BMJ Open

Patient complexity scored by the Patient Centered Assessment Method in a primary care setting in a Japanese island area and its validity and reliability: a cross-sectional study

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-050566
Article Type:	Original research
Date Submitted by the Author:	23-Feb-2021
Complete List of Authors:	Sugiyama, Yoshifumi; Jikei University School of Medicine, Mutai, Rieko; Jikei University School of Medicine, Clinical Epidemiology Yoshimoto, Hisashi; University of Tsukuba, Faculty of Medicine Horiguchi, Ryoko; Jikei University School of Medicine, Division of Clinical Epidemiology Yoshida, Shuhei; Hiroshima University, 1. Department of Community-Based Medical System; Matsushima, Masato; Jikei University School of Medicine, Division of Clinical Epidemiology
Keywords:	EPIDEMIOLOGY, GENERAL MEDICINE (see Internal Medicine), PRIMARY CARE, SOCIAL MEDICINE

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

TITLE PAGE

Title

Patient complexity scored by the Patient Centered Assessment Method in a primary care setting in a Japanese island area and its validity and reliability: a cross-sectional study

Authors

Yoshifumi Sugiyama[1, 2, 3], Rieko Mutai[1, 4], Hisashi Yoshimoto[5], Ryoko Horiguchi[1], Shuhei Yoshida[6], Masato Matsushima[1]

Author affiliations

[1]Division of Clinical Epidemiology, Research Center for Medical Sciences, The Jikei University School of Medicine, Tokyo, Japan

[2]Tarama Clinic, Okinawa Miyako Hospital, Miyakojima, Japan

[3]Division of Community Health and Primary Care, Center for Medical Education, The Jikei University School of Medicine, Tokyo, Japan

[4]Department of Adult Nursing, The Jikei University School of Nursing, Chofu, Japan

[5]Department of Family Medicine, General Practice and Community Health, Faculty of Medicine, University of Tsukuba, Tsukuba, Japan

[6]Department of Community-Based Medical System, Graduate School of Biomedical and Health Sciences, Hiroshima University, Hiroshima, Japan

Corresponding author

Yoshifumi Sugiyama

Division of Community Health and Primary Care, Center for Medical Education, The Jikei University School of Medicine, 3-25-8, Nishishimbashi, Minato-ku, Tokyo 105-8461, Japan

Tel: +81-3-3433-1111 (ext. 2390)

Email: yoshifumi.sugiyama@jikei.ac.jp

Word count

3792

ABSTRACT

Objectives The primary objective was to clarify the differences in patient complexity between a primary care setting in a Japanese island area and other care settings/areas. The secondary objective was to examine the validity and reliability of the original English version of the Patient Centered Assessment Method (PCAM) in a primary care setting.

Design Cross-sectional study.

Setting A clinic on a remote island in Okinawa, Japan, that provides general outpatient and 24-hour emergency services.

Participants This study included 355 patients who visited Tarama Clinic from April 1, 2018 to June 30, 2018, were aged ≥20 years, lived in Tarama Village, and had decision-making capacity.

Main outcome measures Patient complexity scored by the PCAM.

Results The mean (standard deviation) PCAM score was 21.4 (5.7) and the distribution was skewed to the right. Confirmatory factor analysis found that the previously reported two- and three-factor structures did not show a good fit (root mean square error of approximation 0.18 and 0.16, comparative fit index 0.83 and 0.89, and standardized root mean square residual 0.14 and 0.11, respectively). Exploratory factor analysis revealed a new two-factor structure: "biomedical complexity" and "psychosocial complexity." The Cronbach's alpha values for the total PCAM score, the "biomedical complexity" factor, and the "psychosocial complexity" factor were 0.81, 0.82, and 0.74, respectively.

Conclusions The distribution of and mean PCAM scores differed from those reported in previous studies conducted in Japanese secondary care and Japanese urban primary care settings. Additionally, confirmatory factor analysis found that the data did not fit sufficiently using the previously reported factor structures. Instead, exploratory factor analysis revealed a new two-factor structure, for which the Cronbach's alpha values exceeded the threshold level. Therefore, the construct validity and internal consistency of the English version of the PCAM were verified in a primary care setting in a Japanese island area.

Keywords

patient complexity, the Patient Centered Assessment Method, primary care, island area, validity, reliability

Strengths and limitations of this study

- Most patients on Tarama Island are expected to choose Tarama Clinic because of geographical restrictions; therefore, this study was population-based.
- The generalizability of these findings may be limited because this study was conducted at a single medical institution in an island area of Okinawa Prefecture, Japan.
- Inter-rater reliability was not evaluated because Tarama Clinic is the only medical institution (other than a dental clinic) on Tarama Island, and the primary investigator was the sole physician.
- Some eligible participants were excluded, and exclusion of possible participants with high or low patient complexity might have resulted in under- or over-estimation of PCAM scores.

INTRODUCTION

Increased attention has been paid to both biological and psychosocial aspects of patients. In the latter half of the 1970s, Engel proposed a biopsychosocial model as a holistic alternative to the biological model that was predominant in the mid-20th century, but was considered to have substantial limitations caused by understanding and responding to patients' suffering from a biological perspective.[1] As its name indicates, the biopsychosocial model adopts biological, psychological, and social perspectives, and seeks to understand and respond to patients' suffering holistically.[1] From a biopsychosocial perspective, patients' characteristics are incorporated into a concept called "patient complexity."[2] This is defined as "person-specific factors that interfere with the delivery of usual care and decision-making for whatever conditions the patient has."[2]

Various tools have been developed to assess patient complexity. INTERMED is one such tool, for which the validity and reliability have been evaluated in secondary care settings.[3,4] The Minnesota Complexity Assessment Method (MCAM) was developed for use in primary care settings based on INTERMED.[2] The Patient Centered Assessment Method (PCAM) is an advanced version of the MCAM and assesses patient complexity using 12 items across four domains: "Health and Well-being," "Social Environment," "Health Literacy and Communication," and "Service Coordination."[5] The PCAM enables healthcare professionals to identify and assess patients' problems from a biopsychosocial perspective and deal with these problems in order of priority based on severity and level of urgency.[5] Therefore, the PCAM supports healthcare professionals to make referrals to a wide range of services to better meet patients' needs.[5] Yoshida et al. confirmed the validity and reliability of the original English version of the PCAM in a Japanese secondary care setting.[6] Mutai et al. developed a Japanese version of the PCAM and confirmed its validity and reliability in a primary care setting in a Japanese urban area.[7] Previous research using the PCAM showed that PCAM scores were associated with various health outcomes, such as length of hospital stay,[7] burden for physicians and nurses,[8] and alcohol consumption/alcohol use disorders.[9]

During the past two decades, evidence has increased about the social determinants of health (SDH), which refer to non-medical social factors that influence health outcomes such as income, education, and employment.[10,11] Accordingly, SDH influence patients' biopsychological aspects as

well as their social aspects. Therefore, differences in SDH between primary and secondary care settings or across geographical areas are expected to result in different distributions of patient complexity.

Although a number of studies regarding patient complexity and PCAM have been published,[6,8,9] no research has clarified the differences in patient complexity between a primary care setting in a Japanese island area and other care settings/areas. In addition, the validity and reliability of the original English version of the PCAM have not been examined in a primary care setting. The primary objective of this study was to clarify the differences in patient complexity between a primary care setting in a Japanese island area and other care settings/areas. This information will enable healthcare professionals to more accurately assess patient complexity and better understand patients' needs from a biopsychosocial perspective, especially given differences across care settings or areas. The secondary objective of this study was to examine the validity and reliability of the original English version of the PCAM in a primary care setting. The rationale for this was that it will promote more research on the association between PCAM and other health outcomes, which will lead to better assessment and understanding of patient complexity and provide healthcare professionals with guidance on optimal medical care.

METHODS

This study was conducted in conjunction with another study that examined the association between alcohol consumption/alcohol use disorders and patient complexity.[9]

Design

This study used a cross-sectional design and was reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines.[12]

Setting

We conducted this study at Tarama Clinic, Okinawa Miyako Hospital, which is located on Tarama Island, Okinawa Prefecture, Japan.[13] Tarama Island is situated approximately 67 km west of Miyako Island (125 minutes by ferry[14] or 25 minutes by airplane[15]),[16] which is approximately

300 km southwest of the main island of Okinawa Prefecture (55 minutes by airplane[15]).[17] Tarama Island is the main part of Tarama Village,[16] which had a population of 1,194 people (555 women and 639 men) in 2015.[18] The population aging rate for that year was 26.4%,[19] which was almost same as the national average (26.6%).[19] In Tarama Village, 41.6% of the population work in primary industries (agriculture, forestry, and fishery) and almost all of these workers (41.2% of 41.6%) are engaged in agriculture.[20, 21] This proportion is considerably higher than the national average (3.8%).[22] Overall, 92.0% of the land on Tarama Island is devoted to raising beef cattle and growing sugar cane, vegetables, and tobacco.[16, 23] The average annual income is 1,765,000 yen,[24] which is substantially lower than the national average (3,217,000 yen).[25]

Tarama Clinic, which has four staff (a physician, a nurse, a nurse assistant, and a clerk), is the only medical institution on the island (other than a dental clinic) and provides general outpatient and 24-hour emergency services.[26] Japan has a "free access" healthcare system where patients are free to choose any medical institution.[27] However, most patients on Tarama Island are expected to choose Tarama Clinic because of geographical restrictions. This condition enabled this study to be population-based.

Participants

We consecutively included patients who visited Tarama Clinic from April 1, 2018 to June 30, 2018. Of these patients, those who were aged ≥20 years, lived in Tarama Village, and had decision-making capacity were judged to be eligible for this study. Patients who refused to participate in this study were excluded. Patients whose participation was judged to have an unfavorable influence on the patient–physician relationship were also excluded. Finally, patients were excluded if the primary investigator was out of office and unable to obtain informed consent from a patient, or when many patients were in the waiting room and obtaining informed consent from a patient interfered with usual medical practice.

Data collection

We collected data for this study from April 1, 2018 to March 31, 2019.

Outcome measures

PCAM

The PCAM is a tool for assessing patient complexity from a biopsychosocial perspective[5] and has four domains: "Health and Well-being," "Social Environment," "Health Literacy and Communication," and "Service Coordination."[28] Each domain has two or four items: "Health and Well-being" has four items (#1 "Physical health needs," #2 "Physical health impacting on mental well-being," #3 "Lifestyle impacting on physical or mental well-being," and #4 "Other mental well-being concerns"); "Social Environment" has four items (#1 "Home environment," #2 "Daily activities," #3 "Social networks," and #4 "Financial resources"); "Health Literacy and Communication" has two items (#1 "Health literacy" and #2 "Engagement in discussion"); and "Service Coordination" has two items (#1 "Other services" and #2 "Service coordination").[28] Each item has four levels of increasing complexity ("Routine Care," "Active Monitoring," "Plan Action," and "Act Now") and is scored from 1 to 4 as complexity increases.[28,29] This gives a total PCAM score from 12 (minimum) to 48 (maximum).[29] The validity and reliability of the original English version of the PCAM have been verified in a secondary care setting,[6] and those of the Japanese version of the PCAM have been verified in a primary care setting.[7] However, the validity and reliability of the original English version of the PCAM in a primary care setting remain unclear. When patients visited Tarama Clinic, the sole physician (primary investigator) scored the PCAM in accordance with the "PCAM User Guide for Conducting the Assessment,"[30] which eliminated inter-rater variability.

Other variables

We obtained patients' age and sex from their medical records and calculated their annual medical expenses during the prior year using medical fee receipts. We used a self-administered questionnaire to obtain information about educational background ("below a high school diploma" or "equivalent to a high school diploma or above"), employment status ("in work" or "out of work"), physical activity status ("exercising" or "not exercising"), smoking status ("current smoker," "ex-smoker," or "never smoked"), and the number of family members living with the patient. A nurse

assisted patients to respond to the questionnaire as necessary. “In work” was defined as full-time or part-time workers and housewives/househusbands, and “out of work” as those without an occupation. “Exercising” was defined as engaging in physical activity for more than half an hour twice a week for 1 year or more.

Sample size

Various methods of sample size calculation have been proposed for factor analysis, which are expressed as either the sample size or the ratio of sample size to the number of variables. A sample size of 300 is reported to be good.[31] A large ratio of sample size to the number of variables (e.g., 20:1) is also considered to be good,[32] which gave a sample size of 240 for the 12 PCAM items. Based on these two methods, a sample size of 300 patients was used in this study.

Statistical analysis

We performed confirmatory factor analysis with weighted least square mean and variance adjusted (WLSMV) estimation, using the scores for each PCAM item as categorical variables. First, in accordance with previous study findings for the validity of the original English version of the PCAM in a secondary care setting, a two-factor structure (“Patient-oriented complexity” and “Medicine-oriented complexity”) was hypothesized.[6] Patient-oriented complexity included three “Health and Well-being” items (#2, #3, and #4); two “Social Environment” items (#2 and #3); and two “Health Literacy and Communication” items (#1 and #2). Medicine-oriented complexity included one “Health and Well-being” item (#1); two “Social Environment” items (#1 and #4); and two “Service Coordination” items (#1 and #2).[6] Second, in accordance with previous study findings for the validity of the Japanese version of the PCAM in a primary care setting, a three-factor structure (“Personal well-being,” “Social interaction,” and “Needs for care/service”) was also hypothesized.[7] Personal well-being included three “Health and Well-being” items (#1, #2, and #4), and one “Social Environment” item (#2). Social interaction included one “Social Environment” item (#3) and two “Health Literacy and Communication” items (#1 and #2). Needs for care/service included one “Social Environment” item (#1) and two “Service Coordination” items (#1 and #2). The fit indices were judged to be good if

root mean squared error of approximation (RMSEA) was ≤0.08, comparative fit index (CFI) was ≥0.90, and standardized root mean square residual (SRMR) was ≤0.08.[33]

Where statistical testing found the model fit to be poor, exploratory factor analysis with WLSMV estimation and promax rotation was used to examine the construct validity of the PCAM. A scree plot and a cut-off value for factor loading of 0.4 were adopted to determine how many factors there were, and which items should be included on each factor.

Additionally, Cronbach's alpha, which is considered satisfactory if the value is ≥0.7,[34] was calculated as an index of internal consistency to examine the reliability of the PCAM.

We performed descriptive analysis and calculated Cronbach's alpha values using Stata/MP version 15.1.[35] Confirmatory and exploratory factor analyses were performed using Mplus version 8.4.[36]

Patient and public involvement

We conducted this study without patient and public involvement.

RESULTS

During the inclusion period, 521 patients visited Tarama Clinic. Of these, 57 patients were younger than 20 years, 13 patients did not live in Tarama Village, and 25 patients did not have decision-making capacity, which left 426 eligible patients. We excluded 28 patients who refused to participate in this study and nine patients whose participation was judged to have an unfavorable influence on the patient–physician relationship. The primary investigator was unable to obtain informed consent from two patients because he was out of office, and from a further 32 patients because many patients were in the waiting room at that time. As a result, 355 patients were included in this study (see figure 1 of Sugiyama et al.[9]). There were no missing values for outcome measures or other variables among the study participants.

The characteristics of study participants are shown in table 1 of Sugiyama et al.[9] The mean (SD, standard deviation) PCAM score was 21.4 (5.7) and the distribution was skewed to the right (see figure 2 of Sugiyama et al.[9]).

Confirmatory factor analysis found that using the previously reported two-factor structure,[6] the fit indices were: RMSEA = 0.18, CFI = 0.83, and SRMR = 0.14. Confirmatory factor analysis also found that using the three-factor structure,[7] the fit indices were: RMSEA = 0.16, CFI = 0.89, and SRMR = 0.11. Because the data did not fit sufficiently, we performed exploratory factor analysis to evaluate the factor structure.

Table 1. Exploratory factor analysis of Patient Centered Assessment Method scores

Domain and item	First factor	Second factor
Health and Well-being		
1 Physical health needs	0.701	−0.035
2 Physical health impacting on mental well-being	0.081	0.578
3 Lifestyle impacting on physical or mental well-being	0.895	−0.136
4 Other mental well-being concerns	0.190	0.442
Social Environment		
1 Home environment	−0.122	0.630
2 Daily activities	−0.059	0.683
3 Social networks	−0.266	0.715
4 Financial resources	0.256	0.452
Health Literacy and Communication		
1 Health literacy	0.894	0.117
2 Engagement in discussion	0.621	0.358
Service Coordination		
1 Other services	0.109	0.806
2 Service coordination	0.137	0.835

Note: Underlining indicates included items.

This exploratory factor analysis revealed a new two-factor structure (table 1), which differed from previous studies.[6,7] The first factor extracted comprised four items: two "Health and Well-being" items (#1 and #3) and two "Health Literacy and Communication" items (#1 and #2). This factor was labeled "biomedical complexity" because it concerned biomedical issues such as physical health needs, lifestyle behaviors, and understanding of/engagement in mainly physical health needs. The second factor extracted comprised eight items: two "Health and Well-being" items (#2 and #4); four "Social Environment" items (#1, #2, #3, and #4); and two "Service Coordination" items (#1 and #2). This factor

was labeled “psychosocial complexity” because it concerned psychosocial issues such as mental well-being, home environment, daily activities, social networks, financial resources, and service coordination.

The Cronbach’s alpha values for the total PCAM score, the “biomedical complexity” factor, and the “psychosocial complexity” factor were 0.81, 0.82, and 0.74, respectively.

DISCUSSION

In this study, the distribution of and mean PCAM scores differed from those reported in previous studies conducted in Japanese secondary care and Japanese urban primary care settings. Additionally, confirmatory factor analysis found that the data did not fit sufficiently using the previously reported two- and three- factor structures. Instead, exploratory factor analysis revealed a new two-factor structure, for which the Cronbach’s alpha values exceeded the threshold level. Therefore, the construct validity and internal consistency of the English version of the PCAM were verified in a primary care setting in a Japanese island area.

In this study, the distribution of PCAM scores was skewed to the right; that is, inclined to be low. Yoshida et al. showed a widespread distribution of scores and a higher mean (SD) PCAM score at 25.0 (7.3) compared with our study.[6] This discrepancy may be attributable to differences in clinical settings between the studies. Yoshida et al.[6] conducted their study in a secondary care setting and the participants were inpatients who were presumed to be biomedically and psychosocially more complex than outpatients in a primary care setting. Furthermore, the mean age (66.4 years) in this study was lower than that reported by Yoshida et al. (77.4 years). Older people are expected to be more complex, and have more diverse and complicated backgrounds, such as multimorbidity, dementia, and social isolation.[37, 38, 39] Similarly, confirmatory factor analysis using the previously reported two-factor structure (Patient-oriented complexity and Medicine-oriented complexity)[6] revealed that the poor fit may be attributable to differences in clinical settings and disparities between the island area in this study and the urban area in Yoshida et al.[6] It is important to note that interlinking mechanisms cascade from social–structural conditions down to biomedical and psychological problems.[40] Therefore, healthcare

professionals should recognize that differences in care settings need to be considered when assessing patient complexity.

Conversely, Mutai et al. showed a distribution with a floor effect similar to that in this study, but a lower mean (SD) PCAM score than our study at 16.5 (5.1).[7] Both our study and Mutai et al. were conducted in primary care settings. Mutai et al. used the Japanese version of the PCAM, which was developed using forward translation, back translation, and cognitive debriefing for cultural adaptation,[7] whereas this study used the original English version of the PCAM. The modification of the tool might have contributed to the discrepancies. However, this was minimized because the contents of the Japanese and original English versions were almost the same. Instead, as described above, disparities between the island area in this study and the urban area in Mutai et al. should be considered. For example, 52.7% of the participants in this study and 29.0% in Mutai et al. had an education level below a high school diploma. Educational background is associated with various aspects of patient complexity, such as health risks and protective behaviors, wages and income, and resources for health.[41] In addition, the items "Daily activities (including employment status)" and "Financial resources" were directly associated with the proportion of participants who were out of work[28] (13.5% and 56.7% in this study and Mutai et al., respectively). Although the mean age in this study (66.4 years) was lower than that in Mutai et al. (72.4 years), educational background might have had a greater influence on patient complexity given the higher PCAM score in this study than in Mutai et al. These differences may explain the poor fit as shown by confirmatory factor analysis of the previously reported three-factor structure (Personal well-being, Social interaction, and Needs for care/service).[7] Compared with urban areas, healthcare professionals in areas with lower accessibility to medical services (such as island areas) may have to provide services to patients with higher complexity caused by underlying factors, including lower educational background. Therefore, they may need training to appropriately assess patients' biopsychosocial needs.

In this study, the construct validity and internal consistency of the English version of the PCAM were verified in a primary care setting in a Japanese island area. Exploratory factor analysis identified a new two-factor structure, comprising biomedical and psychosocial complexity. The first factor comprised items related to biomedical issues (e.g., physical health needs, lifestyle behaviors, and

understanding of/engagement in mainly physical health needs). The second factor covered psychosocial issues (e.g., mental well-being, home environment, daily activities, social networks, financial resources, and service coordination). This provided strong support for the construct validity of the PCAM, especially as the PCAM was developed to assess patient complexity from both biomedical and psychosocial perspectives.[5] As described above, various factors contributed to our finding of a new two-factor structure. For example, "Health literacy"/"Engagement in discussion" and "Social networks" loaded on a common factor in Japanese urban areas.[6,7] Mutai et al. discussed why these items loaded on a common factor and explained that "Health literacy" and "Engagement in discussion" were associated with health literacy, including communicative/interactive literacy, which was also necessary for active participation in "Social networks."[7] However, "Health literacy" and "Engagement in discussion" loaded on a different factor from "Social networks" in this study. Communicative/interactive literacy associated with "Health literacy" and "Engagement in discussion" may not always be necessary to participate in "Social networks" in a small community in a Japanese island area, where participation is presumably "forced" through stronger peer pressure than in urban areas.[42] The Cronbach's alpha values in this study exceeded the threshold level, and confirmed the reliability of the PCAM. Therefore, the PCAM is a valid and reliable tool for assessing patient complexity in a primary care setting in a Japanese island area.

There are important points to consider relating to this study. The accuracy of estimating factor structures might have resulted in discrepancies between the studies. In this study, we performed factor analysis using the scores for each PCAM item as categorical variables, although these were regarded as continuous variables in the previous studies.[6,7] This variable was scored 1, 2, 3, or 4 as complexity increased,[29] and therefore the estimation method for categorical data was considered more appropriate and extracted the factor structure more accurately.[43] Additionally, difficulty in evaluating the PCAM might also have influenced the discrepancy between studies. The PCAM has 12 items across four domains, and each item includes a variety of topics.[28] For example, the item "Social network" covers social networks with friends as well as with family members and work colleagues.[28] It may therefore take more time, which could be spent with patients, to collect all related information. Furthermore, some items are personal questions. For example, the item "Financial resources" asks about

financial insecurity, such as ability to make medical payments.[28] Some patients might perceive it as inappropriate to discuss such financial topics with healthcare professionals;[44] therefore, these items might have been answered incorrectly, as noted in previous research.[7] Evaluating the PCAM correctly in a short consultation is difficult, which further complicates the issues of the variety of topics covered and collection of personal information. In this study, the primary investigator was the only physician in Tarama Village and lived together with the other residents (including study participants) in a small community,[26] which created close patient–physician relationships. This might have enabled the primary investigator to understand a variety of topics and personal information, and evaluate the PCAM more correctly.[45] These differences in evaluation may also explain the discrepancies between studies.

There were several limitations in this study. First, we conducted this study at a single medical institution in an island area of Okinawa Prefecture, Japan, which may limit the generalizability of the findings. To ensure some degree of generalizability, further multicenter studies are warranted. Second, Tarama Clinic is the only medical institution (other than a dental clinic) on Tarama Island and the primary investigator was the only physician there; therefore, patients did not receive assessment from two physicians and inter-rater reliability was not evaluated. Consequently, we might have over- or under-estimated PCAM scores. Third, although we included study participants consecutively, 16.7% of eligible participants were excluded. Nine patients were excluded because their participation was judged to have an unfavorable influence on the patient–physician relationships. The main reason was that they had confirmed or suspected mental or personality disorders, which is likely to cause high psychological complexity. Exclusion of these possible participants might have resulted in underestimation of PCAM scores. Additionally, the primary investigator was unable to obtain informed consent from two patients because he was out of office, and from a further 32 patients because many patients were in the waiting room at that time. These patients visited the clinic only once during the inclusion period and therefore could not be enrolled in this study during a subsequent visit. These patients usually had mild acute diseases, such as upper respiratory tract inflammation or gastroenteritis, and were otherwise healthy, which meant their patient complexity was likely to be low. Exclusion of these possible participants might have resulted in overestimation of PCAM scores.

CONCLUSION

In this study, the distribution of and mean PCAM scores differed from those reported in previous studies conducted in Japanese secondary care and Japanese urban primary care settings. Additionally, confirmatory factor analysis found that the data did not fit sufficiently using the previously reported two- and three- factor structures. Instead, exploratory factor analysis revealed a new two-factor structure, for which the Cronbach's alpha values exceeded the threshold level. Therefore, the construct validity and internal consistency of the English version of the PCAM were verified in a primary care setting in a Japanese island area.

Acknowledgments

The authors express their appreciation to Ms. C Higa (Tarama Clinic, Okinawa Miyako Hospital) for supporting data collection. We thank Audrey Holmes, MA, from Edanz Group (https://en-author-services.edanz.com/ac) for editing a draft of this manuscript.

Contributors

YS designed this study, collected, analyzed, and interpreted the data, and prepared and reviewed the manuscript. RM, HY, RH, and SY contributed to the design of the study and reviewed the manuscript. MM contributed to the design of the study, analyzed and interpreted the data, and reviewed the manuscript.

Funding

This study was supported by The Jikei University Research Fund for Graduate Students (grant number: N/A).

Disclaimer

The sponsor of this study had no role in the study design; the study conduct: collection, analysis, or interpretation of the data; preparation of the manuscript; or the decision to submit the manuscript for publication.

Competing interests

YS, HY, and SY are former trainees of the Jikei Clinical Research Program for Primary-care. MM received lecture fees and lecture travel fees from the Centre for Family Medicine Development of the Japanese Health and Welfare Co-operative Federation. MM is an adviser for the Centre for Family Medicine Development Practice-Based Research Network and a program director of the Jikei Clinical Research Program for Primary-care. MM's son-in-law works at IQVIA Services Japan K.K., which is a contract research organization and a contract sales organization. All other authors declare no competing interests.

Ethics approval

This study was approved by the Ethics Committee of Okinawa Miyako Hospital (approval date: February 8, 2018) and the Ethics Committee of The Jikei University School of Medicine (acceptance number: 30-412 (9433)).

Data sharing statement

No additional data are available.

REFERENCES

1. Engel GL. The need for a new medical model: a challenge for biomedicine. *Science* 1977;196:129–36.
2. Peek CJ, Baird MA, Coleman E. Primary care for patient complexity, not only disease. *Fam Syst Health* 2009;27:287–302.
3. Huyse FJ, Lyons JS, Stiefel FC, et al. "INTERMED": a method to assess health service needs. I. Development and reliability. *Gen Hosp Psychiatry* 1999;21:39–48.
4. Stiefel FC, de Jonge P, Huyse FJ, et al. "INTERMED": a method to assess health service needs. II. Results on its validity and clinical use. *Gen Hosp Psychiatry* 1999;21:49–56.
5. Pratt R, Hibberd C, Cameron IM, et al. The Patient Centered Assessment Method (PCAM): integrating the social dimensions of health into primary care. *J Comorb* 2015;5:110–9.
6. Yoshida S, Matsushima M, Wakabayashi H, et al. Validity and reliability of the Patient Centred Assessment Method for patient complexity and relationship with hospital length of stay: a prospective cohort study. *BMJ Open* 2017;7:e016175.
7. Mutai R, Sugiyama Y, Yoshida S, et al. Development and validation of a Japanese version of the Patient Centred Assessment Method and its user guide: a cross-sectional study. *BMJ Open* 2020;10:e037282.
8. Yoshida S, Matsushima M, Wakabayashi H, et al. Correlation of patient complexity with the burden for health-related professions, and differences in the burden between the professions at a Japanese regional Hospital: a prospective cohort study. *BMJ Open* 2019;9:e025176.
9. Sugiyama Y, Matsushima M, Yoshimoto H. Association between alcohol consumption/alcohol use disorders and patient complexity: a cross-sectional study. *BMJ Open* 2020;10:e034665.
10. World Health Organization. Social determinants of health. Available: https://www.who.int/health-topics/social-determinants-of-health#tab=tab_1 (accessed Nov 23, 2020).
11. World Health Organization Europe. Social determinants of health: the solid fact, 2nd edition. Available: https://www.euro.who.int/__data/assets/pdf_file/0005/98438/e81384.pdf (accessed Nov 23, 2020).

12. von Elm E, Altman DG, Egger M, et al. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. *BMJ* 2007;335:806–8.
13. Tarama Clinic, Okinawa Miyako Hospital [In Japanese]. Available: http://www.hosp.pref.okinawa.jp/sinryo/tarama/tarama.html (accessed Nov 23, 2020).
14. Tarama Kaiun [In Japanese]. Available: http://www.taramakaiun.com (accessed Nov 23, 2020).
15. Japan Airlines [In Japanese]. Available: https://www.jal.co.jp (accessed Nov 23, 2020).
16. Tarama Village [In Japanese]. Available: http://www.vill.tarama.okinawa.jp/?p=89 (accessed Nov 23, 2020).
17. Miyakojima City [In Japanese]. Available: https://www.city.miyakojima.lg.jp/syoukai/gaiyou.html (accessed Nov 23, 2020).
18. e-Stat. Population by sex, sex ratio and households and household members, by type of household (2 groups) - Japan*, all shi, all gun, prefectures*, all shi of prefectures, all gun of prefectures, shi*, ku*, machi*, mura* and municipalities in 2000 [In Japanese]. Available: https://www.e-stat.go.jp/en/stat-search/file-download?statInfId=000031473211&fileKind=1 (accessed Nov 23, 2020).
19. e-Stat. Population (total and Japanese population), by age (single years) and sex, percentage by age, average age and median age - Japan*, all shi, all gun, prefectures*, all shi of prefectures, all gun of prefectures, shi*, ku*, machi*, mura* and municipalities in 2000 [In Japanese]. Available: https://www.e-stat.go.jp/en/stat-search/file-download?statInfId=000031473213&fileKind=1 (accessed Nov 23, 2020).
20. Okinawa Prefectural Government. Basic complete tabulation on labour force [In Japanese]. https://www.pref.okinawa.jp/toukeika/pc/2015/shugyou/gaiyou.pdf (accessed Nov 23, 2020).
21. Ministry of Agriculture, Forestry and Fisheries. Detailed data of Tarama Village [In Japanese]. http://www.machimura.maff.go.jp/machi/contents/47/375/details.html (accessed Nov 23, 2020).
22. Statistics Bureau of Japan. Basic complete tabulation on labour force [In Japanese]. https://www.stat.go.jp/data/kokusei/2015/final/pdf/01-02.pdf (accessed Nov 23, 2020).

23. Tarama Village. Tarama Village population vision and comprehensive strategy [In Japanese]. http://www.vill.tarama.okinawa.jp/wp-content/uploads/2016/04/tarama_vision.pdf (accessed Nov 23, 2020).
24. Okinawa Prefectural Government. Income in cities, towns and villages of Okinawa Prefecture for 2015 [In Japanese]. https://www.pref.okinawa.jp/toukeika/ctv/H27/00all(h27).pdf (accessed Nov 23, 2020).
25. Cabinet Office. Annual report on prefectural accounts for 2016 [In Japanese]. https://www.esri.cao.go.jp/jp/sna/data/data_list/kenmin/files/contents/pdf/gaiyou.pdf (accessed Nov 23, 2020).
26. Tarama Clinic, Okinawa Miyako Hospital [In Japanese]. Available: https://www.ritoushien.net/tarama.shtml (accessed Nov 23, 2020).
27. World Health Organization. Japan health system. Available: https://apps.who.int/iris/bitstream/handle/10665/259941/9789290226260-eng.pdf (accessed Nov 23, 2020).
28. Patient Centered Assessment Method Tool. Available: https://med.umn.edu/sites/med.umn.edu/files/pcam_assessment_tool_2.0.pdf (accessed Nov 23, 2020).
29. Patient Centered Assessment Method for Research. Available: https://med.umn.edu/sites/med.umn.edu/files/pcam_2.0-research_scoring.pdf (accessed Nov 23, 2020).
30. Patient Centered Assessment Method Assessor Guide. Available: https://med.umn.edu/sites/med.umn.edu/files/pcam_assessor_guide.pdf (accessed Nov 23, 2020).
31. Comrey AL, Lee HB. A first course in factor analysis. second edition. Hillsdale, NJ: Lawrence Erlbaum Associates, 1992:205–28.
32. Costello AB, Osborne JW. Best practices in exploratory factor analysis: four recommendations for getting the most from your analysis. *Pract Assess Res Evaluation* 2005;10.
33. Hooper D, Coughlan J, Mullen M. Structural equation modelling: guidelines for determining model fit. *Elecron J Bus Res Methods* 2008;6:53–60.

34. Bland JM, Altman DG. Cronbach's alpha. *BMJ* 1997;314:572.
35. StataCorp. 2017. Stata: Release 15. Statistical Software. College Station, TX: StataCorp LL.
36. Muthén, L.K. and Muthén, B.O. (1998-2017). Mplus User's Guide. Eighth Edition. Los Angeles, CA: Muthén & Muthén.
37. Salisbury C, Johnson L, Purdy S, et al. Epidemiology and impact of multimorbidity in primary care: a retrospective cohort study. *Br J Gen Pract* 2011;61:e12–21.
38. Prince M, Bryce R, Albanese E, et al. The global prevalence of dementia: a systematic review and metaanalysis. *Alzheimers Dement* 2013;9:63–75.
39. Steptoe A, Shankar A, Demakakos P, et al. Social isolation, loneliness, and all-cause mortality in older men and women. *Proc Natl Acad Sci U S A* 2013;110:5797–801.
40. Berkman LF, Glass T, Brissette I, et al. From social integration to health: Durkheim in the new millennium. *Soc Sci Med* 2000;51:843–57.
41. Hahn RA, Truman BI. Education improves public health and promotes health equity. *Int J Health Serv* 2015;45:657–78.
42. Smith RJ. The Japanese rural community: norms, sanctions, and ostracism. *Am Anthropol* 1961;63:522–33.
43. Rhemtulla M, Brosseau-Liard PÉ, Savalei V. When can categorical variables be treated as continuous? A comparison of robust continuous and categorical SEM estimation methods under suboptimal conditions. *Psychol Methods* 2012;17:354–73.
44. Maxwell M, Hibberd C, Aitchison P, et al. The Patient Centred Assessment Method for improving nurse-led biopsychosocial assessment of patients with long-term conditions: a feasibility RCT. *Health Services and Delivery Research* 2018;6:17–29.
45. Lipkin M Jr, Putnam SM, Lazare A, eds. The medical interview: clinical care, education, and research. New York, NY: Springer-Verlag, 1995.

Reporting checklist for cross sectional study.

Based on the STROBE cross sectional guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the STROBE cross sectionalreporting guidelines, and cite them as:

von Elm E, Altman DG, Egger M, Pocock SJ, Gotzsche PC, Vandenbroucke JP. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: guidelines for reporting observational studies.

		Reporting Item	Page Number
Title and abstract			
Title	#1a	Indicate the study's design with a commonly used term in the title or the abstract	1
Abstract	#1b	Provide in the abstract an informative and balanced summary of what was done and what was found	3
Introduction			
Background / rationale	#2	Explain the scientific background and rationale for the investigation being reported	5, 6
Objectives	#3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	#4	Present key elements of study design early in the paper	6
Setting	#5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6, 7

Eligibility criteria	#6a	Give the eligibility criteria, and the sources and methods of selection of participants.	7
	#7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8, 9
Data sources / measurement	#8	For each variable of interest give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group. Give information separately for for exposed and unexposed groups if applicable.	8, 9
Bias	#9	Describe any efforts to address potential sources of bias	7, 8
Study size	#10	Explain how the study size was arrived at	9
Quantitative variables	#11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why	9
Statistical methods	#12a	Describe all statistical methods, including those used to control for confounding	9, 10
Statistical methods	#12b	Describe any methods used to examine subgroups and interactions	n/a
Statistical methods	#12c	Explain how missing data were addressed	10
Statistical methods	#12d	If applicable, describe analytical methods taking account of sampling strategy	n/a
Statistical methods	#12e	Describe any sensitivity analyses	Sensitivity analyses were not performed.
Results			
Participants	#13a	Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed. Give information separately for for exposed and unexposed groups if applicable.	10
Participants	#13b	Give reasons for non-participation at each stage	10

Participants	#13c	Consider use of a flow diagram	A flow diagram was not used.
Descriptive data	#14a	Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders. Give information separately for exposed and unexposed groups if applicable.	10
Descriptive data	#14b	Indicate number of participants with missing data for each variable of interest	10
Outcome data	#15	Report numbers of outcome events or summary measures. Give information separately for exposed and unexposed groups if applicable.	10–12
Main results	#16a	Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	10–12
Main results	#16b	Report category boundaries when continuous variables were categorized	n/a
Main results	#16c	If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
Other analyses	#17	Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses	Other analyses were not performed
Discussion			
Key results	#18	Summarise key results with reference to study objectives	12
Limitations	#19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias.	15
Interpretation	#20	Give a cautious overall interpretation considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence.	12–15
Generalisability	#21	Discuss the generalisability (external validity) of the study results	15

Other Information			
Funding	#22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	16

BMJ Open

The structural validity and internal consistency of the Patient Centered Assessment Method in a primary care setting in a Japanese island area: a cross-sectional study

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-050566.R1
Article Type:	Original research
Date Submitted by the Author:	27-Nov-2021
Complete List of Authors:	Sugiyama, Yoshifumi; Jikei University School of Medicine, Mutai, Rieko; Jikei University School of Medicine, Clinical Epidemiology Yoshimoto, Hisashi; University of Tsukuba, Faculty of Medicine Horiguchi, Ryoko; Jikei University School of Medicine, Division of Clinical Epidemiology Yoshida, Shuhei; Hiroshima University, 1. Department of Community-Based Medical System; Matsushima, Masato; Jikei University School of Medicine, Division of Clinical Epidemiology
Primary Subject Heading:	General practice / Family practice
Secondary Subject Heading:	Epidemiology
Keywords:	EPIDEMIOLOGY, GENERAL MEDICINE (see Internal Medicine), PRIMARY CARE, SOCIAL MEDICINE

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

TITLE PAGE

Title

The structural validity and internal consistency of the Patient Centered Assessment Method in a primary care setting in a Japanese island area: a cross-sectional study

Authors

Yoshifumi Sugiyama[1, 2, 3], Rieko Mutai[1, 4], Hisashi Yoshimoto[5], Ryoko Horiguchi[1], Shuhei Yoshida[6], Masato Matsushima[1]

Author affiliations

[1]Division of Clinical Epidemiology, Research Center for Medical Sciences, The Jikei University School of Medicine, Tokyo, Japan

[2]Tarama Clinic, Okinawa Miyako Hospital, Miyakojima, Japan

[3]Division of Community Health and Primary Care, Center for Medical Education, The Jikei University School of Medicine, Tokyo, Japan

[4]Department of Adult Nursing, The Jikei University School of Nursing, Chofu, Japan

[5]Department of Family Medicine, General Practice and Community Health, Faculty of Medicine, University of Tsukuba, Tsukuba, Japan

[6]Department of Community-Based Medical System, Graduate School of Biomedical and Health Sciences, Hiroshima University, Hiroshima, Japan

Corresponding author

Yoshifumi Sugiyama

Division of Clinical Epidemiology, Research Center for Medical Sciences, The Jikei University School of Medicine, 3-25-8, Nishishimbashi, Minato-ku, Tokyo 105-8461, Japan

Tel: +81-3-3433-1111 (ext. 2390)

Email: yoshifumi.sugiyama@jikei.ac.jp

1

2 **Word count**

3 4349

4

ABSTRACT

Objectives The objective of this study was to examine the structural validity and internal consistency of the original English version of the Patient Centered Assessment Method (PCAM) in a primary care setting in a Japanese island area.

Design Cross-sectional study.

Setting A clinic on a remote island in Okinawa, Japan, that provides general outpatient and 24-hour emergency services.

Participants This study included 355 patients who visited Tarama Clinic from April 1, 2018 to June 30, 2018, were aged ≥20 years, lived in Tarama Village, and had decision-making capacity.

Main outcome measures Patient complexity scored by the PCAM.

Results The mean (standard deviation) PCAM score was 21.4 (5.7). The distribution was skewed to the right and there were no ceiling and floor effects. Confirmatory factor analysis found that the previously reported two- and three-factor structures did not show a good fit (root mean square error of approximation 0.18 and 0.16, comparative fit index 0.83 and 0.89, and standardized root mean square residual 0.14 and 0.11, respectively). Exploratory factor analysis revealed a new two-factor structure: "biomedical complexity" and "psychosocial complexity." The Cronbach's alpha values for the total PCAM score, the "biomedical complexity" factor, and the "psychosocial complexity" factor were 0.81, 0.82, and 0.74, respectively.

Conclusions In this study, confirmatory factor analysis found that the data did not fit sufficiently using the previously reported two- and three- factor structures. Instead, exploratory factor analysis revealed a new two-factor structure, for which the Cronbach's alpha values exceeded the threshold level. Therefore, the structural validity and internal consistency of the English version of the PCAM were verified in a primary care setting in a Japanese island area.

Keywords

patient complexity, the Patient Centered Assessment Method, primary care, island area, structural validity, internal consistency

Strengths and limitations of this study

- Most patients on Tarama Island are expected to choose Tarama Clinic because of geographical restrictions; therefore, this study collected data regarding almost all patients who needed to visit a medical institution for any reason during the inclusion period.
- The generalizability of these findings may be limited because this study was conducted at a single medical institution in an island area of Okinawa Prefecture, Japan.
- Although most patients on Tarama Island are expected to choose Tarama Clinic because of geographical restrictions, some might have visited a medical institution located off the island, which could have led to over- or under-estimation of PCAM scores.
- Patients with presumably high patient complexity, who were highly dependent on medical and nursing care or who required advanced medical care, would have been forced to move off the island because of the lack of medical and nursing care resources there, which could have led to underestimation of PCAM scores.
- Some eligible participants were excluded, and exclusion of possible participants with high or low patient complexity might have resulted in under- or over-estimation of PCAM scores.

INTRODUCTION

Increased attention has been paid to both biological and psychosocial aspects of patients. In the latter half of the 1970s, Engel proposed a biopsychosocial model as a holistic alternative to the biological model that was predominant in the mid-20th century, but was considered to have substantial limitations caused by understanding and responding to patients' suffering from a biological perspective.[1] As its name indicates, the biopsychosocial model adopts biological, psychological, and social perspectives, and seeks to understand and respond to patients' suffering holistically.[1] From a biopsychosocial perspective, patients' characteristics are incorporated into a concept called "patient complexity."[2] This is defined as "person-specific factors that interfere with the delivery of usual care and decision-making for whatever conditions the patient has."[2]

Various tools have been developed to assess patient complexity. INTERMED is one such tool, for which the validity and reliability have been evaluated in secondary care settings.[3,4] The Minnesota Complexity Assessment Method (MCAM) was developed for use in primary care settings based on INTERMED.[2] Both INTERMED and MCAM, which are not patient self-assessment type questionnaires, were designed to be completed by healthcare workers who conduct patient interviews.[2,3,4] The Patient Centered Assessment Method (PCAM) is an advanced version of the MCAM and assesses patient complexity using 12 items across four domains: "Health and Well-being," "Social Environment," "Health Literacy and Communication," and "Service Coordination."[5] The PCAM is also designed to be completed by healthcare workers.[5] The PCAM enables healthcare professionals to identify and assess patients' problems from a biopsychosocial perspective and deal with these problems in order of priority based on severity and level of urgency.[5] Therefore, the PCAM supports healthcare professionals to make referrals to a wide range of services to better meet patients' needs.[5]

Several studies regarding patient complexity and the PCAM have been published. Pratt et al. developed and established the face validity of the original English version of the PCAM.[5] Yoshida et al. confirmed the structural/criterion validity and internal consistency of the original English version of the PCAM in a Japanese secondary care setting.[6] Mutai et al. developed a Japanese version of the PCAM and confirmed its structural validity and internal consistency in a primary care setting in a

Japanese urban area.[7] Previous research using the PCAM showed that PCAM scores were associated with various health outcomes, such as length of hospital stay,[6] burden for physicians and nurses,[8] and alcohol consumption/alcohol use disorders.[9]

However, no research has clarified the structural validity and internal consistency of the original English version of the PCAM in a primary care setting in a Japanese island area. Verification of the validity and reliability of the PCAM will promote more research on the association between the PCAM and other health outcomes, which will lead to better assessment and understanding of patient complexity and provide healthcare professionals with guidance regarding optimal medical care. The objective of this study was to examine the structural validity and internal consistency of the original English version of the PCAM in a primary care setting in a Japanese island area.

METHODS

This study was conducted in conjunction with another study that examined the association between alcohol consumption/alcohol use disorders and patient complexity.[9]

Design

This study used a cross-sectional design and was reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines.[10]

Setting

We conducted this study at Tarama Clinic, Okinawa Miyako Hospital, which is located on Tarama Island, Okinawa Prefecture, Japan.[11] Tarama Island is situated approximately 67 km west of Miyako Island (125 minutes by ferry[12] or 25 minutes by airplane[13]),[14] which is approximately 300 km southwest of the main island of Okinawa Prefecture (55 minutes by airplane[13]).[15] Tarama Island is the main part of Tarama Village,[14] which had a population of 1,194 people (555 women and 639 men) in 2015.[16] The percentage of population aging (the percentage of the population aged 65 years or older) for that year was 26.4%,[17] which was almost same as the national average (26.6%).[17] In Tarama Village, 41.6% of the population work in primary industries (agriculture,

forestry, and fishery) and almost all of these workers (41.2% of 41.6%) are engaged in agriculture.[18, 19] This proportion is considerably higher than the national average (3.8%).[20] Overall, 92.0% of the land on Tarama Island is devoted to raising beef cattle and growing sugar cane, vegetables, and tobacco.[14, 21] The average annual income is 1,765,000 yen,[22] which is substantially lower than the national average (3,203,000 yen) in 2015.[23]

Tarama Clinic, which has four staff (a physician, a nurse, a nurse assistant, and a clerk), is the only medical institution on the island (other than a dental clinic) and provides general outpatient and 24-hour emergency services.[24] Japan has a "free access" healthcare system where patients are free to choose any medical institution.[25] However, most patients on Tarama Island are expected to choose Tarama Clinic because of geographical restrictions. Therefore, this study collected data regarding almost all patients who needed to visit a medical institution for any reason during the inclusion period.

Participants

We consecutively included patients who visited Tarama Clinic from April 1, 2018 to June 30, 2018. We included patients only once, even if they visited more than once during the inclusion period. Of these patients, those who were aged ≥20 years, lived in Tarama Village, and had decision-making capacity were judged to be eligible for this study. Patients who refused to participate in this study were excluded. Patients whose participation was judged to have an unfavorable influence on the patient–physician relationship were also excluded. Some questions regarding personal issues, such as financial insecurity, which needed to be asked to complete the PCAM,[26,27] might be psychologically invasive for some patients and could potentially damage the patient–physician relationship. In the medical context of Tarama Island, patients had no choice of medical institutions other than Tarama Clinic.[24] Thus, if the patient–physician relationship was impaired, the patient would not be able to visit another medical institution, which could cause them to drop out from any treatment they were receiving. For this reason, careful attention was paid to the patient–physician relationship. Finally, patients were excluded if the primary investigator was out of office and unable to obtain informed consent from a patient, or when many patients were in the waiting room and obtaining informed consent from a patient interfered with usual medical practice.

Data collection

We collected data for this study from April 1, 2018 to March 31, 2019. When patients visited Tarama Clinic, the sole physician (primary investigator) scored the PCAM during and after the visit in accordance with the "PCAM User Guide for Conducting the Assessment."[28] Japanese is widely and commonly used in Japan, and all interviews for scoring the PCAM were conducted in Japanese. However, a Japanese version of the PCAM,[7] which was published in 2020, was not available when the study was conducted. Therefore, using and translating the original English version of the PCAM[26,27] and the user guide containing its sample questions[28] during the interview, the scorer asked appropriate questions in Japanese to score the items of the PCAM.

Outcome measures

PCAM

The PCAM is a tool for assessing patient complexity from a biopsychosocial perspective[5] and has four domains: "Health and Well-being," "Social Environment," "Health Literacy and Communication," and "Service Coordination."[26,27] Each domain has two or four items: "Health and Well-being" has four items (#1 "Physical health needs," #2 "Physical health impacting on mental well-being," #3 "Lifestyle impacting on physical or mental well-being," and #4 "Other mental well-being concerns"); "Social Environment" has four items (#1 "Home environment," #2 "Daily activities," #3 "Social networks," and #4 "Financial resources"); "Health Literacy and Communication" has two items (#1 "Health literacy" and #2 "Engagement in discussion"); and "Service Coordination" has two items (#1 "Other services" and #2 "Service coordination").[26,27] Each item has four levels of increasing complexity ("Routine Care," "Active Monitoring," "Plan Action," and "Act Now") and is scored from 1 to 4 as complexity increases.[26,27] This gives a total PCAM score from 12 (minimum) to 48 (maximum).[27] The PCAM was developed for a range of primary care providers, such as general practitioners and nurses, and also for teams of providers assisting with communication in team-based care approaches.[5] The PCAM, in accordance with the user guide, enables people in these professions to ask appropriate questions, to score items of the PCAM, and to assess patient complexity.[26,27,28]

Participants' characteristics

We collected the following variables to describe the characteristics of study participants. We obtained patients' age and sex from their medical records and calculated their annual medical expenses during the prior year using medical expense receipts. A medical expense receipt is an invoice issued by a medical institution to a public medical insurer for medical expenses. This receipt contains information about examinations, medication, surgery, as well as the total medical expenses of both a patient and an insurer.[29] We used a self-administered questionnaire to obtain information about educational background ("below a high school diploma" or "equivalent to a high school diploma or above"), employment status ("in work" or "out of work"), physical activity status ("exercising" or "not exercising"), smoking status ("current smoker," "ex-smoker," or "never smoker"), and the number of family members living with the patient. A nurse assisted patients to respond to the questionnaire as necessary. "In work" was defined as full-time or part-time workers and housewives/househusbands, and "out of work" as those without an occupation. "Exercising" was defined as engaging in physical activity for more than half an hour twice a week for 1 year or more.

Sample size

Various methods of sample size calculation have been proposed for factor analysis, which are expressed as either the sample size or the ratio of sample size to the number of variables. A sample size of 300 is reported to be good.[30] A large ratio of sample size to the number of variables (e.g., 20:1) is also considered to be good,[31] which gave a sample size of 240 for the 12 PCAM items. Based on these two methods, a sample size of 300 patients was used in this study.

Statistical analysis

We performed descriptive analysis on the characteristics of study participants and PCAM scores. Descriptive data were expressed as mean (standard deviation [SD]) for continuous variables and count (%) for categorical variables.

We performed confirmatory factor analysis with weighted least square mean and variance adjusted (WLSMV) estimation, using the scores for each PCAM item as categorical variables. First, in accordance with previous study findings for the structural validity of the original English version of the PCAM in a secondary care setting, a two-factor structure ("Patient-oriented complexity" and "Medicine-oriented complexity") was hypothesized.[6] Patient-oriented complexity included three "Health and Well-being" items (#2, #3, and #4); two "Social Environment" items (#2 and #3); and two "Health Literacy and Communication" items (#1 and #2). Medicine-oriented complexity included one "Health and Well-being" item (#1); two "Social Environment" items (#1 and #4); and two "Service Coordination" items (#1 and #2).[6] Second, in accordance with previous study findings for the structural validity of the Japanese version of the PCAM in a primary care setting, a three-factor structure ("Personal well-being," "Social interaction," and "Needs for care/service") was also hypothesized.[7] Personal well-being included three "Health and Well-being" items (#1, #2, and #4), and one "Social Environment" item (#2). Social interaction included one "Social Environment" item (#3) and two "Health Literacy and Communication" items (#1 and #2). Needs for care/service included one "Social Environment" item (#1) and two "Service Coordination" items (#1 and #2).[7] The fit indices were judged to be good if root mean squared error of approximation (RMSEA) was ≤0.08, comparative fit index (CFI) was ≥0.90, and standardized root mean square residual (SRMR) was ≤0.08.[32]

Where statistical testing found the model fit to be poor, exploratory factor analysis with WLSMV estimation and promax rotation was used to examine the structural validity of the PCAM. A scree plot and a cut-off value for factor loading of 0.4 were adopted to determine how many factors there were, and which items should be included on each factor.

In this study, we performed factor analysis using the scores for each PCAM item as categorical variables, although these were regarded as continuous variables in previous studies.[6,7] These variables were scored 1, 2, 3, or 4 as complexity increased.[27] When categorical variables, which are discrete in nature, are treated as continuous variables, bias caused by the approximation procedure cannot be excluded.[33] Estimation methods designed for categorical variables are recommended in cases in which the variables are measured in relatively few (e.g., two to four) categories.[33] Therefore,

the estimation method for categorical data was considered to be more appropriate and extracted the factor structure more accurately in this study.

Additionally, Cronbach's alpha, which is considered satisfactory if the value is ≥0.7,[34] was calculated to examine the internal consistency of the PCAM.

We performed descriptive analysis and calculated Cronbach's alpha values using Stata/MP version 15.1.[35] Confirmatory and exploratory factor analyses were performed using Mplus version 8.4.[36]

Patient and public involvement

We conducted this study without patient and public involvement.

RESULTS

During the inclusion period, 521 patients visited Tarama Clinic. Of these, 57 patients were younger than 20 years, 13 patients did not live in Tarama Village, and 25 patients did not have decision-making capacity, which left 426 eligible patients. We excluded 28 patients who refused to participate in this study and nine patients whose participation was judged to have an unfavorable influence on the patient–physician relationship. The primary investigator was unable to obtain informed consent from two patients because he was out of office, and from a further 32 patients because many patients were in the waiting room at that time. As a result, 355 patients were included in this study (figure 1, reproduced from Sugiyama et al.[9]). There were no missing values for outcome measures or participant characteristics among the study participants.

The characteristics of study participants are shown in table 1 reproduced from Sugiyama et al.[9] The mean (SD) PCAM score was 21.4 (5.7). The distribution was skewed to the right and there were no ceiling and floor effects (figure 2, modified from Sugiyama et al.[9]).

Table 1. Characteristics of study participants

Age, mean (SD), years	66.4 (13.6)
By age group, No. (%)	
<35 years	6 (1.7)
35 to <45 years	19 (5.4)
45 to <55 years	42 (11.8)
55 to <65 years	86 (24.2)
65 to <75 years	85 (23.9)
≥75 years	117 (33.0)
Sex, No. (%)	
Women	163 (45.9)
Men	192 (54.1)
Education, No. (%)	
<High school	187 (52.7)
≥High school	168 (47.3)
Occupation, No. (%)	
In work	307 (86.5)
Out of work	48 (13.5)
Physical activity, No. (%)	
Exercising	53 (14.9)
Not exercising	302 (85.1)
Smoking, No. (%)	
Current smoker	50 (14.1)
Ex-smoker	118 (33.2)
Never smoker	187 (52.7)
Annual medical expenses, No. (%)	
<100,000 yen	194 (54.6)
100,000 to <200,000 yen	108 (30.4)
200,000 to <300,000 yen	31 (8.7)
≥300,000 yen	22 (6.2)
Number of family members living with the patient, No. (%)	
0	66 (18.6)
1	165 (46.5)
2	73 (20.6)
3	29 (8.2)
4	8 (2.3)
≥5	14 (3.9)

SD, standard deviation.

Confirmatory factor analysis found that using the previously reported two-factor structure,[6] the fit indices were: RMSEA = 0.18, CFI = 0.83, and SRMR = 0.14. Confirmatory factor analysis also found that using the three-factor structure,[7] the fit indices were: RMSEA = 0.16, CFI = 0.89, and

SRMR = 0.11. Because the data did not fit sufficiently, we performed exploratory factor analysis to evaluate the factor structure.

Table 2. Exploratory factor analysis of Patient Centered Assessment Method scores

Domain and item	First factor	Second factor
Health and Well-being		
1 Physical health needs	0.701	−0.035
2 Physical health impacting on mental well-being	0.081	0.578
3 Lifestyle impacting on physical or mental well-being	0.895	−0.136
4 Other mental well-being concerns	0.190	0.442
Social Environment		
1 Home environment	−0.122	0.630
2 Daily activities	−0.059	0.683
3 Social networks	−0.266	0.715
4 Financial resources	0.256	0.452
Health Literacy and Communication		
1 Health literacy	0.894	0.117
2 Engagement in discussion	0.621	0.358
Service Coordination		
1 Other services	0.109	0.806
2 Service coordination	0.137	0.835

Note: Underlining indicates included items.

This exploratory factor analysis revealed a new two-factor structure (table 2), which differed from previous studies.[6,7] The first factor extracted comprised four items: two "Health and Well-being" items (#1 and #3) and two "Health Literacy and Communication" items (#1 and #2). The second factor extracted comprised eight items: two "Health and Well-being" items (#2 and #4); four "Social Environment" items (#1, #2, #3, and #4); and two "Service Coordination" items (#1 and #2).

The Cronbach's alpha values for the total PCAM score, the first factor, and the second factor were 0.81, 0.82, and 0.74, respectively.

DISCUSSION

In this study, confirmatory factor analysis found that the data did not fit sufficiently using the previously reported two- and three- factor structures. Instead, exploratory factor analysis revealed a new two-factor structure, for which the Cronbach's alpha values exceeded the threshold level. Therefore, the structural validity and internal consistency of the English version of the PCAM were verified in a primary care setting in a Japanese island area.

While the distribution of PCAM scores was skewed to the right, or inclined to be low, Yoshida et al. showed a widespread distribution of scores and a higher mean (SD) PCAM score at 25.0 (7.3) compared with our study.[6] This discrepancy may be attributable to differences in clinical settings between the studies. Yoshida et al. conducted their study in a secondary care setting and the participants were inpatients who were presumed to be biomedically and psychosocially more complex than outpatients in a primary care setting. Furthermore, the mean age (66.4 years) in this study was lower than that reported by Yoshida et al. (77.4 years). Older people are expected to be more complex, and have more diverse and complicated backgrounds, such as multimorbidity, dementia, and social isolation.[37, 38, 39] Similarly, confirmatory factor analysis using the previously reported two-factor structure (Patient-oriented complexity and Medicine-oriented complexity)[6] revealed that the poor fit may be attributable to differences in clinical settings and disparities between the island area in this study and the urban area in Yoshida et al. It is important to note that interlinking mechanisms cascade from social–structural conditions down to biomedical and psychological problems.[40] Therefore, healthcare professionals should recognize that differences in care settings need to be considered when assessing patient complexity.

Conversely, Mutai et al. showed a distribution with a floor effect similar to that in this study, but a lower mean (SD) PCAM score than our study at 16.5 (5.1).[7] Both our study and Mutai et al. were conducted in primary care settings. Mutai et al. used the Japanese version of the PCAM, which was developed using forward translation, back translation, and cognitive debriefing for cultural adaptation, whereas this study used the original English version of the PCAM. The modification of the tool might have contributed to the discrepancies. However, this was minimized because the contents of the Japanese and original English versions were almost the same. Instead, as described above, disparities between the island area in this study and the urban area in Mutai et al. should be considered.

For example, 52.7% of the participants in this study and 29.0% in Mutai et al. had an education level below a high school diploma. Educational background is associated with various aspects of patient complexity, such as health risks and protective behaviors, wages and income, and resources for health.[41] In addition, the items "Daily activities (including employment status)" and "Financial resources" were directly associated with the proportion of participants who were out of work[26,27] (13.5% and 56.7% in this study and Mutai et al., respectively). Although the mean age in this study (66.4 years) was lower than that in Mutai et al. (72.4 years), educational background might have had a greater influence on patient complexity given the higher PCAM score in this study than in Mutai et al. These differences may explain the poor fit as shown by confirmatory factor analysis of the previously reported three-factor structure (Personal well-being, Social interaction, and Needs for care/service).[7] Compared with urban areas, healthcare professionals in areas with lower accessibility to medical services (such as island areas) may have to provide services to patients with higher complexity caused by underlying factors, including lower educational background. Therefore, they may need training to appropriately assess patients' biopsychosocial needs.

In this study, the structural validity and internal consistency of the English version of the PCAM were verified in a primary care setting in a Japanese island area. Exploratory factor analysis identified a new two-factor structure. The first factor was labeled "biomedical complexity" because it concerned biomedical issues such as physical health needs, lifestyle behaviors, and understanding of/engagement in mainly physical health needs. The second factor was labeled "psychosocial complexity" because it concerned psychosocial issues such as mental well-being, home environment, daily activities, social networks, financial resources, and service coordination. This provided strong support for the structural validity of the PCAM, especially as the PCAM was developed to assess patient complexity from both biomedical and psychosocial perspectives.[5] As described above, various factors contributed to our finding of a new two-factor structure. For example, "Health literacy"/"Engagement in discussion" and "Social networks" loaded on a common factor in Japanese urban areas.[6,7] Mutai et al. discussed why these items loaded on a common factor and explained that "Health literacy" and "Engagement in discussion" were associated with health literacy, including communicative/interactive literacy, which was also necessary for active participation in "Social networks."[7] However, "Health literacy" and

"Engagement in discussion" loaded on a different factor from "Social networks" in this study. Communicative/interactive literacy associated with "Health literacy" and "Engagement in discussion" may not always be necessary to participate in "Social networks" in a small community in a Japanese island area, where participation is presumably "forced" through stronger peer pressure than in urban areas.[42] Additionally, the Cronbach's alpha values in this study exceeded the threshold level, and confirmed the internal consistency of the PCAM. However, other types of validity, such as content validity and criterion validity, and other types of reliability, such as test-retest reliability or inter-rater reliability, were not evaluated in this study. Further studies are warranted to examine the validity and reliability of the PCAM. Thus, the current findings provided partial evidence that the PCAM is a valid and reliable tool for assessing patient complexity in a primary care setting in a Japanese island area.

There are important points to consider relating to this study. The accuracy of estimating factor structures might have resulted in discrepancies between the studies. In this study, we performed factor analysis using the scores for each PCAM item as categorical variables, although these were regarded as continuous variables in the previous studies.[6,7] The estimation method for categorical data was considered more appropriate and extracted the factor structure more accurately.[43] Additionally, difficulty in evaluating the PCAM might also have influenced the discrepancy between studies. The PCAM has 12 items across four domains, and each item includes a variety of topics.[26,27] For example, the item "Social network" covers social networks with friends as well as with family members and work colleagues.[26,27] It may therefore take more time, which could be spent with patients, to collect all related information. Furthermore, some items are personal questions. For example, the item "Financial resources" asks about financial insecurity, such as ability to make medical payments.[26,27] Some patients might perceive it as inappropriate to discuss such financial topics with healthcare professionals;[44] therefore, these items might have been answered incorrectly, as noted in previous research.[7] Evaluating the PCAM correctly in a short consultation is difficult, which further complicates the issues of the variety of topics covered and collection of personal information. It is reported to take approximately 20 minutes to assess all items of the PCAM,[44] although outpatient consultation time is less than 10 minutes for approximately 70% of patients visiting medical institutions in Japan.[45] We needed to suspend the interviews and carry them over to the next consultation in some

patients because of the limited consultation time. However, in this study, the primary investigator was the only physician in Tarama Village and lived together with the other residents (including study participants) in a small community,[24] which created close patient–physician relationships. This might have enabled the primary investigator to understand a variety of topics and personal information,[46] and thereby evaluate the PCAM more accurately than previous studies during a short consultation.[6,7] These differences in evaluation may also explain the discrepancies between studies.

The PCAM might be able to improve long-term care services in communities in island areas. Japan is experiencing unprecedented aging of the population, a phenomenon that has been termed the "super-aged" society.[47] Moreover, island areas were reported to have a substantially higher percentage of population aging on average (34.2%[48]) compared with the national average (26.6%)[17] in 2015. To address the challenge of population aging, Japan has established the "Community-based Integrated Care System," which comprehensively ensures the provision of health care, nursing care, preventive long-term care, housing, and livelihood support.[49] However, in areas isolated from their surroundings, such as remote islands, these services are not usually well developed.[50] The PCAM can be helpful for identifying and highlighting the services that are necessary but lacking in communities. Based on these assessments, small communities may be able to address problems and improve services in a quick and flexible manner, with closer relationships among organizations including medical institutions, local governments, and the private sector, related to the Community-based Integrated Care System.[50]

There were several limitations in this study. First, we conducted this study at a single medical institution in an island area of Okinawa Prefecture, Japan, which may limit the generalizability of the findings. To ensure some degree of generalizability, further multicenter studies are warranted. Second, although most patients on Tarama Island are expected to choose Tarama Clinic because of geographical restrictions, some might have visited a medical institution located off the island, which could have led to over- or under-estimation of PCAM scores. Additionally, patients who were highly dependent on medical and nursing care, such as terminal cancer patients, or those who required advanced medical care, such as dialysis patients, would have been forced to move off the island because of the lack of medical and nursing care resources there. These patients were presumed to have high patient complexity,

which could have led to underestimation of PCAM scores. Third, although we included study participants consecutively, 16.7% of eligible participants were excluded. Nine patients were excluded because their participation was judged to have an unfavorable influence on the patient–physician relationships. The main reason was that they had confirmed or suspected mental or personality disorders, which is likely to cause high psychological complexity. Exclusion of these possible participants might have resulted in underestimation of PCAM scores. Additionally, the primary investigator was unable to obtain informed consent from two patients because he was out of office, and from a further 32 patients because many patients were in the waiting room at that time. These patients visited the clinic only once during the inclusion period and therefore could not be enrolled in this study during a subsequent visit. These patients usually had mild acute diseases, such as upper respiratory tract inflammation or gastroenteritis, and were otherwise healthy, which meant their patient complexity was likely to be low. Exclusion of these possible participants might have resulted in overestimation of PCAM scores.

CONCLUSION

In this study, confirmatory factor analysis found that the data did not fit sufficiently using the previously reported two- and three- factor structures. Instead, exploratory factor analysis revealed a new two-factor structure, for which the Cronbach's alpha values exceeded the threshold level. Therefore, the structural validity and internal consistency of the English version of the PCAM were verified in a primary care setting in a Japanese island area.

Acknowledgments

The authors express their appreciation to Ms. C Higa (Tarama Clinic, Okinawa Miyako Hospital) for supporting data collection. We thank Audrey Holmes, MA, from Edanz Group (https://en-author-services.edanz.com/ac) for editing a draft of this manuscript.

Contributors

YS designed this study, collected, analyzed, and interpreted the data, and prepared and reviewed the manuscript. RM, HY, RH, and SY contributed to the design of the study and reviewed the manuscript. MM contributed to the design of the study, analyzed and interpreted the data, and reviewed the manuscript.

Funding

This study was supported by The Jikei University Research Fund for Graduate Students (grant number: N/A).

Disclaimer

The sponsor of this study had no role in the study design; the study conduct: collection, analysis, or interpretation of the data; preparation of the manuscript; or the decision to submit the manuscript for publication.

Competing interests

YS, HY, and SY are former trainees of the Jikei Clinical Research Program for Primary-care. MM received lecture fees and lecture travel fees from the Centre for Family Medicine Development of the Japanese Health and Welfare Co-operative Federation. MM is an adviser for the Centre for Family Medicine Development Practice-Based Research Network and a program director of the Jikei Clinical Research Program for Primary-care. MM's son-in-law works at IQVIA Services Japan K.K., which is a contract research organization and a contract sales organization. All other authors declare no competing interests.

Ethics approval

This study was approved by the Ethics Committee of Okinawa Miyako Hospital (approval date: February 8, 2018) and the Ethics Committee of The Jikei University School of Medicine (acceptance number: 30-412 (9433)).

Data sharing statement

No additional data are available.

REFERENCES

1. Engel GL. The need for a new medical model: a challenge for biomedicine. *Science* 1977;196:129–36.
2. Peek CJ, Baird MA, Coleman E. Primary care for patient complexity, not only disease. *Fam Syst Health* 2009;27:287–302.
3. Huyse FJ, Lyons JS, Stiefel FC, et al. "INTERMED": a method to assess health service needs. I. Development and reliability. *Gen Hosp Psychiatry* 1999;21:39–48.
4. Stiefel FC, de Jonge P, Huyse FJ, et al. "INTERMED": a method to assess health service needs. II. Results on its validity and clinical use. *Gen Hosp Psychiatry* 1999;21:49–56.
5. Pratt R, Hibberd C, Cameron IM, et al. The Patient Centered Assessment Method (PCAM): integrating the social dimensions of health into primary care. *J Comorb* 2015;5:110–9.
6. Yoshida S, Matsushima M, Wakabayashi H, et al. Validity and reliability of the Patient Centred Assessment Method for patient complexity and relationship with hospital length of stay: a prospective cohort study. *BMJ Open* 2017;7:e016175.
7. Mutai R, Sugiyama Y, Yoshida S, et al. Development and validation of a Japanese version of the Patient Centred Assessment Method and its user guide: a cross-sectional study. *BMJ Open* 2020;10:e037282.
8. Yoshida S, Matsushima M, Wakabayashi H, et al. Correlation of patient complexity with the burden for health-related professions, and differences in the burden between the professions at a Japanese regional Hospital: a prospective cohort study. *BMJ Open* 2019;9:e025176.
9. Sugiyama Y, Matsushima M, Yoshimoto H. Association between alcohol consumption/alcohol use disorders and patient complexity: a cross-sectional study. *BMJ Open* 2020;10:e034665.
10. von Elm E, Altman DG, Egger M, et al. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. *BMJ* 2007;335:806–8.
11. Tarama Clinic, Okinawa Miyako Hospital [In Japanese]. Available: http://www.hosp.pref.okinawa.jp/sinryo/tarama/tarama.html (accessed Nov 23, 2020).
12. Tarama Kaiun [In Japanese]. Available: http://www.taramakaiun.com (accessed Nov 23, 2020).

13. Japan Airlines [In Japanese]. Available: https://www.jal.co.jp (accessed Nov 23, 2020).
14. Tarama Village [In Japanese]. Available: http://www.vill.tarama.okinawa.jp/?p=89 (accessed Nov 23, 2020).
15. Miyakojima City [In Japanese]. Available: https://www.city.miyakojima.lg.jp/syoukai/gaiyou.html (accessed Nov 23, 2020).
16. e-Stat. Population by sex, sex ratio and households and household members, by type of household (2 groups) - Japan*, all shi, all gun, prefectures*, all shi of prefectures, all gun of prefectures, shi*, ku*, machi*, mura* and municipalities in 2000 [In Japanese]. Available: https://www.e-stat.go.jp/en/stat-search/file-download?statInfId=000031473211&fileKind=1 (accessed Nov 23, 2020).
17. e-Stat. Population (total and Japanese population), by age (single years) and sex, percentage by age, average age and median age - Japan*, all shi, all gun, prefectures*, all shi of prefectures, all gun of prefectures, shi*, ku*, machi*, mura* and municipalities in 2000 [In Japanese]. Available: https://www.e-stat.go.jp/en/stat-search/file-download?statInfId=000031473213&fileKind=1 (accessed Nov 23, 2020).
18. Okinawa Prefectural Government. Basic complete tabulation on labour force [In Japanese]. Available: https://www.pref.okinawa.jp/toukeika/pc/2015/shugyou/gaiyou.pdf (accessed Nov 23, 2020).
19. Ministry of Agriculture, Forestry and Fisheries. Detailed data of Tarama Village [In Japanese]. Available: http://www.machimura.maff.go.jp/machi/contents/47/375/details.html (accessed Nov 23, 2020).
20. Statistics Bureau of Japan. Basic complete tabulation on labour force [In Japanese]. Available: https://www.stat.go.jp/data/kokusei/2015/final/pdf/01-02.pdf (accessed Nov 23, 2020).
21. Tarama Village. Tarama Village population vision and comprehensive strategy [In Japanese]. Available: http://www.vill.tarama.okinawa.jp/wp-content/uploads/2016/04/tarama_vision.pdf (accessed Nov 23, 2020).

22. Okinawa Prefectural Government. Income in cities, towns and villages of Okinawa Prefecture for 2015 [In Japanese]. Available: https://www.pref.okinawa.jp/toukeika/ctv/H27/00all(h27).pdf (accessed Nov 23, 2020).
23. Cabinet Office. Prefectural income per capita [In Japanese]. Available: https://www.esri.cao.go.jp/jp/sna/data/data_list/kenmin/files/contents/tables/2018/soukatu7.xlsx (accessed Nov 11, 2021)
24. Tarama Clinic, Okinawa Miyako Hospital [In Japanese]. Available: https://www.ritoushien.net/tarama.shtml (accessed Nov 23, 2020).
25. World Health Organization. Japan health system. Available: https://apps.who.int/iris/bitstream/handle/10665/259941/9789290226260-eng.pdf (accessed Nov 23, 2020).
26. Patient Centered Assessment Method Tool. Available: https://med.umn.edu/sites/med.umn.edu/files/pcam_assessment_tool_2.0.pdf (accessed Nov 23, 2020).
27. Patient Centered Assessment Method for Research. Available: https://med.umn.edu/sites/med.umn.edu/files/pcam_2.0-research_scoring.pdf (accessed Nov 23, 2020).
28. Patient Centered Assessment Method Assessor Guide. Available: https://med.umn.edu/sites/med.umn.edu/files/pcam_assessor_guide.pdf (accessed Nov 23, 2020).
29. Ministry of Health, Labour and Welfare. Medical expense receipt. Available: https://www.mhlw.go.jp/file/06-Seisakujouhou-10800000-Iseikyoku/0000056939.pdf (accessed Nov 11, 2021)
30. Comrey AL, Lee HB. A first course in factor analysis. second edition. Hillsdale, NJ: Lawrence Erlbaum Associates, 1992:205–28.
31. Costello AB, Osborne JW. Best practices in exploratory factor analysis: four recommendations for getting the most from your analysis. *Pract Assess Res Evaluation* 2005;10.
32. Hooper D, Coughlan J, Mullen M. Structural equation modelling: guidelines for determining model fit. *Elecron J Bus Res Methods* 2008;6:53–60.

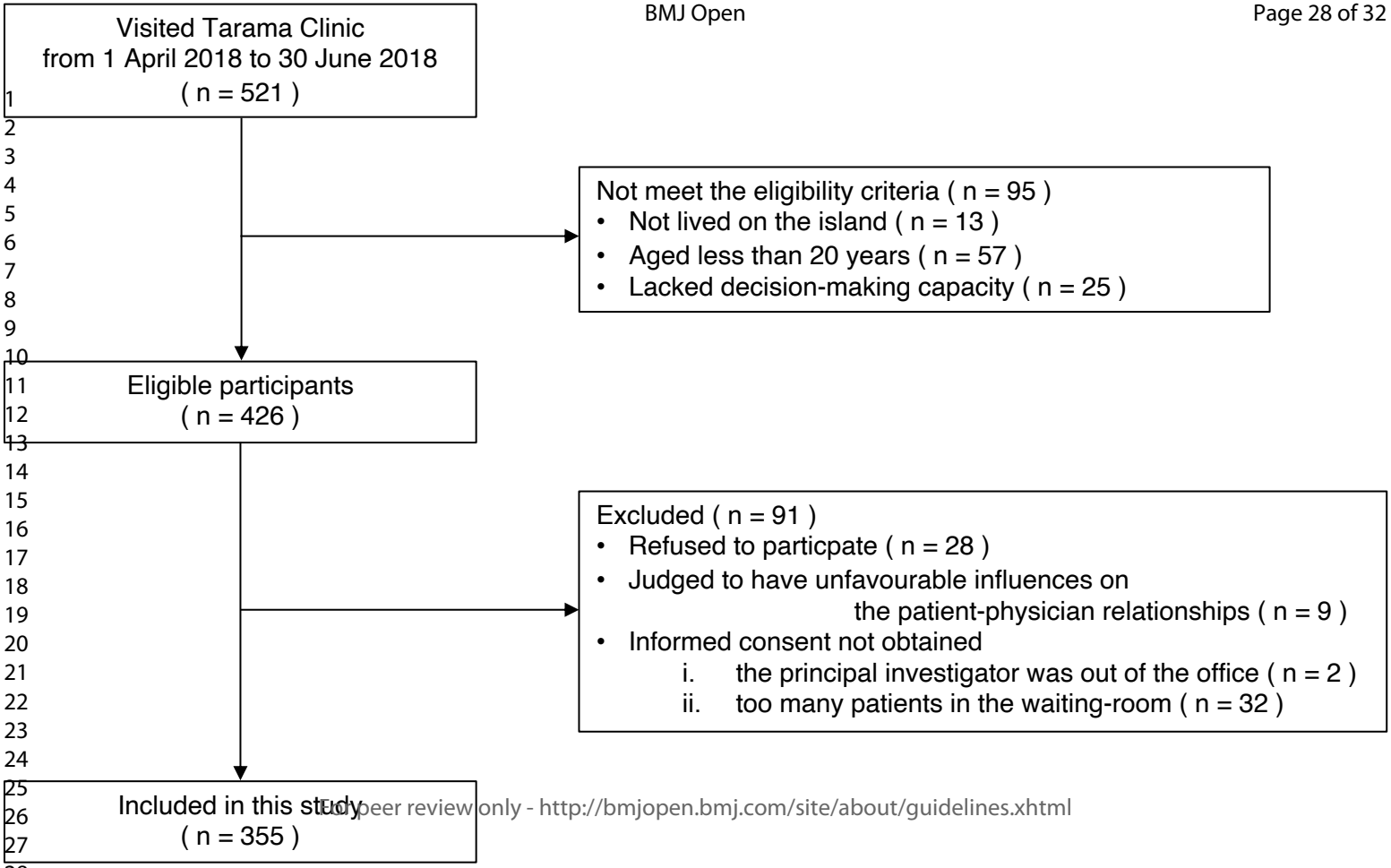
33. Finney SJ, DiStefano C. Non-normal and categorical data in structural equation modeling. In: Hancock GR, Mueller RO, eds. Structural equation modeling: a second course, second edition. Charlotte, NC: Information Age Publishing 2013:439–492.
34. Bland JM, Altman DG. Cronbach's alpha. *BMJ* 1997;314:572.
35. StataCorp. 2017. Stata: Release 15. Statistical Software. College Station, TX: StataCorp LL.
36. Muthén, L.K. and Muthén, B.O. (1998-2017). Mplus User's Guide. Eighth Edition. Los Angeles, CA: Muthén & Muthén.
37. Salisbury C, Johnson L, Purdy S, et al. Epidemiology and impact of multimorbidity in primary care: a retrospective cohort study. *Br J Gen Pract* 2011;61:e12–21.
38. Prince M, Bryce R, Albanese E, et al. The global prevalence of dementia: a systematic review and metaanalysis. *Alzheimers Dement* 2013;9:63–75.
39. Steptoe A, Shankar A, Demakakos P, et al. Social isolation, loneliness, and all-cause mortality in older men and women. *Proc Natl Acad Sci U S A* 2013;110:5797–801.
40. Berkman LF, Glass T, Brissette I, et al. From social integration to health: Durkheim in the new millennium. *Soc Sci Med* 2000;51:843–57.
41. Hahn RA, Truman BI. Education improves public health and promotes health equity. *Int J Health Serv* 2015;45:657–78.
42. Smith RJ. The Japanese rural community: norms, sanctions, and ostracism. *Am Anthropol* 1961;63:522–33.
43. Rhemtulla M, Brosseau-Liard PÉ, Savalei V. When can categorical variables be treated as continuous? A comparison of robust continuous and categorical SEM estimation methods under suboptimal conditions. *Psychol Methods* 2012;17:354–73.
44. Maxwell M, Hibberd C, Aitchison P, et al. The Patient Centred Assessment Method for improving nurse-led biopsychosocial assessment of patients with long-term conditions: a feasibility RCT. *Health Services and Delivery Research* 2018;6:17–29.
45. Ministry of Health, Labour and Welfare. Overview of the Patient's Behavior Survey 2020 [In Japanese]. Available: https://www.mhlw.go.jp/toukei/saikin/hw/jyuryo/20/index.html (accessed Nov 11, 2021).

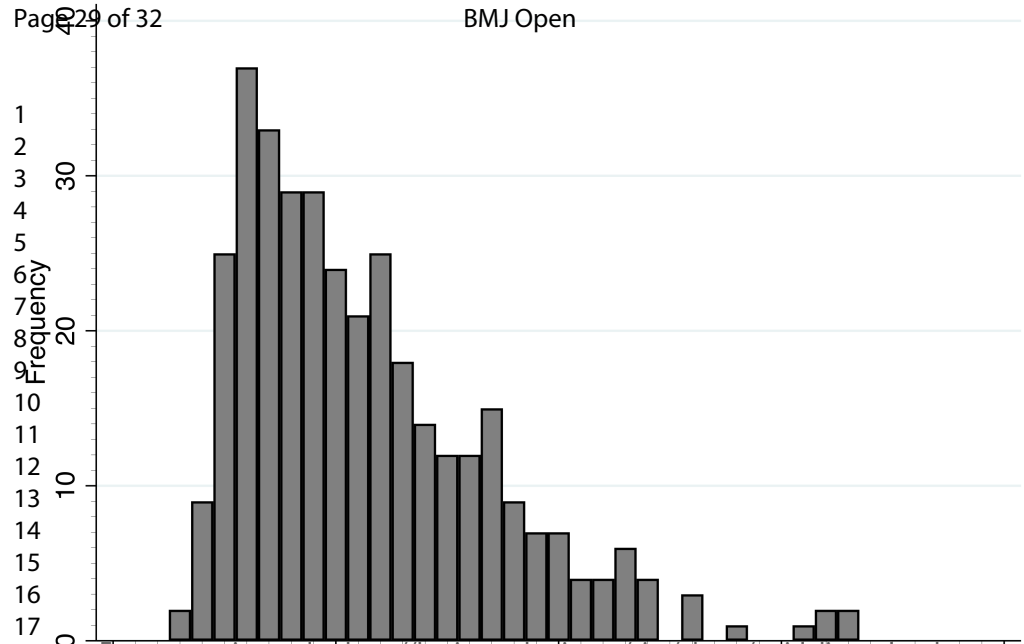
46. Lipkin M Jr, Putnam SM, Lazare A, eds. The medical interview: clinical care, education, and research. New York, NY: Springer-Verlag, 1995.
47. Cabinet Office. Annual report on the ageing society [Summary] FY2020. Available: https://www8.cao.go.jp/kourei/english/annualreport/2020/pdf/2020.pdf (accessed Nov 11, 2021).
48. Center for Research and Promotion of Japanese Islands. Annual statistical report on remote islands 2019 [In Japanese]. Tokyo, Japan: Center for Research and Promotion of Japanese Islands, 2021.
49. Ministry of Health, Labour and Welfare. Establishing "the Community-based Integrated Care System". Available: https://www.mhlw.go.jp/english/policy/care-welfare/care-welfare-elderly/dl/establish_e.pdf (accessed Nov 11, 2021).
50. Japan National Health Insurance Clinics and Hospitals Association. Survey and research project report on measures and existing policies to ensure the provision of long-term care services in remote islands and other areas [In Japanese]. Available: https://www.kokushinkyo.or.jp/index/principalresearch/tabid/57/ItemId/743/dispmid/1547/Default.aspx (accessed Nov 11, 2021).

Figure 1. A flow chart detailing the process of inclusion and exclusion of study participants

Figure 2. Distribution of PCAM scores

PCAM, the Patient Centered Assessment Method.





Reporting checklist for cross sectional study.

Based on the STROBE cross sectional guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the STROBE cross sectionalreporting guidelines, and cite them as:

von Elm E, Altman DG, Egger M, Pocock SJ, Gotzsche PC, Vandenbroucke JP. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: guidelines for reporting observational studies.

		Reporting Item	Page Number
Title and abstract			
Title	#1a	Indicate the study's design with a commonly used term in the title or the abstract	1
Abstract	#1b	Provide in the abstract an informative and balanced summary of what was done and what was found	3
Introduction			
Background / rationale	#2	Explain the scientific background and rationale for the investigation being reported	5, 6
Objectives	#3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	#4	Present key elements of study design early in the paper	6
Setting	#5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6–8

Eligibility criteria	#6a	Give the eligibility criteria, and the sources and methods of selection of participants.	7
	#7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8, 9
Data sources / measurement	#8	For each variable of interest give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group. Give information separately for for exposed and unexposed groups if applicable.	8, 9
Bias	#9	Describe any efforts to address potential sources of bias	7
Study size	#10	Explain how the study size was arrived at	9
Quantitative variables	#11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why	9–11
Statistical methods	#12a	Describe all statistical methods, including those used to control for confounding	9–11
Statistical methods	#12b	Describe any methods used to examine subgroups and interactions	n/a
Statistical methods	#12c	Explain how missing data were addressed	11
Statistical methods	#12d	If applicable, describe analytical methods taking account of sampling strategy	n/a
Statistical methods	#12e	Describe any sensitivity analyses	Sensitivity analyses were not performed.
Results			
Participants	#13a	Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed. Give information separately for for exposed and unexposed groups if applicable.	11
Participants	#13b	Give reasons for non-participation at each stage	11

Participants	#13c	Consider use of a flow diagram	26
Descriptive data	#14a	Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders. Give information separately for exposed and unexposed groups if applicable.	11, 12
Descriptive data	#14b	Indicate number of participants with missing data for each variable of interest	11
Outcome data	#15	Report numbers of outcome events or summary measures. Give information separately for exposed and unexposed groups if applicable.	11–13
Main results	#16a	Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	11–13
Main results	#16b	Report category boundaries when continuous variables were categorized	n/a
Main results	#16c	If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
Other analyses	#17	Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses	Other analyses were not performed
Discussion			
Key results	#18	Summarise key results with reference to study objectives	14
Limitations	#19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias.	17, 18
Interpretation	#20	Give a cautious overall interpretation considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence.	14–18
Generalisability	#21	Discuss the generalisability (external validity) of the study results	17
Other			

Information

Funding	#22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	19