automatic knee flexion in lower limb orthoses. <i>J Braz Soc Mech Sci</i> 2009; <b>31</b> :305–11	Laboratory setting only
ACTRN12609000034235. A randomised clinical trial to determine the relative benefits of botulinum toxin injections, ankle foot orthosis or a combination of both on knee hyperextension during walking in people with chronic stroke. 2009	Unavailable
ACTRN12612000218897. Investigating fatigue, balance, falls and mobility in people with multiple sclerosis. 2012	Not instability of the knee
ACTRN12614000260628. The Foot Orthosis versus Hip eXercises (FOHX) trial: predicting success in patellofemoral pain patients. 2014	No patients with NMD or CNS condition
Aguirre-Ollinger G, Colgate JE, Peshkin MA, Goswami A. A one-degree-of-freedom assistive exoskeleton with inertia compensation: the effects on the agility of leg swing motion. <i>Proc Inst Mech Eng H</i> 2011; <b>225</b> :228–45	No patients with NMD or CNS condition
Alemdarotlu E, Mandirotlu S, Ucan H, Celik C. [Evaluation of regular orthosis use in paraplegics after inpatient rehabilitation.] <i>Turk Fiz Tip Rehab D</i> 2013; <b>59</b> :245	Not orthotic intervention
American Academy of Orthotists and Prosthetics Proceedings. Knee-ankle-foot orthoses for ambulation. <i>J Prosthet Orthot</i> 2006; <b>7</b> :131–208	Unavailable
Anderson EG, Frank PL, Henshaw JT, Rae HG. Clinical assessment of a new weight-relieving brace. <i>J Bone Joint Surg Br</i> 1977; <b>59-B</b> :439–45	No patients with NMD or CNS condition
Andrysek J, Klejman S, Kooy J. Examination of knee joint moments on the function of knee-ankle-foot orthoses during walking. <i>J Appl Biomech</i> 2013; <b>29</b> :474–80	Laboratory setting only
Andrysek J, Redekop S, Matsui NC, Kooy J, Hubbard S. A method to measure the accuracy of loads in knee-ankle-foot orthoses using conventional gait analysis, applied to persons with poliomyelitis. <i>Arch Phys Med Rehabil</i> 2008; <b>89</b> :1372–9	Laboratory setting only
Aoki M, Moriizumi S, Toki M, Murakami T, Ishiai S. Rehabilitation and long-term course of nontraumatic myelopathy associated with surfing. <i>Am J Phys Med Rehabil</i> 2013; <b>92</b> :828–32	Not instability of the knee
Appasamy M, Oreste A, Patel NM. Genu recurvatum in adult patients with spastic hemiparesis. Treatment strategies: a case series. <i>PM R</i> 2012; <b>1</b> :S261	No patients with NMD or CNS condition
Aprile I, Bordieri C, Gilardi A, Lainieri Milazzo M, Russo G, De Santis F, <i>et al.</i> Balance and walking involvement in facioscapulohumeral dystrophy: a pilot study on the effects of custom lower limb orthoses. <i>Eur J Phys Rehabil Med</i> 2013; <b>49</b> :169–78	Not instability of the knee
Aprile I, Padua LL, Iosa M, Gilardi A, Bordieri C, Frusciantè R, <i>et al.</i> Balance and walking in facioscapulohumeral muscular dystrophy: multiperspective assessment. <i>Eur J Phys Rehabil Med</i> 2012; <b>48</b> :393–402	Not orthotic intervention
Arazpour M, Mehrpour SR, Bani MA, Hutchins SW, Bahramizadeh M, Rahgozar M. Comparison of gait between healthy participants and persons with spinal cord injury when using a powered gait orthosis: a pilot study. <i>Spinal Cord</i> 2014; <b>52</b> :44–8	Laboratory setting only
Arazpour M, Bani MA, Hutchins SW, Sayyadfar M. The Araz medial linkage orthosis: a new orthosis for walking in patients with spinal cord injury: a single patient study. <i>Prosthet Orthot Int</i> 2014; <b>38</b> :155–9	Laboratory setting only

Reference	Reason for exclusion
Arazpour M, Ahmadi Bani M, Kashani RV, Tabatabai Ghomshe F, Mousavi ME, Hutchins SW. Effect of powered gait orthosis on walking in individuals with paraplegia. <i>Prosthet Orthot Int</i> 2013; <b>37</b> :261–7	Laboratory setting only
Arazpour M, Chitsazan A, Bani MA, Rouhi G, Ghomshe FT, Hutchins SW. The effect of a knee ankle foot orthosis incorporating an active knee mechanism on gait of a person with poliomyelitis. <i>Prosthet Orthot Int</i> 2013; <b>37</b> :411–14	Laboratory setting only
Arazpour M, Bani MA, Chitsazan A, Ghomshe FT, Kashani RV, Hutchins SW. The effect of an isocentric reciprocating gait orthosis incorporating an active knee mechanism on the gait of a spinal cord injury patient: a single case study. <i>Disabil Rehabil Assist Technol</i> 2013; <b>8</b> :261–6	Not primary study
Arazpour M, Bani MA, Hutchins SW, Jones RK. The physiological cost index of walking with mechanical and powered gait orthosis in patients with spinal cord injury. <i>Spinal Cord</i> 2013; <b>51</b> :356–9	Laboratory setting only
Arazpour M, Chitsazan A, Hutchins SW, Ghomshe FT, Mousavi ME, Takamjani EE, et al. Design and simulation of a new powered gait orthosis for paraplegic patients. <i>Prosthet Orthot Int</i> 2012; <b>36</b> :125–30	No patients with NMD or CNS condition
Arazpour M, Chitsazan A, Hutchins SW, Mousavi ME, Takamjani EE, Ghomshe FT, et al. Evaluation of a novel powered gait orthosis for walking by a spinal cord injury patient. <i>Prosthet Orthot Int</i> 2012; <b>36</b> :239–46	Laboratory setting only
Arfaoui FZ, Karkouri S, Bennis N, Eloumri AA, Hajjaj-Hassouni N. Patient satisfaction survey on knee-ankle-foot orthoses carried out during an apparatus workshop at the El-Ayachi hospital. <i>Ann Phys Rehabil Med</i> 2011; <b>54</b> :e10	No patients with NMD or CNS condition
Atrice MB. Lower extremity orthotic management for the spinal-cord-injured client. <i>Top Spinal Cord Inj Rehabil</i> 2000; <b>5</b> :1–10	Not primary study
Baardman G, IJzerman MJ, Hermens HJ, Veltink PH, Boom HB, Zilvold G. The influence of the reciprocal hip joint link in the Advanced Reciprocating Gait Orthosis on standing performance in paraplegia. <i>Prosthet Orthot Int</i> 1997; <b>21</b> :210–21	Not instability of the knee
Baba M, Saitoh E, Sarai S, Teranishi T, Okada M, Mizuno A. Clinical Experience with a HKAFO System Using a Medial Single Hip Joint for Patients with Locomotive Problems. 8th World Congress of International Rehabilitation Medicine Association, Monduzzi Editore, 1997, Bologna, Italy, pp.1307–10	No patients with NMD or CNS condition
Bakker JP, de Groot IJ, Beckerman H, de Jong BA, Lankhorst GJ. The effects of knee-ankle-foot orthoses in the treatment of Duchenne muscular dystrophy: review of the literature. <i>Clin Rehabil</i> 2000; <b>14</b> :343–59	Not primary study
Bakker JP, de Groot IJ, de Jong BA, van Tol-De Jager MA, Lankhorst GJ. Prescription pattern for orthoses in The Netherlands: use and experience in the ambulatory phase of Duchenne muscular dystrophy. <i>Disabil Rehabil</i> 1997; <b>19</b> :318–25	All participants aged < 16 years
Banala SK, Kim SH, Agrawal SK, Scholz JP. Robot assisted gait training with active leg exoskeleton (ALEX). <i>IEEE Trans Neural Syst Rehabil Eng</i> 2009; <b>17</b> :2–8	Not orthotic intervention
Banala SK, Agrawal SK, Fattah A, Krishnamoorthy V, Hsu WL, Scholz J, Rudolph K. Gravity-balancing leg orthosis and its performance evaluation. <i>IEEE Trans Robot</i> 2006; <b>22</b> :1228–39	Laboratory setting only
Bani MA, Arazpour M, Ghomshe FT, Mousavi ME, Hutchins SW. Gait evaluation of the advanced reciprocating gait orthosis with solid versus dorsi flexion assist ankle foot orthoses in paraplegic patients. <i>Prosthet Orthot Int</i> 2013; <b>37</b> :161–7	Not instability of the knee
Baptiste P. [Biomechanical Effects of Knee Orthoses (experimental characterization and modelling).] PhD thesis. Saint-Étienne: École Nationale Supérieure des Mines de Saint-Étienne; 2013	No patients with NMD or CNS condition
Barbu DM, Barbu I. <i>Dynamical Model for an Original Mechatronical Rehabilitation System</i> . Proceedings of the 14th WSEAS International Conference on Applied Mathematics, 14–16 December 2000, pp. 23–6	No patients with NMD or CNS condition
Barela JA, Whitall J, Black P, Clark JE. An examination of constraints affecting the intralimb coordination of hemiparetic gait. <i>Hum Mov Sci</i> 2000; <b>19</b> :251–73	Laboratory setting only

Reference	Reason for exclusion
Barnicle K, Andrews BJ, Phillips GF, Chizeck HJ. <i>Hybrid Orthosis for Paraplegic Standing with Percutaneous Electrodes</i> . Proceedings of the IEEE/Engineering in Medicine and Biology Society Annual Conference, 4–7 November 1988, New Orleans, LA, pp. 164–5	No outcomes reported
Barton CJ, Munteanu SE, Menz HB, Crossley KM. The efficacy of foot orthoses in the treatment of individuals with patellofemoral pain syndrome: a systematic review. <i>Sports Med</i> 2010; <b>40</b> :377–95	Not primary study
Bartonek A, Saraste H, Samuelsson L, Skoog M. Ambulation in patients with myelomeningocele: a 12-year follow-up. <i>J Pediatr Orthop</i> 1999; <b>19</b> :202–6	Not orthotic intervention
Bassett GS, Fleming BW. The Lenox Hill brace in anterolateral rotatory instability. <i>Am J Sports Med</i> 1983; <b>11</b> :345–8	No patients with NMD or CNS condition
Beck C, Drez D, Young J, Cannon WD, Stone ML. Instrumented testing of functional knee braces. <i>Am J Sports Med</i> 1986; <b>14</b> :253–6	No patients with NMD or CNS condition
Beekman C, Perry J, Boyd LA, Newsam CJ, Mulroy SJ. The effects of a dorsiflexion-stopped ankle-foot orthosis on walking in individuals with incomplete spinal cord injury. <i>Top Spinal Cord Inj Rehabil</i> 2000; <b>5</b> :54–62	Not instability of the knee
Beer S, Aschbacher B, Manoglou D, Gamper E, Kool J, Kesselring J. Robot-assisted gait training in multiple sclerosis: a pilot randomised trial. <i>Multiple Sclerosis</i> 2008; <b>14</b> :231–6	Not instability of the knee
Belforte G, Gastaldi L, Pastorelli S, Sorli M. <i>A Novel Actuation for the Pneumatic Active Gait Orthosis</i> . International Conference on Climbing and Walking Robots, Paris, France, 25–27 September 2002	No patients with NMD or CNS condition
Bellantoni L, Heffernan C, Oyedijo O, Reding M. The effect of knee-ankle-foot orthosis on ambulation outcome after stroke. <i>Clin Res</i> 1992; <b>40</b> :A119	Not instability of the knee
Belmahfoud R, Sautreuil P. [The orthotic knee in poliomyelitis patients.] <i>Lett Méd Phys Réadapt</i> 2010; <b>26</b> :150–4	No outcomes reported
Beltramo F. Lower limb orthoses. <i>Ann Readapt Med Phys</i> 2001; <b>44</b> :170–5	Not primary study
Benvenuti E, Galantini P, Del Lungo I, Cecchi F, Giardini S, Federighi G, et al. [Ankle foot orthosis: which one to choose for a correct prescription.] <i>G Geronto</i> 2003; <b>51</b> :107–18	Unavailable
Bergquist RJ. Brace conversion: long leg to short leg. <i>Phys Ther</i> 1973; <b>53</b> :1071	No patients with NMD or CNS condition
Bernardi M, Canale I, Castellano V, Di Filippo L, Felici F, Marchetti M. The efficiency of walking of paraplegic patients using a reciprocating gait orthosis. <i>Paraplegia</i> 1995; <b>33</b> :409–15	Not instability of the knee
Bernhardt KA, Kaufman KR. Loads on the uprights of a knee-ankle-foot orthosis. <i>Prosthet Orthot Int</i> 2011; <b>35</b> :106–12	Laboratory setting only
Bernhardt KA, Irby SE, Kaufman KR. Consumer opinions of a stance control knee orthosis. <i>Prosthet Orthot Int</i> 2006; <b>30</b> :246–56	All participants aged < 16 years
Bertomeu JM, Lois JM, Guillem RB, Pozo AP, Lacuesta J, Molla CG, et al. Development of a hinge compatible with the kinematics of the knee joint. <i>Prosthet Orthot Int</i> 2007; <b>31</b> :371–83	No patients with NMD or CNS condition
Beyl P, Naudet J, Van Ham R, Lefeber D. <i>Mechanical Design of an Active Knee Orthosis for Gait Rehabilitation</i> . Proceedings of the IEEE 10th International Conference on Rehabilitation Robotics, Noordwijjk, The Netherlands, 13–15 June 2007, pp. 100–5	No patients with NMD or CNS condition
Biden EN. Free knee brace system. <i>J Rehabil Res Dev</i> 1991; <b>28</b> :311	No outcomes reported
Biedermann L. [Orthopädie-technische versorgung von knieband- instabilitäten mit einer leichtbau-orthese.] <i>Orthop Tech</i> 1989:119–124	No outcomes reported
Bijlenga G, Cook JK, Gelb J, de Wit JJ. Development and use of the H strain of avian infectious bronchitis virus from the Netherlands as a vaccine: a review. <i>Avian Pathol</i> 2004; <b>33</b> :550–7	No patients with NMD or CNS condition
Bizzini M, Childs JD, Piva SR, Delitto A. Systematic review of the quality of randomized controlled trials for patellofemoral pain syndrome. <i>J Orthop Sports Phys Ther</i> 2003; <b>33</b> :4–20	Not primary study



Reference	Reason for exclusion
Blanton S, Grissom SP, Riolo L. Use of a static adjustable ankle-foot orthosis following tibial nerve block to reduce plantar-flexion contracture in an individual with brain injury. <i>Phys Ther</i> 2002; <b>82</b> :1087–97	Not instability of the knee
Blauth W, Ulrich HW, Hahne HJ. [Evaluation of knee orthoses.] <i>Unfallchirurg</i> 1990; <b>93</b> :221–7	No patients with NMD or CNS condition
Bleyenheuft C, Bleyenheuft Y, Hanson P, Deltombe T. Treatment of genu recurvatum in hemiparetic adult patients: a systematic literature review. <i>Ann Phys Rehabil Med</i> 2010; <b>53</b> :189–99	Not primary study
Bocker B, Hoelig C, Smolenski UC. [Orthosis management in patients after poliomyelitis anterior acuta.] <i>Phys Med Rehab Kuror</i> 2013; <b>23</b> :16–21	Needs translation
Bolden I. Full Leg Joint Pad Appliance. Abstract for a Google patent. 2006. URL: <a href="http://www.google.com/patents/US7096507">www.google.com/patents/US7096507</a> (accessed 23 May 2016)	No outcomes reported
Boldingh EJK, Van Pijkeren T, Wijkmans DW. A study on the value of the modified KBM prosthesis compared with other types of prosthesis. <i>Prosthet Orthot Int</i> 1985; <b>9</b> :79–82	Not orthotic intervention
Bonaroti D, Akers JM, Smith BT, Mulcahey MJ, Betz RR. Comparison of functional electrical stimulation to long leg braces for upright mobility for children with complete thoracic level spinal injuries. <i>Arch Phys Med Rehabil</i> 1999; <b>80</b> :1047–53	No patients with NMD or CNS condition
Bos RPM, Grady JH, Vierhout PAM, de Vries J. A comparison of two custom-made and two off-the-shelf rigid knee orthoses in the treatment of ACL-deficient knees. <i>J Prosthet Orthot</i> 1997; <b>9</b> :25–32	No patients with NMD or CNS condition
Boudarham J, Marchiori C, Zory R, Genet F, Bensmail D, Roche N, et al. Effects of dynamic ankle-foot orthosis on biomechanical gait parameters in hemiparetic patients. <i>Ann Phys Rehabil Med</i> 2011; <b>54</b> :e9–10	Not instability of the knee
Bowers R. Biomechanical basis for use of ankle-foot orthoses after stroke. <i>BJNN</i> 2013; <b>4</b> :20	Not primary study
Branch T, Hunter R, Reynolds P. Controlling anterior tibial displacement under static load: a comparison of two braces. <i>Orthopedics</i> 1988; <b>11</b> :1249–52	No patients with NMD or CNS condition
Brandt JM. To lock or unlock? That is the question. <i>Rehab Manag</i> 2010; <b>23</b> :16	Not primary study
Brehm M, Bus SA, Harlaar J, Nollet F. A candidate core set of outcome measures based on the International Classification of Functioning, Disability and Health for clinical studies on lower limb orthoses. <i>Prosthet Orthot Int</i> 2011; <b>35</b> :269–77	Not primary study
Brill J. Assistive device for locking brace knee joint. <i>J Am Phys Ther Assoc</i> 1963; <b>43</b> :807	No outcomes reported
Bromwich W, James M, Stewart C, Emery N, Quinlivan R. Outcomes using ambulatory ankle foot orthoses in Duchenne muscular dystrophy. <i>Gait Posture</i> 2012; <b>36</b> :S94–5	All participants aged < 16 years
Bromwich W, Emery N, Stewart C, James M, Quinlivan R. A novel ankle foot orthoses/ footwear combination to aid walking in Duchenne muscular dystrophy. <i>Neuromuscular Disord</i> 2010; <b>20</b> :S7	All participants aged < 16 years
Brown J, Tindall G, Nitschke R, Haake P, Jackman KV. Hip, knee, ankle foot orthosis: lateral bar design with spring extension assist hip joints. <i>Orthotics Prosthet</i> 1982; <b>36</b> :44–9	No outcomes reported
Brunel P. Concepts of knee-ankle-foot and knee-ankle-heel orthosis used for neurological diseases. <i>Ann Phys Rehabil Med</i> 2011; <b>54</b> :e7	Not primary study
Brutsch K, Schuler T, Koenig A, Zimmerli L, Koenke SM, Lunenburger L, et al. Influence of virtual reality soccer game on walking performance in robotic assisted gait training for children. <i>J Neuroeng Rehabil</i> 2010; <b>7</b> :15	All participants aged < 16 years
Buckton CE, Thomas SS, Jakobson-Huston S, Sussman M, Aiona M. Comparison of three ankle-foot orthosis configurations for children with spastic hemiplegia. <i>Dev Med Child Neurol</i> 2001; <b>43</b> :371–8	All participants aged < 16 years
Bulea TC, Kobetic R, Audu ML, Triolo RJ. Stance controlled knee flexion improves stimulation driven walking after spinal cord injury. <i>J Neuroeng Rehabil</i> 2013; <b>10</b> :68	Laboratory setting only
Bulea TC, Kobetic R, Triolo RJ. Restoration of stance phase knee flexion during walking after spinal cord injury using a variable impedance orthosis. <i>Conf Proc IEEE Eng Med Biol Soc</i> 2011:608–11	No patients with NMD or CNS condition

Reference	Reason for exclusion
Bumbea AM, Popescu R, Traistaru R, Bighea A, Patru S. Rehabilitation program in secondary knee osteoarthritis with GENU recurvatum in hemi-paretic patients. <i>Ann Rheum Dis</i> 2013; <b>71</b>	Not orthotic intervention
Burdett RG, Borello-France D, Blatchly C, Potter C. Gait comparison of subjects with hemiplegia walking unbraced, with ankle-foot orthosis, and with Air-Stirrup brace. <i>Phys Ther</i> 1988; <b>68</b> :1197–203	Not instability of the knee
Butler PB, Farmer SE, Stewart C, Jones PW, Forward M. The effect of fixed ankle foot orthoses in children with cerebral palsy. <i>Disabil Rehabil Assist Technol</i> 2007; <b>b</b> :51–8	All participants aged < 16 years
Butler PB, Farmer SE, Major RE. Improvement in gait parameters following late intervention in traumatic brain injury: a long-term follow-up report of a single case. <i>Clin Rehabil</i> 1997; <b>11</b> :220–6	Not primary study
Byl NN. Mobility training using a bionic knee orthosis in patients in a post-stroke chronic state: a case series. <i>J Med Case Rep</i> 2012; <b>6</b> :216	Not orthotic intervention
Campbell JH. Linked hip-knee-ankle-foot orthoses designed for reciprocal gait. <i>J Prosthet Orthot</i> 2006; <b>18</b> :P204–8	Not primary study
Carlow WA, Almeida MJ. Plastics in lower-limb orthotics. <i>Orthotics Prosthet</i> 1978; <b>32</b> :25–31	No outcomes reported
Carlson JM, French J. Knee orthoses for valgus protection. Experiments on 11 designs with related analyses of orthosis length and rigidity. <i>Clin Orthop Relat Res</i> 1989:175–92	No patients with NMD or CNS condition
Carlson WE, Vaughan CL, Damiano DL, Abel MF. Orthotic management of gait in spastic diplegia. <i>Am J Phys Med Rehabil</i> 1997; <b>76</b> :219–25	All participants aged < 16 years
Carse B, Bowers RJ, Meadows BC, Rowe PJ. Visualisation to enhance biomechanical tuning of ankle-foot orthoses (AFOs) in stroke: study protocol for a randomised controlled trial. <i>Trials</i> 2011; <b>12</b> :254	Not orthotic intervention
Cassvan A, Wunder KE, Fultonberg DM. Orthotic management of the unstable knee. <i>Arch Phys Med Rehabil</i> 1977; <b>58</b> :487–91	No patients with NMD or CNS condition
Cerny K, Walker J, Perry J. The effect of a knee-ankle-foot orthosis on the stance phase of gait. <i>Phys Ther</i> 1988; <b>68</b> :801	No patients with NMD or CNS condition
Cerny D, Waters R, Hislop H, Perry J. Walking and wheelchair energetics in persons with paraplegia. <i>Phys Ther</i> 1980; <b>60</b> :1133–9	Not instability of the knee
Chandrapal M, Chen XQ. <i>Intelligent Active Assistive and Resistive Orthotic Device for Knee Rehabilitation</i> . 7th IEEE International Conference on Control and Automation, Christchurch, New Zealand, 9–11 December 2009. pp. 1880–5	No patients with NMD or CNS condition
Charrette M. When to consider orthotics: research-based recommendations. <i>Dynamic Chiropr</i> 2010; <b>34</b> (9)	Not primary study
Charrette M. Lateral knee pain and orthotic support. <i>Dynamic Chiropr</i> 2008; <b>26</b> (26)	Not primary study
Charrette MN. Foot care: thirteen ways orthotics can help your patients. <i>Dynamic Chiropr</i> 2008; <b>26</b> (14)	Not primary study
Charrette MN. Foot care: musculoskeletal problems and orthotic support. <i>Dynamic Chiropr</i> 2007; <b>25</b> (34)	No outcomes reported
Chen CH, Lin KH, Lu TW, Chai HM, Chen HL, Tang PF, Hu MH. Immediate effect of lateral-wedged insole on stance and ambulation after stroke. <i>Am J Phys Med Rehabil</i> 2010; <b>89</b> :48–55	Not instability of the knee
Chisholm AE, Perry SD. Ankle-foot orthotic management in neuromuscular disorders: recommendations for future research. <i>Disabil Rehabil Assist Technol</i> 2012; <b>7</b> :437–49	Not primary study
Chiu YY. The effectiveness of Knee Extension Splint (KES) on weight shifting control of stroke patient: pilot study. <i>Int J Stroke</i> 2012; <b>7</b> :51	Not instability of the knee
Collins NJ, Bisset LM, Crossley KM, Vicenzino B. Efficacy of nonsurgical interventions for anterior knee pain: systematic review and meta-analysis of randomized trials. <i>Sports Med</i> 2012; <b>42</b> :31–49	Not primary study
Colombo G, Dietz V. <i>Powered Gait Orthosis Improves Locomotor Training in Paraplegic Patients</i> . In Buhler C, H Knops H, editors. <i>Assistive Technology on the Threshold of the New</i>	Not orthotic intervention

Reference	Reason for exclusion
Millenium 1999; <b>6</b> :580–4. Proceedings of the 5th Biennial European Conference for the Advancement of Assistive Technology in Europe, 1999	
Colombo G, Jorg M, Dietz V. <i>Driven Gait Orthosis to do Locomotor Training of Paraplegic Patients</i> . Proceedings of the IEEE Engineering in Medicine and Biology Society Conference, 23–28 July 2000, Chicago, IL, pp. 3159–63	No patients with NMD or CNS condition
Colombo G, Joerg M, Schreier R, Dietz V. Treadmill training of paraplegic patients using a robotic orthosis. <i>J Rehabil R D</i> 2000; <b>37</b> :693–700	Not orthotic intervention
Conil JL, Fico G, Bardot A, Delarque A, Viton JM, Kraenzler R, <i>et al</i> . Knee-ankle-foot orthosis for poliomyelitis sequelae: structural and technical evolution. <i>Eura Medicophys</i> 2001; <b>37</b> :171–9	No outcomes reported
Crossley K, Bennell K, Green S, McConnell J. A systematic review of physical interventions for patellofemoral pain syndrome. <i>Clin J Sport Med</i> 2001; <b>11</b> :103–10	No patients with NMD or CNS condition
Cruz TH, Dhaher YY. Impact of ankle-foot-orthosis on frontal plane behaviors post-stroke. <i>Gait Posture</i> 2009; <b>30</b> :312–16	Not instability of the knee
Cullell A, Moreno JC, Rocon E, Forner-Cordero A, Pons JL. Biologically based design of an actuator system for a knee-ankle-foot orthosis. <i>Mech Mach Theory</i> 2009; <b>44</b> :860–72	Laboratory setting only
Cybulski GR, Jaeger RJ. Standing performance of persons with paraplegia. <i>Arch Phys Med Rehabil</i> 1986; <b>67</b> :103–8	Not primary study
Cybulski G, Jaeger R, Troyk P. Quantitative analysis of standing balance in paraplegic individuals. Conference of the Rehabilitation Engineering Society of North America 1984	Not instability of the knee
Dall P. The function of the reciprocal link in paraplegic orthotic gait. <i>J Prosthet Orthot</i> 2001; <b>13</b> :10–13	Not primary study
Daly JJ, Ruff RL. Construction of efficacious gait and upper limb functional interventions based on brain plasticity evidence and model-based measures for stroke patients. <i>Scientific World J</i> 2007; <b>7</b> :2031–45	No outcomes reported
Daly JJ, Roenigk K, Holcomb J, Rogers JM, Butler K, Gansen J, <i>et al</i> . A randomized controlled trial of functional neuromuscular stimulation in chronic stroke subjects. <i>Stroke</i> 2006; <b>37</b> :172–8	Not orthotic intervention
Daly JJ, Roenigk KL, Gansen JL, Fredrickson E, Marsolais EB, Rogers J, Ruff RL. Response of sagittal plane gait kinematics to weight-supported treadmill training and functional neuromuscular stimulation following stroke. <i>J Rehabil Res Dev</i> 2004; <b>41</b> :807–20	Not orthotic intervention
Dandurand E, Gaurier E, Lauvin E, Soster D, Valat C. [Helping gait with ankle foot orthoses for hemiplegic patients.] <i>Kinesitherapie</i> 2011; <b>11</b> :55–60	Not primary study
Danielsson A, Sunnerhagen KS. Energy expenditure in stroke subjects walking with a carbon composite ankle foot orthosis. <i>J Rehabil Med</i> 2004; <b>36</b> :165–8	Laboratory setting only
Dao TT, Pouletaut P, Marin F, Aufaure P, Charleux F, Ho Ba Tho MC. <i>Simulation of the Gait of a Patient Specific Model of Post Polio Residual Paralysis (PPRP): Effect of the Orthosis</i> . Third International Conference on the Development of Biomedical Engineering in Vietnam, 2010	No patients with NMD or CNS condition
De Azevedo ERFBM, Cacho EWA, Alonso KC, Martin FTB, Cliquet A. <i>Kinetic and Kinematic Gait Assessment of Paraplegic Patients With and Without Ankle Foot Orthoses</i> . BIODEVICES 2010, Institute for Systems and Technologies of Information Control and Communication 3rd International Conference on Biomedical Electronics and Devices, Valencia, Spain, 20–23 January 2010, Proceedings 2010	Laboratory setting only
De Lecluse J. [Which knee-brace should be prescribed?] <i>Rhumatologie</i> 1997; <b>49</b> :191–5	Not primary study
De Moraes Barros Fucs PM, Svartman C, de Assumpcao RM. Knee flexion deformity from poliomyelitis treated by supracondylar femoral extension osteotomy. <i>Int Orthop</i> 2005; <b>29</b> :380–4	Not orthotic intervention
De Pisi F. Aids and orthoses in patients with stroke consequences. <i>Clin Exp Hypertens</i> 2006; <b>28</b> :383–5	Not primary study
De Seze MP, Bonhomme C, Daviet JC, Burguete E, Machat H, Rousseaux M, <i>et al</i> . Effect of early compensation of distal motor deficiency by the Chignon ankle-foot orthosis on gait in hemiplegic patients: a randomised pilot study. <i>Clin Rehabil</i> 2011; <b>25</b> :989–98	Not instability of the knee

Reference	Reason for exclusion
De Vries J. Evaluation of lower leg orthosis use following cerebro-vascular accident. <i>Int J Rehabil Res</i> 1991; <b>14</b> :239–43	Not instability of the knee
De Vries J. [Knee flexion extension orthosis.] <i>Orthop Tech</i> 1987:707–9	Not primary study
De Wit DC, Buurke JH, Nijlant JM, Ijzerman MJ, Hermens HJ. The effect of an ankle-foot orthosis on walking ability in chronic stroke patients: a randomised controlled trial. <i>Clin Rehabil</i> 2004; <b>18</b> :550–7	Not instability of the knee
Del Bianco JD, Fatone S. Comparison of silicone and posterior leaf spring ankle-foot orthoses in a subject with Charcot–Marie–Tooth disorder. <i>J Prosthet Orthot</i> 2008; <b>20</b> :155–62	Not instability of the knee
Dias LS, Tappit-Emas E, Boot EJ, Kelly L. The use of the reciprocating reciprocating hip-knee-ankle-foot orthosis in spina bifida the Childrens Memorial Hospital Chicago Illinois USA experience. <i>Dev Med Child Neurol</i> 1985; <b>27</b> :93–4	All participants aged < 16 years
Dlamini N, Messina S, Padua DL, Main M, Knight R, Manzur A, et al. Quality of life outcomes following rehabilitation in knee-ankle-foot orthoses (KAFOs) in Duchenne muscular dystrophy. <i>Neuromuscular Disord</i> 2005; <b>15</b> :701–2	All participants aged < 16 years
Dogan A, Mengulluoglu M, Ozgirgin N. Evaluation of the effect of ankle-foot orthosis use on balance and mobility in hemiparetic stroke patients. <i>Disabil Rehabil</i> 2011; <b>33</b> :1433–9	Not instability of the knee
Doria L, Minge M, Riedel L, Kraft M. User-centred evaluation of lower-limb orthoses: a new approach. <i>Biomed Tech (Berl)</i> 2013; <b>58</b>	Laboratory setting only
Dos Anjos Fernandes N, Troise DC, Favero FM, Fontes SV, Oliveira ASB. [The importance of orthosis for the lower limbs in Duchenne muscular dystrophy.] <i>Revista Neurociências</i> 2012; <b>20</b> :584–7	Not primary study
Dubowitz V. Clinical myology at the crossroads; the gospel truth. <i>Neuromuscul Disord</i> 2010; <b>20</b> :95–6	Not primary study
Dufek JS, Neumann ES, Hawkins MC, O'Toole B. Functional and dynamic response characteristics of a custom composite ankle foot orthosis for Charcot–Marie–Tooth patients. <i>Gait Posture</i> 2014; <b>39</b> :308–13	Not instability of the knee
Dunlap HV, MacNeil LG, Tarnopolsky MA. Functional impairment in patients with sporadic inclusion body myositis. <i>Can J Neurol Sci</i> 2014; <b>41</b> :253–9	Not orthotic intervention
Dunsky A, Dickstein R, Marcovitz E, Levy S, Deutsch JE. Home-based motor imagery training for gait rehabilitation of people with chronic poststroke hemiparesis. <i>Arch Phys Med Rehabil</i> 2008; <b>89</b> :1580–8	Not orthotic intervention
Dwivedi M, Shetty KD, Nath LN. Design and development of anthropometric device for the standardization of sizes of knee-ankle-foot orthoses. <i>J Med Eng Technol</i> 2009; <b>33</b> :87–94	Not orthotic intervention
Edberg E. Paralytic dysfunction. IV. Bracing for patients with traumatic paraplegia. <i>Phys Ther</i> 1967; <b>47</b> :818–23	Not primary study
Edelstein JE. Ambulatory KAFOs: a physical therapist's perspective. <i>J Prosthet Orthot</i> 2006; <b>7</b> :183–6	Not primary study
Edelstein JE. Orthotic options for standing and walking. <i>Top Spinal Cord Inj Rehabil</i> 2000; <b>5</b> :11–23	Not primary study
Eng JJ, Pierrynowski MR. Effect of foot orthotics on the kinematics of the knee joint. <i>J Biomech</i> 1989; <b>22</b> :1007	All participants aged < 16 years
Erel S, Uygur F, Engin Simsek I, Yakut Y. The effects of dynamic ankle-foot orthoses in chronic stroke patients at three-month follow-up: a randomized controlled trial. <i>Clin Rehabil</i> 2011; <b>25</b> :515–23	Not instability of the knee
Esquenazi A, Coulter T, Packel A, Saulino M, Talaty M. Safety and performance evaluation of rewalk reciprocating gait orthosis. <i>PM R</i> 2010; <b>1</b> :S158–9	Not orthotic intervention
Farncombe PM. The Swedish knee cage. Management of the hyperextended hemiplegic knee. <i>Physiotherapy</i> 1980; <b>66</b> :33–4	Not orthotic intervention
Farris RJ, Quintero HA, Murray SA, Ha KH, Hartigan C, Goldfarb M. A preliminary assessment of legged mobility provided by a lower limb exoskeleton for persons with paraplegia. <i>IEEE Trans Rehabil Eng</i> 2014; <b>22</b> :482–90	Laboratory setting only

Reference	Reason for exclusion
Farris RJ, Quintero HA, Goldfarb M. Performance evaluation of a lower limb exoskeleton for stair ascent and descent with paraplegia. <i>Conf Proc IEEE Eng Med Biol Soc</i> 2012:1908–11	Laboratory setting only
Farris RJ, Quintero HA, Goldfarb M. Preliminary evaluation of a powered lower limb orthosis to aid walking in paraplegic individuals. <i>IEEE Trans Neural Syst Rehabil Eng</i> 2011; <b>19</b> :652–9	Laboratory setting only
Fatone S. A review of the literature pertaining to KAFOs and HKAFOS for ambulation. <i>J Prosthet Orthot</i> 2006; <b>18</b> :P137–68	Not primary study
Fatone S, Gard SA, Malas BS. Effect of ankle-foot orthosis alignment and foot-plate length on the gait of adults with poststroke hemiplegia. <i>Arch Phys Med Rehabil</i> 2009; <b>90</b> :810–18	Not instability of the knee
Felmet G, Piro M. [Report of orthopedic technical experience: 2.5 years with the ULTRATECH knee orthosis.] <i>Orthop Tech</i> 1995:407–15	No patients with NMD or CNS condition
Fengler Reinoud KB, Holtslag Herman R. Compensating weakness of the quadriceps muscles due to poliomyelitis using a custom-made orthopedic shoe. <i>J Prosthet Orthot</i> 2011; <b>23</b> :199–203	Not primary study
Ferguson KA, Polando G, Kobetic R, Triolo RJ, Marsolais EB. Walking with a hybrid orthosis system. <i>Spinal Cord</i> 1999; <b>37</b> :800–4	Not orthotic intervention
Finger S, Paulos LE. Clinical and biomechanical evaluation of the unloading brace. <i>J Knee Surg</i> 2002; <b>15</b> :155–8	No patients with NMD or CNS condition
Fisher LR, McLellan DL. Questionnaire assessment of patient satisfaction with lower limb orthoses from a district hospital. <i>Prosthet Orthot Int</i> 1989; <b>13</b> :29–35	No patients with NMD or CNS condition
Fishman A, Kudelka AP, Tresukosol D, Edwards CL, Freedman RS, Kaplan AL, et al. Leuprolide acetate for treating refractory or persistent ovarian granulosa cell tumor. <i>J Reprod Med</i> 1996; <b>41</b> :393–6	Not orthotic intervention
Flandry F, Burke S, Roberts JM, Hall S, Drouilhet A, Davis G, et al. Functional ambulation in myelodysplasia: the effect of orthotic selection on physical and physiologic performance. <i>J Pediatr Orthop</i> 1986; <b>6</b> :661–5	All participants aged < 16 years
Forin V. Lower limb orthosis and standing position in neuromuscular disease: indications, limits, contraindications, modalities, expected benefits. <i>Ann Readapt Med Phys</i> 2001; <b>44</b> :225–8	Not primary study
Franceschini M, Baratta S, Zampolini M, Loria D, Lotta S. Reciprocating gait orthoses: a multicenter study of their use by spinal cord injured patients. <i>Arch Phys Med Rehabil</i> 1997; <b>78</b> :582–6	All participants aged < 16 years
Freeman D, Orendurff M, Moor M. Case study: improving knee extension with floor-reaction ankle-foot orthoses in a patient with myelomeningocele and 20 degree knee flexion contractures. <i>J Prosthet Orthot</i> 1999; <b>11</b> :63–8	All participants aged < 16 years
Freivogel S, Mehrholz J, Husak-Sotomayor T, Schmalohr D. Gait training with the newly developed 'LokoHelp'-system is feasible for non-ambulatory patients after stroke, spinal cord and brain injury. A feasibility study. <i>Brain Inj</i> 2008; <b>22</b> :625–32	Not orthotic intervention
Fuchs A, Doderlein L. Orthotics and cerebral palsy. Established treatments and trends in orthopaedic devices for patients with cerebral palsy. <i>Orthopade</i> 2004; <b>33</b> :1173–82	All participants aged < 16 years
Furia JP, Willis FB, Shanmugam R, Curran SA. Systematic review of contracture reduction in the lower extremity with dynamic splinting. <i>Adv Ther</i> 2013; <b>30</b> :763–70	Not primary study
Galvez JA, Budovitch A, Harkema SJ, Reinkensmeyer DJ. Trainer variability during step training after spinal cord injury: Implications for robotic gait-training device design. <i>J Rehabil R D</i> 2011; <b>48</b> :147–60	Not orthotic intervention
Galvez JA, Budovitch A, Harkema SJ, Reinkensmeyer DJ. Quantification of therapists' manual assistance on the leg during treadmill gait training with partial body-weight support after spinal cord injury. <i>Conf Proc IEEE Eng Med Biol Soc</i> 2007:4028–32	Not orthotic intervention
Garralda ME, Muntoni F, Cunniff A, Caneja AD. Knee-ankle-foot orthosis in children with Duchenne muscular dystrophy: user views and adjustment. <i>Eur J Paediatr Neurol</i> 2006; <b>10</b> :186–91	All participants aged < 16 years
Gatti MA, Freixes O, Fernandez SA, Rivas ME, Crespo M, Waldman SV, et al. Effects of ankle foot orthosis in stiff knee gait in adults with hemiplegia. <i>J Biomech</i> 2012; <b>45</b> :2658–61	Not instability of the knee

Reference	Reason for exclusion
Gatti MA, Sundblad M, Freixes O, Fernández SA, Olmos LE, Rubel IF. Usage follow-up after a knee-ankle-foot orthoses selection and training program in spinal cord injury patients. <i>J Prosthet Orthot</i> 2010; <b>22</b> :146–9	Background
Genda E, Oota K, Suzuki Y, Koyama K, Kasahara T. A new walking orthosis for paraplegics: hip and ankle linkage system. <i>Prosthet Orthot Int</i> 2004; <b>28</b> :69–74	Not primary study
Genet F, Schnitzler A, Mathieu S, Autret K, Thefenne L, Dizien O, <i>et al.</i> Orthotic devices and gait in polio patients. <i>Ann Phys Rehabil Med</i> 2010; <b>53</b> :51–9	Not primary study
Geurts MA, Boog GJ, van der Graaff L, Meyer JW, Janssen M. Neuro-arthropathy, a painless but very destructive disorder of frequently one joint. <i>Ned Tijdschr Geneeskd</i> 1996; <b>140</b> :1869–72	No patients with NMD or CNS condition
Gharooni S, Heller B, Tokhi MO. A new hybrid spring brake orthosis for controlling hip and knee flexion in the swing phase. <i>IEEE Trans Rehabil Eng</i> 2001; <b>9</b> :106–7	No patients with NMD or CNS condition
Glinn JE, Huckert G. Building bridges. <i>Rehab Manag</i> 2005; <b>18</b> :34, 36	Unavailable
Gombert C, Percebois-Macadre L, Tambosco L, Rapin A, Belassian G, Coulon JM, <i>et al.</i> Osteoclasia following femoral condylar fracture in a patient suffering from poliomyelitis sequelae. <i>Ann Phys Rehabil Med</i> 2011; <b>54</b> :e26–7	Not orthotic intervention
Goodman MJ, Menown JL, West JM, Barr KM, Vander Linden DW, McMulkin ML. Secondary gait compensations in individuals without neuromuscular involvement following a unilateral imposed equinus constraint. <i>Gait Posture</i> 2004; <b>20</b> :238–44	No patients with NMD or CNS condition
Goodwin V, Jones-Hughes T, Thompson-Coon J, Boddy K, Stein K. Implementing the evidence for preventing falls among community-dwelling older people: a systematic review. <i>J Safety Res</i> 2011; <b>42</b> :443–51	Not primary study
Grant AD, Atar D, Lehman WB. Postpoliomyelitis syndrome problems of knee function: a review. <i>Bull Hosp Jt Dis</i> 1995; <b>53</b> :27–9	Not primary study
Greene PJ, Granat MH. A knee and ankle flexing hybrid orthosis for paraplegic ambulation. <i>Med Eng Phys</i> 2003; <b>25</b> :539–45	Laboratory setting only
Greene WB. Treatment of hip and knee problems in myelomeningocele. <i>J Bone Joint Surg Am</i> 1998; <b>80</b> :1068–82	Not primary study
Grimby G, Li J, Vandenakker C, Sandel ME. Post-polio syndrome: a perspective from three countries. <i>PM R</i> 2009; <b>1</b> :1035–40	Not primary study
Grissom SP, Blanton S. Treatment of upper motoneuron plantarflexion contractures by using an adjustable ankle-foot orthosis. <i>Arch Phys Med Rehabil</i> 2001; <b>82</b> :270–3	Not instability of the knee
Groah SL, Cifu DX. The rehabilitative management of the traumatic brain injury patient with associated femoral neuropathy. <i>Arch Phys Med Rehabil</i> 1995; <b>76</b> :480–3	Not orthotic intervention
Guenther N. Below-knee Orthotic Device. United States Patent No. US 7,112,180 B2. 2006.	Not primary study
Guse ST, Alvine FG. Treatment of diabetic foot ulcers and Charcot neuroarthropathy using the patellar tendon-bearing brace. <i>Foot Ankle Int</i> 1997; <b>18</b> :675–7	Not instability of the knee
Hachisuka K, Arai K, Arai M. Carbon fibre reinforced plastic knee-ankle-foot orthosis with a partially flexible thigh cuff: a modification for comfort while sitting on a toilet seat. <i>Prosthet Orthot Int</i> 2007; <b>31</b> :133–7	Not primary study
Hahn HR. Lower extremity bracing in paraplegics with usage follow-up. <i>Paraplegia</i> 1970; <b>8</b> :147–53	All participants aged < 16 years
Handford F. Handford knee brace. <i>Physiotherapy</i> 1987; <b>73</b> :254	No outcomes reported
Hebela N, Keenan MA. Neuro-orthopedic management of the dysfunctional extremity in upper motor neuron syndromes. <i>Eura Medicophys</i> 2004; <b>40</b> :145–56	Not orthotic intervention
Hebert JS. Ambulatory KAFOs: a physiatry perspective. <i>J Prosthet Orthot</i> 2006; <b>74</b>	Not primary study
Hebert JS, Liggins AB. Gait evaluation of an automatic stance-control knee orthosis in a patient with postpoliomyelitis. <i>Arch Phys Med Rehabil</i> 2005; <b>86</b> :1676–80	Laboratory setting only
Hebert JS, Liggins AB. Post-polio gait with an automatic stance control KAFO a case study. <i>Gait Posture</i> 2004; <b>20</b> (Suppl. 1):42–3	Laboratory setting only



Reference	Reason for exclusion
Heinemann AW, Magiera-Planey R, Schiro-Geist C, Gimines G. Mobility for persons with spinal cord injury: an evaluation of two systems. <i>Arch Phys Med Rehabil</i> 1987; <b>68</b> :90–3	Not primary study
Heizer D. Structural insufficiency. 3. Bracing design for knee joint instability. <i>Phys Ther</i> 1967; <b>47</b> :859–63	Not primary study
Herr H, Kornbluh R. New Horizons for Orthotic and Prosthetic Technology: Artificial Muscle for Ambulation. In Bar-Cohen Y, editor. <i>Proc SPIE 5385, Smart Structures and Materials 2004: Electroactive Polymer Actuators and Devices (EAPAD)</i> , 27 July 2004	Not instability of the knee
Heydarian K, Akbarnia BA, Jabalameli M, Tabador K. Posterior capsulotomy for the treatment of severe flexion contractures of the knee. <i>J Pediatr Orthop</i> 1984; <b>4</b> :700–4	Not orthotic intervention
Hijmans JM, Geertzen JHB. Development of clinical guidelines for the prescription of orthoses in patients with neurological disorders in the Netherlands. <i>Prosthet Orthot Int</i> 2006; <b>30</b> :35–43	Not primary study
Hockin J, Banister G. The extended role of a physiotherapist in an out-patient orthopaedic clinic. <i>Physiotherapy</i> 1994; <b>80</b> :281–4	Not orthotic intervention
Hong C, San Luis EB, Chung S. Follow-up study on the use of leg braces issued to spinal cord injury patients. <i>Paraplegia</i> 1990; <b>28</b> :172–7	No outcomes reported
Horwood A. Lateral wedges. <i>Podiatry Now</i> 2012; <b>15</b> :48	Unavailable
Hruby V. Simple supporting device for genu valgum, genu varum and the unstable knee joint. <i>Zdrav Prac</i> 1974; <b>24</b> :685	not primary study
Hsu CC, Chen JS. <i>On the Design and Implementation of a Wearable Hybrid Assisted Lower Limb Orthosis</i> . Proceedings of the 2011 2nd International Congress on Computer Applications and Computational Science, Tuban, Indonesia, 15–17 November 2011. pp. 43–51	No patients with NMD or CNS condition
Hung JW, Chen PC, Yu MY, Hsieh YW. Long-term effect of an anterior ankle-foot orthosis on functional walking ability of chronic stroke patients. <i>Am J Phys Med Rehabil</i> 2011; <b>90</b> :8–16	Not instability of the knee
Hurley EA. Use of KAFOs for patients with cerebral vascular accident, traumatic brain injury, and spinal cord injury. <i>J Prosthet Orthot</i> 2006; <b>20</b> 1	Not primary study
Hussey RW, Stauffer ES. Spinal cord injury: requirements for ambulation. <i>Arch Phys Med Rehabil</i> 1973; <b>54</b> :544–7	No outcomes reported
Hwang S, Kang S, Cho K, Kim Y. Biomechanical effect of electromechanical knee-ankle-foot-orthosis on knee joint control in patients with poliomyelitis. <i>Med Biol Eng Comput</i> 2008; <b>46</b> :541–9	Laboratory setting only
Ijzerman MJ, Baardman G, Hermens HJ, Veltink PH, Boom HB, Zilvold G. Comparative trials on hybrid walking systems for people with paraplegia: an analysis of study methodology. <i>Prosthet Orthot Int</i> 1999; <b>23</b> :260–73	Not primary study
Inaba M. Control dysfunction. 3. Bracing the unstable knee and ankle in hemiplegia. <i>Phys Ther</i> 1967; <b>47</b> :838–43	No patients with NMD or CNS condition
Irby SE, Bernhardt KA, Kaufman KR. Gait of stance control orthosis users: the dynamic knee brace system. <i>Prosthet Orthot Int</i> 2005; <b>29</b> :269–82	All participants aged < 16 years
IRCT201101015520N1. <i>Comparison of Pressure Distribution Among Three Kind of AFOs</i> . 2011	No patients with NMD or CNS condition
IRCT201206295520N7. <i>A Comparison between the Effects of Hip Flexion Assist Orthosis and Conventional Ankle Foot Orthosis on Walking in Multiple Sclerosis Patients</i> . 2012	Laboratory setting only
ISRCTN21404893. <i>Ankle-foot Orthoses by Laser-Scanning or Existing Methods</i> . 2010	Not instability of the knee
ISRCTN52126764. <i>Biomechanics Visualisation in Ankle-foot Orthoses (AFO) Tuning for Stroke</i> . 2011	Not orthotic intervention
ISRCTN61814249. <i>A Pilot Study of a Cross Trial with Randomised use of Ankle Foot Orthoses and Ligaflex for People with CMT Disease</i> . 2006	Not instability of the knee
ISRCTN72463123. <i>Clinical Trial to Compare Electrical Stimulation and the Conventional Ankle-foot Orthosis (AFO) in the Treatment of Dropped Foot Following Stroke</i> . 2001	Not instability of the knee

Reference	Reason for exclusion
ISRCTN94187624. <i>The Effect of Two Different Ankle-foot-orthoses on Walking and Quality of Life in Children with Hereditary Motor and Sensory Neuropathy (HMSN) – Also Known as Charcot-Marie Tooth (CMT) Disease</i> . 2005	All participants aged < 16 years
Itokazu M, Yamamoto S. Examination of gait improvement in spina bifida elicited by an ankle-foot orthosis with double-braking function. <i>Rigakuryoho Kagaku</i> 2011; <b>26</b> :69–74	All participants aged < 16 years
Iwata Y, Sakamoto T, Maruyama A, Tateishi T, Yorimoto K, Yajima H, <i>et al.</i> Utility of subjective pain scales for assessments of standing with knee-ankle-foot-orthoses in Duchenne muscular dystrophy. <i>Neuromuscul Disord</i> 2012; <b>22</b> :880	All participants aged < 16 years
Jaeger RJ. Electromyographic activity in paraplegic individuals during standing in knee-ankle-foot orthoses. <i>Abstr Soc Neurosci</i> 1984; <b>10</b> :904	Not orthotic intervention
Jagadamma KC, Owen E, Coutts FJ, Herman J, Yirrell J, Mercer TH, <i>et al.</i> The effects of tuning an ankle-foot orthosis footwear combination on kinematics and kinetics of the knee joint of an adult with hemiplegia. <i>Prosthet Orthot Int</i> 2010; <b>34</b> :270–6	Not primary study
Jarrod-Gaudes R, Rodríguez-Pérez A, Hidalgo-Mendía B, Bouzas-Pérez D, Ruiz-Alejos Garrido S, Muro-Martínez de Quel J. [KAFO orthosis in glass fibre in patient with hemiparesis and hemiagnosia in post-cerebral stroke.] <i>Rehabilitacion</i> 2008; <b>42</b> :153–7	Not orthotic intervention
Johnson WB, Fatone S, Gard SA. Walking mechanics of persons who use reciprocating gait orthoses. <i>J Rehabil Res Dev</i> 2009; <b>46</b> :435–46	No patients with NMD or CNS condition
Jones Oen, K, Myhr KM, Rundhovde Skar AB, Moen Brandal K, Smedal T. WalkAide: a multidisciplinary model for adjustment and evaluation (#46). <i>Multiple Sclerosis</i> 2012; <b>18</b> :S30	Not instability of the knee
JPRN-UMIN000007422. <i>The Effect of an Ankle-foot Orthosis with Dorsiflexion Resistance on Stance Phase in Hemiplegic Gait</i> . 2012	No outcomes reported
JPRN-UMIN000010308. <i>The Real-Time Effect of Double Upright Ankle Foot Orthosis for Walking Ability with Acute Hemiplegic Patients</i> . 2013	Not instability of the knee
JPRN-UMIN000010917. <i>Development of Ankle Foot Orthosis by applying Magnetic Rheological Fluid Brake</i> . 2013	Not orthotic intervention
Junn C, Groah SL. Rehabilitation of severe guillain-barre syndrome resembling clinical brain death: a case report. <i>PM R</i> 2012; <b>1</b> :S280	Not orthotic intervention
Kameyama S, Osawa A, Maeshima S, Takeda K, Hirano Y, Nishio D, <i>et al.</i> Refinement of the knee ankle foot orthosis for stroke patients with severe hemiplegia. <i>Int J Stroke</i> 2010; <b>5</b> :292	Not orthotic intervention
Kaneko K, Koshi A, Matsuda Y, Kondoh K. Development of knee ankle foot orthosis made of magnesium alloy with high strength and toughness. <i>Keikinzo</i> 2008; <b>58</b> :617–21	No patients with NMD or CNS condition
Kaoru A. Comparison of static balance, walking velocity, and energy consumption with knee-ankle-foot orthosis, walkabout orthosis, and reciprocating gait orthosis in thoracic-level paraplegic patients. <i>J Prosthet Orthot</i> 2006; <b>18</b> :6	Laboratory setting only
Kaplan LI, Grynbaum BB, Rusk HA, Anastasia T, Gassler S. A reappraisal of braces and other mechanical aids in patients with spinal cord dysfunction: results of a follow-up study. <i>Arch Phys Med Rehabil</i> 1966; <b>47</b> :393–405	No patients with NMD or CNS condition
Karimi MT. The physiological benefits and problems associated with using standing and walking orthoses in individuals with spinal cord injury-a meta-analytic review. <i>JOTR</i> 2012; <b>16</b> :37–40	Not primary study
Karimi MT. What are the next steps in designing an orthosis for paraplegic subjects? <i>Int J Prev Med</i> 2012; <b>3</b> :145–59	Not primary study
Karimi MT, Mostamand J, Fatoye F. The use of motion analysis system and orthosis in patients with neuro-musculoskeletal disorders. <i>J Mech Med Biol</i> 2014; <b>14</b>	No patients with NMD or CNS condition
Karimi MT, Amiri P, Esrafilian A, Sedigh J, Fatoye F. Performance of spinal cord injury individuals while standing with the Mohammad Taghi Karimi reciprocal gait orthosis (MTK-RGO). <i>Australas Phys Eng Sci Med</i> 2013; <b>36</b> :35–42	Laboratory setting only
Kaufman KR, Irby SE. Ambulatory KAFOs: a biomechanical engineering perspective. <i>J Prosthet Orthot</i> 2006; <b>82</b>	Not primary study
Kaufman KR, Irby SE, Mathewson JW, Wirta BW, Sutherland DH. Energy-efficient knee-ankle-foot orthosis: a case study. <i>J Prosthet Orthot</i> 1996; <b>8</b> :79–85	Laboratory setting only



Reference	Reason for exclusion
Kawamoto H, Taal S, Niniss H, Hayashi T, Kamibayashi K, Eguchi K, Sankai Y. Voluntary motion support control of Robot Suit HAL triggered by bioelectrical signal for hemiplegia. <i>Conf Proc IEEE Eng Med Biol Soc</i> 2010;462–6	Not orthotic intervention
Kawamoto H, Hayashi T, Sakurai T, Eguchi K, Sankai Y. Development of single leg version of HAL for hemiplegia. <i>Conf Proc IEEE Eng Med Biol Soc</i> 2009;5038–43	Not orthotic intervention
Kelleher KJ, Spence WD, Solomonidis S, Apatsidis D. The effect of textured insoles on gait patterns of people with multiple sclerosis. <i>Gait Posture</i> 2010; <b>32</b> :67–71	Not instability of the knee
Kent HO. Vannini-Rizzoli stabilising orthosis (boot): preliminary report on a new ambulatory aid for spinal cord injury. <i>Arch Phys Med Rehabil</i> 1992; <b>73</b> :302–7	Not instability of the knee
Kesikburun S, Koroglu Omac O, Yasar E, Yilmaz B, Kenan Tan A. Ultrasound guided block of the saphenous neuroma following use of an AFO in a patient with paraplegia. A case report. <i>Eur J Phys Rehabil Med</i> 2014; <b>50</b> :197–86	Not instability of the knee
Khanna I, Roy A, Rodgers MM, Krebs HI, Macko RM, Forrester LW. Effects of unilateral robotic limb loading on gait characteristics in subjects with chronic stroke. <i>J Neuroeng Rehabil</i> 2010; <b>7</b> :23	Laboratory setting only
Kim CM, Eng JJ, Whittaker MW. Effects of a simple functional electric system and/or a hinged ankle-foot orthosis on walking in persons with incomplete spinal cord injury. <i>Arch Phys Med Rehabil</i> 2004; <b>85</b> :1718–23	Not instability of the knee
Kim DH, Joa KL, Shin YK, Lee JJ. Immediate effect of Walkbot robotic gait training on neuromechanical knee stiffness in spastic hemiplegia: a case report. <i>NeuroRehabilitation</i> 2013; <b>32</b> :833–8	Not orthotic intervention
Kim G, Kang S, Kang S, Ryu J, Mun M, Kim K. Unlockable knee joint mechanism for powered gait orthosis. <i>Int J Precis Eng Man</i> 2009; <b>10</b> :83–9	Not orthotic intervention
Kimishima K, Hachisuka K, Ogata H, Tanaka S, Tajima F. Supracondylar knee-ankle-foot orthosis for post-polio syndrome. <i>J UOEH</i> 1991; <b>13</b> :251–5	Not orthotic intervention
Kinali M, Main M, Eliahoo J, Messina S, Knight RK, Lehovsky J, et al. Predictive factors for the development of scoliosis in Duchenne muscular dystrophy. <i>Eur J Paediatr Neurol</i> 2007; <b>11</b> :160–6	All participants aged < 16 years
Kirtley C. Principles and practice of paraplegic locomotion: experience with the walkabout walking system. <i>Aust Orthotics Prosthet Mag</i> 1992; <b>7</b> :4–8	Unavailable
Kobayashi T, Leung AK, Akazawa Y, Hutchins SW. The effect of varying the plantarflexion resistance of an ankle-foot orthosis on knee joint kinematics in patients with stroke. <i>Gait Posture</i> 2013; <b>37</b> :457–9	Laboratory setting only
Kobayashi H, Hashimoto T, Nakayama S, Irie K. Development of an active walker and its effect. <i>JMR</i> 2012; <b>24</b> :275–83	Laboratory setting only
Kobetic R, To CS, Schnellenberger JR, Audu ML, Bulea TC, Gaudio R, et al. Development of hybrid orthosis for standing, walking, and stair climbing after spinal cord injury. <i>J Rehabil R D</i> 2009; <b>46</b> :447–62	Not orthotic intervention
Kobetic R, Marsolais EB, Triolo RJ, Davy DT, Gaudio R, Tashman S. Development of a hybrid gait orthosis: a case report. <i>J Spinal Cord Med</i> 2003; <b>26</b> :254–8	Not orthotic intervention
Kobetic R, Marsolais EB, Triolo RJ, Davy DT, Gaudio R, Tashman S. Technical perspective development of a hybrid gait orthosis: a case report. <i>J Spinal Cord Med</i> 2003; <b>26</b> :254–8	Not orthotic intervention (duplicate publication)
Kofman J, Allard P, Sibille J, Duhaime M, Vanasse M. <i>A Spring-loaded Knee-ankle Orthosis in the Management of Duchenne Muscular Dystrophy Patients</i> . Second International Conference on Rehabilitation Engineering, Ottawa, ON, Canada, 1984. pp. 255–6	Unavailable
Kottink AI, Tenniglo MJ, de Vries WH, Hermens HJ, Buurke JH. Effects of an implantable two-channel peroneal nerve stimulator versus conventional walking device on spatiotemporal parameters and kinematics of hemiparetic gait. <i>J Rehabil Med</i> 2012; <b>44</b> :51–7	Not orthotic intervention
Kottink AI, Hermens HJ, Nene AV, Tenniglo MJ, Groothuis-Oudshoorn CG, IJzerman MJ. Therapeutic effect of an implantable peroneal nerve stimulator in subjects with chronic stroke and footdrop: a randomized controlled trial. <i>Phys Ther</i> 2008; <b>88</b> :437–48	Not orthotic intervention

Reference	Reason for exclusion
Koutsou AD, Rocon E, Pons JL, Moreno JC. Output-error model system identification for FES-driven control of knee extensor muscles. <i>Artif Organs</i> 2010; <b>34</b> :A42	No outcomes reported
Krishnamoorthy V, Hsu WL, Kesar TM, Benoit DL, Banala SK, Perumal R, <i>et al.</i> Gait training after stroke: a pilot study combining a gravity-balanced orthosis, functional electrical stimulation, and visual feedback. <i>J Neurol Phys Ther</i> 2008; <b>32</b> :192–202	Not orthotic intervention
Krishnan C, Ranganathan R, Dhaher YY, Rymer WZ. A pilot study on the feasibility of robot-aided leg motor training to facilitate active participation. <i>PLOS ONE</i> 2013; <b>8</b>	Not orthotic intervention
Kuhn DR, Yochum TR, Cherry AR, Rodgers SS. Immediate changes in the quadriceps femoris angle after insertion of an orthotic device. <i>J Manipulative Physiol Ther</i> 2002; <b>25</b> :465–70	Not instability of the knee
La Torre RR, Richards M, Ramcharran S. Ischial thigh knee ankle orthosis. <i>Orthotics Prosthet</i> 1973; <b>27</b> :3–8	No outcomes reported
Laffont I, Julia M, Tiffreau V, Yelnik A, Herisson C, Pelissier J. Aging and sequelae of poliomyelitis. <i>Ann Phys Rehabil Med</i> 2010; <b>53</b> :24–33	Not primary study
Lam WK, Leong JC, Li YH, Hu Y, Lu WW. Biomechanical and electromyographic evaluation of ankle foot orthosis and dynamic ankle foot orthosis in spastic cerebral palsy. <i>Gait Posture</i> 2005; <b>22</b> :189–97	All participants aged < 16 years
Lampe R, Mitternacht J, SchrodL S, Gerdesmeyer L, Natrath M, Gradinger R. Influence of orthopaedic-technical aid on the kinematics and kinetics of the knee joint of patients with neuro-orthopaedic diseases. <i>Brain Dev</i> 2004; <b>26</b> :219–26	All participants aged < 16 years
Lan Y, Xu GQ, Huang DF, Mao YR, Chen SZ, Pei Z, <i>et al.</i> Association between improved trunk stability and walking capacity using ankle-foot orthosis in hemiparetic patients with stroke: evidence from three-dimensional gait analysis. <i>Chin Med J</i> 2013; <b>126</b> :3869–73	Laboratory setting only
Landsman A, Defronzo D, Anderson J, Roukis T. Scientific assessment of over-the-counter foot orthoses to determine their effects on pain, balance, and foot deformities. <i>J Am Podiat Med Assoc</i> 2009; <b>99</b> :206–15	Not instability of the knee
LeBlanc MA. Clinical evaluation of a comprehensive approach to below knee orthotics. <i>Orthotics Prosthet</i> 1973; <b>27</b> :20–35	No outcomes reported
Lee DY, Choi IH, Chung CY, Shim JS. A modified Wagner technique for femoral lengthening in skeletally mature patients with poliomyelitis. <i>Int Orthop</i> 1993; <b>17</b> :154–7	Not orthotic intervention
Lee KH, Johnston R. Effect of below-knee bracing on knee movement: biomechanical analysis. <i>Arch Phys Med Rehabil</i> 1974; <b>55</b> :179–82	No patients with NMD or CNS condition
Lee KH, Johnston R. Bracing below the knee for hemiplegia: biomechanical analysis. <i>Arch Phys Med Rehabil</i> 1973; <b>54</b> :466–70	No outcomes reported
Lefebvre R, Boucher JP. Effects of foot orthotics upon the ankle and knee mechanical alignment. <i>J Biomech</i> 1989; <b>22</b> :1046	No patients with NMD or CNS condition
Lehmann JF. Push-off and propulsion of the body in normal and abnormal gait. Correction by ankle-foot orthoses. <i>Clin Orthop Relat Res</i> 1993; <b>288</b> :97–108	Not primary study
Lehmann JF. Biomechanics of ankle-foot orthoses: prescription and design. <i>Arch Phys Med Rehabil</i> 1979; <b>60</b> :200–7	No outcomes reported
Lehmann JF, Stonebridge JB. Knee lock device for knee ankle orthoses for spinal cord injured patients: an evaluation. <i>Arch Phys Med Rehabil</i> 1978; <b>59</b> :207–11	Not primary study
Lehmann JF, Stonebridge JB, deLatuer BJ. Pneumatic and standard double upright orthoses: comparison of their biomechanical function in three patients with spinal cord injuries. <i>Arch Phys Med Rehabil</i> 1977; <b>58</b> :72–80	Laboratory setting only
Lehmann JF, Warren CG. Restraining forces in various designs of knee ankle orthoses: their placement and effect on the anatomical knee joint. <i>Arch Phys Med Rehabil</i> 1976; <b>57</b> :430–7	Laboratory setting only
Lehmann JF, Warren CG. Ischial and patellar tendon weight bearing braces: function, design, adjustment, and training. <i>Bull Prosthet Res</i> 1973; <b>19</b> :6–19	No patients with NMD or CNS condition
Lehmann JF, deLateur BJ, Price R. Knee-ankle-foot orthoses for paresis and paralysis. <i>Phys Med Rehabil Clin N Am</i> 1992; <b>3</b> :161–83	Not primary study

Reference	Reason for exclusion
Lehmann JF, Condon SM, Price R, deLateur BJ. Gait abnormalities in hemiplegia: their correction by ankle-foot orthoses. <i>Arch Phys Med Rehabil</i> 1987; <b>68</b> :763–71	Not primary study
Lehmann JF, Condon SM, deLateur BJ, Price R. Gait abnormalities in peroneal nerve paralysis and their corrections by orthoses: a biomechanical study. <i>Arch Phys Med Rehabil</i> 1986; <b>67</b> :380–6	No patients with NMD or CNS condition
Lehmann JF, Condon SM, deLateur BJ, Smith JC. Gait abnormalities in tibial nerve paralysis: a biomechanical study. <i>Arch Phys Med Rehabil</i> 1985; <b>66</b> :80–5	No patients with NMD or CNS condition
Lehmann JF, Ko MJ, deLateur BJ. Origin of knee moments during ambulation and their modification by ankle foot orthoses. <i>J Biomech</i> 1983; <b>16</b> :283–4	No patients with NMD or CNS condition
Lehmann JF, Esselman PC, Ko MJ, Smith JC, deLateur BJ, Dralle AJ. Plastic ankle-foot orthoses: evaluation of function. <i>Arch Phys Med Rehabil</i> 1983; <b>64</b> :402–7	Not instability of the knee
Lehmann JF, Ko MJ, deLateur BJ. Knee moments: origin in normal ambulation and their modification by double-stopped ankle-foot orthoses. <i>Arch Phys Med Rehabil</i> 1982; <b>63</b> :345–51	No patients with NMD or CNS condition
Lehmann JF, Ko MJ, deLateur BJ. Origin of knee moments during ambulation and their modification by ankle-foot orthoses. <i>Arch Phys Med Rehabil</i> 1982; <b>63</b> :523	No patients with NMD or CNS condition
Lehmann JF, Warren CG, Hertling D, McGee M, Simons BC, Dralle A. Craig-Scott orthosis: a biochemical and functional evaluation. <i>Arch Phys Med Rehabil</i> 1976; <b>57</b> :438–42	Laboratory setting only
Lehmann JF, Warren CG, Kirkpatr G. Distribution of forces on leg in various designs of foot-ankle-knee orthoses. <i>Arch Phys Med Rehabil</i> 1973; <b>54</b> :586	Laboratory setting only
Lehmann JF, Warren CG, deLateur BJ. A biomechanical evaluation of knee stability in below knee braces. <i>Arch Phys Med Rehabil</i> 1970; <b>51</b> :688–95	No patients with NMD or CNS condition
Lehneis HR. The Swedish knee cage. <i>Artificial Limbs</i> 1968; <b>12</b> :54–7	No outcomes reported
Lemaire ED. Mechanical and biomechanical analysis of a linear piston design for angular-velocity-based orthotic control. <i>J Rehabil R D</i> 2013; <b>50</b> :43–52	No outcomes reported
Leung AK, Wong AF, Wong EC, Hutchins SW. The Physiological Cost Index of walking with an isocentric reciprocating gait orthosis among patients with T(12)–L(1) spinal cord injury. <i>Prosthet Orthot Int</i> 2009; <b>33</b> :61–8	Laboratory setting only
Li YFD, Hsiao-Weckler ET. Gait mode recognition using an inertial measurement unit to control an ankle-foot orthosis during stair ascent and descent. <i>IEEE Int Conf Rehabil Robot</i> 2013, June	No patients with NMD or CNS condition
Limbird TJ, Stills M, Elliott D, Wharton G. Lower extremity telescopic orthosis for immediate fitting in paraplegia. <i>Orthopedics</i> 1989; <b>12</b> :851–4	Laboratory setting only
Lister MJ. Paralytic dysfunction. II. Bracing the unstable knee in flacid paralysis. <i>Phys Ther</i> 1967; <b>47</b> :807–15	Not primary study
Liu XH. [Application of lower limb orthosis in paralysis rehabilitation.] <i>CRTER</i> 2007; <b>11</b> :6252–5	Not primary study
Lobley S, Rogerson J, Cullen J, Freed M. Orthotic design from the New England Regional Spinal Cord Injury Center. <i>Phys Ther</i> 1985; <b>65</b> :492–3	No outcomes reported
Loke M. New concepts in lower limb orthotics. <i>Phys Med Rehabil Clin N Am</i> 2000; <b>11</b> :477–96	Not primary study
Long JT, Sirota N, Klein JP, Wertsch JJ, Janisse D, Harris GF. Biomechanics of the double rocker sole shoe: gait kinematics and kinetics. <i>Conf Proc IEEE Eng Med Biol Soc</i> 2004; <b>7</b> :5107–10	No patients with NMD or CNS condition
Lotta S, Fiocchi A, Giovannini R, Silvestrin R, Tesio L, Raschi A, et al. Restoration of gait with orthoses in thoracic paraplegia: a multicentric investigation. <i>Paraplegia</i> 1994; <b>32</b> :608–15	Not instability of the knee
Lugris U, Carlin J, Luaces A, Cuadrado J. Gait analysis system for spinal cord-injured subjects assisted by active orthoses and crutches. <i>Proc Inst Mech Eng K</i> 2013; <b>227</b> :363–74	Not orthotic intervention
MacLean IC, Granger CV. Use of a short leg brace to support the knee in hemiplegia. <i>Arch Phys Med Rehabil</i> 1967; <b>48</b> :250–2	No outcomes reported
Maeshima S, Osawa A, Nishio D, Hirano Y, Takeda K, Kigawa H, et al. Efficacy of a hybrid assistive limb in post-stroke hemiplegic patients: a preliminary report. <i>BMC Neurol</i> 2011; <b>11</b> :116	Not orthotic intervention

Reference	Reason for exclusion
Maeshima S, Osawa A, Nishio D, Hirano Y, Kigawa H, Sankai Y. Ambulation support for stroke patient using the hybrid assistive limb (HAL). <i>Int J Stroke</i> 2010; <b>5</b> :298	Not primary study
Magnusson L, Ramstrand N, Fransson EI, Ahlstrom G. Mobility and satisfaction with lower-limb prostheses and orthoses among users in Sierra Leone: a cross-sectional study. <i>J Rehabil Med</i> 2014; <b>46</b> :438–46	No patients with NMD or CNS condition
Magora A, Robin GC, Rozin R, Gonen B, Saltiel J. Investigation of gait. 5. Effect of a below-knee brace on the contralateral, unbraced leg. <i>Electromyogr Clin Neurophysiol</i> 1973; <b>13</b> :355–61	No patients with NMD or CNS condition
Magora A, Robin GC, Adler E, Libai A, Eitan A. Dynamic strain analysis of below-knee orthopedic braces. A preliminary report. <i>Am J Phys Med</i> 1968; <b>47</b> :31–40	No patients with NMD or CNS condition
Major RE, Stallard J, Farmer SE. A review of 42 patients of 16 years and over using the ORLAU Parawalker. <i>Prosthet Orthot Int</i> 1997; <b>21</b> :147–52	Not instability of the knee
Maki BE, Rosen MJ, Simon SR. Modification of spastic gait through mechanical damping. <i>J Biomech</i> 1985; <b>18</b> :431–43	All participants aged < 16 years
Malas BS. What variables influence the ability of an AFO to improve function and when are they indicated? Myelomeningocele. <i>Clin Orthop Relat Res</i> 2011; <b>469</b> :1308–14	All participants aged < 16 years
Martin D, Dixon J, Hatton A, Rome K, Hodgson D, Warnett R, <i>et al.</i> Moderate/severe pain affects function in people with multiple sclerosis. <i>J Pain</i> 2011; <b>1</b> :P26	No outcomes reported
Martin D, Lamoreux L, Skinner H. An ankle-foot orthosis for dynamic alteration of varus valgus knee moments. <i>J Biomech</i> 1985; <b>18</b> :536	No outcomes reported
Martinet N, Maaref K, Paysant J. Quantitative gait analysis of polio patients walking with orthotic devices. <i>Ann Phys Rehabil Med</i> 2010; <b>53</b> :e122	Not orthotic intervention
Massucci M, Brunetti G, Piperno R, Betti L, Franceschini M. Walking with the advanced reciprocating gait orthosis (ARGO) in thoracic paraplegic patients: energy expenditure and cardiorespiratory performance. <i>Spinal Cord</i> 1998; <b>36</b> :223–7	Not instability of the knee
Mat Dzhahir MA, Nobutomo T, Yamamoto SI. Development of body weight support gait training system using pneumatic McKibben actuators: control of lower extremity orthosis. <i>Conf Proc IEEE Eng Med Biol Soc</i> 2013:6417–20	No patients with NMD or CNS condition
Matsumoto S, Kawahira K, Makita M, Nitta H, Hirao K, Fuse Y, <i>et al.</i> Effect of knee brace combined with pneumatic artificial muscles on muscle strength. <i>J Rehabil Med</i> 2012; <b>44</b> :25–6	No patients with NMD or CNS condition
Mazur JM, Sienko-Thomas S, Wright N, Cummings RJ. Swing-through vs. reciprocating gait patterns in patients with thoracic-level spina bifida. <i>Z Kinderchir</i> 1990; <b>45</b> (Suppl. 1):23–5	All participants aged < 16 years
McCall RE, Schmidt WT. Clinical experience with the reciprocal gait orthosis in myelodysplasia. <i>J Pediatr Orthop</i> 1986; <b>6</b> :157–61	All participants aged < 16 years
McCollough NC. Orthotic management in adult hemiplegia. <i>Clin Orthop Relat Res</i> 1978; <b>131</b> :38–46	Not primary study
McCollough NC. Rationale for orthotic prescription in the lower extremity. <i>Clin Orthop Relat Res</i> 1974; <b>102</b> :32–45	Not primary study
McGhee RB, Tomovic R, Yang PY, MacLean IC. An experimental study of a sensor-controlled external knee locking system. <i>IEEE Trans Biomed Eng</i> 1978; <b>25</b> :195–9	No patients with NMD or CNS condition
McHugh B, Campbell J. Below-knee orthoses. <i>Physiotherapy</i> 1987; <b>73</b> :380–5	Not primary study
McMillan AG, Kendrick K, Michael JW, Aronson J, Horton GW. Preliminary evidence for effectiveness of a stance control orthosis. <i>J Prosthet Orthot</i> 2004; <b>16</b> :6–15	Laboratory setting only
McMillan AG, Kendrick K, Zabel R, Aronson J, Horton G. Stance control orthosis to improve functional gait: a pilot study. Platform & poster presentations for CSM 2003. <i>Neurol Report</i> 2002; <b>26</b> :209	Laboratory setting only
Mefoued S. <i>Robust and Intention-based Control of an Active Orthosis for Assistance of Knee Movements</i> . Thesis. Paris: Université Paris-Est; 2012	Not orthotic intervention
Mefoued S, Mohammed S, Amirat Y. <i>Knee Joint Movement Assistance through Robust Control of an Actuated Orthosis</i> . Proceedings of the IEEE International Conference on Intelligent Robots and Systems, 2011	No patients with NMD or CNS condition

Reference	Reason for exclusion
Merkel KD, Miller NE, Merritt JL. Energy expenditure in patients with low-, mid-, or high-thoracic paraplegia using Scott-Craig knee-ankle-foot orthoses. <i>Mayo Clin Proc</i> 1985; <b>60</b> :165–8	Laboratory setting only
Merkel KD, Miller NE, Westbrook PR, Merritt JL. Energy expenditure of paraplegic patients standing and walking with two knee-ankle-foot orthoses. <i>Arch Phys Med Rehabil</i> 1984; <b>65</b> :121–4	Laboratory setting only
Merkel KD, Merritt JL, Miller NE. Energy expenditure comparison in paraplegic patients during stance and ambulation with 2 types of knee ankle foot orthoses. <i>Arch Phys Med Rehabil</i> 1981; <b>62</b> :513	Laboratory setting only
Merritt JL, Yoshida MK. Knee-ankle-foot orthoses: indications and practical applications of long leg braces. <i>Phys Med Rehabil</i> 2000; <b>14</b> :395–422	Not primary study
Meyer PR. Lower limb orthotics. <i>Clin Orthop Relat Res</i> 1974; <b>102</b> :58–71	Not primary study
Meyers AH, Lewis MM. Orthotic management of patients following limb sparing procedures. <i>Arch Phys Med Rehabil</i> 1991; <b>72</b> :783	No patients with NMD or CNS condition
Michael JW. KAFOs for ambulation: an orthotist's perspective. <i>J Prosthet Orthot</i> 2006; <b>18</b> :187–91	Not primary study
Michael JW. Summary from the Academy's seventh State-of-the-Science conference on knee-ankle-foot orthoses for ambulation. <i>J Prosthet Orthot</i> 2006; <b>18</b> :132–6	Not primary study
Michael JW, McMillan AG, Kendrick K. Stance control orthoses: history, overview and case example of improved KAFO function. <i>Alignment</i> 2003;60–70	Background
Middleton JW, Sinclair PJ, Smith RM, Davis GM. Postural control during stance in paraplegia: effects of medially linked versus unlinked knee-ankle-foot orthoses. <i>Arch Phys Med Rehabil</i> 1999; <b>80</b> :1558–65	Not primary study
Middleton JW, Fisher W, Davis GM, Smith RM. A medial linkage orthosis to assist ambulation after spinal cord injury. <i>Prosthet Orthot Int</i> 1998; <b>22</b> :258–64	Laboratory setting only
Millard JB. Automatic release knee stabilizing calliper. <i>Ann Phys Med</i> 1970; <b>10</b> :243	No outcomes reported
Miller MK, Hamill J, Ricard MD. Effect of ankle orthoses on lower extremity function. <i>Med Sci Sports Exerc</i> 1988; <b>20</b> :S55	No patients with NMD or CNS condition
Millet A, Paquin JM, Ostermann P. [Nicholas' orthosis.] <i>Revue de Readaptation Fonctionnelle Professionnelle et Sociale</i> 1982; <b>9</b> :35–43	Unavailable
Mishra DK, Daniel DM, Stone ML. The use of functional knee braces in the control of pathologic anterior knee laxity. <i>Clin Orthop Relat Res</i> 1989;213–20	No patients with NMD or CNS condition
Modisane MR, Stewart A, Riley M. The effect of a knee brace on gait parameters of hypertonic hemiplegic patients. <i>SAJPA</i> 2008; <b>64</b> :43–7	Laboratory setting only
Moreno J, Pons JL, Koutsou A. <i>The Rehabot-Knee Project approach for recovery of neuromuscular control of the knee with controllable braces</i> . Proceedings of the 10th Congress of the European Federation for Research in Rehabilitation, Riga, Latvia, 09–12 September 2009. <i>Int J Rehabil Res</i> 2009; <b>32</b> (Suppl. 1):112	No patients with NMD or CNS condition
Moreno JC, Brunetti F, Rocon E, Pons JL. Immediate effects of a controllable knee ankle foot orthosis for functional compensation of gait in patients with proximal leg weakness. <i>Med Biol Eng Comput</i> 2008; <b>46</b> :43–53	Laboratory setting only
Morinaka Y, Matsuo Y, Nojima M, Inami Y, Nojima K. Biomechanical study of a knee-ankle-foot-orthosis for hemiplegic patients. <i>Prosthet Orthot Int</i> 1984; <b>8</b> :97–9	No outcomes reported
Morinaka Y, Matsuo Y, Nojima M, Morinaka S. Clinical evaluation of a knee-ankle-foot-orthosis for hemiplegic patients. <i>Prosthet Orthot Int</i> 1982; <b>6</b> :111–15	Not primary study
Mulder AJ, Veltink PH, Boom HB, Zivold G. Low-level finite state control of knee joint in paraplegic standing. <i>J Biomed Eng</i> 1992; <b>14</b> :3–8	Not orthotic intervention
Mulroy SJ, Eberly VJ, Gronely JK, Weiss W, Newsam CJ. Effect of AFO design on walking after stroke: impact of ankle plantar flexion contracture. <i>Prosthet Orthot Int</i> 2010; <b>34</b> :277–92	Not instability of the knee

Reference	Reason for exclusion
Murray S, Goldfarb M. Towards the use of a lower limb exoskeleton for locomotion assistance in individuals with neuromuscular locomotor deficits. <i>Conf Proc IEEE Eng Med Biol Soc</i> 2012;1912–15	No patients with NMD or CNS condition
Nagarkatti DG, Banta JV, Thomson JD. Charcot arthropathy in spina bifida. <i>J Pediatr Orthop</i> 2000;20:82–7	All participants aged < 16 years
Nakamura T, Saito K, Wang ZD, Kosuge K; IEEE. <i>Realizing a Posture-based Wearable Antigravity Muscles Support System for Lower Extremities</i> . Proceedings of the IEEE 9th International Conference on Rehabilitation Robotics 2005, Chicago, IL, 28 June–1 July 2005. pp. 273–6	No patients with NMD or CNS condition
NCT00199589. <i>Treatment of Spastic Equinovarus Foot After Stroke</i> . 2005	Not instability of the knee
NCT00216320. <i>Efficacy of the WalkAide and AFOs for CVA</i> . 2005	Not instability of the knee
NCT00961103. <i>Motor Development and Orthoses in Spinal Muscular Atrophy (SMA)</i> . 2009	All participants aged < 16 years
NCT01006772. <i>Rehabilitation of Early Stroke Patients Using an AFO: An RCT</i> . 2009	Unavailable
NCT01087957. <i>WalkAide Compared to Ankle-Foot Orthosis (AFO) in Stroke Patients</i> . 2010	Not instability of the knee
NCT01251549. <i>Safety and Performance Evaluation of ReWalk Reciprocating Gait Orthosis (RGO)</i> . 2010	Laboratory setting only
NCT01320839. <i>Effects of an Ankle-Foot Orthosis on Gait While Performing an Attention Demanding Task</i> . 2011	Not instability of the knee
NCT01415700. <i>Comparison Between Implanted Functional Electrical Stimulation and Foot Orthosis</i> . 2011	Not instability of the knee
NCT01499862. <i>Mobility Training Using a Bionic Knee Orthosis in Patients Chronic Post-Stroke: A Case Series</i> . 2011	Unavailable
NCT01558232. <i>A Prospective Study to Evaluate Use of the Tibion Bionic Leg in Sub-Acute Post-stroke Patients</i> . 2012	Not orthotic intervention
NCT01626417. <i>Evaluation of Transfer Kinematics and Kinetics in Patients Chronic Post-stroke Using the Tibion Bionic Leg</i> . 2012	Unavailable
NCT01704807. <i>Duration of Spinal Manipulation Effects as Influenced by Orthotics</i> . 2012	No patients with NMD or CNS condition
NCT01723046. <i>Therapeutic Effects of a New Upper Limb Robot Assisted Therapy Device for Persons After Stroke</i> . 2012	Not instability of the knee
NCT01796860. <i>Effectiveness of Ankle Foot Orthoses on Gait in Multiple Sclerosis</i> . 2013	Unavailable
NCT01798927. <i>Effect of Lower Extremity Ankle Foot Orthoses in Parkinson's Disease</i> . 2013	Unavailable
NCT01943669. <i>Exoskeletons for Spinal Cord Injury: A Feasibility Study</i> . 2013	Not instability of the knee
NCT01947582. <i>The Effects of Ankle Foot Orthoses (AFOs) on Mobility in Persons With Multiple Sclerosis (MS)</i> . 2013	Not instability of the knee
NCT01961557. <i>Evaluating a New Knee-Ankle-Foot Brace to Improve Crouch Gait in People With Cerebral Palsy</i> . 2013	All participants aged < 16 years
NCT02089880. <i>Comparing Functional Outcomes in Individuals Using Micro-processor Controlled Orthosis Versus Stance Control Orthosis</i> . 2014	Unavailable
NCT02109393. <i>Use of Lokomat in Patients With Progressive Supranuclear Palsy</i> . 2014	No outcomes reported
NCT02113189. <i>Impact of Walking Practice on Persons With PD</i> . 2014	Not instability of the knee
NCT02122783. <i>Comparison of the Functional Walking Outcomes of Two Settings of a Commercially Available Ankle Foot Orthosis in Adult Stroke Patients</i> . 2014	Unavailable
Nolan KJ, Savalia KK, Yarossi M, Elovic EP. Evaluation of a dynamic ankle foot orthosis in hemiplegic gait: a case report. <i>Neurorehabilitation</i> 2010;27:343–50	Not primary study
NTR1930. <i>Timing of providing ankle-foot orthoses in stroke rehabilitation</i> . 2009	Unavailable



Reference	Reason for exclusion
Obinata G, Fukada S, Matsunaga T, Iwami T, Shimada Y, Miyawaki K, <i>et al.</i> Hybrid control of powered orthosis and functional neuromuscular stimulation for restoring gait. <i>Conf Proc IEEE Eng Med Biol Soc</i> 2007; <b>48</b> :79–82	Laboratory setting only
O'Daniel WE, Hahn HR. Follow-up usage of the Scott-Craig Orthosis in paraplegia. <i>Paraplegia</i> 1981; <b>19</b> :373–8	Not appropriate comparator
Ofir R, Sell H. Orthoses and ambulation in hemiplegia: a ten year retrospective study. <i>Arch Phys Med Rehabil</i> 1980; <b>61</b> :216–20	Not orthotic intervention
Ogilvie C, Messenger N, Bowker P, Rowley DI. Orthotic compensation for non-functioning hip extensors. <i>Z Kinderchir</i> 1988; <b>43</b> (Suppl. 2):33–5	Not instability of the knee
Ohsawa S, Ikeda S, Tanaka S, Takahashi T, Takeuchi T, Utsunomiya M, <i>et al.</i> A new model of plastic ankle foot orthosis (FAFO (II)) against spastic foot and genu recurvatum. <i>Prosthet Orthot Int</i> 1992; <b>16</b> :104–8	Not instability of the knee
Ohta Y, Yano H, Suzuki R, Yoshida M, Kawashima N, Nakazawa K. A two-degree-of-freedom motor-powered gait orthosis for spinal cord injury patients. <i>Proc Inst Mech Eng H</i> 2007; <b>221</b> :629–39	Laboratory setting only
Pardo AC, Do T, Ryder T, Meyer A, Miles L, Wong BL. Combination of steroids and ischial weight-bearing knee ankle foot orthoses in Duchenne's muscular dystrophy prolongs ambulation past 20 years of age: a case report. <i>Neuromuscul Disord</i> 2011; <b>21</b> :800–2	Not primary study
Parker HG. Chronic anteromedial instability of the knee. <i>Clin Orthop Relat Res</i> 1979; <b>142</b> :123–30	No patients with NMD or CNS condition
Pavlik AJ. The effect of long-term ankle-foot orthosis use on gait in the poststroke population. <i>J Prosthet Orthot</i> 2008; <b>20</b> :49–52	Not primary study
Peaco A, Halsne E, Hafner BJ. Assessing satisfaction with orthotic devices and services: a systematic literature review. <i>J Prosthet Orthot</i> 2011; <b>23</b> :95–105	Not primary study
Peizer E, Lorenze EJ, Dixon M. The genucentric joint orthosis. <i>Med Instrum</i> 1982; <b>16</b> :207–8	No outcomes reported
Perrin C, Condemine A, Giroux P. [Efficacy and satisfaction of a lowered dynamical ankle-foot orthosis in chronic walking hemiparetic subjects.]. <i>Ann Phys Rehabil Med</i> 2012; <b>55</b> :e106–8	Laboratory setting only
Perry J. Lower-extremity bracing in hemiplegia. <i>Clin Orthop Relat Res</i> 1969; <b>63</b> :32–8	Not primary study
Perry J, Mulroy SJ, Renwick SE. The relationship of lower extremity strength and gait parameters in patients with post-polio syndrome. <i>Arch Phys Med Rehabil</i> 1993; <b>74</b> :165–9	Not orthotic intervention
Perry J, Gronley JK, Lunsford T. Rocker shoe as walking aid in multiple sclerosis. <i>Arch Phys Med Rehabil</i> 1981; <b>62</b> :59–65	Not instability of the knee
Phillips GF, Andrews BJ, Chizeck H, Barnicle K. <i>Finite State Control of Paraplegic Gait Using a Hybrid FNS Orthosis</i> . IEEE/Engineering in Medicine and Biology Society Annual Conference, 4–7 November 1988	No outcomes reported
Pierrat B, Calmels P, Molimard J, Navarro L, Avril S. [Mechanical assessment of knee orthoses: finite element modeling. Preliminary data.] <i>Ann Phys Rehabil Med</i> 2012; <b>55</b> :e106–8	No patients with NMD or CNS condition
Plassat R, Perrouin-Verbe B, Stephan A, Rome J, Brunel P, Richard I, <i>et al.</i> Gait orthosis in patients with complete thoracic paraplegia. Review of 43 patients. <i>Ann Readapt Med Phys</i> 2005; <b>48</b> :240–7	Exclude but flag for qualitative
Ploeger HE, Bus SA, Brehm MA, Nollet F. Ankle-foot orthoses that restrict dorsiflexion improve walking in polio survivors with calf muscle weakness. <i>Gait Posture</i> 2014; <b>40</b> :391–8	Laboratory setting only
Portnoy S, Schwartz I. Gait characteristics of post-poliomyelitis patients: standardization of quantitative data reporting. <i>Ann Phys Rehabil Med</i> 2013; <b>56</b> :527–41	Not orthotic intervention
Pratt DJ. Three-dimensional electrogoniometric study of selected knee orthoses. <i>Clin Biomech</i> 1991; <b>6</b> :67–72	No patients with NMD or CNS condition
Quentin B, Wissel J. Recommendations for remobilisation therapies following stroke. <i>Nervenheilkunde</i> 2010; <b>29</b> :537	No outcomes reported

Reference	Reason for exclusion
Quintero H, Farris R, Hartigan C, Clesson I, Goldfarb M. A powered lower limb orthosis for providing legged mobility in paraplegic individuals. <i>Top Spinal Cord Inj Rehabil</i> 2011; <b>17</b> :25–33	Laboratory setting only
Quintero HA, Farris RJ, Goldfarb M. <i>Control and Implementation of a Powered Lower Limb Orthosis to Aid Walking in Paraplegic Individuals</i> . Proceedings of the IEEE International Conference on Rehabilitation Robotics, Zurich, Switzerland, 29 June–2 July 2011	Not primary study
Quintero HA, Farris RJ, Hartigan C, Clesson I, Goldfarb M. <i>A Powered Lower Limb Orthosis for Providing Legged Mobility in Paraplegic Individuals</i> . The North American Neurorehabilitation Symposium: Advances in Robotics and Neurorehabilitation in SCI and Other Neurotrauma, August 2010, Atlanta, Georgia. <i>Top Spinal Cord Inj Rehabil</i> 2011; <b>17</b> :25–33	Laboratory setting only
Ramdharry GM, Pollard A, Marsden JF, Reilly MM. Comparing gait performance of people with Charcot-Marie-Tooth disease who do and do not wear ankle foot orthoses. <i>J Peripher Nerv Syst</i> 2010; <b>15</b> :32	Not instability of the knee
Ransom CL. Orthoses and adaptive equipment. <i>Continuum (Minneapolis)</i> 2011; <b>17</b> :494–509	Not primary study
Rasmussen AA, Smith KM, Damiano DL. Biomechanical evaluation of the combination of bilateral stance-control knee-ankle-foot orthoses and a reciprocating gait orthosis in an adult with a spinal cord injury. <i>J Prosthet Orthot</i> 2007; <b>19</b> :42–7	Laboratory setting only
Raveh E, Schwartz I, Portnoy S. Comparison of dynamic muscle activity and 3D gait kinematics acquired while wearing an electronic stance control orthosis versus a locked knee-ankle-foot orthosis: a case study. <i>Gait Posture</i> 2013; <b>38</b> :S23–4	Laboratory setting only
Rocha CT, Hoffman EP. Limb-girdle and congenital muscular dystrophies: current diagnostics, management, and emerging technologies. <i>Curr Neurol Neurosci Rep</i> 2010; <b>10</b> :267–76	Not orthotic intervention
Roehrig S, Yates DA. Case report: effects of a new orthosis and physical therapy on gait in a subject with longstanding hemiplegia. <i>J Geriatr Phys Ther</i> 2008; <b>31</b> :38–46	Not primary study
Roggow D, Strasser DC, Fletcher GF, Frankowiak R. Bilateral knee extensor assist ankle foot orthoses for an 80-year-old man with inclusion body myositis and heart disease. <i>Arch Phys Med Rehabil</i> 1991; <b>72</b> :813	Not primary study
Romkes J, Brunner R. Comparison of a dynamic and a hinged ankle-foot orthosis by gait analysis in patients with hemiplegic cerebral palsy. <i>Gait Posture</i> 2002; <b>15</b> :18–24	All participants aged < 16 years
Rosa MC, Marques AS, Rodrigues J, Metcalf CD, Demain S. Relationship between the time spent in double support phase of gait and the knee strength in subjects with stroke. <i>Cerebrovasc Dis</i> 2013; <b>35</b> :788	Not orthotic intervention
Rosenbaum D, Rodl R, Entrup M, Klein D. Shoe modification or inserts can effect relief of the knee joint. <i>Z Orthop Ihre Grenzgeb</i> 2002; <b>140</b> :579–80	No patients with NMD or CNS condition
Rosenthal RK, Deutsch SD, Miller W. A fixed ankle, below the knee orthosis for the management of genu recurvatum in spastic cerebral palsy. <i>J Bone Joint Surg Am</i> 1975; <b>57</b> :545–7	All participants aged < 16 years
Rosman N, Spira E. Paraplegic use of walking braces: a survey. <i>Arch Phys Med Rehabil</i> 1974; <b>55</b> :310–14	No patients with NMD or CNS condition
Rubin G, Danisi M. A knee stabilising ankle foot orthosis. <i>Orthotics Prosthet</i> 1975; <b>29</b> :11–14	Not orthotic intervention
Saitoh E, Suzuki T, Sonoda S, Fujitani J, Tomita Y, Chino N. Clinical experience with a new hip-knee-ankle-foot orthotic system using a medial single hip joint for paraplegic standing and walking. <i>Am J Phys Med Rehabil</i> 1996; <b>75</b> :198–203	Laboratory setting only
Sarikaya S, Basaran A, Ortancil O, Balbaloglu O. A new modification of KAFO for assistance in knee extension. <i>Disabil Rehabil Assist Technol</i> 2007; <b>2</b> :67–70	Not primary study
Sarno JE, Lehneis HR. Prescription considerations for plastic below-knee orthoses. <i>Arch Phys Med Rehabil</i> 1971; <b>52</b> :503–10	Not primary study
Sautreuil P, Belmahfoud R, Vandermeersch T, Thoumie P, Bendaya S. [Lower limb's device for poliomyelitic adult patient.] <i>Lett Med Phys Readapt</i> 2009; <b>25</b> :127–35	Not primary study



Reference	Reason for exclusion
Scivoletto G, Mancini M, Fiorelli E, Morganti B, Molinari M. A prototype of an adjustable advanced reciprocating gait orthosis (ARGO) for spinal cord injury (SCI). <i>Spinal Cord</i> 2003; <b>41</b> :187–91	Laboratory setting only
Scott CM. <i>Functional Long Leg Brace Research</i> 1971. URL: <a href="http://www.ntis.gov/search/product.aspx?ABBR=PB2165141">www.ntis.gov/search/product.aspx?ABBR=PB2165141</a>	Unavailable
Seymour RJ, Knapp CF, Anderson TR, Kearney JT. Paraplegic use of the Orlau swivel walker: case report. <i>Arch Phys Med Rehabil</i> 1982; <b>63</b> :490–4	Laboratory setting only
Sheffler LR, Bailey SN, Chae J. Spatiotemporal and kinematic effect of peroneal nerve stimulation versus an ankle-foot orthosis in patients with multiple sclerosis: a case series. <i>PM R</i> 2009; <b>1</b> :604–11	Not instability of the knee
Shurr D, Miller H, Albright J, Feldick H. The Iowa Knee Orthosis. <i>Orthotics Prosthet</i> 1978; <b>32</b> :20–4	Not primary study
Silver-Thorn B, Herrmann A, Current T, McGuire J. Effect of ankle orientation on heel loading and knee stability for post-stroke individuals wearing ankle-foot orthoses. <i>Prosthet Orthot Int</i> 2011; <b>35</b> :150–62	Not orthotic intervention
Simoens S, Guillaume P, Moldenaers I, Depoorter A, De Coster S, Van den Steen D, et al. International comparison of orthotic brace prices. <i>Eur J Health Econ</i> 2009; <b>10</b> :149–55	Not orthotic intervention
Simoens S, Debruyne H, Moldenaers I, Guillaume P, De Coster S, Van den Steen D, et al. Do tariffs and prices correspond with costs? A case study of orthotic braces. <i>J Med Econ</i> 2008; <b>11</b> :245–54	Not orthotic intervention
Singer M, Kobayahi T, Lincoln L, Orendurff M, Foreman KB. The effect of AFO stiffness on the knee joint during the heel strike phase of gait in stroke patients. <i>FASEB J</i> 2014; <b>1</b>	Not instability of the knee
Sliwa J. Postpolio syndrome and rehabilitation. <i>Am J Phys Med Rehabil</i> 2004; <b>83</b> :909	Not primary study
Smith GC, Moutvic MA, Oh TH. Use of stance-control knee-ankle-foot orthoses in a patient with inclusion body myositis and falls. Poster presented at the Association of Academic Physiatrists Annual Meeting, Nashville, TN, 25 February–1 March 2014	Unavailable
Smits J, Zepf A. [Orthotic management of the unstable knee joint.] <i>Orthop Tech</i> 1993;268–73	Not primary study
Solomonow M, Baratta R, D'Ambrosia R. Standing and walking after spinal cord injury: experience with the Reciprocating Gait Orthosis powered by electrical muscle stimulation. <i>Top Spinal Cord Inj Rehabil</i> 2000; <b>5</b> :29–53	Not orthotic intervention
Solomonow M, Reisin E, Aguilar E, Baratta RV, Best R, D'Ambrosia R. Reciprocating gait orthosis powered with electrical muscle stimulation (RGO II). Part II: medical evaluation of 70 paraplegic patients. <i>Orthopedics</i> 1997; <b>20</b> :411–18	Not instability of the knee
Solomonow M, Baratta R, Hirokawa S, Rightor N, Walker W, Beaudette P, et al. The RGO Generation II: muscle stimulation powered orthosis as a practical walking system for thoracic paraplegics. <i>Orthopedics</i> 1989; <b>12</b> :1309–15	Laboratory setting only
Sonoda S, Imahori R, Saitoh E, Tomita Y, Domen K, Chino N. Clinical application of the modified medially-mounted motor-driven hip gear joint for paraplegics. <i>Disabil Rehabil</i> 2000; <b>22</b> :294–7	Not primary study
Spector P, Davis J. Hip-abduction, knee-extension orthosis. <i>Am J Occup Ther</i> 1982; <b>36</b> :461–2	Not instability of the knee
Stallard J, Henshaw JH, Lomas B, Poiner R. The ORLAU VCG (variable centre of gravity) swivel walker for muscular dystrophy patients. <i>Prosthet Orthot Int</i> 1992; <b>16</b> :46–8	No outcomes reported
Stein RB, Hayday F, Chong S, Thompson AK, Rolf R, James KB, Bell G. Speed and efficiency in walking and wheeling with novel stimulation and bracing systems after spinal cord injury: a case study. <i>Neuromodulation</i> 2005; <b>8</b> :264–71	Not orthotic intervention
Steinfeldt F, Seifert W, Gunther KP. [Modern carbon fibre orthoses in the management of polio patients: a critical evaluation of the functional aspects.] <i>Z Orthop Ihre Grenzgeb</i> 2003; <b>141</b> :357–61	Not primary study
Stevens PM. Lower limb orthotic management of Duchenne muscular dystrophy: a literature review. <i>J Prosthet Orthot</i> 2006; <b>18</b> :111–19	Not primary study

Reference	Reason for exclusion
Suga T, Kameyama O, Ogawa R, Matsuura M, Oka H. Newly designed computer controlled knee-ankle-foot orthosis (Intelligent Orthosis). <i>Prosthet Orthot Int</i> 1998; <b>22</b> :230–9	No patients with NMD or CNS condition
Sulzer JS, Gordon KE, Dhaher YY, Peshkin MA, Patton JL. Preswing knee flexion assistance is coupled with hip abduction in people with stiff-knee gait after stroke. <i>Stroke</i> 2010; <b>41</b> :1709–14	Laboratory setting only
Summers P, Singleton C. Sizable functional improvement in a recently diagnosed case of adult onset muscular dystrophy and multiple sclerosis after outpatient therapy failure: a case report. <i>PM R</i> 2013; <b>1</b> :S156	Not orthotic intervention
Suzuki N, Shinohara T, Kimizuka M, Yamaguchi K, Mita K. Energy expenditure of diplegic ambulation using flexible plastic ankle foot orthoses. <i>Bull Hosp Jt Dis</i> 2000; <b>59</b> :76–80	All participants aged < 16 years
Suzuki T, Sonoda S, Saitoh E, Onogi K, Fujino H, Teranishi T, <i>et al.</i> Prediction of gait outcome with the knee-ankle-foot orthosis with medial hip joint in patients with spinal cord injuries: a study using recursive partitioning analysis. <i>Spinal Cord</i> 2007; <b>45</b> :57–63	Not instability of the knee
Suzuki T, Sonoda S, Saitoh E, Murata M, Uno A, Shimizu Y, <i>et al.</i> Development of a novel type of shoe to improve the efficiency of knee-ankle-foot orthoses with a medial single hip joint (Primewalk orthoses): a novel type of shoe for Primewalk orthosis. <i>Prosthet Orthot Int</i> 2005; <b>29</b> :303–11	Not primary study
Swift TA, Strausser KA, Zoss AB, Kazerooni H. <i>Control and Experimental Results for Post Stroke Gait Rehabilitation with a Prototype Mobile Medical Exoskeleton</i> . ASME 2010 Dynamic Systems and Control Conference, 12–15 September 2010, Cambridge, MA	Not instability of the knee
Swinnen E, Beckwee D, Meeusen R, Baeyens JP, Kerckhofs E. Does robot-assisted gait rehabilitation improve balance in stroke patients? A systematic review. <i>Top Stroke Rehabil</i> 2014; <b>21</b> :87–100	Not primary study
Taiar R, Boyer FC, Roche N, Pradon D. Technical and smart fabrics fibres orthosis for recurvatum knee in hemiplegic patients. <i>Ann Phys Rehabil Med</i> 2013; <b>56</b> :e25–6	Laboratory setting only
Tanabe S, Hirano S, Saitoh E. Wearable Power-Assist Locomotor (WPAL) for supporting upright walking in persons with paraplegia. <i>Neurorehabilitation</i> 2013; <b>33</b> :99–106	Not primary study
Tatar Y. [Lower extremity orthoses in spinal cord injury.] <i>Turk Fiz Tip Rehab</i> 2006; <b>52</b> :B12–17	Not primary study
Taylor MK. KAFOs for patients with neuromuscular deficiencies. <i>J Prosthet Orthot</i> 2006; <b>3</b>	Not primary study
Thoumie P, Sautreuil P, Mevellec E. [Knee orthosis. Evaluation of clinical efficiency with a review of the literature.] <i>Ann Readapt Med Phys</i> 2002; <b>45</b> :1–11	Not primary study
Thoumie P, Sautreuil P, Mevellec E. [Knee orthosis. First part: evaluation of physiological properties based on a review of the literature.] <i>Ann Readapt Med Phys</i> 2001; <b>44</b> :567–80	Not primary study
Thoumie P, Le Claire G, Beillot J, Dassonville J, Chevalier T, Perrouin-Verbe B, <i>et al.</i> Restoration of functional gait in paraplegic patients with the RGO-II hybrid orthosis. A multicenter controlled study. II: Physiological evaluation. <i>Paraplegia</i> 1995; <b>33</b> :654–9	Not instability of the knee
Tian F, Elahinia M, Hefzy MS. <i>A Dynamic Knee-Ankle-Foot Orthosis with Superelastic Actuators</i> . ASME 2013 Conference on Smart Materials, Adaptive Structures and Intelligent Systems (SMASIS), 16–18 September 2013, Snowbird, UT	No patients with NMD or CNS condition
To CS, Kobetic R, Bulea TC, Audu ML, Schnellenberger JR, Pinault G, <i>et al.</i> Sensor-based stance control with orthosis and functional neuromuscular stimulation for walking after spinal cord injury. <i>J Prosthet Orthot</i> 2012; <b>24</b> :124–32	Not orthotic intervention
To CS, Kobetic R, Bulea TC, Audu ML, Schnellenberger JR, Pinault G, <i>et al.</i> Stance control knee mechanism for lower-limb support in hybrid neuroprosthesis. <i>J Rehabil R D</i> 2011; <b>48</b> :839–50	Laboratory setting only
Trotter LC, Pierrynowski MR. Changes in gait economy between full-contact custom-made foot orthoses and prefabricated inserts in patients with musculoskeletal pain: a randomized clinical trial. <i>J Am Podiatr Med Assoc</i> 2008; <b>98</b> :429–35	No patients with NMD or CNS condition
Trotter LC, Pierrynowski MR. The short-term effectiveness of full-contact custom-made foot orthoses and prefabricated shoe inserts on lower-extremity musculoskeletal pain: a randomized clinical trial. <i>J Am Podiatr Med Assoc</i> 2008; <b>98</b> :357–63	No patients with NMD or CNS condition
Tuck WH. The Stanmore cosmetic calliper. <i>J Bone Joint Surg Br</i> 1974; <b>56</b> :115–20	No outcomes reported

Reference	Reason for exclusion
Tyson SF, Thornton HA. The effect of a hinged ankle foot orthosis on hemiplegic gait: objective measures and users' opinions. <i>Clin Rehabil</i> 2001; <b>15</b> :53–8	Not instability of the knee
Tyson SF, Sadeghi-Demneh E, Nester CJ. A systematic review and meta-analysis of the effect of an ankle-foot orthosis on gait biomechanics after stroke. <i>Clin Rehabil</i> 2013; <b>27</b> :879–91	Not primary study
Vicenzino B. Foot orthotics in the treatment of lower limb conditions: a musculoskeletal physiotherapy perspective. <i>Man Ther</i> 2004; <b>9</b> :185–96	Not primary study
Vinci P, Gargiulo P. Poor compliance with ankle-foot-orthoses in Charcot-Marie-Tooth disease. <i>Eur J Phys Rehabil Med</i> 2008; <b>44</b> :27–31	Not instability of the knee
Vinci P, Paoloni M, Ioppolo F, Gargiulo P, Santilli V. Gait analysis in a patient with severe Charcot-Marie-Tooth disease: a case study with a new orthotic device for footdrop. <i>Eur J Phys Rehabil Med</i> . 2010; <b>46</b> :355–61	Not instability of the knee
Ward J, Sugar T, Standeven J, Engsborg JR. <i>Stroke Survivor Gait Adaptation and Performance After training on a Powered Ankle Foot Orthosis</i> . Proceedings of the IEEE International Conference on Robotics and Automation, Anchorage, AK, 3–8 May 2010	Laboratory setting only
Waring WP, Maynard F, Grady W, Grady R, Boyles C. Influence of appropriate lower extremity orthotic management on ambulation, pain, and fatigue in a postpolio population. <i>Arch Phys Med Rehabil</i> 1989; <b>70</b> :371–5	Not instability of the knee
Warren CG, Lehmann JF, deLateur BJ. Pelvic band use in orthotics for adult paraplegic patients. <i>Arch Phys Med Rehabil</i> 1975; <b>56</b> :221–3	Not instability of the knee
Watanabe H, Yonemitsu H. Short leg brace for knee extensor weakness (K. U. short leg brace). <i>Kumamoto Med J</i> 1973; <b>26</b> :90–5	Not primary study
Watanabe H, Asami T, Itoh Y, Arizono O. <i>Lower Limb Orthotic Management for Hemiplegia</i> . 8th World Congress of the International Rehabilitation Medicine Association, Kyoto, Japan, 31 August–4 September 1997. pp. 645–8	No outcomes reported
Waters R, Montgomery J. Lower extremity management of hemiparesis. <i>Clin Orthop Relat Res</i> 1974;133–43	Not primary study
Waters RL, Yakura JS, Adkins R, Barnes G. Determinants of gait performance following spinal cord injury. <i>Arch Phys Med Rehabil</i> 1989; <b>70</b> :811–18	Not primary study
Webster JB, Miknevich MA, Stevens P, Hansen C. Lower extremity orthotic management in neurological rehabilitation. <i>Crit Rev Phys Rehabil Med</i> 2009; <b>21</b> :1–23	Not primary study
Wiener-Ogilvie S, Jones RB. A randomised trial of exercise therapy and foot orthoses as treatment for knee pain in primary care. <i>Br J Podiatr</i> 2004; <b>7</b> :43–9	No patients with NMD or CNS condition
Wiest B. A pilot study of Orthodream foot orthose. Preliminary results of a new orthopaedic treatment in torsional low limb disorders. <i>Journal de l'orthopedie</i> 2003; <b>18</b> :793–5	All participants aged < 16 years
Wijesinha C. Hemiplegia and bracing. <i>Med J Aust</i> 1979; <b>2</b> :76–8	Not primary study
Winchester PK, Carollo JJ, Parekh RN, Lutz LM, Aston JW. A comparison of paraplegic gait performance using two types of reciprocating gait orthoses. <i>Prosthet Orthot Int</i> 1993; <b>17</b> :101–6	Laboratory setting only
Wong CK, Bishop L, Stein J. A wearable robotic knee orthosis for gait training: a case-series of hemiparetic stroke survivors. <i>Prosthet Orthot Int</i> 2012; <b>36</b> :113–20	Not orthotic intervention
Wu Q, Ma ZH, He CQ. Comparison of different orthosis for improving gait in patients with spinal cord injury. <i>CJTER</i> 2013; <b>17</b> :4152–60	Laboratory setting only
Wu SK, Jordan M, Shen X. A pneumatically-actuated lower-limb orthosis. <i>Conf Proc IEEE Eng Med Biol Soc</i> 2011; <b>2011</b> :8126–9	No patients with NMD or CNS condition
Xu GX, Gu SQ, Li JA. Poliomyelitis sequela in Pizhou city. <i>Chin J Clin Rehabil</i> 2005; <b>9</b> :238–40	All participants aged < 16 years
Yadav SL, Saha PK, Panwar L. <i>Floor Reaction Orthosis an Alternative Device for Quadriceps Paresis</i> . IEEE/Engineering in Medicine and Biology Society Annual Conference, 1995	Not primary study
Yakimovich T, Lemaire ED, Kofman J. Engineering design review of stance-control knee-ankle-foot orthoses. <i>J Rehabil R D</i> 2009; <b>46</b> :257–67	Not primary study

Reference	Reason for exclusion
Yakimovich T, Kofman J, Lemaire ED. Design and evaluation of a stance-control knee-ankle-foot orthosis knee joint. <i>IEEE Trans Rehabil Eng</i> 2006; <b>14</b> :361–9	Laboratory setting only
Yakimovich T, Lemaire ED, Kofman J. Gait evaluation of a new electromechanical stance-control knee-ankle-foot orthosis. <i>Conf Proc IEEE Eng Med Biol Soc</i> 2006; <b>1</b> :5924–7	Laboratory setting only
Yakimovich T, Lemaire ED, Kofman J. Preliminary kinematic evaluation of a new stance-control knee-ankle-foot orthosis. <i>Clin Biomech</i> 2006; <b>21</b> :1081–9	Laboratory setting only
Yakimovich T, Kofman J, Lemaire E. Design, construction and evaluation of an electromechanical stance-control knee-ankle-foot orthosis. <i>Conf Proc IEEE Eng Med Biol Soc</i> 2005; <b>7</b> :6934–41	Laboratory setting only
Yamamoto S, Hagiwara A, Mizobe T, Yokoyama O, Yasui T. Development of an ankle-foot orthosis with an oil damper. <i>Prosthet Orthot Int</i> 2005; <b>29</b> :209–19	Not orthotic intervention
Yang A, Pena S, Spungen AM, Harel NY. Dynamic knee bracing to improve weight bearing during SCI balance training. <i>J Spinal Cord Med</i> 2014; <b>37</b> :454	Not orthotic intervention
Yang W, Burgess HR, Lamb GA, Lanciault P, Perez M, Ramos R, Wong LA. Application of microprocessor stance control knee ankle foot orthoses: a case series report. <i>PM R</i> 2010; <b>1</b> :S160	No patients with NMD or CNS condition
Yano H, Kaneko S, Nakazawa K, Yamamoto SI, Bettoh A. A new concept of dynamic orthosis for paraplegia: the weight bearing control (WBC) orthosis. <i>Prosthet Orthot Int</i> 1997; <b>21</b> :222–8	No patients with NMD or CNS condition
Yokoyama O, Sashika H, Hagiwara A, Yamamoto S, Yasui T. Kinematic effects on gait of a newly designed ankle-foot orthosis with oil damper resistance: a case series of 2 patients with hemiplegia. <i>Arch Phys Med Rehabil</i> 2005; <b>86</b> :162–6	Laboratory setting only
Zacharias B, Kannenberg A. Clinical benefits of stance control orthosis systems: an analysis of the scientific literature. <i>J Prosthet Orthot</i> 2012; <b>24</b> :2–9	Not primary study
Zancan A, Beretta MV, Schmid M, Schieppati M. A new hip-knee-ankle-foot sling: kinematic comparison with a traditional ankle-foot orthosis. <i>J Rehabil R D</i> 2004; <b>41</b> :707–12	Laboratory setting only
Ziter FA, Allsop KG. The value of orthoses for patients with Duchenne muscular dystrophy. <i>Phys Ther</i> 1979; <b>59</b> :1361–5	All participants aged < 16 years



## Appendix 12 Data extraction tables

### Bernhardt (2011) methods

Study details	Study participants	Interventions	Analysis
Bernhardt (2011)	Number of participants: 9	Type of orthotic: SCKAFO	Duration of follow-up: 6 months
Country: USA	% male: 78	Manufacture: custom-made SensorWalk (Otto Bock Health Care, Minneapolis), MN, USA	How were patient outcomes elicited?: questionnaire covering donning and doffing, brace cosmesis and weight, stability during standing, walking and postural transitions
Language: English	Mean or median age: mean 61 (SD 9) yrs	Material: not reported	
Funding source: Myositis Association	Ethnicity: not reported	Specified orthotic dose: not reported	How was gait assessed?: using a 10-camera motion analysis system and four force platforms. Three left and right force plate strikes were included in analysis. Trials were averaged and strides normalised to 100% gait cycle, with 0% being foot-strike and 100% indicating ipsilateral foot-strike
Conflict of interest: yes, one of the authors is an inventor of the technology used in the study and holds two US patents on the device	Weight: not reported	Fitting procedure: fitted by certified orthotist	
Study type: case series	BMI: mean 27.2 kg/m <sup>2</sup> (SD 4.0 kg/m <sup>2</sup> )	Cointerventions: not reported	
	Type of disorder: inclusion body myositis	Comparator: before and 6 months after fitting of SCO	Statistical analysis: if normally distributed comparisons were made between the braced and unbraced conditions using a paired <i>t</i> -test and between the two strength groups using a two-sample two-sided <i>t</i> -test. When not normally distributed comparisons were made with the Wilcoxon Signed-Rank test for paired data
	Affected knee: both, braced side was chosen based on participants' subjective evaluation of the weaker leg		
	Nature of instability: patients had functional deficits due to quadriceps weakness. All participants had knee buckling and falls		
	Previous use of orthotics: no		

## Bernhardt (2011) results

### Patient-reported outcomes

Functionality of device: data not reported. The authors state that participants felt that the SCO was helpful for protecting against falls and providing stability

Satisfaction with device: data not reported. The authors state that all participants had complaints regarding size, bulk, cosmesis and noise of the SCO as well as difficulty donning and doffing the brace. Most participants stated that they would prefer a less intrusive assistive device. Participants with less weakness tended to have positive feedback on the SCO. This was found to be regardless of the amount of time spent using it. The weakest participants had mixed feelings on the orthotic and had less use of the brace

Usage of device: use of the brace ranged from about 2 hrs per day to all day every day

### Objective assessments

Walking ability: data mainly presented in small scale graphs. Participants walked slower ( $p = 0.025$ ) and with a lower cadence ( $p = 0.0007$ ) with the SCO. Stride length with the SCO was not significantly different between conditions. Participants had a wider step width with the brace (0.035). When wearing the SCO the weaker participants walked slower ( $p = 0.022$ ), had a lower cadence ( $p = 0.019$ ) and a shorter stride length ( $p = 0.048$ ) when compared to participants with less weakness. Peak knee flexion during swing significantly decreased when using the SCO [from mean 74.7 (2.9) degrees to mean 62.9 (10.8) degrees ( $p = 0.021$ )]. There was no significant difference in peak hip flexion during swing when using the SCO [from mean 41.4 (4.6) degrees to mean 39.7 (6.5) degrees ( $p = 0.355$ )]

### Resource utilisation and adverse effects

Not reported

## Bocker (2013) methods

Study details	Study participants	Interventions	Analysis
Bocker (2013)	Number of participants: 10		Duration of follow-up: 3 months
Country: Germany	% male: 30	Type of orthotic: KAFO	How were patient outcomes elicited?: SF-36
Language: English	Mean or median age: 64.5 years	Type-eight orthosis	How was gait assessed?: duration of the stance phase and the knee joint angle at the stance-to-swing transition was analysed. Patients walked 4.5 m three times forwards and backwards on flat ground. The Zebris WinGait-HS v3.1.35 (zebris Medical GmbH, Isny, Germany) was used
Funding source: not reported	Ethnicity: not reported	Manufacture: custom-made. Mechanical lockable knee joint as well as Glenzack joints to lift the foot. There is a brace area on the tibia, soft areas of contact proximal and dorsal to the calf and the thigh	
Conflict of interest: no	Weight: not reported	Material: carbon fibre	
Study type: case series	BMI: not reported	Specified orthotic dose: orthosis used over the whole day	Statistical analysis: Friedman-Test. Median and quartiles were calculated
	Type of disorder: paralysis of the lower limb caused by poliomyelitis	Fitting procedure: not reported	
	Affected knee: not reported	Cointerventions: gait training with the orthosis twice a week for 3 months. Physical pain therapy and exercises to prevent cardiopulmonary and muscular reduction twice a week for 3 months	
	Nature of instability: clinical paresis of the lower limb with partial paralysis of the quadriceps, instability of the knee joint: decentralisation of the patella, hyperextension of the knee joint while standing, varus or valgus misalignment	Comparator: no comparator group	
	Previous use of orthotics: no		

## Bocker (2013) results

### Patient-reported outcomes

Impact on daily living, quality of life: SF-36 including physical and psychological domains. The authors stated that no significant changes were observed in SF-36 at all time points. They stated that in the summary of the physical and mental score no improvement was observed. SF-36 data were reported in a figure only and it was not possible to extrapolate the data due to the scale

### Objective assessments

Muscle activity was described using surface electromyography (S-EMG) at 3 months before the orthosis, at the time of fitting the orthosis and 3 months after getting the orthosis. The s-EMG was analysed while walking and the average value of the amplitude was used as a parameter of the current muscle activity during the process of standing and walking. On the side without the orthosis, statistically significantly increased s-EMG values of m obliquus abdominus internus and m multifideus during standing and of the m gluteus medius during walking were observed. On the side with the orthosis support changes of both abdominal muscles as well as m multifideus, mm.rectus and biceps femoris showed statistically significantly higher s-EMG whereas both vasti and m gluteus medius had decreased values. Full results were provided in the paper. Kinematic gait analysis. There were no significant changes in the knee joint angles. The knee angle of both legs seemed to be stabilised. The angle of the leg with the orthosis showed a difference of 13 degrees from baseline to follow-up. In the leg without the orthosis the knee angle decreased by about 8 degrees. An increased stance duration of 24% was seen in the leg with orthosis whereas there were no differences in the opposite leg during the intervention (not possible to extract actual duration)

### Resource utilisation and adverse effects

Not reported

## Boudarham (2013) methods

Study details	Study participants	Interventions	Analysis
Boudarham (2013)	Number of participants: 11	Type of orthotic: KAFO	Duration of follow-up: participants were required to have been prescribed the device within the previous 6 months
Country: France	% male: 64	Manufacture: custom-made (details provided in the text)	How were patient outcomes elicited?: no patient outcomes
Language: English	Mean or median age: mean 51 (SD 15) years	Material: carbon fibre with polypropylene foot part	How was gait assessed?: each patient performed two sessions of gait analysis at preferred walking velocity without and with KAFO in a 10 m gait corridor. Six trials were carried out. Each patient performed the two gait analyses successively with a 10-minute rest in between. Gait was analysed using a motion capture system with eight optoelectronic cameras. The trajectories of 30 reflective markers placed on anatomical landmarks were collected and filtered. In KAFO condition reflective markers were placed directly on the KAFO joint in the axis of the centres of rotation of the knee and the ankle of the paretic limb. Ground reaction forces were measured synchronously with the kinematic data using two force plates staggered along the walkway
Funding source: not reported	Ethnicity: not reported	Material: carbon fibre with polypropylene foot part	How was gait assessed?: each patient performed two sessions of gait analysis at preferred walking velocity without and with KAFO in a 10 m gait corridor. Six trials were carried out. Each patient performed the two gait analyses successively with a 10-minute rest in between. Gait was analysed using a motion capture system with eight optoelectronic cameras. The trajectories of 30 reflective markers placed on anatomical landmarks were collected and filtered. In KAFO condition reflective markers were placed directly on the KAFO joint in the axis of the centres of rotation of the knee and the ankle of the paretic limb. Ground reaction forces were measured synchronously with the kinematic data using two force plates staggered along the walkway
Conflict of interest: unclear	Weight: mass 70 (SD 15) kg	Specified orthotic dose: reported. Had worn daily for at least one month	Statistical analysis: a Wilcoxon test was used (control vs. KAFO condition) to assess the effects of KAFO on the primary outcome measure (angle of knee extension during stance) and for secondary outcomes
Study type: case series	BMI: Not reported	Fitting procedure: not reported	
	Type of disorder: CNS. Hemiplegia after stroke occurring six months prior to study (chronic phase)	Cointerventions: not reported	
	Affected knee: left 5, right 6	Comparator: no comparator group	
	Nature of instability: genu recurvatum with aetiology: spasticity of quadriceps (6), weakness of quadriceps (2), spasticity of triceps surae (3)	Compared gait with and without KAFO	
	Previous use of orthotics: not reported		



## Boudarham (2013) results

### Objective assessments

Walking ability: spatio-temporal parameters: gait velocity was significantly greater in the KAFO condition than in the control condition (+21%,  $p=0.025$ ). Stride length and cadence were also significantly greater in the KAFO condition (15%,  $p=0.030$  and 11%,  $p=0.049$ ). There was no significant difference between the two conditions for step width ( $p=0.384$ ). Step length of the non-paretic limb was greater in the KAFO condition (14%,  $p=0.005$ ) and swing phase duration of the paretic limb was significantly shorter in the KAFO condition (-29%,  $p=0.003$ ). Gait symmetry: symmetry between the paretic and non-paretic limbs increased with the KAFO. Asymmetry ratio was significantly lower in the KAFO condition [from 1.93 (0.77) to 1.27 (0.10)]. There was no significant difference between the two conditions for the stance phase duration asymmetry ratio [from 0.82 (0.11) to 0.86 (0.08),  $p=0.132$ ]. The knee flexor moment was significantly decreased during initial double stance phase with the KAFO: without KAFO, paretic side median -0.23, mean -0.30 (SD 0.22), with KAFO, paretic side median -0.10, mean -0.12 (SD 0.15),  $p=0.047$ . There were no significant differences between conditions for the knee moment in simple support and final double contact phases. There were no significant differences between conditions for peak knee flexion for the non-paretic limb. Full details of hip, knee and ankle moments are provided in the paper

### Resource utilisation

Number and nature of follow-up appointments

One at 6 months

Device malfunction

Not reported

### Patient-reported outcomes and adverse events

Not reported

## Brehm (2007) methods

Study details	Study participants	Interventions	Analysis
Brehm (2007)	Number of participants: 23	Type of orthotic: KAFO with a locked knee-joint fitted according to total-contact principle. Weight ranged from 0.9 to 2.1 kg	Duration of follow-up: 26 weeks
Country: the Netherlands	% male: 61		How were patient outcomes elicited?: an individualised satisfaction evaluation was made to quantify patient-specific improvements on various aspects of KAFO use. Patients chose five areas for improvement and, at baseline, rated these for satisfaction with regard to the old KAFO on a 10-point Likert scale (1 = extremely unsatisfied, 10 = extremely satisfied). At follow-up the patients rated the items again for the new KAFO
Language: English	Mean or median age: mean age 55 years (SD 9.2 years)	Material: carbon fibre	SF-36 Physical functioning
Funding source: grants from Anna Fonds and ZonMw	Ethnicity: not reported	Manufacture: custom-made Noppe Orthopaedie BV (The Netherlands) manufactured the new KAFOs	
Conflict of interest: unclear	Weight: mean body mass 72 kg (SD 11.8 kg)	Specified orthotic dose: not reported	
Study type: case series	BMI: mean 25.9 kg/m <sup>2</sup> (SD 4.1 kg/m <sup>2</sup> )	Fitting procedure: reported	
	Type of disorder: neuromuscular. Patients with former polio	Cointerventions: some participants used cane(s) as a walking aid	How was gait assessed?: patient wore KAFO and shoes and used usual walking aids and walked at a comfortable speed along a 10 m walkway. A 3D-movement analysis system was used (OPTOTRAK, Northern Digital Inc., Canada). Patients performed three trials. Energy cost of walking was measured by a portable gas-analysis system
	Affected knee: left, right, both	Comparator: yes. Leather/metal KAFO or plastic metal KAFO used by the same patients. Weight ranged from 1.0 to 4.1 kg	
	Nature of instability: polio residual disability		
	Previous use of orthotics: yes. All patients had previously used a conventional locked knee-joint KAFO made of leather/metal or plastic/metal with no technical deficits for at least 2 years		

Study details	Study participants	Interventions	Analysis
			<p>(Vmax ST, Sensormedics, The Netherlands). The distance covered during the last 2 minutes of the walking test was registered to calculate the patient's walking speed</p> <p>Statistical analysis: generalised estimated equations used to test for changes in gross energy cost, net energy cost, walking speed and physical function and to investigate whether changes in gross and net energy cost were associated with changes in 15 biomechanical gait parameters and KAFO weight. Paired <i>t</i>-tests used to assess differences between old and new KAFO for biomechanical gait parameters and patient satisfaction</p>

## Brehm (2007) results

### Patient-reported outcomes

Satisfaction with device: mean patient satisfaction scores were 48% higher for the new KAFO than for the old KAFO ( $p < 0.01$ ) (data not provided)

A total of 26 items for improvement were mentioned. Items that were most frequently mentioned for improvement were weight, fitting and cosmesis of the KAFO, stability and walking performance (no data provided)

### Objective assessments

Walking ability: the gross and net energy cost of walking were both significantly lower for the new KAFO than for the old KAFO. Gross energy cost J/kg/m: mean difference (%)  $-0.42$  ( $-7\%$ , 95% CI  $-0.63$  to  $-0.21$ ). Net energy cost J/kg/m: mean difference (%)  $-0.36$  ( $-8\%$ ) (95% CI  $-0.54$  to  $-0.18$ ). Increments in gross and net energy cost above norm values with the old KAFO were both reduced with the new KAFO: Gross energy cost above norm: mean difference (%)  $-0.47$  ( $-18\%$ ) (95% CI  $-0.27$  to  $-0.67$ ). Net energy cost above norm: mean difference (%)  $-0.37$  ( $-18\%$ ) (95% CI  $-0.19$  to  $-0.55$ ). Walking speed remained unchanged: speed (m/minute): mean change (%)  $1.8$  ( $3\%$ ) (95% CI  $-4.35$  to  $0.57$ ). An improvement in knee flexion, forward excursion of the centre of pressure, peak ankle moment and timing of peak ankle power were significantly associated with the decrease in energy cost. Reduction in KAFO weight was not significantly associated with decrease in energy cost. Full details are provided in the paper

Other functional ability. physical functioning was assessed using the SF-36 physical functioning scale. The authors report there was no significant difference in physical function between the old and new KAFO (no further details reported)

### Resource utilisation

Device malfunction: seven patients reported technical deficits relating to the hinge at the ankle or knee which could be easily repaired. Seven patients reported wear to the cloth upholstery inside the KAFO. One patient needed a replacement of the orthosis due to a break of the KAFO

### Adverse effects

Not reported

## Davis (2010) methods

Study details	Study participants	Interventions	Analysis
Davis (2010)	Number of participants: 10	Type of orthotic: SCKAFO	Duration of follow-up: the average use was 6.2 (5.2) months
Country: Australia	% male: 40	Manufacture: custom-made. All participants had a SCO that incorporated a Horton Stance Control knee joint	How were patient outcomes elicited?: NA
Language: English	Mean or median age: mean 61.9 (SD 7.7) years	Material: Carbon fibre. Laminate with carbon and fibreglass reinforcing	How was gait assessed?: a GAITRite walkway (CIR systems, USA) was used to measure temporospatial characteristics. A Cosmed K4b2 metabolic system (Cosmed, Italy) was used to measure oxygen consumption. For temporospatial measurements participants were asked to walk at their comfortable walking velocity over a 9 m GAITRite walkway four times for each condition. A 30-minute break was allowed between the two conditions
Funding source: International Society for Prosthetics and Orthotics (Australian National Member Society)	Weight: ranged from 49 kg to 111 kg	Specified orthotic dose: reported. Participants had to regularly use the SCO for at least 4 hours per day	Statistical analysis: GAITRite data for four trials were averaged to determine average walking velocity, left and right step cadence, stance time and swing time for both conditions for each participant. Net oxygen consumption for walking was calculated for each condition by measuring total oxygen consumption over the 15-minute test and subtracting baseline oxygen consumption averaged over the last 2 minutes of the initial resting period. Oxygen cost was calculated by dividing net oxygen consumed by the distance walked. Values were normalised for body weight. The Physiological Cost Index was calculated as the ratio of heart rate difference (exercise – rest) to walking velocity in metres per minute. Heart rates from the Cosmed system were averaged over the last 2 minutes of the initial rest period and the last 2 minutes of exercise. Where distributions were normal, <i>t</i> -tests for matched pairs were used to compare means between the two orthosis conditions. Otherwise a Wilcoxon signed-rank test was used to compare conditions. Due to testing for both walking velocity and energy expenditure 0.025 was chosen for tests of statistical significance
Conflict of interest: no	BMI: not reported	Fitting procedure: reported	
Study type: case series	Type of disorder: neuromuscular. MND 1, post-polio 9	Cointerventions: walking aids – none (4), 2 walking sticks (2), 1 walking stick (2), 2 forearm crutches (1), 1 forearm crutch (1)	
	Affected knee: left, right	Comparator: yes. KAFO in locked mode worn by same participants	
	Nature of instability: significant lower limb weakness or paralysis		
	Previous use of orthotics: yes. Previous use of orthotics included Solid GRAFO (4), LKAFO (1) posterior offset KAFO (1), knee brace (1), none (3)		

## Davis (2010) results

### Objective assessments

Walking ability: walking velocity was significantly increased in the stance control condition based on the results of 10 participants: locked condition 65.0 cm/s (SD 24.5), stance control 72.9 (95.7) cm/s,  $p=0.000107$ . This was a result of significantly increased cadence and increased step length on the sound limb ( $p < 0.001$ ). Affected limb step length and unaffected limb swing time were not significantly different (full details in paper). There was no difference in the oxygen cost of walking between the two conditions: (9 participants) locked condition 0.213 (0.081) ml/kg/minute, stance control 0.224 (0.069) ml/kg/minute  $p=0.515$ . There was no difference in the physiological cost index between the two conditions: (8 participants) locked condition 0.65 (0.32) b/m, stance control 0.70 (0.34) b/m  $p=0.093$ . During energy expenditure testing there was no significant difference in walking speed between conditions: (9 participants) locked condition 36.34 (11.3) cm/s, stance control 38.42 (10.2) cm/s  $p=0.235$ . Walking velocity during energy expenditure testing was significantly slower than during temporospatial testing in both the locked and stance control conditions ( $p=0.00006$  and  $p=0.00004$  respectively)

### Patient-related outcomes, resource utilisation and adverse events

Not reported

## Hachisuka (2007) methods

Study details	Study participants	Interventions	Analysis
Hachisuka (2007)	Number of participants: 11	Type of orthotic: KAFO	Duration of follow-up: not reported
Country: Japan	% male: 18	Manufacture: custom-made. Carbon fibre frame and sole (Otto Bock Japan and Carbon Fiber Fabrics, Toray Industries Inc., Japan), pair of Swiss knee joints and free ankle joints. Two participants had a solid ankle, one a ring lock knee joint and one off-set knee joint. Mean weight 992 g (SD 168)	How were patient outcomes elicited?: eight participants who had experienced both ordinary and carbon KAFOs evaluated walking with a carbon KAFO. The questionnaire had ten categories and used a visual analogue scale to cover: awareness of weight, speed, walking distance, fatigue during walking, safety during walking, back pain, hip pain, knee pain, foot pain and appearance. These were rated on a visual analogue scale with 0% (completely unsatisfied with carbon orthosis and 100% completely satisfied with carbon orthosis when compared to previous orthosis
Language: English	Mean or median age: mean 53.9 (SD 9.8) years	Material: carbon fibre	How was gait assessed?: oxygen consumption was measured using a telemetric breath-by-breath gas analyser. Participants had to walk along a 50 m rectangular line in the training room with the condition randomly assigned (without orthosis, with ordinary KAFO, with carbon fibre KAFO). Participants rested before each trial condition until both oxygen consumption and heart rate reached a steady state. They also stood for two minutes before each trial condition. Oxygen consumption and heart rate were averaged for the last 30 seconds of
Funding source: unclear	Ethnicity: not reported	Specified orthotic dose: not reported	
Conflict of interest: unclear	Weight: not reported	Fitting procedure: reported. Fitting included use of a temporary orthosis for 2–4 weeks, modification as required then 2 further weeks trial followed by fabrication of carbon fibre orthosis in the same alignment and shape as the modified temporary orthosis based on discussion with the patient	
Study type: case series	BMI: not reported	Cointerventions: walking aids. Canes and crutches used as necessary	
	Type of disorder: neuromuscular. Post-polio		
	Affected knee: both. 10 participants had a carbon KAFO for unilateral lower extremity and one had two carbon KAFOs for bilateral lower extremities		
	Nature of instability: post-polio		
	Previous use of orthotics: yes. Eight of 11 participants had used an ordinary KAFO with double-metal uprights for more than 10 years. Three had no previous use		

Study details	Study participants	Interventions	Analysis
		Comparator: yes. 'Ordinary' KAFO. Mean weight 1403g (SD 157) and no orthosis	each walking phase. Physiological cost index was obtained from the formula [heart rate (beats/minute) at 3-minute walk – heart rate (beats/minute) at rest] divided by speed (m/minute)  Statistical analysis: differences between walking conditions analysed using Wilcoxon matched pairs signed-ranks test or the paired t-test

## Hachisuka (2007) results

### Patient-reported outcomes

Satisfaction with device: participants were more satisfied with their carbon KAFO than with their previous ordinary KAFO especially relating to fatigue during walking, safety during walking and appearance (6 patients).

### Objective assessments

Walking ability: all participants walking with both KAFOs showed a significant increase in scores of the functional ambulation category compared with walking without an orthosis, ( $p < 0.05$ ). There was no significant difference between walking with an ordinary KAFO and with a carbon KAFO (data not reported)

Other: there were no significant differences in the number of steps per minute between walking without an orthosis and with a carbon KAFO: (steps per minute) 77.0 (12.5) vs. 84.3 (13.2)  $p > 0.05$  nor in walking with an ordinary KAFO and a carbon KAFO (steps per minute) 92.9 (6.3) vs. 92.0 (11.1)  $p > 0.05$ . Step length while walking with a carbon KAFO longer when compared with no KAFO: (step length cm) 45.6 (7.0) vs. 39.7 (7.5) and when compared with an ordinary KAFO 45.7 (8.2) vs. 41.3 (7.0),  $p < 0.1$ . Speed while walking with a carbon KAFO was significantly faster than walking without an orthosis: (m/minute) 39.5 (9.8) vs. 31.0 (8.6) and walking with an ordinary KAFO 42.6 (7.8) vs. 38.5 (7.0), both  $p < 0.05$

Oxygen consumption per body weight (ml/minute/kg), oxygen cost and physiological cost index while walking with a carbon KAFO were significantly lower than those without an orthosis (–16%, –35% and –33% respectively) and with an ordinary KAFO (–9%, –14% and –15% respectively), all  $p < 0.05$

### Resource utilisation

Number and nature of follow-up appointments: Not reported

Device malfunction: participants were followed up for at least 2 years and the carbon KAFO remained undamaged, but a plastic cable and two steel springs of the Swiss lock knee joints needed to be changed

Cost: price of standard carbon KAFO was 180,000 yen (US \$1700), 50% more expensive than the ordinary KAFO

### Adverse effects

Not reported

## Harvey (1997) methods

Study details	Study participants	Interventions	Analysis
Harvey (1997)	Number of participants: 10	Type of orthotic: HKAFO, Walkabout Orthosis	Duration of follow-up: mean 14 weeks with each orthosis
Country: Australia	% male: 90		
Language: English	Mean or median age: Mean: 37 years (SD 8.4 years)	Manufacture: custom-made. KAFO component was manufactured by an experienced on-site orthotist working within Spinal Injuries Unit and other components were made by two companies: Center for Orthotic Designs Inc., The RGO Center, Redwood City, California and Poly Medic Australia, Queensland, Australia	How were patient outcomes elicited?: 18-point questionnaire at end of each training and home trial period. 10-point Likert scale. Summary sheet on context of use (when, where, what for) 5-point scale assessing usefulness. Questionnaire on device preference (beginning and end of study)
Funding source: Motor Accident Authority of New South Wales and Center for Orthotic Designs	Ethnicity: not reported		
Conflict of interest: unclear	Weight: mean: 70 kg (SD 11.1 kg)	Material: not reported	
Study type: randomised crossover trial. There was a 2-month washout period of nonorthotic use before participants began the trial with the second orthosis	BMI: not reported	Specified orthotic dose: reported. Participants could use each orthosis as they wished but had to complete a brief summary sheet each time the orthosis was worn	How was gait assessed?: performed with elbow crutches. Level of independence and time to perform task assessed. Average speed of walking assessed for flat surface and up and down two ramps of different gradients
	Type of disorder: CNS. Complete spinal injury between 4 and 19 years previously. 4 patients had no spasticity, two had moderate to severe spasticity and four had mild spasticity		Statistical analysis: only those who could walk with minimal assistance or less in both orthoses included in the analysis. The 19 specific skills associated with functional ambulation were grouped into five categories and a mean score for each patient derived for each cluster of skills. Wilcoxon's signed-rank test used to determine differences between orthotics. The number of times participants used each orthosis was compared using <i>t</i> -tests. Patient preference for orthotic was assessed with binomial probability distributions. A Fischer Exact test used to determine whether or not participants' preferences changed over the course of the study
	Nature of instability: T9-12 paraplegia	Fitting procedure: not reported	
	Previous use of orthotics: yes. None had prior experience with HKAFO but all had some standing experience in KAFOs. One patient mainly used KAFOs and walking sticks for ambulation whilst the remainder were dependent on wheelchairs for functional mobility but had undertaken standing or gait training with KAFOs during the initial period of inpatient rehabilitation	Cointerventions: walking aids, elbow crutches	
		Other: gait training. Patients attended individualised gait training sessions 2–3 times a week over a 6- to 8-week period. Each session lasted between 2 and 3 hours. At the end of each 8-week training period, levels of skill performing 19 specific tasks associated with functional ambulation were assessed	
		Comparator: yes, IRGO	

## Harvey (1997) results

### Patient-reported outcomes

Functionality of device: all participants could sit in the wheelchair with the WO on but no participants could do so with the IRGO

Satisfaction with device: at the end of the study seven people preferred the IRGO and three preferred the WO ( $p=0.17$ ). Based on finding to significant difference between groups on any of the items the authors pooled data for both orthoses and across both testing periods and reported satisfaction overall rather than by device (not extracted)

Usage of device: there was no significant difference in the number of times that the two orthoses were used. During the home trial period no participant wore either orthosis for more than 2 hours at any one time. The most common reasons for using either orthosis were for exercise, practice or for the long term benefits. Most participants scored both orthoses between 3 (moderately useful) and 5 (extremely useful), (taken from text, numerical data not available). Six participants used the WO at home with one requiring assistance. Four of seven participants using the IRGO needed assistance, mainly for sitting and standing. Three participants wore the WO under clothes but no participants wore the IRGO under clothes. Both orthoses were worn indoors and outdoors by most participants (no further details). When participants were asked why they did not make more use of their orthoses, the most common response was being 'too busy'. Additionally, participants stated that using the orthoses prevented them from undertaking certain activities in the home as their hands were unavailable due to holding elbow crutches

### Objective assessments

Walking ability: speed of walking on the flat (8 participants): Participants walked significantly faster with the IRGO than with the WO on the flat surface, IRGO mean = 0.34 m/sec (SD 0.18), WO mean = 0.14 m/sec (0.12),  $p=0.002$ . Speed of walking up and down ramps (5 participants). Participants walked significantly faster with the IRGO than with the WO up and down ramps, (IRGO mean = 0.25 m/sec (SD 0.09), WO mean = 0.14 m/sec (SD 0.06),  $p=0.02$

Other functional ability: there was no significant difference between orthoses in the extent of assistance required to don and doff their orthoses; in the ability of participants to get up and down stairs and curbs; and in the ability of participants to walk on the flat. Participants required significantly more assistance when using the WO to walk over inclined surfaces (medians IRGO = 'independent', WO = 'minimal',  $p=0.03$ ) and significantly less assistance when using the WO to get from sitting to standing and from standing to sitting (medians IRGO = 'moderate', WO = 'minimal',  $p=0.03$ )

Other: no participants required more than minimal assistance to walk on the flat surface using the IRGO but one participant required moderate assistance and one maximal assistance to walk on the flat surface using the WO. No participants required more than minimal assistance to walk up and down ramps using the IRGO but five participants required either moderate or maximal assistance using the WO. Heart rate (HR, beats/minute), Oxygen uptake ( $VO_2$ , l/minute), expired ventilation (l/minute),  $O_2$  cost (ml/kg/m) and PCI measured at rest before and after three 6-minute walking trials (1 over flat-tiled surface, 1 over flat carpeted surface, 1 up a 4 degree concrete ramp). Data were collected using a tight-fitting mask and chest electrodes. There were no differences in HR or  $VO_2$  between orthoses for any surface or among surfaces. When HR and  $VO_2$  were expressed relative to walking speed, PCI and  $O_2$  cost of gait were significantly greater with WO compared with IRGO on all three surfaces. Participants' PCI (beats/minute) ranged from 8.4 to 10.3 beats/minute with WO compared to 4.3 to 7.0 beats/minute with IRGO ( $p < 0.05$ ).  $O_2$  cost during WO gait was between 3.95 and 4.91 ml/kg/m versus 1.65 to 1.80 ml/kg/m for IRGO gait ( $p < 0.05$ )

### Resource utilisation and adverse effects

Not reported

PCI, physical cost index.

## Heim (1997) methods

Study details	Study participants	Interventions	Analysis
Heim (1997)	Number of participants: 30	Type of orthotic: KAFO	Duration of follow-up: mean 30 months (range 15 to 39 months)
Country: Israel	% male: 33	Manufacture: custom-made. Gapim Ltd, Israel (33 braces)	How were patient outcomes elicited?: structured questionnaire (no further details provided)
Language: English	Mean or median age: mean age 44 years	Esched Advanced Orthopedics (three braces)	How was gait assessed?: gait not assessed
Funding source: Lewis National Rehabilitation Institute and orthotic manufacturers Gapim and Eshed	Ethnicity: not reported	Material: carbon fibre braces weighted on average 1150 g (metal braces previously used weighed on average 1720 g)	Statistical analysis: not reported
Conflict of interest: yes. Manufacturers helped fund the study	Weight: not reported	Specified orthotic dose: not reported	
Study type: case series	BMI: not reported	Fitting procedure: not reported	
	Type of disorder: neuromuscular, post-polio	Cointerventions: not reported	
	Affected knee: left, right, both	Comparator: no comparator group	
	Nature of instability: post-polio		
	Previous use of orthotics: yes. All patients had used orthoses and were eligible to have new orthotics (replaced every 3 years at the time of study)		

## Heim (1997) results

### Patient-reported outcomes

Satisfaction with device: 19 of 27 patients reported that they would like to have a permanent carbon fibre orthosis due to it being lighter, better fitting and more aesthetic

Usage of device: 21 of 27 patients wore their orthosis throughout the day

### Objective assessments

Not reported

### Resource utilisation

Device malfunction: within 30 months, 19 braces had undergone minor repair in the workshop

### Adverse effects

Eight patients chose a metal orthosis rather than the carbon fibre brace due to skin irritation from the material, excessive sweating due to proximity of orthosis to skin and inability to alter the shape in accordance with circumferential limb changes



## Jaspers (1997) methods

Study details	Study participants	Interventions	Analysis
Jaspers (1997)	Number of participants: 14 (out of 23 people fitted with a device in the study period)	Type of orthotic: RGO, ARGO	Duration of follow-up: at least 1 year (from 1 year 7 months to 4 years 8 months)
Country: Belgium		Manufacture: custom-made. STEEPER ARGO, Hugh Steeper Limited, London	
Language: English	% male: 86		How were patient outcomes elicited?: telephone interview (approximately 30 minutes) with an independent researcher using a standardised questionnaire (full details in paper)
Funding source: the government agency for Innovation by Science and Technology, Belgium	Mean or median age: mean 33.6 years	Specified orthotic dose: not reported	
Conflict of interest: unclear	Ethnicity: not reported	Fitting procedure: reported	
Study type: case series	Weight: not reported	Cointerventions: walking aids. 12 patients used a walker, 2 used crutches	How was gait assessed?: not applicable
	BMI: not reported		
	Type of disorder: CNS. Paraplegia with levels of lesion mid-thoracic to L1 except two patients with high level C7 lesions	Other. patients were trained 4 weeks prior to fitting of the orthotic followed by a 4- to 6-week training period with the appliance. which was usually continued at home under the supervision of a private physiotherapist	Statistical analysis: none
	Affected knee: not reported		
	Nature of instability: result of paraplegia	Comparator: no comparator group	
	Previous use of orthotics: yes. Four patients had used long leg braces previously		

## Jaspers (1997) results

### Patient-reported outcomes

Functionality of device: all patients used the ARGO mainly to stand and walk without a real functional goal. A few (unspecified) tried to use it at work but did not continue as they considered the ARGO to be too heavy and cumbersome for use in a really functional way. They also found the walking speed to be too slow. One user could make a transfer into a car without much difficulty, two others were able to transfer but found it too difficult to do on a regular basis. The other participants had never tried this

Impact on daily living, quality of life: the ARGO was used outdoors by Four participants (for walking in the garden). No participants used it for walking in the street. Seven out of 14 of the regular users could use the ARGO fully independently. Three needed help with donning, five needed assistance with rising

Satisfaction with device: all patients stated that they had been well informed about the possibilities of walking with the ARGO prior to fitting and two said that they were disappointed in their expectations. Of the 12 active ARGO users, two found it 'very good', six 'good', three did not state their opinion and one found it 'bad'. Of the two non-users one rated the device 'good' and one did not answer

Usage of device: 12 of 14 were still using the ARGO on a regular basis. One patient who had stopped using the ARGO was planning to resume use. Principal reasons for abandoning ARGO use were mechanical problems with the ARGO and lack of time due to employment or preoccupation because of various interests. All four patients who had used long leg braces had discontinued use of these braces. The frequency of using the ARGO ranged from daily to twice a month with an average of three times a week. On each occasion, the ARGO was used for 1–2 hours

Other: of the 12 regular users, one reported problems with the cosmesis of the ARGO or with the appearance of gait. Although the ARGO could be worn under clothing, none of the users did so

### Resource utilisation

Device malfunction. Most complaints were related to the functioning of the knee-locking cables and the knee-locking mechanism when rising and sitting down (numbers unclear). Further complaints about the ARGO were its weight, the fact that it was too big to use in an active wheelchair and the discomfort whilst sitting due to the back tube

### Adverse effects

There were no complications of a physiological nature. Two patients had fallen but without serious injury

## Kakurai and Akai (1996) methods

Study details	Study participants	Interventions	Analysis
Kakurai and Akai (1996)	Number of participants: 28 % male: 50	Type of orthotic: KAFO (Convertible KAFO to AFO)	Duration of follow-up: not reported
Country: Japan	Mean or median age: mean	Manufacture: custom-made	How were patient outcomes elicited?: not applicable
Language: English	54.5 years	Material: plastic solid. Convertible KAFO - plastic shoe-horn type AFO connected with a knee orthosis using metal plunger lock. KAFO can then be replaced by AFO after functional recovery of active knee control	How was gait assessed?: not reported
Funding source: not reported	Ethnicity: not reported		
Conflict of interest: unclear	Weight: not reported		Statistical analysis: those changing to AFO were compared with those remaining on KAFO using Student's <i>t</i> -test and chi-squared test to consider differences in ambulation capability using the modified Barthel index
Study type: case series	BMI: not reported	Specified orthotic dose: not reported	
	Type of disorder: CNS. Hemiplegic patients whose 'functional recovery was less than expected'. 60.7% had moderate to severe sensory disturbances, 42.9% had shoulder hand syndrome, 34% had aphasia, 25% unilateral spatial neglect, 17.9% apraxia and 17.9% dementia	Fitting procedure: reported. Orthosis was fitted when patients began gait training after onset of stroke. In 12 cases this was within 3 months, in nine cases between 3 and 6 months and in seven cases > 6 months after onset of stroke	
	Affected knee: left, right	Cointerventions: not reported	
	Nature of instability: hemiplegia	Comparator: yes. Patients who had changed to AFO during the study were compared with those remaining on KAFO	
	Previous use of orthotics: no		

## Kakurai and Akai (1996) results

### Objective assessments

Walking ability: during the period of observation (unclear) 11 patients could control their knee actively between 1.5 and 10 months (average 4 months) after initial prescription of the orthosis. Their KAFOs were changed to AFOs (AFO group). The 17 remaining patients were unchanged and continued to use their KAFO (KAFO group). In the AFO group three were outdoor independent, one indoor independent and seven were indoor dependent. In the KAFO group two cases were indoor independent, 11 indoor dependent and four were non-ambulant

Other functional ability: mean AFO group Barthel index score was 72.8 (7.2), mean KAFO group Barthel index score was 43.1 (4.6),  $p < 0.01$

### Patient-reported outcomes, resource utilisation and adverse effects

Not reported

## Middleton (1997) methods

Study details	Study participants	Interventions	Analysis
Middleton (1997)	Number of participants: 25	Type of orthotic: Walkabout orthosis	Duration of follow-up: at least 18 months for those who continued to use the device after successful training (five discontinued, three were unsuccessfully trained and one was lost to follow-up)
Country: Australia	% male: 76	Manufacture: custom-made.	How were patient outcomes elicited?: questionnaire at outpatient review or by telephone interview of all patients who completed gait training and continued to use Walkabout.
Language: English	Mean or median age: mean 35 (SD 13) years	All patients required adaptations to the Walkabout orthosis and could not stand or balance well without individual customisation of the device. Adaptations included shoe raises, heel wedges, carbon fibre inserts, medial knee extensions and pads, bridging plates and lateral extension bars fitted with a pelvic strap and an abdominal pad	All patients who used the Walkabout for 18 months or more were interviewed at least twice, between 7 and 12 months and approximately 12 months later.
Funding source: AMP Society, Orthotic Department of the Royal North Shore Hospital and Polymedic Pty Ltd	Ethnicity: not reported	Material: not reported	Five patients who discontinued use of Walkabout were interviewed after withdrawing from programme
Conflict of interest: unclear	Weight: not reported	Specified orthotic dose: not reported	How was gait assessed?: not assessed
Study type: case series	BMI: not reported	Fitting procedure: reported	Statistical analysis: analysis of variance of differences in pattern of orthotic usage between complete and incomplete spinal cord injured individuals was conducted
	Type of disorder: CNS. Spinal cord injury resulting in paralysis (traumatic 76% and non-traumatic 24%)	Cointerventions: walking aids, parallel bars, forearm crutches or frames	
	Affected knee: both	Comparator: no comparator group	
	Nature of instability: paralysis due to spinal cord injury		
	Previous use of orthotics: yes. 22 had previous experience of orthotics including KAFOs and Backslabs		

## Middleton (1997) results

### Patient-reported outcomes

Functionality of device: 24 of 25 patients were able to apply the Walkabout orthosis independently and transfer themselves between standing and sitting while wearing it. Improved standing stability was reported by all patients. Several examples of improved functionality were given but overall indoor accessibility was not improved and was often hampered by the accompanying walking aid

Satisfaction with device: no significant differences were found between patients with complete and incomplete lesions in terms of perceived benefits of the Walkabout device. Physical and psychological benefits were reported more frequently than exercise or functional benefits. Read from graph physical benefits were reported by > 90% of patients, psychological by approximately 50%, exercise approximately 40% and functional benefits by < 10%

Usage of device: 16 of 25 patients still use the Walkabout with 15 of these having continued for > 18 months. No statistically significant differences in usage between the two groups of patients were found at either review time point. No significant differences in variables within groups were found over time (data not given). The mean intensity of Walkabout usage for both spinal cord injured groups combined was 150 (24) minutes/week at the first review and 169 (36) minutes/week at the second review. The median at both time points was 120 minutes. Five patients discontinued usage of the Walkabout device between 7 and 20 months, three patients were unsuccessfully trained due to spinal immobility and one patient was lost to follow-up. Four of five who discontinued usage reported a lack of functional enhancement over either pre-programme orthoses (KAFO, RGO) or the wheelchair. One of these patients had problems with ankle contractures. The fifth patient was satisfied with the Walkabout but was forced to withdraw after 11 months due to previous surgery-related back pain

### Resource utilisation

Device malfunction: The authors reported that all devices required adaptation. Once set up, few devices required any adjustment, maintenance or repairs (no data provided)

### Objective assessments and adverse effects

Not reported

## Morinaka (1982) methods

Study details	Study participants	Interventions	Analysis
Morinaka (1982)	Number of participants: 25 (of 36 patients fitted with the device)	Type of orthotic: KAFO	Duration of follow-up: mean 14.6 months (range 1–35 months)
Country: Japan		Manufacture: custom-made	How were patient outcomes elicited?: not applicable
Language: English	% male: 64	Material: plastic solid. Long leg shelled, flexible plastic laminate 'Subortholen'.	How was gait assessed?: twelve characteristics of gait (10 unfavourable signs) were compared between the 25 cases fitted with KAFOs and 50 cases fitted with AFOs. The time to walk 5–10 m using a straight line drawn on the floor was measured and compared for each group and for a group of 30 adult males who had not had a stroke. The same groups were compared on walking and returning a distance of 10 m in an L-shaped line (a total of 20 m) and walking and returning for 5 m in an S-shaped line (total of 10 m)
Funding source: not reported	Mean or median age: mean 56 years	Weight approx 500 g	
Conflict of interest: not reported	Ethnicity: not reported	Specified orthotic dose: not reported	
Study type: cohort study	Weight: not reported	Fitting procedure: reported	
	BMI: not reported	Cointerventions: not reported	
	Type of disorder: CNS. Hemiplegia as a result of stroke. Graded as 3-3-5 in Brunnstrom's functional classification of hemiplegia	Comparator: yes. Comparison with 50 patients fitted with AFOs for evaluation of gait. A group of 30 adult males who had not had a stroke was also used for comparison of gait	
	Affected knee: not reported		Statistical analysis: not reported
	Nature of instability: hemiplegia		
	Previous use of orthotics: yes. Three patients had previously received an AFO		

## Morinaka (1982) results

### Objective assessments

Walking ability: the authors state that all 25 patients were able to walk smoothly after fitting of the KAFO. Two could walk independently after 12–15 months, two could ambulate independently but preferred to wear the orthosis. Results of gait characteristics were more favourable for KAFO users than for AFO users for 8 of 12 characteristics (from figure and author summary, statistical significance was not reported). Knee flexion was better in AFO users. The KAFO group was about 'a half to a third' faster than AFO group but slightly slower than non-stroke group. The authors state that almost all of KAFO seemed able to turn easily and ambulate on the S-shaped line smoothly. Outcomes were not reported in full (only qualitatively and in figures)

Other: all 25 patients continued to wear the orthosis without rejection

### Patient-reported outcomes, resource utilisation and adverse effects

Not reported

## Peethambaran (2000) methods

Study details	Study participants	Interventions	Analysis
Peethambaran (2000)	Number of participants: 5	Type of orthotic: anterior approach KAFO	Duration of follow-up: 6 weeks
Country: USA	% male: 40	Manufacture: custom-made	How were patient outcomes elicited?: three questionnaires on 1. satisfaction (5-point scale)
Language: English	Mean or median age: mean 61.40 (SD 12.44) years	Material: carbon titanium with cable control locking mechanism	2. performance (5-point scale) and 3. body part discomfort map (6-point scale)
Funding source: not reported	Ethnicity: not reported	Specified orthotic dose: reported.	How was gait assessed?: patients completed a performance evaluation questionnaire, which included a question on gait
Conflict of interest: not reported	Weight: mean 153 lb (SD 34 lb)	New anterior approach KAFO was to be worn for 6 weeks	Statistical analysis: the non-parametric Wilcoxon signed-rank test to compare performance, satisfaction and wellbeing. A one-tailed test was used with alpha = 0.05 to determine statistical significance
Study type: case series	BMI: mean BMI 24.14 kg/m <sup>2</sup> (SD 2.62 kg/m <sup>2</sup> )	Fitting procedure: reported. At the initial visit, subjects were evaluated and casting procedures completed for the new KAFO. The KAFO system was ready for application in 3 weeks. Regular follow-up was carried out to ensure the integrity of the system	
	Type of disorder: neuromuscular. Patients with post-polio paralysis	Cointerventions: not reported	
	Affected knee: not reported	Comparator: yes. Within group comparison with posterior approach KAFO. Plastic solid conventional design – standard polypropylene thigh foot and ankle section	
	Nature of instability: post-polio paralysis		
	Previous use of orthotics: yes. Previously using the conventional KAFO		

## Peethambaran (2000) results

### Patient-reported outcomes

Functionality of device: results were statistically significantly in favour of the new KAFO for ease of putting on [mean 4.4 (SD 0.548) vs. 2.60 (SD 0.894)] and ease of removal [(4.6 (0.548) vs. 3.0 (0.000)] and interference with sitting [4.80 (0.447) vs. 1.20 (0.447)]. It was not statistically significant for the other domains of strap application, shoe application, maintenance and cleaning, balance, stability in level and uneven ground walking and adequacy for sports

Pain and disability: the new KAFO was statistically significantly favoured for discomfort in ankle, thigh (back) [4.4 (0.548) vs. 1.6 (0.894)], knee (back) [4.8 (0.447) vs. 2.8 (1.483)], lower leg (back) [4.8 (0.447) vs. 2.0 (1.414)] and foot [4.6 (0.548) vs. 3.6 (0.894)]. It was not statistically significantly favoured for thigh (front), knee (front) or lower leg (front)

Satisfaction with device: patients were statistically significantly more satisfied with the new KAFO in terms of its comfort [4.2 (0.447) vs. 3.4 (0.548)], gait [5.00 (0.000) vs. 3.8 (0.447)], appearance [5.00 (0.00) vs. 3.00 (0.707)], effort [5.00 (0.00) vs. 4.40 (0.548)], support [4.8 (0.447) vs. 4.00 (0.00)], donning/doffing [4.80 (0.447) vs. 3.20 (0.837)], not catching on clothes [2.00 (0.00) vs. 1.00 (0.00)] and not rubbing on skin [2.00 (0.00) vs. 1.40 (0.548)]. Other criteria were not statistically significantly different (hours of wearing, loss of function, wearing an orthosis, device weight, device soiling clothes and device encouraging perspiration)

### Adverse effects

Pain/discomfort results reported under patient satisfaction

### Objective assessments and resource utilisation

Not reported

## Scivoletto (2000) methods

Study details	Study participants	Interventions	Analysis
Scivoletto (2000)	Number of participants: 24	Type of orthotic: RGO	Duration of follow-up: 1 year
Country: Italy	% male: 79	Manufacture: custom-made	How were patient outcomes elicited?: neurological and physical examination and social history at the beginning of the study. At follow-up patients took the Eysenck Personality questionnaire and the Cognitive Behavioural Assessment Schedule 3 for self-rating anxiety and Schedule 8 for self-rating depression. Patients were defined as 'anxious' and 'depressed' when their scores on the two scales were one standard deviation above the mean of the norms
Language: English	Mean or median age: mean 33.6 (SD 3.2) years	Material: not reported	
Funding source: not reported	Ethnicity: not reported	Specified orthotic dose: not reported	
Conflict of interest: not reported	Weight: not reported	Fitting procedure: not reported	
Study type: case series	BMI: not reported	Cointerventions: not reported	
	Type of disorder: CNS. Complete spinal cord injury of traumatic aetiology all of thoracic level	Comparator: yes. RGO non-users	
	Affected knee: not reported		How was gait assessed?: not applicable
	Nature of instability: result of spinal cord injury		Statistical analysis: chi-squared test and Student's <i>t</i> -test used to consider differences between RGO-users (Group A) and RGO-non-users (Group B)
	Previous use of orthotics: not reported		

## Scivoletto (2000) results

### Patient-reported outcomes

Functionality of device: users and non-users did not differ on donning and doffing time, the need for help with donning and doffing, walking speed, walking aids and ability to go up and down stairs at the end of training ( $p=0.003$ ) and at 1 year follow-up (details provided). There was a significant difference between users and non-users both at the end of training ( $p=0.005$ ) and at follow-up ( $p=0.003$ ) with functional capacity as measured by the Garrett score. RGO users had a functional level between home ambulation with limitations and home ambulation while RGO non-users had a functional level between hospital ambulation and home ambulation with limitations

Usage of device: 11 patients (46%) no longer used the RGO. This included one patient with a fractured femur and several (unspecified) finding the orthosis uncomfortable or too difficult to don or doff, or too slow or too hard to use, or poor fitting

### Objective assessments, resource utilisation and adverse effects

Not reported

## Steinfeldt (2003) methods

Study details	Study participants	Interventions	Analysis
Steinfeldt (2003)	Number of participants: 55 (of 78 patients treated in the time period)	Type of orthotic: KAFO	Duration of follow-up: at least 3 months
Country: Germany		Manufacture: prefabricated	How were patient outcomes elicited?: postal questionnaire
Language: German	% male: 44	Material: carbon fibre	How was gait assessed?: not assessed
Funding source: not reported	Mean or median age: mean 58 years	Specified orthotic dose: not reported	Statistical analysis: score counting and calculation of percentages
Conflict of interest: yes. One of the authors was involved in the company manufacturing the orthotic	Ethnicity: not reported	Fitting procedure: reported	
Study type: case series (retrospective)	Weight: not reported	Cointerventions: not reported	
	BMI: not reported	Comparator: no comparator group	
	Type of disorder: neuromuscular. Polio		
	Affected knee: both		
	Nature of instability: resulting from polio		
	Previous use of orthotics: not reported		

## Steinfeldt (2003) results

### Patient-reported outcomes

Satisfaction with device: patient's perception of the following activities was retrospectively assessed pre- and post-device (10-point Likert scale): walking: pre 3.8, post 8.3, sitting: pre 4.8, post 8.9, driving a car: pre 5.8, post 9.1, comfort: pre 4, post 8.8, putting the device on/taking it off: pre 4.7, post 8.6

Other: two-thirds of patients did not need orthopaedic shoes with the KAFO

### Objective assessments

Walking ability: maximal walking distance assessed by patient report, increased 1.2–11 times once patients were used to their KAFO compared to pre-intervention but use of other walking aids was only reduced for four patients (7%)

### Resource utilisation

Device malfunction: 'patient reports of the need for repairs did not show substantial problems'

### Adverse effects

Not reported

## Summers (1988) methods

Study details	Study participants	Interventions	Analysis
Summers (1988)	Number of participants: 20	Type of orthotic: HGO (Parawalker)	Duration of follow-up: mean: 1 year 8 month; range 6 months to 3 years 8 months
Country: UK	% male: 100	Manufacture: custom-made	
Language: English	Mean or median age: mean: 28 years (range 20–39)	Material: not reported	How were patient outcomes elicited?: nine patients were interviewed in person and 11 by phone by one of the study authors. Level of walking ability was classified according to the ability to don, doff and transfer independently or dependently, the value of the orthosis to the patient (functional or therapeutic) and how far and where the patient was able to walk (indoor or outdoor > 50 metres over varying terrain)
Funding source: not reported	Ethnicity: not reported	Specified orthotic dose: not reported	
Conflict of interest: unclear	Weight: mean 69 kg	Fitting procedure: not reported	
Study type: case series	BMI: not reported	Cointerventions: walking aids: crutches used as decided by patient	
	Type of disorder: CNS. Spinal cord injury	Comparator: no comparator group	How was gait assessed?: not assessed
	Affected knee: both		
	Nature of instability: paraplegic patients with neurologically complete lesions between C8 and T12		
	Previous use of orthotics: yes. 11 patients had previously used long leg callipers. At the time of fitting of the ParaWalker 10 of 11 had stopped using these		Statistical analysis: summary data only, no analysis

## Summers (1988) results

### Patient-reported outcomes

Functionality of device: eight patients used the HGO outdoors independently for therapeutic purposes, nine used the device independently for therapeutic purposes indoor only and three abandoned the device (two found it too tiring and one with an arm injury hoped to return to using it). All three were dependent therapeutic indoor walkers. In total 17 of 20 patients achieved independent donning and doffing and standing from and sitting in a wheelchair. The three who could not achieve this abandoned their HGO

Ten patients were able to get into the passenger seat of a car, with some difficulty. Two patients had driven a car with the device on but found it difficult and did not often repeat this task

Satisfaction with device: two patients complained that the device was unsightly to wear. Overall five patients were highly pleased with the device, 10 were pleased, three were non-committal and two disliked it

Usage of device: four patients used the device > 3 times a week, 11 used it 1–3 times a week, two < week and three abandoned it. Of the 17 users, two used the device for > 3 hours on each occasion, 13 for 1–3 hours and two for < 1 hour per occasion

### Resource utilisation

Number and nature of follow-up appointments: Patients were followed up at the gait laboratory every 6 months

Device malfunction: the authors stated that minor repairs were usually required at 6-monthly follow-up sessions but there were no breakages

### Adverse effects

Reported. The authors reported that there were no pressure sores. They stated that 'most' patients had one or two falls during early use and one patient sustained a significant injury (fractured distal end of radius)

### Objective assessments

Not reported



## Sun (2007) methods

Study details	Study participants	Interventions	Analysis
Sun (2007)	Number of participants: 15	Type of orthotic: RGO	Duration of follow-up: unclear
Country: China	% male: 66.7	Manufacture: not reported	How were patient outcomes elicited: not applicable
Funding source: not reported	Mean or median age: mean 33.7 years	Material: not reported	How was gait assessed?: not applicable
Conflict of interest: unclear	Ethnicity: Chinese	Specified orthotic dose: reported. Twice per day; 1 hour for each time; for 2 months	The outcome assessed walking distance within 6 minutes and mean walking time for 10 m
Study type: case series	Weight: not reported	Fitting procedure: not reported	
	BMI: not reported	Cointerventions: not reported	
	Type of disorder: CNS. Spinal cord injury	Comparator: no comparator group	
	Nature of instability: unclear		
	Previous use of orthotics: not reported		

## Sun (2007) results

### Objective assessments

Walking ability:

- Mean step length: 37.6 cm
- Mean walking distance within 6 minutes: 75.3 m
- Mean walking time for 10 m: 54.9 seconds

Other:

- Number of cases achieving household ambulation: 12 out of 15
- Number of cases achieving community ambulation: 5 out of 15
- Number of cases achieving therapeutic ambulation: 3 out of 15

### Patient-reported outcomes, resource utilisation and adverse effects

Not reported

## Tang (2009) methods

Study details	Study participants	Interventions	Analysis
Tang (2009)	Number of participants: 58	Type of orthotic: KAFO ( $n = 6$ ), RGO ( $n = 15$ ), AGO ( $n = 27$ )	Duration of follow-up: 4 months after commencement of rehabilitation (8 weeks following fitting of device)
Country: China	% male: 82.8%	Manufacture: not reported	
Funding source: not reported	Mean or median age: mean 32.35 years	Material: not reported	How were patient outcomes elicited?: Barthel index, Functional Independence Measure and WHO-QoL were administered.
Conflict of interest: unclear	Ethnicity: Chinese	Specified orthotic dose: reported. Twice per day; 50 minutes per time; for 6–8 weeks	
Study type: controlled trial	Weight: not reported		
	BMI: not reported	Fitting procedure: not reported. After fitting there was 6–8 weeks' standing and walking training	How was gait assessed?: not applicable
	Type of disorder: CNS. spinal cord injury		
	Nature of instability: unclear	Cointerventions: rehabilitation training for 8 weeks (including training in muscle strength, balance, transferring, wheelchair using and activities of daily living)	
	Previous use of orthotics: not reported	Comparator: yes. Conventional rehabilitation training ( $n = 10$ )	

## Tang (2009) results

### Patient-reported outcomes

Barthel index (BI), functional independence measure (FIM) (The paper also reports  $p$ -values for between and within group differences; however, due to the quality of the reproduction we could not confidently distinguish the between and within group comparisons and it was not possible to determine from the accompanying text)

Group	BI			FIM		
	Baseline	Before fitting the device	After fitting the device at 8 weeks	Baseline	Before fitting the device	After fitting the device at 8 weeks
AGO	42.11 (11.63)	71.48 (6.62)	80.04 (4.44)	81.19 (9.40)	98.30 (4.21)	105.07 (5.31)
RGO	43.0 (14.37)	73.47 (7.72)	82.67 (6.23)	83.0 (14.15)	97.2 (3.69)	105.6 (7.02)
KAFO	43.33 (11.25)	72.50 (8.22)	77.5 (6.90)	81.5 (7.12)	98.5 (3.08)	102.5 (6.09)
Control	44.0 (9.94)	72.0 (6.75)	74.5 (5.50)	83.5 (5.48)	97.9 (4.04)	98.6 (6.83)

WHO-QoL measure (The paper also reports *p*-values for between and within group differences; however, due to the quality of the reproduction we could not confidently distinguish the between and within group comparisons and it was not possible to determine from the accompanying text)

Group	AGO	RGO	KAFO	Control
Physical				
Baseline	37.25 (13.62)	36.13 (14.45)	36.66 (17.2)	38.7 (9.79)
Before fitting device	53.25 (17.38)	56.13 (9.65)	54.33 (12.27)	53.9 (9.42)
After fitting device at 8 weeks	68.18 (13.24)	70 (10.12)	58.51 (4.03)	55.8 (9.54)
Psychology				
Baseline	46.70 (13.13)	49.06 (15.35)	48.33 (11.63)	49.9 (10.32)
Before fitting device	53.85 (18.35)	57.06 (13.71)	54.5 (7.03)	56.5 (12.98)
After fitting device at 8 weeks	65.81 (12.31)	67.46 (12.18)	57.83 (11.16)	56.91 (1.78)
Interpersonal relationship				
Baseline	52.77 (11.90)	52.73 (17.72)	54.66 (17.39)	55.2 (12.18)
Before fitting device	54.88 (10.6)	53.93 (11.37)	55.66 (11.77)	53.7 (5.25)
After fitting device at 8 weeks	54.85 (9.57)	55.6 (8.23)	55.5 (10.85)	55 (8.19)
Environment surrounding patients				
Baseline	49.7 (14.37)	48.41 (3.38)	48.1 (4.04)	49 (8.27)
Before fitting device	54.74 (15.37)	55.73 (14.56)	54.16 (12.71)	54.9 (15.72)
After fitting device at 8 weeks	55.4 (12.92)	53.66 (8.94)	54.16 (10.88)	57.5 (11.97)

#### Objective assessments, resource utilisation and adverse effects

Not reported

## Whittle (1991) methods

Study details	Study participants	Interventions	Analysis
Whittle (1991)	Number of participants: 22	Type of orthotic: ParaWalker (adult HGO)	Duration of follow-up: 8 months (4 months for each orthotic)
Country: UK	% male: 82	Manufacture: custom-made	
Language: English	Mean age: 34 years	Material: metal solid	How were patient outcomes elicited?: unclear
Funding source: not reported	Ethnicity: not reported	Specified orthotic dose: not reported	How was gait assessed?: not assessed
Conflict of interest: no	Weight: not reported	Fitting procedure: reported. Participants were placed in pairs matched for age and level of spinal injury. One member used the HGO first, the other the RGO first.	Statistical analysis: unclear
Study type: case series	BMI: not reported	Participants performed upper limb and trunk exercise for 4 weeks, the first orthosis was fitted and training given so that the patient could put on and take off the	

Study details	Study participants	Interventions	Analysis
	Type of disorder: CNS. Paraplegia due to spinal cord injury	orthosis, stand up and sit down safely and walk at least 30 m. Participants wore the orthosis at home for 4 months then the pattern was repeated for the other orthosis.	
	Affected knee: both	Training in the use of either orthosis generally took about 3 hours per day for 4–5 days	
	Nature of instability: spinal cord injury		
	Previous use of orthotics: not reported	Cointerventions: walking aids: Nineteen patients using the RGO used a rollator, one used crutches. Fourteen patients using the HGO used crutches, five used a rollator	
		Comparator: yes. Custom-made RGO	

## Whittle (1991) results

### Patient-reported outcomes

Functionality of device: 17 patients successfully used the HGO, three did not and two left the study. Fifteen were successful with the RGO, five were not and two left the trial

Impact on daily living, quality of life: the authors made the following statements but did not provide numerical data to support them. The HGO was much quicker to put on or to take off. The RGO was quicker on most other tests but this was statistically significant only for standing up and climbing up a kerb. When sitting in a wheelchair, wearing an orthosis did not cause any serious problems. It was difficult to use a car when wearing one of the orthoses as either driver or passenger although patients reported it was a little easier with the RGO

Satisfaction with device: at the end of the study 12 patients chose to keep the RGO, four the HGO and six neither orthotic device. The main reasons given for the final choice (no numerical data provided): HGO – ease of putting on and taking off, RGO – cosmesis and ease of standing with hands free, neither – fear of developing pressure sores and difficulty using either orthosis. Final choice of orthosis did not appear to be influenced by intelligence or by any previous knowledge of one or other orthosis. The RGO was preferred by those who tended to be anxious and by those who did not regard themselves as particularly persistent in the face of difficulty (no data provided)

Other: there was little difference in comfort between the two orthoses (no data provided)

### Objective assessments

Walking ability: there were no significant differences between orthoses in gait parameters of cadence, stride length and velocity after 4 months' use (no data provided). The average walking velocity was about 0.24 m/s (about one-fifth normal speed). The effort involved in walking estimated by changes in pulse rate and oxygen consumption was similar for the two orthoses (no data provided)

### Resource utilisation

Device malfunction: the authors stated that frequent adjustments were needed initially for both orthoses and this was done by the on-site orthotist. The RGO particularly required attention to ensure patients did not get pressure sores (no data provided). No major failures occurred with the HGO. The RGO was damaged in two cases due to overstretching. In 4 months of use for both orthoses about one third of participants' devices needed minor repairs, replacements or adjustments

Other: fabrication of the RGO was statistically significantly more expensive (£1772 vs. £1116 for the HGO). Training and out-of-pocket expenses were similar between the orthoses. Combined cost of training and 4 months' maintenance was about £330 for each device. Patients and their carers had an average of 8 days off work and out-of-pocket expenses of £160 to £200

### Adverse effects

Not reported

## Wu (2003) methods

Study details	Study participants	Interventions	Analysis
Wu (2003)	Number of participants: 6	Type of orthotic: HKAFO	Duration of follow-up: unclear
Country: China	% male: 67	Manufacture: custom-made	How were patient outcomes elicited?: activities of daily living determined by Barthel index. However results presented were above the 20-point maximum on this scale
Language: English	Mean or median age: mean 27.6 years	Material: plastic solid, propene polymer	How was gait assessed?: unclear
Funding source: not reported	Ethnicity: not reported	Specified orthotic dose: not reported	Statistical analysis: pre-post data for Barthel index, motor plan score and sensory plan score were provided and statistical significance was assessed between the two time points (t-test)
Conflict of interest: not reported	Weight: not reported	Fitting procedure: reported	
Study type: case series	BMI: not reported	Cointerventions: other. Gait training including balance and walking exercises	
	Type of disorder: CNS. Spinal cord injury	Comparator: no comparator group	
	Affected knee: not reported		
	Nature of instability: paraplegia due to spinal cord injury		
	Previous use of orthotics: no		

## Wu (2003) results

### Patient-reported outcomes

Functionality of device

Barthel index: pre treatment 26 (SD 8), post treatment 47 (SD 7),  $p < 0.01$

### Objective assessments

Walking ability: 1 week after use of the orthotic all six patients could stand or walk better between parallel bars (no data provided). After 2 weeks of exercises with the orthoses patients could 'continuously walk for 40 m and complete therapeutic walking

Other functional ability: motor plan score: pre treatment 32 (SD 10), post treatment 37 (SD 6) ( $p > 0.1$ ); Sensory plan score: pre treatment 54 (SD 12), post treatment 61 (SD 12) ( $p > 0.1$ )

### Resource utilisation and adverse effects

Not reported

## Yang (2005) methods

Study details	Study participants	Interventions	Analysis
Yang (2005)	Number of participants: 67	Type of orthotic: KAFO, AFO	Duration of follow-up: not reported (duration of intervention 2 months)
Country: China	% male: 83.6	Manufacture: not reported	
Funding source: not reported	Mean or median age: intervention group mean 58.2 years control group mean 57.6 years	Material: not reported	How were patient outcomes elicited?: not reported
Conflict of interest: unclear	Ethnicity: Chinese	Specified orthotic dose: not reported	How was gait assessed?: not reported
Study type: RCT	Weight: not reported	Fitting procedure: not reported	
	BMI: not reported	Cointerventions: not reported	
	Type of disorder: CNS. post-stroke hemiplegic patients	Comparator: yes, conventional rehabilitation, kinaesthetics	
	Nature of instability: knee over-stretching		
	Previous use of orthotics: no		

## Yang (2005) results

### Objective assessments

Effectiveness	<i>n</i>	Highly effective	Moderately effective	No effect	% effective
Intervention	35	26	8	1	97
Control	32	17	9	6	81

### Patient-reported outcomes, resource utilisation and adverse effects

Not reported



## Appendix 13 Demographic characteristics of participants in qualitative study

Participant	Age (years)	Gender	Ethnicity	Condition
P1 (NHS)	36	Female	Black African	Poliomyelitis
P2 (NHS)	52	Female	White British	Spinal injury at birth (?spina bifida/cerebral palsy)
P3 (NHS)	50	Male	White and black African	Poliomyelitis
P4 (NHS)	70	Female	White British	Stroke
P5 (NHS)	53	Male	Asian Indian	Poliomyelitis
P6 (NHS)	59	Female	White British	Poliomyelitis
P7 (NHS)	55	Female	Black British	Multiple sclerosis
P8 (NHS)	63	Male	White British	Poliomyelitis
P9 (NHS)	67	Male	White British	Poliomyelitis
P10 (NHS)	62	Female	White British	Multiple sclerosis
P11 (NHS)	73	Male	White British	Multiple sclerosis
P12 (NHS)	53	Male	White British	Multiple sclerosis
P13 (NHS)	54	Female	White British	Multiple sclerosis
P14 (non-NHS)	64	Female	White British	Poliomyelitis
P15 (non-NHS)	72	Female	White British	Poliomyelitis
P16 (non-NHS)	64	Male	White British	Poliomyelitis
P17 (NHS)	72	Male	White British	Spinal injury/drop foot
P18 (non-NHS)	73	Female	White European	Poliomyelitis
P19 (NHS)	48	Female	White British	Spina bifida; amputation
P20 (NHS)	80	Male	White British	Spinal injury
P21 (NHS)	58	Female	White British	CMT disease
P22 (non-NHS)	63	Male	White British	CMT disease
P23 (NHS)	57	Male	Arab	Poliomyelitis
P24 (NHS)	63	Male	White British	Poliomyelitis

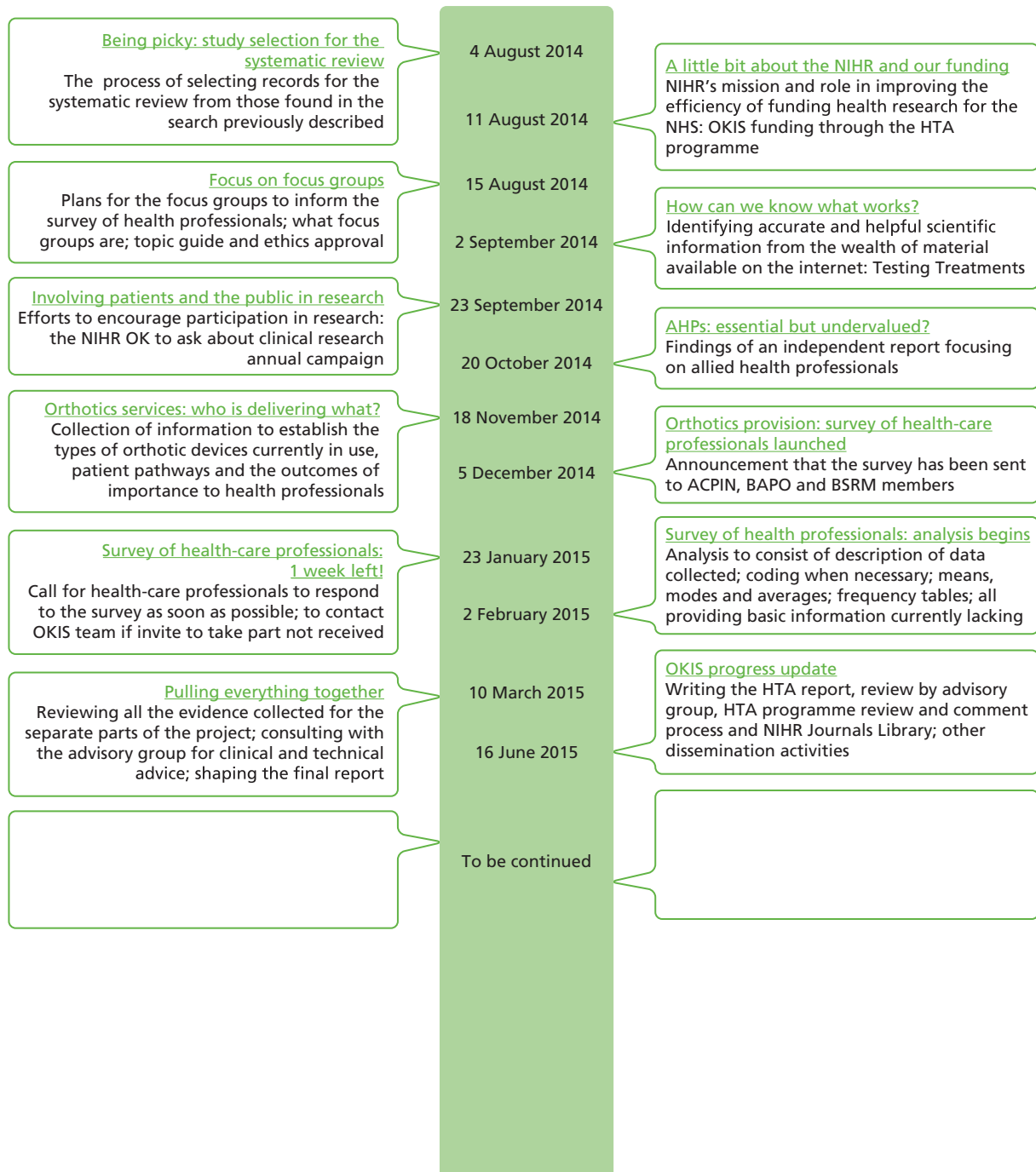




## Appendix 14 Orthotics for Knee Instability blog post timeline



PICO, population, intervention, comparator, outcomes. (continued)





A decorative graphic consisting of numerous thin, parallel green lines that curve from the left side of the page towards the right, creating a sense of movement and depth.

**EME  
HS&DR  
HTA  
PGfAR  
PHR**

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*This report presents independent research funded by the National Institute for Health Research (NIHR). The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health*

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