



Research Article

www.ijrap.net

(ISSN Online:2229-3566, ISSN Print:2277-4343)



DEVELOPMENT AND VALIDATION OF A TOOL TO ASSESS ASSOCIATED FEATURES OF MILD COGNITIVE IMPAIRMENT

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Received on: 28/10/21 Accepted on: 05/01/22

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DOI: 10.7897/2277-4343.13016

ABSTRACT

Aim and objectives: The study aimed to develop assessment criteria for clinical features associated with mild cognitive impairment. The aim was to create and validate a questionnaire based on concepts approved by Ayurveda experts to assess patients with memory complaints associated or not associated with MCI. **Materials and Methods:** The study was conducted in two sections in Vaidyaratnam P.S Varier Ayurveda College and Hospital, Kottakkal. The first section was to frame a new questionnaire based on experts' approved concept and validate it. A literary survey to establish the role of tridosha in the concepts of cognition with various pathological states discussed in Ayurveda was done. Four concepts were identified from analyzing the classical textbooks of Ayurveda. Three rounds of consensus building were done, and 98% consensus was obtained in considering prabuta dosha in Rasa dhatu as the critical determinant of MCI. Based on the above findings, item generation was performed to develop and validate a questionnaire to assess prabuta dosha in intellectual impairment as a part of developing the Ayurvedic perspective of MCI. The tool was systematically developed through different stages, from conceptualization to factor analysis. Face validity, content validity, reliability measures were also done. **Results and Conclusion:** The prabuta dosha assessment questionnaire was developed and validated to assess associated clinical features of cognitive disturbances.

Keywords: Mild cognitive impairment, prabuta dosha, questionnaire.

INTRODUCTION

As the age expectancy in developed and developing countries rises, increased attention is being paid to the ageing population's structural and functional deterioration of the ageing population¹. Special attention must be paid to neurodegenerative disorder, hindering motor and cognitive functions. In the last decade, Mild cognitive impairment (MCI) emerged as a principal target for studies on early signs and symptoms for dementia². MCI is conceptualized as the transitional stage between normal ageing and dementia³. The conversion rate of MCI into dementia is as high as 40%⁴. So, the development of new diagnostic protocols and assessment tools from the existing concepts of Ayurveda and to contemporary frame management or curative strategies needs special attention. In Ayurveda classic texts, various clinical features associated with cognitive disturbances are explained in different areas. Compilation of these clinical features, primarily subjective, showed association with cognitive disorders. The features include aalasya, tandra, atinidra, gourava, nidra nasa, kandu⁵ etc. The different cognitive disruptions associated with these features include budhi moha⁶, budhi vaishamy⁷, abudhitva⁸, budhi vibrama⁹, budhi upaghata¹⁰, etc. Various concepts like heena matra ahara¹¹, asatmya indriya artha samyoga¹², unmada samprapti¹³, and accumulation of prabuta dosha in rasa vaha srotas¹⁴ has been observed by acharyas as prime reasons in creating intellectual and cognitive disturbances. This study is an attempt to create a better assessment tool for clinicians to assess clinical features more probably associated with MCI based on the concepts approved by experts from the above concepts and to create a platform to develop logical management or curative protocol to help patients to lead a good quality of life.

METHODOLOGY OF TOOL DEVELOPMENT

Objective: To develop and validate a tool in the form of a questionnaire to assess clinical features associated with cognitive disturbances.

Study design: Qualitative Analytical

Study setting: Vaidyaratnam P S Varier Ayurveda College and Hospital, Kottakkal, India.

Participants: Ten faculties of Ayurveda Colleges in Kerala - To approve the concept and to generate items and item wording

Steps in the questionnaire development¹⁵

Conceptualization: A literary review was carried out through brihat thrayi to derive the concepts from developing a perspective of mild cognitive impairment.

Item generation: Items generated based on a review of literature and conceptualization. Questions formulated to measure the variables of prabuta dosha mentioned in the chikitsaprabrutheeyam chapter of Charaka samhita¹⁶.

Item selection: The formulated questions were submitted to an expert panel for refinement and reduction by in-depth interviews for item selection.

In-depth interview: The four steps involved in conducting in-depth interviews are (1) developing a sampling strategy, (2) writing an in-depth interview guide, (3) conducting the interviews, (4) analyzing the data.

An in-depth interview was done among five experts with more than 15 years of experience in the field of Ayurveda. The sample size of participants was adequate. We took 45 to 60 minutes for each interview. The questions were open-ended. The purpose of in-depth interviews was to refine and reduce the questions. An essential dimension of the variable was identified with the help of expert opinion. Experts are requested to analyze the items' clarity, relevance, and suitability. This step ensures the feasibility and understandability of the questionnaire.

Item wording, sequencing, and formatting: Questions need a logical sequence, and they must be in order from general to specific. So, the developed questionnaire was changed into a scientific format and sequence. The main aim was to avoid overlapping, discard synonymous words and arrange this questionnaire in an order. The measurement scale was done using the Likert scale with bipolar scaling method ranging from 1-4.

Translation and back translation: If the tool are in the English language, it must be translated into the local language by an expert, and the translated tool must be back-translated to English by a language expert. Back-translation is a helpful method while considering particular attention to sensitive translation problems. It minutely observes the conceptual correspondence. The back-translation process ensures the absolute quality and accuracy of the questionnaire. The latter's resemblance with the primary tool is noted, and any words that are different from the original were replaced.

Cognitive interview: Cognitive interviews assess respondents understanding of questionnaire items and are increasingly used to improve instrument design. It will be a positive addition to current pretesting questionnaires before distribution to the sample. It's essential to test the survey questionnaire before collecting data. Pretesting and piloting can help identify questions that don't make sense to participants or problems with the questionnaire that might lead to biased answers. This process helps identify confusing questions or response options and misinterpretations by the respondents so that such questions can be refined or reframed to convey the intended meaning precisely.

Face validity: Face validity indicates whether the instrument appears to be assessing the desired qualities on the face of it. It evaluates the appearance of the questionnaire in terms of feasibility, readability, consistency of style and formatting, and the clarity of the language used.

Content validity: Content validity indicates whether the scale items represent the proposed domains or concepts the questionnaire is intended to measure¹⁷. It ensures that all aspects of the constructs are represented by an adequate number of articles and should not include unrelated items. Independent of the other experts, each expert is asked to rate each item as "Strongly Agree, Agree, Disagree, Strongly disagree." A value is assigned to each rating. After that content validity index and the ratio was calculated.

Data analysis: Statistical tests were done by SPSS

OBSERVATION AND ANALYSIS

Item generation

The first step in item generation was to draw structured information from the literature review. A discussion was done about the conceptual framework. Then item generation was done

based on this literature review and conceptual analysis. A total of 24 items have been devised to study prabuta dosha lakshana.

Item selection

This step aimed to identify an item pool to the validation process. So, for item selection, this semi-structured questionnaire was given to the expert members, and an in-depth interview was done to refine and reduce the questions.

In-depth interview

Consent from experts was obtained before conducting the interview. The interview among five experts lasted from 30 to 60 minutes each. It was a loosely structured interview.

Even most experts agreed on almost all questions, and all made some suggestions. The responses are typically audio-recorded and complemented with written notes. The data in interviews were transcribed, organized, analyzed, and reported. The critical elements in their suggestions were noted. The prevalent opinions among the experts were noticed that was about question number 24 regarding strength and color. After this stage, specific questions changed, and items with 100 per cent were selected.

Suggestions: Strength and colour should be assessed with a separate tool concerning *brahmana*. So, this question was also deleted

Item wording, sequencing, and formatting

Selected 23 items were worded appropriately to suit the level of understanding of the participating population. Experts suggested reframing the ambiguous and confusing statements. Considering the suggestions, questions were modified.

Level of agreement using Likert scale

The Likert scale was used to measure the attitude of participants. The questions were close ended. Frequency Likert scale was used in the questionnaire (never, occasionally, frequently, always).

Translation and back translation

At first, the translator needs to translate the original version into Malayalam. The second translator back translates the translated version into English.

Assessment of face validity

Face validity was measured in terms of grammar, spelling, clarity of the word layout and style, readability, and overall appearance likelihood the target population would answer the questions. After that percentage of agreement was noted. This step was done among ten faculties of different Ayurveda Colleges in Kerala. The response was monitored to ensure face validity. Here face validity rate was 90 per cent seems like a good representation of what we want to test. So, the tool looks valid on its face.

Content validity

Content validity assessment was done by filling the Google Form with a content validity assessment sheet. Evaluating the agreement among subject experts regarding how essential a particular item was done. Content validity was done among 20 doctors with more than ten years of experience. Relevance, clarity, simplicity, and ambiguity were tested after calculating the content validity ratio.

Table 1: Content validity ratio

Items	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
CVR	2.92	3.35	0.45	3	2.23	2.23	2.84	2.84	2.84	2.3	3.2	3	3.15	3.07	2.69	3	2.84	2.53	3.23	2.3	3

SCVR=2.716667

Calculating the Content Validity Ratio (CVR)

CVR= (ne - N/2)/(N/2).ne is the number of experts identifying an item as agreeing. N is the total number of experts. The item with a CVR of 0.78 or higher could be considered reasonable and selected. Because of the low content validity ratio, question number 3, the question on sthoulya was deleted. Scale content validity ratio is 2.71 was, exceeding 0.8 that is 2.71. So, it is favored.

Cognitive interview

The questionnaire with 22 items is administered to select the number of subjects and elicit responses. In this step, survey respondents were asked to complete this questionnaire and tell them everything they were thinking. This allows an

understanding of the questionnaire from the respondent's perspective rather than the researchers. Here we tried to get a range of different people representing the target group. We include some who are younger, older, boys, and with different socioeconomic backgrounds.

In the cognitive interview, we assessed 25 respondents. Even with this small number of people, we should identify the most significant issues. During testing, ask them to complete the survey one at a time. While they completed the survey, we asked them to think aloud. Each time they read and answer a question, they tell us precisely what comes into their mind. Take notes on everything they said. I looked for places where they hesitate or make mistakes. This indicates that the survey questions and layout are not clear enough and need to be improved. After this step, two questions were deleted, i.e. questions on libido and paleness. Now the questionnaire to assess prabuta dosa includes 20 items.

Table 2: Final questionnaire to assess prabuta doṣa lakshana

No	Questions	Never	Occasionally	Frequently	Always
1.	I. Do you feel true hunger thrice every day?	1	2	3	4
2.	Do you feel the food you eat is not tasty?	1	2	3	4
3.	Do you feel any aversion towards those things that you like to do?	1	2	3	4
4.	Do you get tired soon while engaged in any kind of work?	1	2	3	4
5.	Do you feel sad without any particular reason?	1	2	3	4
6.	Do you feel reluctant to do chores?	1	2	3	4
7.	Do you have boils in your body?	1	2	3	4
8.	Do you feel bad body odour?	1	2	3	4
9.	Do you observe raised reddish patches on skin?	1	2	3	4
10.	Do you feel heaviness?	1	2	3	4
11.	Do you have sleeplessness at night?	1	2	3	4
12.	Do you feel your mouth filled with thick saliva?	1	2	3	4
13.	Do you feel itchy in your body?	1	2	3	4
14.	Do you oversleep?	1	2	3	4
15.	Do you become restless?	1	2	3	4
16.	Do you have weaknesses while engaged in any kind of work?	1	2	3	4
17.	Do you have acid reflux?	1	2	3	4
18.	Do you see morbid dreams that interrupt your sleep?	1	2	3	4
19.	Do you have difficulty correctly understanding things?	1	2	3	4
20.	Do you feel drowsy during day time?	1	2	3	4

DISCUSSION

By these steps, good content validity was established. So, we assumed that the present tool could provide a good measurement of prabuta doṣa lakṣaṇā. Through this study, we created the EVa scoring pattern of prabuta doṣa.

The prabuta doṣa score is divided into mild and severe. The symptoms that contributed to mild prabuta doṣa are gauravaṃ, kandu, kaphautklesham, abúddhitvaṃ. The symptoms contributed to severe prabuta doṣa are avipākam, klamam, śramaḥ, avasādaka, ālasyaṃ, atinidrā, dourbalyaṃ, pittautkleśaḥ, aśasta svāpnadārśana and tandrā.

CONCLUSION

The prabuta doṣa assessment tool in a questionnaire was developed and validated to assess clinical features associated with cognitive disturbances.

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Cite this article as:

Vinod D.S. and Usha Patil. Development and validation of a tool to assess associated features of mild cognitive impairment. Int. J. Res. Ayurveda Pharm. 2022;13(1):23-26 <http://dx.doi.org/10.7897/2277-4343.13016>

Source of support: Nil, Conflict of interest: None Declared

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