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Original Article

Physical Medicine and Rehabilitation Section

Development of a Screening Tool for Analysing the Risk of Acquiring Cognitive Decline in Middle-aged Adults using the Modified Delphi Technique

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ABSTRACT

Introduction: In India, cognitive decline is increasingly recognised as a midlife concern; one in ten individuals exhibits signs of cognitive decline after age 45 years. Demographic variations, lifestyle behaviours, and physical and mental capacities influence heterogeneous trajectories of cognitive function. Declines in cognition adversely affect task performance and daily functioning, undermining occupational capacity and overall health and wellbeing. Early identification of at-risk middle-aged adults may enable targeted prevention and health-promotion interventions.

Aim: To achieve expert consensus on a novel screening tool for identifying the risk of cognitive decline in middle-aged adults using the modified Delphi technique.

Materials and Methods: A consensus study using the modified Delphi technique was conducted from July 2024 to March 2025 at Mahatma Gandhi Occupational Therapy College, Jaipur, Rajasthan, India. Three rounds of the modified Delphi method were utilised. A panel of multidisciplinary experts was selected, comprising individuals with at least a Master's degree in their respective disciplines and at least 10 years of experience in the field. In Rounds 1 and 2, experts rated item relevance on a 5-point Likert scale; Round 3 focused on establishing the Content Validity Index (CVI). Statistical analysis was conducted using the median and Interquartile Range (IQR), along with item- and scale-level CVI, to compute universal agreement.

Results: An initial pool of 30 items was designed, from which the panel reached consensus on 18 (60%) and 20 (83.3%) items in the first two rounds, respectively. Three items were removed after achieving >75% consensus for disagreement, with a wider IQR and higher variability. Using an I-CVI threshold of ≥0.79 in the final round, 20 items met content-validity criteria and were retained in the final instrument. The CVR and CVI values on the scale were 0.78 and 0.89, demonstrating good content validity of the tool, with a 65.2% rate of universal agreement.

Conclusion: The 20-item screening tool was developed through structured expert consensus and demonstrates strong content validity. This tool could facilitate the identification of middle-aged adults at risk of cognitive decline and inform preventive and health promotion strategies.

Keywords: Cognitive dysfunction, Content validity, Health promotion, Risk assessment

INTRODUCTION

Cognitive decline has increasingly been recognised as a midlife concern, with one in ten individuals exhibiting signs of cognitive decline after the age of 45 years in the Indian population, with a significant impact on occupational performance and daily participation [1]. The Longitudinal Ageing Study in India (LASI) reported the 6% of adults aged 45 to 60 years with early signs of cognitive decline had mean composite cognition scores in the lowest 10th percentile, with 3% males and 7.2% females [2]. This data indicates that middle adulthood (ages 40 to 60 years) may be a critical window during which multiple risk factors converge to influence cognitive outcomes later in life, underscoring the need to identify individuals at risk for cognitive decline to promote health [3].

Heterogeneous trajectories of multiple risk factors have been identified as associated with cognitive decline, including both protective factors, such as social engagement, diet, and formal education, and risk factors, such as low levels of physical activity, alcohol and tobacco consumption, sleep difficulties, and obesity [4,5]. Most available tools can evaluate cognitive functions, such as the Montreal Cognitive Assessment (MoCA) or Mini-Mental State Examination (MMSE), yielding results indicating the presence or absence of mild cognitive impairment, but they are limited in detecting early risk of cognitive decline [6]. Few tools exist to assess the risk of cognitive decline; one is the Australian National University Alzheimer's Disease Risk Index (ANU-ADRI), developed to identify the risk of Alzheimer's disease in the Australian context, or the United Kingdom Biobank Dementia Risk Prediction (UKB-DRP) for citizens of the United Kingdom [7]. These tools were developed on an older population of 70+ years primarily to identify the risk index of Alzheimer's disease and validated among Western populations with different lifestyles and cultural backgrounds [8,9]. No such tool exists in the Indian context to identify the risk of cognitive decline in early middle adulthood, while accounting for variability in socio-economic status and access to literacy and healthcare across rural and urban settings. This study aimed to develop a screening tool for middle-aged adults aged 40 to 60 years to identify the risk of cognitive decline using the modified Delphi technique and to establish content validity using the CVI.

MATERIALS AND METHODS

The study employed a consensus study design, using a modified Delphi technique and content validity assessment conducted from July 2024 to March 2025, and developed a screening tool to identify the risk of cognitive decline among middle-aged adults in the Indian population. The study was conducted at Mahatma Gandhi Occupational Therapy College, Jaipur, Rajasthan, India. The study was approved by the Institutional Ethics Committee (IEC) of Mahatma Gandhi University of Medical Sciences and Technology (IEC Number: MGMC&H/JPR/2024/1887). It included two stages: 1) Developing the draft of the tool based on the literature review; and 2) a modified Delphi process to achieve consensus.

Literature review and item generation: The literature review was conducted to identify modifiable determinants of cognitive decline in cognitively healthy adults aged 40 to 60 years. The following databases, including PubMed, PLOS ONE, BMJ Open, and PsycINFO, were searched for English-language articles published from January 2011 to January 2024. Studies that examined associations between modifiable risk determinants and cognitive decline were included. In contrast, studies involving clients with dementia or mild cognitive impairment, or those using blood-based biomarkers, were excluded. The primary and corresponding authors performed a preliminary search, and screening was conducted on titles, abstracts, and full texts.

The included studies were mostly longitudinal or cohort-based and identified more than 30 risk determinants across five thematically distinct categories [1,10-22]. Two categories of non-modifiable factors were identified: socio-demographic factors (age, gender, socio-economic status, marital status, living conditions, and level of education) and higher sensory functions (vision, olfactory function, and hearing abilities) [22-24]. Three categories of modifiable risk determinants were identified: physical and mental capacities; lifestyle routines and habits; and the number of chronic conditions an individual has [25,26]. Based on the identified modifiable determinants, the first draft of the tool was prepared with 30 items for review in the modified Delphi process to achieve consensus.

Modified Delphi method: The 3-step modified Delphi methodology was used to establish the tool's validity, including the CVI and Content Validity Ratio (CVR) at both item and scale levels. This method has been a reliable measure of developing consensus for clinical problems in the healthcare system. The study was conducted in accordance with the Guidelines on Conducting and Reporting Delphi Studies (CREDES) Checklist [27]. The modified Delphi technique has been considered superior due to its more cooperative nature and its effectiveness in achieving consensus, and the 3-round process was considered to reduce the risk of participant fatigue and attrition [28].

Selection of the experts was based on the following criteria: a minimum of a master's degree in their respective fields and 10 years of clinical experience. A panel of multidisciplinary experts, including occupational therapists, speech-language pathologists, clinical psychologists, physiatrists, neurologists, and nutritionists, was selected to consider diverse perspectives. Trevelyan EG and Robinson N and Škrinjar I et al., study supports selecting a 10- to 15-member panel in each round to reduce the risk of attrition and considers panel members with multidisciplinary backgrounds and higher qualifications [29,30]. Baseline demographic information was gathered for all experts to support invitations at different stages of the process and to ensure a balanced representation of regions across the country. The cover letter, informed consent, study information sheet, and a copy of the draft tool were sent via email to the experts selected through purposive sampling, with an expected response time of 30 days or less. The anonymity of responses was maintained throughout the process to avoid bias and ensure clear communication of insights on the topic.

Data collection and analysis: In the first round, experts were asked to rate the Level of agreement of each item on a 5-point Likert scale, ranging from 1 (strongly disagree) to 5 (strongly agree). Additional input, in the form of comments and suggestions, was requested for the expert's opinion. Consensus was predefined as 75% agreement for an item, meaning an item is considered agreed upon when 75% of respondents rate it 4 or 5. Meanwhile, consensus on disagreement with an item was established if 75% of respondents scored 1 or 2 on a particular item. Ambivalence of an item or no consensus was reached for items receiving 75% or more rating with scores of 3 [31]. A threshold of 75% was consistent with literature suggesting it to be the median threshold value for Delphi studies and widely accepted across healthcare research [32]. In the second round, based on the received responses, items achieving consensus were kept, items with disagreement were removed, and items that hadn't received consensus were reviewed, revised, or merged and moved forward to the next round. Suggestions and comments on the items were requested in each round to help refine the tool.

In the third round, the items that passed rounds 1 and 2 were categorised by essentiality, and the CVI at the scale level was calculated using Lawshe's methodology, which is widely used to assess the content validity of tools [33]. All the items were rated into two categories, namely essential (scored as 1) and non-essential (scored as 0), along with comments and suggestions by the experts. Based on the number of experts who considered an item essential, the CVR, item-level CVI (I-CVI), and scale-level CVI (S-CVI) were calculated for each item. Using Lynn's work, a minimum I-CVI of 0.79 or higher indicates the item would be included; a value between 0.70 and 0.79 suggests revision; and a value of less than 0.70 would be removed [34]. Ayre C and Scally AJ considered the minimum threshold for the S-CVR for a 10-member panel to be 0.65, along with the calculation of universal agreement to assess the tool's content validity [33].

STATISTICAL ANALYSIS

All responses from all three rounds were tabulated and analysed in Microsoft Excel. For the first two rounds, descriptive statistics were computed using measures of central tendency (median) and IQRs for each item to assess the variability of expert ratings. For the third round, the CVR, Item- and Scale-level CVI (I-CVI and S-CVI), and universal agreement were calculated to assess content validity.

RESULTS

Initially, a set of 30 items was generated to undergo the modified Delphi process. The items were established based on a literature review and underwent multiple reviews by the authors and the parent organisation to improve clarity and reduce wordiness. Demographic details of the experts involved in the study are mentioned in [Table/Fig-1]. In the first round, 15 participants were emailed, with an 80% response rate, and 12 experts completed the forms within the timeframe. Round 2 had a response rate of 62.5%, with 10 of 16 experts completing the forms. The third-round response rate was 66.66%, with 10 out of 15 experts submitting their responses. All rounds included different experts from different disciplines to provide a multidisciplinary perspective. [Table/Fig-2] presents a flowchart showing the number of experts who participated in the study. Heterogeneity in backgrounds and geographic locations was considered when selecting the expert panel to ensure diverse perspectives on the tool and to include a broader range of geographic regions.

Multidisciplinary experts (Total experts - 32)	Occupational therapists	22 (68.75%)
	Neurologists	03 (9.37%)
	Physiatrists	02 (6.25%)
	Clinical psychologist	02 (6.25%)
	Speech language pathologist	02 (6.25%)
	Nutritionist	01 (3.13%)
Gender	Male	21 (65.63%)
	Female	11 (34.37%)
Education	Fellowships programs post masters	04 (12.5%)
	Masters degree	17 (53.13%)
	Doctorate	11 (34.37%)
Experience (in years)	10 to 15	11 (34.37%)
	15 to 20	08 (25%)
	>20	13 (40.63%)

[Table/Fig-1]: Demographic data for experts who participated in the modified Delphi panel of all 3 rounds.

Round 1	Round 2	Round 3
• Email shared: 15 • Responses received: 12 • Response rate: 80%	• Email shared: 16 • Responses received: 10 • Response rate: 62.5%	• Email shared: 15 • Responses received: 10 • Response rate: 66.66%

[Table/Fig-2]: Expert participation in 3 rounds of the modified Delphi process.

For the first round, of the 30 items reviewed, 18 reached consensus, with some items achieving full consensus, such as age and gender (Median=5.00; IQR=0.00), and were included in the final tool. Though three items (employment status, marital status, and odour identification) reached consensus on disagreement (median ≤2.00, IQR > 2.00), wider IQRs and variability scores were observed, reflecting weak consensus and a directive of limited relevance to the tool. Although living arrangements also received a median of 1 and an IQR of 3, it was reconsidered for the second round due to cultural adaptation of the tool, as in the Indian population, varied living situations could impact cognitive decline. The authors and the panel members suggested reviewing it with reference to the target population. After reviewing all the comments and considering the consensus scores, these items were removed from the tool. The nine remaining items were considered ambivalent, with moderate variability and wider IQR (e.g., dietary habits, self-rated mental health, frequency of alcohol and tobacco), and were either revised or three items were merged based on the feedback and comments received; 24 items were moved to the second round [Table/Fig-3].

For the second round, 24 items were reviewed and re-evaluated by the experts, and most items (20, 83.33%) reached consensus, with an overall agreement rate of 89.0%. Most items gained strong consensus (median=5.00, IQR=0) and were included in the tool. Some items, such as self-rated mental health, spiritual activities, social participation, and adjustments to schedules, showed improved agreement (Median=4-5, IQR ≤1). [Table/Fig-3] presents the median and IQR for the 24 items across rounds 1 and 2. Persistently low-rated 4 items (residential status, living arrangement, adjustment to living situation, frequency of tobacco or alcohol) remained non-consensual due to wider IQRs, reinforcing exclusion from the scale. However, after reviewing comments and consensus results, the authors decided to re-evaluate all 24 items in the final third round. If the item-level CVI also suggests removal, the items will be removed from the final tool [Table/Fig-3].

In the third round, a 10-member expert panel was selected to evaluate the tool's content validity. [Table/Fig-4] presents item-level results for the CVR and CVI of the tool's content validity. Fifteen items achieved a unanimous consensus (CVR=1.0, I-CVI=1.0), including socio-demographic, physical, and mental capacities, as well as routine habits such as sleep, leisure, and dietary patterns. Five items achieved high CVR and I-CVI values, including body structure (CVR=0.8, I-CVI=0.9), spiritual activities (CVR=0.8, I-CVI=0.9), alcohol and tobacco habits (CVR=0.8, I-CVI=0.9), and medication use (CVR=0.8, I-CVI=0.9). Four items received low scores on both CVR and I-CVI, including frequency of alcohol or tobacco use, living arrangement (CVR=0.2, I-CVI=0.6), and residential status and adjustment to living situation, which had extremely low values (CVR=-0.2, I-CVI=0.4), leading to exclusion from the tool [Table/Fig-4]. The scale CVR and I-CVI values (S-CVR=0.78, S-CVI=0.89) exceeded the minimum threshold of 0.65, confirming the scale's strong overall content validity. Polit DF and Beck CT recommended calculating universal agreement as the proportion of items that received a unanimous expert response among all items evaluated; 65.2% of items reached universal agreement, indicating high consensus [35]. [Table/Fig-5] shows the overall refinement process for the items in the three rounds of the modified Delphi technique.

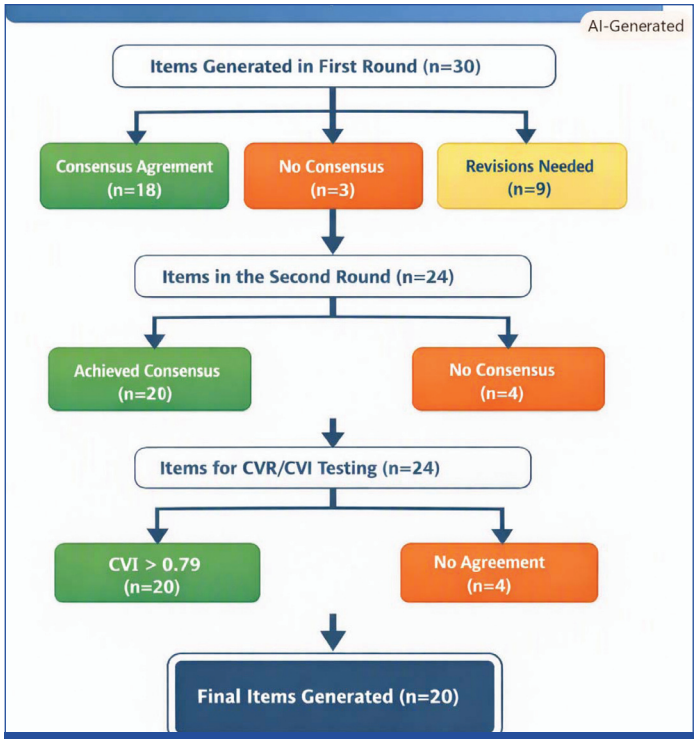
Item	Median R1	IQR R1	Median R2	IQR R2	Consensus change
Age	5	0	5	0	Stable, perfect consensus
Gender	5	0	5	0	Stable, perfect consensus
Level of education	5	1	5	1	Acceptable; consensus achieved
Socio-economic status	5	1	5	1	Acceptable; consensus achieved
Employment status	1	3	-	-	Removed after 1st round
Occupation	5	0	5	1	Acceptable; consensus achieved
Residential status	2	1	2	2	Persistently low consensus
Marital status	2	3	-	-	Removed after 1st round
Living arrangement	1	3	2	1	Persistently low consensus
Odour identifiaction	1	3	-	-	Removed after 1st round
Body structure	4	1	4	1	Acceptable; consensus achieved
Physical activity	5	0	5	0	Stable, perfect consensus
Memory difficulties	5	0	5	0	Stable, perfect consensus
Loneliness	5	1	5	1	Acceptable; consensus achieved
Adjustments to schedules	4	2	4	1	Acceptable; consensus achieved
Unhealthy mental days in a month	2	3	-	-	Merged with item 17
Self-rated mental health	3	1	4	2	Acceptable; consensus achieved
Leisure activities	5	1	5	1	Acceptable; consensus achieved
Sleep difficulties	5	0	5	1	Acceptable; consensus achieved
Spiritual activities	4	1	5	1	Acceptable; consensus achieved
Social participation	5	1	4	1	Acceptable; consensus achieved
Adjustment to living situation	3	1	2	1	Persistently low consensus
Weekly food consumption	5	1	5	1	Acceptable; consensus achieved
Dietary patterns -2 servings of fresh fruits/vegetables	2	3	-	-	Merged with item 23
High sugar/cereal diet	4	1	4	1	Acceptable; consensus achieved
Alcohol/tobacco habits	5	0	5	1	Acceptable; consensus achieved
Consumption patterns	3	2	5	1	Acceptable; consensus achieved
Frequency of alcohol drinks	3	2	2	2	Median decreased, weak consensus
Frequency of tobacco	2	3	-	-	Merged with item 28
Medications use	4	1	4	1	Acceptable; consensus achieved

[Table/Fig-3]: Median and IQR for Round 1 and 2.

Item	ne*	CVR†	I-CVI‡	Consensus
Age	10	1.0	1.0	Yes
Gender	10	1.0	1.0	Yes
Level of education	10	1.0	1.0	Yes
Socio-economic status	10	1.0	1.0	Yes
Occupation	10	1.0	1.0	Yes
Residential status	4	-0.2	0.4	No
Living arrangement	6	0.2	0.6	No

Body structure	9	0.8	0.9	Yes
Level of physical activity	10	1.0	1.0	Yes
Memory-related difficulties	10	1.0	1.0	Yes
Loneliness	10	1.0	1.0	Yes
Adjustments to changing schedules	10	1.0	1.0	Yes
Self-rated mental health	10	1.0	1.0	Yes
Leisure activities engagement	10	1.0	1.0	Yes
Sleep difficulties	10	1.0	1.0	Yes
Spiritual/religious activities	9	0.8	0.9	Yes
Social participation	10	1.0	1.0	Yes
Adjustment to living situation	4	-0.2	0.4	No
Dietary patterns – weekly food consumption	10	1.0	1.0	Yes
Dietary patterns – high sugar/cereal diet	10	1.0	1.0	Yes
Alcohol consumption habits	9	0.8	0.9	Yes
Tobacco consumption habits	9	0.8	0.9	Yes
Frequency of tobacco/alcohol	6	0.2	0.6	No
Medications use	9	0.8	0.9	Yes

[Table/Fig-4]: Item-level CVR and I-CVI values demonstrating content validity results of the 3rd round.
*ne- number of experts who marked essential for an item, †- Content Validity Ratio, ‡- Content Validity Index



[Table/Fig-5]: Flow diagram representing the modified Delphi process used for development of the tool.

The final tool comprised 20 items and achieved high item- and scale-level consensus through three rounds of the Delphi study, demonstrating strong content validity and serving as the final multifactorial screening tool for assessing the risk of cognitive decline.

DISCUSSION

This study developed a 20-item screening tool to assess the risk of cognitive decline among middle-aged adults of 40 to 60 years. The tool has been developed in English for use among the Indian population, using the modified Delphi technique to achieve consensus through expert-led input, with anonymity maintained to reduce bias. The findings of the tool align with existing studies showing that midlife risk factors strongly affect cognitive outcomes in later stages, including subjective memory difficulties that impair executive functioning and participation in daily routines.

Items with unanimous consensus, such as levels of physical activity, mental health, levels of leisure and social participation, or sleep schedules, have significant clinical relevance. A study in 2016 identified the correlation of low levels of physical activity with increased chances of depression, which could lead to accelerated cognitive decline among 50 to 60-year-old [13]. Zaninotto P et al., explored the impact of multiple factors on cognitive decline alongside age trajectories and identified that with increasing age, consumption of alcohol, reduced physical function, and continued smoking could lead to faster cognitive decline at the later stages, aligning with the results of high consensus on these items during the consensus process [16]. Literature suggested the association between social determinants of cognitive decline as people who had hobbies, enhanced social support, and active leisure engagement had better cognitive outcomes at later stages, identifying these factors as important for risk analysis in the middle-aged group [36,37].

Meanwhile, some items achieved moderate levels of agreement, such as spiritual activities, body structure, and use of medications for previously diagnosed conditions, including diabetes and hypertension, as these items were retained due to their significant clinical relevance, though they showed slight variability across expert settings. Evidence revealed the association between type 2 diabetes and poor glycaemic control among 35- to 55-year-old adults, with a 45% rapid decline in memory, 29% in reasoning, and 24% in global cognitive functions, indicating accelerated cognitive decline [12]. A negative correlation was identified between high systolic blood pressure and smoking with cognitive decline, although cholesterol did not reveal any association with cognitive decline [11]. Other studies revealed a positive association between chronic obesity and cognitive decline, while a negative association was found between underweight and cognitive outcomes, considering body structure as an important clinical item in the tool [17,38]. Items like residential status, adjustment to living situation, or frequency of substance use didn't meet the agreement criteria for consensus and were excluded.

Overall evidence from the literature, combined with the three process-modified Delphi results showing 65.2% universal agreement and an S-CVI of 0.89, indicates strong content validity and further supports the novel tool's validity. The use of a multidisciplinary expert panel would be a strength of the study, as it would consider diverse perspectives and, together with the robust modified Delphi approach, promote rigorous refinement of tool items within a comprehensive framework.

Limitation(s)

Limitations included a relatively small panel size, attrition bias due to varying response rates, a need for broader cross-cultural validation for wider application, and the need for further psychometric testing to evaluate reliability and assess the generalisability of the results.

Recommendations to further study the tool through pilot testing in communities and to conduct factor analyses or longitudinal studies to determine the tool's predictive value. To ensure broader adaptability, cross-cultural adaptation or translation to different languages could be done.

CONCLUSION(S)

The tool integrates multiple health-associated modifiable risk factors for middle-aged adults, making it suitable for screening and prevention. The developed tool facilitates the identification of individuals at risk of cognitive decline, supporting health professionals and occupational therapists in designing targeted health promotion and intervention strategies to enhance cognitive health.

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