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Original Article

Physiotherapy Section

Development of a Valid Outcome Measure for Sensory Testing in Children with Cerebral Palsy: An Exploratory Sequential Research Design

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ABSTRACT

Introduction: In Cerebral Palsy (CP), sensory perception is affected in addition to the motor symptoms. Now-a-days, treatment solely focuses on diagnosed motor deficiencies, often overlooking underlying sensory abnormalities and their examination. Therefore, including a clinical sensory examination in the evaluation of children with CP is crucial.

Aim: To develop a validated measure for assessing sensory processing among children with CP.

Materials and Methods: This study, conducted as part of a Ph.D. research project, employed an exploratory sequential research design. It commenced on March 1, 2020, and concluded on October 18, 2021, at the Physiotherapy Out Patient Department (OPD) of Swami Vivekanand Subharti University in Meerut, Uttar Pradesh, India. Validity tests, including Scale Level Content Validity Index (CVI) and Spearman rank correlation methods, were used alongside other subtests. The study consisted of two phases: Development and Validation. An extensive literature search and parent interviews were conducted to comprehensively understand and collect information on sensory issues. Based on this information, a preliminary questionnaire draft was created. Three categories of validity-content, face, and concurrent-were tested. Content validation involved employing a three-round online Delphi approach. Face validity was assessed through opinions from clinicians regarding the questionnaire's appearance. Concurrent validity was established by comparing the Sensory Outcome Measure (SOM) with the criterion measure scale, Short Sensory Profile (SSP).

Results: For all items, Content Validity Ratio (CVR) and item-level CVI values ranged from 0.8 to 1. The overall Scale Level CVI (average) for the scale was 0.890625. Experts exhibited a 96% agreement regarding the appearance of the questionnaire, indicating complete agreement. The Spearman rank correlation coefficient value was 0.866, and the correlation graph indicated a positive association between the two scales in terms of concurrent validity.

Conclusion: The Sensory Outcome Measure (SOM) has been developed as a valid scale with high content and face validity, along with excellent concurrent validity. SOM is the first measuring scale developed in India and used for assessing sensory deficits in children with CP.

Keywords: Content validity index, Content validity ratio, Sensory outcome measure, Short sensory profile

INTRODUCTION

Although CP is primarily characterised by physical impairments, a significant number of people with CP also experience cognitive and sensory deficits, which can affect the prognosis of the condition. Since motor recovery relies on sensory involvement, it is crucial to develop a scale that encompasses all associated sensory domains. Currently, existing scales have been designed and validated primarily with a focus on motor difficulties [1]. Sensory processes such as stereognosis, two-point discrimination, proprioception, and visual perception have frequently been found to be linked to motor functions [2]. Deficits in lower extremity senses and tactile perception have a significant impact on gait [3]. Moreover, sensory processing in CP children is correlated with their abilities for daily living and social interactions with their environment [4]. There are limited tools available for evaluating sensory processing. One comprehensive and validated checklist for assessing integrated sensory processing is the sensory profile, which is a parent-reporting instrument that captures children's reactions to sensory events in their daily lives. However, no studies have been found that specifically utilise this instrument to assess and characterise sensory processing in children with CP [5]. The aim of this study was to develop an outcome measure that can document all sensory modalities in children with CP by correlating it with other available tools for sensory testing. This study created an assessment scale that can be used to examine sensory problems in children with CP. The results demonstrate that this newly developed tool is effective in assessing sensory issues in children with CP.

MATERIALS AND METHODS

The study follows an exploratory sequential research design, consisting of two phases and subphases, aimed at creating and validating SOM for children with CP. The research was carried out at the physiotherapy OPD of Swami Vivekanand Subharti University in Meerut, Uttar Pradesh, India. It spanned two years, beginning with a literature search on 10/10/2019 to gather items related to the target domains. Subsequently, the questionnaire draft was formulated, and validity testing commenced upon receiving approval from the university's ethical committee (ref no SMC/UECM/2021/24/153) on 21/4/2021. The validity testing concluded on 12/10/2021, with the last sample received.

Development Phase

Domain identification and item generation [6]: The items for the newly developed SOM were generated using two techniques: an extensive literature search and in-depth direct interviews. Items that exhibited a certain relationship were identified, grouped, and used to create domains [7].

Literature search: Between January 1990 and February 2020, relevant English literature was searched in databases such as

PubMed, Cochrane Library, and Google Scholar to identify sensory domains and assessment tools. Following a comprehensive literature search, a total of 14 tools were selected for item generation: Infant/Toddler Sensory Profile Caregiver Questionnaire, Paediatric Clinical Test of Sensory Interaction for Balance, Nottingham Sensory Assessment, The Classroom Sensory Environment Assessment, Sensory Eating Problem Scale, The Sensory Processing Scale (Expanded), Sensory Experiences Questionnaire Version 3.0, DeGangi-Berk Test of Sensory Integration, Short Sensory Profile (SSP), Sensorimotor Clinical Observation, Sensory Processing Measure, Comprehensive Observation of Proprioception, Test of Ideational Praxis, and the Miller Assessment for Preschoolers.

Interview: The investigator conducted direct interviews with 20 parents of children with CP in the OPD. Unstructured interview questions were designed, and interviews lasted approximately one hour on various days. The questions addressed the problems that these children experience in their day-to-day lives related to vision, hearing, movement, and other Activities of Daily Living (ADLs). Data related to sensory symptoms were collected within a one-month period from March 1, 2020, to April 1, 2020.

Grouping of items: After generating items from the literature and interviews, they were combined and carefully selected to form a large pool of items categorised into 11 domains.

Formation of rough draft (Set 1): Questions were formulated based on the items and relevant terms obtained from the literature and interviews. The questions were designed to address the needs of all types of CP.

Validity Assessment

Content validation: The content validation was conducted using the online Delphi approach [8]. The items and domains were entered into an online Google Forms and emailed to the expert panel. The panel of experts, consisting of 10 members, responded to a series of questions [9]. It was determined that having more than 10 members in the panel was unnecessary [10].

To represent and identify patient demands, a panel of specialists in the related field with a minimum of 10 years and upto 25 years of clinical experience from various geographical locations was selected. The panel included individuals with qualifications such as Masters in Physiotherapy, Ph.D., PDF, and MBBS, specialising in paediatrics and physiotherapy. Most of the experts held positions as professors in medical institutions. The study was conducted in three rounds, as shown in [Table/Fig-1], with each round being analysed. The responses from the second and third rounds were assessed for relevancy (importance of the question for the tool), clarity (the clarity of language), and necessity (the importance of each question). The answers were graded on a 4-point Likert scale, with the following marking criteria:

1. Not necessary/Not relevant/Not clear,
2. Useful but not essential/The item needs some revision (for relevancy)/The item needs some revision (for clarity),
3. Essential/Relevant but needs minor revision/Clear but needs minor revision,
4. Very essential/Very relevant/Very clear.

Content with ratings of one and two were considered invalid, while content with ratings of three and four were deemed acceptable.

Pilot study: After the content validation, the SOM was further pilot-tested to assess practical challenges, understandability, word interchange usage, time requirements, grading criteria, and final interpretations. Children with hypoxic CP between the ages of 3 and 14 years were recruited for the study. A sample size of 20 was determined to be sufficient for the pilot study, considering the low prevalence of the condition and the impact of the COVID pandemic. This sample size was recommended by Julious SA [11]. The pilot study involving CP children was completed within 15 days, with the targeted sample of 20 participants successfully obtained.

Online Delphi	First round	Second round	Third round
Procedure	A Google form was created of 118 questions and sent to the expert panel for question grading of two possibilities (Yes and No).	After rephrasing the questions as per the expert's suggestion received from the second round along with removing the questions that scored less than 80% agreement (from the first round), 93 questions were sent to the same expert panel again.	Total 64 questions were received from the second round. Google form of a total of 32 questions (with low critical value) was constructed again and sent for marking. Remaining 32 questions kept as it is in questionnaire.
	Option "Yes" indicated that the question should be included in the research, whereas option "No" indicated that the question should not be included in the questionnaire any longer.	A Google form was developed once again, along with a cover letter including instructions for grading clarity, necessity, and relevancy.	For clarity (23 questions) and relevancy (9 questions).
Time frame	(Last response received on 20/09/2020).	(Last response was received on 17/04/2021).	(The last response was received on 27/08/2021).

[Table/Fig-1]: Three rounds of Online Delphi.

Scoring: The scoring criteria were developed based on the opinions of experts who conducted the content validation of items, previous research on existing tools, and the practical insights gained from the pilot study.

Face validity: Face validity was assessed through face-to-face interviews with 10 clinicians who intended to utilise the instrument in their practice. Factors such as clarity, unambiguity, logical scoring, interpretations, and relevance were considered [12,13]. An interview with all 10 physiotherapists was scheduled for September 15, 2021. Assistant professors with master's degrees in their respective subjects and 5-12 years of clinical experience served as the subject matter experts for face validity. Each expert was provided with a form to fill out, which consisted of closed-ended questions with a yes/no response option. A score of 1 was assigned for "Yes" and 0 for "No," thereby converting qualitative assessments into quantitative scores.

Concurrent validity: The concurrent validity of the SOM was evaluated by comparing it with the Short Sensory Profile (SSP) as a criteria measure. The study included the participation of 20 children with CP, ranging in age from 3 to 14 years. Both the SSP and the newly designed SOM scales were used to assess sensory issues.

RESULTS

Online Delphi Method

Online Delphi method: The percent agreement for CVR and item-level CVI was calculated [Table/Fig-2] [14]. For the development of a new tool, a CVI cut-off score of 0.78 was considered acceptable when the number of panel experts was 9 or above [15]. The overall scale-level CVI for the 64-item scale was 0.890625, which exceeded the acceptable limit [16]. Kappa statistics for all items ranged from 0.79 to 1, indicating excellent content validity for the instrument [17].

Online Delphi	First round	Second round	Third round
Analysis	Percent agreement was calculated through, Item level CVI	Content Validity Ratio (CVR) for necessity and Item level Content Validity Index (CVI) for clarity and relevance	Item level CVI for clarity and relevancy

Domain	11	10 (One domain kinesthesia remove due to less CVR (i.e., less than 0.8 critical value)	10
Item level CVI and CVR (Less than 0.70) Questions eliminated [14]	25	29	0
Item level CVI and CVR (0.70 to 0.8) Revision [14]	10	23	0
Item level CVI and CVR (0.8 to 1) Questions retained for further analysis [14]	83	41	64
Questions retain in the questionnaire	118	93	64

[Table/Fig-2]: Result of Online Delphi.

Pilot testing: The time taken for the first caregiver of a CP child recruited for the pilot study was 40 minutes, and this decreased by 20 minutes for the last caregiver. A practical challenge identified during the pilot study was that certain questions were misleading regarding motor power, necessitating their removal. Some patients did not achieve certain milestones, and one question in the auditory domain appeared to be repeated [Table/Fig-3].

Set of questions	Draft 1	Draft 2	Draft 3	Final
Received after	Literature search and interview	Removing delicacy	From online Delphi	Pilot testing
Gustatory	35	19	5	4
Tactile	62	33	14	12
Vestibular	11	10	8	2
Proprioception	28	16	8	3
Kinesthesia	01	01	0	0
Movement processing	06	05	1	1
Visual	23	13	12	12
Auditory	23	10	6	5
Olfactory	06	02	2	2
General processing	10	08	7	7
Steriognosis	01	01	1	1
Total	206	118	64	49

[Table/Fig-3]: Set of questions received from different steps of the study.

Scoring: The SOM was scored on a 5-point ordinal scale to represent the level of sensory involvement in children with CP [18,19].

Face validity: The lowest allowable item-level Face Validity Index (FVI) value was set at 0.80 [15]. For all questions, item-level FVI values ranged from 0.9 to 1. The experts' reactions showed a 96% agreement, indicating complete agreement. All questions in the questionnaire were retained [Table/Fig-4] [20,21].

Concurrent validity: The concurrent validity of the SOM with the criterion measure, the SSP, was reported as 0.866 by the Spearman rank correlation coefficient (ρ), indicating excellent concurrent validity.

Correlation graph: A regression line was constructed using the least squares approach to represent the SOM values [22]. There were not many data points falling above or below the line of best fit. The value of r was 0.793 with a p-value of 0.023, indicating a strong positive correlation between the SOM and SP scales [Table/Fig-5].

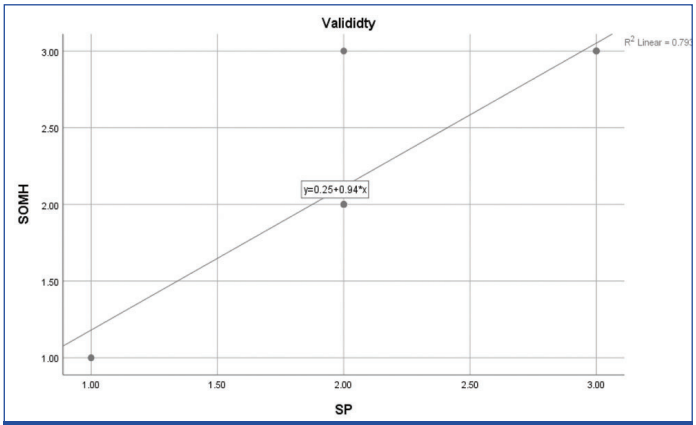
DISCUSSION

Somatosensory information plays a crucial role in motor learning and the development of cognitive skills. In neurodevelopmental disorders, especially CP, abnormalities in somatosensory processing have been associated with deficits in communicative, motor, and social skills. Clinical research suggests that sensory processing abnormalities contribute to motor planning and execution deficits, affecting postural control and motor performance in CP [3]. Studies on somatosensory evoked potentials have shown a strong correlation between the severity of motor deficits and the extent of sensory loss [23].

Questionnaire	
Questions for under responsiveness (negative signs): Set-A	Question for over responsiveness (abnormal positive signs): Set-B
Gustatory	
1. Does your child react to the temperature of food given to him/her? 2. Does your child tolerate tooth brushing?	31. Do you usually see saliva expelled from the mouth of your child? 32. Does your child want to eat only specific textures of food?
Tactile	
3. Does your child is able to differentiate between soft and hard touch 4. Does your child allow bathing and wiping of the face 5. Does the child show favourites for certain textures of clothes? 6. Does your child like to be hugged? 7. Does your child allow wiping with a towel/cloth? 8. Can your child deal with situations, like going in public places (no fear of physical contact)? 9. Does your child allow the trimming of nails? 10. Can your child notice hurdles on the way? 11. Does your child react to touch? 12. Does your child is able to pay attention (to someone's contact)?	33. Does your child become irritated when anyone suddenly touches him (does not tolerate touch)? 34. Does your child use it to cause injury to himself/herself (pinch, bite, hit, or scratch)?
Vestibular	
13. Does your child react to moving activities (e.g., in games or swing)?	35. Does your child feel fear while traveling (e.g., cry while traveling in a car, bus, or train)?
Proprioception	
14. Does your child able to bear deep pressure (e.g., deep pressure massage and tight hug)? 15. Does your child like to play with moving objects? 16. Does your child react to playing activities in which he/she has to hang out? (enjoy)	-
Movement processing	
17. Does your child react to bouncing activities? (enjoy trampoline)	-
Visual	
18. Does your child give attention to visual stimuli (e.g., blinking of a light bulb)? 19. Does your child able to judge the direction? 20. Does your child pay attention to moving objects? 21. Does your child enjoy looking at bright objects? 22. Does your child seem keen on bright-coloured objects? 23. Does your child respond in front of the mirror?	36. Does your child squint to improve visual input? 37. Does your child feel more comfortable in darkness or dim lighting? 38. Does your child look markedly towards the object and person? 39. Does your child frequently stair off into space? 40. Does your child is usually having a double vision? 41. Does your child feel difficulty in tracking moving objects?
Auditory	
24. Does your child pay attention to noise? 25. Does your child pay attention during calling him/her? 26. Does your child react to unfamiliar sounds on the road?	42. Does your child distort by loud sounds? (seems fearful) 43. Does your child stop playing with loud noise?
Olfactory	
27. Does your child is able to differentiate smell (pleasant or unpleasant)?	44. Does your child smell a toy before playing with them?

General processing	
28. Does your child follow the set routine for sleeping? 29. Does your child make eye contact (whenever require)?	45. Does your child is being irritated when his or her daily routine is disturbed? (reacts very oddly) ? 46. Does your child take more time to respond to a question (than other children of the same age)? 47. Does your child leave from situations (e.g., noise, unfamiliar)? 48. Does your child awake from sleep easily (sometimes without any cause)? 49. Does your child feel uneasy in new situations?
Stereognosis	
30. Does your child is able to judge the shape of an object (a child of the same age)?	-

[Table/Fig-4]: Final set of questions.



[Table/Fig-5]: Sensory Outcome Measure for Hypoxic Cerebral Palsy Children (SOMH), Sensory Profile (SP).

Sensory abnormalities in children with CP are often caused by white matter lesions, which are present in 45% of cases [5]. These sensory processing challenges affect the child's ability to participate in the educational environment and process auditory, visual, and tactile information [24].

While there are 21 tools available for assessing sensory processing in children between the ages of 3-11, only 15 of them are widely supported by psychometric research, mostly conducted in the United States (US). However, none of these tools specifically target children with CP [25]. The quality of an assessment instrument, such as a questionnaire, is a fundamental aspect of research evaluation [26]. Validity, including face validity and construct validity, is crucial in determining the accuracy and consistency of the collected data [27-29].

CVR analysis, conducted by Lawshe CH, was used to determine the validity of each attribute in the CVR database (1975). This analysis determined whether an attribute was acceptable or invalid based on its CVR value [30]. The newly developed SOM is a unique tool for documenting sensory symptoms in children with CP. Three sources were used to identify the items in the scale, and all items were assessed using the consumer-provider model. Face validity, construct validity, and other forms of validity testing yielded positive results, indicating that the instrument is valid for documenting sensory impairments in children with CP.

The SOM is an ordinal scale that can be converted into an interval scale to calculate percentage scores for each domain. It can also be translated into Indian regional languages to enhance understanding and comprehensibility. A new column called "milestone not achieved" can be added to include items that were eliminated due to failure to achieve the specific milestones. The newly designed scale has the potential to successfully document significant changes in clinical outcomes for children with CP in India, with a focus on sensory impairment.

Limitation(s)

1. Construct validation was not investigated in the study, as the need to generate construct validity only arises when traditional validation approaches are ineffective.
2. At the time of data collection, the type of CP was not documented, despite the fact that sensory impairment is present in all forms of CP [29].

CONCLUSION(S)

The SOM scale has been developed as a valid measure for children with CP. Experts in relevant fields such as paediatricians, neuro-paediatricians, and physiotherapists (paediatrics) validated the items and the overall measure. The instrument was also reviewed by clinical physiotherapists to ensure its appropriateness. It demonstrated excellent concurrent validity when compared to the SSP. This is the first measurement scale developed in India specifically for assessing sensory impairments in CP children.

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