

Development and validation of a questionnaire assessing disease knowledge and self-care (ARKSc) level among allergic rhinitis patients

Ahmad Hazim Hazlami Ahmad Nizar^{1,2}, Azliana Aziz¹, Baharudin Abdullah¹, Azidah Abdul Kadir³, Wan Mohd Zahiruddin Wan Mohammad⁴, Nor Shahida Abd Mutalib²

¹Department of Otorhinolaryngology-Head & Neck Surgery, School of Medical Sciences, Universiti Sains Malaysia Health Campus, Kubang Kerian, Kelantan, Malaysia, ²Department of Otorhinolaryngology-Head Neck Surgery, Hospital Sultan Abdul Halim, Sungai Petani, Kedah, Malaysia, ³Department of Family Medicine, School of Medical Sciences, Universiti Sains Malaysia Health Campus, Kubang Kerian, Kelantan, Malaysia, ⁴Department of Community Medicine, School of Medical Sciences, Universiti Sains Malaysia Health Campus, Kubang Kerian, Kelantan, Malaysia

ABSTRACT

Introduction: Understanding a patient's knowledge and self-care level regarding allergic rhinitis (AR) is essential these factors significantly influence treatment outcomes. Currently, there is a lack of validated measurement tools specifically designed to assess disease knowledge and self-care among patients with AR. Therefore, this study aimed to develop and validate a new questionnaire - the Allergic Rhinitis Knowledge and Self-care (ARKSc) questionnaire for this purpose.

Material and Methods: A questionnaire development and validation study was conducted in two phase. The first phase involved developing a self-administered questionnaire through literature review and consultations with an expert panel. Content validation was evaluated by a group of content experts using the content validity index (CVI), while face validity was assessed by AR patients using the Face Validity Index (FVI). In the second phase, construct validity of the final ARKSc questionnaire was examined at Hospital Sultan Abdul Halim, Kedah, Malaysia and Universiti Sains Malaysia Specialist Hospital (HPUSM), Kelantan, Malaysia involving 136 AR patients. Exploratory factor analysis (EFA) and reliability analysis were performed to assess the factorial structure and internal consistency of the questionnaire.

Results: The preliminary questionnaire included 16 questions (22 items) assessing AR knowledge and 11 questions on self-care. During content validation, three items with low item-CVI (I-CVI) score were removed. The average Scale-CVI (S-CVI/Ave) for both knowledge and self-care domains was 0.83. The scale-level face validity index value (S-FVI/Ave) 0.95, indicating excellent clarity and comprehensibility. Following construct validation, the final version of questionnaire consisted of 11 items in the knowledge section and 4 items in self-care section. The Cronbach's alpha was 0.659 for the knowledge section, and 0.663 for the self-care section, reflecting acceptable internal consistency.

Conclusion: The newly developed and validated ARKSc questionnaire is a valid and reliable instrument for assessing disease knowledge and self-care among patients with allergic rhinitis. This study provides a foundation for future development of more refined tools and underscores the importance of evaluating these domains to enhance disease management and patient outcomes.

KEYWORDS:

Allergic rhinitis, Knowledge, Self-care, Questionnaire, Development, Validation

INTRODUCTION

Allergic rhinitis (AR) is a hypersensitivity disorder affecting the upper respiratory tract and is one of the most common chronic conditions globally, with a reported prevalence ranging from 5% to 40% of the population.¹ In Malaysia, the average prevalence of AR is approximately 7.1% and has shown a rising trend over recent decades.² AR contributes significantly to the socioeconomic burden, particularly among the working population, leading to increased healthcare expenditure and productivity loss. Despite its prevalence and associated impact, AR remains underdiagnosed and undertreated worldwide.³ The clinical manifestations of AR include nasal congestion, rhinorrhea, sneezing, postnasal drip and itchy or watery eye typically triggered by an allergen-induced, immunoglobulin E (IgE)-mediated inflammatory response.⁴ These symptoms can adversely affects patients' daily activities, work productivity, self-esteem, social interactions and in children, their learning process.⁵ Management of AR involves both pharmacological and non-pharmacological strategies, both of which are vital in achieving optimal symptoms control.⁶ Non-pharmacological approaches, such as allergen identification and avoidance, complement pharmacological treatments that include antihistamines, intranasal corticosteroids, and decongestants.

Adequate patient knowledge about AR plays a crucial role in ensuring effective treatment and disease management.

Inadequate understanding may lead to inappropriate self-treatment and poor disease control, despite the availability of effective therapeutic options. Basic knowledge of AR encompasses its causes, preventive strategies, available treatments and potential complications. A lack of such knowledge often results in poor self-care, ultimately diminishing quality of life. Therefore, evaluating and understanding patients' knowledge and self-care practices is essential for delivering optimal care.

From literature reviews, most existing questionnaires adopt a broad focus, assessing general knowledge, attitudes and behaviours related to allergic rhinitis. Many of these instruments are non-standardised, not validated or designed for one-time use. Furthermore, they are often not adapted to specific clinical settings or reviewed by multidisciplinary experts. In response to these limitations, this study aims to develop and validate a disease-specific questionnaire to assess knowledge and self-care among AR patients, tailored for use in the Malaysian healthcare setting.

MATERIALS AND METHODS

The development and validation of the questionnaire were conducted in two main stages. The first stage focused on the development of the questionnaire, while the second stage involved its validation, which included content and face validity assessment, followed by psychometric validation using Exploratory Factor Analysis (EFA).

Phase 1 : Development of questionnaire

The initial phase involved the development of a self-administered questionnaire, based on comprehensive literature review and expert panels consultations. The literature was reviewed to identify relevant concepts to guide item selection and the formation of questionnaire sections. The expert panel comprised three Otorhinolaryngologists, one Family Medicine physician and one Community Medicine physician.

The newly developed questionnaire aimed to assess the patient's knowledge and self-care related to AR. It was structured into three sections. The first section is the demographic data. This section included eight items capturing demographic characteristics such as age, gender, ethnicity, education level, occupation, family history of atopy (bronchial asthma, atopic eczema or AR), smoking status and time since diagnosis. Section two is regarding the knowledge of AR. This section consisted of 16 questions divided into four domains: aetiology, symptoms, complications and treatment. A total of 22 items were included and each was assessed using a three-option scoring system ("Yes", "No" and "Not sure"). Section three is about Self-care of AR. This section contained 11 items designed to assess self-care practices. A four-point Likert scale was used for responses: "Always", "Often", "Sometimes" and "Never". In total, the initial draft of the questionnaire comprised of 27 questions encompassing 33 items - 22 in the knowledge section and 11 in the self-care section.

Regarding conceptual definitions, knowledge is defined as the information, understanding, and skills aquired through

education or experience.⁷ The knowledge items aim to assess the patient's understanding of the causes, symptoms, complications and treatment of AR. Self-care, as defined by the World Health Organization (WHO), refers to the ability of individuals, families and communities to promote health, prevent disease, maintain health, and cope with illness and disability, with or without the support from healthcare providers.⁸ The self-care items in the questionnaire were developed to assess patients' behaviours, routine and management strategies in relation to AR. The questionnaire was initially developed in the Malay language, considering its intended use in the Malaysian healthcare context.

Phase 2

Content and face validity

Content validity is defined as the extent to which the items of an assessment instrument are relevant to and representative of the intended construct for a specific assessment purpose.⁹ This process is crucial as it provides preliminary evidence of construct validity, offers insights into the clarity and appropriateness of the items, and facilitates the refinement of the instrument through expert feedback.¹⁰ The content validity index (CVI) is the most widely used method to evaluate content validity.¹¹ In this study, five experts were recruited to assess content validity – three Otorhinolaryngologists, one Family Medicine physician and one Community Medicine physician. The Otorhinolaryngologists and family medicine physician served as subject matter experts, while the community medicine physician contributed expertise in questionnaire design.

The draft questionnaire was pretested by the panel to identify potential issues in wording, relevance and interpretation. Both qualitative and quantitative approaches were employed. Each item was rated independently by the experts using a 4-point Likert scale: 1 = not relevant, 2 = somewhat relevant, 3 = relevant, and 4 = very relevant. In addition to that, the panel of experts also gave their recommendations and feedback on whether any modifications need to be made to the items or new items to be added to the questionnaire. Responses are dichotomized for CVI calculation, where the rating of 3 or 4 was scored as 1 (relevant) and ratings of 1 or 2 as 0 (not relevant). The Item-CVI (I-CVI) was calculated by dividing the number of experts who rated the item as relevant (3 or 4) by the total number of experts (12). For example, an I-CVI of $3/5 = 0.6$ indicates insufficient agreement, with a recommended threshold of 1.0 when using five experts. The Scale-CVI Average (S-CVI/Ave) was then calculated by summing all I-CVI and dividing by the total number of items. The acceptable cutoff for S-CVI/Ave is ≥ 0.83 .¹²

Face validity index (FVI) assesses the clarity and comprehensibility of the questionnaire items from the respondent's perspective. This study followed the method proposed by Yusof (2019).¹³ Ten AR patients from the Otorhinolaryngology (ORL) clinic at Hospital Sultan Abdul Halim (Kedah, Malaysia) participated in the face validity assessment. These were not part of the actual validation cohort. Each was provided with a printed version of the questionnaire and asked to evaluate each items based on

Table I: Content validation analysis by the panel of experts

	R1	R2	R3	R4	R5	I-CVI
Knowledge						
Q1	1	1	1	1	1	1
Q2	1	1	1	1	0	0.8
Q3	1	1	0	1	1	0.8
Q4	0	1	1	1	1	0.8
Q5	1	1	0	0	1	0.6
Q6	0	0	0	0	0	0
Q7.1	1	1	1	1	1	1
Q7.2	1	1	1	1	1	1
Q7.3	1	1	1	1	1	1
Q7.4	1	1	1	1	1	1
Q8.1	1	1	0	1	1	0.8
Q8.2	1	1	0	1	1	0.8
Q8.3	1	0	0	1	1	0.6
Q8.4	1	0	1	1	1	0.8
Q9	1	0	1	1	0	0.6
Q10	1	1	0	0	1	0.6
Q11	1	1	1	1	1	1
Q12	1	1	0	1	1	0.8
Q13	1	1	0	1	1	0.8
Q14	1	1	1	1	1	1
Q15	1	1	1	1	1	1
Q16	1	1	1	1	1	1
Q17	1	1	0	1	1	0.8
Q18	0	1	0	1	1	0.6
Q19	1	1	0	1	1	0.8
Self-care						
Q1	1	1	1	1	1	1
Q2	1	1	1	1	1	1
Q3	0	1	1	1	1	0.8
Q4	0	1	1	1	1	0.8
Q5	1	1	1	1	1	1
Q6	1	1	1	1	1	1
Q7	1	1	1	1	1	1
Q8	1	1	0	1	1	0.8
Q9	0	1	0	1	1	0.6
Q10	1	1	1	1	1	1
Q11	1	1	1	1	1	1
					S-CVI/Ave	0.83

R - rater

I-CVI - Item Content Validity Index

S-CVI/Ave - Average CVI

clarity and understanding, using a 5-point Likert scale. Items rated as 4 or 5 were considered “very clear and comprehensible” and scored as 1, while those rated from 1 to 3 scored as 0. The Item-face validity index (I-FVI) was calculated by dividing the number of respondents who rated the item as 4 or 5 by the total number of participants. The Scale-FVI Average (S-FVI/Ave) was derived by averaging all I-FVIs. A minimum S-FVI/Ave of 0.83 is considered acceptable.¹³ This indicates that the questionnaire items are generally well understood and appropriately worded for the target population. All queries, comments and suggestions from participants during the face validity phase were reviewed and used to refine the questionnaire. The final draft at this stage included three sections with a total of 27 questions (33 items): demographic information (8 items), disease knowledge (22 items) and self-care practices (11 items). This revised version was then used in the subsequent psychometric validation phase.

Psychometric validation study

The psychometric validation was conducted through a cross-

sectional study involving Ar patients who attended the ORL Department at Hospital Sultan Abdul Halim (HSAH) and Universiti Sains Malaysia Specialist Hospital (HPUSM), between 16 April 2021 to 31 December 2021. To determine the required sample size for Exploratory Factor Analysis (EFA), a commonly used ratio of 5 participants per item, was applied.¹⁴ With a total of 27 questions across two domains, the target sample size was 135. Convenience sampling was used to recruit participants who met the following inclusion criteria: aged between 18 to 60 years old, clinically diagnosed with AR, positive skin prick test and able to comprehend either Malay or English. Patients with non allergic rhinitis, nasal polypositis or rhinosinusitis were excluded.

Each participant provided informed consent and received an explanation of the study's purpose, procedures, risks, benefits and confidentiality. The questionnaire was self-administered and the completion time was approximately 10 minutes. The finalised questionnaire was then subjected to construct validity analysis through EFA and reliability testing to assess internal consistency.

Table II: Face validation analysis by respondents who were not involved in the actual study

	R1	R2	R3	R4	R5	R6	R7	R8	R9	R10		I-FVI
Knowledge												
Q1	1	0	1	1	1	1	1	1	1	1		0.9
Q2	1	0	1	0	1	1	1	1	1	1		0.8
Q3	1	0	1	1	1	1	1	1	1	1		0.9
Q4	1	1	1	1	1	1	1	1	1	1		1
Q5	1	1	1	1	1	1	1	1	1	1		1
Q6	1	0	1	1	1	1	1	1	1	1		0.9
Q7.1	1	1	1	1	1	1	1	1	1	1		1
Q7.2	1	1	1	1	1	1	1	1	1	1		1
Q7.3	1	1	1	1	1	1	1	1	1	1		1
Q7.4	1	1	1	1	1	1	1	1	1	1		1
Q8.1	1	1	1	1	1	1	1	1	1	1		1
Q8.2	1	1	1	1	1	1	1	1	1	1		1
Q8.3	1	1	1	1	1	1	1	1	1	1		1
Q8.4	1	1	1	1	1	1	1	1	1	1		1
Q9	1	0	1	1	1	1	1	1	1	1		0.9
Q10	1	1	1	1	1	1	1	1	1	1		1
Q11	1	1	1	1	1	1	1	1	1	1		1
Q12	1	1	1	1	1	1	1	1	1	1		1
Q13	1	1	1	1	1	1	1	1	1	1		1
Q14	1	0	1	1	1	1	1	1	1	1		
0.9												
Q15	1	1	1	1	1	1	1	1	1	1		1
Q16	1	1	1	1	1	1	1	1	1	1		1
Q17	1	1	1	1	1	1	1	1	1	1		1
Q18	1	0	1	1	1	1	1	1	1	1		
0.9												
Q19	0	0	1	1	1	1	1	1	1	1		
0.8												
Self-care												
Q1	1	1	1	1	1	1	1	1	1	1		1
Q2	1	1	1	1	1	1	1	1	1	1		1
Q3	1	0	1	1	1	1	1	1	1	1		0.9
Q4	1	1	1	1	1	1	1	1	1	1		1
Q5	1	0	1	1	1	1	1	1	1	1		0.9
Q6	1	1	1	1	1	1	1	1	1	1		1
Q7	0	1	1	1	1	1	1	1	1	1		0.9
Q8	0	0	1	1	1	1	1	1	1	1		
0.8												
Q9	0	0	1	1	1	1	1	1	1	1		0.8
Q10	1	0	1	1	1	1	1	1	1	1		0.9
Q11	1	0	1	1	1	1	1	1	1	1		0.9
											S-FVI/Ave	0.95

R – rater

I-FVI - Item-Face Validity Index

S-FVI/Ave - Scale-Face Validity Index

Statistical analysis

Data entry and statistical analysis were performed using Microsoft Excel and IBM SPSS version 26.0 for Windows. Descriptive statistics were used to summarise the demographic characteristics of participants. Numerical data were represented as mean (standard deviation, SD) and frequency (n, %) for categorical variables.

Exploratory Factor Analysis (EFA) was used to assess the construct validity of the questionnaire in both the knowledge and self-care domains. Prior to EFA, Bartlett's Test of Sphericity was conducted to determine whether sufficient correlations among the items.¹⁵ Additionally, the Kaiser-Meiyer-Olkin (KMO) Measure of Sampling Adequacy was used to evaluate the proportion of common variance among variables. A Bartlett's Test p-value of <0.05 and a KMO value

≥0.5 were considered indicative of suitability for factor analysis.¹⁵ Factor loadings were used to extract underlying factors and items with communalities and factor loadings ≥0.3 were retained for further analysis. The internal consistency of each domain was evaluated using Cronbach's alpha coefficient, with values ≥0.6 considered acceptable for newly developed instruments.¹⁶

Ethical considerations

This study received ethical approval from the Medical Research and Ethics Committee (MREC) under the National Medical Research Register (NMRR-21-243-58303 (IIR)) and the Human Research Ethics Committee of Universiti Sains Malaysia (JEPeM-USM) under protocol code USM/JEPeM/20090454.

Table III: Demographic data of the participants (N=136)

Variable	Mean (SD)
Age of the respondent	
18 - 29	54 (39.7)
30 - 40	39 (28.7)
41 - 50	20 (14.7)
51 - 60	23 (16.9)
Gender	
Male	40 (29.4)
Female	96 (70.6)
Ethnicity	
Malay	107 (78.7)
Chinese	12 (8.8)
Indian	16 (11.8)
Others	1 (0.7)
Education level	
Primary	5 (3.7)
Secondary	67 (49.3)
Tertiary	61 (44.9)
Others	3 (2.2)
Family history of atopy (Bronchial asthma)	
Yes	50 (36.8)
No	86 (63.2)
Family history of atopy (Atopic eczema)	
Yes	17 (12.5)
No	119 (87.5)
Family history of atopy (Allergic rhinitis)	
Yes	66 (48.5)
No	70 (51.5)
Smoking	
Yes	13 (9.6)
No	117 (86.0)
Ex-smoker	6 (4.4)
Time since diagnosis (years)	7.76 (7.24) *

* Mean (SD)

All participants provided written informed consent prior to participation. They were fully briefed on the purpose of the study, procedures, potential risks and benefits, and their right to withdraw at any time. All collected data were treated with strict confidentiality and used solely for research purposes.

RESULTS

Content validity

The Item-Level Content Validity Index (I-CVI) for the questionnaire items ranged from 0 to 1 (Table I). The Scale-Level Content Validity Index Average (S-CVI/Ave) was 0.83 for both the knowledge and self-care sections, meeting the recommended threshold.

In the knowledge section (25 items initially), 9 items achieved an I-CVI of 1.0, indicating perfect agreement among the expert panel. Ten items with an I-CVI of 0.8 and three items with an I-CVI value of 0.6 were retained following expert panel discussions, as they were considered important to the construct being measured and were subsequently revised. Three items with an I-CVI \leq 0.6 were removed.

In the self-care section (11 items initially), 7 items had an I-CVI of 1.0, three items had an I-CVI of 0.8 and one item had an I-CVI of 0.6. All items below perfect agreement were retained with modifications after expert consultation. At this stage, the revised questionnaire consisted of 22 items in the knowledge section and 11 items in the self-care section.

Face validity

The Item-Level Face Validity Index (I-FVI) for the knowledge and self-care sections ranged from 0.8 to 1.0 (Table II). The overall Scale-Level Face Validity Index Average (S-FVI/Ave) was 0.95 for both sections, indicating excellent clarity and comprehensibility. Based on feedback from the participants, several items were modified to improve understanding and ease of interpretation.

Psychometric analysis

A total of 136 participants completed the questionnaire. The demographic characteristics of the respondents are presented in Table III. The majority were aged 18 – 29 years old (39.7%), female (70.6%), Malay (78.7%) and had attained secondary education level (49.3%). Most participants reported no family history of bronchial asthma (63.2%), atopic eczema (87.5%) or allergic rhinitis (51.5%) and 86% were non-smokers. The mean time since diagnosis was 7.76 years.

Validation and reliability

EFA was conducted separately for the knowledge and self-care sections. A total of 33 items initially underwent EFA. In the knowledge section, the KMO measure of sampling adequacy was 0.663 and Bartlett's Test of Sphericity was significant ($p < 0.001$), confirming the data's suitability for factor analysis. Parallel analysis suggested a three-domain structure: domain 1-typical symptoms, domain 2- related symptoms, domain 3- general information. A total of 10

Table IV: EFA and Reliability of Knowledge and Self-care section

	Factor loading	Cronbach alpha
Knowledge Section		
Domain 1		0.626
Typical symptoms of allergic rhinitis are :		
<i>Gejala-gejala tipikal alahan rinitis adalah seperti :</i>		
Runny nose	0.546	
<i>Hidung berair</i>		
Sneezing	0.670	
<i>Bersin</i>		
Blocked nose	0.428	
<i>Hidung tersumbat</i>		
Nasal itchiness	0.583	
<i>Gatal hidung</i>		
Domain 2		0.787
These symptoms are also related to allergic rhinitis :		
<i>Gejala-gejala berikut juga berkait rapat dengan alahan rinitis:</i>		
Yellow coloured nasal discharge	0.618	
<i>Hingus berwarna kuning</i>		
Nose bleeding	0.897	
<i>Pendarahan hidung</i>		
Facial pain	0.607	
<i>Sakit di bahagian muka</i>		
Loss of smell	0.667	
<i>Hilang deria bau</i>		
Domain 3		0.609
Intranasal corticosteroid spray causes long term side effects	0.723	
<i>Ubat semburan hidung steroid menyebabkan kesan sampingan dalam jangka masa panjang</i>		
Medications to treat allergic rhinitis can cause drug dependence	0.567	
<i>Penggunaan ubat-ubatan bagi merawat alahan rinitis boleh menyebabkan kebergantungan kepada ubat</i>		
Allergic rhinitis is a curable disease	0.397	
<i>Penyakit alahan rinitis boleh disembuhkan</i>		
Overall Knowledge section Cronbach alpha		0.659
Self-care Section		
I adhere to my scheduled clinic appointments	0.576	
<i>Saya hadir sesi temujanji klinik yang ditetapkan</i>		
Avoiding exposure to dust is part of my daily routine	0.403	
<i>Mengelakkan diri daripada terdedah kepada habuk adalah amalan saya</i>		
I use the intranasal steroid spray as instructed by my doctor	0.788	
<i>Saya menggunakan ubat semburan hidung steroid mengikut arahan doktor</i>		
My allergic rhinitis self-care is good.	0.427	
<i>Saya mengamalkan pengurusan sendiri terhadap alahan rinitis yang baik.</i>		
Overall Self-care section Cronbach alpha		0.663

items were removed due to low factor loadings (<0.3). The communality values for all retained items were above 0.3, supporting the validity of the three- domain model. A factor loading value of more than 0.3 is considered acceptable.¹⁷ One additional item was removed from Domain 3 to improve internal consistency. The final Cronbach's alpha for domain 1 was 0.626, domain 2 was 0.787, and domain 3 was 0.609. The overall Cronbach's alpha for all three domains in the knowledge section was 0.659.

In the self-care section, the KMO value was 0.611 and Bartlett's Test of Sphericity was also significant ($p<0.001$). The EFA revealed that the self-care section was unidimensional. A total of 7 items with low factor loadings (<0.3) were excluded. The final Cronbach's alpha for the self-care section was 0.663. The factor loadings and reliability

statistics are presented in Table IV. The final validated ARKSc questionnaire (Appendix 1) consists of 11 items in the knowledge section and 4 items in the self-care section.

DISCUSSION

Allergic rhinitis (AR) remains a significant public health concern due to its increasing prevalence over the past decade. Globally, the prevalence of AR ranges from 10% to 40%.¹⁸ Several contributing factors have been proposed, including increased exposure to pollutants due to urbanization, global climate changes, and dietary shifts.⁴ AR imposes a considerable socioeconomic burden on healthcare systems and individuals. Its common association with comorbidities such as asthma, atopic dermatitis, allergic conjunctivitis, otitis media and rhinosinusitis further complicates disease

management. And increases treatment costs. Additional, impairment in school and work performance due to AR contributes to productivity loss and overall economic impact. Rhinitis is broadly classified into two major types: AR and nonallergic rhinitis (NAR). AR is characterised as an IgE-mediated disorder of the nasal mucosa triggered by allergen exposure.¹⁹ In contrast, NAR is associated with chronic nasal symptoms, such as nasal obstruction and rhinorrhea, typically caused by nonallergic, non-infectious triggers such as weather changes or exposure to strong odors. The skin prick test remains a widely accepted diagnostic tool for AR due to its ease of use and less-invasive nature.²⁰ Unlike AR patients, those with NAR usually test negative for allergens via skin prick testing or allergen-specific antibody tests.²¹ Therefore, only patients with positive skin prick test were included in this study to accurately distinguish AR from NAR. Patients with AR frequently seek treatment from general practitioners (GPs), health clinics, Otorhinolaryngology clinics or pharmacists, especially during symptoms exacerbations. Physicians play a pivotal role in providing accurate diagnoses and effective management strategies. However, a study conducted in Southeast Asian revealed a significant gap between guidelines-recommended AR management and actual clinical practice.²² Primary care physicians, particularly GPs, were found to inadequately implement clinical guidelines, underscoring the need for improved disease education and training. Moreover, several studies, including those conducted in the United States and other countries, consistently reported that patients had poor knowledge and inappropriate practices regarding AR.²³⁻²⁵ These findings highlight the critical importance of patient education in achieving optimum treatment outcomes.

Self-care is another crucial components in AR management. According to WHO, self-care refers to the ability of individuals to manage their health through awareness, self-control, and self-reliance.²⁶ Effective self-care can significantly reduce symptom burden and disease morbidity, contributing to improved long-term disease control.

This study involved the development and validation of a novel questionnaire to assess AR patients' knowledge and self-care practices. The initial version comprised of 22 items in knowledge domain and 11 items in self-care domain. During the content validity phase, items deemed irrelevant or difficult to understand were removed or revised based on expert panel feedback. As content validity is foundational to the overall validity of a measurement instrument, it was given high priority during tool development. The face validity phase, conducted among non-study patients, was used to assess clarity and relevance from the end-users' perspective. Both quantitative and qualitative feedback were incorporated, resulting in important adjustments to item wording, structure and content. Items with I-CVI or I-FVI scores below acceptable thresholds were revised or removed based on rater recommendations. The validation phase of the questionnaire is important as it express the degree to which a measurement measures what it aims to measure.²⁷ Meanwhile, the reliability measured the degree to which the result obtained by a measurement and procedure can be replicated.²⁷

Following these steps, the questionnaire underwent EFA. In the knowledge section, three domains emerged- typical symptoms, related symptoms and general information, with acceptable Cronbach's alphas values (0.626, 0.787, and 0.609 respectively). The overall reliability of the knowledge section was 0.659, indicating acceptable internal consistency for a newly developed tool. The self-care section revealed a unidimensional structure, with a Cronbach's alpha of 0.663, also reflecting acceptable reliability.

The final validated questionnaire includes 11 items in the knowledge section and 4 items for the self-care section. The retained knowledge items focus primarily on AR symptoms, aligning with the key elements that affect patient recognition and response to their condition.. Despite the item reduction, the instrument remain robust and effective in assessing patient understanding and management practices.

A unique strength of the ARKSc questionnaire lies in its development and validation in Malay, with bilingual (Malay and English) version available to ensure accessibility. Designed specifically for AR, the items reflect real-world symptoms and treatment behaviours. The questionnaire was intentionally constructed to be clear, easy to score and comprehensible to the target populations, thereby improving response accuracy. In clinical settings, this tool can help assess whether patients have adequate disease education and whether further intervention is needed. It also directly evaluates patient-driven self-management behaviours.

Furthermore, this validated tool provides a platform for future research to assess knowledge and self-care levels among AR patients, identify associated factors, and evaluate the impact of educational or behavioural interventions.

CONCLUSION

The newly developed and validated ARKSc questionnaire is a valid and reliable instrument for measuring disease knowledge and self-care levels among patients with allergic rhinitis. This study offers an essential foundation for future refinement and supports the importance of assessing these sections as part of comprehensive AR management. Enhancing patients' knowledge and self-care capacity is fundamental to improving treatment outcomes and reducing the burden of allergic rhinitis.

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DECLARATION OF CONFLICT OF INTEREST

The authors declare that all primary investigators and co-researchers have no conflict of interest.

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Appendix 1

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QUESTIONNAIRE ASSESSING DISEASE KNOWLEDGE AND SELF-CARE LEVEL AMONG ALLERGIC RHINITIS PATIENTS

DEMOGRAPHIC SECTION**BAHAGIAN DEMOGRAFIK**

Please tick (✓) or write the appropriate answer to each question.

Sila tandakan (✓) atau isikan jawapan yang berkenaan bagi setiap soalan.

1. Age :

Umur :

 2. Gender : Male ☐ Female ☐
Jantina : Lelaki Perempuan

 3. Ethnicity : Malay ☐ Chinese ☐ Indian ☐ Others ☐
Etnik : Melayu Cina India Lain-lain

 4. Education level : Primary ☐ Secondary ☐ Tertiary ☐ Others ☐
Tahap pelajaran : Rendah Menengah Tinggi Lain-lain

 5. Occupation :
Pekerjaan :

 6. Family history of atopy : Bronchial asthma ☐ atopic eczema ☐ allergic rhinitis ☐
Sejarah penyakit alergi Asma Ekzema Alahan rinitis
di dalam keluarga :

 7. Smoking : Yes ☐ No ☐ Ex-smoker ☐
Merokok : Ya Tidak Bekas perokok

 8. Time since diagnosis (years) :
Jangka masa selepas diagnosis dilakukan (tahun) :

SECTION 2 : SELF-CARE OF ALLERGIC RHINITIS**BAHAGIAN 2 : PENGURUSAN KENDIRI ALAHAN RINITIS**

Please tick (✓) the appropriate answer for each question.

Sila tandakan (✓) bagi jawapan yang berkenaan untuk setiap soalan.

QUESTIONS SOALAN	ANSWER JAWAPAN			
	ALWAYS SENTIASA	OFTEN KERAP	SOMETIMES KADANG- KADANG	NEVER TIDAK PERNAH
1) I adhere to my scheduled clinic appointments. <i>Saya hadir sesi temujanji klinik yang ditetapkan.</i>				
2) Avoiding exposure to dust is part of my daily routine. <i>Mengelakkan diri daripada terdedah kepada habuk adalah amalan saya.</i>				
3) I use the intranasal steroid spray as instructed by my doctor. <i>Saya menggunakan ubat semburan hidung steroid mengikut arahan doktor.</i>				
4) My allergic rhinitis self care is good. <i>Saya mengamalkan pengurusan sendiri terhadap alahan rinitis yang baik.</i>				

SECTION 1 : KNOWLEDGE OF ALLERGIC RHINITIS**BAHAGIAN 1 : PENGETAHUAN BERKENAAN ALAHAN RINITIS**

Please tick (✓) the appropriate answer for each question.

Sila tandakan (✓) bagi jawapan yang berkenaan untuk setiap soalan.

KNOWLEDGE QUESTION SOALAN PENGETAHUAN	ANSWER JAWAPAN		
	YES YA	NO TIDAK	NOT SURE TIDAK PASTI
1. Typical symptoms of allergic rhinitis are : <i>Gejala-gejala tipikal alahan rinitis adalah seperti :</i>			
1) Runny nose <i>Hidung berair</i>			
2) Sneezing <i>Bersin</i>			
3) Blocked nose <i>Hidung tersumbat</i>			
4) Nasal itchiness <i>Gatal hidung</i>			
2. These symptoms are also related to allergic rhinitis : <i>Gejala-gejala berikut juga berkait rapat dengan alahan rinitis :</i>			
1) Yellow coloured nasal discharge <i>Hingus berwarna kuning</i>			
2) Nose bleeding <i>Pendarahan hidung</i>			
3) Facial pain <i>Sakit di bahagian muka</i>			
4) Loss of smell <i>Hilang deria bau</i>			
3. Intranasal corticosteroid spray causes long term side effects. <i>Ubat semburan hidung steroid menyebabkan kesan sampingan dalam jangka masa panjang.</i>			
4. Medications to treat allergic rhinitis can cause drug dependence. <i>Penggunaan ubat-ubatan bagi merawat alahan rinitis boleh menyebabkan kebergantungan kepada ubat.</i>			
5. Allergic rhinitis is a curable disease. <i>Penyakit alahan rinitis boleh disembuhkan.</i>			