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Defining and grouping children's therapeutic footwear and criteria for their prescription: an international expert Delphi consensus study

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ABSTRACT

Objectives This study aimed to achieve an expert consensus on how to define and group footwear interventions for children, with a further focus on the design characteristics and prescription of off-the-shelf stability footwear for children with mobility impairment.

Setting A group of multinational professionals, from clinicians to those involved in the footwear industry, were recruited to ensure a spectrum of opinions.

Participants Thirty panellists were contacted, of which 24 consented to participate and six withdrew before round 1, a further two withdrew after round 1. Sixteen panellists completed the consensus exercise.

Primary and secondary outcome measures A Delphi consensus method was employed with round 1 split into three sections: (1) terms and definitions, (2) specifics of off-the-shelf stability footwear design and (3) criteria for clinical prescription of off-the-shelf stability footwear. The panel was asked to rate their level of agreement with statements and to provide further insights through open-ended questions. The opinions of the experts were analysed to assess consensus set at 75% agreement or to modify or form new statements presented through the subsequent two rounds.

Results Therapeutic footwear was the agreed term to represent children's footwear interventions, with grouping and subgrouping of therapeutic footwear being dependent on their intended clinical outcomes (accommodative, corrective or functional). Both the heel counter and topline as well as the stiffness and width of the sole were identified as potentially influencing mediolateral stability in children's gait. A consensus was achieved in the prescription criteria and outcome measures for off-the-shelf stability therapeutic footwear for cerebral palsy, mobile symptomatic pes planus, Duchenne muscular dystrophy, spina bifida and Down's syndrome.

Conclusions Through a structured synthesis of expert opinion, this study has established a standardisation of terminology and groupings along with prescription criteria for the first time. Reported findings have implications for communication between stakeholders, evidence-based clinical intervention and standardised outcome measures to assess effectiveness.

Strengths and limitations of this study

- A multinational sample of professionals from clinicians to those involved in the footwear industry was sought to ensure a spectrum of opinions were included.
- Analysis followed a standard mixed-method approach for Delphi consensus surveys and employed both qualitative and quantitative analysis.
- The study was limited to countries with English as their first language, and there may be differences in expert opinions outside the selected expert's countries (Australia, UK and USA).
- This research paves the way for the development of appropriate mechanical testing methods for off-the-shelf therapeutic stability footwear.

INTRODUCTION

Footwear is a fundamental common boundary between the ground and the foot in daily activities; it modifies forces and sensory stimulus with demonstratable effects on children's gait.[1–3] Correspondingly footwear has been used both historically and in modern healthcare practice as an assistive aid for children with mobility impairment.[4 5] However, a recent scoping review[6] highlighted that footwear as a clinical intervention for children lacks a common understanding of terms and definition as to the specifics of its clinical role. The development of recognised terms, definitions and characteristics of a healthcare intervention afford an understanding of how it should work, the value it should provide, who should benefit, how to measure its success, what risks are present and what is and is not included within the intervention.[7 8] The scoping review[6] demonstrated that numerous terms have been used in the literature concerning clinical footwear interventions, including orthopaedic shoes, rehabilitative boots, modified shoes, supportive shoes and special shoes. Additionally, there was no clear definition of the clinical role and outcome measures to classify and group the range of available children's footwear interventions. The results of the

scoping review suggested therapeutic footwear as a potential overarching term to represent the myriad roles and designs of children's clinical footwear interventions, with three primary groupings of therapeutic footwear categorised according to common identified clinical roles. The groupings were: corrective (footwear designed to bring about the correction of congenital skeletal lower limb alignment), accommodative (footwear designed to reduce stresses on children's foot deformity through the matching of footwear dimensions to the child's foot) and functional (footwear designed to improve dynamic gait parameters of mobility-impaired children, reducing pathological movements and facilitating typical walking patterns inclusive of stability).[6]

Among the therapeutic footwear groupings suggested in the scoping review,[6] those that offered a stabilising role were the most studied. Research has demonstrated potentially beneficial clinical outcomes to children with mobility impairment with increased velocity and lowered mediolateral excursions of the centre of mass in walking.[9–11] Children's stability footwear may be bespoke or have uppers that come in a range of modular adaptions but are most commonly made to a manufacturer's standard stock model, which are termed off the shelf.[10 12] The body of research concerning off-the-shelf stability footwear has chiefly focused on its biomechanical effects. However, the specific standard design characteristics for this footwear that are requisite for stability were not clearly identified or consistently reported in the literature.[6 9] The lack of recognised characteristics of an intervention prevents a common understanding of how it should work clinically[7 8] and preclude a meaningful comparison throughout any evidence-based research.[9] Thus, it is important that a consensus understanding of design characteristics required to enhance stability during gait is obtained, from both a manufacturing and clinical perspective, for this footwear.

In respect to who may benefit from this intervention,[7 8] there were seven childhood mobility impairments considered for off-the-shelf stability footwear intervention among the research identified through the scoping review: cerebral palsy, pes planus, toe walking, Duchenne muscular dystrophy, spina bifida, Down's syndrome and intoeing.[6] However, there appeared to be no clear prescription criteria for the use of off-the-shelf stability footwear in these conditions. Specific gaps in prescription criteria included the stated clinical role, the grade/severity of the condition when this footwear should be used as a sole assistive aid or an adjunct to other aids such as ankle foot orthoses (AFOs) and the suitable age range for intervention.[6 9] In addition, there appears to be no standardised set of agreed outcome measures, both physical and psychosocial, to ascertain the effectiveness of this footwear.[9] Identification and consensus agreement of outcome measures for both research and clinical practice allows for a unified measure of the effectiveness of an intervention, informing on value-driven healthcare and the development of a consistent evidence base.[13]

Although terminology and means of grouping clinical footwear interventions as a whole have been suggested by a synthesis of the available research,[6 9] a common understanding and usage of these terms would require an opinion on their practical application from experts who provide footwear to children with mobility impairment. Once the overall groupings and terminology of clinical footwear interventions have been established among experts in this area, it will be possible to identify and define individual intervention footwear categories for childhood mobility impairment, such as stability footwear. Off-the-shelf stability footwear appears to offer a beneficial effect on the broadest range of childhood mobility impairments.[6 9] However, as stated, a common understanding of the specifics and purpose of their design and the proposed clinical outcomes of this treatment is not apparent in the research.[6 9]

Where there is contradictory or insufficient information, the ability to formulate effective clinical reasoning can be affected; here consensus surveys such as the Delphi offers a valid and reliable method of determining expert opinion to inform on these areas.[14–16] Delphi surveys incorporate the collective opinion of a panel of experts fed back to the panel through a series of iterative rounds in an anonymised and controlled manner, with the underlying goal to achieve expert consensus on a certain issue where no agreement previously existed. This technique has been used successfully to achieve professional consensus on school footwear design[17] and the use of orthoses for mobility impairment.[18 19] The only previous study relating to the synthesis of expert opinion on footwear interventions was performed by Staheli and Giffin in 1980.[4] This was a single round cross-section survey of practice and opinion that lacked the staged systematic approach of a Delphi survey and was restricted to the correction of musculoskeletal alignments that are mainly found in typically developing children. The survey did not consider the footwear terminology used, the purpose of the specific designs of footwear or any effects on children's gait.[4] Establishing a common understanding of terms, definitions and groupings of clinical footwear as a whole, alongside design characteristics and prescription criteria for specific footwear groupings, may be achieved by conducting a Delphi consensus with experts in the field of clinical footwear provision and design. The consensus opinion may then be used to develop consistent terms and definitions for footwear interventions and prescription criteria and design characteristics for off-the-shelf stability footwear for children with mobility impairment.

Aims and objectives

The overall aim of this study was to achieve an expert consensus on how to define and group clinical footwear interventions for children, with a further focus on the design characteristics and clinical prescription of off-the-shelf stability footwear for children with mobility impairment.

The objectives were:

- To establish expert consensus on the terms, definitions and groupings of children's clinical footwear

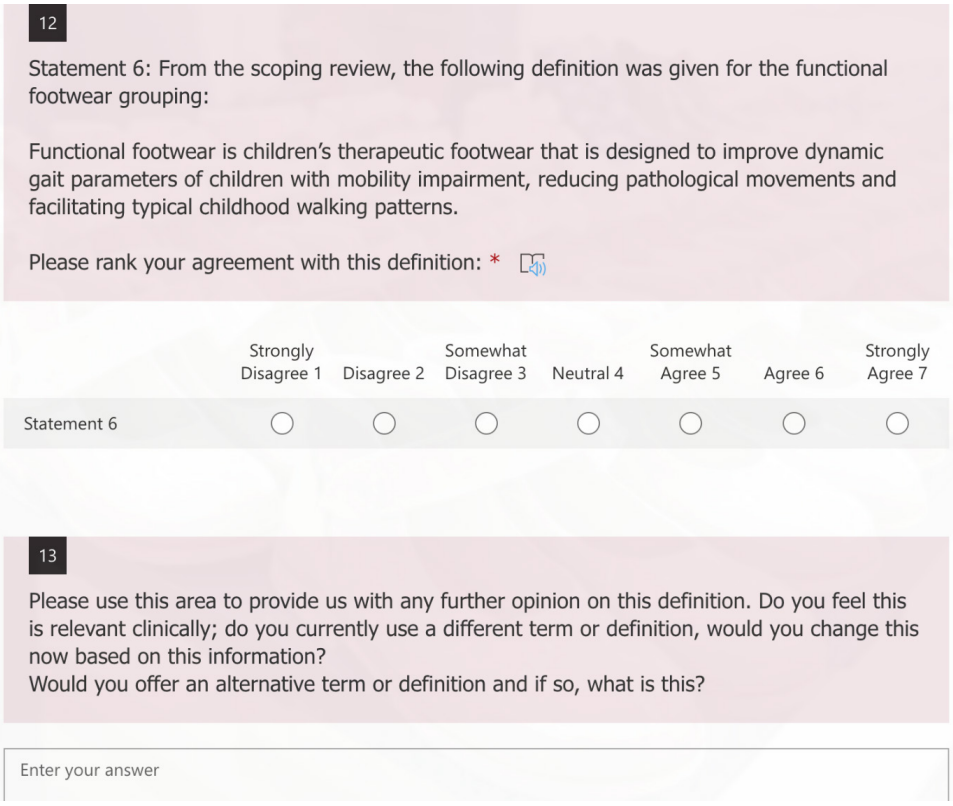

Figure 1 An example of a question from section 1 exploring consistent terms and definition of clinical footwear interventions (* indicates required answer).

interventions, providing a consistent and common clinical understanding to identify and categorise the purpose of these footwear types as an assistive aid for children.

- To establish a consensus of expert opinion of the ideal design characteristics of off-the-shelf stability footwear and the purpose of these characteristics.
- To develop expert consensus recommendations for the prescription criteria and outcome measures for off-the-shelf stability therapeutic footwear.

METHOD

This Delphi consensus study followed the methodological and reporting recommendations suggested by Keeney, Hasson and Mckenna.[20 21] The development and purpose of this survey were informed by scoping and systematic reviews performed by the authors.[6 9]

All panellists provided written informed consent to participate in this study.

Patient and public involvement

Due to the nature of this study, no patients or public were involved in the design, implementation or analysis of results.

Identifying panellists

Experts were recruited by the purposeful sampling of individuals meeting specific criteria:

- Registered practitioner in healthcare or clinical footwear manufacture.
- ≥10 years of practice in clinical footwear provision/manufacture.
- ≥25% clinical caseload involving the provision of footwear interventions to children with mobility impairment or ≥25% of their workload involved with the design or manufacture of footwear intended for therapeutic use in children with mobility impairment.

Recruitment was initially through professional networks of the research team and subsequently recruited experts were asked to identify additional experts who they felt met the criteria for this study. A multinational sample of professionals from clinicians, researchers and those involved in the footwear industry was sought to ensure a spectrum of opinions were included. Although there are no agreed definitions for an effective size convention ranging from 10 to 100 panellists within the literature,[22] researchers have suggested a sample size of 10 will provide a diversity of expert opinion.[23]

Contacting experts

Experts were contacted with the information sheet by email, with consent and a participant professional characteristic survey captured by Microsoft Forms.

Questionnaire design

The study took the form of a modified Delphi[15]; the first round was informed by scoping and systematic reviews of research in relation to children's clinical footwear interventions[6 9] and benchtop analysis of design characteristics

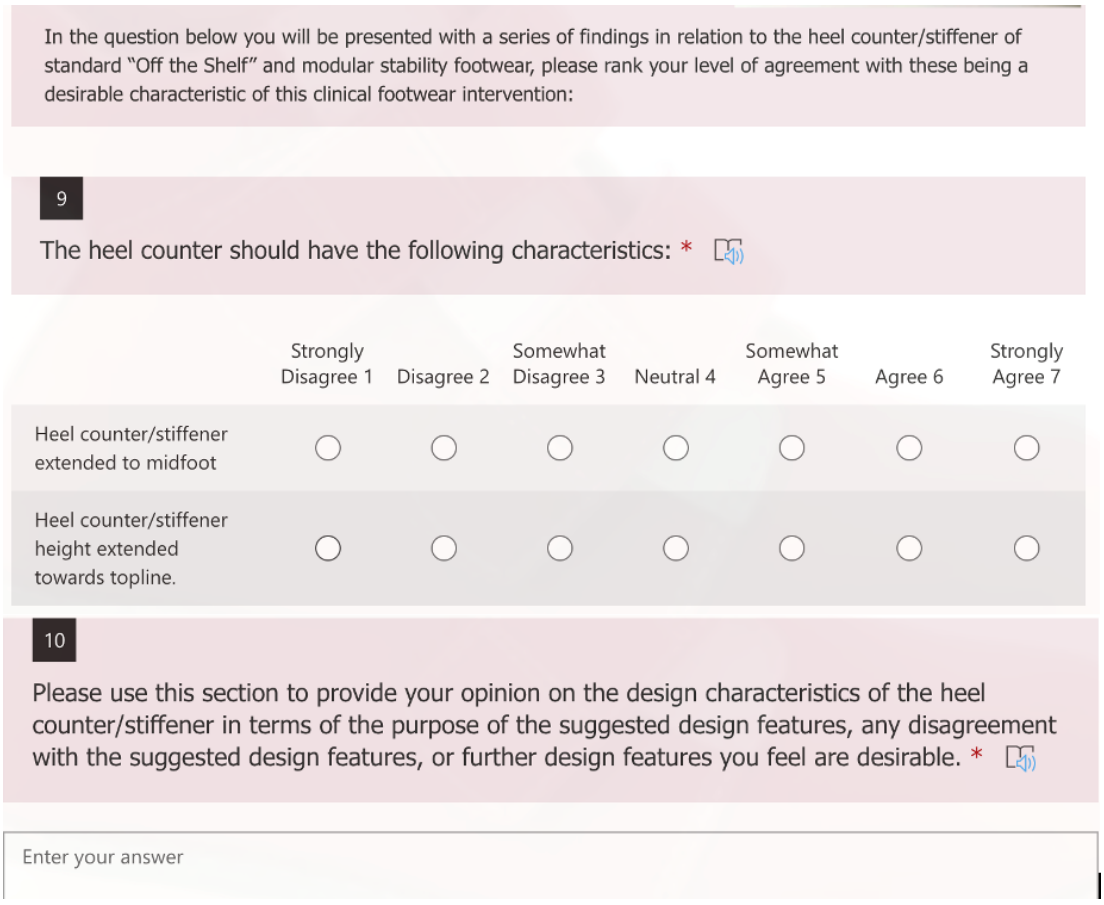

Figure 2 An example of a question from section 2 exploring recognised design characteristics of children's off-the-shelf stability footwear (* indicates required answer).

of a range of off-the-shelf footwear proposed to offer a stabilising effect on mobility impaired children. This approach allowed the development of informed questions from the available evidence. The survey consisted of closed-ended ranked and option questions, with ranked questions using a 7-point Likert scale. Open-ended questions were also provided to explore the panellists' opinions on the statements and questions posed and to allow them to offer alternatives or raise further salient items in relation to children's clinical footwear interventions. The first round of the survey, therefore, captured qualitative and quantitative data. This generated a combined synthesis of the current literature evidence base in relation to children's clinical footwear interventions alongside that of the experts' opinions from working in the area of clinical footwear provision.

The survey was designed by the first author with calibration and modification of questions among all authors. The survey was also piloted on an expert in clinical footwear provision to ensure the questions were appropriately framed and phrased to avoid ambiguity or multiple events within any question.[24] The first round consisted of three sections:

Section 1 asked the panellists for their opinion on consistent terms, definitions and groupings of clinical footwear interventions for children with mobility impairment. An example of the type and structure of the questions is provided in figure 1, with the full section 1 survey available in online supplemental appendix S1.

Section 2 asked the panellists for their opinion on the ideal design characteristics of off-the-shelf stability footwear and the purpose of these characteristics. An example of the type and structure of the questions is provided in figure 2, with the full section 2 survey available in online supplemental appendix S2.

Section 3 asked the panellists for their opinion on the prescription criteria of issuing commercially available off-the-shelf stability footwear in a range of mobility impairments and the outcome measures to be used to assess the effectiveness of this footwear. An example of the type and structure of the questions is provided in figure 3, with the full section 3 survey available in online supplemental appendix S3.

The panellists were given instructions on how to complete the survey in the introduction of each section.

Distribution

The survey was distributed among panellists electronically via Microsoft Forms. Panellists were reminded to complete the survey 1 week before the deadline. Late responders were followed up and offered an appropriate extension if required.

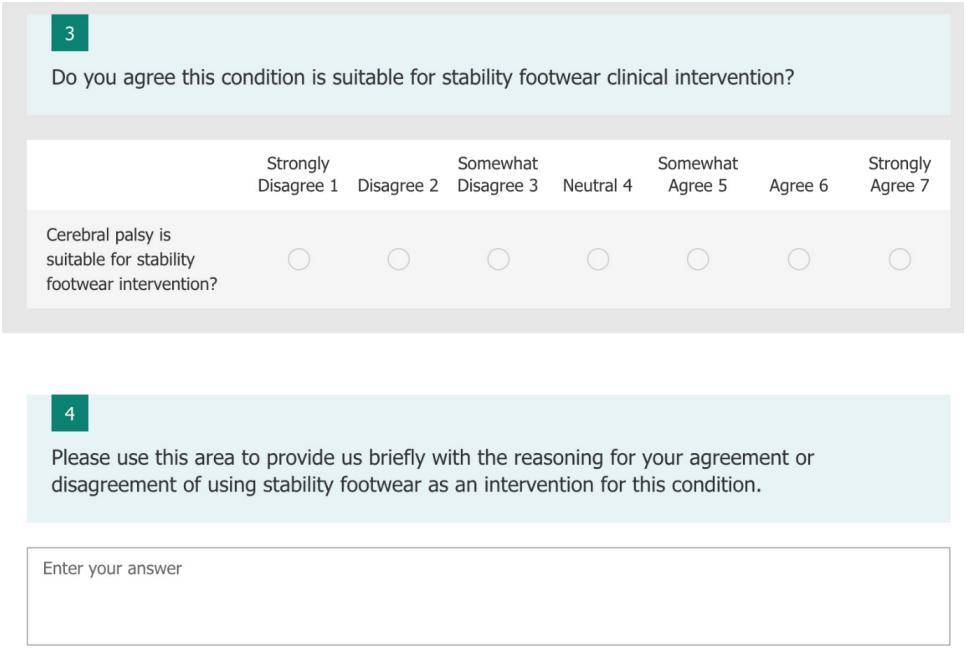

Figure 3 An example of a question from section 3 exploring prescription criteria for the provision of children's off-the-shelf stability footwear.

Analysis of results

Analysis followed a standard mixed-method approach for Delphi consensus surveys and employed both qualitative and quantitative analysis. The combined findings were used to inform the development of subsequent rounds of Delphi (two and three) in addition to the final results.

Analysis of open-ended questions involved an inductive themed content analysis framework performed by the first author.[25] The process involved the identification of statements that were the same or could be constructed to mean the same thing. These statements were grouped together, and themes were developed around similar statements. Once statements were grouped under a common theme, a decision was made among the research team as to whether these themes should be collapsed into one statement to be presented to the Delphi panel in the subsequent round. Unique statements that did not fall into any common theme were kept as the original statements. The wording of all statements was assessed by the research team for potential multiclauses and ambiguity.

The grouped themed and unique statements were presented to the panellists alongside a summary of the collective panellists' reasoning in rounds 2 and 3. These were in a series of ranked Likert scale questions or options alongside the original statements from round 1 or 2. Rounds 2 and 3 followed the same format of round 1 with three sections (online supplemental appendices S1–3).

Descriptive statistics: central tendency and dispersion of the responses (median analysis, IQR) and % frequency to the ranked questions were fed back to the panellists in rounds 2 and 3 for an estimation of the general response of the other expert panellists (online supplemental appendices S1–3). The quantitative values were also recorded for consistency analysis across the rounds.

Consensus

There is no agreed guidance on consensus but is often achieved through generating a predetermined percentage level of consensus of ranked questions or panellists preferred option (frequency).[14 15] The range of preset agreement is variable among Delphi studies; however, a value of 75% is a commonly reported value[26] and the one chosen to define consensus among the recruited panel in the present study. Statements would reach consensus when there was 75% or greater frequency of response for a preferred option or ranked questions of 'agree' to 'strongly agree'.

Cut-off

The Delphi was set a priori to run over three rounds or if there was a greater than 30% drop off of panellists.

RESULTS

Thirty panellists were contacted in January 2020, of which 24 consented to participate; six participants withdrew from the study prior to commencement of the first round. Eighteen panellists participated in round 1; the panel consisted of orthotists, podiatrists and a physiotherapist with a range of experience and roles in clinical footwear provision for children, including direct patient contact, education, research and commercial sales and manufacture. The international panel was composed of panellists from the UK, Australia and the USA; a full breakdown of the panellists' characteristics are provided in (table 1).

Of the 18 panellists, 16 completed all rounds of the Delphi survey resulting in an 11% drop off from the initial round (figure 4). From the initial 45 statements (11 in section 1, 27 in section 2 and 7 in section 3), a

Table 1 Participant characteristics

	7 females	39%
Sex	11 males	61%
Experience with clinical footwear provision for children	Median 18 years	IQR 11.75
% workload dedicated to either: assessment, manufacture or commercial distribution of footwear interventions for children with mobility impairment	Median 36.5%	IQR 25%
Profession:		
Orthotist	10	55.60%
Physiotherapist	1	5.60%
Podiatrist	7	38.80%
Professional role		
Clinician	5	27.80%
Clinician; researcher	3	16.70%
Clinician; education	3	16.70%
Clinician; education; researcher	3	16.70%
Clinician; commercial (sales and manufacture)	2	11.10%
Clinician; researcher; commercial (sales and manufacture)	1	5.60%
Clinician; education; commercial (sales and manufacture)	1	5.60%
Highest qualification		
PhD/professional doctorate	5	27.80%
Master's degree	5	27.80%
Bachelor's degree	6	33.30%
Professional diploma	2	11.10%

further 238 statements were developed or modified from panellist feedback (figure 4) for a total of 283 statements. Consensus agreement among the panel was reached on a total of 150 statements (figure 4). The statements for each section inclusive of the original, modified and those that reached consensus are found in supporting information files (online supplemental appendix S4–6). The results for each section are presented and discussed separately.

Section 1

The 11 consensus statements from section 1 were taken forward to establish consistent terms and definitions to broadly group and categorise children's clinical footwear interventions. There was a considerable majority consensus of the panel (81% agreement) who favoured therapeutic footwear as the overarching term for children clinical footwear interventions (figure 5). This term was felt by the majority of the panel to reflect the holistic aspect of footwear interventions on childhood mobility rather than be limited to aspects of aligning body structure that would be suggested by 'orthopaedic' and 'orthotic'. A broad overarching definition was established by panellists (82% agreement) for these interventions as:

> Footwear that is designed or adapted specifically to protect, support, align, prevent, or correct foot deformity, or to assist mobility and standing in children.

This definition comprised the scope of the potential role of footwear as a clinical intervention while also recognising that designs may incorporate specific therapeutic footwear or standard shoes that are adapted to meet a clinical purpose. Groupings of footwear fell under the overarching term therapeutic footwear (100% agreement), and panellists felt they should be grouped and categorised according to intended clinical outcomes of the components of the footwear (100% agreement). This was modified from the suggested method of groupings from the scoping review[6] in which the groupings assigned footwear as an individual design. The current grouping recognised that footwear might have more than one clinical role, that is, footwear may have both a direct functional component on gait and an accommodative component of the child's foot deformity. The main groupings of therapeutic footwear were those offered in round 1, which were taken from the scoping review[6]: accommodative, corrective and functional (figure 5). However, the definitions were modified by panellist's feedback with all achieving consensus in the second round:

> Accommodative footwear is children's therapeutic footwear that is designed to prevent deterioration of children's foot deformities through the dimensional matching of the footwear to the child's foot. (76% agreement)
>
> Corrective footwear is footwear that is designed or adapted to support correction of congenital or acquired foot and ankle deformity in children. This may be secondary to a primary corrective measure such as serial casting or surgery. (82% agreement)
>
> Functional footwear is children's therapeutic footwear that is designed or adapted to directly assist mobility and standing in children. (76% agreement)

Panellists felt that functional footwear could be placed into subgroupings dependent on the design and intended clinical outcomes of the footwear similarly to that suggested for the main groupings of therapeutic footwear (76% agreement). The panellists favoured the subgrouping of stability footwear suggested from the scoping review provided in round 1 (94% agreement) (figure 5). However, the definition was modified by panellists' feedback and did not achieve consensus until the third round:

> Stability Footwear is footwear that is designed to assist mobility and standing in children by influencing

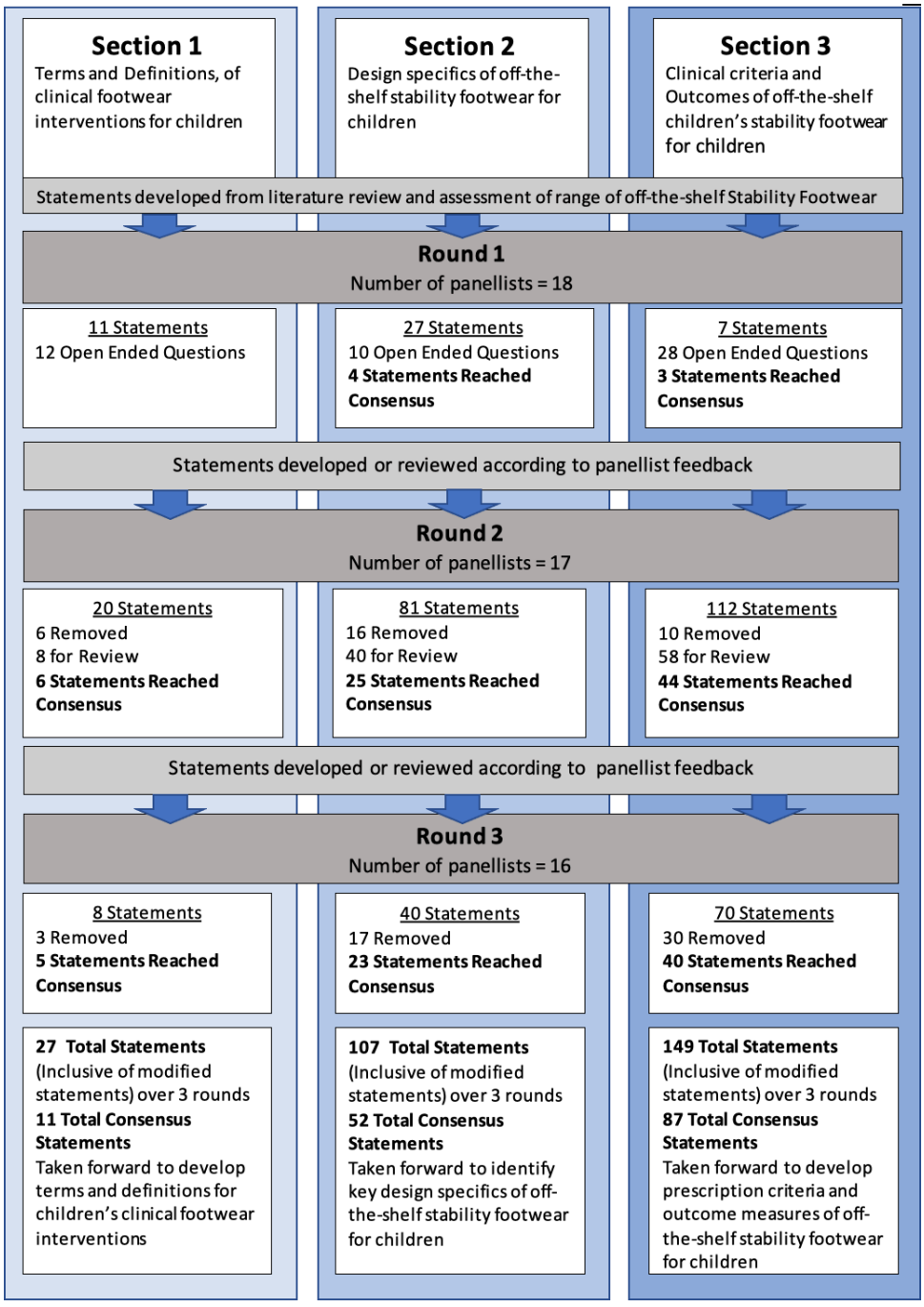

Figure 4 The Delphi survey three-round process and individual sections results.

movements and potentially proprioception of the foot and ankle. (94% agreement)

Panellists felt that the separate subgroupings of lift (raise*), rounded bottom (rocker bottom*) suggested from the scoping review in round 1 should be considered to fall collectively under one subgrouping. Therefore, a new separate subgrouping of functional footwear adapted sole was suggested from panellist feedback; this reached consensus in round 2 (76% agreement) (*preferred alternative terminology suggested by the majority of panellists in round 1) (figure 5). This was defined as:

A range of customised sole or heel adaptions to any suitable children's footwear, with the adaptions designed to assist mobility or standing in children.

From panellist feedback, the subgrouping of adapted sole recognised that there is a range of sole adaptions offering varied functional roles broader than stability. However, it was beyond the scope of the current Delphi to fully categorise and define the many sole adaptions that could fall into this subgrouping. Further detail on panellist opinion in the development of the subgrouping adapted sole may be found in online supplemental appendix S4.

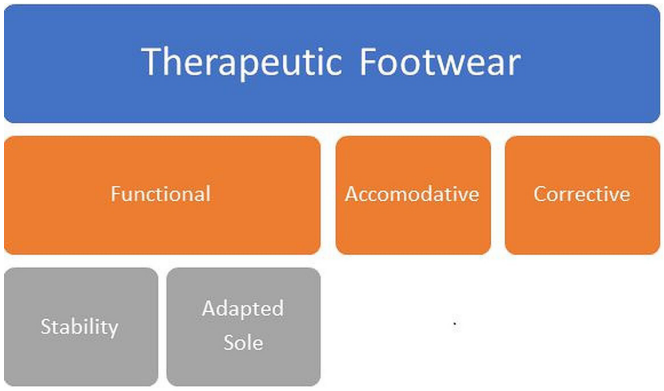

Figure 5 Terms and groupings of clinical footwear interventions for children derived from section 1.

Section 2

The 52 consensus statements from section 2 concerning the specific ideal design characteristics and purpose of off-the-shelf stability therapeutic footwear were distributed in nine regions of the shoe: topline, upper, facings and fastenings, heel counter/stiffener, heel, inlay, sole unit, sole rocker, in addition to overall consideration of the footwear's mass (table 2). Three key themes emerged from panellist feedback concerning the ideal design characteristics and their purpose those of stability, ergonomics and aesthetics (table 2). Stability was felt to be achieved by material stiffens of the heel counter (81% agreement), which may be assisted by an increased topline height in offering mediolateral stability to the foot and ankle (81% agreement). Panellists also felt that the fitting of the shoe inlay/insole to the child's heel should not be overlooked to increase vertical ground reaction forces in this area in addition to the firm anchorage of the counter to the welt and outer sole (88% agreement) (table 2). Although a proprioceptive effect of the heel counter and topline was suggested by some panellists, full consensus

Table 2 Themes of the ideal design specifics and purpose of off-the-shelf therapeutic stability footwear derived from section 2

Theme	Region	Dimension/manufacture	Material/properties
Stability	Heel counter/stiffener	Extended to midfoot and towards topline. Robust anchorage to welt and outsole.	Stiffened material.
	Topline	Extended above ankle To assist leverage of heel counter.	Leather.
	Outer sole	Wider than heel cup of upper Range of tread depths. Deepened tread for uneven terrain. Shallower for indoor use to avoid catching on the walking surface. Minimal heel forefoot differential to maximise stability.	Stiffer at the heel and midfoot. Hard wearing sole material.
	Upper		Leather with stiffened material properties.
	Inlay/insole	Contoured to cup the child's heel to improve the rearfoot fit.	
	Fastenings/facings	Facings extended to midfoot.	Lace fastenings.
	Forefoot rocker	Should not be so large to affect ground clearance in swing.	
Ergonomics	Heel counter/stiffener	Range of available extensions to accommodate ankle anatomy.	
	Topline	Padded collar and contoured to ankle anatomy.	
	Outer sole	Flexibility focused at the toe flex line.	
	Upper	Range of available dimensional adaptions to accommodate foot anatomy. Tongue adapted to avoid slippage under fastenings. Tongue length to provide comfort from fastenings.	Range of materials to allow breathability in warm climates. Wipeable material dependent on user's continence.
	Fastening/facings	Facings extended to toe box to allow greater access to footwear for limited foot and ankle mobility.	Velcro or lace dependent on the patient's dexterity.
	Inlay/insole	Contoured to cup the child's heel to improve rearfoot fitting. Deep enough to simulate potential prescriptive orthoses.	
	Footwear kept to the lowest reasonable mass to reduce the physiological cost to a child in mobility.		
Aesthetics	Upper	Range of colours.	Range of material.

(69% agreement) could not be achieved as a number of panellists were not convinced that the current evidence base supported the design components influence on proprioception. Other design features that were thought to impart stability and reached consensus were the: width of the heel in relation to the upper (87% agreement), stiffness of the outsole at the midfoot and rearfoot (88% agreement), tread depth of the outsole (87% agreement), lace fastenings (81% agreement) and leather upper of high tensile strength properties (93% agreement). The overall mass of the shoe was not thought to improve the stability properties of the shoe; it was, however, proposed and achieved consensus as a potential cause of instability in the swing phase of gait if too heavy.

The second key theme concerning the ideal design characteristics of off-the-shelf stability therapeutic footwear was in relation to ergonomics. Ergonomic aspects considered the fit and comfort of the shoe during wear and the ease in which the shoe could be donned and doffed on a child's foot with limited mobility. Originally in round 1, specific statements were presented to the panellists in relation to the design of this footwear, for example, '*Extended topline height above the ankle*' and '*The fastening should have the following characteristics: Lace*'. However, panellist opinion and feedback established a consensus preference to a pragmatic range of ergonomic options based on the child's ability, age and clinical need over the course of rounds 2 and 3, for example:

> The topline extension should come in an optional range both above and below the ankle dependent on the patient's ability and needs. (93% agreement), and The Fastenings should be Optional dependent on patient's ability and desired goal (eg, Velcro for limited hand dexterity, lace for greater stability). (93% agreement)

Panellists felt that the upper (93% agreement) and heel counter (80% agreement) should be available in a range of dimensions for any given size of off-the-shelf stability therapeutic footwear to accommodate a child's foot and ankle anatomy. The material of the upper should come in a range of materials to include breathable and wipeable fabrics for warm climates and issues with continence (100% agreement). The topline should be padded at the collar (88% agreement) and contoured to the ankle anatomy (80% agreement) to minimise mechanical stress to this region. Facings should be offered extended to the toe box to allow easy access (donning and doffing of the footwear) for children with limited movement of the foot and ankle (93% agreement).

Fastening should be in both lace and Velcro fastening to accommodate children's manual dexterity and allow a degree of independence (93% agreement). The mass of the footwear should be the lowest reasonable to reduce the physiological cost of walking (100% agreement). However, it was recognised that older children might require heavier footwear to account for increased mobility or enhanced stability requirements such as a stiffened outsole or extended heel counter that may additionally increase the footwear's mass (93% agreement). A consensus of the panellist was reached concerning the inlay/insole of off-the-shelf stability footwear, in that contouring at the heel improves rearfoot fit (81% agreement), and the inlay should be removable and thick enough to represent replacement by a possible adjunct orthosis (100% agreement). However, the specifics of the design in relation to contouring to the arch and heel failed to reach a consensus (63% agreement). Similarly, the purpose of a forefoot rocker to facilitate forward progression in gait and not affect the swing phase of gait reached a consensus (93% agreement). However, the standard design requirements of the rocker did not reach a consensus (56% agreement). Aesthetics of the footwear was proposed by the panellists in recognition of the psychosocial needs of children and felt that the visual appeal of the shoe was important to facilitate social interaction with peers with this statement receiving 100% agreement among the panel on initial consideration in round 2.

Section 3

The 87 consensus statements concerning children's mobility impairments suitable for off-the-shelf stability therapeutic footwear intervention resulted in consensus recommendations for the prescription criteria and outcome measures for five of the initial seven conditions: cerebral palsy (92% agreement), mobile symptomatic pes planus (86% agreement), Duchenne muscular dystrophy (92% agreement), spina bifida (80% agreement) and Down's syndrome (85% agreement) (tables 3–4). Five further conditions were suggested and reached a consensus among the panel: Charcot-Marie-Tooth (92% agreement), hypermobility (Ehlers-Danlos type) (92% agreement), developmental coordination disorder (100% agreement), Rett's syndrome (80% agreement) and chronic lateral ankle instability (77% agreement) (online supplemental appendix S6). However, the prescription criteria and outcome measures for the treatment of these further conditions were unable to be explored without further extending the Delphi survey and risking panellist fatigue.[14]

In relation to the prescription criteria for off-the-shelf stability therapeutic footwear, there were three areas that reached a general consensus for the five conditions:

1. The footwear provides mediolateral stability at the foot and ankle in walking and standing. Meaning it could act as both a walking aid and transfer aid (range 79%–88% agreement) (table 3).
2. The provision of off-the-shelf stability therapeutic footwear should only be issued to children with mobility impairment after a critical assessment of the child's mobility needs in respect to other assistive aids or footwear modifications and with clear clinical outcomes (range 86%–92% agreement). Panellists voiced their concern that this footwear had been historically uncritically prescribed in the conditions exampled. Panellists

Table 3 Prescription criteria for off-the-shelf stability therapeutic footwear

Condition	Indications for treatment	Sole or adjunct treatment
Cerebral palsy	Where mediolateral stability is required for standing and walking.	**Sole aid** May be used to assist both foot and ankle walking stability in children with GMFCS 1 and no significant tonal issues. **Adjunct** Used simultaneously with other assistive aids* to assist walking and standing in ambulant children GMFCS 1–3 with tonal issues. Used simultaneously with other assistive aids* to assist standing in non-ambulant children GMFCS 4.
Down's syndrome		**Sole aid** In prewalking and learning to walk stages with associated hypotonia and delayed motor milestones. **Adjunct** Used simultaneously with: 1. Foot orthoses to assist walking in individuals with ankle instability. 2. AFOs to assist walking in individuals with knee instability.
Duchenne muscular dystrophy		**Adjunct** Used simultaneously with: 1. Foot orthoses to assist foot and ankle stability in early ambulatory stages. 2. AFOs and walking frames to assist walking in late ambulatory stages. 3. AFOs and standing frames to assist standing and transfer in early non-ambulatory stages.
Spina bifida		**Adjunct** Used simultaneously with: 1. Foot orthoses to assist foot and ankle stability in sacral level 1 (meningocele). 2. AFOs and walking frames to assist walking and standing in lumbar level 4–5 (meningocele and myelomeningocele). 3. HKAFO or KAFO and walking frames to assist walking and standing in lumbar level 1–3 (meningocele and myelomeningocele).
Symptomatic mobile pes planus	Secondary line intervention to improve mediolateral stability in walking where foot orthoses have not resolved associated symptoms.	**Adjunct** Used simultaneously with foot orthoses in: 1. Children with significant foot and ankle instability associated with tripping and falling. 2. Children with insufficiency of posterior tibialis function. 3. Children with conditions associated with motor delay.

*Other assistive devices to include AFOs, crutches, foot orthoses, standing frames and walking frames.
†Adjunct AFO with stability footwear intervention requires a review of prescription of the sole to address any potential exacerbation of knee hyperextension in midstance.
AFO, ankle foot orthoses; GMFCS, Gross Motor Functioning Classification Score; HKAFO, hip knee ankle foot orthoses; KAFO, knee ankle foot orthoses.

felt foot orthoses serving similar function are less obtrusive and potentially cheaper. Consequently, a consensus (86% agreement) was reached that off-the-shelf stability therapeutic footwear should only be used as a secondary line of intervention for symptomatic pes planus where foot orthoses had failed to resolve symptoms.

3. In relation to the suitable age range for off-the-shelf stability therapeutic footwear intervention, a pragmatic approach to initiation and endpoints reached consensus in that it should be based on the functional ability and the mobility needs of the child rather than a specified age (range 77%–94% agreement).

Other areas suggested by panellists were concerning the use of this footwear as a sole aid or adjunct to other assistive devices. Most indications for the use of off-the-shelf stability therapeutic footwear was as an adjunct to other assistive devices (range 77%–92% agreement) to aid mediolateral stability in walking and standing (table 3). These other assistive devices included foot orthoses, AFOs, knee ankle foot orthoses (KAFOs), hip knee ankle foot orthoses and walking and standing frames. Indications for off-the-shelf stability therapeutic footwear as a sole aid were limited to low-grade cerebral palsy with no tonal issues (81% agreement) and the early walking stage of individuals with Down's syndrome (94% agreement).

Table 4 Clinical outcome measures for off-the-shelf stability therapeutic footwear in children with mobility impairment

Biomechanical	Physiological	Gross motor proficiency	Quality of life measures
Kinematic Optimising gait movement patterns (foot and ankle) Edinburgh Gait Score† Hoffer Ambulation Score‡ *Static Ankle Range of Motion:* Passive§: measured with the knee flexed and extended within the child's limits Weightbearing lunge¶: provided child can safely stand and get the heel to the ground **Spatiotemporal:** Walking velocity TUG 6MWT 10 m walk test.	Physiological cost Index** Perceived exertion** (BORG)	Number of falls BOT2†† Hoffer ambulation Score‡ Four square step test	Paediatric pain scale Daily mobility and social interaction

*Outcomes must consider the stage/grade of the condition and the capability of the child to perform the tasks.
†Specific outcome for cerebral palsy.
‡Specific outcome for spina bifida.
§Range of motion outcome for cerebral palsy and symptomatic mobile pes planus
¶Range of motion outcome for cerebral palsy, Symptomatic mobile pes planus and duchenne muscular dystrophy
**Physiological outcomes for cerebral palsy, symptomatic mobile pes planus and spina bifida.
††Gross motor proficiency outcome for cerebral palsy, symptomatic mobile pes planus and Down's syndrome.
6MWT, 6 min walk test; TUG, Timed Up and Go.

It was also noted by panellists that the foot anatomy of children with Down's syndrome presents a challenge with footwear fitting. Therefore, the practitioner should consider available last adaptions to accommodate the dimensions of these children during prescription (85% agreement).

Two of the seven originally proposed conditions suggested from the scoping review toe walking and intoeing failed to reach any consensus statements concerning the suitability and clinical indications for stability footwear intervention. However, it must be noted that idiopathic toe walking moved closer towards consensus statements for clinical indications (range 60%–67% agreement) than intoeing (range 25%–44% agreement).

Outcome measures proposed by the panellist were broadly aligned to biomechanical, physiological, gross motor proficiency and quality of life (QoL) measures. In relation to biomechanical measures, ankle range of motion reached consensus as an outcome measure for cerebral palsy, symptomatic pes planus and Duchenne muscular dystrophy (range 80%–88% agreement). Spatiotemporal outcome measures including walking velocity, 6 min walk test and Timed Up and Go reached consensus among the five conditions (range 77%–90% agreement). Kinematic outcome measures also achieved consensus among the five groupings (range 77%–90% agreement); these were in relation to optimising gait movement patterns of the foot and ankle against disease-specific scores, Edinburgh Gait Score and Hoffer Ambulation Score or normal available data sets. None of the suggested kinetic outcome measures achieved a consensus level of agreement (range 60%–67% agreement). Physiological outcome measures concerning cardiovascular and metabolic exertion were proposed and reached consensus (range 75%–91% agreement) for cerebral palsy, spina bifida and mobile pes planus. Outcome measures based on the child's ability to perform activities via measures of gross motor skills reached a consensus among the five conditions (range 75%–88% agreement) (table 4). Consensus was also reached by the panel in that suitability of physical outcome measures must consider the stage/grade of Duchenne muscular dystrophy and the capability of the child to perform the tasks (88% agreement). QoL measures, pain and activities of daily living outcome measures for off-the-shelf stability footwear intervention reached consensus agreement for all five conditions to a relatively high level (range 79%–100% agreement). With the majority of QoL outcome measures reaching consensus on initial consideration in round 2.

DISCUSSION

Despite the historical and relatively common usage of clinical footwear interventions in children with mobility impairment,[5 6] there has been a lack of common understanding of how to define and characterise this intervention. The collective opinion of the expert panel and the consensus formed through the inductive and iterative process of this study allowed novel ideas to be synthesised alongside previously published information. Clinical footwear interventions for children with mobility impairment reached a common understanding and were collectively

grouped and defined under the overarching term therapeutic footwear. This allowed the identification and categorisation of one of the more potentially effective of these interventions, stability footwear[9] as a subgrouping of functional footwear. The process also provided a consensus understanding of the ideal design characteristics for off-the-shelf stability therapeutic footwear and how this intervention may be used in a range of childhood mobility impairments. As stated, only one previous study had explored expert opinion on footwear as a clinical intervention for children.[4] The current study has provided a more detailed synthesis of expert opinion providing consensus on terms and definitions for children's clinical footwear interventions in addition to identifying the specifics and purpose of off-the-shelf stability therapeutic footwear design and criteria for clinical prescription for children.

Section 1 sought to obtain consensus on definitions terms and groupings for clinical footwear interventions in children. Although this represented the smallest section in the total number of statements and open-ended questions in round 1, it received the most detailed and rich comments for qualitative analysis, underlining the potential contentiousness of this section. However, this was the only section that received a consensus statement for each area presented to the panel. It is highlighted that a consistent language of terms and definitions is required in healthcare practice to improve interprofessional communication, healthcare research and provide optimal patient outcomes.[8 27] The suggested terms definitions and groupings, incorporating children's footwear interventions from this study, have been obtained using a valid consensus approach.[15]

The survey also sought to focus on off-the-shelf stability therapeutic footwear, which is a potentially effective footwear intervention for children's mobility impairment[9] The survey provided consensus agreement of a number of ideal design characteristics that should be offered on off-the-shelf stability therapeutic footwear for children, and the purpose of these. Identification of the key design specifics of an assistive aid affords an understanding of how and where the aid should support and assist mobility and has been used to help develop interventions such as AFOs.[27–29] However, the panellists pointed out there was a limited evidence base to support these stability design characteristics. Some panellist proposed potential neurodynamic properties of the footwear through proprioceptive feedback at the heel counter and extended topline. However, panellists felt that further evidence was required to justify this claim. In comparison with stability features of the footwear, the panellists appeared more certain with their opinion on ergonomic factors as this achieved consensus in earlier rounds and is probably due to the established body of work in footwear science that relates comfort and fit to function.[30–33] Although there is a lack of evidence to substantiate the design characteristics purported to offer stability, the identification of these areas may inform further mechanical testing of off-the-shelf stability therapeutic footwear.

In addition to the design characteristics of children's off-the-shelf stability therapeutic footwear, the survey sought to gain opinion and consensus on the clinical criteria for providing this footwear and the outcome measures to ascertain its effectiveness. Uncertainty on prescription criteria and goals of treatment can lead to inconsistent practice and lack of confidence in providing assistive aids to mobility-impaired children.[34 35] This section initially started with the least number of statements in round 1 but went on to generate a total of 149 statements for panellist consideration. Criteria for prescription were largely to improve mediolateral stability in mobility and standing. Off-the-shelf stability therapeutic footwear may often be prescribed by clinicians as a first-line intervention based on historical practice. However, expert consensus recommends that prescription of this footwear be assessed critically against the mobility needs of the child and the evidence base of other assistive devices, with the most suitable intervention being issued. Off-the-shelf stability footwear was to be used simultaneously with other assistive devices (AFOs KAFOs walking frames) in more severe gradings (Gross Motor Functioning Classification Score (GMFCS) 2–4) with only minor gradings indicated for sole line treatment with off-the-shelf stability therapeutic footwear (GMFCS 1). The exception to this was symptomatic pes planus where it may be used only as a secondary line intervention after foot orthoses had failed to resolve symptoms. Body structure and function outcome measures were chiefly focused on spatiotemporal and kinematic measures in addition to the physiological cost. Kinetic measures did not reach consensus; however, this was largely due to the perceived compliance with in-shoe measurement devices and availability of force plates in clinical settings rather than the validity of these outcome measures. It was, therefore, uncertain if the panellists considered if outcomes were inclusive of research settings as well as daily clinical practice. QoL measures appeared to be considered an important outcome for off-the-shelf stability therapeutic footwear intervention in children with mobility impairment as these reached a higher frequency of strongly agree and in earlier rounds compared with the other outcomes. Conversely, the current body of research is limited, exploring the effects of footwear interventions on the QoL of children.[9]

Idiopathic toe walking and intoeing did not achieve any consensus for clinical criteria of off-the-shelf stability therapeutic footwear provision. Idiopathic toe walking was not felt by the panel to be completely unsuitable for off-the-shelf stability therapeutic footwear intervention. It was noted that it presented with a nebulous aetiology with variable responses to many interventions.[36] The establishment of criteria therefore required more complex stratification than the closed-ended statements offered in the current survey. Intoeing again was cited as heterogeneous in nature[37]; however, this achieved the highest frequency of panellists scoring disagree or strongly disagree with panellists reaching a general consensus there was no clear evidence base to indicate off-the-shelf stability therapeutic

footwear for this clinical presentation even in the subcategories suggested by the modified statements offered across rounds 2 and 3.

Five further conditions were suggested through consensus of the panellists; however, it was beyond the capacity of the current survey to explore the clinical criteria and proposed outcomes for off-the-shelf stability therapeutic footwear intervention in these additional conditions. This will require further exploratory work among experts in the area of clinical footwear provision to establish this.

The Medical Research Council[38] provides a list of recommendations in developing and evaluating complex interventions. Paramount to the development process is that an intervention should be able to be fully defined in what it is expected to do and under what situations. There should be a full understanding of the components of the intervention and how these should act, who the intervention is aimed at and what the salient outcome measures expected to be achieved.[7 38] The results of the Delphi consensus process have outlined and defined the spectrum of roles footwear may play as a clinical intervention. Further to this, the results of the study provided an expert consensus of off-the-shelf stability therapeutic footwear including the identification of the design characteristics purported to enhance mediolateral stability in children's gait, the childhood mobility impairments that may benefit from stability footwear intervention and the necessary outcomes to evaluate the footwear's effectiveness in these children. While this consensus has identified several design characteristics, which the experts considered pertinent for off-the-shelf stability therapeutic footwear, further consideration should be given on how to assess these characteristics using mechanical testing procedures and in turn link them to International Organization for Standardization (ISO standards.

The Delphi technique has limitations in that it does not necessarily produce the right or definitive answers; instead, it produces a valid consensus of expert opinion.[21] The method uses both qualitative and quantitative analysis in a mixed-method approach; however, the data provided from Delphi's are of inductive level 5 evidence[39] and are not authoritative requiring further deductive empirical research to support the findings of the work.[15] The recruitment to the Delphi panel was limited to countries with English as their first language, and potential differences in expert opinions may exist outside the selected experts' countries (Australia, UK and USA). We actively sought a range of professionals from both the clinical and manufacturing sectors to have a full, balanced understanding of the design specifics and purpose of the footwear. While there is a possibility of unconscious bias among the participants' response as a result of their personal affiliations with either the clinical and commercial sectors, it has certainly not affected the credibility of the results. Although we did not require a formal declaration of conflict of interest, the professionals were required to state their role in children's footwear intervention and any conflict of interests has been detailed on the table of participant characteristics.

The themes were derived by content analysis performed by one author. This may potentially have introduced some bias in interpretation of the expert opinions; however, this was mitigated by a collective agreement of statement generation between the authors from the themes, and the opportunity for panellists to correct any misrepresentation or omission of their opinions in the subsequent Delphi rounds.

This study has achieved an expert consensus on defining and grouping clinical footwear interventions for children, where none previously existed. Additionally, the ideal design characteristics for off-the-shelf stability therapeutic footwear for children with mobility impairment and suitable clinical populations for their provision have been identified.

The consensus will facilitate:

- A common understanding of therapeutic footwear terminology to facilitate communication between clinicians, researchers and manufacturers.
- Research-informed evidence for selection of appropriate off-the-shelf stability therapeutic footwear based on identified design characteristics.
- Research-informed evidence for dispensing off-the-shelf stability therapeutic footwear to suitable clinical populations.
- Standardised outcome measures for clinical assessment of the effectiveness of off-the-shelf stability therapeutic footwear interventions.

CONCLUSION

The current study is the first to establish a structured synthesis of expert opinion on defining and grouping children's therapeutic footwear, in addition to identifying the design characteristics of off-the-shelf stability therapeutic footwear and relevant criteria for clinical prescription. Also, this study, through clear terminology and definitions, provides a framework for the development of appropriate mechanical testing methods for off-the-shelf stability therapeutic footwear.

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WHAT ARE CHILDREN'S CLINICAL FOOTWEAR INTERVENTIONS AND HOW TO PRESCRIBE THEM?

Delphi survey Round 1

Introduction

Thank you for participating in this Delphi survey for the consensus on children's clinical footwear interventions.
Please note this is Round 1 of the survey and will be the lengthiest in respect to your time.

This first round aims to:

1) Gather information and seek consensus for the general definition of clinical footwear interventions in children.
These will be: The specific terms to be used, the categorisation of the footwear, and the proposed clinical role of these footwear.

2) To gather specific information on "off the shelf"* and modular** clinical footwear interventions that would be considered to offer a stability effect on children with mobility impairment. This would be in terms of design characteristics and suggested clinical protocols (guidelines) for the prescription of stability footwear as an assistive aid.

* Footwear taken from stock or supplies and not individually designed.
** Standard range of dimensional adaptations (maximum 3) to stock upper.

Your responses from this round will be analysed and collated into statements. These will be returned to you along with the anonymised responses of the other panellists, and you will be asked to rank your agreement or non-agreement with them. You can review the previous information you provided, and considering the information provided by the other panellists, maintain or change your opinion.

Please note you are free to withdraw from the study at any time.

For withdrawal from the study or any further questions, please contact:
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1)

Name *

OVERVIEW OF SURVEY

There are three sections in round 1 of this survey which will be available in a separate link.

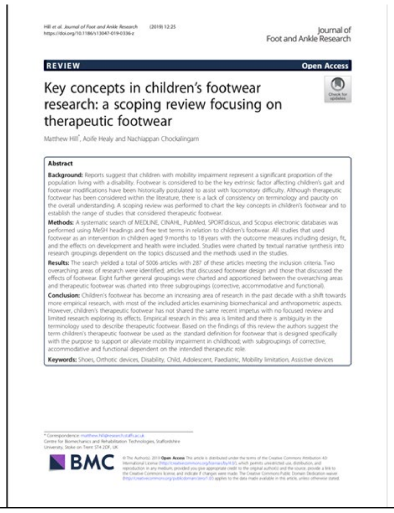
The first section is aimed at determining how to define clinical footwear interventions for children with mobility impairment. This will be the terminology used, categorisation and the proposed clinical role of the footwear.

The second section will consist of your ideas and opinions on design characteristics of "off the shelf" and modular clinical footwear that offers stability to children with mobility impairment.

The third section will consist of your ideas and opinions on clinical protocols and outcomes for the provision of "off the shelf" and modular footwear that offers stability for children with mobility impairment.

Please note!
There is no "save and complete later" option available for the survey; therefore, you must complete and submit your answers for each section in one sitting. You may, however, complete each of the three sections on separate occasions if you wish.

Section 1 Round 1



Journal of Foot and Ankle Research

REVIEW Open Access

Key concepts in children's footwear research: a scoping review focusing on therapeutic footwear

Matthew Hill*, Aoife Healy and Nachiappan Chockalingam

Abstract

Background: Reports suggest that children with mobility impairment represent a significant proportion of the population living with a disability. Footwear is considered to be the key extrinsic factor affecting children's gait and footwear modifications have been historically postulated to assist with locomotory difficulty. Although therapeutic footwear has been considered within the literature, there is a lack of consistency on terminology and paucity on the overall understanding. A scoping review was performed to chart the key concepts in children's footwear and to establish the range of studies that considered therapeutic footwear.

Methods: A systematic search of MEDLINE, CINAHL, PubMed, SPORTdiscus, and Scopus electronic databases was performed using MeSH headings and free text terms in relation to children's footwear. All studies that used footwear as an intervention in children aged 9 months to 18 years with the outcome measures including design, fit, and the effects on development and health were included. Studies were charted by textual narrative synthesis into research groupings dependent on the topics discussed and the methods used in the studies.

Results: The search yielded a total of 5008 articles with 287 of these articles meeting the inclusion criteria. Two overarching areas of research were identified; articles that discussed footwear design and those that discussed the effects of footwear. Eight further general groupings were charted and apportioned between the overarching areas and therapeutic footwear was charted into three subgroupings (corrective, accommodative and functional).

Conclusion: Children's footwear has become an increasing area of research in the past decade with a shift towards more empirical research, with most of the included articles examining biomechanical and anthropometric aspects. However, children's therapeutic footwear has not shared the same recent impetus with no focused review and limited research exploring its effects. Empirical research in this area is limited and there is ambiguity in the terminology used to describe therapeutic footwear. Based on the findings of this review the authors suggest the term children's therapeutic footwear be used as the standard definition for footwear that is designed specifically with the purpose to support or alleviate mobility impairment in childhood, with subgroupings of corrective, accommodative and functional dependent on the intended therapeutic role.

Keywords: Shoes, Orthotic devices, Disability, Child, Adolescent, Paediatric, Mobility limitation, Assistive devices

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BMC

Defining clinical footwear interventions for children with mobility impairment. Terms, Categorisation and Proposed clinical roles.

Definition together with standard terminology is essential for any intervention to allow a consistent understanding of who will benefit, the value it will provide, what is and isn't included, how it will work and how to measure its success.

The work in this section has been informed from the results of our recently published scoping review, https://rdcu.be/b1tKM

We derived general terminology definitions and groupings of footwear that had been used from a therapeutic perspective from the collective body of research considering children's footwear.
We will ask you to rate your agreement with these proposed terms, definitions and groupings. These will be in the form of a Likert scale where you will rank your level of agreement on a scale of 1-7 ranging from Strongly Disagree (1) to Strongly Agree (7).

We will provide you with the opportunity to offer your opinion to modify these proposed terms, definitions and groupings. All answers will be anonymised and will not be identifiable as your responses.

What can you base your answers on?

The validity of the data obtained relies on your answers, being your opinion. This may be based on research or your own clinical or manufacturing experience.

How do you provide detail to your answer?

It is recommended that your answers be clear and unambiguous. You should provide enough detail to qualify what you are basing your opinion on. General comments are therefore not recommended. On some answers, you may wish to provide more information.

i.e., The following statement provides insufficient information
"Stability footwear would improve children's gait ."

A qualified statement may read:

"Stability footwear would potentially increase children's walking velocity, stride length and reduce mediolateral (side to side) displacement of the centre of mass "

The answers and rationale you provide may influence the opinion of other panellists. i.e., a panellist may change their opinion dependent on the strength of your response.

* Required Filed

2)

From the collective body of research, various terms have been used in relation to clinical footwear interventions in childhood. Statement 1: The scoping review recommended the term "Children's Therapeutic Footwear" as the standard terminology to be used for clinical footwear interventions for children with mobility impairment.

Please rank your agreement with the term children's therapeutic footwear as a standard term for this purpose. *

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Statement 1	☐	☐	☐	☐	☐	☐	☐

3)

Please use this area to provide us with any further opinion on this terminology. Do you feel this is relevant clinically; do you currently use a different term, would you change this now based on this information?
Would you offer alternative terminology and if so, what is this? *

4

Statement 2: The term therapeutic footwear was defined in the scoping review as: "footwear that is designed specifically with the purpose to support or alleviate mobility impairment in childhood." Please rank your agreement with this Definition. *							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Statement 2	☐	☐	☐	☐	☐	☐	☐

5)

Please use this area to provide us with any further opinion on this definition. Do you feel this is relevant clinically; do you currently use a different term, would you change this now based on this information? Would you offer alternative terminology and if so, what is this? *

6)

Statement 3: From the scoping review footwear for clinical interventions in childhood was categorised into groupings dependent on their intended therapeutic role. Please rank your agreement for this approach to categorise clinical footwear interventions.*							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Statement 3	☐	☐	☐	☐	☐	☐	☐

7)

Please use this area to provide us with any further opinion on this method of categorisation. Do you feel this is relevant clinically; do you currently use a different term, would you change this now based on this information? Would you offer alternative terminology and if so, what is this? *

8)

Statement 4: From the scoping review, the following definition was given for the corrective footwear grouping:

Corrective footwear is children's therapeutic footwear that is designed to bring about the correction of congenital skeletal lower limb alignment.

Please rank your agreement with this definition:*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Statement 4	☐	☐	☐	☐	☐	☐	☐

9)

Please use this area to provide us with any further opinion on this definition. Do you feel this is relevant clinically; do you currently use a different term, would you change this now based on this information?
Would you offer alternative terminology and if so, what is this? *

10)

Statement 5: From the scoping review, the following definition was given for the accommodative footwear grouping:

Accommodative footwear is children's therapeutic footwear that is designed (modular or bespoke) to reduce compression, and shearing stresses on children's foot deformities through dimensional matching of footwear upper, insole, and sole to that of the child's foot.

Please rank your agreement with this definition: *

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Statement 5	☐	☐	☐	☐	☐	☐	☐

11)

Please use this area to provide us with any further opinion on this definition. Do you feel this is relevant clinically; do you currently use a different term, would you change this now based on this information?
Would you offer alternative terminology and if so, what is this? *

12)

Statement 6: From the scoping review, the following definition was given for the functional footwear grouping:

Functional footwear is children's therapeutic footwear that is designed to improve dynamic gait parameters of children with mobility impairment, reducing pathological movements and facilitating typical childhood walking patterns.

Please rank your agreement with this definition: *

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Statement 6	☐	☐	☐	☐	☐	☐	☐

13)

Please use this area to provide us with any further opinion on this definition. Do you feel this is relevant clinically; do you currently use a different term, would you change this now based on this information?
Would you offer alternative terminology and if so, what is this? *

14)

Statement 7: From the scoping review functional therapeutic footwear was divided into subgroupings which are categorised dependent on the design and functional role.

Please rank your agreement with this method of categorisation. *

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Statement 7	☐	☐	☐	☐	☐	☐	☐

15)

Please use this area to provide us with any further opinion on this method of categorisation. Do you feel this is relevant clinically; do you currently use a different term, would you change this now based on this information?
Would you offer alternative terminology and if so, what is this? *

16)

Statement 8: From the scoping review the following definition was given for the stability footwear subgrouping

Stability functional therapeutic footwear is a range of footwear that is designed to limit extreme movements of the lower limb to maintain a controlled displacement of the centre of force during gait.

Please rank your agreement with this definition: *

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Statement 8	☐	☐	☐	☐	☐	☐	☐

17)

Please use this area to provide us with any further opinion on this definition. Do you feel this is relevant clinically; do you currently use a different term, would you change this now based on this information?
Would you offer alternative terminology and if so, what is this? *

18)

Statement 9: From the scoping review, the following definition was given to lift footwear subgrouping:

Lift functional therapeutic footwear is a range of footwear designed with a unilateral modular outer or midsole addition to conservatively achieve postural and functional symmetry in individuals with limb length inequality.

Please rank your agreement with this definition: *

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Statement 9	☐	☐	☐	☐	☐	☐	☐

19)

Please use this area to provide us with any further opinion on this definition. Do you feel this is relevant clinically; do you currently use a different term, would you change this now based on this information?
Would you offer alternative terminology and if so, what is this? *

20)

Statement 10: From the scoping review the following definition was given for rounded bottom (rocker sole)

Rounded bottom (rocker sole) is a range of functional therapeutic footwear with a forefoot rocker design to assist the sagittal plane progression of the lower limb.

Please rank your agreement with this definition.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Statement 10	☐	☐	☐	☐	☐	☐	☐

21)

Please use this area to provide us with any further opinion on this definition. Do you feel this is relevant clinically; do you currently use a different term, would you change this now based on this information?
Would you offer alternative terminology and if so, what is this? *

22)

Statement 11: From the scoping review, the following definition was given for instability footwear:

Instability therapeutic functional footwear consists of a sole designed to promote imbalance to train the individuals motor coordination.

Please rank your agreement with this definition.*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Statement 11	☐	☐	☐	☐	☐	☐	☐

23)

Please use this area to provide us with any further opinion on this definition. Do you feel this is relevant clinically; do you currently use a different term, would you change this now based on this information?
Would you offer alternative terminology and if so, what is this? *

END OF SECTION 1 ROUND 1

Thank you for taking the time to complete section 1. Your time and participation in this survey are greatly appreciated.

Please remember to submit your answers before closing this form.

You can find the link for next section of Round 1 attached to the Delphi survey email.

ROUND 2 (S1) WHAT ARE CHILDREN'S CLINICAL FOOTWEAR INTERVENTIONS AND HOW TO PRESCRIBE THEM?

Delphi survey Round 2

Introduction

Thank you for participation in Round 1 of this Delphi survey for the consensus on children's clinical footwear interventions.

Please note this is Round 2 of the survey which will provide you with the collective responses from Round 1 of the expert panel. The panel consisted of 18 participants (orthotists, podiatrists and physiotherapists) with clinical expertise in footwear provision including research, commercial distribution as well as clinical practitioners. The panel is international comprising of panellists from the UK, Australia and the U.S.A.

The feedback from responses will be presented as the median and distribution of level of agreement, as well as a summary of the reasoning for panellists' answers.

This second round aims to:

1) Seek consensus for the general definition of footwear used as a clinical intervention for children.
These will be: The specific terms to be used, the categorisation of the footwear, and the proposed clinical role of these footwear.

2) To gain consensus on "off the shelf"† clinical footwear interventions that would be considered to offer a stability effect on children with mobility impairment. This would be in terms of design characteristics and suggested clinical protocols (guidelines) for the prescription of stability footwear as an assistive aid.

†Footwear taken from stock or supplies and not individually designed.

This questionnaire is completed differently to the first round, and the instructions within the form will guide you through this process. Please read the instructions carefully and complete the Delphi questionnaire as fully as you can.

You will receive the original statements from Round 1 alongside modified statements that have been informed by yours and other panellists' responses.

You will be asked to give your preferential option or your level of agreement with them. You can review the previous information you provided (in the document emailed to you), and

considering the information provided by the other panellists, maintain or change your opinion.

Please note you are free to withdraw from the study at any time.

For withdrawal from the study or any further questions, please contact:
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Staffordshire University, Leek Road, Stoke on Trent, ST4 2DF, U.K,
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Email: Matthew.Hill@research.staffs.ac.uk1)

* Required Filed

Name *

OVERVIEW OF SURVEY

There are three sections in round 2 of this survey which will be available in three separate links.

The first section will consist of yours and the panellists' collective opinions on determining how to define clinical footwear interventions for children with mobility impairment. This will be the terminology used, categorisation and the proposed clinical role of the footwear.

The second section will consist of yours and the panellists' collective opinions on design characteristics of "off the shelf" clinical footwear that offers stability to children with mobility impairment.

The third section will consist of yours and the panellists' collective opinions on clinical protocols and outcomes for the provision of "off the shelf" footwear that offers stability for children with mobility impairment.

Please note!
There is no "save and complete later" option available for the survey; therefore, you must complete and submit your answers for each section in one sitting. You may, however, complete each of the three sections on separate occasions if you wish.

Section 1

Defining clinical footwear interventions for children with mobility impairment. Terms, Categorisation and Proposed clinical roles.

The original statements concerning terminology, definitions and groupings of footwear that had been used from a therapeutic perspective for children suggested by the scoping review are listed alongside modified statements informed from the opinions gained from yourself and the other panellists in round 1. You will be asked to give your preferential option or your level of agreement or non-agreement with them (Strongly Disagree to Strongly Agree).
You can review the previous information you provided (in the document emailed to you), and considering the information provided by the other panellists, You may maintain your position with the original statement or change your opinion and align yourself with the new statement

We will provide you with the opportunity to offer your reasoning for your stance or to suggest any further amendments to the statements (You may also leave these areas blank in this round). All answers will be anonymised and will not be identifiable as your responses.

* Required Filed

2)

From Round 1 panellists were presented with Statement 1: "The scoping review recommended the term Children's Therapeutic Footwear as the standard terminology to be used for footwear used as a clinical intervention for children with mobility impairment." The median level of agreement amongst the panellists was "agree" with the majority of responses between "somewhat agree" to "strongly agree". From panellist feedback there was support for this term in preference to orthopaedic footwear as some felt this term had negative social connotations and could be associated with over-medicalisation. Other feedback indicated that therapeutic may be ambiguous inferring that the footwear healed the disease. Some panellists suggested alternate terms that matched International Organisation for Standardisation (ISO) terminology, with Orthopaedic footwear matching ISO 9999:2016 and more recently Orthotic footwear matching ISO 21064:2017. It was also discussed that ISO terminology aligned footwear with orthotic therapies. Please choose your preferred standard term for footwear that is used as a clinical intervention for children with mobility impairment. *	
☐	Therapeutic Footwear (Term from Round 1)
☐	Orthopaedic Footwear
☐	Orthotic Footwear
☐	Prescriptive Footwear
☐	Other

3)

You may use this optional area if you wish to provide any further information for your response.

4)

From Round 1 panellists were presented with Statement 2 which offered the following definition for footwear used as a clinical intervention for children:

“footwear that is designed specifically with the purpose to support or alleviate mobility impairment in childhood.”

The median level of agreement amongst the panellists was "somewhat agree" with the majority of responses between "neutral" to "agree".

From panellist feedback suggestions were made to improve the definition. Alleviate was seen as an ambiguous term that may be misinterpreted as curing the problem. The terminology should include that standard retail footwear may be adapted to offer a therapeutic role as well as therapeutic footwear that is specifically designed. The definition should also recognise the role footwear may play to accommodate or prevent foot deformities and the role it can offer to assist standing as well as mobility. Some panellist also requested the definition Follow ISO or World Health Organisation (WHO) terminology and be more biomechanically specific.

From panellist feedback, the following modified definitions for footwear used as a clinical intervention in children were derived.

Statement 2a: "Footwear that is designed or adapted specifically to protect, support, align, prevent, or correct foot deformity, or to assist mobility and standing in children."

Please choose your preferred definition. *

☐	Statement 2 (Original statement)
☐	Statement 2a
☐	Other

5)

You may use this optional area if you wish to provide any further information for your response.

6)

From Round 1 panellists were presented with Statement 3:

"footwear for clinical interventions in childhood should be categorised into groupings dependent on their intended therapeutic role."

The median level of agreement amongst the panellists was " agree" with the majority of responses between "somewhat agree" to "strongly agree".

Panellist feedback suggested that this was a suitable method of grouping clinical footwear interventions as it recognised the different characteristics and requirements for footwear prescriptions in a similar manner to orthoses. Suggestions to improve this method of grouping footwear included ensuring the therapeutic role had measurable outcomes. The method should recognise that footwear may offer more than one therapeutic role e.g. "accommodative and stability", therefore the method to classify should address that they are not separate footwear groupings, but potential therapeutic components of the footwear and a coding method could be employed to classify multiple therapeutic components of the footwear.

From panellist feedback, the following modified statement has been offered as an alternate method to group clinical footwear interventions for children.

Statement 3a: "Footwear used as a clinical intervention in childhood should be classified via the intended therapeutic outcomes of its components."

Please choose your preferred method for classifying footwear as a clinical intervention for children. *

☐	Statement 3 (Original statement)
☐	Statement 3a
☐	Other

7)

You may use this optional area if you wish to provide any further information for your response.

8)

From Round 1, panellists were presented with Statement 4 as a definition for the corrective footwear grouping:

"Corrective footwear is children's therapeutic footwear that is designed to bring about the correction of congenital skeletal lower limb alignment."

The median level of agreement amongst the panellists was "Neutral" with the majority of responses between "somewhat disagree" to "agree".

Panellist feedback suggested modifications to improve the definition. It was noted that footwear could not act as a curative intervention on its own and should be used alongside other corrective interventions (serial casting, surgery). Correction of lower limb alignment is misleading as footwear can only affect the foot and ankle. The definition should also include acquired deformity.

From panellist feedback, the following modified statement has been offered as an alternate definition.

Statement 4a: "Corrective footwear is children's therapeutic footwear that is designed or adapted to support correction of congenital or acquired foot and ankle deformity in children."

Please choose your preferred definition.*

☐	Statement 4 (Original statement)
☐	Statement 4a
☐	Other

9)

You may use this optional area if you wish to provide any further information for your response.

10)

From Round 1, panellists were presented with Statement 5 as a definition for the accommodative footwear grouping:

"Accommodative footwear is children's therapeutic footwear that is designed (off the shelf or bespoke) to reduce compression, and shearing stresses on children's foot deformities through dimensional matching of footwear upper, insole, and sole to that of the child's foot."

The median level of agreement amongst the panellists was "agree" with the majority of responses between "somewhat agree" to "strongly agree".

Panellist feedback suggested modifications to the definition. This included the role accommodative footwear may play in preventing deterioration of the child's foot deformity and reducing excessive details of the footwear design.

From panellist feedback, the following modified statement has been offered as an alternate definition.

Statement 5a: "Accommodative footwear is children's therapeutic footwear that is designed to prevent deterioration of children's foot deformities through the dimensional matching of the footwear to the child's foot."

Please choose your preferred definition.*

☐	Statement 5 (Original statement)
☐	Statement 5a
☐	Other

11)

You may use this optional area if you wish to provide any further information for your response.

12)

From Round 1, panellists were presented with Statement 6 as a definition for the functional therapeutic footwear grouping:

"Functional footwear is children's therapeutic footwear that is designed to improve dynamic gait parameters of children with mobility impairment, reducing pathological movements and facilitating typical childhood walking patterns."

The median level of agreement amongst the panellists was "agree" with the majority of responses between "neutral" to "agree".

Panellist feedback suggested that the definition represented the direct dynamic role footwear may play in supporting walking in children with mobility impairment. Suggested modifications to improve the definition included avoiding ambiguous terms such as pathological movement and typical patterns. Recognise the role functional footwear may play in assisting standing as well as mobility. Two panellists suggested disagreement with the term functional as all therapeutic footwear groupings had a function, however, no alternate term was suggested to represent this grouping.

From panellist feedback, the following modified statement has been offered as an alternate definition.

Statement 6a: "Functional footwear is children's therapeutic footwear that is designed or adapted to directly assist mobility and standing in children."

Please choose your preferred definition.*

☐	Statement 6 (Original statement)
☐	Statement 6a
☐	Other

13)

You may use this optional area if you wish to provide any further information for your response.

14)

From Round 1, panellists were presented with Statement 7 as a method to categorize functional footwear into subgroupings:

"Functional therapeutic footwear was divided into subgroupings which are categorised dependent on the design and functional role."

The median level of agreement amongst the panellists was "agree" with the majority of responses between "somewhat agree" to "strongly agree".

Panellist feedback was similar to the previous statement on methods of grouping footwear, in that footwear may offer more than one therapeutic role. The classification should recognise that they are not separate footwear groupings but therapeutic components of the footwear.

From panellist feedback, the following modified statement has been offered as an alternate method to subgroup functional therapeutic footwear for children.

Statement 7a "Functional therapeutic footwear should be classified via its design and the intended therapeutic outcomes of its components."

Please choose your preferred method for classifying functional therapeutic footwear for children.*

☐	Statement 7 (Original statement)
☐	Statement 7a
☐	Other

15)

You may use this optional area to provide us with any further information for your response.

16)

From Round 1, panellists were presented with Statement 8 as a definition for the stability footwear subgrouping.

"Stability functional therapeutic footwear is a range of footwear that is designed to limit extreme movements of the lower limb to maintain a controlled displacement of the centre of force during gait."

The median level of agreement amongst the panellists was "somewhat agree" with the majority of responses between "somewhat disagree" to "agree".

Feedback from the panellists suggested that the definition attempted to represent the effects of this footwear. Suggestions for improvement of the definition included avoiding ambiguous terms such as extreme movements, and recognising that this footwear would only effectively control forces at the foot and ankle but not the knee. The definition should recognise the potential proprioceptive effect of the footwear and the additional ability to assist standing in children.

From panellist feedback, the following modified statement has been offered as an alternate definition.

Statement 8a: "Stability therapeutic footwear is a range of footwear that is designed to assist mobility and standing in children by enhancing proprioception and influencing movements of the foot and ankle."

In the section below, please choose your preferred definition.*

☐	Statement 8 (Original statement)
☐	Statement 8a
☐	Other

17)

You may use this optional area if you wish to provide any further information for your response.

18)

From the feedback of panellists, there was a collective suggestion that a number of the groupings offered in the first round, (lift, rounded bottom, instability) should fall under another Functional Footwear subgrouping termed Adapted Sole.

Panellists suggested this represented footwear either therapeutic or standard retail footwear that had a custom adaption to the sole which would facilitate gait or standing posture in children with mobility impairment.

Panellist feedback also suggested alternative terms for adapted soles that would fall under this subgrouping, raise instead of lift and rocker sole instead of rounded bottom.

The following term and definition were derived from panellist feedback.

Term: Adapted Sole

Definition: "A range of customised sole adaptions to standard retail or children's therapeutic footwear that would assist mobility or standing in children."

In the section below please rank your agreement with the term and definition: *

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Term Adapted sole	☐	☐	☐	☐	☐	☐	☐
Definition of Adapted sole	☐	☐	☐	☐	☐	☐	☐

19)

You may use this optional area if you wish to provide any further information for your response.

END OF SECTION 1 ROUND 2

Thank you for taking the time to complete section 1. Your time and participation in this survey are greatly appreciated.

Please remember to submit your answers before closing this form.

You can find the link for next section of Round 2 attached to the Delphi survey email.

ROUND 3 (S1) WHAT ARE CHILDREN'S CLINICAL FOOTWEAR INTERVENTIONS AND HOW TO PRESCRIBE THEM?

Thank you for taking the time to complete section 1. Your time and participation in this survey are greatly appreciated.

Please remember to submit your answers before closing this form.

You can find the link for next section of Round 1 attached to the Delphi survey email.

* Required Filed

Name *

To recognise the valued work you have provided on this project the research team would like to acknowledge you as a panel member on any report or publication generated from the completed work. Please indicate your consent to your name and profession being released as an expert panel member below.. *	
☐	I consent to my name and profession being included in the acknowledgment section of any publication generated from the completed work
☐	I do not consent to my name being acknowledged in this work

OVERVIEW OF SURVEY

There are three sections in round 3 of this survey which will be available in three separate links.

The first section will consist of yours and the panellists' collective choices and opinions on determining how to define clinical footwear interventions for children with mobility impairment. This will be the terminology used, categorisation and the proposed clinical role of the footwear.

The second section will consist of yours and the panellists' collective choices and opinions on design characteristics of "off the shelf" clinical footwear that offers stability to children with mobility impairment.

The third section will consist of yours and the panellists' choices and collective opinions on clinical protocols and outcomes for the provision of "off the shelf" footwear that offers stability for children with mobility impairment.

Please note!
There is no "save and complete later" option available for the survey; therefore, you must complete and most importantly submit your answers for each section in one sitting. You may, however, complete each of the three sections on separate occasions if you wish.

Section 1

Defining clinical footwear interventions for children with mobility impairment. Terms, Categorisation and Proposed clinical roles.

You will be presented with the collective preference (Median, relative frequency of response) and opinions of the panellists to the modified and original statements from round 1 and 2 of the survey concerning terminology, definitions and groupings of footwear that had been used from a clinical perspective for children. You will again be asked to give your preferential option or your level of agreement or non-agreement with them ("Strongly Disagree" to "Strongly Agree").
You can review the previous information you provided (in the document emailed to you), and considering the information provided by the other panellists, you may maintain your option or level of agreement with your chosen statement or change your opinion.

Full consensus for a statement is reached when a statement gains ≥75% of panellists with a level of agreement of "agree" or above, or ≥ 75% of panellists preferred option.

If you choose a level of agreement below "agree" we would ask that you provide us with the reason for your choice in the optional open-ended section provided.

* Required Filed

3)

From Round 2 panellists were presented with a series of options from the original scoping review and suggestions from the panel for standard terminology to be used for footwear used as a clinical intervention for children with a mobility impairment :

The relative frequency of response is detailed below:

Term “Therapeutic Footwear” 59%
Term "Orthotic Footwear" 23%
Term "Prescriptive Footwear" 12%
Term "Orthopaedic Footwear" 6%

From panellist feedback:
The reasoning for choosing "Therapeutic Footwear" was that it was felt that orthotic and orthopaedic footwear would appear to be limited to the body structure aspect of the WHO ICF-CY as it still implies a “straightening” approach to care and did not embrace a holistic approach of health care delivery, as also outlined in the WHO ICF-CY, such as those involved with Quality of Life, activity and participation. They also felt that orthotic "straightening" could be misleading for some treatment goals such as accommodative footwear. It was also pointed out Prescriptive Footwear may not be applicable if using unmodified “off the shelf footwear”. It was felt that Therapeutic Footwear was consistent with the language used in the research literature. The importance of embracing consistent international terminology as outlined by the ISO was proposed, however, even here there has been inconsistency with both the terms Orthopaedic footwear (ISO 9999:2016) and Orthotic footwear ISO (21064:2017) being used.

The reasoning for choosing "Orthotic footwear" was that it embraced
reputable terminology from ISO without the perceived negative social connotations of orthopaedic footwear.

The reasoning for choosing "Prescriptive Footwear" evoked setting out specific parameters of footwear treatment that were potentially measurable.

No specific reasoning was given for choosing "Orthopaedic footwear"

One panellist suggested overall term could be interchangeable dependent on clinical preference as long as there was an agreed definition and understanding of how footwear could be applied and used for the treatment of mobility impairment in childhood.

Considering the collective panellist feedback please choose your preferred standard term for footwear that is used as a clinical intervention for children with mobility impairment.

☐	Therapeutic Footwear (Term from Round 1)
☐	Orthopaedic Footwear
☐	Orthotic Footwear
☐	Prescriptive Footwear

4)

You may use this optional area if you wish to provide any further information for your response.

5)

From Round 2 panellists were presented with a series of options from the original scoping review and suggestions from the panel which offered a definition for footwear used as a clinical intervention for children:

The relative frequency of response is detailed below:

Statment 2a "Footwear that is designed or adapted specifically to protect, support, align, prevent, or correct foot deformity, or to assist mobility and standing in children." (82%)

Statement 2 “footwear that is designed specifically with the purpose to support or alleviate mobility impairment in childhood.” (12%)

Other (6%)

A Consensus was reached to Statement 2a

Panellist feedback from those who chose "Other"
One panellist objected to the aligning and corrective aspect in the definition due to limited evidence base for this and suggested the following definition: "Footwear that is designed or adapted specifically to protect, support or assist mobility and standing in children".
One preferred a definition that encompassed ISO and WHO terminology and suggested the following definition: “Footwear intended to address the effect of a neuromusculoskeletal impairment(s). These can encompass the ankle joint. They can be custom made or prefabricated”

6)

From Round 2 panellists were presented with a series of options from the original scoping review and suggestions from the panel for the process of categorising clinical footwear interventions for children.

The relative frequency of response is detailed below:

Statement 3a: "Footwear used as a clinical intervention in childhood should be classified via the intended therapeutic outcomes of its components." (70%)

Statement 3 "footwear for clinical interventions in childhood should be categorised into groupings dependent on their intended therapeutic role." (18%)

Other (12%)

From panellist feedback, there was agreement throughout the panel that it was important that the method of classification/grouping of the footwear relates to the intended clinical role or outcome, However, consensus failed to be reached due to the terminology used within the statement.
Panellists who did not choose therapeutic footwear as a preferred term objected to the reference to therapeutic in the statement, others wanted WHO terminology to be included within the definition.

Slight modification to the statement has been made to this definition to address panellist feedback and gain consensus within the panel, please rank your agreement with the following statement *

"Footwear used as a clinical intervention in childhood should be classified by the intended outcomes of its components."

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
"Footwear used as a clinical intervention in childhood should be classified by the intended outcomes of its components."	☐	☐	☐	☐	☐	☐	☐

7)

If your level of agreement was "somewhat agree" or lower please use this optional area to provide us with your reasoning.

8)

From Round 2 panellists were presented with a series of options from the original scoping review and suggestions from the panel for the grouping and definition of Corrective footwear.

The relative frequency of response is detailed below:

Statement 4a: "Corrective footwear is children's therapeutic footwear that is designed or adapted to support correction of congenital or acquired foot and ankle deformity in children."* (82%)

Other (18%)

Statment 4 "Corrective footwear is children's therapeutic footwear that is designed to bring about the correction of congenital skeletal lower limb alignment."(0%)

A Consensus was reached to Statement 4a

From panellists who chose "Other" one objected to the inclusion of the term therapeutic footwear in the statement*. One panellist did not agree to the corrective footwear grouping established from the research literature and advocated for different groupings based on a different structural tree however no alternative suggestions were offered.

Even those panellists who agreed to the new definition advocated that the definition needs to be clearer that this footwear works as a subsequent step to support and maintain primary corrective interventions such as serial casting and surgery,

*(To respect panellists variation in preferred overarching terminology for clinical footwear interventions reference to therapeutic, orthotic, orthopaedic and prescriptive will be removed from all definitions including those that have reached consensus)

In light of panellist feedback concerning corrective footwear's role in supporting primary corrective measures, a slight modification to this statement has been made.

"Corrective footwear is footwear that is designed or adapted to support correction of congenital or acquired foot and ankle deformity in children. This may be secondary to a primary corrective measure such as serial casting or surgery."

Please indicate if you agree to this modified statement below.*

☐	Yes I agree
☐	No I don't agree

9)

You may use this optional area if you wish to provide any further information for your response.

10)

From Round 2 panellists were presented with a series of options from the original scoping review and suggestions from the panel for the grouping and definition Accommodative footwear

The relative frequency of response is detailed below:

Statement 5a:
"Accommodative footwear is children's therapeutic footwear that is designed to prevent deterioration of children's foot deformities through the dimensional matching of the footwear to the child's foot."
(76%)

Statement 5
"Accommodative footwear is children's therapeutic footwear that is designed (off the shelf or bespoke) to reduce compression, and shearing stresses on children's foot deformities through the dimensional matching of footwear upper, insole, and sole to that of the child's foot." (12%)

Other (12%)

A Consensus was reached to Statement 5a

From panellists who chose "Other" one objected to the inclusion of the term therapeutic footwear in the statement*. One panellist did not agree to the Accommodative footwear grouping established from the research literature and advocated for different groupings based on a different structural tree however no alternative suggestions were offered.

11)

From Round 2 panellists were presented with a series of options from the original scoping review and suggestions from the panel for the grouping and definition Functional footwear

The relative frequency of response is detailed below:

Statement 6a: "Functional footwear is children's therapeutic footwear that is designed or adapted to directly assist mobility and standing in children." (76%)

Statement 6"Functional footwear is children’s therapeutic footwear that is designed to improve dynamic gait parameters of children with mobility impairment, reducing pathological movements and facilitating typical childhood walking patterns." (12%)

Other (12%)

A Consensus was reached to Statement 6a

From panellists who chose "Other" one objected to the inclusion of the term therapeutic footwear in the statement*. One panellist did not agree to the Functional footwear grouping established from the research literature and advocated for different groupings based on a different structural tree however no alternative suggestions were offered.

One panellist who agreed to statement 6a questioned if psychosocial factors such as cosmesis should be considered in function for those individuals who are immobile.

12)

From Round 2 panellists were presented with a series of options from the original scoping review and suggestions from the panel for the process of categorising functional footwear into subgroupings:
The relative frequency of response is detailed below:

Statement 7a "Functional therapeutic footwear should be classified via its design and the intended therapeutic outcomes of its components." (76%)

Statement 7 "Functional therapeutic footwear was divided into subgroupings which are categorised dependent on the design and functional role." (12%)

Other (12%)

A Consensus was reached to Statement 7a

From panellists who chose "Other" one objected to the inclusion of the term therapeutic footwear in the statement*. One panellist did not agree to the footwear groupings established from the research literature and advocated for different groupings based on a different structural tree however no alternative suggestions were offered.
The panellist who queried the psychosocial aspect missing from the functional footwear group definition in 6a felt this method of subgrouping would address their suggestion.

13)

From Round 2 panellists were presented with a series of options from the original scoping review and suggestions from the panel for the subgrouping and definition Stability footwear

The relative frequency of response is detailed below:

Statement 8a "Stability therapeutic footwear is a range of footwear that is designed to assist mobility and standing in children by enhancing proprioception and influencing movements of the foot and ankle." (65%)

Other (23%)

Statement 8 "Stability functional therapeutic footwear is a range of footwear that is designed to limit extreme movements of the lower limb to maintain a controlled displacement of the centre of force during gait." (12%)

From panellists who chose "Other" one objected to the term therapeutic footwear in the statement. A number of panellists were uncertain of the evidence for the footwear influencing proprioception and that by placing this prior to its role on influencing movements in the definition may imply that this was the footwear's primary role. It was suggested to move proprioception to the end of the definition to deemphasize its role in this footwear subgrouping

A slight modification has been made to this definition to address panellist feedback and gain consensus within the panel, please rank your agreement with the following statement

"Stability Footwear is footwear that is designed to assist mobility and standing in children by influencing movements and potentially proprioception of the foot and ankle."

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
"Stability Footwear is footwear that is designed to assist mobility and standing in children by influencing movements and potentially proprioception of the foot and ankle."	☐	☐	☐	☐	☐	☐	☐

14)

If your level of agreement was "somewhat agree" or lower please use this optional area to provide us with your reasoning.

15)

From Round 2 panellists were presented with a new subgrouping of functional footwear and definition for this subgrouping suggested by panellist feedback in Round 1, this was "Adapted sole". This subgrouping would incorporate raise, rocker sole and possibly instability footwear.

The median level of agreement and relative frequency of response for both the term and definition is presented below.

Term "Adapted Sole"
Median level of agreement 6 ("Agree")
Relative frequency of agreement: 6% "Somewhat Disagree", 6% "Neutral",
12% "Somewhat Agree", 41% "Agree", 35% "Strongly Agree"
Panellist Consensus reached (76%)

Definition "A range of customised sole adaptions to standard retail or children's therapeutic footwear that would assist mobility or standing in children."
Median level of agreement 6 ("Agree")
Relative frequency of agreement: 6% "Somewhat Disagree", 6% "Neutral", 23% "Somewhat Agree", 41% "Agree", 24% "Strongly Agree"

From Panellist feedback reasons for lack of agreement with the statement
is that the definition should include a reference to the heel as well as the sole to ensure heel modifications are represented in the subgrouping of functional footwear.
Also, therapeutic footwear was not every panellist's preferred terminology for clinical footwear interventions,

A slight modification has been made to this definition to address panellist feedback and gain consensus within the panel; please rank your agreement with the following definition for Adapted Sole Footwear

"A range of customised sole or heel adaptions to any suitable children's footwear, with the adaptions designed to assist mobility or standing in children."

In the section below, please rank your agreement with the modified definition.*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7

"A range of customised sole or heel adaptions to any suitable children's footwear, with the adaptions designed to assist mobility or standing in children."	☐	☐	☐	☐	☐	☐	☐

16)

You may use this optional area if you wish to provide any further information for your response.

END OF SECTION 1 ROUND 3

Thank you for taking the time to complete section 1. Your time and participation in this survey are greatly appreciated.

Please remember to submit your answers before closing this form.

You can find the link for next section of Round 1 attached to the Delphi survey email.

WHAT ARE CHILDREN'S CLINICAL FOOTWEAR INTERVENTIONS AND HOW TO PRESCRIBE THEM? (SECTION2 ROUND 1)

The second section asks for your ideas and opinions on identifiable and or desirable design characteristics of “off the shelf” and modular clinical footwear interventions that offers stability to children with mobility impairment.

Section 2

Establishing identifiable and desirable design characteristics for "off the shelf"* and modular** footwear clinical interventions that offer stability to children with mobility impairment.
* Footwear taken from stock or supplies and not individually designed.
** Standard range of dimensional adaptations e.g. width, girth, (maximum 3) to stock upper.

This section consists of a series of ranked and open-ended questions concerning identifiable or desirable characteristics of standard "off the shelf" and modular clinical stability footwear interventions.

The information provided in this section was informed by a study of the design and dimensional characteristics of a sample of standard children's off-the-shelf footwear (EU size range 19-41*) from a range of manufacturers that are currently marketed to offer stability to children with some form of mobility impairment.

We will ask you to rate your agreement with the findings of the characteristics identified from the sample. These will be in the form of a Likert scale where you will rank your level of agreement on a scale of 1 Strongly Disagree to Strongly Agree 7.

We will provide you with the opportunity to offer your opinion on these characteristics and to suggest their possible purpose to facilitate stability in children with mobility

impairment. You will also be free to suggest additional aspects you view as important and your reasons for this. All answers will be anonymised and will not be identifiable as your responses.

Example of answers to a series of questions concerning a specific area of "off the shelf" modular stability footwear.

Please rate your agreement with the following findings of the topline of "off the shelf" modular stability footwear.

1) "Off the shelf" and modular stability footwear should have an extended topline height

Agree (6)

2) "Off the shelf" and modular stability footwear should have a padded foam collar.

Agree (6)

3) Please provide your opinion and the possible purpose of these characteristics

Answer:
The topline should extend above the ankle. The purpose of this is to offer a degree of proprioceptive stability and increased leverage at the ankle and rearfoot. This has been shown to help in previous studies on the elderly. High topped shoes appear to improve stability in comparison to lower toplines on children in my clinical practice. The padding of the collar allows for a reduction of shearing during ambulation, enhancing the ergonomics of the shoe design.

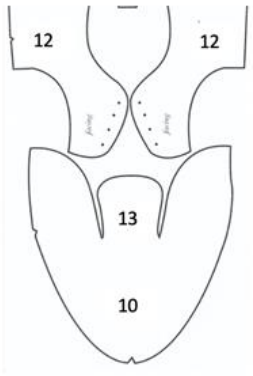
Please note when answering the following questions we are asking you to consider the characteristics of standard stability footwear and not adaptations for specific clinical presentations.

Required Field *

1)

Name: *

Glossary of Footwear Anatomy



1) Topline/Collar
2) Topline height
3) Upper
4) Fastening/Facing
5) Heel counter
6) Heel
7) Shank
8) Outsole
9) Toe spring
10) Vamp
11) Toe box
12) Quarters
13) Tongue

Image adapted from www.made-in-china.com

This section provides a brief glossary to the footwear terms used in this survey.

1) Topline: the opening of the shoe at the rearfoot and ankle region,
Collar: Sometimes padded, a strip of material attached to the topline/opening of a shoe.

2) Topline height, The height between the base of the upper at the heel cup to the topline.

3) Upper: The part of a shoe that covers the entire top, sides and back of the foot and attaches to the insole and outsole

4) Fastening: The part of the shoe that can adjust and secure the fitting of the vamp and the quarters to the foot.
Facing: The area of the shoe where the fastenings are located.

5) Heel counter: stiffened material placed between the shoe's inner lining and the upper located at the heel cup region of the shoe just above the heel.

6) Heel: The part of the outsole that raises the rear of the shoe (maybe part/or a separate attachment of the outsole)

7) Shank: The Reinforced strip of material located between the insole and the sole of the shoe running from the heel region to the midfoot.

8) Outsole: The base of the shoe that is attached to the upper and contacts the ground.

9) Toe spring: The elevation angle from the ball region of the shoe to the distal aspect of the toe box.

10) Vamp: The area of the upper that covers the front part of the shoe,

11) Toe box: Distal region of the shoe upper that provides space and protection for the toes.

12) Quarters: The back half of the upper. Attached at the front to the vamp, making up both sides of a shoe, and wrapping around the rear of the shoe.

13) Tongue: Flap of material attached to the vamp shoe, extending centrally along the instep from the forefoot to the topline.

Topline/collar

In the question below you will be presented with a series of findings in relation to the topline/collar of standard "Off the Shelf" and modular stability footwear, please rank your level of agreement with these being a desirable characteristic of this clinical footwear intervention:

2)

The topline or collar should have the following characteristics: *							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Extended topline height above ankle	☐	☐	☐	☐	☐	☐	☐
Foam padded collar	☐	☐	☐	☐	☐	☐	☐
Collar contoured to malleoli	☐	☐	☐	☐	☐	☐	☐
Collar contoured to Achilles tendon	☐	☐	☐	☐	☐	☐	☐
Pull tab to back of collar	☐	☐	☐	☐	☐	☐	☐

3)

Please use this section to provide your opinion on the design characteristics of the topline/collar in terms of the purpose of the suggested design features, any disagreement with the suggested design features, or further design features you feel are desirable. *

Upper

In the question below you will be presented with a series of findings in relation to the upper of standard "Off the Shelf" and modular stability footwear, please rank your level of agreement with these being a desirable characteristic of this clinical footwear intervention:

4)

The upper should have the following characteristics: *							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Leather material	☐	☐	☐	☐	☐	☐	☐
Tongue in line with topline	☐	☐	☐	☐	☐	☐	☐
Tongue extended above topline	☐	☐	☐	☐	☐	☐	☐

5)

Please use this section to provide your opinion on the design characteristics of the upper in terms of the purpose of the suggested design features, any disagreement with the suggested design features, or further design features you feel are desirable. *

Fastening and Facing

In the question below you will be presented with a series of findings in relation to the Fastening and Facing of standard "Off the Shelf" and modular stability footwear, please rank your level of agreement with these being a desirable characteristic of this clinical footwear intervention:

6)

The fastening should have the following characteristics: (You may suggest an alternative by typing your suggestion in the other option) *	
☐	Velcro
☐	Lace
☐	No Preference
☐	Other

7)

The facings should have the following characteristics: (You may suggest an alternative by typing your suggestion in the other option)*	
☐	Facings extended to the midfoot
☐	Facings extended to just behind the toe box
☐	No Preference
☐	Other

8)

Please use this section to provide your opinion on the design characteristics of the fastening and facing in terms of the purpose of the suggested design features, any disagreement with the suggested design features, or further design features you feel are desirable. *

Heel counter/stiffener

In the question below you will be presented with a series of findings in relation to the heel counter/stiffener of standard "Off the Shelf" and modular stability footwear, please rank your level of agreement with these being a desirable characteristic of this clinical footwear intervention:

9)

The heel counter should have the following characteristics: *							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Heel counter /stiffener extended to midfoot	☐	☐	☐	☐	☐	☐	☐
Heel counter/ stiffener height extended towards topline.	☐	☐	☐	☐	☐	☐	☐

10)

Please use this section to provide your opinion on the design characteristics of the heel counter/stiffener in terms of the purpose of the suggested design features, any disagreement with the suggested design features, or further design features you feel are desirable. *

Heel

In the question below you will be presented with a series of findings in relation to the heel of standard "Off the Shelf" and modular stability footwear, please rank your level of agreement with these being a desirable characteristic of this clinical footwear intervention:

11)

The heel should have the following characteristics: (You may suggest an alternative by typing your suggestion in the other option)*	
☐	Heel width in line with heel counter width
☐	Heel width extended wider than heel counter width
☐	No Preference
☐	Other

12)

Please use this section to provide your opinion on the design characteristics of the heel in terms of the purpose of the suggested design features, any disagreement with the suggested design features, or further design features you feel are desirable. *

Inlay

In the question below you will be presented with a series of findings in relation to the inlay of standard "Off the Shelf" and modular stability footwear, please rank your level of agreement with these being a desirable characteristic of this clinical footwear intervention:

13)

The Inlay unit should have the following characteristics: *							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Stability footwear should come with a standard removable inlay.	☐	☐	☐	☐	☐	☐	☐
The inlay should be contoured to simulate the medial longitudinal arch.	☐	☐	☐	☐	☐	☐	☐

14)

Please use this section to provide your opinion on the design characteristics of the inlay in terms of the purpose of the suggested design features, any disagreement with the suggested design features, or further design features you feel are desirable. *

Sole unit

In the question below you will be presented with a series of findings in relation to the heel counter/stiffener of standard "Off the Shelf" and modular stability footwear, please rank your level of agreement with these being a desirable characteristic of this clinical footwear intervention:

15)

The sole unit should have the following characteristics: *

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
A deepened tread	☐	☐	☐	☐	☐	☐	☐
Be made of hard wearing material	☐	☐	☐	☐	☐	☐	☐

16)

Please rank the degree of flexibility for the sole unit you feel would constitute a desirable characteristic of this clinical footwear intervention. *

0	1	2	3	4	5	6	7	8	9	10

0-Completely flexible 10-Completely rigid

17)

Please use this section to provide your opinion on the design characteristics of the inlay in terms of the purpose of the suggested design features, any disagreement with the suggested design features, or further design features you feel are desirable. *

Toe spring forefoot/heel rocker

In the question below you will be presented with a series of findings in relation to the toe spring/forefoot rocker and heel rocker of standard "Off the Shelf" and modular stability footwear, please rank your level of agreement with these being a desirable characteristic of this clinical footwear intervention:

18)

*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Stability footwear should have a reasonable forefoot rocker.	☐	☐	☐	☐	☐	☐	☐
Stability footwear should have a heel rocker.	☐	☐	☐	☐	☐	☐	☐

19)

Please use this section to provide your opinion on the design characteristics of the toe spring forefoot heel rockers in terms of the purpose of the suggested design features, any disagreement with the suggested design features, or further design features you feel are desirable.*

Weight of the footwear

In the question below, we will ask you your opinion on the weight of "Off the Shelf" and modular stability footwear when considering these as a clinical intervention:

20)

*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
The weight of the stability footwear is an important consideration when issuing footwear to children with mobility impairment?	☐	☐	☐	☐	☐	☐	☐

21)

Please use this section to provide your opinion on the weight of stability footwear and how you feel it may impact on the gait of children with mobility impairment or may change with the age of the patient.*

Optional Further Information

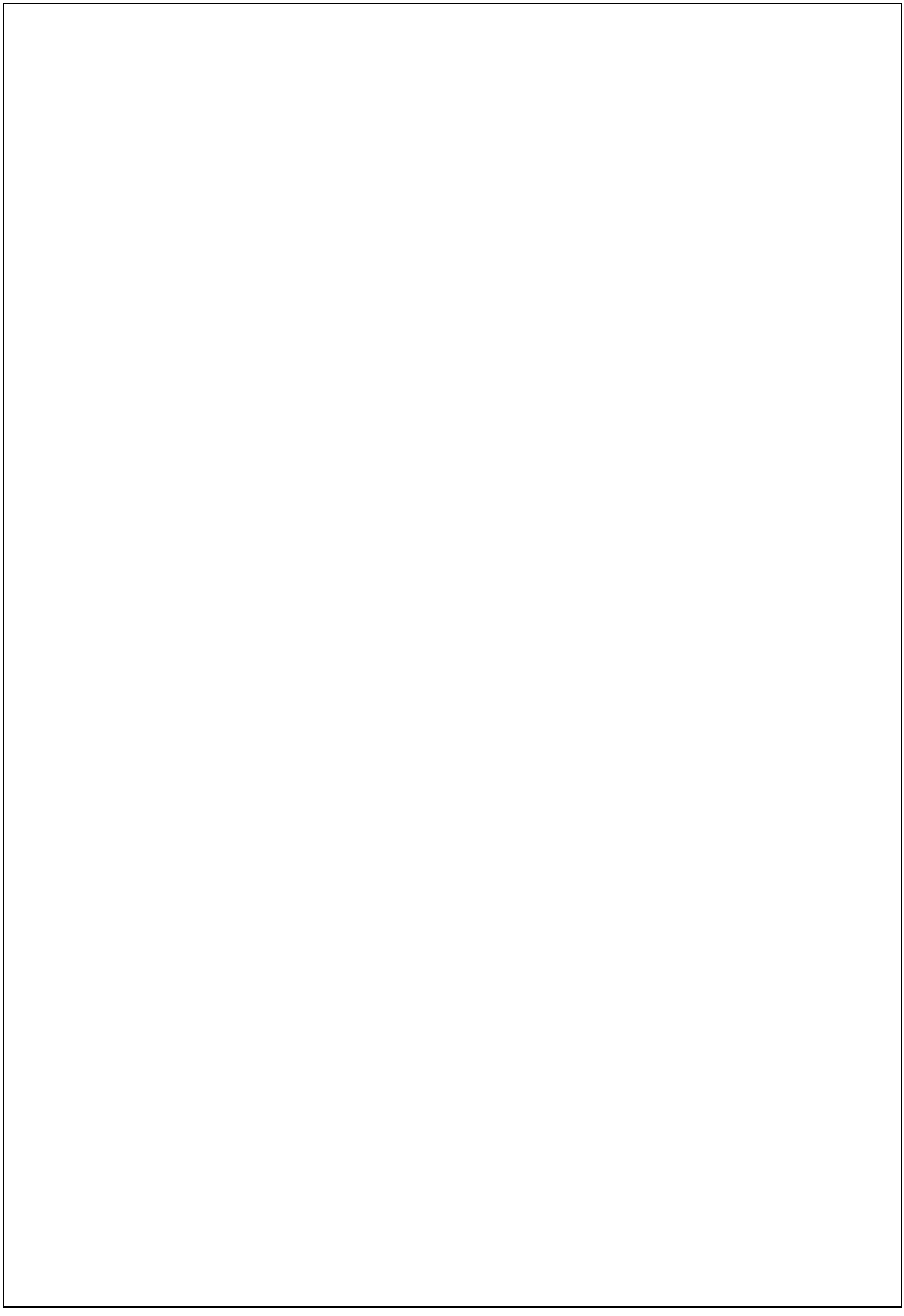
You may use this additional section to provide further suggestions that you feel are important characteristics of children's "Off the Shelf" and modular stability footwear.

Please remember to detail your answer where appropriate with the following information:

Constituents or area of the footwear
Material
Shape or dimension
Degree of rigidity flexibility.
Purpose

22)

Which other areas do you feel are important design characteristics of children's "Off the Shelf" and modular stability footwear?



END OF SECTION 2 ROUND 1

Thank you for taking the time to complete section 2. Your time and participation in this survey are greatly appreciated.

Please remember to submit your answers before closing this form.

You can find the link for next section of Round 1 attached to the Delphi survey email.

ROUND 2(S2) WHAT ARE CHILDREN'S CLINICAL FOOTWEAR INTERVENTIONS AND HOW TO PRESCRIBE THEM?

The second section will present the feedback of panellists opinions from Round 1 on the desired design characteristics of “off the shelf” stability footwear and the purpose of these as a clinical intervention for children with mobility impairment.

Section 2

Establishing desired design characteristics of “off the shelf”† stability footwear and the purpose of these as a clinical intervention for children with mobility impairment.
†*Footwear taken from stock or supplies and not individually designed.*

The original statements provided from the study of a range of children's "off the shelf" stability footwear is listed alongside modified statements informed by the collective opinions gained from the panellists in round 1. The panel in this section consisted of 17 experts in the clinical provision of footwear for children with mobility impairment.

You will be asked to give your preferred option or your level of agreement with the original or modified statements (Strongly Disagree to Strongly Agree)

You can review the previous information you provided (in the document emailed to you), and considering the information provided by the other panellists, You may maintain your position with your original statement or change your opinion and align yourself with the new statement

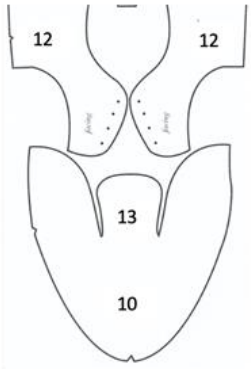
We will provide you with the opportunity to offer your reasoning for your stance or to suggest any further amendments to the statements at the end of each section (You may also leave these areas blank in this round). All answers will be anonymised and will not be identifiable as your responses.

Required Field *

1)

Name*

Glossary of Footwear Anatomy



1) Topline/Collar
2) Topline height
3) Upper
4) Fastening/Facing
5) Heel counter
6) Heel
7) Shank
8) Outsole
9) Toe spring
10) Vamp
11) Toe box
12) Quarters
13) Tongue

Image adapted from www.made-in-china.com

This section provides a brief glossary to the footwear terms used in this survey.

1) Topline: the opening of the shoe at the rearfoot and ankle region,
Collar: Sometimes padded, a strip of material attached to the topline/opening of a shoe.

2) Topline height, The height between the base of the upper at the heel cup to the topline.

3) Upper: The part of a shoe that covers the entire top, sides and back of the foot and attaches to the insole and outsole

4) Fastening: The part of the shoe that can adjust and secure the fitting of the vamp and the quarters to the foot.
Facing: The area of the shoe where the fastenings are located.

5) Heel counter: stiffened material placed between the shoe's inner lining and the upper located at the heel cup region of the shoe just above the heel.

6) Heel: The part of the outsole that raises the rear of the shoe (maybe part/or a separate attachment of the outsole)

7) Shank: The Reinforced strip of material located between the insole and the sole of the shoe running from the heel region to the midfoot.

8) Outsole: The base of the shoe that is attached to the upper and contacts the ground.

9) Toe spring: The elevation angle from the ball region of the shoe to the distal aspect of the toe box.

10) Vamp: The area of the upper that covers the front part of the shoe,

11) Toe box: Distal region of the shoe upper that provides space and protection for the toes.

12) Quarters: The back half of the upper. Attached at the front to the vamp, making up both sides of a shoe, and wrapping around the rear of the shoe.

13) Tongue: Flap of material attached to the vamp shoe, extending centrally along the instep from the forefoot to the topline.

Topline/collar

In the questions below you will be presented with the collective opinion of panellists to the findings form Round 1 in relation to the topline/collar of standard “Off the Shelf” stability footwear used as a clinical intervention for children with mobility impairment. Please consider the options offered or rank your level of agreement with the suggested characteristic or purpose of these design characteristics:

2)

"Extended topline height above the ankle":
The median level of agreement amongst the panellists was "agree" with the majority of responses between "somewhat agree" to "agree".

From panellist feedback, it was proposed the purpose of a topline extended above the ankle (supra-malleolar) increases proprioceptive input around the rearfoot and ankle in addition to assisting the leverage of the heel counters. This was thought to assist in reducing frontal plane movements at the foot and ankle. Other panellists suggested toplines extended above the ankle may adversely affect ankle plantarflexion and dorsiflexion power generation and limit mobility in some patients.

Please consider the following options suggested by panellists' feedback in relation to the desired design characteristic of the topline height for stability footwear. *

☐	The topline should be extended above the ankle (Original)
☐	The topline should not be extended above the ankle
☐	The topline extension should come in an optional range both above and below the ankle dependent on the patient's ability and needs.

3)

Please rank your level of agreement with the following purpose or potential adverse effects suggested from panellists' feedback of an extended topline.*							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Purpose: An extended topline height increases proprioception input at the rearfoot and ankle	☐	☐	☐	☐	☐	☐	☐
Purpose: An extended topline height assists heel counter leverage to resist frontal plane movement of the rearfoot and ankle.	☐	☐	☐	☐	☐	☐	☐
Adverse Effect: An extended topline height may reduce sagittal plane power generation at the ankle.	☐	☐	☐	☐	☐	☐	☐

4)

"Padded collar"

The median level of agreement amongst the panellists was "agree" with the majority of responses being "agree".
A consensus was reached in Round 1 with respect to this design feature being an ideal characteristic.

Panellist feedback suggested that the purpose of this design feature was to lower compression and shear stress to structures to the sides and the back of the supra-malleolar region. Some panellists indicated that foam padding may increase shear therefore the padded area should be covered in a low shear material.

Please rank your level of agreement with the following purpose or characteristic suggested from panellists' feedback of a padded collar. *

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Design Characteristic: The foam padded collar should be covered with low shear material.	☐	☐	☐	☐	☐	☐	☐
Purpose: Foam Padding reduces compression to lower limb anatomy from an extended topline height	☐	☐	☐	☐	☐	☐	☐

5)

"Collar contoured to Malleoli"

The median level of agreement amongst the panellists was "agree" with the majority of responses being "agree".
A consensus was reached in Round 1 with respect to this design feature being an ideal characteristic.

Although a consensus was reached on this design characteristic panellist feedback suggested there is potential ambiguity with "contoured to malleoli" if the topline is extended above the ankle (supra-malleolar), therefore, the description of the contouring is dependent on the topline height (supra or inframalleolar). Concerning the suggested

purpose of the design, panellists felt that due to the increased topline height the contoured padding would ergonomically incorporate ankle structures to reduce shear and compression.

Based on panellist feedback a modified description and purpose of the desired design characteristic is offered, please rank your agreement with these. *

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Design Characteristic: The foam padded collar should be covered with low shear material.	☐	☐	☐	☐	☐	☐	☐

6)

"Collar contoured to the Achilles tendon"

The median level of agreement amongst the panellists was "agree" with the majority of responses being between "somewhat agree" to "agree".

From the feedback of panellists, there did not appear to be any specific reason for only a partial level of agreement other than a lack of research to support the design adaption. There was no feedback to suggest an ideal modified design characteristic. Concerning the purpose of the suggested characteristic, it was proposed contouring to the Achilles tendon would reduce shear and compression to the area.

Please consider the following options suggested by panellists' feedback in relation to the desired design characteristic of contouring of the collar at the Achilles tendon for stability footwear.*

☐	Collar contoured to Achilles tendon (Original)
☐	Collar contoured to Achilles tendon is not a desired design characteristic.

7)

Please rank your level of agreement with the following purpose suggested from panellists feedback of a collar contoured to the Achilles tendon. *							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Purpose: Contouring the collar to the Achilles tendon reduces shear and compression to the tendon.	☐	☐	☐	☐	☐	☐	☐

8)

"Pull tab to the back of collar": The median level of agreement amongst the panellists was "agree" with the majority of responses being between "neutral" to "agree". Panellist feedback suggested that the purpose of pull-tab was to assist donning of the footwear; however, a number of panellists stated that they had never seen a child use the pull-tab to don stability footwear. Please consider the following options suggested by panellists' feedback in relation to the desired design characteristic of a collar pull tab for stability footwear.*	
☐	Pull tab to back of collar (Original)
☐	Pull tab to back of collar is not a desired design characteristic.

9)

Please rank your level of agreement with the following purpose suggested from panellists' feedback of a pull tab to the collar.*							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Purpose: A collar pull tab aids the child in donning the shoe.	☐	☐	☐	☐	☐	☐	☐

10)

You may use this optional area to provide us with any further information to your responses on the topline/collar.

Upper

In the questions below you will be presented with the collective opinion of panellists to the findings form Round 1 in relation to the upper of standard “Off the Shelf” stability footwear used as a clinical intervention for children with mobility impairment, please consider the options offered or rank your level of agreement with the suggested characteristic or purpose of these design characteristics:

11)

"The Upper should be constructed of leather:"

The median level of agreement amongst the panellists was "agree" with the majority of responses being between "neutral" to "agree".

From panellist feedback, it was suggested that the purpose and advantages of leather material was that it adapts to foot structures over time and can enhance stability adaptions of the footwear through material stiffness. A number of panellists suggested that the upper should be available in optional materials, such as breathable materials for hot climates or sweaty feet, in addition, wipeable washable fabric for issues with incontinence.

Please consider the following options suggested by panellists' feedback in relation to the desired design characteristic of the material of the upper for stability footwear.*

☐	Upper should be constructed of leather (Original)
☐	Optional range of upper material to include; leather, breathable material and wipeable material.

12)

Please rank your level of agreement with the following purpose suggested from panellists' feedback of leather as an upper material.*							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Leather adapts to foot structures over time	☐	☐	☐	☐	☐	☐	☐
Leather enhances material stiffness of the footwear	☐	☐	☐	☐	☐	☐	☐

13)

"Tongue to topline relationship:"

"Tongue in line with the topline:"
The median level of agreement amongst the panellists was "agree" with the majority of responses being between "neutral" to "agree".

"Tongue extended above topline:"
this reached the same level of agreement with the median level
amongst the panellists being "agree" with the majority of responses being between "neutral" to "agree".

Panellist feedback concerning the tongue being in line with the topline suggested that this would cause less irritation to the front of the ankle than an extended tongue. However, panellists who were in favour of an extended topline suggested that an extended tongue allowed comfort with lacing and the ability for the patient to pull up the tongue to stop slippage of the tongue during wear. Other feedback suggested that the tongue length should be optional depending on the patient's preference and manual dexterity.

Please consider the following options suggested by panellists' feedback in relation to the desired design characteristic of the tongue to topline relationship for stability footwear.
Please consider the following options suggested by panellists' feedback in relation to the desired design characteristic of the material of the upper for stability footwear.*

☐	Tongue extended above topline (Original)
☐	Tongue should be in line with topline (Original)
☐	Tongue length optional dependent on patient's preference and manual dexterity

14)

Please rank your level of agreement with the following purpose suggested from panellists' feedback of the Tongue to topline relationship.*							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Purpose: Tongue in line with topline is to minimise irritation to the anterior aspect of the ankle	☐	☐	☐	☐	☐	☐	☐
Purpose: Tongue extended above topline allows for comfort with lacing	☐	☐	☐	☐	☐	☐	☐
Purpose: Tongue extended above topline allows the wearer to minimise slippage of the tongue under the fastenings during wear	☐	☐	☐	☐	☐	☐	☐

15)

From panellist feedback other suggestions for the upper design were offered these included:

An option for an open upper in the form of a high topped sandal for standard stability footwear ranges for hotter climates.
The upper design should consider the effects and location of the internal seams in relation to compression and shearing of children's foot anatomy.

A slit or loop be placed in the tongue for the fastening (lace or velcro strap) to pass through to minimise tongue slippage in the shoe.

Please rank your agreement with the following panellists' suggestions in relation to further desired design characteristics for the uppers of stability footwear.*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
High topped sandals to be offered as an option for stability footwear ranges for warm weather	☐	☐	☐	☐	☐	☐	☐
Ergonomic consideration of internal seams to reduce skin irritation	☐	☐	☐	☐	☐	☐	☐
Slit or loop in tongue for fastening to minimise tongue slippage	☐	☐	☐	☐	☐	☐	☐

16)

You may use this optional area to provide us with any further information to your responses on the upper.

Fastening and Facing

In the questions below you will be presented with the collective opinion of panellists to the findings form Round 1 in relation to the Fastenings and Facings of standard “Off the Shelf” stability footwear used as a clinical intervention for children with mobility impairment, please consider the options offered or rank your level of agreement with the suggested characteristic or purpose of these design characteristics:

17)

"The type of fastenings"

Most panellists (53%) choose "other", next was Velcro (23%), no preference (18%) and lace (6%).

Those panellists that chose the other option suggested that the chosen fastenings be optional depending on the ability of the child or the desired therapeutic goal (e.g. Velcro for limited hand dexterity to enhance independence, lace if greater stability is required).

From panellist feedback Velcro fastenings were proposed to assists with independence making it easier for children to don/doff the shoes. A number of panellists proposed that lace fastenings allowed a firmer grip to the contours of the foot to enhance the stability offered by the shoe.

Please consider the following options suggested by panellists' feedback in relation to the desired design characteristic of the type of fastenings for stability footwear.*

☐	Velcro (Original)
☐	Lace (Original)
☐	No Preference (Original)
☐	Optional dependent on patient's ability and desired goal (e.g. Velcro for limited hand dexterity, lace for greater stability)

18)

Please rank your level of agreement with the following purpose suggested from panellists' feedback for the type of fastenings.*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Purpose of Velcro fastenings: Assists independenc e with limited hand dexterity in donning and doffing	☐	☐	☐	☐	☐	☐	☐
Purpose of lace fastenings: Enhances stability through potential firmer grip to contours of the foot	☐	☐	☐	☐	☐	☐	☐

19)

"Position of the facings"

Most panellists (47%) choose 'extended to just behind the toebox, 23% choose "other", 18% suggested "facings extended to the midfoot" and 12% had no preference.

From panellist feedback facings extended to the toe box were suggested to allow greater access into the footwear with patients who had limited foot and ankle ROM. Whereas facings extended to the midfoot allowed the upper to offer greater stability.
Similar to the fastenings a number of panellists felt the facings of stability footwear should be offered in an optional range dependent on the ability of the patient and desired therapeutic role. Extended to the toebox for limited patient foot and ankle mobility, extended to the midfoot for greater shoe stability.

Please consider the following options suggested by the panellists' feedback in relation to the desired design characteristic of the position of the facings for stability footwear.*

☐	Facings extended to the midfoot (Original)
☐	Facings extended to just behind the toe box (Original)
☐	No Preference (Original)

☐	Optional dependent on patient's foot and ankle mobility or therapeutic goal (i.e. facings extended to toe box for ease of foot and ankle access, extended to midfoot for greater upper stability)

20)

Please rank your level of agreement with the following purpose suggested from panellists' feedback of the position of the facings.*							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Purpose: Facings extended to just behind the toe box allows greater access into the footwear for the child with limited foot and ankle range of motion	☐	☐	☐	☐	☐	☐	☐
Purpose: Facing extended to the midfoot allows the upper to offer greater stability to the foot and ankle.	☐	☐	☐	☐	☐	☐	☐

21)

Other considerations suggested by the panellist in relation to the facings and fastenings were the gap between facings should be enough to allow an adequate range of fastening adjustment.
A side zip along the rearfoot was suggested alongside a lace fastening to allow easy donning and doffing to pre-tightened laced footwear.

Please rank your agreement with the following panellists' suggestions in relation to further desired design characteristics for the fastenings and facings of stability footwear.*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
The gap between facings should allow an adequate range of fastening adjustment.	☐	☐	☐	☐	☐	☐	☐
Side zip lace combination fastening	☐	☐	☐	☐	☐	☐	☐

22)

You may use this optional area to provide us with any further information to your responses on fastening and facing.

Heel counter/stiffener

In the questions below you will be presented with the collective opinion of panellists to the findings form Round 1 in relation to the Heel Counter/Stiffener of standard “Off the Shelf” stability footwear used as a clinical intervention for children with mobility impairment, please consider the options offered or rank your level of agreement with the suggested characteristic or purpose of these design characteristics:

23)

The heel counter/stiffener extension

"Heel counter/stiffener extended to midfoot:"
The median level of agreement amongst the panellists was "agree" with the majority of responses being between "somewhat agree" to "agree".

"Heel counter/stiffener extended towards the topline."
The median level of agreement amongst the panellists was "somewhat agree" with the majority of responses being between "somewhat agree" to "agree".

From panellist feedback, it was suggested that this was one of the most important design characteristics to enhance the stability of this footwear. It was thought the material stiffness of the counter and its extension could resist frontal plane movements of the foot and ankle and the midfoot if extended to this region. It was also suggested that this design feature can enhance proprioception at the rearfoot and ankle. Some panellists suggested that heel counters should come in a range of extensions both in length and height dependent on the therapeutic need (high to moderate stability) and to account for any impingement on the varied foot and ankle anatomy of patients.

Please consider the following options suggested by the panellists' feedback in relation to the desired design characteristic of the heel counter/ stiffener extensions for stability footwear.*

☐	Heel counter/stiffener extended to the midfoot only
☐	Heel counter/stiffener extended towards the topline only
☐	Heel counter stiffener, extended to the midfoot and towards topline

☐	Optional range of heel counter extensions dependent on therapeutic need and the patient's foot and ankle anatomy

24)

Please rank your level of agreement with the following purpose suggested from panellists' feedback of the heel counter/stiffener:*							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Purpose: Heel counter/stiffener extensions can enhance proprioception at the foot and ankle	☐	☐	☐	☐	☐	☐	☐
Purpose: Heel counter/stiffener extension offers material stiffness to restrict frontal plane movements at the foot, ankle and midfoot dependent on the extension profile.	☐	☐	☐	☐	☐	☐	☐

25)

You may use this optional area to provide us with any further information to your responses on heel counter/stiffener.

Heel

In the questions below you will be presented with the collective opinion of panellists to the findings form Round 1 in relation to the Heel of standard “Off the Shelf” stability footwear used as a clinical intervention for children with mobility impairment, please consider the options offered or rank your level of agreement with the suggested characteristic or purpose of these design characteristics:

26)

"Heel width in relation to the heel counter"

The majority (47%) felt that the heel should be extended wider than the heel counter followed by 23% who felt it should be in line, the remaining 30% chose no preference or other.

Feedback from the panellists suggested that the purpose of an increased heel width allowed greater medial-lateral stability. Panellists suggested that a welted sole construction provided a slight width increase from standard retail footwear. Others suggested that wider heels affect aesthetics and the mass of the shoe or potentially cause weakening to the upper and sole adhesion. Other feedback stated that heel width extension needs to be quantified and come in a range of prescriptive adaptions (heel float) dependent on clinical need rather than a standard characteristic.

Please consider the following options suggested by panellists' feedback in relation to the desired design characteristic of the heel to heel counter width relationship for stability footwear.*

☐	Heel width in line with heel counter width (Original)
☐	Heel width extended wider than heel counter width (Original)
☐	No preference (Original)

☐	Heel width extensions should be provided as an optional sole adaption with the heel width extension on standard stability footwear being no wider than the welted seam.

27)

Please rank your level of agreement with the following purpose suggested from panellists' feedback of an extended heel width:*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Purpose: Heel width extensions assist medial-lateral stability of the foot and ankle through an increased base of support	☐	☐	☐	☐	☐	☐	☐

28)

Other heel design considerations suggested by the panellists were the heel pitch; heel pitch should not be so high as to impart instability at the ankle or be incompatible with the fitting of adjunct orthotic therapy:

Please rank your agreement with the following panellists' suggestions in relation to further desired design characteristics for the heel of stability footwear:*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Heel Pitch should not increase ankle instability	☐	☐	☐	☐	☐	☐	☐
Heel pitch should allow for adjunct orthotic therapy	☐	☐	☐	☐	☐	☐	☐

29)

You may use this optional area to provide us with any further information to your responses on the heel

Inlay

In the questions below, you will be presented with the collective opinion of panellists to the findings form Round 1 in relation to the Inlay of standard “Off the Shelf” stability footwear used as a clinical intervention for children with mobility impairment, please consider the options offered or rank your level of agreement with the suggested characteristic or purpose of these design characteristics:

30)

The inlay should have the following characteristics:

"Stability footwear should come with a standard removable inlay."
The median level of agreement amongst the panellists was "strongly agree" with the majority of responses being between "agree" to "strongly agree".
Consensus was reached on this design feature in Round 1.

"The inlay should be contoured to simulate the medial longitudinal arch. "
The median level of agreement amongst the panellists was "neutral" with the majority of responses being between "somewhat disagree" to "somewhat agree".

From panellist feedback, it was suggested that a removable inlay would allow for soft covering over the inner base layer of the sole and be thick enough to allow replacement with a prescriptive foot orthotic device if required. The majority of panellists did not feel contouring to the arch was necessary as this not be representative of an early walkers foot; however, panellists did suggest contouring to the heel cup to improve rearfoot fitting in the footwear.

Please consider the following options suggested by the panellists' feedback in relation to the desired design characteristic of the inlay for stability footwear.*

☐	The inlay should be contoured to simulate the medial longitudinal arch (Original)

☐	The inlay should be contoured to cup the heel but not the medial longitudinal arch
☐	The inlay should be contoured to simulate the medial longitudinal arch and to cup the heel

31)

Please rank your level of agreement with the following purpose suggested from panellists' feedback of the inlay.*							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Removable Inlay should be thick enough to allow for a potential prescriptive foot orthoses.	☐	☐	☐	☐	☐	☐	☐
An inlay contoured to cup the heel improves rearfoot fitting	☐	☐	☐	☐	☐	☐	☐

32)

You may use this optional area to provide us with any further information to your responses on the inlay.

Sole unit

In the questions below you will be presented with the collective opinion of panellists to the findings form Round 1 in relation to the sole unit of standard “Off the Shelf” stability footwear used as a clinical intervention for children with mobility impairment, please consider the options offered or rank your level of agreement with the suggested characteristic or purpose of these design characteristics:

33)

The sole unit should have "A deepened tread"
The median level of agreement amongst the panellists was "somewhat agree" with the majority of responses being between "neutral" to "agree".

Panellist feedback suggested that a deepened tread allows for greater traction over different terrains however it may also be a trip hazard especially with low ground clearance in some mobility impairments.

Please consider the following options suggested by the panellists' feedback in relation to the desired design characteristic of the tread depth for stability footwear.*

☐	A deepened tread (Original)
☐	The tread depth should come in an optional range dependent (on the ability of the child and the environment where the footwear is to be used.

34)

The sole unit should: "Be made of hard-wearing material"
The median level of agreement amongst the panellists was "agree" with the majority of responses being between "somewhat agree" to "agree".

Panellist feedback suggested the benefit of a hard-wearing sole unit is that it would resist abnormal sole wear from pathological gait and prolong the stability effect of the footwear. Other suggestions indicated that hard-wearing soling material may not be so important for younger children as growth would entail replacement before significant wear. There was also the suggestion that hard-wearing soling material may increase walking effort in early walkers.

Please consider the following options suggested by the panellists' feedback in relation to the desired design characteristic of the wear resilience of the sole material for stability footwear.*

☐	Hard-wearing material (Original)
☐	Optional wear resilience of the sole material dependent on the age and ability of the patient.

35)

In relation to a hard wearing sole material please rank your level of agreement with the following purpose or characteristic suggested from panellists feedback.*							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Purpose: Hard wearing sole material will prolong the stability effect of the footwear by resisting wear patterns associated with gait pathologies.	☐	☐	☐	☐	☐	☐	☐

36)

"The degree of flexibility" for the sole unit. The value range for flexibility 10 completely rigid and 0 completely flexible the median level of flexibility amongst the panel was 6 with the majority of values falling between 5 and 7. Panellist feedback suggested that although a rigid sole may enhance stability, flexion of the metatarsophalangeal joints (MPJ) is a requisite of the Hick's windlass and potential development of the arched complex of the foot. It was suggested that the sole stiffness may come in a range dependent on the ability of the child and therapeutic goals. Please consider the following options suggested by the panellists' feedback in relation to the desired design characteristic of the sole unit flexibility for stability footwear.*	
☐	The sole unit should come in a range of sole stiffness dependent on the patient's ability or the therapeutic goals, with flexibility of the sole focused at the MPJ area
☐	Other: (Please state)

37)

Other sole unit design considerations suggested by the panellists were:

That the rearfoot to forefoot sole width should be kept to the lowest practical ratio to manage mediolateral stability of the footwear.
That the sole unit should be stiffer at the midfoot and rearfoot to assist stability in these regions

Please rank your agreement with the following panellists' suggestions in relation to further desired design characteristics for the sole unit of stability footwear.*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Rearfoot to Forefoot width of the sole unit kept to lowest practical ratio to assist medial-lateral stability	☐	☐	☐	☐	☐	☐	☐
The sole unit should be stiffer at the midfoot and rearfoot to assist stability in these regions.	☐	☐	☐	☐	☐	☐	☐

38)

You may use this optional area to provide us with any further information to your responses on the sole unit.

Toe spring forefoot/heel rocker

In the questions below, you will be presented with the collective opinion of panellists to the findings form Round 1 in relation to the Toespring forefoot/heel rocker of standard "Off the Shelf" stability footwear used as a clinical intervention for children with mobility impairment, please consider the options offered or rank your level of agreement with the suggested characteristic or purpose of these design characteristics:

39)

"Stability footwear should have a reasonable forefoot rocker."

The median level of agreement amongst the panellists was "agree" with the majority of responses being between "somewhat agree" to "agree".

Panellist feedback suggested that forefoot rockers should come in a range depending on the patient's condition from increased in Charoct Marie Tooth to avoid tripping in propulsion and swing, to reduced in conditions such as Idiopathic toe walking to reduce the 3rd rocker (MPJ) loading. It was pointed out a range of forefoot rockers would also be required dependent on the stiffness of the sole. Panellists suggested the purpose of an appropriate rocker was to facilitate sagittal progression in propulsion without impacting on stability and also allowing for adequate ground clearance in swing phase.

Please consider the following options suggested by the panellists' feedback in relation to the desired design characteristic of the forefoot rocker for stability footwear.*

☐	Stability footwear should have a reasonable forefoot rocker. (Original)
☐	Stability footwear should come in a range of forefoot rockers dependent on the patient's condition and the stiffness of the sole.

40)

In relation to the forefoot rocker please rank your level of agreement with the following purpose or characteristic suggested from panellists feedback.*							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Purpose of forefoot rocker: Should facilitate forward progression in terminal stance without impacting on stability	☐	☐	☐	☐	☐	☐	☐
Design characteristic of forefoot rocker: Should allow adequate ground clearance in swing	☐	☐	☐	☐	☐	☐	☐

41)

"Stability footwear should have a heel rocker."

The median level of agreement amongst the panellists was "neutral" with the majority of responses being between "somewhat disagree" to "somewhat agree".

Panellist feedback suggested that a heel rocker may speed up the 1st rocker and cause instability during the initial loading phase of gait. A number of panellists suggested that heel rockers should be offered as a sole adaption prescription dependent on the child's condition rather than a standard design.

Please consider the following options suggested by the panellists' feedback in relation to the desired design characteristic of the heel rocker for stability footwear.*

☐	Stability footwear should have a heel rocker. (Original)

☐	Heel rockers should be offered as a sole adaption prescription dependent on the child's condition rather than a standard design of stability footwear.

42)

You may use this optional area to provide us with any further information to your responses on toe spring forefoot/heel rocker.

Weight of the footwear

In the questions below you will be presented with the collective opinion of panellists to the findings from Round 1 in relation to the weight of "Off the Shelf" Please consider the options offered or rank your level of agreement with the suggested characteristic or purpose of these design characteristics:

20)

"The weight of stability footwear is an important consideration when issuing footwear to children with mobility impairment?"
The median level of agreement amongst the panellists was "agree" with the majority of responses being "agree."
Consensus was reached in Round 1 with respect to this being an important design characteristic.

Panellist feedback suggested that the footwear should be the lowest reasonable mass to reduce physiological cost during mobility. The design should, however, consider the mass of the child and the stability requirements of the child's condition, with more stabilising features associated with a higher mass. It was also highlighted some mobility-impaired conditions might allow the child to become more mobile with age; therefore, requiring sturdier footwear conversely other conditions may entail the child becoming weaker requiring lighter footwear. It was suggested that heavier shoes could assist stability in stance and the pendular motion in swing. Others noted that the perceived increased weight of stability footwear by children might be due to its stiffness rather than the actual mass.

The following design considerations in respect to the weight of stability footwear and its purpose have been formed from panellist feedback; please rank your agreement with these.*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Stability footwear should be the lowest reasonable	☐	☐	☐	☐	☐	☐	☐

mass to reduce physiological cost during mobility.							
The mass of the shoe should be dependent on the mass and age of the child.							
The mass of the shoe should be dependent on the child's stability needs.							
Purpose of increased mass: Assist stability in stance							
Purpose of increased mass: Assists pendular motion in swing							

21)

You may use this optional area to provide us with any information for your responses on the weight of the footwear.

Further Design Considerations

The following section provides additional design considerations for "Off the Shelf" Stability footwear suggested by the panellists.

45)

Children's "Off the Shelf" stability footwear should come in a range of last dimensions to accommodate proportional differences in foot types.

Please rank your agreement with the following panellists' suggestion in relation to further desired design characteristics for stability footwear.*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Children's stability footwear should be available in a range of last dimensions to accommodate different foot types.	☐	☐	☐	☐	☐	☐	☐

46

Children's "Off the Shelf" stability footwear should come in a range of colours and styles to appeal to children's preferences.

Please rank your agreement with this design feature suggested from the panellists' feedback.*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Stability footwear should come in a range of colours and styles to appeal to children's aesthetics.	☐	☐	☐	☐	☐	☐	☐

47)

You may use this optional area to provide us with any information for your responses.

END OF SECTION 2 ROUND 2

Thank you for taking the time to complete section 2. Your time and participation in this survey are greatly appreciated.

Please remember to submit your answers before closing this form.

You can find the link for the next section of Round 2 attached to the Delphi survey email.

ROUND 3(S2) WHAT ARE CHILDREN'S CLINICAL FOOTWEAR INTERVENTIONS AND HOW TO PRESCRIBE THEM?

The second section will present yours and the panellists' collective choices and opinions from Round 2 on the desired design characteristics of “off the shelf” stability footwear and the purpose of these as a clinical intervention for children with mobility impairment.

Section 2

Establishing desired design characteristics of “off the shelf” stability footwear and the purpose of these as a clinical intervention for children with mobility impairment.
* Footwear taken from stock or supplies and not individually designed.

In this section, you will be presented with the collective preference (Median, relative frequency of response) and opinions of the panellists to the modified and original statements from round 1 and 2 of the survey concerning the desired design characteristics of “off the shelf” stability footwear and the purpose of these as a clinical intervention for children with mobility impairment. You will again be asked to give your preferential option or your level of agreement or non-agreement with them ("Strongly Disagree" to "Strongly Agree").
You can review the previous information you provided (in the document emailed to you), and considering the information provided by the other panellists, you may maintain your option or level of agreement with your chosen statement or change your opinion.

Full consensus for a statement is reached when a statement gains ≥75% of panellists with a level of agreement of "agree" or above, or ≥ 75% of panellists preferred option.

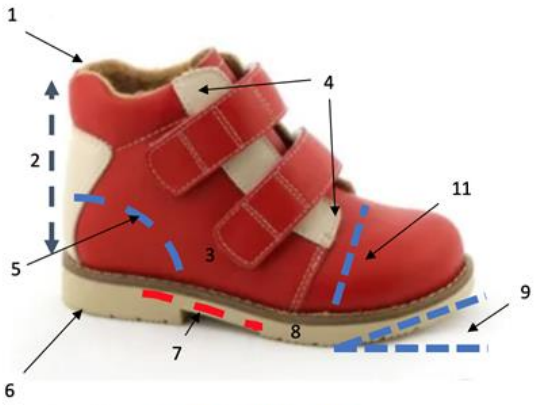
If you choose a level of agreement below "agree" we would ask that you provide us with the reason for your choice in the optional open-ended section provided.

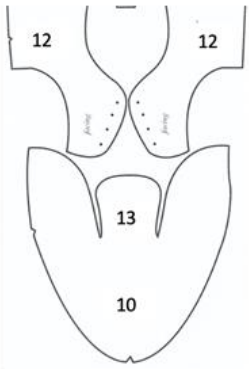
Required Field *

1)

Name*

Glossary of Footwear Anatomy





1) Topline/Collar
2) Topline height
3) Upper
4) Fastening/Facing
5) Heel counter
6) Heel
7) Shank
8) Outsole
9) Toe spring
10) Vamp
11) Toe box
12) Quarters
13) Tongue

Image adapted from www.made-in-china.com

This section provides a brief glossary to the footwear terms used in this survey.

1) Topline: the opening of the shoe at the rearfoot and ankle region,
Collar: Sometimes padded, a strip of material attached to the topline/opening of a shoe.

2) Topline height, The height between the base of the upper at the heel cup to the topline.

3) Upper: The part of a shoe that covers the entire top, sides and back of the foot and attaches to the insole and outsole

4) Fastening: The part of the shoe that can adjust and secure the fitting of the vamp and the quarters to the foot.
Facing: The area of the shoe where the fastenings are located.

5) Heel counter: stiffened material placed between the shoe's inner lining and the upper located at the heel cup region of the shoe just above the heel.

6) Heel: The part of the outsole that raises the rear of the shoe (maybe part/or a separate attachment of the outsole)

7) Shank: The Reinforced strip of material located between the insole and the sole of the shoe running from the heel region to the midfoot.

8) Outsole: The base of the shoe that is attached to the upper and contacts the ground.

9) Toe spring: The elevation angle from the ball region of the shoe to the distal aspect of the toe box.

10) Vamp: The area of the upper that covers the front part of the shoe,

11) Toe box: Distal region of the shoe upper that provides space and protection for the toes.

12) Quarters: The back half of the upper. Attached at the front to the vamp, making up both sides of a shoe, and wrapping around the rear of the shoe.

13) Tongue: Flap of material attached to the vamp shoe, extending centrally along the instep from the forefoot to the topline.

Topline/collar

In the questions below you will be presented with the collective choices and opinions from Round 2 in relation to the topline/collar of standard “Off the Shelf” stability footwear used as a clinical intervention for children with mobility impairment.
Please consider the options offered or rank your level of agreement with the suggested characteristic or purpose of these design characteristics some of which may have been slightly modified based on panellist feedback in Round 2:

2)

rom Round 2 panellists were presented with a series of options from suggestions from the panel and the original study of stability footwear in relation to the height of the topline. The relative frequency of response is detailed below:

Option 1: The topline extension should come in an optional range both above and below the ankle dependent on the patient's ability and needs. (93%)
Option 2: The topline should be extended above the ankle (Original) (7%)
Option 3: The topline should not be extended above the ankle (0%)

A Consensus was reached to Option 1.

Panellist feedback suggested that it was difficult to recommend standard design as different foot types (pes planus, pes cavus) will affect the efficacy of the topline and collar options

3)

Panellists were asked to rank their agreement with the following purpose and potential adverse effects of an extended topline in Round 2.
The median level of agreement and relative distribution of response is detailed below.

Purpose: Extended topline increases proprioception at the Foot and Ankle
Median level of Agreement 5 ("Somewhat Agree")
20% "Neutral", 33% "Somewhat Agree", 40% "Agree", 7% "Strongly Agree"

Purpose: Extended topline assist heel counter leverage to resist frontal plane motion at foot and ankle
Median level of Agreement 6 ("Agree")
13% "Neutral", 34% "Somewhat Agree", 40% "Agree", 13% "Strongly Agree"

Adverse Effect: An extended topline height may reduce sagittal plane power generation at the ankle
Median level of Agreement 5 ("Somewhat Agree")
7% "Somewhat Disagree", 20% "Neutral", 40% "Somewhat Agree"
13% "Agree", 20% "Strongly Agree"

Panellist Feedback suggested that partial agreement could only be reached due to limited peer-reviewed evidence to support the purpose of the design characteristics.
The research team appreciates that there is a paucity of scientific or structured clinical research but we would ask you to consider your years of clinical experience and expertise as to the perceived role of this design adaption.

Based on your clinical experience please rank your level of agreement with these proposed purposes of an extended topline.*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Purpose: An extended topline height may increase proprioception input at the rearfoot and ankle.	☐	☐	☐	☐	☐	☐	☐
Purpose: An extended topline height may assist heel counter leverage to	☐	☐	☐	☐	☐	☐	☐

resist frontal plane movement of the rearfoot and ankle.							
Adverse Effect: An extended topline height may reduce sagittal plane power generation at the ankle.	☐	☐	☐	☐	☐	☐	☐

4)

"Padded collar"
The panellists were presented with the following design characteristic and purpose of a foam padded collar in Round 2
The median level of agreement and the relative distribution of response is detailed below.

Design Characteristic: Foam Padded collar covered with low sheer material
Median level of Agreement 6 ("Agree")
13% "Neutral", 20% "Somewhat Agree", 47% "Agree", 20% "Strongly Agree"

Purpose Foam padding collar reduces compression from an extended topline height.
Median level of Agreement 6 ("Agree")
7% "Disagree", 13% "Neutral", 27% "Somewhat Agree", 33% "Agree"
20% "Strongly Agree"

Panellist Feedback again suggested that partial agreement could only be reached due to limited peer-reviewed evidence to support the design characteristics and their purpose. It was difficult to recommend standard design as different foot types (pes planus, pes cavus) will affect the efficacy of the topline and collar options.
The research team appreciates that there is a paucity of scientific or structured clinical research but we would ask you to consider your years of clinical experience and expertise as to the perceived role of this design adaption.

Based on your clinical experience please rank your level of agreement with these proposed purposes of a foam padded collar.*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Design Characteristic: The foam padded collar	☐	☐	☐	☐	☐	☐	☐

should be covered with low shear material.							
Purpose: Foam Padding may reduce compression to lower limb anatomy from an extended topline height.	☐	☐	☐	☐	☐	☐	☐

5)

The panellists were presented with the following purpose to the contouring of the topline to the ankle region in Round 2

The median level of agreement and relative distribution of response is detailed below.

Purpose: contouring of topline reduces compression and sheer to ankle region.
Median level of Agreement 6 ("Agree")
13% "Somewhat Disagree", 7% "Neutral", 20% "Somewhat Agree", 47% "Agree", 13% "Strongly Agree"

Panellist Feedback again suggested that partial agreement could only be reached due to limited peer-reviewed evidence to support the purpose. However, some panellists did acknowledge contouring to anatomical structures above or below the ankle improves tolerance fit and comfort.
The research team appreciates that there is a paucity of scientific or structured clinical research but we would ask you to consider your years of clinical experience and expertise as to the perceived role of this design adaption.

Based on your clinical experience please rank your level of agreement with these proposed purposes of a contoured topline.*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Purpose: Contouring of topline may reduce shear and compression stress to the ankle region.	☐	☐	☐	☐	☐	☐	☐

6)

The panellists were presented with the following options in relation to the contouring of the collar to the Achilles tendon in Round 2
The relative distribution of response is detailed below:

Option 1: Collar contoured to Achilles tendon (Original) (80%)
Option 2: Collar contoured to the Achilles tendon is not a desired design characteristic (20%)
A Consensus was reached to Option 1.*

7)

The following purpose was presented to the panellists in Round 2 in relation to contouring the collar to the Achilles tendon.
The median level of agreement and relative distribution of response is detailed below.

Purpose: Contouring the collar to the Achilles tendon reduces shear and compression to the tendon.
Median level of Agreement 6 (Agree)
13% "Neutral", 27% "Somewhat Agree", 53% "Agree", 7% "Strongly Agree"

Panellist Feedback again suggested that partial agreement could only be reached due to limited peer-reviewed evidence to support the purpose. However, some panellists did acknowledge contouring to anatomical structures above or below the ankle improves tolerance fit and comfort.
The research team appreciates that there is a paucity of scientific or structured clinical research but we would ask you to consider your years of clinical experience and expertise as to the perceived role of this design adaption.

Based on your clinical experience please rank your level of agreement with these proposed purposes of a topline contoured to the Achilles tendon.*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Purpose: Contouring the collar to the Achilles tendon may reduce shear and compression	☐	☐	☐	☐	☐	☐	☐

to the tendon.							

8)

The panellists were presented with the following options in relation to the pull tab at the back of the collar in Round 2

Option 1: Pull tab to back of collar (Original) 53%
Option 2: Pull tab to back of collar is not a desired design characteristic 47%

Panellist feedback suggested that the pull tab may aid the child or those offering assistance to the child in donning the shoe.
The pull tab may inadvertently assist sliding of an AFO into the boot.

Please consider again the following options.*

☐	Pull tab to back of collar (Original)
☐	Pull tab to back of collar is not a desired design characteristic.

9)

The following purpose was presented to the panellists in Round 2 in relation to the pull tab to the back of the collar.
The median level of agreement and relative distribution of response is detailed below.

Purpose: A collar pull tab aids the child in donning the shoe
Median level of Agreement 5 ("Somewhat Agree")
7% "Disagree", 33% "Neutral", 26% "Somewhat Agree", 27% "Agree"
7% "Strongly Agree"

The statement has been slightly modified based on panellist feedback please rank your level of agreement with this.*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Purpose: A collar pull tab may aid the child or those offering assistance in donning the stability shoe	☐	☐	☐	☐	☐	☐	☐

10)

If your level of agreement was "somewhat agree" or lower for any of the statements in relation to the topline/collar please use this optional area to provide us with your reasoning.

Upper

In the questions below you will be presented with the collective choices and opinions from Round 2 in relation to the upper of standard “Off the Shelf” stability footwear used as a clinical intervention for children with mobility impairment.

Please consider the options offered or rank your level of agreement with the suggested characteristic or purpose of these design characteristics some of which may have been slightly modified based on panellist feedback in Round 2:

11)

The panellists were presented with the following options in relation to the ideal material for the upper in Round 2
The relative distribution of response is detailed below:

Option 1: Optional range of upper material to include; leather, breathable material and wipeable material. 100%

Option 2: Upper should be constructed of leather (Original) 0%

A Consensus was reached for Option 1

12)

The following purpose was presented to the panellists in Round 2 in relation to leather as an upper material.
The median level of agreement and relative distribution of response is detailed below.

Purpose: Leather adapts to foot structures over time
Median level of Agreement 6 ("Agree")
7% "Neutral", 20% "Somewhat Agree", 53% "Agree", 20% "Strongly Agree"

Purpose: Leather enhances material stiffness of the footwear
Median level of Agreement 6 ("Agree")
7% "Somewhat Disagree", 20% "Neutral", 20% "Somewhat Agree",
53% "Agree"

Panellist feedback suggested that Leather material do not have uniform tensile strength. The upper material needs to account for the mass of the patient and the potential for increased mechanical stress.

The statements have been slightly modified based on panellist feedback please rank your level of agreement with these.*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Purpose: Leather may adapt to foot structures over time dependent on the tensile strength of the leather.	☐	☐	☐	☐	☐	☐	☐
Purpose: Leather may enhance material stiffness of the footwear dependent on the tensile strength of the leather.	☐	☐	☐	☐	☐	☐	☐

13)

The panellists were presented with the following options in relation to the desired design characteristic of the tongue to topline relationship for stability footwear In Round 2.
The relative distribution of response is detailed below:

Option 1: Tongue length optional dependent on patient's preference and manual dexterity 67%
Option 2:Tongue extended above topline (Original) 33%
Option 3:Tongue should be in line with topline (Original) 0%

No specific panellist feedback was given to inform any further modification of these options.

Please consider the following two options in reference to the tongue to topline relationship.*

☐	Option 1:Tongue length optional dependent on patient's preference and manual dexterity
☐	Option 2: Tongue extended above topline (Original)

14)

The following purposes were presented to the panellists in Round 2 in relation to the tongue to topline relationship.
The median level of agreement and the relative distribution of response is detailed below.

Purpose: Tongue in line with topline is to minimise irritation to the anterior aspect of the ankle.
Median level of Agreement 5 ("Somewhat Agree")
13% "Somewhat Disagree", 13% "Neutral", 40% "Somewhat Agree",
27% "Agree", 7% "Strongly Agree"

Purpose: Tongue extended above topline allows for comfort with lacing
Median level of Agreement 6 ("Agree")
13% "Neutral", 27% "Somewhat Agree", 40% "Agree", 20% "Strongly Agree"

Purpose: Tongue extended above topline allows the wearer to minimise slippage of the tongue under the fastenings during wear
Median level of Agreement 6 ("Agree")
13% "Somewhat Disagree", 13% "Neutral", 13% "Somewhat Agree",
40% "Agree", 21% "Strongly Agree"

No specific panellist feedback was given to inform any further modification of these statements, However, you may consider the distribution of the panel's response to either change or maintain your previous choice.

Please consider the following statements from Round 2 in relation to the purpose of the tongue to topline relationship and rank your agreement with them..*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Purpose: Tongue in line with topline is to minimise irritation to the anterior aspect of the ankle	☐	☐	☐	☐	☐	☐	☐
Purpose: Tongue extended above topline allows for comfort with lacing	☐	☐	☐	☐	☐	☐	☐
Purpose: Tongue extended above topline allows the wearer to minimise slippage of the tongue under the fastenings during wear	☐	☐	☐	☐	☐	☐	☐

15)

The panellists were presented with following design considerations for the upper of off the shelf stability footwear in Round 2 based on panellist suggestions in Round 1.
The median level of agreement and relative distribution of response is detailed below.

High topped sandals to be offered as an option for stability footwear ranges for warm weather.
Median level of Agreement 6 ("Agree")
13% "Neutral", 33%, "Somewhat Agree", 27% "Agree", 27% "Strongly Agree"

Ergonomic consideration of internal seams to reduce skin irritation
Median level of Agreement 6 ("Agree")

67% "Agree", 33% "Strongly Agree"
A Consensus was reached for this design option

Slit or loop in the tongue for fastening to minimise tongue slippage
Median level of Agreement 6 ("Agree")
13% "Somewhat Agree", 60% "Agree", 27% "Strongly Agree"
A Consensus was reached for this design option

No specific panellist feedback was given to inform any further modification of the design option of high topped sandals, However, you may consider the distribution of the panel's response to either change or maintain your previous choice.

Please consider the following statement from Round 2 in relation to the design option for the upper.*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
High topped sandals to be offered as an option for stability footwear ranges for warm weather	☐	☐	☐	☐	☐	☐	☐

16)

If your level of agreement was "somewhat agree" or lower for any of the statements in relation to the upper please use this optional area to provide us with your reasoning.

Fastening and Facing

In the questions below you will be presented with the collective choices and opinions from Round 2 in relation to the Fastenings and Facings of standard "Off the Shelf" stability footwear used as a clinical intervention for children with mobility impairment. Please consider the options offered or rank your level of agreement with the suggested characteristic or purpose of these design characteristics some of which may have been slightly modified based on panellist feedback in Round 2:

17)

The panellists were presented with the following options in relation to the desired design characteristic of the type of fastening in Round 2 The relative distribution of response is detailed below:

Option 1: Optional dependent on patient's ability and desired goal (e.g. Velcro for limited hand dexterity, lace for greater stability) 93%
Option 2: Velcro (Original) 7%
Option 3: Lace (Original) 0%
Option 4:No preference (Original) 0%

A consensus was reached for Option 1.

Panellist feedback suggested that having combination fastenings on offer may also assist donning with adjunct assistive aids such as AFO's

18)

The following purposes were presented to the panellists in Round 2 for the type of fastenings.
The median level of agreement and relative distribution of response is detailed below.

Purpose of Velcro fastenings: Assists independence with limited hand dexterity in donning and doffing.
Median level of Agreement 6 ("Agree")
7% "Somewhat Agree", 46% "Agree", 47% "Strongly Agree"
A Consensus was reached for this purpose

Purpose of lace fastenings: Enhances stability through potential firmer grip to contours of the foot.
Median level of Agreement 6 (Agree)
7% "Somewhat Disagree", 7% "Neutral", 13% "Somewhat Agree", 47% "Agree", 26% "Strongly Agree"

No specific panellist feedback was given to inform any further modification of the purpose of lace fastenings. However, you may consider the distribution of the panel's response to either change or maintain your previous choice.

Please consider the following statement from Round 2 in relation to the purpose of a lace fastening.*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Purpose of lace fastenings: Enhances stability through potential firmer grip to the contours of the foot	☐	☐	☐	☐	☐	☐	☐

19)

The panellists were presented with the following options in relation to the desired design characteristic of the Position of the facings in Round 2
The relative distribution of response is detailed below:

Option 1: Optional dependent on patient's foot and ankle mobility or therapeutic goal (i.e. facings extended to toe box for ease of foot and ankle access, extended to midfoot for greater upper stability) 93%
Option 2: Facings extended to just behind the toe box (original)
7%
Option 3: Facings extended to midfoot (original) 0%
Option 4: No Preference (original) 0%

A consensus was reached for Option 1.

20)

The following purposes were presented to the panellists in Round 2 in relation to the position of the facings.
The median level of agreement and the relative distribution of response is detailed below.

Purpose: Facings extended to just behind the toe box allows greater access into the footwear for the child with limited foot and ankle range of motion
Median level of Agreement 6 ("Agree")
7% "Neutral", 66% "Agree", 27% "Strongly Agree"
A consensus was reached for this Purpose

Purpose: Facing extended to the midfoot allows the upper to offer greater stability to the foot and ankle.
Median level of Agreement 6 ("Agree")
7% "Somewhat Disagree", 20% "Neutral", 20% "Somewhat Agree"
, 53% "Agree"

No feedback was given to explain the lack of consensus agreement to the purpose of the facings extended to the midfoot, or to suggest further modification of the statement, although a strong majority of the panel advocated for an optional range of facing extensions to be incorporated in Question 19.

Please consider the following statement from Round 2 in relation to the purpose of facings extended to the midfoot..*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Purpose: Facing extended to the midfoot allows the upper to offer greater stability to the foot and ankle.	☐	☐	☐	☐	☐	☐	☐

21)

The panellists were presented with following design considerations for the fastenings and facings of off the shelf stability footwear in Round 2 based on panellist suggestions in Round 1.
The median level of agreement and the relative distribution of response is detailed below.

The Gap between the facings should allow adequate range of fastening adjustment
Median level of Agreement 6 ("Agree")
13% "Somewhat Agree", 40% "Agree", 47% "Strongly Agree"
A consensus was reached for this statement

Side Zip combination fastening
Median level of Agreement 6 ("Agree")
7% "Somewhat Disagree", 20% "Neutral", 13% "Somewhat Agree", 47% "Agree", 13% "Strongly Agree"

Panellist feedback suggested potential difficulty with side zip fastening including easy to damage zip mechanism, dangers of damaging skin or nails, and difficulty in fastening zip if lace fastenings are tightened tight enough to contour to the foot and ankle.

Considering panellist feedback please rank your level of agreement to side zip lace combination fastening..*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Side zip lace combination fastening	☐	☐	☐	☐	☐	☐	☐

22)

If your level of agreement was "somewhat agree" or lower for any of the statements in relation to the fastening and facings please use this optional area to provide us with your reasoning.

Heel counter/stiffener

In the questions below you will be presented with the collective choices and opinions from Round 2 in relation to the Heel counter/stiffener of standard "Off the Shelf" stability footwear used as a clinical intervention for children with mobility impairment. Please consider the options offered or rank your level of agreement with the suggested characteristic or purpose of these design characteristics some of which may have been slightly modified based on panellist feedback in Round 2:

23)

The panellists were presented with the following options in relation to the desired design characteristic of the heel counter/stiffener extension in Round 2.
The relative distribution of response is detailed below:

Option1: Optional range of heel counter extensions dependent on therapeutic need and the patient's foot and ankle anatomy (80%)
Option 2: Heel counter/stiffener extended to the midfoot only (13%)
Option 3: Heel counter stiffener, extended to the midfoot and towards topline (7%)
Option 4: Heel counter/stiffener extended towards the topline only (0%)

A Consensus was reached for Option 1:

Panellist Feedback suggested a concern that requesting too many optional features may present manufactures with difficulty in providing a stock boot. Additionally, heel counter changes may affect the fixation of the upper to the sole unit.

24)

The following purposes were presented to the panellists in Round 2 in relation to the heel counter/stiffener.
The median level of agreement and the relative distribution of response is detailed below.

Purpose: Heel counter/stiffener extensions can enhance proprioception at the foot and ankle
Median level of Agreement 5 ("Somewhat Agree")

20% "Neutral", 46% "Somewhat Agree", 27% "Agree", 7% "Strongly Agree"

Purpose: Heel counter/stiffener extension offers material stiffness to restrict frontal plane movements at the foot, ankle and midfoot dependent on the extension profile.
Median level of Agreement 6 ("Agree")
7% "Neutral", 40% "Somewhat Agree", 40% "Agree", 13% "Strongly Agree"

Panellist feedback suggested partial agreement due to the limited evidence base to support the purpose of the heel counter. Additionally, it was felt control at the heel counter area of the shoe should also consider the vertical ground reaction force component through increased contact area between the inner sole of the shoe and the plantar surface of the child's heel.
The research team appreciates that there is a paucity of scientific or structured clinical research but we would ask you to consider your years of clinical experience and expertise as to the perceived role of this design adaption.

Based on your clinical experience please rank your level of agreement with these proposed purposes and design considerations of the Heel counter/stiffener:*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Purpose: Heel counter/stiffener extensions may enhance proprioception at the foot and ankle.	☐	☐	☐	☐	☐	☐	☐
Purpose: Heel counter/stiffener extension offers material stiffness that may restrict frontal plane movements at the foot, ankle and midfoot dependent on the extension profile.	☐	☐	☐	☐	☐	☐	☐
Control of frontal plane movements of the foot and ankle at the	☐	☐	☐	☐	☐	☐	☐

heel counter area should also consider vertical ground reaction force contact area, through close contact between the plantar surface of the child's heel and the inner sole of the shoe.							

25)

If your level of agreement was "somewhat agree" or lower for any of the statements in relation to the heel counter/stiffener please use this optional area to provide us with your reasoning.

Heel

In the questions below you will be presented with the collective choices and opinions from Round 2 in relation to the Heel of standard "Off the Shelf" stability footwear used as a clinical intervention for children with mobility impairment.
Please consider the options offered or rank your level of agreement with the suggested characteristic or purpose of these design characteristics some of which may have been slightly modified based on panellist feedback in Round 2:

26)

The panellists were presented with the following options in relation to the desired design characteristic of the "Heel width in relation to the heel counter" in Round 2.
The relative distribution of response is detailed below:

Option 1: Heel width extensions should be provided as an optional sole adaption with the heel width extension on standard stability footwear being no wider than the welted seam. (53%)
Option 2: Heel width extended wider than heel counter width (Original) (40%)
Option 3: No preference (Original) (7%)
Option 4: Heel width in line with heel counter width (Original) 0%

No specific panellist feedback was given to inform any further modification of the options of heel width in relation to the heel counter. However, you may consider the distribution of the panel's response to either change or maintain your previous choice.

Please consider the following 3 options from Round 2 of the heel width in relation to the heel counter.*

☐	Heel width in line with heel counter width (Original)
☐	Heel width extended wider than heel counter width (Original)
☐	No preference (Original)
☐	Heel width extensions should be provided as an optional sole adaption with the heel width extension on standard stability footwear being no wider than the welted seam.

27)

The following purpose was presented to the panellists in Round 2 in relation to an extended heel width
The median level of agreement and relative distribution of response is detailed below.
Purpose: Heel width extensions assist medial-lateral stability of the foot and ankle through an increased base of support.
Median level of Agreement 6 ("Agree")
7% "Neutral", 7% "Somewhat Agree:, 53% "Agree", 33% "Strongly Agree"
A consensus was reached for this statement.

Panellist feedback suggested for a wide sole to offer increased stability maximum contact with the insole of the shoe and the plantar surface of the foot is required to maximise vertical GRF contact area:*

28)

The panellists were presented with following design considerations for the heel of off the shelf stability footwear in Round 2 based on panellist suggestions in Round 1.
The median level of agreement and relative distribution of response is detailed below.

Heel Pitch should not increase ankle instability
Median level of Agreement 6 ("Agree")
13% "Somewhat Agree", 67% "Agree", 20% "Strongly Agree"
A consensus was reached for this statement

Heel pitch should allow for adjunct orthotic therapy
Median level of Agreement 6 ("Agree")
7% "Somewhat Agree", 73% "Agree", 20% "Strongly Agree"
A consensus was reached for this statement

Panellist feedback suggested that ankle Instability would be inevitable due to plantarflexion in propulsion.

29)

You may use this optional area to provide us with any further information to your responses on the heel

Inlay

In the questions below you will be presented with the collective choices and opinions from Round 2 in relation to the Inlay of standard “Off the Shelf” stability footwear used as a clinical intervention for children with mobility impairment.
Please consider the options offered or rank your level of agreement with the suggested characteristic or purpose of these design characteristics some of which may have been slightly modified based on panellist feedback in Round 2:

30)

The panellists were presented with the following options in relation to the desired design characteristic of the Inlay in Round 2.
The relative distribution of response is detailed below:

Option 1: The inlay should be contoured to simulate the medial longitudinal arch and to cup the heel 54%

Option 2: The inlay should be contoured to cup the heel but not the medial longitudinal arch 33%

Option 3: The inlay should be contoured to simulate the medial longitudinal arch (Original) 13%

Panellist feedback suggested, That "off the shelf" stability footwear not just for early walkers therefore contouring to MLA may be required for larger sizes. Mild arch contour similar to that offered in standard retail footwear would be appropriate. The Arch may be easily reduced by clinician to control blistering in low arch feet.
Ambiguous statement unsure if heel cupping would improve the fit of inlay to shoe or inlay and shoe to patient's foot

Slight modification to the options have been addressed panellist based on panellist feedback.*

☐	The inlay should cup the child's heel to improve rearfoot fit and be appropriately contoured to the medial longitudinal arch
☐	The inlay should cup the child's heel to improve rearfoot fit but not be contoured to the medial longitudinal arch
☐	The inlay should be appropriately contoured to the medial longitudinal arch

31)

The following purpose and design characteristics were presented to the panellists in Round 2 in relation to inlay
The median level of agreement and the relative distribution of response is detailed below.

Removable Inlay should be thick enough to simulate a potential prescriptive foot orthoses
Median level of Agreement 6 ("Agree")
67% "Agree", 33% "Strongly Agree"
A consensus was reached for this statement

Purpose: An inlay contoured to cup the heel improves rearfoot fitting Median level of Agreement 5 ("Somewhat Agree")
7% "Somewhat Disagree", 13% "Neutral", 34% "Somewhat Agree", 33% "Agree", 13% "Strongly Agree"

Panellist feedback suggested ambiguity if cupping of the heel would improve the fit of inlay to shoe or the inlay and shoe to the patient's foot

The statement has been slightly modified based on panellist feedback please rank your level of agreement with this.*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
An inlay contoured to cup the heel improves rearfoot fitting of the child's foot to the shoe	☐	☐	☐	☐	☐	☐	☐

32)

If your level of agreement was "somewhat agree" or lower for any of the statements in relation to the Inlay please use this optional area to provide us with your reasoning.

Sole unit

In the questions below you will be presented with the collective choices and opinions from Round 2 in relation to the Sole unit of standard "Off the Shelf" stability footwear used as a clinical intervention for children with mobility impairment.
Please consider the options offered or rank your level of agreement with the suggested characteristic or purpose of these design characteristics some of which may have been slightly modified based on panellist feedback in Round 2:

33)

The panellists were presented with the following options in relation to the desired design characteristic of the tread depth of the sole unit in Round 2.
The relative distribution of response is detailed below:

Option 1: The tread depth should come in an optional range dependent on the ability of the child and the environment where the footwear is to be used. (87%)

Option 2: A deepened tread (Original) 13%

A consensus was reached for Option 1

34)

The panellists were presented with the following options in relation to the desired design characteristic of the wear characteristics of the sole unit in Round 2.
The relative distribution of response is detailed below:

Option 1: Optional wear resilience of the sole material dependent on the age and ability of the patient. (87%)

Option 2: Hard-wearing material (Original) (13%)

A consensus was reached for Option 1

35)

The following purpose was presented to the panellists in Round 2 in relation to hard wearing sole material.
The median level of agreement and relative distribution of response is detailed below.

Purpose: Hard-wearing sole material will prolong the stability effect of the footwear by resisting wear patterns associated with gait pathologies.
Median level of Agreement 6 ("Agree")
7% "Neutral", 7% "Somewhat Agree", 79% "Agree", 7% "Strongly Agree"

A consensus was reached for this Statment.

36)

"The panellists were presented with the following options in relation to the desired design characteristic of the degree of flexibility for the sole unit. in Round 2.
The relative distribution of response is detailed below:

Option 1: The sole unit should come in a range of sole stiffness dependent on the patient's ability or the therapeutic goals, with flexibility of the sole focused at the MPJ area
(100%)
Option2 (Other)
(0%)

A consensus was reached for option 1.

37)

The panellists were presented with following design considerations for the sole unit of off the shelf stability footwear in Round 2 based on panellist suggestions in Round 1.
The median level of agreement and relative distribution of response is detailed below.

Rearfoot to Forefoot width ratio's kept to lowest practical ratio to assist medial lateral stability
Median level of Agreement 5 ("Somewhat Agree")
27% "Neutral", 27% "Somewhat Agree', 40% "Agree", 6% "Strongly Agree"

The sole unit should be stiffer at the midfoot and rearfoot to assist stability in these regions.
Median level of Agreement 5 (Somewhat Agree)
7% "Somewhat Disagree", 20% "Neutral", 26% "Somewhat Agree", 20% "Agree", 27% "Strongly Agree"

Panellist feedback suggested the width ratio of forefoot and rearfoot was ambiguous and required further explanation.

The statement in relation to the sole unit rearfoot to forefoot ratio has been slightly modified based on panellist feedback No specific feedback was offered to offer modification of the statement concerning the stiffness at midfoot and rearfoot sole unit,

However, you may consider the distribution of the panel's response to either change or maintain your previous choice to this statement.

Please rank your level of agreement with these statements..*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
The ground contact area ratio between the rearfoot and forefoot of the sole unit should be kept to the lowest practical ratio to assist medial-lateral stability	☐	☐	☐	☐	☐	☐	☐
The sole unit should be stiffer at the midfoot and rearfoot to assist stability in these regions.	☐	☐	☐	☐	☐	☐	☐

38)

If your level of agreement was "somewhat agree" or lower for any of the statements in relation to the sole unit please use this optional area to provide us with your reasoning.

Toe spring forefoot/heel rocker

In the questions below you will be presented with the collective choices and opinions from Round 2 in relation to the toe spring forefoot/heel rocker of standard "Off the Shelf" stability footwear used as a clinical intervention for children with mobility impairment.
Please consider the options offered or rank your level of agreement with the suggested characteristic or purpose of these design characteristics some of which may have been slightly modified based on panellist feedback in Round 2:

39)

The panellists were presented with the following options in relation to the desired design characteristic of the forefoot rocker in Round 2.
The relative distribution of response is detailed below:

Option 1: Stability footwear should come in a range of forefoot rockers dependent on the patient's condition and the stiffness of the sole. (73%)

Option 2: Stability footwear should have a reasonable forefoot rocker. (Original) (27%)

Panellist feedback suggested that although the variation of rocker's and sole stiffeners offered for conditions such as Charcot Marie Tooth and toe walking were important these should be offered as a sole adaption prescription rather than a standard design on stability footwear.

A modified option as been offered based on panellist feedback.*

☐	Option 1: Stability footwear should come in a range of forefoot rockers dependent on the patient's condition and the stiffness of the sole.
☐	Option 2: Stability footwear should have a reasonable forefoot rocker as a standard design. With forefoot rocker adaption prescriptions available to meet patient's needs.

40)

The following purposes were presented to the panellists in Round 2 in relation to the forefoot rocker
The median level of agreement and relative distribution of response is detailed below.

Purpose of forefoot rocker: Should facilitate forward progression in terminal stance without impacting on stability.
Median level of Agreement 6 ("Agree")
7% "Somewhat Agree", 66% "Agree", 27% "Strongly Agree"
A consensus was reached for this statement

Design characteristic of forefoot rocker: Should allow adequate ground clearance in swing
Median level of Agreement 6 ("Agree")
7% "Somewhat Agree", 66% "Agree', 27% "Strongly Agree"
A consensus was reached for this statement

41)

The panellists were presented with the following options in relation to the desired design characteristic of the heel rocker in Round 2.
The relative distribution of response is detailed below:

Option 1: Heel rockers should be offered as a sole adaption prescription dependent on the child's condition rather than a standard design of stability footwear. (100%)
Option 2: Stability footwear should have a heel rocker. (Original) (0%)

A Consensus was reached for Option 1

42)

You may use this optional area to provide us with any further information to your responses on toe spring forefoot/heel rocker.

Weight of the footwear

In the questions below you will be presented with the collective choices and opinions from Round 2 in relation to the weight of the footwear of standard “Off the Shelf” stability footwear used as a clinical intervention for children with mobility impairment. Please consider the options offered or rank your level of agreement with the suggested characteristic or purpose of these design characteristics some of which may have been slightly modified based on panellist feedback in Round 2:

43)

The following purpose and design characteristics were presented to the panellists in Round 2 in relation to the weight of the footwear
The median level of agreement and relative distribution of response is detailed below.

Stability Footwear should be the lowest reasonable mass to reduce physiological cost during mobility
Median level of Agreement 6 ("Agree")
33% 'Somewhat Agree", 40% "Agree", 27% 'Strongly Agree'

Mass of shoe should be dependent on the mass and age of the child
Median level of Agreement 6 ('Agree")
13% "Neutral", 20% "Somewhat Agree", 54% "Agree", 13% "Strongly Agree"

The mass of the shoe should be dependent on the child's stability needs.
Median level of Agreement 6 ("Agree")
7% "Neutral", 13% "Somewhat Agree", 67% "Agree", 13% "Strongly Agree"
A consensus was reached for this statement

Purpose of Increased mass assists stability in stance,
Median level of Agreement 5 ("Somewhat Agree")
40% "Neutral", 20% "Somewhat Agree", 40% "Agree"

Purpose of Increased Mass Assists pendular motion in swing
Median level of Agreement 5 ("Somewhat Agree")
7% "Somewhat Disagree", 40% "Neutral', 26% "Somewhat Agree"
20% "Agree", 7% "Strongly Agree"

Panellist feedback suggested that pendular motion may be assisted but increased mass may also cause an adverse effect with instability in swing and preloading increasing difficulty in navigating obstacles and stair climbing.
The increased mass of the footwear may unintentionally provide a benefit in strengthening limbs but also may induce early fatigue.

A new statement was generated from panellist feedback concerning a potential adverse effect of the weight of the shoe. No specific panellist feedback was given to inform further modification of the other statements, However, you may consider the distribution of the panel's response to either change or maintain your previous choice.

Please rank your level of agreement with these statements..*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Stability footwear should be the lowest reasonable mass to reduce physiological	☐	☐	☐	☐	☐	☐	☐

cost during mobility.							
The mass of the shoe should be dependent on the mass and age of the child.	☐	☐	☐	☐	☐	☐	☐
Purpose of increased mass: Assist stability in stance	☐	☐	☐	☐	☐	☐	☐
Purpose of increased mass: Assists pendular motion in swing	☐	☐	☐	☐	☐	☐	☐
Adverse Effect: Increased mass of the shoe may lead to difficulty in swing phase with ground clearance, navigating obstacles and stair climbing.	☐	☐	☐	☐	☐	☐	☐

44)

If your level of agreement was "somewhat agree" or lower for any of the statements in relation to the weight of the footwear please use this optional area to provide us with your reasoning.

Further Design Considerations

The following section provides additional design considerations for "Off the Shelf" Stability footwear suggested by the panellists.

45)

The Following design consideration was presented to the panellist in Round 2
The median level of agreement and relative distribution of response is detailed below.

Children's "Off the Shelf" stability footwear should come in a range of last dimensions to accommodate proportional differences in foot types.
Median level of Agreement 6 ("Agree")
7% "Neutral", 46% "Agree", 47% "Strongly Agree",

A consensus was reached for this statement.

46

The Following design consideration was presented to the panellist in Round 2
The median level of agreement and relative distribution of response is detailed below.

Children's "Off the Shelf" stability footwear should come in a range of colours and styles to appeal to children's preferences.
Median level of Agreement 7 ("Strongly Agree")
40% "Agree", 60% "Strongly Agree"

A consensus was reached for this statement.

END OF SECTION 2 ROUND 3

Thank you for taking the time to complete section 2. Your time and participation in this survey are greatly appreciated.

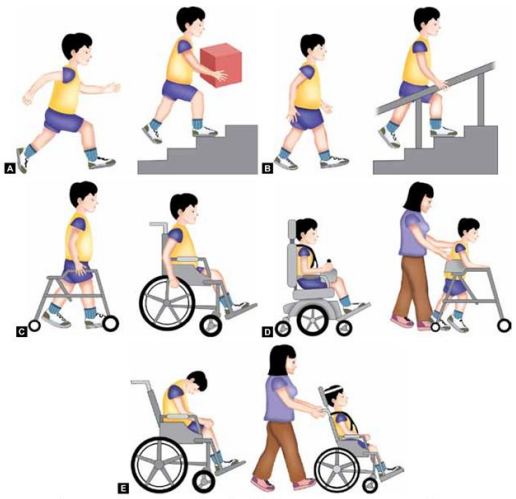
Please remember to submit your answers before closing this form.

You can find the link for the next section of Round 2 attached to the Delphi survey email.

WHAT ARE CHILDREN'S CLINICAL FOOTWEAR INTERVENTIONS AND HOW TO PRESCRIBE THEM? (SECTION 3 ROUND 1)

The third section will consist of your ideas and opinions on clinical protocols and outcomes for the provision of “off the shelf” modular stability clinical footwear interventions for children with mobility impairment.

Section 3



Opinion on prescription and clinical outcomes of "off the shelf" and modular stability footwear clinical interventions for children with mobility impairment.

This section consists of a series of closed-ended and structured open-ended questions concerning clinical protocols for the issuing of stability footwear as a sole assistive aid or in combination with other assistive aids (ankle foot orthoses (AFO*), walking frames) for children with mobility impairment, and the expected clinical outcomes of these footwear.

*Please remember to qualify any abbreviation for mobility aids.

The conditions presented were suggested from the research sourced in the scoping review. However, you will be given the opportunity to suggest further conditions you treat or that you consider from your manufacturing experience may benefit from stability footwear intervention.

For each condition, a range of topics will be considered, and you will be free to suggest additional aspects you view as necessary, and your reasons for these.

- Do you have experience of treating or from a manufacturing perspective recommending footwear for This condition?
- Do you feel that this condition is appropriate for stability footwear intervention?
- Degree of mobility impairment (qualify if the footwear is to be used as a sole aid or in combination with another assistive aid).
- Age of patient, i.e. at what age do you consider appropriate to use this footwear as a mobility intervention.
- Clinical Outcomes: Changes in gait e.g. reduction/increase in velocity/stride length/ side to side movement.

An example of answers to a series of questions in relation to a specific condition that would benefit from the clinical prescription of "off the shelf" and modular stability footwear is presented below.

Cerebral palsy

1) Do you have experience in treating this condition

Answer: (Yes)

2) Do you feel this condition is appropriate for stability footwear intervention

Answer: (Strongly Agree 7)

3) The degree of mobility impairment would be:

Answer: For sole use of footwear: Gross Motor Function Classification Score level 1, mild hemiplegia or diplegia where the child is capable of independent ambulation
For combined use with walking frame Level: Gross Motor Function Classification Score level 3 where independent ambulation is extremely limited,

4) Concerning this condition, the age range would be:

Answer: 1-18 years

5) Concerning this condition, the clinical outcomes of "off the shelf" and modular stability footwear intervention would be:

Answer: Increase in: gait velocity, stride length. Reduce side to side sway. Improved walking distance and participation in daily life activities such as play, family outings, walking to school.

Required Field*

1)

Name: *

Cerebral Palsy

From the research stability footwear has been proposed as a clinical intervention for children with cerebral palsy.
In the questions below, please consider the following in reference to clinical protocols for issuing "off the shelf" and modular stability footwear as a mobility aid for children:

Experience treating this condition
Agreement on the suitability of stability footwear as a treatment for this condition
Degree of mobility impairment
The age range of patients
Clinical outcomes

2)

Do you have experience in treating this condition? If your answer is no move to the next condition (Q 8). *

☐	Yes
☐	No

3)

Do you agree this condition is suitable for stability footwear clinical intervention?

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Cerebral palsy is suitable for stability footwear intervention?	☐	☐	☐	☐	☐	☐	☐

4)

Please use this area to provide us briefly with the reasoning for your agreement or disagreement of using stability footwear as an intervention for this condition.

5)

The degree of mobility impairment that would be suitable for this condition is:
*Please qualify if stability footwear is to be used as a sole aid or in combination with another assistive aid.

6)

Please indicate in years the age range this footwear intervention should be prescribed clinically for this condition: e.g. 1-5 years.

7)

Clinical outcomes:

Pes Planus

From the research stability footwear has been proposed as a clinical intervention for children with pes planus.
In the questions below, please consider the following in reference to clinical protocols for issuing "off the shelf" and modular stability footwear as a mobility aid for children:

Experience treating this condition
Agreement on the suitability of stability footwear as a treatment for this condition
Degree of mobility impairment
The age range of patients
Clinical outcomes

8)

Do you have experience in treating this condition? If your answer is no move to the next condition (Q 14). *	
☐	Yes
☐	No

9)

Do you agree this condition is suitable for stability footwear clinical intervention?							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Pes planus is suitable for stability footwear intervention?	☐	☐	☐	☐	☐	☐	☐

10)

Please use this area to provide us briefly with the reasoning for your agreement or disagreement of using stability footwear as an intervention for this condition.

11)

The degree of mobility impairment that would be suitable for this condition is: †Please qualify if stability footwear is to be used as a sole aid or in combination with another assistive aid.

12)

Please indicate in years the age range this footwear intervention should be prescribed clinically for this condition: e.g. 1-5 years.

13)

Clinical outcomes:

Toe Walking

From the research stability footwear has been proposed as a clinical intervention for children with toe walking.
In the questions below, please consider the following in reference to clinical protocols for issuing "off the shelf" and modular stability footwear as a mobility aid for children:

Experience treating this condition
Agreement on the suitability of stability footwear as a treatment for this condition
Degree of mobility impairment
The age range of patients
Clinical outcomes

14)

Do you have experience in treating this condition? If your answer is no move to the next condition (Q 20). *

☐	Yes
☐	No

15)

Do you agree this condition is suitable for stability footwear clinical intervention?

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Toe walking is suitable for stability footwear intervention?	☐	☐	☐	☐	☐	☐	☐

16)

Please use this area to provide us briefly with the reasoning for your agreement or disagreement of using stability footwear as an intervention for this condition.

17)

The degree of mobility impairment that would be suitable for this condition is:
†Please qualify if stability footwear is to be used as a sole aid or in combination with another assistive aid.

18)

Please indicate in years the age range this footwear intervention should be prescribed clinically for this condition: e.g. 1-5 years.

19)

Clinical outcomes:

Duchenne Muscular Dystrophy

From the research stability footwear has been proposed as a clinical intervention for children with Duchenne muscular dystrophy.
In the questions below, please consider the following in reference to clinical protocols for issuing "off the shelf" and modular stability footwear as a mobility aid for children:

Experience treating this condition
Agreement on the suitability of stability footwear as a treatment for this condition
Degree of mobility impairment
The age range of patients
Clinical outcomes

20)

Do you have experience in treating this condition? If your answer is no move to the next condition (Q 26). *

☐	Yes
☐	No

21)

Do you agree this condition is suitable for stability footwear clinical intervention?

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Duchenne muscular dystrophy is suitable for stability footwear intervention?	☐	☐	☐	☐	☐	☐	☐

22)

Please use this area to provide us briefly with the reasoning for your agreement or disagreement of using stability footwear as an intervention for this condition.

23)

The degree of mobility impairment that would be suitable for this condition is:
†Please qualify if stability footwear is to be used as a sole aid or in combination with another assistive aid.

24)

Please indicate in years the age range this footwear intervention should be prescribed clinically for this condition: e.g. 1-5 years.

25)

Clinical outcomes:

Spina Bifida

From the research stability footwear has been proposed as a clinical intervention for children with spina bifida.
In the questions below, please consider the following in reference to clinical protocols for issuing "off the shelf" and modular stability footwear as a mobility aid for children:

Experience treating this condition
Agreement on the suitability of stability footwear as a treatment for this condition
Degree of mobility impairment
The age range of patients
Clinical outcomes

26)

Do you have experience in treating this condition? If your answer is no move to the next condition (Q 31). *

☐	Yes
☐	No

27)

Do you agree this condition is suitable for stability footwear clinical intervention?

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Spina bifida is suitable for stability footwear intervention?	☐	☐	☐	☐	☐	☐	☐

28)

Please use this area to provide us briefly with the reasoning for your agreement or disagreement of using stability footwear as an intervention for this condition.

29)

The degree of mobility impairment that would be suitable for this condition is:
†Please qualify if stability footwear is to be used as a sole aid or in combination with another assistive aid.

30)

Please indicate in years the age range this footwear intervention should be prescribed clinically for this condition: e.g. 1-5 years.

31)

Clinical outcomes:

Down's Syndrome

From the research stability footwear has been proposed as a clinical intervention for children with Down's syndrome.
In the questions below, please consider the following in reference to clinical protocols for issuing "off the shelf" and modular stability footwear as a mobility aid for children:

Experience treating this condition
Agreement on the suitability of stability footwear as a treatment for this condition
Degree of mobility impairment
The age range of patients
Clinical outcomes

32)

Do you have experience in treating this condition? If your answer is no move to the next condition (Q 38). *

☐	Yes
☐	No

33)

Do you agree this condition is suitable for stability footwear clinical intervention?

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Down's syndrome is suitable for stability footwear intervention?	☐	☐	☐	☐	☐	☐	☐

34)

Please use this area to provide us briefly with the reasoning for your agreement or disagreement of using stability footwear as an intervention for this condition.

35)

The degree of mobility impairment that would be suitable for this condition is:
†Please qualify if stability footwear is to be used as a sole aid or in combination with another assistive aid.

36)

Please indicate in years the age range this footwear intervention should be prescribed clinically for this condition: e.g. 1-5 years.

37)

Clinical outcomes:

Intoeing

From the research stability footwear has been proposed as a clinical intervention for children with Duchenne muscular dystrophy.
In the questions below, please consider the following in reference to clinical protocols for issuing "off the shelf" and modular stability footwear as a mobility aid for children:

Experience treating this condition
Agreement on the suitability of stability footwear as a treatment for this condition
Degree of mobility impairment
The age range of patients
Clinical outcomes

38)

Do you have experience in treating this condition? If your answer is no move to the next condition (Q 44). *

☐	Yes
☐	No

39)

Do you agree this condition is suitable for stability footwear clinical intervention?

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Intoeing is suitable for stability footwear intervention?	☐	☐	☐	☐	☐	☐	☐

40)

Please use this area to provide us briefly with the reasoning for your agreement or disagreement of using stability footwear as an intervention for this condition.

41)

The degree of mobility impairment that would be suitable for this condition is:
†Please qualify if stability footwear is to be used as a sole aid or in combination with another assistive aid.

42)

Please indicate in years the age range this footwear intervention should be prescribed clinically for this condition: e.g. 1-5 years.

43)

Clinical outcomes:

44)

Optional Further Information
Please use the additional area to provide further conditions where you feel "off the shelf" modular stability footwear would act as a mobility aid. Please try to detail your answer with the following considerations • Condition • Severity / Grade of the condition if applicable, • The age of the patient • Clinical Outcomes

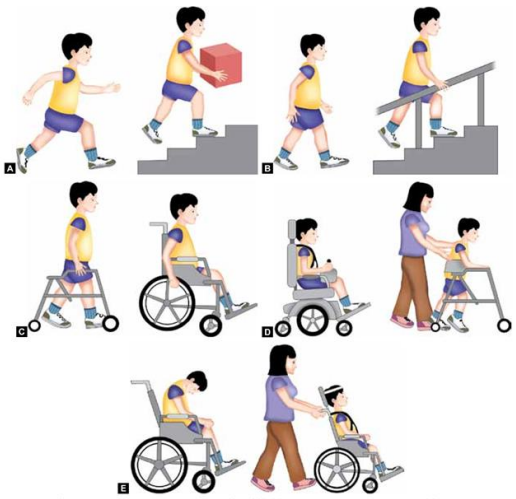
END OF SECTION 3 ROUND 1

Thank you for taking time to complete section 3 of round 1. You have now completed all sections of round 1 of this Delphi survey. Your time and participation is greatly appreciated. Please note that the following rounds will be less time consuming and will be sent in the same format as round 1.
Remember to submit your answers before closing this form.

ROUND 2(S3) WHAT ARE CHILDREN'S CLINICAL FOOTWEAR INTERVENTIONS AND HOW TO PRESCRIBE THEM?

The third section will present the feedback of panellists opinions from Round 1 on clinical protocols and outcomes for the provision of “off the shelf” stability footwear clinical interventions for children with mobility impairment.

Section 3



Opinion on prescription and clinical outcomes of "off the shelf" stability footwear clinical interventions for children with mobility impairment.

This section consists of a series of closed-ended and ranked questions concerning clinical protocols for the issuing of stability footwear as a sole assistive aid or in combination with other assistive aids (ankle foot orthoses AFO†, walking frames) for children with mobility impairment, and the expected clinical outcomes of these footwear interventions.

† *Please remember to qualify any abbreviation for mobility aids.*

The original information provided in this section sourced from the scoping review are listed alongside modified statements informed from the responses gained from panellists in round 1.

You will be asked to give your preferred option or your level of agreement with these statements (Strongly Disagree to Strongly Agree).

We will provide you with the opportunity to offer your reasoning for your stance or to suggest any further amendments to the statements (You may also leave these areas blank in this round). All answers will be anonymised and will not be identifiable as your responses.

Required Field*

1)

Name: *

Cerebral Palsy

From the research stability footwear has been proposed as a clinical intervention for children with cerebral palsy.
In the questions below, you will be presented with the collective opinion of panellists from Round 1 in relation to the suitability of stability footwear as a clinical intervention.

13 of the 15 (86%) panellists had clinical experience with this condition and provided the information for this section.

(If you have no clinical experience in treating this condition, please move to the next condition Question 7)

2)

Panellists were asked if cerebral palsy (CP) was a suitable condition for stability footwear intervention in children and their reasoning for this.

The median level of agreement amongst the panellists was "strongly agree" with the majority of responses between "agree" and "strongly agree.
A Consensus was reached with respect to this condition being suitable for stability footwear intervention in Round 1

Panellist feedback suggested the reasons for stability footwear as an assistive aid for CP were: it could be used alongside other assistive devices such as foot orthoses and walking frames to assist in standing and walking. It assists with mediolateral stability and proprioception to reduce falls. Other feedback stated that footwear could be issued to children with CP but should be thoroughly assessed for its suitability with clear, measurable outcomes. One panellist felt ankle foot orthoses (AFO) and foot orthoses (FO) used with regular footwear or other footwear modifications such as "tuned" footwear were more applicable interventions. However, a number of panellists felt that stability footwear would offer greater ankle stability than regular footwear and foot orthoses combinations. Other panellists suggested stability footwear as an interim stability aid in some cases when not using their AFO and could make mobility easier than their AFO for some tasks such as getting up off the floor.

The following statements have been devised form panellist feedback in relation to the suitability of stability footwear for this condition; please rank your agreement.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Stability footwear may assist mediolateral stability and	☐	☐	☐	☐	☐	☐	☐

proprioception of the foot and ankle in standing and walking in children with CP.							
Stability footwear may be used alongside other assistive aids to assist standing and walking in children with CP.	☐	☐	☐	☐	☐	☐	☐
Stability footwear should only be issued to children with CP after a critical assessment of the child's mobility needs in respect to other assistive aids or footwear modifications, and with clear intervention outcomes.	☐	☐	☐	☐	☐	☐	☐

3)

Panellists were asked the degree of mobility impairment in children with CP that would be suitable for stability footwear both as a sole aid or in combination with another assistive aid.

Panellist feedback suggested Stability footwear may be used as a sole aid to assist foot and ankle stability in walking at GMFCS-1 with no significant tone issues. Stability footwear may also be used alongside other assistive devices (AFO's walking frames) to assist stability in walking and standing from GMFCS 1-3 in ambulant children with tonal issues. May be used alongside other assistive devices as a positioning transfer standing aid in non-ambulant GMFCS 3-4 children.

The following statements have been devised from panellist feedback in relation to the degree of mobility impairment in children with CP suitable for stability footwear intervention, please rank your level of agreement.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Stability footwear may be used as a sole assistive intervention to assist both foot and ankle walking stability in children with GMFCS 1 and no significant tonal issues.	☐	☐	☐	☐	☐	☐	☐
Stability footwear may be used alongside other assistive aids to assist walking and standing in ambulant children GMFCS 1-3 with tonal issues.	☐	☐	☐	☐	☐	☐	☐
Stability footwear may be used alongside other assistive	☐	☐	☐	☐	☐	☐	☐

aids to assist standing and transfer in non-ambulant children GMFCS 3-4.							

4)

Panellists were asked the age range they felt this footwear intervention should be prescribed clinically for in CP

From panellists feedback, a range of ages was stated varying from 1-4 years for initiation and 16 years -adulthood for an endpoint, however from the reasoning; it was decerned even those panellists who indicated an endpoint of 16 years envisioned the potential for ongoing stability footwear intervention into adulthood if required. Some feedback indicated that footwear should only be used in mild cases (GMFCS 1) in the learning to walk stages then should focus on other orthotic aids. In moderate cases (GMFCS 2-3) where surgery was not indicated in teenage years, supportive footwear may be used alongside orthoses. Other panellists felt initiation and endpoints of treatment should be functionally based on the child's abilities and needs rather than specific age ranges such as displaying the potential to stand and endpoint defined as the need for differing assistive aids.

The following options have been suggested by panellist feedback:

☐	1-18 years (with assessed adult transition care)
☐	3-18 years (with assessed adult transition care)
☐	Initiation and end points of treatment indicated by functional ability and the mobility needs of the child (potential or actual).
☐	N/A I do not feel this condition is suitable for stability footwear intervention.

5)

Panellists were asked what clinical outcomes would be used to evaluate the effectiveness of "Off the Shelf" Stability footwear for children with CP:

From panellist feedback outcomes were grouped into therapeutic goals alongside the World Health Organisation International Classification of Functioning Child and Youth version (WHO ICF-CY). These were goals based on body structures and function and those based on Quality of Life measures (QoL).
Concerning body structure, passive ankle range of motion (ROM) was suggested to monitor any flexural contracture. The majority of outcomes were focused on body function. These included kinematic and spatiotemporal measures. Kinematic outcomes suggested optimising or normalising gait movement patterns using referenced scales such as the

Edinburgh Gait Scale. Spatiotemporal outcomes included increased walking velocity, 6-minute walk test (6MWT) Timed Up and Go (TUG), stride length, and cadence. Gross motor proficiency measures were also suggested including, motor milestones and Bruininks-Oseretsky Test of Motor Proficiency (BOT-2), frequency of falls was also suggested as a measure of the child's motor performance. Physiological outcomes such as perceived exertion measures (BORG) with motor tasks were also purposed.
QoL outcome measures suggested included pain rating and measures of activities of daily living (ADL) walking to school, shops, playparks and interaction with peers.

The following outcomes have been suggested from panellist feedback please rank your agreement with these.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Passive Ankle ROM	☐	☐	☐	☐	☐	☐	☐
Kinematics: Optimising gait movement patterns (Edinburgh Gait Scale)	☐	☐	☐	☐	☐	☐	☐
Spatiotemporal: Increased walking velocity, 6MWT, TUG, stride length, cadence	☐	☐	☐	☐	☐	☐	☐
Motor skill proficiency: Number of falls	☐	☐	☐	☐	☐	☐	☐
Motor skill proficiency: Gross Motor Skills (BOT-2)	☐	☐	☐	☐	☐	☐	☐
Physiological: Perceived exertion (BORG)	☐	☐	☐	☐	☐	☐	☐
QoL: Pain	☐	☐	☐	☐	☐	☐	☐
QoL: ADL (daily mobility and social interaction)	☐	☐	☐	☐	☐	☐	☐

6)

You may use this optional area if you wish to provide any further information on stability footwear intervention in children with CP.

Pes Planus

From the research stability footwear has been proposed as a clinical intervention for children with pes planus.
In the questions below, you will be presented with the collective opinion of panellists from Round 1 in relation to the suitability of stability footwear as a clinical intervention.

15 of the 15 panellists 100% had clinical experience with this condition and provided the information for this section.

7)

Panellists were asked if Pes Planus was a suitable condition for stability footwear intervention in children and their reasoning for this.

The median level of agreement amongst the panellists was "somewhat agree" with the majority of responses between "neutral" and "agree".

Panellist feedback suggested that stability footwear may be used to assist foot and ankle stability in children but only in cases that required more control than could be offered by foot orthoses alone. This was thought to be where mobile symptomatic pes planus is associated with significant ankle instability (hypermobility) leading to tripping and falling or developmental delay in gross motor skills.

The following statements have been devised from panellist feedback in relation to the suitability of stability footwear for this condition; please rank your level of agreement.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Stability footwear may assist foot and ankle stability in children with symptomatic mobile pes planus	☐	☐	☐	☐	☐	☐	☐
Stability footwear is a suitable secondary line intervention for symptomatic mobile pes planus in	☐	☐	☐	☐	☐	☐	☐

children where foot orthoses have not resolved associated symptoms							

8)

Panellists were asked the degree of mobility impairment in children with pes planus that would be suitable for stability footwear both as a sole aid or in combination with another assistive aid.

Panellist feedback suggested that stability footwear should be used alongside orthoses in severe symptomatic pes planes. Severe or extreme was characterised by the panellists if the pes planus was associated with marked insufficiency of the posterior tibialis function (accessory navicular, muscle atrophy), significant foot and ankle instability that lead to tripping or falling or if pes planus was associated with developmental conditions that affected gross motor development.

The following statements have been devised from panellist feedback in relation to the degree of mobility impairment in children with symptomatic pes planus suitable for stability footwear intervention.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Stability Footwear may be used alongside foot orthoses in children with insufficiency of posterior tibialis function.	☐	☐	☐	☐	☐	☐	☐
Stability Footwear may be used alongside foot orthoses in children with	☐	☐	☐	☐	☐	☐	☐

significant foot and ankle instability associated with tripping and falling.							
Stability footwear may be used alongside foot orthoses in children with conditions associated with motor delay	☐	☐	☐	☐	☐	☐	☐

9)

Panellists were asked the age range they felt this footwear intervention should be prescribed clinically for Pes Planus, Panellists feedback suggested a range of ages were stated varying from 1-5 years for initiation and 15-21 years for an endpoint, however, like in CP from reasoning; it was decerned even those panellists who indicated an endpoint of 15 years envisioned assessment for ongoing support in adulthood if required. Other panellists suggested initiation and endpoints of treatment should be functionally based on the child's abilities and needs rather than a specific age range such as displaying the potential to stand and endpoint defined as the need for ongoing stability footwear assistance. The following options have been suggested by panellist feedback:	
☐	1-18 years (with assessed adult transition care)
☐	5-18 years (with assessed adult transition care)
☐	Initiation and end points of treatment indicated by functional ability and the mobility needs of the child (potential or actual).
☐	N/A I do not feel this condition is suitable for stability footwear intervention.

10)

Panellists were asked what clinical outcomes would be used to evaluate the effectiveness of "Off the Shelf" Stability footwear for children with pes planus:

From panellist, feedback outcomes were grouped into therapeutic goals alongside the WHO ICF-CY. These were goals based on body structures and function and those based on QoL measures.
Concerning body structure, monitoring foot posture using the FPI was suggested. Body function outcomes included kinematic and spatiotemporal measures. Kinematic outcomes suggested optimising or normalising gait movement patterns, specifically those of the foot and ankle. Spatiotemporal outcomes included increased walking velocity, 6MWT and TUG. Gross motor proficiency measures were also discussed, Gross motor milestones, BOT-2 and frequency of falls.
QoL measures suggested by the panellists included pain rating and measures of ADL, walking to school, shops, playparks and interaction with peers.

The following outcomes have been suggested from panellist feedback; please rank your agreement with these.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Foot Posture FPI-6	☐	☐	☐	☐	☐	☐	☐
Kinematics: Optimising gait movement patterns (Foot and ankle)	☐	☐	☐	☐	☐	☐	☐
Spatiotemporal: Increase walking velocity, 6MWT, TUG	☐	☐	☐	☐	☐	☐	☐
Motor skill proficiency: Number of falls	☐	☐	☐	☐	☐	☐	☐
Motor skill proficiency: Gross Motor Skills (BOT-2)	☐	☐	☐	☐	☐	☐	☐
QoL: Pain	☐	☐	☐	☐	☐	☐	☐
QoL: ADL (daily mobility and social interaction)	☐	☐	☐	☐	☐	☐	☐

11)

You may use this optional area if you wish to provide any further information on stability footwear intervention in children with pes planus.

Toe Walking

From the research stability footwear has been proposed as a clinical intervention for children with toe walking.
In the questions below you will be presented with the collective opinion of panellists from Round 1 in relation to the suitability of stability footwear as a clinical intervention.

15 of the 15 panellists 100% had clinical experience with this condition and provided the information for this section.

12)

Panellists were asked if toe walking was a suitable condition for stability footwear intervention in children and their reasoning for this.

The median level of agreement amongst the panellists was "neutral" with the majority of responses between "neutral" and "somewhat agree".

Panellist feedback suggested that the issue with the suitability for stability footwear used as an intervention for this condition was the highly heterogeneous nature of toe walking. Some panellist stated that it may only be used in mild to moderate idiopathic toe walking (ITW) it was not to be used if toe walking was severe or associated with Autistic Spectrum Disorder or hypertonia. Other suggestions were the stability footwear should have a stiffened sole or used alongside carbon plate insole addition to limit 3rd rocker engagement. If the toe walking was associated with hypermobility and foot posture issues stability footwear may be used. Other panellist felt there was limited evidence for this intervention even in ITW.

The following statements have been devised from panellist feedback in relation to the suitability of stability footwear for this condition, please rank your level of agreement.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Stability footwear may be a suitable	☐	☐	☐	☐	☐	☐	☐

treatment if used alongside other stiffened components (insole, sole) for ITW with no associated hypertonia							
Stability footwear may be used for toe walking in developmental conditions with hypermobility and gross motor delay	☐	☐	☐	☐	☐	☐	☐

13)

Panellists were asked the degree of mobility impairment in children with toe walking that would be suitable for stability footwear both as a sole aid or in combination with another assistive aid.

Panellist feedback suggested that stability footwear may be used in combination with restrictive components (reduced forefoot rocker, carbon fibre insole plate) in type 1-2 ITW patients, the child must be able to achieve a standing plantargrade position. Other panellist felt the use for this footwear only if the child's own footwear could not accommodate an AFO.

The following statements have been devised from panellist feedback in relation to the degree of mobility impairment in children with toe walking suitable for stability footwear intervention, please rank your level of agreement.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Stability footwear may be used alongside other stiffened components for ITW Type 1-2, when the child is able to	☐	☐	☐	☐	☐	☐	☐

achieve a plantargrade position							

14)

Panellists were asked the age range they felt this footwear intervention should be prescribed clinically for in toe walking

Panellists feedback suggested a range of ages were stated varying from 1-4 years for initiation and 8-18 years for an endpoint. Other panellists suggested initiation and endpoints of treatment should be functionally based on the child's abilities and needs rather than age-specific.

The following options have been suggested by panellist feedback

☐	1-18 years
☐	4-18 years
☐	4-8 years
☐	Initiation and end points of treatment indicated by functional ability and the mobility needs of the child (potential or actual).
☐	N/A I do not feel this condition is suitable for stability footwear intervention.

15)

Panellists were asked what clinical outcomes would be used to evaluate the effectiveness of "Off the Shelf" Stability footwear for children with Toe Walking:

From panellist, feedback outcomes were grouped into therapeutic goals alongside the WHO ICF-CY. These were goals based on body structures and function and those based on QoL measures.
Concerning body structure, passive ankle ROM was suggested to monitor any flexural contracture. Body function outcomes included kinematic, kinetic and spatiotemporal measures. Kinematic outcomes suggested optimising or normalising gait patterns including heel and forefoot contact timing ankle ROM, Kinetic outcomes purposed in-shoe pressure measurements of heel and forefoot loading. Spatiotemporal outcomes included increased walking velocity, 6MWT and TUG.
QoL measures suggested by the panellists included pain rating and measures of ADL walking to school, shops, playparks and interaction with peers.

The following outcomes have been suggested from panellist feedback please rank your agreement with these.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Passive Ankle ROM	☐	☐	☐	☐	☐	☐	☐

Kinematics: Optimising gait movement patterns (Heel forefoot contact timing ankle ROM)	☐	☐	☐	☐	☐	☐	☐
Kinetic: In-shoe pressure measurement (Heel and Forefoot loading)	☐	☐	☐	☐	☐	☐	☐
Spatiotemporal Increased walking velocity, 6MWT, TUG	☐	☐	☐	☐	☐	☐	☐
QoL: Pain	☐	☐	☐	☐	☐	☐	☐
QoL: ADL (daily mobility and social interaction)	☐	☐	☐	☐	☐	☐	☐

16)

You may use this optional area if you wish to provide any further information on stability footwear intervention in children who toe walk.

Duchenne Muscular Dystrophy
From the research stability footwear has been proposed as a clinical intervention for children with Duchenne Muscular Dystrophy (DMD). In the questions below you will be presented with the collective opinion of panellists from Round 1 in relation to the suitability of stability footwear as a clinical intervention. 11 of the 15 panellists 73% had clinical experience with this condition and provided the information for this section.

(If you have no clinical experience in treating this condition please move to the next condition Question 22)

17)

Panellists were asked if DMD was a suitable condition for stability footwear intervention in children and their reasoning for this.

The median level of agreement amongst the panellists was "somewhat agreel" with the majority of responses between "neutral" and "strongly agree".

Panellist feedback suggested there was a dispersion of responses concerning the suitability of stability footwear for this condition. Some panellist felt there were no significant foot posture issues with DMD and if there were that foot orthoses were a more cost-effective measure. Whereas others felt it could help stabilise rearfoot and ankle motion in early stages and could be used in later stages if there was a loss of ankle range of motion or assist standing balance alongside other assistive aids (AFO). Some felt it may hinder walking in later stages due to muscle weakness and knee extension ability.

The following statements have been devised from panellist feedback in relation to the suitability of stability footwear for this condition, please rank your level of agreement.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Stability footwear should only be issued to children with DMD after a critical assessment of the child's mobility needs in respect to other assistive aids	☐	☐	☐	☐	☐	☐	☐

18)

Panellists were asked the degree of mobility impairment in children with DMD that would be suitable for stability footwear both as a sole aid or in combination with another assistive aid.

Panellist feedback suggested that stability footwear may be used as a sole aid or in combination with foot orthosis for foot and ankle instability in early ambulatory stage DMD (walks with some limitations to velocity and balance, can stair climb). In late

ambulatory stage DMD, (Loss of ankle ROM, difficulty with walking distances and stair climbing) stability footwear may be used in combination with an AFO and walking frames to assist with mobility. In Early non-ambulatory DMD, (Mobility requires a wheelchair, but the child may still weight-bear for a limited time) stability footwear may be used with AFOs and standing frames to assist with standing and transfer tasks.

The following statements have been devised from panellist feedback in relation to the degree of mobility impairment in children with DMD suitable for stability footwear intervention; please rank your level of agreement.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Stability Footwear may be used alongside foot orthoses to assist foot and ankle stability in early ambulatory stages.	☐	☐	☐	☐	☐	☐	☐
Stability Footwear may be used alongside AFO's and walking frames to assist walking in late ambulatory stages.	☐	☐	☐	☐	☐	☐	☐
Stability Footwear may be used alongside AFO's and standing frames to assist	☐	☐	☐	☐	☐	☐	☐

standing and transfer in early non ambulatory stages.							

19)

Panellists were asked the age range they felt this footwear intervention should be prescribed clinically for in DMD Panellists feedback suggested a range of ages were stated varying from 1-5 for initiation and 9-18 for an endpoint. Other panellists suggested initiation and endpoints of treatment should be functionally based on the child's abilities and needs rather than chronological. The following options have been suggested by panellist feedback	
☐	1-18 years
☐	4-18 years
☐	4-9 years
☐	Initiation and end points of treatment indicated by functional ability and the mobility needs of the child (potential or actual).
☐	N/A I do not feel this condition is suitable for stability footwear intervention.

20)

Panellists were asked what clinical outcomes would be used to evaluate the effectiveness of "Off the Shelf" Stability footwear for children with DMD:

From panellist feedback outcomes were grouped into therapeutic goals alongside the WHO ICF-CY. These were goals based on body structures and function and those based on QoL measures.
Concerning body structure, passive ankle ROM was suggested to monitor any flexural contracture. Body function outcomes included kinematic, kinetic and spatiotemporal measures. Kinematic outcomes suggested optimising or normalising gait patterns including heel and forefoot contact timing and ankle ROM, Kinetic outcomes purposed in-shoe pressure measurements of heel and forefoot loading. Spatiotemporal outcomes included increased walking velocity, 6MWT. Gross motor proficiency measures were suggested such as frequency of falls and the four square step test.
QoL measures suggested by the panellists included pain rating and measures of ADL walking to school, shops, playparks and interaction with peers.

The following outcomes have been suggested from panellist feedback please rank your agreement with these.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree

	1	2	3	4	5	6	7
Passive Ankle ROM	☐	☐	☐	☐	☐	☐	☐
Kinematics: Optimising gait movement patterns (Heel and forefoot contact timing, ankle ROM)	☐	☐	☐	☐	☐	☐	☐
Kinetic: In-shoe pressure measurement (Heel and Forefoot loading)	☐	☐	☐	☐	☐	☐	☐
Spatiotemporal Increased walking velocity, 6MWT	☐	☐	☐	☐	☐	☐	☐
Gross motor proficiency: four square step test	☐	☐	☐	☐	☐	☐	☐
Gross motor proficiency: Number of falls	☐	☐	☐	☐	☐	☐	☐
QoL: Pain	☐	☐	☐	☐	☐	☐	☐
QoL: ADL (daily mobility and social interaction)	☐	☐	☐	☐	☐	☐	☐

21)

You may use this optional area if you wish to provide any further information on stability footwear intervention in children with DMD.

Spina Bifida

From the research stability footwear has been proposed as a clinical intervention for children with spinal bifida.
In the questions below you will be presented with the collective opinion of panellists from Round 1 in relation to the suitability of stability footwear as a clinical intervention.

10 of the 15 panellists 66% had clinical experience with this condition and provided the information for this section.

(If you have no clinical experience in treating this condition please move to the next condition Question 27)

22)

Panellists were asked if spina bifida (SB) was a suitable condition for stability footwear intervention in children and their reasoning for this.

The median level of agreement amongst the panellists was " agree" with the majority of responses between "agree" and "strongly agree.
A Consensus was reached with respect to this condition being suitable for stability footwear intervention in Round 1

Panellist feedback suggested that although stability footwear was suitable for children with SB even with low-level spinal involvement other assistive aids would be required alongside stability footwear. Additionally, stability footwear would have to offer a range of dimensional measures to the last to accommodate foot deformity with underlying sensory neuropathy.

The following statements have been devised from panellist feedback in relation to the suitability of stability footwear for this condition, please rank your level of agreement.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Stability footwear should only be issued to children with SB after a critical assessment of the child's mobility needs in respect to	☐	☐	☐	☐	☐	☐	☐

other assistive aids.							

23)

Panellists were asked the degree of mobility impairment in children with SB that would be suitable for stability footwear both as a sole aid or in combination with another assistive aid.

Panellist feedback suggested that stability footwear may be used with other assistive aids such as AFO's and Walking Frames to assist standing and walking for lumbar level 1-5 dysraphisms. In mild dysraphism at lumbar level 5, stability footwear used alongside foot orthoses may offer adequate mobility assistance.

The following statements have been devised from panellist feedback in relation to the degree of mobility impairment in children with SB suitable for stability footwear intervention, please rank your level of agreement.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Stability footwear may be used alongside foot orthoses to assist foot and ankle stability in mild level lumbar 5 vertebral involvement.	☐	☐	☐	☐	☐	☐	☐
Stability Footwear may be used alongside AFO's and walking frames to assist walking and standing in lumbar 1-5 vertebral involvement.	☐	☐	☐	☐	☐	☐	☐

24)

Panellists were asked the age range they felt this footwear intervention should be prescribed clinically for in SB

Panellists feedback suggested an age range 1-2 years for initiation and 18-21 years for an endpoint with assessment for adult need. Other panellists suggested initiation and endpoints of treatment should be functionally based on the child's abilities and needs rather than age-specific.

The following options have been suggested by panellist feedback

☐	1-18 years (with assessed adult transition care)
☐	3-18 years (with assessed adult transition care)
☐	Initiation and end points of treatment indicated by functional ability and the mobility needs of the child (potential or actual).
☐	N/A I do not feel this condition is suitable for stability footwear intervention.

25)

Panellists were asked what clinical outcomes would be used to evaluate the effectiveness of "Off the Shelf" Stability footwear in children with Spina Bifida:

From panellist feedback outcomes were grouped into therapeutic goals alongside the WHO ICF-CY. These were goals based on body structures and function and those based on QoL measures.
Concerning body structure, passive ankle range of motion (ROM) was suggested to monitor any flexural contracture. The majority of outcomes were focused on body function. These included kinematic and spatiotemporal biomechanical measures. Kinematic outcomes suggested optimising or normalising gait movement patterns using referenced scales such as the Hoffer Ambulation Scale. Spatiotemporal outcomes included increased walking velocity, 6-minute walk test (6MWT) Timed Up and Go (TUG), stride length, and cadence. Gross motor proficiency measures were also suggested including, motor milestones and Hoffer Ambulation Scale. Physiological outcomes such as perceived exertion measures (BORG) with motor tasks were also purposed. QoL outcome measures suggested included pain rating and measures of activities of daily living (ADL) walking to school, shops, playparks and interaction with peers.

The following outcomes have been suggested from panellist feedback please rank your agreement with these.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Kinematics: Optimising gait movement patterns (Hoffer Ambulation scale)	☐	☐	☐	☐	☐	☐	☐

Spatiotemporal: Increased walking velocity, 6MWT, TUG	☐	☐	☐	☐	☐	☐	☐
Gross motor proficiency: (Hoffer Ambulation Score)	☐	☐	☐	☐	☐	☐	☐
Physiological: Perceived exertion (BORG)	☐	☐	☐	☐	☐	☐	☐
QoL: Pain	☐	☐	☐	☐	☐	☐	☐
QoL: ADL (daily mobility and social interaction)	☐	☐	☐	☐	☐	☐	☐

11)

You may use this optional area if you wish to provide any further information on stability footwear intervention in children with SB.

Down's Syndrome
From the research stability footwear has been proposed as a clinical intervention for children with Down's Syndrome. In the questions below you will be presented with the collective opinion of panellists from Round 1 in relation to the suitability of stability footwear as a clinical intervention 13 of the 15 panellists 87% had clinical experience with this condition and provided the information for this section. (If you have no clinical experience in treating this condition please move to the next condition Question 32)

27)

Panellists were asked if Down's Syndrome was a suitable condition for stability footwear intervention in children and their reasoning for this.

The median level of agreement amongst the panellists was " agree" with the majority of responses between "agree" and "strongly agree.
A consensus was reached in Round 1 with respect to this condition being suitable for stability footwear intervention.

Panellist feedback suggested that this footwear could assist the mediolateral stability of the foot and ankle due to low tone and hypermobility. This would aid gross motor skill acquisition and mobility in these children. Other panellist suggested only consider stability footwear if the child's foot dimensions were outside a standard last. There was also the discussion that stability footwear offer modular sizing to accommodate altered foot anthropometrics in these children.

The following statements have been devised from panellist feedback in relation to the suitability of stability footwear for this condition, please rank your level of agreement.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Stability footwear may assist mediolateral stability and proprioception of the foot and ankle in standing and walking in children with Down's syndrome	☐	☐	☐	☐	☐	☐	☐
Stability footwear design should consider last adaptions to accommodate the foot dimensions of children with Down's syndrome	☐	☐	☐	☐	☐	☐	☐

28)

Panellists were asked the degree of mobility impairment in children with Down's syndrome that would be suitable for stability footwear both as a sole aid or in combination with another assistive aid.

Panellist feedback suggested that stability footwear may be used as a sole intervention in children with delayed motor skills alongside hypermobility and hypotonia in the pre-walking and early walking stages. If associated with ankle instability (tripping, falling) in older children use stability footwear to support foot orthoses interventions. If associated with knee instability stability footwear may be used to support AFO interventions

The following statements have been devised from panellist feedback in relation to the degree of mobility impairment in children with Down's syndrome suitable for stability footwear intervention, please rank your level of agreement.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Stability footwear may be used as a sole assistive aid in pre-walking and learning to walk stages with associated hypotonia and delayed motor milestones.	☐	☐	☐	☐	☐	☐	☐
Stability Footwear may be used alongside foot orthoses to assist walking in individuals	☐	☐	☐	☐	☐	☐	☐

with ankle instability							
Stability Footwear may be used alongside AFO's to assist walking in individuals with knee instability	☐	☐	☐	☐	☐	☐	☐

29)

Panellists were asked the age range they felt this footwear intervention should be prescribed clinically for in Down's syndrome Panellists feedback suggested an age range 1-4 for initiation and 18 for an endpoint with ongoing assessment for adult need. Other panellists suggested initiation and endpoints of treatment should be functionally based on the child's abilities and needs rather than age-specific. The following options have been suggested by panellist feedback	
☐	1-18 years (with assessed adult transition care)
☐	4-18 years (with assessed adult transition care)
☐	Initiation and end points of treatment indicated by functional ability and the mobility needs of the child (potential or actual).
☐	N/A I do not feel this condition is suitable for stability footwear intervention.

30)

Panellists were asked what clinical outcomes would be used to evaluate the effectiveness of "Off the Shelf" Stability footwear for children with Down's syndrome:

From panellist feedback outcomes were grouped into therapeutic goals alongside the World Health Organisation International Classification of Functioning Child and Youth version (WHO ICF-CY). These were goals based on body structures and function and those based on Quality of Life measures (QoL).
Concerning body structure, passive ankle range of motion (ROM) was suggested to monitor any flexural contracture. The majority of outcomes were focused on body function. These included kinematic and spatiotemporal measures. Kinematic outcomes suggested optimising or normalising gait movement patterns using referenced scales such as the Edinburgh Gait Scale. Spatiotemporal outcomes included increased walking velocity, 6-minute walk test (6MWT) Timed Up and Go (TUG), stride length, and cadence. Gross motor

proficiency measures were also suggested including, motor milestones and Bruininks-Oseretsky Test of Motor Proficiency (BOT-2), frequency of falls was also suggested as a measure of the child's motor performance. Physiological outcomes such as perceived exertion measures (BORG) with motor tasks were also purposed.
QoL outcome measures suggested included pain rating and measures of activities of daily living (ADL) walking to school, shops, playparks and interaction with peers.

The following outcomes have been suggested from panellist feedback please rank your agreement with these.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Foot posture FPI-6	☐	☐	☐	☐	☐	☐	☐
Kinematics: Optimising gait movement patterns (foot and ankle)	☐	☐	☐	☐	☐	☐	☐
Spatiotemporal Increase Velocity, 6MWT	☐	☐	☐	☐	☐	☐	☐
Gross motor proficiency: number of falls	☐	☐	☐	☐	☐	☐	☐
Motor skill proficiency: Gross Motor Skills (BOT-2)	☐	☐	☐	☐	☐	☐	☐
QoL: Pain	☐	☐	☐	☐	☐	☐	☐
QoL Comfort with Footwear	☐	☐	☐	☐	☐	☐	☐
QoL: ADL (daily mobility and social interaction)	☐	☐	☐	☐	☐	☐	☐

31)

You may use this optional area if you wish to provide any further information on stability footwear intervention in children with Down's syndrome.

Intoeing

From the research stability footwear has been proposed as a clinical intervention for children with intoeing.
In the questions below you will be presented with the collective opinion of panellists from Round 1 in relation to the suitability of stability footwear as a clinical intervention.

12 of the 15 panellists 80% had clinical experience with this condition and provided the information for this section.

(If you have no clinical experience in treating this condition please move to Question 36)

32)

Panellists were asked if Intoeing was a suitable condition for stability footwear intervention in children and their reasoning for this.

The median level of agreement amongst the panellists was " somewhat disagree" with the majority of responses between "disagree" and "neutral".

Feedback form panellists suggested that intoeing was generally a skeletal rotational issue associated with typical development and stability footwear has no effect on the natural progression on this.
Panellist suggested that only significant cases of metatarsus adductus required footwear intervention and this was corrective footwear (reverse last and straight last) not stability footwear.
Some panellists suggested that if the intoeing was associated with a neuromuscular pathology or tripping stability footwear may be considered. (These indications were also the same as the suggested level of mobility impairment)

The following statements have been devised from panellist feedback in relation to the suitability of stability footwear for this condition, please rank your level of agreement.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Stability footwear may a suitable intervention for intoeing if associated with tripping	☐	☐	☐	☐	☐	☐	☐

Stability footwear may a suitable intervention for intoeing if associated with an underlying neurological condition	☐	☐	☐	☐	☐	☐	☐

33)

Panellists were asked the age range they felt this footwear intervention should be prescribed clinically for in Intoeing

The age range was only given by a limited number of panellist as the majority of panellists did not feel this condition was a suitable indication for stability footwear intervention.

3 years was given for the initiation of intervention. Other panellists suggested initiation and endpoints of treatment should be functionally based on the child's abilities and needs rather than age-specific.

☐	3 years onwards
☐	Initiation and end points of treatment indicated by functional ability and the mobility needs of the child (potential or actual).
☐	N/A I do not feel this condition is suitable for stability footwear intervention.

10)

Panellists were asked what clinical outcomes would be used to evaluate the effectiveness of "Off the Shelf" Stability footwear in children with Intoeing:

From panellist feedback outcomes were grouped into therapeutic goals alongside the WHO ICF-CY. These were goals based on body structures and function and those based on QoL measures.
Body function outcomes included kinematic and spatiotemporal measures. Kinematic outcomes suggested optimising or normalising gait patterns specifically Angle of Gait. Spatiotemporal outcomes included increased walking velocity, 6MWT and TUG, Motor skills proficiency was discussed in relation to the frequency of tripping. QoL measures suggested by the panellists included pain rating, perceived comfort with footwear and measures of activities of daily living (walking to school, shops, playparks and interaction with peers).

The following outcomes have been suggested from panellist feedback please rank your agreement with these.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7

Kinematics: Optimising gait movement patterns (Angle of Gait)	☐	☐	☐	☐	☐	☐	☐
Spatiotemporal: Increased walking velocity, 6MWT, TUG	☐	☐	☐	☐	☐	☐	☐
Gross motor proficiency: reduction in tripping	☐	☐	☐	☐	☐	☐	☐
QoL: Pain	☐	☐	☐	☐	☐	☐	☐
QoL: ADL (daily mobility and social interaction)	☐	☐	☐	☐	☐	☐	☐

11)

You may use this optional area if you wish to provide any further information on stability footwear intervention in children with intoeing.

Additional Conditions:

36)

	I have no clinical experience with this condition	Disagree	Neutral	Agree
Charcot Marie Tooth, Hereditary Motor Sensory Neuropathy	☐	☐	☐	☐

Hypermobility (Ehlers Danlos Type)	☐	☐	☐	☐
Developmental Coordination Disorder	☐	☐	☐	☐
Rett's Syndrome	☐	☐	☐	☐
Foetal Alcohol syndrome	☐	☐	☐	☐
Accessory navicular	☐	☐	☐	☐
Chronic lateral ankle instability	☐	☐	☐	☐

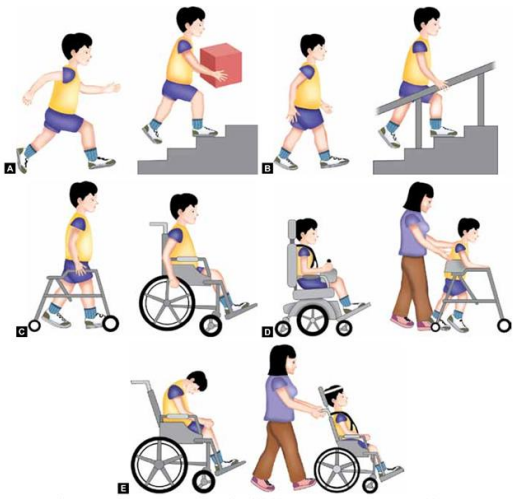
END OF SECTION 3 ROUND 2

Thank you for taking the time to complete section 3 of round 2. You have now completed all sections of round 2 of this Delphi survey. Your time and participation is greatly appreciated.
Remember to submit your answers before closing this form.

ROUND 3(S3) WHAT ARE CHILDREN'S CLINICAL FOOTWEAR INTERVENTIONS AND HOW TO PRESCRIBE THEM?

The third section will present yours and the panellists' collective choices and opinions from Round 2 on clinical protocols and outcomes for the provision of “off the shelf” stability footwear clinical interventions for children with mobility impairment.

Section 3



Opinion on prescription and clinical outcomes of "off the shelf" stability footwear clinical interventions for children with mobility impairment.

In this section, you will be presented with the collective preference (Median, relative frequency of response) and opinions of the panellists to the modified and original statements from round 1 and 2 of the survey concerning clinical protocols for the issuing of stability footwear as a sole assistive aid or in combination with other assistive aids (Ankle Foot Orthosis (AFO)*, walking frames) for children with mobility impairment, and the expected clinical outcomes of these footwear interventions.

* Please remember to qualify any abbreviation for mobility aids.

You will again be asked to give your preferential option or your level of agreement or non-agreement with them ("Strongly Disagree" to "Strongly Agree").

You can review the previous information you provided (in the document emailed to you), and considering the information provided by the other panellists, you may maintain your option or level of agreement with your chosen statement or change your opinion.

Full consensus for a statement is reached when a statement gains ≥75% of panellists with a level of agreement of "agree" or above, or ≥ 75% of panellists preferred option.

If you choose a level of agreement below "agree" we would ask that you provide us with the reason for your choice in the optional open-ended section provided.

Required Field*

1)

Name: *

Cerebral Palsy

In the questions below you will be presented with the collective choices and opinions from Round 2
concerning suggested protocols and measurable outcomes of stability footwear as a clinical intervention for this condition.

(100%) panellists in Round 2 had clinical experience with this condition and provided the information for this section.

2)

Panellists were asked to rank their agreement with the following statements concerning the issuing of stability footwear for individuals with Cerebral Palsy (CP) in Round 2.
The median level of agreement and the relative distribution of response is detailed below.

Purpose: Stability footwear may assist mediolateral stability and proprioception of the foot and ankle in standing and walking in children with CP.
Median level of Agreement 6 (Agree)
7% "Somewhat Disagree", 7% "Neutral", 7% "Somewhat Agree", 36% "Agree", 43% "Strongly Agree"
A consensus was reached for this statement.

Stability footwear may be used alongside other assistive aids to assist standing and walking in children with CP.
Median level of Agreement 7 ("Strongly Agree")
14% "Neutral", 29% "Agree", 57% "Strongly Agree"
A consensus was reached for this statement.

Stability footwear should only be issued to children with CP after a critical assessment of the child's mobility needs in respect to other assistive aids or footwear modifications and with clear intervention outcomes.
Median level of Agreement 6 ("Agree")
14% "Neutral", 36% "Agree", 50% "Strongly Agree"
A consensus was reached for this statement.

Panellists feedback suggested there may be potential overlap between stability footwear and oversplint footwear, and that stability footwear was only to be issued to provide further stability and not just to accommodate the adjunct assistive aid such as an Ankle Foot Orthosis (AFO) or Knee Ankle Foot Orthosis (KAFO).

The following statement has been added based on panellist feedback.*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7

Stability footwear is only to be issued as an adjunct to AFO's KAFO's where additional medio-lateral stability is required, and not just to accommodate the orthotic.	☐	☐	☐	☐	☐	☐	☐

3)

Panellists were asked to rank their agreement with the following statements concerning the degree of mobility impairment in children with CP that would be suitable for stability footwear both as a sole aid or in combination with another assistive aid in Round 2.
The median level of agreement and the relative distribution of response is detailed below.

Stability footwear may be used as a sole assistive intervention to assist both foot and ankle stability in walking in children with Gross Motor Functioning Classification Score (GMFCS) 1 and no significant tonal issues.
Median level of Agreement 6 ("Agree")
7% "Somewhat Disagree", 7% "Neutral", 14% "Somewhat Agree", 43% "Agree", 29% "Strongly Agree"

Stability footwear may be used alongside other assistive aids to assist walking and standing in ambulant children GMFCS 1-3 with tonal issues.
Median level of Agreement 6 ("Agree")
14% "Neutral", 7% "Somewhat Agree", 43% "Agree", 36% "Strongly Agree"
A consensus was reached for this statement.

Stability footwear may be used alongside other assistive aids to assist standing and transfer in non-ambulant children GMFCS 3-4.
Median level of Agreement 6 ("Agree")
14% "Neutral", 14% "Somewhat Agree", 43% "Agree", 29% "Strongly Agree"

Panellists feedback suggested there was potential ambiguity with the term "alongside"; panellists questioned did this mean stability footwear was to be used at different times or simultaneously with the other assistive aid.

The following statements have been slightly modified based on panellist feedback.*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree

	1	2	3	4	5	6	7
Stability footwear may be used as a sole assistive intervention to assist both foot and ankle stability in walking in children with GMFCS 1 and no significant tonal issues.	☐	☐	☐	☐	☐	☐	☐
Stability footwear may be used simultaneously with other assistive aids to assist standing and transfer in non-ambulant children GMFCS 3-4. This footwear must be issued to assist stability and not just to accommodate the associated assistive aid	☐	☐	☐	☐	☐	☐	☐

4)

Panellists were presented with the following options in relation to the suitable age range for stability footwear intervention for CP in Round 2.
The relative distribution of response is detailed below.

Option 1, Initiation and end points of treatment indicated by functional ability and the mobility needs of the child (potential or actual).69%
Option 2, 1-18 years (with assessed adult transition care) 15%
Option 3, 3-18 years (with assessed adult transition care) 8%
Option 4, N/A I do not feel this condition is suitable for stability footwear intervention 8%

No specific panellist feedback was given to inform any further modification of these options. However, you may consider the distribution of the panel's response to either change or maintain your previous option.	
☐	Option 1, Initiation and end points of treatment indicated by functional ability and the mobility needs of the child (potential or actual).
☐	Option 2, 1-18 years (with assessed adult transition care)
☐	Option 3, 3-18 years (with assessed adult transition care)
☐	Option 4, N/A I do not feel this condition is suitable for stability footwear intervention.

5)

Panellists were asked to rank their agreement with the following statements concerning the clinical outcomes that would be used to evaluate the effectiveness of "Off the Shelf" Stability footwear for children with CP in Round 2:
The median level of agreement and the relative distribution of response is detailed below.

Passive Ankle ROM
Median level of Agreement 6 ("Agree")
7% "Somewhat Disagree", 14% "Neutral", 22% "Somewhat Agree", 43% "Agree"
14% "Strongly Agree"

Kinematics: Optimising gait movement patterns (Edinburgh Gait Scale)
Median level of Agreement 6 ("Agree")
21% "Somewhat Agree", 57% "Agree", 22% "Strongly Agree"
A consensus was reached for this statement

Spatiotemporal: Increased walking velocity, 6 Minute Walk Test (6MWT), Timed Up and Go (TUG), stride length, cadence
Median level of Agreement 6 ("Agree")
14% "Somewhat Agree", 50% "Agree", 36% "Strongly Agree"
A consensus was reached for this statement

Motor skill proficiency: Number of falls
Median level of Agreement 6 ("Agree")
14% "Neutral", 7% "Somewhat Agree", 57% "Agree", 22% "Strongly Agree"
A consensus was reached for this statement

Motor skill proficiency:
Gross Motor Skills (BOT-2)
Median level of Agreement 6 ("Agree")
14% "Neutral", 14% "Somewhat Agree", 50% "Agree", 22% "Strongly Agree"

Physiological: Perceived exertion (Borg)
Median level of Agreement 5 ("Somewhat Agree")
7% "Neutral", 43% "Somewhat Agree", 36% "Agree", 14% "Strongly Agree"

Quality of Life (QoL): Pain
Median level of Agreement 6 ("Agree")
7% "Neutral", 14% "Somewhat Agree", 50% "Agree", 29% "Strongly Agree"
A consensus was reached for this statement

QoL: Activities of Daily Living (ADL) (daily mobility and social interaction)
Median level of Agreement 6 ("Agree")
21% "Somewhat Agree", 50% "Agree", 29% "Strongly Agree"
A consensus was reached for this statement

Panellist feedback suggested the following additional outcomes be included:
Passive Ankle Range of Motion (ROM) includes measures with the knee flexed and extended. Weight-bearing lunge may be used if the child can get the heel to ground in addition to passive Ankle ROM. Physiological cost index also to be considered. No specific panellist feedback was given to inform further modification of the other outcomes that did not reach consensus. However, you may consider the distribution of the panel's response to either change or maintain your previous choice.

Please rank your agreement with the following outcomes.*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Passive Ankle ROM measured with knee flexed and extended within child's limits	☐	☐	☐	☐	☐	☐	☐
Ankle ROM Weight Bearing lunge provided child can get heel to ground	☐	☐	☐	☐	☐	☐	☐
Motor skill proficiency: Gross Motor Skills (BOT-2)	☐	☐	☐	☐	☐	☐	☐
Physiological: Perceived exertion (BORG)	☐	☐	☐	☐	☐	☐	☐
Physiological: Physiological Cost Index	☐	☐	☐	☐	☐	☐	☐

6)

If your level of agreement was "somewhat agree" or lower for any of the statements in relation to stability footwear intervention in children with CP please use this optional area to provide us with your reasoning.

Pes Planus

In the questions below you will be presented with the collective choices and opinions from Round 2
concerning suggested protocols and measurable outcomes of stability footwear as a clinical intervention for this condition.

(100%) panellists in Round 2 had clinical experience with this condition and provided the information for this section.

7)

Panellists were asked to rank their agreement with the following statements concerning the issuing of stability footwear for individuals with mobile pes planus in Round 2.
The median level of agreement and the relative distribution of response is detailed below.

Suitability and Purpose
Stability footwear may assist foot and ankle stability in children with symptomatic mobile pes planus
Median level of Agreement 6 ("Agree")
7% "Disagree", 7% "Neutral", 7% "Somewhat Agree", 57% "Agree", 22% "Strongly Agree"
A consensus was reached for this statement.

Stability footwear is a suitable secondary line intervention for symptomatic mobile pes planus in children where foot orthoses have not resolved associated symptoms
Median level of Agreement 7 ("Strongly Agree")
14% "Neutral", 29% "Agree", 57% "Strongly Agree"
A consensus was reached for this statement.

8)

Panellists were asked to rank their agreement with the following statements concerning the grade of mobility impairment in children with pes planus that would be suitable for stability footwear both as a sole aid or in combination with another assistive aid in Round 2.
The median level of agreement and the relative distribution of response is detailed below.

Stability Footwear may be used alongside foot orthoses in children with insufficiency of posterior tibialis function.
Median level of Agreement 6 ("Agree")
14% "Neutral", 14% "Somewhat Agree", 65% "Agree", 7% "Strongly Agree"

Stability Footwear may be used alongside foot orthoses in children with significant foot and ankle instability associated with tripping and falling.
Median level of Agreement 6 ("Agree")
14% "Neutral", 7% "Somewhat Agree", 43% "Agree", 36% "Strongly Agree"
A consensus was reached for this statement.

Stability footwear may be used alongside foot orthoses in children with conditions associated with motor delay
Median level of Agreement 6 ("Agree")
7% "Disagree", 29% "Somewhat Agree", 50% "Agree", 14% "Strongly Agree"

There was also potential ambiguity with the term "alongside"; panellists questioned did this mean stability footwear was to be used at different times or simultaneously with the other assistive aid.

The following statements have been slightly modified based on panellist feedback. *

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Stability Footwear may be be used simultaneously with foot orthoses in children with insufficiency of posterior tibialis function.	☐	☐	☐	☐	☐	☐	☐
Stability footwear may be used simultaneously with foot orthoses in children with conditions associated with motor delay	☐	☐	☐	☐	☐	☐	☐

9)

Panellists were presented with the following options concerning the suitable age range for stability footwear intervention for mobile pes planus in Round 2.
The relative distribution of response is detailed below.

Option 1, Initiation and end points of treatment indicated by functional ability and the mobility needs of the child (potential or actual).77%

Option 2, 1-18 years (with assessed adult transition care) 15%
Option 3, N/A I do not feel this condition is suitable for stability footwear intervention 8%
Option 4, 5-18 years (with assessed adult transition care) 0%

A consensus was reached to Option 1,

10)

Panellists were asked to rank their agreement with the following statements in relation to the clinical outcomes that would be used to evaluate the effectiveness of "Off the Shelf" Stability footwear for children with mobile pes planus in Round 2:
The median level of agreement and the relative distribution of response is detailed below.

Foot Posture FPI-6
Median level of Agreement 5 ("Somewhat Agree")
7% "Disagree", 7% "Somewhat Disagree", 22% "Neutral", 14% "Somewhat Agree", 36% "Agree",
14% "Strongly Agree"

Kinematics: Optimising gait movement patterns (Foot and ankle)
Median level of Agreement 6 ("Agree")
23% "Somewhat Agree", 62% "Agree", 15% "Strongly Agree"
A consensus was reached for this statement

Spatiotemporal: Increased walking velocity, 6MWT, TUG, stride length, cadence
Median level of Agreement 6 ("Agree")
7% "Neutral", 21% "Somewhat Agree", 36% "Agree", 36% "Strongly Agree"

Motor skill proficiency: Number of falls
Median level of Agreement 6 ("Agree")
29% "Somewhat Agree", 57% "Agree", 14% "Strongly Agree"

Motor skill proficiency:
Gross Motor Skills (BOT-2)
Median level of Agreement 6 ("Agree")
36% "Somewhat Agree", 43% "Agree", 21% "Strongly Agree"

QoL: Pain
Median level of Agreement 6 ("Agree")
21% "Somewhat Agree", 58% "Agree", 21% "Strongly Agree"
A consensus was reached for this statement

QoL: ADL (daily mobility and social interaction)
Median level of Agreement 6 ("Agree")
36% "Somewhat Agree", 43% "Agree", 21% "Strongly Agree"

Panellist feedback suggested that the FPI-6 is a semi-quantitative description of foot posture and should not be considered as an outcome measure. Panellist suggested the

following further outcomes to be included: Passive Ankle ROM including measures with the knee flexed and extended within the child's limits of knee extension. Weight-bearing lunge may also be used to measure ankle ROM if the child can get their heel to the ground. 10-meter walk test as a valid spatiotemporal measure. Physiological Cost Index also to be considered. No specific panellist feedback was given to inform further modification of the other outcomes that did not reach consensus. However, you may consider the distribution of the panel's response to either change or maintain your previous choice.

Please rank your agreement with the following outcomes.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Foot Posture FPI-6	☐	☐	☐	☐	☐	☐	☐
Passive Ankle ROM measured with knee flexed and extended within child's limits	☐	☐	☐	☐	☐	☐	☐
Ankle ROM Weight Bearing lunge provided child can get heel to ground	☐	☐	☐	☐	☐	☐	☐
Spatiotemporal: Increase walking velocity, 6MWT, TUG 10 meter walk test	☐	☐	☐	☐	☐	☐	☐
Motor skill proficiency: Number of falls	☐	☐	☐	☐	☐	☐	☐
Motor skill proficiency: Gross Motor Skills (BOT-2)	☐	☐	☐	☐	☐	☐	☐
Physiological: Physiological Cost Index	☐	☐	☐	☐	☐	☐	☐
QoL: ADL (daily mobility and social interaction)	☐	☐	☐	☐	☐	☐	☐

11)

If your level of agreement was "somewhat agree" or lower for any of the statements in relation to stability footwear intervention in children with Mobile Pes Planus please use this optional area to provide us with your reasoning.

Toe Walking

In the questions below you will be presented with the collective choices and opinions from Round 2
concerning suggested protocols and measurable outcomes of stability footwear as a clinical intervention for this condition.

(100%) panellists in Round 2 had clinical experience with this condition and provided the information for this section.

12)

Panellists were asked to rank their agreement with the following statements concerning the issuing of stability footwear for individuals with toe walking in Round 2.
The median level of agreement and relative distribution of response is detailed below.

Stability footwear may be a suitable treatment if used alongside other stiffened components (insole, sole) for ITW with no associated hypertonia
Median level of Agreement 6 ("Agree")
21% "Neutral", 21% "Somewhat Agree", 37% "Agree", 21% "Strongly Agree"

Stability footwear may be used for toe walking in developmental conditions with hypermobility and gross motor delay
Median level of Agreement 6 ("Agree")
43% "Somewhat Agree", 29% "Agree", 28% "Strongly Agree"

Panellist feedback suggested better alternative assistive aids from their clinical experience with all cases of Idiopathic Toe Walking (ITW); such as Dynamic AFOs that inhibit plantarflexion and stimulate dorsiflexion offering more effective treatment than stiffened footwear, however, no specific feedback was given to inform modification of the statements.

Based on panellist feedback please rank your agreement with the following statements.*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree

	1	2	3	4	5	6	7
Stability footwear may be a suitable treatment if used simultaneously with other stiffened components (insole, stiffend sole) for ITW with no associated hypertonia	☐	☐	☐	☐	☐	☐	☐
Stability footwear may be used for toe walking in developmental conditions with hypermobility and gross motor delay	☐	☐	☐	☐	☐	☐	☐

13)

Panellists were asked to rank their agreement with the following statements concerning the grade of mobility of impairment in children with toe walking that would be suitable for stability footwear, both as a sole aid or in combination with another assistive aid in Round 2.
The median level of agreement and the relative distribution of response is detailed below.

Stability footwear may be used alongside other stiffened components for ITW Type 1-2, when the child is able to achieve a plantargrade position
Median level of Agreement 5 ("Somewhat Agree")
7% "Disagree", 14% "Neutral", 43% "Somewhat Agree", 22% "Agree", 14% "Strongly Agree".

Panellist feedback suggested stability footwear may cause issues with knee hyperextension if used in conjunction with AFO's and suggested their use only if gait requires mediolateral stability.

The following statements have been slightly modified based on panellist feedback.*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree

	1	2	3	4	5	6	7
Stability footwear may be used to provide mediolateral stability when used simultaneously with stiffened components for ITW Type 1-2, when the child is able to achieve a plantargrade position	☐	☐	☐	☐	☐	☐	☐

14)

Panellists were presented with the following options in relation to the suitable age range for stability footwear intervention for toe walking in Round 2.
The relative distribution of response is detailed below.

Option 1, Initiation and end points of treatment indicated by functional ability and the mobility needs of the child (potential or actual).77%
Option 2, 4-8 years (15%)
Option 3, 4-18years (8%)
Option 4 1-18 years (0%)
Option 5 N/A I do not feel this condition is suitable for stability footwear intervention (0%)

A Consensus was reached for Option 1

15)

Panellists were asked to rank their agreement with the following statements concerning the clinical outcomes that would be used to evaluate the effectiveness of "Off the Shelf" Stability footwear for children with toe walking in Round 2:
The median level of agreement and the relative distribution of response is detailed below.

Passive Ankle ROM
Median level of Agreement 6 ("Agree")
8% "Neutral", 38% "Somewhat Agree", 46% "Agree"
8% "Strongly Agree"

Kinematics: Optimising gait movement patterns (Foot and Ankle)

Median level of Agreement 6 ("Agree")
21% "Somewhat Agree", 36% "Agree", 43% "Strongly Agree"

Kinetic: In-shoe pressure measurement (Heel and Forefoot loading)
Median level of Agreement 5 ("Somewhat Agree")
7% "Somewhat Disagree", 29% "Neutral", 21% "Somewhat Agree", 29% "Agree"
14% "Strongly Agree"

Spatiotemporal: Increased walking velocity, 6MWT, TUG, stride length, cadence
Median level of Agreement 6 ("Agree")
7% "Neutral", 29% "Somewhat Agree," 50% "Agree", 14% "Strongly Agree"

QoL: Pain
Median level of Agreement 6 ("Agree")
14% "Somewhat Agree", 72% "Agree", 14% "Strongly Agree"
A consensus was reached for this statement

QoL: ADL (daily mobility and social interaction)
Median level of Agreement 6 ("Agree")
36% "Somewhat Agree", 50% "Agree", 14% "Strongly Agree"

Panellist feedback suggested modifications and additions to the outcomes.
The weight bearing lunge test to measure Ankle ROM in addition to Passive ROM in children who can get the heel to the floor. Consider adding 10-metre walk test as a valid spatiotemporal measure. Finally the addition of plantar callus patterns and sole wear patterns of the footwear. No specific panellist feedback was given to inform further modification of the other outcomes that did not reach consensus. However, you may consider the distribution of the panel's response to either change or maintain your previous choice.

Please rank your agreement with the following outcomes.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Passive Ankle ROM measured with knee flexed and extended within child's limits	☐	☐	☐	☐	☐	☐	☐
Ankle ROM Weight Bearing lunge provided child can get heel to ground	☐	☐	☐	☐	☐	☐	☐

Kinematics: Optimising gait movement patterns (Heel forefoot contact timing ankle ROM)	☐	☐	☐	☐	☐	☐	☐
Kinetic: In-shoe pressure measurement (Heel and Forefoot loading)	☐	☐	☐	☐	☐	☐	☐
Spatiotemporal Increased walking velocity, 6MWT, TUG 10-meter walk test	☐	☐	☐	☐	☐	☐	☐
QoL: ADL (daily mobility and social interaction)	☐	☐	☐	☐	☐	☐	☐

16)

If your level of agreement was "somewhat agree" or lower for any of the statements in relation to stability footwear intervention in children with Toe Walking please use this optional area to provide us with your reasoning.

Duchenne Muscular Dystrophy
In the questions below you will be presented with the collective choices and opinions from Round 2 concerning suggested protocols and measurable outcomes of stability footwear as a clinical intervention for this condition.

(93%) of panellists in Round 2 had clinical experience with this condition and provided the information for this section.

(If you have no clinical experience in treating this condition, please move to the next condition)

17)

Panellists were asked to rank their agreement with the following statements concerning the issuing of stability footwear for individuals with Duchenne Muscular Dystrophy (DMD) in Round 2.
The median level of agreement and the relative distribution of response is detailed below.

Stability footwear should only be issued to children with DMD after a critical assessment of the child's mobility needs in respect to other assistive aids
Median level of Agreement 7 ("Strongly Agree")
8% "Neutral", 31% "Agree", 61% "Strongly Agree"
A consensus was reached for this statement.

18)

Panellists were asked to rank their agreement with the following statements concerning the grade of mobility impairment in children with DMD that would be suitable for stability footwear both as a sole aid or in combination with another assistive aid in Round 2.
The median level of agreement and the relative distribution of response is detailed below.

Stability Footwear may be used alongside foot orthoses to assist foot and ankle stability in early ambulatory stages.
Median level of Agreement 6 ("Agree")
8% "Neutral", 23% "Somewhat Agree", 54% "Agree", 15% "Strongly Agree"

Stability Footwear may be used alongside AFO's and walking frames to assist walking in late ambulatory stages.
Median level of agreement 6 ("Agree")
15% "Somewhat Disagree", 23% "Somewhat Agree", 54% "Agree", 8% "Strongly Agree"

Stability Footwear may be used simultaneously with AFO's and standing frames to assist standing and transfer in early non-ambulatory stages.
Median level of Agreement 5 ("Somewhat Agree")
15% "Somewhat Disagree", 8% "Neutral", 31% "Somewhat Agree", 31% "Agree", 15% "Strongly Agree"

Panellist feedback indicated there was potential ambiguity with the term "alongside"; panellists questioned did this mean stability footwear was to be used at different times or simultaneously with the other assistive aid.

The following statements have been slightly modified based on panellist feedback

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree

	1	2	3	4	5	6	7
Stability Footwear may be used simultaneously with foot orthoses to assist foot and ankle stability in early ambulatory stages.	☐	☐	☐	☐	☐	☐	☐
Stability Footwear may be used simultaneously with AFO's and walking frames to assist walking in late ambulatory stages.	☐	☐	☐	☐	☐	☐	☐
Stability Footwear may be used simultaneously with AFO's and standing frames to assist standing and transfer in early non ambulatory stages.	☐	☐	☐	☐	☐	☐	☐

19)

Panellists were presented with the following options in relation to the suitable age range for stability footwear intervention DMD in Round 2.
The relative distribution of response is detailed below.

Option 1, Initiation and end points of treatment indicated by functional ability and the mobility needs of the child (potential or actual).68%
Option 2, 1-18 years 8%
Option 3, 4-9 years 8%

Option 4, 4-18 years 8% Option 5, N/A I do not feel this condition is suitable for stability footwear intervention 8% No specific panellist feedback was given to inform any further modification of these options. However, you may consider the distribution of the panel's response to either change or maintain your previous option.	
☐	Option1, Initiation and end points of treatment indicated by functional ability and the mobility needs of the child (potential or actual)
☐	Option 2, 1-18 years
☐	Option 3, 4-9 years
☐	Option 4, 4-18 years
☐	Option 5, N/A I do not feel this condition is suitable for stability footwear intervention.

20)

Panellists were asked to rank their agreement with the following statements in relation to the clinical outcomes that would be used to evaluate the effectiveness of "Off the Shelf" Stability footwear for children with DMD in Round 2:
The median level of agreement and the relative distribution of response is detailed below.

Passive Ankle ROM
Median level of Agreement 5 ("Somewhat Agree")
8% "Somewhat Disagree", 8% "Neutral", 61% "Somewhat Agree", 15% "Agree"
8% Strongly Agree

Kinematics: Optimising gait movement patterns (Foot and Ankle)
Median level of Agreement 6 ("Agree")
23% "Somewhat Agree", 54% "Agree", 23% "Strongly Agree"
A consensus was reached for this statement.

Kinetic: In-shoe pressure measurement (Heel and Forefoot loading)
Median level of Agreement 5 ("Somewhat Agree")
8% "Somewhat Disagree", 16% "Neutral", 30% "Somewhat Agree", 30% "Agree"
16% "Strongly Agree"

Spatiotemporal: Increased walking velocity, 6MWT, TUG, stride length, cadence
Median level of Agreement 6 ("Agree")
8% "Neutral", 15% "Somewhat Agree", 54% "Agree", 23% "Strongly Agree"
A consensus was reached for this statement

Gross motor proficiency: four square step test
Median level of Agreement 6 ("Agree")
15% "Neutral", 31% "Somewhat Agree", 46% "Agree", 8% "Strongly Agree"

Gross motor proficiency: Number of falls
Median level of Agreement 6 ("Agree")

8% "Neutral", 15% "Somewhat Agree", 69% "Agree", 8% "Strongly Agree"
A consensus was reached for this statement

QoL: Pain
Median level of Agreement 6 ("Agree")
8% "Neutral", 8% "Somewhat Agree", 76% "Agree", 8% "Strongly Agree"
A consensus was reached for this statement

QoL: ADL (daily mobility and social interaction)
Median level of Agreement 6 ("Agree")
15% "Somewhat Agree", 70% "Agree", 15% "Strongly Agree"
A consensus was reached for this statement

Panellist feedback suggested the following modifications to the outcomes.
Use weight bearing lunge test to measure Ankle ROM in addition to Passive ROM in children who can get their heel to the floor. Consider adding the 10-meter walk test as a valid spatiotemporal measure. A pragmatic point was raised in relation to degenerative conditions and outcomes, in that they need to consider the stage of the condition in light of the capability of the child to perform the tasks required. No specific panellist feedback was given to inform further modification of the other outcomes that did not reach consensus. However, you may consider the distribution of the panel's response to either change or maintain your previous choice.

Please rank your agreement with the following outcomes.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Passive Ankle ROM measured with knee flexed and extended within child's limits	☐	☐	☐	☐	☐	☐	☐
Ankle ROM Weight Bearing lunge provided child can get heel to ground	☐	☐	☐	☐	☐	☐	☐
Kinetic: In-shoe pressure measurement (Heel and Forefoot loading)	☐	☐	☐	☐	☐	☐	☐

Spatiotemporal 10-meter walk test	☐	☐	☐	☐	☐	☐	☐
Gross motor proficiency: four square step test	☐	☐	☐	☐	☐	☐	☐
Outcomes for a degenerative condition must consider the stage of the condition and the capability of the child to perform the tasks.	☐	☐	☐	☐	☐	☐	☐

21)

If your level of agreement was "somewhat agree" or lower for any of the statements in relation to stability footwear intervention in children with DMD please use this optional area to provide us with your reasoning.

Spina Bifida
In the questions below you will be presented with the collective choices and opinions from Round 2 concerning suggested protocols and measurable outcomes of stability footwear as a clinical intervention for this condition. (86%) of panellists in Round 2 had clinical experience with this condition and provided the information for this section. (If you have no clinical experience in treating this condition, please move to the next condition)

22)

Panellists were asked to rank their agreement with the following statements concerning the issuing of stability footwear children with Spina Bifida (SB) from Round 2.
The median level of agreement and the relative distribution of response is detailed below.

Stability footwear should only be issued to children with SB after a critical assessment of the child's mobility needs in respect to other assistive aids.
Median level of Agreement 6 ("Agree")
8% "Neutral", 42% "Agree", 50% "Strongly Agree"
A consensus was reached for this statement.

23)

Panellists were asked to rank their agreement with the following statements concerning the grade of mobility impairment in children with SB that would be suitable for stability footwear both as a sole aid or in combination with another assistive aid in Round 2.
The median level of agreement and the relative distribution of response is detailed below.

Stability footwear may be used alongside foot orthoses to assist foot and ankle stability in mild level lumbar 5 vertebral involvement.
Median level of Agreement 5 ("Somewhat Agree")
8% "Strongly disagree", 42% "Somewhat Agree", "50% Agree",

Stability Footwear may be used alongside AFO's and walking frames to assist walking and standing in lumbar 1-5 vertebral involvement.
Median level of agreement 6 ("Agree")
8% "Strongly disagree", 8% "Somewhat Disagree", 26% "Somewhat Agree", 50% "Agree", 8% "Strongly Agree"

Panellist feedback suggested the recommendations should consider actual severity of dysraphism as well as spinal level (Occulta, Meningocele, Myelomeningcele) and incorporate assistive aid recommendations from 'Orthoses for Myelomeningocele' in the Atlas of Orthoses and Assistive Devices, 2019. L1-3 level lesions would need Hip Knee Ankle Foot Orthosis (HKAFO) or Knee Ankle Foot Orthoses (KAFO) to be able to stand/walk. Level L4-5 lesions would walk with AFOs and S1 walk without AFO.

There was potential ambiguity with the term "alongside"; panellists questioned did this mean stability footwear was to be used at different times or simultaneously with the other assistive aid.

The following statements have been modified and developed based on panellist feedback

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Stability footwear may be used simultaneously with foot orthoses	☐	☐	☐	☐	☐	☐	☐

to assist foot and ankle stability in sacral level 1 (Meningocele).							
Stability Footwear may be used simultaneously with AFO's and walking frames to assist walking and standing in lumbar level 4-5 (Meningocele, Myelomeningocele).	☐	☐	☐	☐	☐	☐	☐
Stability Footwear may be used simultaneously with HKAFO or KAFO and walking frames to assist walking and standing in lumbar level 1-3 (Meningocele, Myelomeningocele).	☐	☐	☐	☐	☐	☐	☐

24)

Panellists were presented with the following options concerning the suitable age range for stability footwear intervention for SB in Round 2.
The relative distribution of response is detailed below.

Option 1, Initiation and end points of treatment indicated by functional ability and the mobility needs of the child (potential or actual). (73%)
Option 2, 1-18 years (with assessed adult transition care) (18%)
Option 3, 4-18 years (with assessed adult transition care) (9%)
Option 4, N/A I do not feel this condition is suitable for stability footwear intervention (0%)

No specific panellist feedback was given to inform any further modification of these options. However, you may consider the distribution of the panel's response to either change or maintain your previous option.

☐	Option 1 Initiation and end points of treatment indicated by functional ability and the mobility needs of the child (potential or actual).
☐	Option 2, 1-18 years (with assessed adult transition care)
☐	Option 3, 4-18 years (with assessed adult transition care)
☐	Option 4, N/A I do not feel this condition is suitable for stability footwear intervention.

25)

Panellists were asked to rank their agreement with the following statements concerning the clinical outcomes that would be used to evaluate the effectiveness of "Off the Shelf" Stability footwear for children with SB in Round 2:
The median level of agreement and the relative distribution of response is detailed below.

Kinematics: Optimising gait movement patterns (Hoffer Ambulation Scale)
Median level of Agreement 6 ("Agree")
18% "Neutral" 9% "Somewhat Agree", 64% "Agree", 9% "Strongly Agree"

Spatiotemporal: Increased walking velocity, 6MWT, TUG,
Median level of Agreement 6 ("Agree")
9% "Somewhat Agree", 82% "Agree", 9% "Strongly Agree"
A consensus was reached for this statement

Motor skill proficiency: Hoffer Ambulation Score
Median level of Agreement 6 ("Agree")
9% "Neutral", 9% "Somewhat Agree", 73% "Agree", 9% "Strongly Agree"
A consensus was reached for this statement

Physiological Perceived exertion (BORG)
Median level of Agreement 6 ("Agree")
9% "Neutral", 82% "Agree", 9% "Strongly Agree"
A consensus was reached for this statement

QoL: Pain
Median level of Agreement 6 ("Agree")
9% "Somewhat Agree", 82% "Agree", 9% "Strongly Agree"
A consensus was reached for this statement

QoL: ADL (daily mobility and social interaction)
Median level of Agreement 6 ("Agree")
18% "Somewhat Agree", 73% "Agree", 9% "Strongly Agree"
A consensus was reached for this statement

No specific panellist feedback was given to inform any further modification of the outcomes for SB. However, you may consider the distribution of the panel's response to either change or maintain your previous level of agreement with the following outcome.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Kinematics: Optimising gait movement patterns (Hoffer Ambulation scale)	☐	☐	☐	☐	☐	☐	☐

11)

If your level of agreement was "somewhat agree" or lower for any of the statements in relation to stability footwear intervention in children with SB please use this optional area to provide us with your reasoning.

Down's Syndrome
In the questions below you will be presented with the collective choices and opinions from Round 2 concerning suggested protocols and measurable outcomes of stability footwear as a clinical intervention for this condition. (93%) of panellists in Round 2 had clinical experience with this condition and provided the information for this section. (If you have no clinical experience in treating this condition, please move to the next condition)

27)

Panellists were asked to rank their agreement with the following statements concerning the issuing of stability footwear children with Down's Syndrome from Round 2. The median level of agreement and the relative distribution of response is detailed below. Stability footwear may assist mediolateral stability and proprioception of the foot and ankle in standing and walking in children with Down's syndrome Median level of Agreement 6 ("Agree") 15% "Somewhat Agree", 62% "Agree", 23% "Strongly Agree" A consensus was reached for this statement. Stability footwear design should consider last adaptions to accommodate the foot dimensions of children with Down's syndrome Median level of Agreement 6 (Agree) 8% "Neutral", 42% "Agree", 50% "Strongly Agree" A consensus was reached for this statement.

28)

Panellists were asked to rank their agreement with the following statements concerning the grade of mobility impairment in children with Down's Syndrome that would be suitable for stability footwear both as a sole aid or in combination with another assistive aid in Round 2. The median level of agreement and relative distribution of response is detailed below.

Stability footwear may be used as a sole assistive aid in pre-walking and learning to walk stages with associated hypotonia and delayed motor milestones.
Median level of Agreement 6 (Agree)
8% "Strongly disagree", 42% "Somewhat Agree", 50% "Agree",

Stability Footwear may be used alongside foot orthoses to assist walking in individuals with ankle instability
Median level of agreement 6 (Agree)
8% "Somewhat Agree", 69% "Agree", 23% "Strongly Agree"
A consensus was reached for this statement

Stability Footwear may be used alongside foot orthoses to assist walking in individuals with knee instability
Median level of agreement 6 (Agree)
8% "Strongly disagree", 15% "Somewhat Agree", 54% "Agree", 23% "Strongly Agree"
A consensus was reached for this statement

Although consensus was reached in respect to knee instability and the use of stability footwear a potential adverse event was elaborated from panellist feedback in that associated knee hyperextension would contraindicate stiffened sole therapy in combination with AFO, as this would increase hyperextension in midstance,

The following statements have been modified and developed based on panellist feedback

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Stability footwear may be used as a sole assistive aid in pre-walking and learning to walk stages with associated hypotonia and delayed motor milestones.	☐	☐	☐	☐	☐	☐	☐
Stability Footwear may be used alongside foot	☐	☐	☐	☐	☐	☐	☐

orthoses to assist walking in individuals with ankle instability							
Stability Footwear with a stiffened sole is contraindicated with simultaneous AFO use in individuals with knee hyperextension.	☐	☐	☐	☐	☐	☐	☐

29)

Panellists were presented with the following options in relation to the suitable age range for stability footwear intervention for Down's Syndrome in Round 2.
The relative distribution of response is detailed below.

Option 1, Initiation and end points of treatment indicated by functional ability and the mobility needs of the child (potential or actual). (77%)
Option 2, 1-18 years (with assessed adult transition care) (15%)
Option 3, 4-18 years (with assessed adult transition care) (8%)
Option 4, N/A I do not feel this condition is suitable for stability footwear intervention (0%)

A consensus was reached for Option 1

30)

Panellists were asked to rank their agreement with the following statements in relation to the clinical outcomes that would be used to evaluate the effectiveness of "Off the Shelf" Stability footwear for children with Down's Syndrome in Round 2:
The median level of agreement and relative distribution of response is detailed below.

Foot Posture FPI-6
Median level of Agreement 5 (Somewhat Agree)
8% "Disagree", 15% "Somewhat Disagree", 15% "Neutral", 23% "Somewhat Agree", 31% "Agree",
8% "Strongly Agree"

Kinematics: Optimising gait movement patterns (Foot and ankle)
Median level of Agreement 6 (Agree)
8% "Somewhat Disagree", 23% "Somewhat Agree", 46% "Agree", 23% Strongly Agree

Spatiotemporal: Increased walking velocity, 6MWT,
Median level of Agreement 6 (Agree)
8% "Neutral", 15% "Somewhat Agree", 54% "Agree", 23% "Strongly Agree"
A consensus was reached for this statement.

Gross Motor skill proficiency: Number of falls
Median level of Agreement 6 (Agree)
8% "Neutral", 8% "Somewhat Agree", 61% "Agree", 23% "Strongly Agree"
A consensus was reached for this statement

Motor skill proficiency:
Gross Motor Skills (BOT-2)
Median level of Agreement 6 (Agree)
31% "Somewhat Agree", 61% "Agree", 8% "Strongly Agree"

QoL: Pain
Median level of Agreement 6 (Agree)
8% "Somewhat Agree", 69% "Agree", 23% "Strongly Agree"
A consensus was reached for this statement

QoL: Comfort with Footwear
Median level of Agreement 6 (Agree)
23% "Somewhat Agree", 54% "Agree", 23% "Strongly Agree"
A consensus was reached for this statement

QoL: ADL (daily mobility and social interaction)
Median level of Agreement 6 (Agree)
15% "Somewhat Agree", 62% "Agree", 23% "Strongly Agree"
A consensus was reached with this statement.

Panellist feedback suggested that the FPI-6 is a semi-quantitative description of foot posture and should not be considered as an outcome measure. Panellist suggested adding 10-meter walk test as a valid spatiotemporal measure. No specific panellist feedback was given to inform further modification of the other outcomes that did not reach consensus. However, you may consider the distribution of the panel's response to either change or maintain your previous choice.

Please rank your agreement with the following outcomes.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Foot posture FPI-6	☐	☐	☐	☐	☐	☐	☐
Kinematics: Optimising gait movement patterns	☐	☐	☐	☐	☐	☐	☐

(foot and ankle)							
Spatiotemporal 10-meter walk test	☐	☐	☐	☐	☐	☐	☐
Gross motor proficiency: number of falls	☐	☐	☐	☐	☐	☐	☐
Motor skill proficiency: Gross Motor Skills (BOT-2)	☐	☐	☐	☐	☐	☐	☐

31)

If your level of agreement was "somewhat agree" or lower for any of the statements in relation to stability footwear intervention in children with Down's Syndrome please use this optional area to provide us with your reasoning.

Intoeing
In the questions below you will be presented with the collective choices and opinions from Round 2 concerning suggested protocols and measurable outcomes of stability footwear as a clinical intervention for this condition. (86%) of panellists in Round 2 had clinical experience with this condition and provided the information for this section. (If you have no clinical experience in treating this condition, please move to the next condition)

32)

Panellists were asked to rank their agreement with the following statements concerning the issuing of stability footwear children with Intoeing from Round 2. The median level of agreement and the relative distribution of response is detailed below. Stability footwear may be a suitable intervention for in-toeing if associated with tripping Median level of Agreement 4 (Neutral)

17% "Disagree", 17% "Somewhat Disagree", 41% "Neutral", 8% "Somewhat Agree", 17% "Agree",

Stability footwear may be a suitable intervention for in-toeing if associated with an underlying neurological condition
Median level of Agreement 4 (Neutral)
8% "Disagree", 8% "Somewhat Disagree", 26% "Neutral", 17% "Somewhat Agree", 33% "Agree",
8% "Strongly Agree"

No specific panellist feedback was given to inform any further modification of the statements. However, you may consider the distribution of the panel's response to either change or maintain your previous level of agreement with the following statements.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Stability footwear may a suitable intervention for intoeing if associated with tripping	☐	☐	☐	☐	☐	☐	☐
Stability footwear may a suitable intervention for intoeing if associated with an underlying neurological condition	☐	☐	☐	☐	☐	☐	☐

33)

Panellists were presented with the following options concerning the suitable age range for stability footwear intervention for intoeing in Round 2.
The relative distribution of response is detailed below.

Option 1, Initiation and end points of treatment indicated by functional ability and the mobility needs of the child (potential or actual). (73%)

Option 2, N/A I do not feel this condition is suitable for stability footwear intervention (27%) Option 3, 3 years onwards (0%) No specific panellist feedback was given to inform any further modification of these options. However, you may consider the distribution of the panel's response to either change or maintain your previous option.	
☐	Option 1 Initiation and end points of treatment indicated by functional ability and the mobility needs of the child (potential or actual).
☐	Option 2 N/A I do not feel this condition is suitable for stability footwear intervention.

10)

Panellists were asked to rank their agreement with the following statements concerning the clinical outcomes that would be used to evaluate the effectiveness of "Off the Shelf" Stability footwear for children with intoeing in Round 2:
The median level of agreement and the relative distribution of response is detailed below.

Kinematics: Optimising gait movement patterns (Angle of Gait)
Median level of Agreement 5 (Somewhat Agree)
18% "Neutral", 37% "Somewhat Agree", 37% Agree, 8% Strongly Agree

Spatiotemporal: Increased walking velocity, 6MWT, TUG2
Median level of Agreement 5 (Somewhat Agree)
46% "Neutral", 18% "Somewhat Agree", 27% "Agree", 9% "Strongly Agree"

Gross Motor skill proficiency: Number of falls
Median level of Agreement 6 (Agree)
36% "Somewhat Agree", 46% "Agree", 18% "Strongly Agree"

QoL: Pain
Median level of Agreement 6 (Somewhat Agree)
27% "Neutral" 27% "Somewhat Agree", 46% "Agree"

QoL: ADL (daily mobility and social interaction)
Median level of Agreement 6 (Agree)
46% "Somewhat Agree", 46% "Agree", 8% "Strongly Agree"

There was minimal feedback in relation to modifying the outcomes, other than the suggestion that standing Foot Progression Angle (Fick Angle) may be compared with foot progression angle in gait. No specific panellist feedback was given to inform further modification of the other outcomes. However, you may consider the distribution of the panel's response to either change or maintain your previous choice.

Please rank your agreement with the following outcomes

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7

Kinematics: Optimising gait movement patterns (Angle of Gait). Comparison of standing foot progression angle with walking foot progression angle .	☐	☐	☐	☐	☐	☐	☐
Spatiotemporal: Increased walking velocity, 6MWT, TUG	☐	☐	☐	☐	☐	☐	☐
Gross motor proficiency: reduction in tripping	☐	☐	☐	☐	☐	☐	☐
QoL: Pain	☐	☐	☐	☐	☐	☐	☐
QoL: ADL (daily mobility and social interaction)	☐	☐	☐	☐	☐	☐	☐

11)

If your level of agreement was "somewhat agree" or lower for any of the statements in relation to stability footwear intervention in children with Intoeing please use this optional area to provide us with your reasoning.

Additional Conditions:

A number of additional conditions were presented to the panellists in Round 2 based on suggestions made from panel members in Round 1.

Panellists were asked if they agreed with the suitability of stability footwear as an assistive aid for the suggested conditions.

The relative distribution of responses are detailed below,

(Panellists who had no clinical experience of the condition were discounted from the frequency calculation)

Charcot Marie Tooth, Hereditary Motor Sensory Neuropathy
Agree 92%, Neutral 0%, Disagree 8%
A consensus was reached for this statement

Hypermobility (Ehlers Danlos Type)
Agree 92%, Neutral 8%, Disagree 0%
A consensus was reached for this statement

Developmental Coordination Disorder
Agree 100%, Neutral 0%, Disagree 0%
A consensus was reached for this statement

Rett's Syndrome
Agree 80%, Neutral 0%, Disagree 20%
A consensus was reached for this statement

Foetal Alcohol Syndrome
Agree 50%, Neutral 0%, Disagree 50%

Accessory navicular
Agree 31%, Neutral 46%, Disagree 23%

Chronic lateral ankle instability
Agree 77%, Neutral 15%, Disagree 8%
A consensus was reached for this statement

Concerning the conditions below concerning their suitability for stability footwear clinical intervention.

36)

	I have no clinical experience with this condition	Disagree	Neutral	Agree
Foetal Alcohol syndrome	☐	☐	☐	☐

Accessory navicular	☐	☐	☐	☐

END OF SECTION 3 ROUND 3

Thank you for taking the time to complete section 3 of round 2. You have now completed all sections of round 2 of this Delphi survey. Your time and participation is greatly appreciated.
Remember to submit your answers before closing this form.