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Original Research Article

Preliminary psychometric testing of a novel cognitive decline risk screening tool for middle-aged adults of 40 to 60 years: a pilot study

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ABSTRACT

Background: The cognitive decline risk screening tool (CDRST) was developed using the modified Delphi technique for adults aged 40 to 60 years to identify cognitive decline risk. This pilot study assessed the tool's internal consistency and developed preliminary cut-off scores.
Methods: Community-dwelling adults aged 40 to 60 years who attended the outpatient clinic were included through convenience sampling. Analysis included descriptive statistics, Cronbach's alpha, an inter-item correlation matrix with Spearman's rank correlation, and scale cutoff scores identified using the standard deviation method (Mean±SD).
Results: 103 individuals participated, with a mean age of 50.1±6.55 years. Cronbach's alpha was 0.81, and the inter-item correlation matrix ranged from -0.02 to 0.62, indicating low to moderate correlations. A cut-off score of ≥43.64 (≥Mean+1SD) was noted, with 14.56% as high risk.
Conclusions: The CDRST showed good reliability, with all items contributing to the tool's overall construct, and exploratory score cutoffs provided a preliminary risk-stratification framework.

Keywords: Health promotion, Risk assessment, Cognitive dysfunction

INTRODUCTION

In India, cognitive decline has been a significant health concern in middle adulthood, affecting 1 in 10 individuals aged 45 and older, with 6% (3% males, 7.2% females) of adults showing early signs of decline.[1] Large-scale studies such as the longitudinal aging study in India (LASI) and Harmonized Diagnostic Assessment of Dementia (LASI-DAD) provided evidence that cognitive decline is accelerated through modifiable risk factors such as cardiovascular disease, limited education, lack of physical activity, or reduced social participation, and could increase the risk, with effect sizes larger than global estimates for the Indian population, underlying the urgency of preventive approaches.[2,3] Multiple modifiable risk factors have been associated with cognition in heterogeneous trajectories, such as physical activity, nutritional status, consumption of alcohol and tobacco, sleep habits, obesity, or any associated chronic condition, such as hypertension or diabetes.[4-8] Recent findings revealed an association among middle-aged adults between a sedentary lifestyle, frequent sleep difficulties, and unhealthy lifestyle habits, which influence occupational performance and cognitive outcomes.[9] Collectively, evidence suggests a strong need for preventive approaches and screening strategies to identify at-risk individuals in midlife.

Existing assessment tools, such as the Addenbrooke's cognitive examination-III (ACE-III) and the montreal cognitive assessment (MoCA), identify cognitive impairment and indicate the presence or absence of conditions such as mild cognitive impairment. However, they cannot define an individual's risk.[10] Although literature shows limited tools that could detect the risk of cognitive decline, particularly in the Indian context,

western indices such as the Australian National University Alzheimer's Disease Risk Index (ANU-ADRI), the United Kingdom Biobank Dementia Risk Prediction (UKB-DRP) for citizens of the United Kingdom, have been developed to identify the risk of Alzheimer's disease in Western contexts for the population of 70+ years.[11] No such tool exists that incorporates diverse socioeconomic classes and is culturally appropriate to Indian culture. Thus, developing and validating a risk screening tool tailored for Indian adults in midlife is a critical public health priority.

The CDRST, a 20-item screening tool, was developed using the modified Delphi technique, integrating various modifiable risk factors to facilitate the identification of cognitive decline risk levels in middle-aged adults aged 40-60 years. This pilot study aimed to assess the tool's internal consistency and to identify baseline scale cut-off scores using the standard deviation (SD) method.[12]

METHODS

The study was conducted at the Mahatma Gandhi University of Medical Sciences and Technology, Jaipur, from June 2025 to December 2025, following approval from the institutional ethics committee (IEC Number: MGMC&H/JPR/2024/1887). The study adhered to the ethical guidelines of the Declaration of Helsinki; written informed consent was obtained from all participants before enrolment, and data confidentiality was maintained.

Study design and sample size

A single-center, cross-sectional pilot study design was used; a minimum sample size of 62 was estimated using Bonett's formula for calculating Cronbach's alpha, assuming a reliability of 0.80, a desired precision of ±0.05, and a 95% confidence level (CI).[13] For the inter-item correlations and analysis of the standard deviation-based cut-off score, a sample of 100 participants was selected via convenience sampling to establish a baseline for the pilot test.[14] The sample size was considered based on 5-10 participants per item, which for a 20-item tool suggests a range of 100-200 participants; our recruited sample of 103 aligns with this recommendation.[15] The sample for the main study was calculated to 387 participants based on assumptions of a 95% confidence level and a 5% margin of error. Since this was a pilot study, approximately 10% of the calculated sample size was considered acceptable; therefore, any sample size greater than 38 was acceptable.[14] To perform the preliminary analyses and provide sufficient variability to establish exploratory cut-off scores, 103 participants were selected, exceeding the minimum requirement. This larger pilot sample allowed for more stable estimates of internal consistency and distribution-based thresholds, while acknowledging that definitive validation will require a multi-centric study with the full calculated sample size.

Study population

The study population comprised community-dwelling middle-aged adults aged 40 to 60 years who attended the outpatient clinics of Mahatma Gandhi Hospital, Jaipur. Participants with intact cognitive function, as assessed using the MoCA, and the ability to read/write English, and willingness to provide written informed consent were selected. Exclusion criteria included adults with communication challenges or any diagnosed neuropsychiatric conditions.

Study procedure

The CDRST tool was developed using the modified Delphi process, followed by content validation. A 3-round modified Delphi process was conducted to develop the tool through a panel of multidisciplinary experts (neurologist, physiatrist, nutritionist, occupational therapist, clinical psychologist, speech and language pathologist) with at least a master's degree and 10 years of experience in the field, who had varied backgrounds and were part of the study. The panel developed a 20-item CDRST tool. Using Lawshe's methodology, content validity was found to be good, with a CVR of 0.78, a CVI of 0.86, and a universal agreement of 65%.

This study was the next stage: the pilot testing phase. All participants provided written informed consent and were interviewed using the outcome variables, including administration of the MoCA and CDRST for screening purposes in a single trial, with no follow-up plan or intervention provided to participants.

Statistical analysis

Data analysis was conducted using IBM SPSS 20 software for Windows. The descriptive statistics, including frequencies, were calculated for the variables, along with the mean and standard deviation. For internal consistency, Cronbach's alpha was used primarily, along with alpha after deleting an item, to assess the impact of individual items on the tool's reliability. The inter-item correlation matrix for the ordinal data was analyzed using Spearman's rank correlation to assess item redundancy and ensure item independence. SD-based cut-off scores were established to provide a baseline score for the tool.

RESULTS

The 103 community-dwelling adults participated in the study, with 50.49% males (n=52) and 49.51% females (n=51) reflecting an almost equal gender-based distribution in the dataset. The mean age was 50.1±6.55 years, with education levels indicating that 17.48% were graduates in their respective fields, 37.86% held professional degrees, and 22.33% had a middle school education. The majority belong to the upper-middle class (40.78%), and the minority to both the upper class

(5.83%) and the lower class (5.83%). Table 1 presents the sociodemographic data for the study sample.

The Cronbach's alpha for the complete tool was 0.81 (95% CI), indicating good internal consistency. Alpha if item deleted-scores showed no major change when an item was removed, ranging from 0.79 to 0.81, indicating that all items contribute strongly to the construction of the tool. Table 2 shows the alpha values for all items when items were deleted.

The inter-item correlation matrix revealed a mean of 0.29, with coefficients ranging from -0.02 to 0.73, indicating a low to moderate level of correlation among most items and a healthy relationship at the item-level reliability. Strong correlations were noted among a few items, such as physical activity and body structure (r=0.507) and alcohol and tobacco consumption (r=0.735), indicating an expected relationship between physical health and lifestyle factors.

However, because none of the coefficient values exceeded 0.80, this confirms that no items are in the redundant categories, thereby supporting the tool's unidimensionality and the constructs' independence.[16] Figure 1 shows the diagram of the inter-item correlation matrix and its correlation coefficients across all the items.

The majority of the correlation matrix showed moderate positive correlations ranging from 0.20 to 0.50, indicating that the items measured related but distinct constructs. The key highlights in the matrix were the associations between levels of physical activity and memory (r=0.296), loneliness and adjustment to change (p=0.389), and anxiety and loneliness (r=0.333), indicating an interplay between physical and mental capacities, showing interplay between physical and mental health factors consistent with multidimensional risk patterns for cognitive decline. In contrast, some items in the lifestyle routines domains, such as loneliness and leisure (r=0.111) and memory and sleep (r=0.04), sleep and spirituality (r=0.003), had low correlations, indicating that these factors are relatively independent, supporting the tool's multidimensional nature, with each factor contributing uniquely to the risk scores. Altogether, the matrix suggested the interrelated nature of items, yet their distinct or independent impact on overall risk scores, supporting the tool's internal consistency and the integrity of its construct.

The overall mean score was 35.28 (SD=8.35), calculated using the standard deviation method, with thresholds defined at 1 SD above and below the mean.[17] Table 3 shows the risk stratification scores and their categories defined based on the SD method.

	P1	P2	M1	M2	M3	M4	L1	L2	L3	L4	D1	D2	D3	D4	D5
P1	1.000														
P2	0.507	1.000													
M1	0.043	0.296	1.000												
M2	0.242	0.351	0.257	1.000											
M3	0.157	0.249	0.179	0.389	1.000										
M4	0.255	0.177	0.100	0.333	0.240	1.000									
L1	0.165	0.212	0.157	0.111	0.244	0.231	1.000								
L2	0.198	0.162	0.040	0.067	0.139	0.314	0.355	1.000							
L3	0.197	0.166	0.312	0.138	0.205	0.284	0.306	0.003	1.000						
L4	0.288	0.208	0.098	0.228	0.249	0.263	0.288	0.182	0.257	1.000					
D1	0.147	0.156	0.104	0.253	0.171	0.207	0.256	0.253	0.259	0.267	1.000				
D2	0.116	0.169	0.142	0.081	-0.017	0.184	0.225	0.193	0.214	0.144	0.509	1.000			
D3	0.299	0.269	0.428	0.245	0.047	0.135	0.288	0.030	0.349	0.137	0.354	0.389	1.000		
D4	0.254	0.244	0.419	0.046	0.095	0.096	0.164	0.075	0.217	0.138	0.262	0.257	0.735	1.000	
D5	0.346	0.376	0.360	0.221	0.255	0.159	0.273	0.144	0.271	0.199	0.328	0.327	0.422	0.411	1.000

Figure 1: Inter-item correlation matrix.

Table 1: Sociodemographic data for the pilot sample.

Variables		N (%)
Age groups (in years)	41-45	28 (27.18)
	46-50	19 (18.45)
	51-55	26 (25.25)
	56-60	30 (29.12)
Gender	Male	52 (50.49)
	Female	51 (49.51)
Education	Professional degree	39 (37.86)
	Graduate	18 (17.48)
	Intermediate/ diploma	19 (18.45)
	High school	04 (3.88)
	Middle school (class 8)	23 (22.33)
Occupation	Legislators, senior officials, managers	22 (21.36)
	Clerk, skilled workers, shop and market sales workers	31 (30.10)
	Skilled agricultural/fishery workers, craft/ trade workers	15 (14.56)
	Elementary occupations	21 (20.39)
	Unemployed	14 (13.59)
Socioeconomic status	Upper class	6 (5.83)
	Upper middle class	42 40.78)
	Lower middle class	40 38.83)
	Upper lower class	9 (8.73)
	Lower class	6 (5.83)

Table 2: Cronbach's alpha when items were deleted.

Item deleted	Cronbach's alpha	>0.81
P1-Body structure	0.80	Reliable
P2-Physical activity	0.80	Reliable
M1-Memory changes	0.80	Reliable
M2-Loneliness	0.80	Reliable
M3-Adjustment to change	0.81	Reliable
M4-Emotional disturbance	0.81	Reliable
L1-Leisure	0.80	Reliable
L2-Sleep	0.81	Reliable
L3-Spirituality	0.80	Reliable
L4-Social engagement	0.80	Reliable
D1-Dietary pattern	0.80	Reliable
D2-Fast food consumption	0.80	Reliable
D3-Alcohol consumption	0.79	Reliable
D4-Tobacco consumption	0.79	Reliable
D5-Medicine intake	0.79	Reliable

Table 3: Risk stratification categories and their interpretations.

Number of individuals identified	Cut-off score range (SD method)	Risk category	Interpretation
14 (13.59%)	≤26.93 (≤Mean-1 SD)	Low risk	Minimal risk for cognitive decline
74 (71.85%)	26.94-43.63 (Mean±1 SD)	Medium risk	Needs regular monitoring
15 (14.56%)	≥43.64 (≥ Mean+1SD)	High risk	Critical preventive care required

Cut-off scores for CDRST were derived, and a distribution-based framework was established for risk categorization. Exploratory cut-off scores were established at ≤26.93 for low risk (≤Mean-1SD), 26.94-43.63 (±1 SD of the mean) for moderate risk, and ≥43.64 (≥Mean+1SD) for high risk, ensuring the scores are statistically grounded for risk stratification in the pilot sample and reflecting the sample's natural variability. The pilot sample of 103 individuals, when stratified by risk categorization, showed 14.56% in the high-risk category,

71.84% in the medium-risk category, and 13.59% in the low-risk category, with urgent priority for preventive care and targeted interventions for the high-risk category.

DISCUSSION

This study assisted in understanding the preliminary psychometric evidence for the CDRST, which is designed to identify the risk of cognitive decline among middle-aged Indian adults aged 40 to 60 years. Overall, the tool's internal consistency was good (Cronbach's alpha: 0.81; 95% CI: 0.76-0.81), supporting its reliability and construct validity. Our findings are consistent with methodological recommendations for internal consistency: values above 0.70 are acceptable for a newly developed scale, which is further stabilized by the alpha if items are deleted, and scores consistently above 0.70 across all items support each item's contribution to the tool's overall construct.[13]

The inter-item correlation matrix showed low to moderate associations among multiple variables, indicating that the items measured different, though distinct, constructs. Strong correlations between physical activity and body structure are well supported by a study by Deckers which showed an association between obesity and cognitive decline, with an impact on executive functioning compared with normal-weight individuals.[18] Laughlin et al revealed correlations between concurrent physical activity and improved cognitive function, particularly in those who were physically active after the age of 30 years, signifying the importance of physical activity on cognitive function, making it an important construct of the tool.[19] Another strong association of alcohol and tobacco consumption is supported by a study by Khan which identified that adults who consume both alcohol and tobacco are more prone to cognitive decline and low cognition scores, along with being underweight. These associations reflect the expected clustering of risk determinants. They are consistent with findings from LASI and LASI-DAD, which highlight the impact of lifestyle factors on cognitive trajectories in Indian populations.[3] Moderate correlations were identified among psychosocial factors such as loneliness, anxiety, and adjustment to change, echoing evidence that social participation is a key determinant of cognitive health, as highlighted by a study by Stinchcombe and Hammond in which individuals with better social engagement, hobbies, and higher self-rated health had better cognitive function.[20] Overall, low to moderate correlations in the matrix signify the relevance of each construct, supporting the tool's multidimensional nature.

Preliminary evidence for the scoring framework was developed using exploratory cutoff scores based on the SD method, reflecting the sample's natural variability. The 14.56% of individuals were identified as high risk, representing the most vulnerable group at risk of accelerated cognitive decline and requiring urgent, critical preventive care, including lifestyle modifications, psychosocial support, physical activity, and cardiovascular risk management, to reduce cognitive decline in later life significantly. The majority of participants (71.84%) fell into the moderate-risk category, underscoring the need for screening strategies that align with the National Program for Health Care of the Elderly (NPHCE) and the National Mental Health Program (NMHP). From a public health perspective, this tool, CDRST, emphasizes early detection of at-risk individuals for cognitive decline that could lead to conditions such as mild cognitive impairment or dementia in later life, and improving the quality of life for aging populations.

Limitations

Limitations of this study included a single-center pilot study with a modest sample size, where a large-scale multi-center study is needed to generalize the results. Second, this was a cross-sectional study to understand the tool's predictive outcomes; longitudinal studies are required to evaluate its true ability. Third, the tool has been developed in English, which may exclude adults with lower literacy levels, limiting its cultural applicability.

CONCLUSION

The CDRST, a 20-item screening tool to evaluate individuals at risk for cognitive decline between ages 40 and 60, demonstrated good internal consistency and reliability, along with exploratory cut-off scores that provide a risk-stratification framework. Utilizing and integrating this into community settings and national programs would foster early screening and support preventive care in midlife, reducing the burden of cognitive decline in later stages.

Recommendations

Recommendations would include adapting the tool to regional languages for linguistic applicability and conducting advanced statistical and psychometric testing, such as receiver operating characteristic (ROC) curve analysis and factor analysis, to establish the tool's psychometric properties. Despite the limitations, the study provided a relevant screening tool for middle-aged Indian adults. Integrating this tool into community-based programs under NPHCE could facilitate early risk identification and support preventive interventions.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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