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Development and Validation of a Data Collection Instrument for Identifying Adaptive Clothing Requirements in People with Spinal Cord Injury

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Abstract

The term 'spinal cord injury' (SCI) refers to the damage to the spinal cord that results from trauma (e.g. a car crash) or from disease or degeneration (e.g. cancer). (WHO, 2013) In addition to the challenge of paralysis, individuals with spinal cord injury also develop several secondary conditions that can be extremely debilitating. A person's self-image is significantly influenced by their clothing. Since the 1960s, researchers have investigated clothing solutions that address multiple problems (Hallenbeck, 1966; Phipps, 1977; Schwab & Sindelar, 1973), but they found that the nature of individually distinct disabilities appeared to defy general solutions. (Carrol, 2001). To address this critical gap, this study reports on the development and content validation of a new, user-centered instrument designed to systematically assess the clothing-related challenges faced by individuals with SCI, adopting a 'conceptual framework for inclusive adaptive clothing'. A methodological study was conducted to examine the content validity of the user-centred instrument through a three-phase process of development, recruitment of experts, and quantitative assessment by using Lawsche's content validity ratio. The developed instrument consists of three sections i.e., the psychological state, the psychological state, physical Limitation, and the clothing needs of the user. A panel consisting of 16 professional experts from the apparel industry, spinal injury rehabilitation, SCI patients, and their caregivers was reached out for content validity testing. For quantitative computing of content validity, the Content Validity Ratio (CVR) was calculated, and each item was compared with the minimum value of CVR of 0.50 for all 16 experts as given by the Lawsche table. Items with a CVR of more than 0.50 were retained, and others were removed. From a set of 31 items, the content validity process identified that five items had CVR less than 0.50; hence, the final version of the instrument consisted of 25 items. An examination of the instrument's content validity showed that it is at the appropriate level. Although the instrument's overall content validity index was low, it can be supported given the large number of content experts who made consensus challenging and the high value of the S-CVI with the average approach, which was equivalent to 0.86

The study led to the development of an instrument consisting of 26 items on the psychological and anatomical discomfort experienced by individuals with SCI. This validated instrument provides an essential foundation for the future development of inclusive and user-centric clothing solutions for the SCI community.

Keywords: Spinal cord Injury, Data collection instrument, content validity, Inclusive clothing, psychological discomfort, anatomical discomfort

Introduction

The broader aspects of studies in design and social science research require quantification of abstract, intangible attributes that are essential to critically analyze the key gap in the research area. (Miller, et al., 2009). In this scenario, researchers always wish to know if the employed instrument measures the intended variable or research concept. (Bolarinwa, 2021) Content validation refers to a process that aims to provide assurance that an instrument (checklist, questionnaire, or scale) measures the content area it is expected to measure (Stromberg & Olsen, 2004). Validity is not the property of an instrument, but the property of the scores achieved by an instrument used for a specific purpose on a special group of respondents (Zamanzadeh, et al., 2015). One way of achieving content validity involves a panel of subject matter experts considering the importance of individual items within an instrument. Lawshe's method, initially proposed in a seminal paper in 1975 (Lawshe, 1975), has been widely used to establish and quantify content validity in diverse fields (Wilson & Schumsky, 2012) It involves a panel of subject matter "experts" rating items into one of three categories: "essential," "useful, but not essential," or "not necessary." Items deemed "essential" by a critical number of panel members are then included within the final instrument, with items failing to achieve this critical level discarded. Lawshe (1975) suggested that, based on "established psycho-physical principles," a level of 50% agreement gives some assurance of content validity.

When a new instrument is designed, measurement and report of its content validity have fundamental importance (Zamanzadeh, et al., 2015). Therefore, this study is focused on conducting to design and examining the content validity of the instrument to assess the requirements of people with spinal cord injury.

Methodology

Study design

This research is part of a larger mixed-method research conducted to develop inclusive adaptive clothing for people with spinal cord injury in India. To understand the complex state of people with spinal cord injury, it was essential to develop a valid instrument for data collection. Both qualitative and quantitative reviews have been collected from the expert panel from the National Institute of Fashion Technology, New Delhi, and the Indian Spinal Injury Centre, New Delhi. All ethical considerations were addressed, including approval from the Ethical Committee National Institute of Fashion Technology, New Delhi, and the Indian Spinal Injury Centre, New Delhi, anonymity, respondent's consent, and withdrawal from the study at any stage.

The study was conducted in four phases, including: Instrument Design, Qualitative review, expert panel selection, and quantitative review .

1. **Instrument design:.** To develop the instrument, a three-step process is performed, including determining the content domain, item generation, and instrument construction. (Zamanzadeh, et al., 2015; Nunnally & Bernstein , 1999) As the intent of the instrument is to evaluate the factors influencing the clothing experience of people with spinal cord injury, hence 'Inclusive Adaptive clothing framework' has been adopted for defining the content area. The key attributes of the framework for a holistic approach (1) the physical state: physical limitation due to disability; (2) the

psychological state: mental state due to everyday challenges; and (3) the clothing needs of the user: understanding the aesthetic, functional and expressiveness (trends) needs of users (Chauhan, et al., 2023). The framework provided the precise definition of the attributes and characteristics that are essential for the item generation. Further qualitative research method can also be applied to determine the variables and applicable theory. (TILDEN, et al., 1990) The third step in instrument design is construction, in which the items are refined and organised in a suitable format and sequence in order to generate a structured form. (Zamanzadeh, et al., 2015) The developed instrument consisted of 9 sections and 30 items. The quantitative data is collected through interviews from people familiar with the concept of inclusive adaptive clothing, including a person with a spinal cord injury, an occupational therapist, and a design thinker.

2. **Recruitment of Expert panel:** This phase comprises the details of the number of experts for considering the importance of individual items within the instrument. (Ayre & Scally, 2014). The conscious selection of an expert is essential, as rational analysis of the instrument by the expert enhances the content validity of the instrument. (Bolarinwa, 2021) Determining the number of experts has always been partly arbitrary; however, at least five people are recommended to have sufficient control over chance agreement. (Zamanzadeh, et al., 2015). As the expert panel size increases, the likelihood of chance agreement decreases, improving the rigor of the evaluation. (Zamanzadeh, et al., 2015) To obtain the comprehensive feedback, a total of 16 experts, including a person with spinal cord injury, both para and tetraplegic, an Occupational Therapist, psychologist, physiotherapist, Design Professional, adaptive clothing designer, and caregivers, validated the items of the developed questionnaire.
3. **Quantitative Review: Lawshe's Content Validity Ratio : For** computing content validity quantitatively, the Content Validity Ratio (CVR) was calculated (Lawsche, 1975). In this method, a panel of subject matter experts (SMEs or teams of experts) was asked to indicate whether or not a measurement item in a set of all measurement items is essential to the operationalization of a theoretical construct or not. For documentation of the quantitative review, a spreadsheet was generated in which 31 items were included. Thus, experts were asked to rate the item on the scale as
   - Essential - 1
   - Useful but not essential -2
   - Not necessary – 3

After receiving each expert's ratings, values were entered into a spreadsheet, and CVR was calculated for each item on the formula developed by Lawshe

CVR = (Ne-N/2) / (N/2)

CVR = CVR value for the nth measurement of the item

Ne = Number of experts who rated an item as essential

N = Total Number of an expert in the panel

Results:

During the Instrument design stage, a total of 30 items were generated based on a literature review and qualitative interaction from subject matter experts. These generated items are systemically divided into three sections and colour-coded:

The psychological state	The physical Limitation	Clothing need of user

The generated items were circulated amongst the 16 subject matter experts, in which every item is colour coded based on the category, along with the intent of the question, for a better understanding of the question that will result in a more conscious decision of the expert. (Table:1)
Then the value of the computed value of CVR of each item was compared with the minimum value of CVR, that is 0.49 for 15 expert members as given by the Lawsche table, and items having CVR of more than 0.49 were retained, and others were removed, and then obtained questionnaire was again expert members again reviewed reviews.

	Questions	Intent	CVR Ratio
Item 1	Do you feel that there is a lack of availability of modest clothing for people with mobility impairment?	To understand the respondent's perespective towards available clothing options	0.75
Item 2	Which option of clothing, do you prefer more while shopping	To understand extent of the consciousness and awareness about the available clothing options	0.75
Item 3	Is athleisure* clothing is part of your wardrobe (*Athleisure clothing: ATHLETE + LEISURE: a fashion trend that includes clothing designed to be worn for athletic activities or casual social events and even wore at the workplace.)	As the research is focused on athleisure wear hence it is essential to understand the extent of its acceptance by the respondent.	0.125
Item 4	How much brand conscious are you while shopping for apparels?	To understand the impact of clothing brand on acceptance of clothing	0
Item 5	How long it has been that you got Spinal Cord Injury	To track the variance in responses with respect to passage of time of injury	0.875
Item 6	Please specify the cause of your Spinal cord Injury	To analysis the impact of cause of injury and body image	-0.125
Item 7	Please mention your degree of paralysis due to Spinal Cord Injury	To categories and analyse the response based on their physical state	0.875
Item 8	How often do you require to visit a rehabilitation centre for physical or psychological consultation	To understand the frequency of the exposure of the respondent to the expert consultation in term of their physical and psychological state	0.5

Item 9	Are you able to accept your bodily appearance after Spinal cord injury?	To understand the extent of acceptance of bodily appearance after injury	0.625
Item 10	From below given categories, how do you categorise your ability to dress 'lower body'	To understand the physical capability of dressing the upper body	0.875
Item 11	From below given categories, how do you categorise your ability to dress 'upper body' Mark only one oval.	To understand the physical capability of dressing the lower body	0.875
Item 12	How would you rate your quality of life?	To understand the psychological state and respondent view point towards life	0.375
Item 13	Which mobility aid do you prefer to use for a maximum of hours on a normal day	To understand the interaction of mobility aid with clothing and body	0.75
Item 14	How much are you satisfied with your ability to perform daily living activities (e.g. self-care personal grooming, dressing etc)	To understand the psychological impact of incapability preforming daily activity due to injury	0.6
Item 15	To what extent do you feel your life is meaningful	to understand the respondent's psychological state and response towards situation of life	0.125
Item 16	How satisfied are you with the attributes of available ready-to-wear clothing (especially bottom wear)		
16.a.	Fit, Movement and Comfort	To understand the satisfaction level of respondent towards available ready to wear clothing in terms of functionality and aesthetic	1
16.b.	Fabric Quality		0.875
16.c.	Easy to put on and take off		1
16.d.	Aesthetics appearance of the garment: colour, style, print, etc		0.875
16.e.	Overall experience		0.75
Item 17	Please choose the most appropriate option, In terms of how ofen do you experience the similar situation		
17.a.	Got skin infection caused by sweating due to long seating hours	To understand the medical complications faced by the	1

17.b.	Faced complications related to pressure sores in your lower body	respondent due to changed lifestyle as a result of injury	1
17.c.	Faced issue of wearing out of clothes due to use of mobility aids		0.75
Item 18	Have you used adaptive clothing in the last six months? (Adaptive clothing: Clothing Designed with medical functionality in mind to overcome physical limitation due to conditions like ageing, impairment, or post surgery.)	To categorize the respondent for further responses	1
	IF YES		
Item 19	How satisfied are you with current adaptive clothing		
19.a.	Aesthetics	to understand the satisfaction level towards adaptive clothing in terms of functionality and aesthetic	1
19.b.	Fit and Comfort		0.875
19.c.	Construction and Finishing		1
19.d.	Easy to put on and take off		1
19.e.	Managing fasteners and zippers		1
19.f.	Protection against infections		0.875
19.g.	Fabric Quality		0.875
19.h.	Durability		0.875
19.i.	Availability of the product in market		0.875
Item 20	Does adaptive Clothing makes you feel		
20.a.	More confident	To understand the psychological influence of adaptive clothing and self-imaging of the respondent	0.625
20.b.	More independent		0.875
20.c.	Different from others		0.75
20.e.	Highlight your impairment		0.625
20.f.	Helps to reflect your personality as an individual.		1
	Non-user of adaptive clothing		
Item 21	Rate the reasons for not using adaptive clothing		
21.a.	Non-Availability		1

21.b.	Price Range	To understand the product related limitations for adopting the adaptive clothing	0.875
21.c.	Aesthetic		0.875
21.d.	Fabric Quality		0.875
21.e.	Makes you feel that, it would highlight your impairment	Pyschological barrier in adoption of adaptive clothing	0.75
	Consumer need assessment		
Item 22	How often do you consider garment as a tool to		
22.a.	reflect your personality and mood	To understand the respondent's relation with clothing to expressing their individuality	0.625
22.b.	enhance your confidence		0.625
22.c.	mingle in a specify community or group		0.75
22.d.	conceal your assistive aid/impairment	Psychological barrier in adoption of adaptive clothing	0.75
Item 23	How important are the following functional feature while selecting the bottom wear for yourself?		
23.a.	Fit and comfort	To understand the consumer functional needs related to clothing	0.75
23.b.	Specialized fabrics like moisture wicking and antimicrobial properties		0.875
23.c.	Catheter concealment		0.875
23.d	Fasteners for easy take off and on		0.875
Item 24	How important are the below-mentioned features while selecting the bottom wear for yourself		
24.a.	Aesthetic (Design elements of garment, like color, texture etc)	To anaylse the areas to prioritize while developing the end product	0.875
24.b.	Silhouette (outline of the garment, like baggy or body fitted)		1
24.c.	Inclusivity of design: it would be for all, beyond the ability of a person		0.875
24.d.	Availability in market		1
24.e.	Competitive Price range		0.75
Item 25	Which silhouette/silhouettes would you like to prefer for your athleisure bottom wear?	To analyse the more preferable silhouette by the respondent	0.625

Item 26	Which aesthetic detail/ details would you prefer for the athleisure bottom wear?	To analyse the detailing preferences for the bottom wear	0.625
Item 27	Which colour palette/palettes would you like to prefer for your athleisure bottom wear	To analyse the colour preferences for the bottom wear	0.75
Item 28	Any additional comments on further improvement of size, fit, style and design for professional bottom wear for wheelchair users?	To gather the data if any respondent want to share their specific view point towards the clothing	0.75
Item 29	Gender	To further categories the responses of women and men separately	0.875
Item 30	Age	To analyse the impact of age on the responses and preferences	1
		CVI	8.5964

Table 1 (above): Items in the instrument with colour code and CVR Ratio

Conclusion

Content validity is a systematic four phase process that is essential to develop valid research instrument for a rigorous examination of the primary gap in the research field. It’s a lengthy process including instrument design, expert recruitment and qualitative-quantitative review. Understanding validity is crucial to ensure that instrument used for study is suitable for the construct especially when conducting research involve vulnerable population. As the designed instrument was intent to study the clothing needs of people with spinal cord injury hence to ensure that instrument capture the experience, conditions and perspective of the population. Vulnerable population often exhibit unique characteristics therefore establishing content validity ensures that all relevant domains are comprehensively and appropriately addressed, enhancing both the accuracy and relevance of findings.

An assessment of the instrument's content validity indicated that it is at the requisite level. Despite the instrument's overall content validity index being low, it is justifiable due to the substantial number of content experts that complicated consensus and the elevated S-CVI using the average method, which was 0.86.

The research resulted in the creation of a tool of 25 questions addressing the psychological and anatomical discomfort encountered by individuals with spinal cord injury (SCI). This verified instrument establishes a crucial basis for the future advancement of inclusive and user-centered apparel solutions for the SCI community.

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