Content Validation of Early Intervention Protocol for Preterm Infants in Indian Population

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Abstract

Background: Preterm birth is defined as babies born alive at less than 37 weeks of gestation. Due to the lack of the in-vitro environment and their exposure to harmful environment of the NICU leads to the preterm infants having a long term disability. The awareness of environmental factors on development gave rise to the idea formation of various early intervention programs. The guidelines for early intervention progression should be tailored respecting the growing needs of preterm infants. Hence, the current literature states a need for a protocol with proper dosage in improving the motor outcomes.

Objective: The current study aimed to validate the content of early intervention protocol in Indian population.

Materials and Method: The process of content validation of early intervention protocol involved development stage and expert judgment stage. The early intervention protocol was designed into three stages with extensive review of literature. After designing the protocol, nine experts in field of paediatric & neurological physiotherapy performed the judgemental process. The process of validation includes rating of selected experts in a 5 point likert grading on two parameters namely relevance and ease of performance. Based on expert's inputs on early intervention protocol, the level of agreement, content validation index and kappa value was calculated.

Results: The three staged early intervention protocol almost exhibited an excellent agreement on all stages.

Conclusion: The structured early intervention protocol exhibited excellent content validity to its use in Indian population.

Keywords: *Multimodal sensory stimulation, preterm infants, hammer smith neurological assessment scale, KMC.*

Introduction

WHO defined preterm birth as babies born alive at less than 37 completed weeks of gestation. The highest incidence of preterm births (13.4%) occurs in southern and south-east Asia and India ranks first in yearly prevalence of preterm birth among the South Asian countries.[1]

During normal embryological development, developing brain is highly neuroplastic. The fetal development in the intra uterine environment provides an optimal surrounding for the formation and maturation of the neural synapses.[2]

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Myelination of the central nervous system begins from 14 weeks of gestation and reaches a peak at 25-37 weeks.[3]

Gyrification process occurs from 10-28 weeks of gestation. The fetal brain develops from the lissencephalic structure to that of an adult brain with sulcus and gyri. Surface area of the cortical grey matter increases with more neurons in the cortex, which increases the ability of the cortex to process information.[4,5]

This process of normal development is alteredin preterm infants, further worsened by the early exposure of the preterm to the harmful NICU environment.[6]

These studies suggest that the infants born as very and late preterm will have extended developmental, behavioural problems which needs early intervention to address these morbidities. 'Early intervention' means educational strategies and neuroprotection strategies aimed at enhancing brain development by promotingneural plasticity and neuro-protection at improving the environmental and neurological experiences of the preterm infant during the critical period of development.[7,8]

The CNS receives inputs from all the sensory pathways such as touch, vision, sound, and movement to explore the possibilities of neural connection and forms new synapses, which can be further trained to produce proper developmental outcomes.[9]

Despite the fact that intervention strategies are large in number, all have shown to improve cognitive function but neuromotor outcomesare not well established.[10]

Hence, the current literature states a need for early intervention protocol and ultimately result in improved functional outcomes. The designed early intervention protocol requires a validation process for its relevance and ease of performance.

Validity means to a test/protocol measuring what it intends to measure.[11] The content validity is al similar to face validity using subjective judgement. Hence, an expert opinion is sorted to test the protocol for its intensions and practicality. The present study aimed to validate the content of early intervention protocol in Indian population.

Materials and Method

The process of content validation involved development stage and expert judgment stage. The protocol was designed into three stages with extensive literature.[12-15] The staging of protocol is mannered in a progressive way, meeting the developmental needs of preterm infant. The early intervention protocol follows a set pattern of exercises including kangaroo mother care,tactile stimulation non weight bearing position followed by weight bearing exercises then with functional exercises. Totally ten experts were selected for the validation process but only nine experts in field of paediatric & neuro physiotherapy gave consent to participate in the study. This validation study was approved by the Institutional Ethics Committee of Sri Ramachandra University, Chennai, Tamilnadu, India.

Procedure of Validation: The primary investigator requested 10 independent experts with minimum 10 years of experience in paediatric & neuro physiotherapy to participate in the study. As per recommendations by Lynn MR[16,17], a minimum of five and a maximum of 10 experts are required for the validation process. Out of 10, nine experts agreed to participate and were diversely placed in Southern parts of India. All experts were practicing paediatric & neuro physiotherapy including threeprofessors, two associate professors and four senior physiotherapists. The process of validation included rating of experts selected in a 5 point likert grading on two parameters namely relevance and ease of performance. The scale was scored as 1=strongly disagree, 2=mildly disagree, 3=neutral, 4=agree, 5=strongly agree. The score 4 and 5 were acceptable for calculation, if scored less than 3, experts were requested for suggestions. The key exercise components were listed in three stage manner with likert scale being measured for its relevance and ease of performance. The prepared content was sent through electronic media and basic instructions were given. Based on expert's inputs on early intervetion protocol, the level of agreement, content validation index and kappa value was calculated.

Results and Discussion

Based on the reports of nine experts, the Content Validity Index (CVI) is tabulated in [Tab-1]. The protocol has eight components namely general, tactile, kinesthetic/proprioceptive, vestibular, visual, auditory stimulations with handling & parent education.

Table 1: Content Validity Index (CVI) and kappa (K*) of early intervention protocol

Contents of early intervention protocol	Relevance		Ease of Performance	
	CVI	Kappa	CVI	Kappa
General				
Kangaroo mother care	100	1.00	100	1.00
Tactile stimulation				
Swaddling	89	0.89	89	0.89
Infant massage therapy	100	1.00	89	0.89
Gentle Human Touch	100	1.00	100	1.00
Kinesthetic/Proprioceptive stimulation				
Range of motion exercises	100	1.00	100	1.00
Gentle longitudinal compression of extremities	100	1.00	78	0.76
Infant positioning	100	1.00	100	1.00
Facilitation of head control	100	1.00	100	1.00
Assisted rolling using upper and lower extremities	100	1.00	100	1.00
Assisted kicking/reciprocal movements of legs	100	1.00	100	1.00
Facilitating hand to midline and mouth and legs hands together activities	89	0.89	78	0.76
Encouraging the development of head righting	100	1.00	100	1.00
Reaching in prone/supine	100	1.00	100	1.00
Encouraging creeping/crawling patterns	100	1.00	100	1.00
Vestibular Stimulation				
Cradled rocking	100	1.00	89	0.89
Visual stimulation	100	1.00	100	1.00
Promotion of eye following, to strengthen the eye and neck muscles, to promote head movement	100	1.00	100	1.00
Using Black and white objects	100	1.00	78	0.76
Auditory stimulation				
Maternal voice	89	0.89	100	1.00
Handling & Parent education	89	0.89	100	1.00

The content validation index was calculated by dividing number of experts who scored 4 or 5 by total number of experts participated in the validation process of early intervention protocol. The cut off level for acceptance if >0.78 as in accordance to a study [18], thus seven out of nine agree for an exercise. This further explains that if level of agreement is greater than 78%, the exercise is considered with good agreement among experts and to be included in protocol. A modified kappa was calculated to confirm the relevance of early intervention protocol. The interpretation of kappa values were taken as: fair= 0.40 to 0.60, good= 0.60 to 0.74 and excellent= 0.75 to 1.00.

The 19 item early intervention protocol was examined by all experts with good agreement among them. In tactile stimulation, swaddling & infant massage therapy, Kappa values were moderate in ease of performance.[12] In vestibular stimulation, cradled rocking score showed minimal difficulty in ease of performance.[13-15] The main finding of the present study is that almost all components exhibited excellent agreement. Thus the early intervention protocol was well appreciated by majority of experts and was considered to be the most integral part of early intervention to preterm infants.

Limitation: Experts were recruited only from the Southern parts of India for the validation process.

Conclusion

The early intervention protocol exhibited excellent content validity to its use in Indian population. The protocol is safe and can be administered to infants.

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