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Content Validity and Test-Retest Reliability Study of Oral Cancer Awareness Questionnaire

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ABSTRACT

Background and Aims: Targeted and validated questionnaire is a vital tool in assessing oral cancer awareness (OCA) in the community. This study is aimed at validating a targeted oral cancer awareness questionnaire for people living in Far North Queensland.

Methods: This study was conducted in a Far North Queensland population attending the student led university dental clinic in Cairns. The questionnaire consisted of four domains: sociodemographic information, awareness and knowledge on oral cancer, PMDs and risk factors, source of information for oral cancer and PMDs and exposure to known risk factors such as habits and dietary history. The first stage of this study assessed content validity of questionnaire with clinical experts while the subsequent stage evaluated its reliability in a test-retest study amongst 30 dental patients attending the clinic for routine care. Analysis was performed using SPSS software and appropriate Kappa tests were run for each question to assess the reliability.

Results: In first stage, out of the 25 questions, 22 showed a validity index of 1, suggesting high agreement between two clinical experts that assessed validity with the overall content validity index at 88%. In test-retest reliability study involving 30 participants, 30 out of 38 items (including multiple choice questions converted to binary statements) showed an item content validity index (CVI) of 1 as evidence of full agreement. The OCA questionnaire had 'almost perfect' or 'perfect agreements' for questions related to tobacco smoking: exposure (Fleiss Kappa = 1), duration (Weighted Kappa = 1), and as a risk factor (Weighted Kappa = 1), smoking status ($k = 0.94$) along with alcohol consumption duration (Weighted Kappa $k = 0.91$).

Conclusion: The OCA questionnaire items showed acceptable content validity and test-retest reliability. Based on the preliminary evidence of acceptable reliability for specific items, this questionnaire can be employed for studies investigating OCA in adults living in Far North Queensland.

1 | Introduction

Cancer continues to be one of the most lethal and rapidly expanding group of diseases affecting people worldwide, with 20 million new cases reported in 2022 alone [1]. In 2021, Cancer incidence in Australia was reported at 153,526 new cases and expected to grow to over 169,000 new cases in 2025 [2]. Habits such as alcohol and tobacco use has been universally acknowledged as a common risk factor implicated in multiple types of cancers [3–6] Additionally, presence of human papilloma viruses (HPV) infections are being implicated as additional risk factor in oropharyngeal cancers, a subset of head and neck cancers [5–7].

In Australia, the incidence and mortality rates of various cancers have been on a declining trend but a dire increase in head and neck cancers, specifically oral cancer rates in population aged 50 years or over is concerning [8]. Incidence of cancer is often influenced by a range of factors such as socioeconomic status, nutrition levels, and residential location (regional or remote). Particularly, metropolitan residents have much lower prevalence of cancer in comparison to regional and remote locations [9, 10]. Also, male predilection is a notable feature in oral cancer incidence often attributed to social habits such as excessive smoking and alcohol consumption [11]. Furthermore, behavioral and lifestyle factors for oral cancer have been widely implicated, especially in rural and remote attributed to limited awareness of the known risk factors [12, 13].

Awareness within the community around the risk factors and presentation of pre-cancerous and cancerous conditions of oral cavity is typically evaluated with a cross-sectional questionnaire [14, 15]. However, a notable lack of reliable and validated questionnaire specifically for population in Far North Queensland with a higher proportion of rural and remote communities is evident. Such validated instruments are critical for researchers and health care providers in identifying people living in rural and remote areas that would significantly benefit from early detection and prompt referral. A validated questionnaire is an absolute need for this population identified to be at risk, especially with increasing incidence and mortality rates among elderly population in rural and remote regions [16].

Hence, this study aimed to evaluate the content validity and reliability of targeted Oral Cancer Awareness (OCA) questionnaire developed to assess the awareness about oral cancer presentation and risk factors. The specific objectives included the determination of the Item Content Validity Index (I-CVI) of each question and thereby calculate the average Scale Content Validity Index (S-CVI/Ave) for the questionnaire. In addition, the kappa coefficient (k) for each item along with the Intraclass Correlation Coefficient (ICCs) for questions with continuous responses was measured to derive the test-retest reliability.

2 | Methods

2.1 | Oral Cancer Awareness Questionnaire

The OCA questionnaire that aimed to investigate the awareness around oral cancer risk factors was developed by adapting previously published questionnaires, consultation with clinicians, and discussion with experts to capture relevant data from the participants [13–15].

The deidentified questionnaire developed consisted of 25 questions split across four sections. Section A gathered information about socio-demographic details, including age, gender, highest education obtained, Aboriginal and Torres Strait Islander status and economic status. Additionally, information about whether the participant is a concession card holder or private health insurance holder was recorded.

The other sections (B, C and D) included questions about knowledge of oral cancer. Section B included the questions with multiple options to choose from and focused on oral cancer risk factors and risk factors associated with premalignant diseases. Section C included questions that focused on exploration of the source of information on risk factors associated with awareness and knowledge of oral cancer and premalignant diseases. Section D sought information about smoking and alcohol consumption patterns (frequency and duration) as well as exposure to other known risk factors such as diet and nutrition.

2.2 | Study Design, Research Setting, and Participants

This study was conducted in two parts commencing with content validity, completed to assesses if the instrument contains all the components that are necessary to represent the concept being measured adequately, in this case the awareness around oral cancer risk factors and presentation.

2.3 | Content Validation of the Instrument

Content validation of the questionnaire was conducted between December 2022 and January 2023. Two academic and clinical experts were chosen for assessing questionnaire's content validity. The content experts were contacted though email with their consent. The information sheet explained the objectives of the project along with the English language version of original questionnaire. Questionnaire was emailed to each expert individually to protect the content and to avoid influencing each other's decision. The content experts were identified based on their experience in oral cancer knowledge and their experience in research, as evidenced by their publications in the field.

The experts were asked to provide feedback on each question and its suitability to assess oral cancer awareness among adult population in Far North Queensland region. Each expert was asked to assess each question under the four categories: socio-demographic information, awareness and knowledge of oral cancer, premalignant diseases and risk factors, source of information around oral cancer and PMDs along with exposure to additional known risk factors such as habits and dietary history. In addition, the experts were asked to assess relevance, format and order of questions for the target population. To determine relevance, experts were asked to score each question as relevant (= 1) or irrelevant (= 0). These scores were used to calculate Content Validity Index.

The experts were requested specifically to provide feedback and recommendation for each question for which they scored as irrelevant. For the questions which required revision, the experts were asked to suggest alternative options with clarity to improve the relevance of the question. The experts had 4 weeks to assess the questionnaire, and the reminder was sent at the end of 3 weeks. After receiving the responses from experts, those responses were analyzed at the end of the validation.

2.4 | The Reliability Study

The second part of this study evaluated the reliability of OCA questionnaire by using test-retest study design. The primary objectives were to assess the clarity and practicality of the questionnaire for intended data collection. Previous history of oral cancer and/or cancer in their immediate family members led to exclusion from participation in the reliability study.

Additionally, healthcare professionals or carers of a cancer patient were also excluded to avoid biases. Other exclusion criteria were below 18 years of age, unable to read and understand English language and not willing to consent to participate in the survey.

The test-retest reliability was conducted in two phases. Testing (first phase) of the OCA questionnaire conducted at James Cook University dental clinic and intended to include 30 ($n = 30$) randomly selected adult patients after obtaining informed consent to participate in the study. Printed information sheets outlining the intent and the stages of the study were provided to potential participants in the university dental clinic waiting area. The chief investigator was available to provide further clarification or explanations verbally, when needed. The participants were instructed in the first (test) phase of the survey about the two set of questionnaires that need to be completed. Printed questionnaire (or QR code to access the online questionnaire, if preferred) were provided to the participants. Subsequently, questionnaires were self-administered with participants strongly encouraged to seek clarification, when needed. Upon completion of questionnaire, participants were requested to provide feedback on questions and provided response options. Any aspect of the item, response options, word(s) or phrase(s) flagged by participants was rephrased to the satisfaction of the participant(s). To measure comprehensibility, time taken to complete questionnaires by participants was utilized.

In second phase, same questionnaire was sent to the participants through email and their responses were collected. After the completion of both the phases of test-retest reliability, participants were provided oral hygiene kits to acknowledge their contribution into the project. The interval (2 weeks) was opted to minimize the "carry-over effect" and to limit the chance of altered responses between the tests [17].

2.5 | Ethical and Institutional Approvals

After approval from JCU Human research Ethics Committee (H8922) for the project, additional approvals from the Head of Dentistry were obtained for this study. All the staff and the managers were informed about the dates of the survey involving JCU dental clinic patients attending for routine appointments. Informed consent was obtained from potential participants within the test-retest reliability study.

2.6 | Statistical Analysis

To estimate the Content Validity Index (CVI) quantitatively, one proportion agreement method was utilized [18, 19]. Content experts were asked to rate each question (item) on a binary scale: 0 (not relevant) or 1 (highly relevant). Subsequently, the Item Content Validity Index (I-CVI) was calculated as the number of content valid experts with a rating of either 0 or 1, divided by number of experts [18, 19]. As the I-CVI is expected to be 1 for validity of each question in case of four or less experts involvement [19], total agreement (the number of items with I-CVI of 1 divided by total number of items) was calculated to identify the questions that experts deemed as relevant.

Descriptive statistics were utilized to analyse the demographic characteristics of the participants within the test-retest reliability study. Statistical analyses were performed using SPSS version 28 and significance level was fixed at $p < 0.05$. Data normality for continuous variables (e.g., age) was evaluated with correlation coefficient. For the purposes of analysis, questions with multiple options available for selection were converted to individual questions and agreement was assessed based on selection of specific option. This process resulted in the 25 items questionnaire to be expanded to 38 items during analysis, as noted in Table 2.

Each item completion was assessed, and agreement (%) was deduced (number of agreement scores divided by the total number of scores between studies) for each question [20]. Based on agreement from the experts for the content validity, test-retest reliability was calculated using Cohen's kappa coefficient (k) for the questions with two options [21]. Fleiss Kappa was used for questions with more than three options while items with options in increasing scale used Weighted kappa [17]. Interpretation of kappa coefficients followed the Landis and Koch criteria [22]: Poor agreement < 0; slight agreement: 0–0.20; fair agreement: 0.21–0.40; moderate agreement: 0.41–0.60; substantial agreement: 0.61–0.80; almost perfect agreement: 0.81–1.0.

3 | Results

3.1 | Content Validation

Out of the five experts invited to participate, two experts participated in the study with mean age of 46.2 years. Additionally, two experienced dental assistants from James Cook University, Cairns, Australia, provided feedback on the clarity of questionnaire. The quantity of questions in the OCA questionnaire changed by two questions after the validation process. The I-CVIs of each item in the questionnaire are shown on Table 1. The I-CVI for the survey questionnaire ranged from 0 to 1, where 0 represented disagreement and 1 represented agreement regarding validity. Out of the 25 questions, item validity index of 1 was noted in 22 questions, suggesting agreement between experts. Overall, the questionnaire's content validity index was 0.88.

3.2 | Reliability Test: Participation Rate and Characteristics

Out of 50 eligible participants invited, 30 consented to participate in the test-retest study. Consequently, 30 questionnaires were completed at both the test and retest assessment and were included in further analysis. The retest survey was completed through an email invitation that included the questionnaire link hosted on Qualtrics sent to the same participants who completed first questionnaire on printed copy.

Age data of all the participants was normally distributed with correlation coefficient 1.00. The participants included 23 females and 7 males. The age of the participants ranged from 28 years to 76 years with mean age of 60.46 years. Among 30 participants 14 were high school graduates, 11 were university

TABLE 1 | Results of content validation of the oral cancer awareness questionnaire by clinical content experts.

Question number	Question description	Expert 1 rating - YES or NO	Expert 2 rating - YES or NO	I-CVI
Sociodemographic information				
Q1	Sex of the patient	Yes	Yes	1
Q2	Age	Yes	Yes	1
Q3	Highest level of education obtained	Yes	Yes	1
Q4	Aboriginal or Torres Strait Islander	Yes	Yes	1
Q5	Annual income of family before tax	Yes	No	0
Q6	Concession card holder	Yes	Yes	1
Q7	Private health insurance holder	Yes	Yes	1
Awareness and knowledge of oral cancer, PMDs and risk factors				
Q8	Oral cancer	Yes	Yes	1
Q9	Mouth, tongue, or lip cancer	Yes	Yes	1
Q10	Clinical presentation of oral cancer	Yes	No	0
Q11	Risk factors of oral cancer	Yes	Yes	1
Source of information around oral cancer and PMDs				
Q12	Information about health	Yes	No	0
Q13	Information around oral cancer	Yes	Yes	1
Q14	Assistance for oral cancer	Yes	Yes	1
Q15	Oral cancer examination	Yes	Yes	1
Exposure to known risk factors, i.e., habits and dietary history				
Q16	Factors that can increase the risk of oral cancer	Yes	Yes	1
Q17	Oral cancer as a serious health issue	Yes	Yes	1
Q18	Can oral cancer be prevented	Yes	Yes	1
Q19	Smoking increases the risk of oral cancer	Yes	Yes	1
Q20	Alcohol increases the risk of oral cancer	Yes	Yes	1
Q21	Betel nut chewing increases the risk of oral cancer	Yes	Yes	1
Q22	Smoking status	Yes	Yes	1
Q23	Smoking (years) duration	Yes	Yes	1
Q24	Drinking (years) duration	Yes	Yes	1
Q25	Betel nut chewing (years) duration	Yes	Yes	1

or TAFE graduates and 5 participants were post-graduate degree holders.

The respondents took 10–12 min for the completion of questionnaire. Frequent pauses to seek clarification from the researcher was noted on questions related to clinical presentation of oral cancer, duration of smoking status, and duration of alcohol consumption. However, no changes were suggested on the nature or number of the questions during pre-testing. However, some logistical requirements needs for subsequent data collection procedure were noted including, respondents seating arrangements to avoid deliberate discussions on their responses; presence of researcher during data collection to clarify survey questions and communication prior to data collection to organize optimal location for data collection and possibly seeking assistance from the dental assistants and the practice manager.

A satisfactory item completion rate in test-retest reliability phase was noted with all 30 participants completing all items and phases. Due to the nature of the study, the demographic characteristics such as age, gender, place of residence, and level of education were consistent across the two tests. The test-retest reliability results for the OCA questionnaire expanded for analysis purposes are detailed in Table 2 with the kappa values ranging from 0.16 (slight agreement) to 1 (perfect agreement). The items that evaluated risk factors, including duration of tobacco smoking ($k = 1$), smoking status ($k = 0.94$), duration of alcohol consumption ($k = 0.91$) showed almost perfect to perfect agreements. The questions related to advanced age, alcohol consumption and spicey food as risk factor also showed substantial agreement ($k = 0.68$). The questionnaire items adopted from Landis and Koch assessing functional consequences showed low kappa values (−0.017 to 0.52). However, the

TABLE 2 | Test-retest reliability results for the oral cancer awareness questionnaire ($n = 30$).

Serial no	Question	Kappa test	95% Confidence interval		Kappa results[a]
			Lower	Upper	
1	How do you identify your gender as?	Cohen's Kappa	1.00	1.00	1.00
2	What is your age (in years)?	Correlation coefficient	1.00	1.00	1.00
3	What is the highest level of education you obtained?	Fleiss Kappa	0.675	1.216	0.946
4	Do you identify as Aboriginal and/or Torres Strait Islander?	Fleiss Kappa	1.00	1.00	1.00
5	What is your household annual income before tax?	Weighted Kappa	0.694	0.933	0.813
6	Are you a concession card holder?	Cohen's Kappa	0.776	1.07	0.923
7	Are you a private health insurance holder?	Cohen's Kappa	1.00	1.00	1.00
8	Have you ever heard of oral cancer?	Fleiss Kappa	−0.350	0.215	−0.068[b]
9	Do you have any information about mouth, tongue, or lip cancer?	Fleiss Kappa	−0.092	0.451	0.179[b]
10	Can oral cancer clinically present as non-healing ulcer?	Fleiss Kappa	0.287	0.843	0.565
11	Can oral cancer clinically present as white patch?	Fleiss Kappa	0.267	0.814	0.541
12	Can oral cancer clinically present as a lump in the neck?	Fleiss Kappa	0.198	0.748	0.473
13	Can you identify tobacco as a risk factor for oral cancer?	Fleiss Kappa	1.00	1.00	1.00
14	Can you identify alcohol as a risk factor for oral cancer?	Fleiss Kappa	0.103	0.819	0.461
15	Can you identify betel nut as a risk factor for oral cancer?	Fleiss Kappa	−0.076	0.640	0.282[b]
16	Can you identify aged 60 or above as a risk factor for oral cancer?	Fleiss Kappa	0.240	0.956	0.598
17	Can you identify spicey food as a risk factor for oral cancer?	Fleiss Kappa	0.162	0.878	0.520
18	Do you get your information about health from GP?	Fleiss Kappa	−0.166	0.549	0.191[b]
19	Do you get information about your health from friends?	Fleiss Kappa	0.162	0.878	0.520
20	Do you get information about your health form internet searches?	Fleiss Kappa	0.109	0.825	0.467
21	Do you get information about your health from social media?	Fleiss Kappa	−0.099	0.617	0.259[b]
22	Where do you get information around oral cancer?	Fleiss Kappa	−0.047	0.372	0.163[b]
23	Who would you seek assistance from, if you suspect you or your family member had oral cancer?	Fleiss Kappa	0.108	0.670	0.389[b]
24	Have you received oral cancer examination in the last year?	Fleiss Kappa	0.309	0.856	0.583
25	Can tobacco increase the risk of oral cancer?	Fleiss Kappa	1.00	1.00	1.00
26	Can alcohol increase the risk of oral cancer?	Fleiss Kappa	0.374	1.017	0.695
27	Can betel nut increase the risk of oral cancer?	Fleiss Kappa	−0.064	0.586	0.261[b]
28	Can aged 60 or above increase the risk of oral cancer?	Fleiss Kappa	0.360	1.013	0.687
29	Can spicey food increase the risk of oral cancer?	Fleiss Kappa	0.462	1.073	0.767
30	Do you consider oral cancer as a serious health issue?	Fleiss Kappa	−0.358	0.244	−0.057[b]

(Continues)

TABLE 2 | (Continued)

Serial no	Question	Kappa test	95% Confidence interval		Kappa results[a]
			Lower	Upper	
31	Do you think oral cancer can be prevented?	Fleiss Kappa	0.234	0.766	0.525
32	Are you aware that smoking can increase the risk of oral cancer?	Fleiss Kappa	−0.375	0.341	−0.017[b]
33	Are you aware that alcohol consumption can increase the risk of oral cancer?	Fleiss Kappa	0.316	0.861	0.588
34	Are you aware that betel nut chewing increases the risk of oral cancer?	Fleiss Kappa	−0.025	0.474	0.224[b]
35	Regarding smoking, would you consider yourself to be:	Fleiss Kappa	0.675	1.216	0.946
36	How many years have you been smoking?	Weighted Kappa	1.00	1.00	1.00
37	How many years have you been drinking?	Weighted Kappa	0.815	1.013	0.914
38	How many years have you been chewing betel quid?	Weighted Kappa	0.719	0.926	0.823

[a]Kappa interpretation < 0 = Poor agreement; 0.20 = Slight agreement; 0.21–0.40 = Fair agreement; 0.41–0.60 = Moderate agreement; 0.61–0.80 = Substantial agreement; 0.81–1.00 = Almost perfect agreement [22].
[b]Results suggesting need for modification of questions.

question related to the clinical presentation of oral cancer, advanced age increasing the risk of oral cancer and had substantial agreement ($k = 0.58$).

In addition, perfect agreement was obtained through kappa value of 1.00 for the data (Expanded Q1, 2, 4, 7, 13, 25, and 36) wherein reliability was analyzed using Kappa interpretation based on Landis and Koch [22].

4 | Discussion

Oral cancer is a lethal and deforming disease mostly affecting the elderly population. Existing data suggests people living in low socio-economic, rural, and remote areas are highly disadvantaged due a range of factors including limited access to tertiary care facilities [9, 23–25]. Lack of awareness of risk factors and early signs are known contributors in patients presenting late to the clinic, with advanced stage of the disease and hence increased mortality rates specifically in oral cancers [26, 27]. This is of epidemiological and clinical importance in Queensland, Australia due to the high prevalence of both head and neck cancers and oral cancer affecting elderly population [16, 24]. Hence, this study was conducted to develop and validate a reliable instrument that can be used to identify the awareness levels on the early signs of oral cancer and its associated risk factors as applicable to Queensland. Few studies have specifically conducted the test-retest reliability of a customized OCA questionnaires for adults in Australia and other countries. The results of the present study are comparable to similar studies conducted across the world [17, 28, 29]. A wide range of kappa coefficients ($k = -0.017$–1) were consistently reported for another OCA survey questionnaire among Queensland adults previously [28]. The consistency is attributable to methodological similarities and level of completion achieved across the test-retest studies.

The development and validation of this questionnaire is essential for this population as there are no comparative studies available for Far North Queensland region. Our questionnaire had acceptable content validity indicating that the questions were appropriate and optimal to evaluate awareness of oral cancer in the region. The need for validated questionnaires has been widely acknowledged in literature for precise interpretation of epidemiological findings specific to a geographic location [17]. This tool can be considered reliable to assess OCA in Far North Queensland and could be adapted to other regions with similar demographics. Our reliability assessment suggested that the questionnaire can be effectively utilized for evaluation of OCA associated and risk factors within Far North Queensland adult population. In this study, high reliability in the items that evaluated tobacco (use and duration) as risk factor. Although the participants in study were limited to the adult population in Far North Queensland and the test-retest interval was 2 weeks, our results suggest that the questionnaire employed to collate similar information are reproducible. However, for this study, there were no comparative studies available for the region. There have been no differences between both the questionnaires administered 2 weeks apart, as the memory retention between adults showed significant reproducibility in items that evaluated risk factors for oral cancer and their awareness ($k = -0.07$–1.00). These results compare with others in the literature reporting on socio-demographic details,

awareness on oral cancer early signs, risk factor awareness, where they seek information from about health [30].

In our study, at least 11 questions showed low kappa coefficients (as noted in Table 2) even though there are often minimal ambiguity in the relevance of questions on oral cancer risk factor(s) awareness in epidemiological research. This may be partly explained by the low levels of knowledge around oral cancer in the sampled population or the ambiguity within the questions itself. This finding specifically warrants further simplification or rephrasing the questions, for example, replacing term "oral cancer" with "mouth cancer" so that they are easily understood by all participants.

The results of this study should be interpreted with caution, due to several limitations. The inclusion of two content experts in the validation study may be considered limited level of sampling. In addition, the experts were asked to limit their comments to the relevance of individual question based on recommendations by Davies [31] to simplify and reduce the time commitment needed by the experts due to their busy clinical load. Consequently, the questionnaire will need further content validation by experts belonging to multidisciplinary team involved in cancer research and patient care. In case of test-retest findings, the acknowledged limitations often relate to recall bias and forward telescoping that can alter participants' responses [32]. The participants may also have difficulty remembering the exact feature and purpose of the questionnaire, although this was addressed in our study by keeping the retest time to 2 weeks, which was sufficient time not to remember all the answers and still consistent answers were provided across both the questionnaires. Furthermore, the sample size ($n = 30$), often considered reasonable will need to be expanded to further confirm the reliability of the questionnaire.

5 | Conclusions

Based on the preliminary evidence of acceptable reliability for specific items/domains, the questionnaire was considered to possess acceptable content validity for use in adult patients attending JCU Dental Clinic. However, expanded studies evaluating the content validity of the questionnaire with further experts and refined statistics is needed. Furthermore, representation of all the professionals within multidisciplinary team and evaluation of various parameters of content validation including simplicity and clarity within the target population is warranted.

Author Contributions

Poornima Ramamurthy: conceptualization, investigation, methodology, writing – original draft, writing – review and editing. **William Pinzon Perez:** methodology, investigation, writing – review and editing. **Alan Clough:** conceptualization, investigation, methodology, supervision, writing – original draft, writing – review and editing. **Peter Thomson:** conceptualization, supervision, writing – review and editing.

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Ethics Statement

Ethical approval was obtained from the Human Research Ethics Committee Townsville Hospital and Health Service (HRES/2022/QTHS/90213 dated December 7, 2022).

Consent

All participants provided written informed consent before participating in the study. The participants were informed of the purpose, procedures, risks, and their rights to withdraw at any time without any penalty.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

The authors confirm that the data supporting the findings of this study are available within the article.

Transparency Statement

The lead author Poornima Ramamurthy affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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