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## 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

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3 1 **TITLE PAGE**  
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9 4 **Patient complexity scored by the Patient Centered Assessment Method in a primary care setting**  
10 5 **in a Japanese island area and its validity and reliability: a cross-sectional study**  
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## 1 ABSTRACT

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

6 **Design** Cross-sectional study.

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

9 **Participants** This study included 355 patients who visited Tarama Clinic from April 1, 2018 to June  
10 30, 2018, were aged  $\geq 20$  years, lived in Tarama Village, and had decision-making capacity.

11 **Main outcome measures** Patient complexity scored by the PCAM.

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

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

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28 **Keywords**

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3 1 patient complexity, the Patient Centered Assessment Method, primary care, island area, validity,  
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5 2 reliability  
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9 4 **Strengths and limitations of this study**

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11 5 • Most patients on Tarama Island are expected to choose Tarama Clinic because of geographical  
12 restrictions; therefore, this study was population-based.  
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16 7 • The generalizability of these findings may be limited because this study was conducted at a single  
17 medical institution in an island area of Okinawa Prefecture, Japan.  
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19 8  
20 9 • Inter-rater reliability was not evaluated because Tarama Clinic is the only medical institution (other  
21 than a dental clinic) on Tarama Island, and the primary investigator was the sole physician.  
22 10  
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24 11 • Some eligible participants were excluded, and exclusion of possible participants with high or low  
25 patient complexity might have resulted in under- or over-estimation of PCAM scores.  
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## 1 INTRODUCTION

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

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

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



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

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

## 16 17 **METHODS**

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

### 20 21 **Design**

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

### 24 25 **Setting**

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

1 300 km southwest of the main island of Okinawa Prefecture (55 minutes by airplane[15]).[17] Tarama  
2 Island is the main part of Tarama Village,[16] which had a population of 1,194 people (555 women and  
3 639 men) in 2015.[18] The population aging rate for that year was 26.4%,[19] which was almost same  
4 as the national average (26.6%).[19] In Tarama Village, 41.6% of the population work in primary  
5 industries (agriculture, forestry, and fishery) and almost all of these workers (41.2% of 41.6%) are  
6 engaged in agriculture.[20, 21] This proportion is considerably higher than the national average  
7 (3.8%).[22] Overall, 92.0% of the land on Tarama Island is devoted to raising beef cattle and growing  
8 sugar cane, vegetables, and tobacco.[16, 23] The average annual income is 1,765,000 yen,[24] which  
9 is substantially lower than the national average (3,217,000 yen).[25]

10 Tarama Clinic, which has four staff (a physician, a nurse, a nurse assistant, and a clerk), is the  
11 only medical institution on the island (other than a dental clinic) and provides general outpatient and  
12 24-hour emergency services.[26] Japan has a “free access” healthcare system where patients are free to  
13 choose any medical institution.[27] However, most patients on Tarama Island are expected to choose  
14 Tarama Clinic because of geographical restrictions. This condition enabled this study to be population-  
15 based.

### 17 **Participants**

18 We consecutively included patients who visited Tarama Clinic from April 1, 2018 to June 30,  
19 2018. Of these patients, those who were aged  $\geq 20$  years, lived in Tarama Village, and had decision-  
20 making capacity were judged to be eligible for this study. Patients who refused to participate in this  
21 study were excluded. Patients whose participation was judged to have an unfavorable influence on the  
22 patient–physician relationship were also excluded. Finally, patients were excluded if the primary  
23 investigator was out of office and unable to obtain informed consent from a patient, or when many  
24 patients were in the waiting room and obtaining informed consent from a patient interfered with usual  
25 medical practice.

### 27 **Data collection**

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

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45 2 **Outcome measures**6  
7 3 **PCAM**  
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9 4 The PCAM is a tool for assessing patient complexity from a biopsychosocial perspective[5]  
10 5 and has four domains: “Health and Well-being,” “Social Environment,” “Health Literacy and  
11 6 Communication,” and “Service Coordination.”[28] Each domain has two or four items: “Health and  
12 7 Well-being” has four items (#1 “Physical health needs,” #2 “Physical health impacting on mental well-  
13 8 being,” #3 “Lifestyle impacting on physical or mental well-being,” and #4 “Other mental well-being  
14 9 concerns”); “Social Environment” has four items (#1 “Home environment,” #2 “Daily activities,” #3  
15 10 “Social networks,” and #4 “Financial resources”); “Health Literacy and Communication” has two items  
16 11 (#1 “Health literacy” and #2 “Engagement in discussion”); and “Service Coordination” has two items  
17 12 (#1 “Other services” and #2 “Service coordination”).[28] Each item has four levels of increasing  
18 13 complexity (“Routine Care,” “Active Monitoring,” “Plan Action,” and “Act Now”) and is scored from  
19 14 1 to 4 as complexity increases.[28,29] This gives a total PCAM score from 12 (minimum) to 48  
20 15 (maximum).[29] The validity and reliability of the original English version of the PCAM have been  
21 16 verified in a secondary care setting,[6] and those of the Japanese version of the PCAM have been  
22 17 verified in a primary care setting.[7] However, the validity and reliability of the original English version  
23 18 of the PCAM in a primary care setting remain unclear. When patients visited Tarama Clinic, the sole  
24 19 physician (primary investigator) scored the PCAM in accordance with the “PCAM User Guide for  
25 20 Conducting the Assessment,”[30] which eliminated inter-rater variability.

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4849 22 **Other variables**

50 23 We obtained patients’ age and sex from their medical records and calculated their annual  
51 24 medical expenses during the prior year using medical fee receipts. We used a self-administered  
52 25 questionnaire to obtain information about educational background (“below a high school diploma” or  
53 26 “equivalent to a high school diploma or above”), employment status (“in work” or “out of work”),  
54 27 physical activity status (“exercising” or “not exercising”), smoking status (“current smoker,” “ex-  
55 28 smoker,” or “never smoked”), and the number of family members living with the patient. A nurse

1 assisted patients to respond to the questionnaire as necessary. “In work” was defined as full-time or  
2 part-time workers and housewives/househusbands, and “out of work” as those without an occupation.  
3 “Exercising” was defined as engaging in physical activity for more than half an hour twice a week for  
4 1 year or more.

## 6 **Sample size**

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

## 13 **Statistical analysis**

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

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3 1 root mean squared error of approximation (RMSEA) was  $\leq 0.08$ , comparative fit index (CFI) was  $\geq 0.90$ ,  
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5 2 and standardized root mean square residual (SRMR) was  $\leq 0.08$ . [33]  
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7 3 Where statistical testing found the model fit to be poor, exploratory factor analysis with  
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9 4 WLSMV estimation and promax rotation was used to examine the construct validity of the PCAM. A  
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11 5 scree plot and a cut-off value for factor loading of 0.4 were adopted to determine how many factors  
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13 6 there were, and which items should be included on each factor.  
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15 7 Additionally, Cronbach's alpha, which is considered satisfactory if the value is  $\geq 0.7$ , [34] was  
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17 8 calculated as an index of internal consistency to examine the reliability of the PCAM.  
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19 9 We performed descriptive analysis and calculated Cronbach's alpha values using Stata/MP  
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21 10 version 15.1. [35] Confirmatory and exploratory factor analyses were performed using Mplus version  
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23 11 8.4. [36]  
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### 26 12

### 27 13 **Patient and public involvement**

28 14 We conducted this study without patient and public involvement.  
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### 35 16 **RESULTS**

36 17 During the inclusion period, 521 patients visited Tarama Clinic. Of these, 57 patients were  
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38 18 younger than 20 years, 13 patients did not live in Tarama Village, and 25 patients did not have decision-  
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40 19 making capacity, which left 426 eligible patients. We excluded 28 patients who refused to participate  
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42 20 in this study and nine patients whose participation was judged to have an unfavorable influence on the  
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44 21 patient-physician relationship. The primary investigator was unable to obtain informed consent from  
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46 22 two patients because he was out of office, and from a further 32 patients because many patients were in  
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48 23 the waiting room at that time. As a result, 355 patients were included in this study (see figure 1 of  
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50 24 Sugiyama et al. [9]). There were no missing values for outcome measures or other variables among the  
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52 25 study participants.  
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55 26 The characteristics of study participants are shown in table 1 of Sugiyama et al. [9] The mean  
56  
57 27 (SD, standard deviation) PCAM score was 21.4 (5.7) and the distribution was skewed to the right (see  
58  
59 28 figure 2 of Sugiyama et al. [9]).  
60

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

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

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

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

## 6 7 **DISCUSSION**

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

15 In this study, the distribution of PCAM scores was skewed to the right; that is, inclined to be  
16 low. Yoshida et al. showed a widespread distribution of scores and a higher mean (SD) PCAM score at  
17 25.0 (7.3) compared with our study.[6] This discrepancy may be attributable to differences in clinical  
18 settings between the studies. Yoshida et al.[6] conducted their study in a secondary care setting and the  
19 participants were inpatients who were presumed to be biomedically and psychosocially more complex  
20 than outpatients in a primary care setting. Furthermore, the mean age (66.4 years) in this study was  
21 lower than that reported by Yoshida et al. (77.4 years). Older people are expected to be more complex,  
22 and have more diverse and complicated backgrounds, such as multimorbidity, dementia, and social  
23 isolation.[37, 38, 39] Similarly, confirmatory factor analysis using the previously reported two-factor  
24 structure (Patient-oriented complexity and Medicine-oriented complexity)[6] revealed that the poor fit  
25 may be attributable to differences in clinical settings and disparities between the island area in this study  
26 and the urban area in Yoshida et al.[6] It is important to note that interlinking mechanisms cascade from  
27 social–structural conditions down to biomedical and psychological problems.[40] Therefore, healthcare

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

3         Conversely, Mutai et al. showed a distribution with a floor effect similar to that in this study,  
4 but a lower mean (SD) PCAM score than our study at 16.5 (5.1).[7] Both our study and Mutai et al.  
5 were conducted in primary care settings. Mutai et al. used the Japanese version of the PCAM, which  
6 was developed using forward translation, back translation, and cognitive debriefing for cultural  
7 adaptation,[7] whereas this study used the original English version of the PCAM. The modification of  
8 the tool might have contributed to the discrepancies. However, this was minimized because the contents  
9 of the Japanese and original English versions were almost the same. Instead, as described above,  
10 disparities between the island area in this study and the urban area in Mutai et al. should be considered.  
11 For example, 52.7% of the participants in this study and 29.0% in Mutai et al. had an education level  
12 below a high school diploma. Educational background is associated with various aspects of patient  
13 complexity, such as health risks and protective behaviors, wages and income, and resources for  
14 health.[41] In addition, the items “Daily activities (including employment status)” and “Financial  
15 resources” were directly associated with the proportion of participants who were out of work[28]  
16 (13.5% and 56.7% in this study and Mutai et al., respectively). Although the mean age in this study  
17 (66.4 years) was lower than that in Mutai et al. (72.4 years), educational background might have had a  
18 greater influence on patient complexity given the higher PCAM score in this study than in Mutai et al.  
19 These differences may explain the poor fit as shown by confirmatory factor analysis of the previously  
20 reported three-factor structure (Personal well-being, Social interaction, and Needs for care/service).[7]  
21 Compared with urban areas, healthcare professionals in areas with lower accessibility to medical  
22 services (such as island areas) may have to provide services to patients with higher complexity caused  
23 by underlying factors, including lower educational background. Therefore, they may need training to  
24 appropriately assess patients’ biopsychosocial needs.

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



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

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

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

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

## 1 CONCLUSION

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

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## 15 Contributors

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

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## 25 Disclaimer

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

1

**2 Competing interests**

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

10

**11 Ethics approval**

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

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**16 Data sharing statement**

17 No additional data are available.

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# 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.

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

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

1	Eligibility criteria	<a href="#">#6a</a>	Give the eligibility criteria, and the sources and methods of selection of participants.	7
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5		<a href="#">#7</a>	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8, 9
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10	Data sources /	<a href="#">#8</a>	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
11	measurement			
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18	Bias	<a href="#">#9</a>	Describe any efforts to address potential sources of bias	7, 8
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21	Study size	<a href="#">#10</a>	Explain how the study size was arrived at	9
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23	Quantitative	<a href="#">#11</a>	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why	9
24	variables			
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27	Statistical	<a href="#">#12a</a>	Describe all statistical methods, including those used to control for confounding	9, 10
28	methods			
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31	Statistical	<a href="#">#12b</a>	Describe any methods used to examine subgroups and interactions	n/a
32	methods			
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35	Statistical	<a href="#">#12c</a>	Explain how missing data were addressed	10
36	methods			
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39	Statistical	<a href="#">#12d</a>	If applicable, describe analytical methods taking account of sampling strategy	n/a
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42	Statistical	<a href="#">#12e</a>	Describe any sensitivity analyses	Sensitivity analyses were not performed.
43	methods			
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47	<b>Results</b>			
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50	Participants	<a href="#">#13a</a>	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
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58	Participants	<a href="#">#13b</a>	Give reasons for non-participation at each stage	10
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1	Participants	<a href="#">#13c</a>	Consider use of a flow diagram	A flow diagram was not used.
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5	Descriptive data	<a href="#">#14a</a>	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
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11	Descriptive data	<a href="#">#14b</a>	Indicate number of participants with missing data for each variable of interest	10
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15	Outcome data	<a href="#">#15</a>	Report numbers of outcome events or summary measures. Give information separately for exposed and unexposed groups if applicable.	10–12
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21	Main results	<a href="#">#16a</a>	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
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27	Main results	<a href="#">#16b</a>	Report category boundaries when continuous variables were categorized	n/a
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31	Main results	<a href="#">#16c</a>	If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
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35	Other analyses	<a href="#">#17</a>	Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses	Other analyses were not performed
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40	<b>Discussion</b>			
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43	Key results	<a href="#">#18</a>	Summarise key results with reference to study objectives	12
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45	Limitations	<a href="#">#19</a>	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias.	15
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50	Interpretation	<a href="#">#20</a>	Give a cautious overall interpretation considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence.	12–15
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56	Generalisability	<a href="#">#21</a>	Discuss the generalisability (external validity) of the study results	15
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1 **Other**  
2 **Information**

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4  
5 Funding [#22](#) Give the source of funding and the role of the funders for the 16  
6 present study and, if applicable, for the original study on which  
7 the present article is based  
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10 None The STROBE checklist is distributed under the terms of the Creative Commons Attribution License CC-  
11 BY. This checklist can be completed online using <https://www.goodreports.org/>, a tool made by the [EQUATOR](#)  
12 [Network](#) in collaboration with [Penelope.ai](#)  
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# 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:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2021-050566.R1
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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
<b>Primary Subject Heading</b>:	General practice / Family practice
Secondary Subject Heading:	Epidemiology
Keywords:	EPIDEMIOLOGY, GENERAL MEDICINE (see Internal Medicine), PRIMARY CARE, SOCIAL MEDICINE

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3 1 **TITLE PAGE**  
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9 4 **The structural validity and internal consistency of the Patient Centered Assessment Method in a**  
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15 7 **Authors**  
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## 1 ABSTRACT

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

5 **Design** Cross-sectional study.

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

8 **Participants** This study included 355 patients who visited Tarama Clinic from April 1, 2018 to June  
9 30, 2018, were aged  $\geq 20$  years, lived in Tarama Village, and had decision-making capacity.

10 **Main outcome measures** Patient complexity scored by the PCAM.

11 **Results** The mean (standard deviation) PCAM score was 21.4 (5.7). The distribution was skewed to the  
12 right and there were no ceiling and floor effects. Confirmatory factor analysis found that the previously  
13 reported two- and three-factor structures did not show a good fit (root mean square error of  
14 approximation 0.18 and 0.16, comparative fit index 0.83 and 0.89, and standardized root mean square  
15 residual 0.14 and 0.11, respectively). Exploratory factor analysis revealed a new two-factor structure:  
16 “biomedical complexity” and “psychosocial complexity.” The Cronbach’s alpha values for the total  
17 PCAM score, the “biomedical complexity” factor, and the “psychosocial complexity” factor were 0.81,  
18 0.82, and 0.74, respectively.

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

## 24 **Keywords**

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

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## 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.

## 1 INTRODUCTION

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

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

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

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

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

11

## 12 **METHODS**

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

15

### 16 **Design**

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

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### 20 **Setting**

21 We conducted this study at Tarama Clinic, Okinawa Miyako Hospital, which is located on  
22 Tarama Island, Okinawa Prefecture, Japan.[11] Tarama Island is situated approximately 67 km west of  
23 Miyako Island (125 minutes by ferry[12] or 25 minutes by airplane[13]),[14] which is approximately  
24 300 km southwest of the main island of Okinawa Prefecture (55 minutes by airplane[13]).[15] Tarama  
25 Island is the main part of Tarama Village,[14] which had a population of 1,194 people (555 women and  
26 639 men) in 2015.[16] The percentage of population aging (the percentage of the population aged 65  
27 years or older) for that year was 26.4%,[17] which was almost same as the national average  
28 (26.6%).[17] In Tarama Village, 41.6% of the population work in primary industries (agriculture,

1 forestry, and fishery) and almost all of these workers (41.2% of 41.6%) are engaged in agriculture.[18,  
2 19] This proportion is considerably higher than the national average (3.8%).[20] Overall, 92.0% of the  
3 land on Tarama Island is devoted to raising beef cattle and growing sugar cane, vegetables, and  
4 tobacco.[14, 21] The average annual income is 1,765,000 yen,[22] which is substantially lower than the  
5 national average (3,203,000 yen) in 2015.[23]

6 Tarama Clinic, which has four staff (a physician, a nurse, a nurse assistant, and a clerk), is the  
7 only medical institution on the island (other than a dental clinic) and provides general outpatient and  
8 24-hour emergency services.[24] Japan has a “free access” healthcare system where patients are free to  
9 choose any medical institution.[25] However, most patients on Tarama Island are expected to choose  
10 Tarama Clinic because of geographical restrictions. Therefore, this study collected data regarding  
11 almost all patients who needed to visit a medical institution for any reason during the inclusion period.

### 13 **Participants**

14 We consecutively included patients who visited Tarama Clinic from April 1, 2018 to June 30,  
15 2018. We included patients only once, even if they visited more than once during the inclusion period.  
16 Of these patients, those who were aged  $\geq 20$  years, lived in Tarama Village, and had decision-making  
17 capacity were judged to be eligible for this study. Patients who refused to participate in this study were  
18 excluded. Patients whose participation was judged to have an unfavorable influence on the patient–  
19 physician relationship were also excluded. Some questions regarding personal issues, such as financial  
20 insecurity, which needed to be asked to complete the PCAM,[26,27] might be psychologically invasive  
21 for some patients and could potentially damage the patient–physician relationship. In the medical  
22 context of Tarama Island, patients had no choice of medical institutions other than Tarama Clinic.[24]  
23 Thus, if the patient–physician relationship was impaired, the patient would not be able to visit another  
24 medical institution, which could cause them to drop out from any treatment they were receiving. For  
25 this reason, careful attention was paid to the patient–physician relationship. Finally, patients were  
26 excluded if the primary investigator was out of office and unable to obtain informed consent from a  
27 patient, or when many patients were in the waiting room and obtaining informed consent from a patient  
28 interfered with usual medical practice.

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45 2 **Data collection**

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7 3 We collected data for this study from April 1, 2018 to March 31, 2019. When patients visited  
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9 4 Tarama Clinic, the sole physician (primary investigator) scored the PCAM during and after the visit in  
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11 5 accordance with the “PCAM User Guide for Conducting the Assessment.”[28] Japanese is widely and  
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13 6 commonly used in Japan, and all interviews for scoring the PCAM were conducted in Japanese.  
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15 7 However, a Japanese version of the PCAM,[7] which was published in 2020, was not available when  
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17 8 the study was conducted. Therefore, using and translating the original English version of the  
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19 9 PCAM[26,27] and the user guide containing its sample questions[28] during the interview, the scorer  
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21 10 asked appropriate questions in Japanese to score the items of the PCAM.  
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27 12 **Outcome measures**28 13 **PCAM**

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30 14 The PCAM is a tool for assessing patient complexity from a biopsychosocial perspective[5]  
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32 15 and has four domains: “Health and Well-being,” “Social Environment,” “Health Literacy and  
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34 16 Communication,” and “Service Coordination.”[26,27] Each domain has two or four items: “Health and  
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36 17 Well-being” has four items (#1 “Physical health needs,” #2 “Physical health impacting on mental well-  
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38 18 being,” #3 “Lifestyle impacting on physical or mental well-being,” and #4 “Other mental well-being  
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40 19 concerns”); “Social Environment” has four items (#1 “Home environment,” #2 “Daily activities,” #3  
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42 20 “Social networks,” and #4 “Financial resources”); “Health Literacy and Communication” has two items  
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44 21 (#1 “Health literacy” and #2 “Engagement in discussion”); and “Service Coordination” has two items  
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46 22 (#1 “Other services” and #2 “Service coordination”).[26,27] Each item has four levels of increasing  
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48 23 complexity (“Routine Care,” “Active Monitoring,” “Plan Action,” and “Act Now”) and is scored from  
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50 24 1 to 4 as complexity increases.[26,27] This gives a total PCAM score from 12 (minimum) to 48  
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52 25 (maximum).[27] The PCAM was developed for a range of primary care providers, such as general  
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54 26 practitioners and nurses, and also for teams of providers assisting with communication in team-based  
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56 27 care approaches.[5] The PCAM, in accordance with the user guide, enables people in these professions  
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58 28 to ask appropriate questions, to score items of the PCAM, and to assess patient complexity.[26,27,28]  
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## 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.

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

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

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



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3 1 the estimation method for categorical data was considered to be more appropriate and extracted the  
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5 2 factor structure more accurately in this study.

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7 3 Additionally, Cronbach's alpha, which is considered satisfactory if the value is  $\geq 0.7$ , [34] was  
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9 4 calculated to examine the internal consistency of the PCAM.

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11 5 We performed descriptive analysis and calculated Cronbach's alpha values using Stata/MP  
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13 6 version 15.1. [35] Confirmatory and exploratory factor analyses were performed using Mplus version  
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### 19 9 **Patient and public involvement**

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22 10 We conducted this study without patient and public involvement.  
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## 25 12 **RESULTS**

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27 13 During the inclusion period, 521 patients visited Tarama Clinic. Of these, 57 patients were  
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29 14 younger than 20 years, 13 patients did not live in Tarama Village, and 25 patients did not have decision-  
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31 15 making capacity, which left 426 eligible patients. We excluded 28 patients who refused to participate  
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33 16 in this study and nine patients whose participation was judged to have an unfavorable influence on the  
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35 17 patient-physician relationship. The primary investigator was unable to obtain informed consent from  
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37 18 two patients because he was out of office, and from a further 32 patients because many patients were in  
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39 19 the waiting room at that time. As a result, 355 patients were included in this study (figure 1, reproduced  
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41 20 from Sugiyama et al. [9]). There were no missing values for outcome measures or participant  
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43 21 characteristics among the study participants.  
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48 22 The characteristics of study participants are shown in table 1 reproduced from Sugiyama et  
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50 23 al. [9] The mean (SD) PCAM score was 21.4 (5.7). The distribution was skewed to the right and there  
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52 24 were no ceiling and floor effects (figure 2, modified from Sugiyama et al. [9]).  
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### 55 26 **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
<b>Health and Well-being</b>		
1 Physical health needs	<u>0.701</u>	-0.035
2 Physical health impacting on mental well-being	0.081	<u>0.578</u>
3 Lifestyle impacting on physical or mental well-being	<u>0.895</u>	-0.136
4 Other mental well-being concerns	0.190	<u>0.442</u>
<b>Social Environment</b>		
1 Home environment	-0.122	<u>0.630</u>
2 Daily activities	-0.059	<u>0.683</u>
3 Social networks	-0.266	<u>0.715</u>
4 Financial resources	0.256	<u>0.452</u>
<b>Health Literacy and Communication</b>		
1 Health literacy	<u>0.894</u>	0.117
2 Engagement in discussion	<u>0.621</u>	0.358
<b>Service Coordination</b>		
1 Other services	0.109	<u>0.806</u>
2 Service coordination	0.137	<u>0.835</u>

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

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3 1 In this study, confirmatory factor analysis found that the data did not fit sufficiently using the  
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5 2 previously reported two- and three- factor structures. Instead, exploratory factor analysis revealed a  
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7 3 new two-factor structure, for which the Cronbach's alpha values exceeded the threshold level. Therefore,  
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9 4 the structural validity and internal consistency of the English version of the PCAM were verified in a  
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11 5 primary care setting in a Japanese island area.

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14 6 While the distribution of PCAM scores was skewed to the right, or inclined to be low, Yoshida  
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16 7 et al. showed a widespread distribution of scores and a higher mean (SD) PCAM score at 25.0 (7.3)  
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18 8 compared with our study.[6] This discrepancy may be attributable to differences in clinical settings  
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20 9 between the studies. Yoshida et al. conducted their study in a secondary care setting and the participants  
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22 10 were inpatients who were presumed to be biomedically and psychosocially more complex than  
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24 11 outpatients in a primary care setting. Furthermore, the mean age (66.4 years) in this study was lower  
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26 12 than that reported by Yoshida et al. (77.4 years). Older people are expected to be more complex, and  
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28 13 have more diverse and complicated backgrounds, such as multimorbidity, dementia, and social  
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30 14 isolation.[37, 38, 39] Similarly, confirmatory factor analysis using the previously reported two-factor  
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32 15 structure (Patient-oriented complexity and Medicine-oriented complexity)[6] revealed that the poor fit  
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34 16 may be attributable to differences in clinical settings and disparities between the island area in this study  
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36 17 and the urban area in Yoshida et al. It is important to note that interlinking mechanisms cascade from  
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38 18 social-structural conditions down to biomedical and psychological problems.[40] Therefore, healthcare  
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40 19 professionals should recognize that differences in care settings need to be considered when assessing  
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42 20 patient complexity.

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45 21 Conversely, Mutai et al. showed a distribution with a floor effect similar to that in this study,  
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47 22 but a lower mean (SD) PCAM score than our study at 16.5 (5.1).[7] Both our study and Mutai et al.  
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49 23 were conducted in primary care settings. Mutai et al. used the Japanese version of the PCAM, which  
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51 24 was developed using forward translation, back translation, and cognitive debriefing for cultural  
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53 25 adaptation, whereas this study used the original English version of the PCAM. The modification of the  
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55 26 tool might have contributed to the discrepancies. However, this was minimized because the contents of  
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57 27 the Japanese and original English versions were almost the same. Instead, as described above,  
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59 28 disparities between the island area in this study and the urban area in Mutai et al. should be considered.

1 For example, 52.7% of the participants in this study and 29.0% in Mutai et al. had an education level  
2 below a high school diploma. Educational background is associated with various aspects of patient  
3 complexity, such as health risks and protective behaviors, wages and income, and resources for  
4 health.[41] In addition, the items “Daily activities (including employment status)” and “Financial  
5 resources” were directly associated with the proportion of participants who were out of work[26,27]  
6 (13.5% and 56.7% in this study and Mutai et al., respectively). Although the mean age in this study  
7 (66.4 years) was lower than that in Mutai et al. (72.4 years), educational background might have had a  
8 greater influence on patient complexity given the higher PCAM score in this study than in Mutai et al.  
9 These differences may explain the poor fit as shown by confirmatory factor analysis of the previously  
10 reported three-factor structure (Personal well-being, Social interaction, and Needs for care/service).[7]  
11 Compared with urban areas, healthcare professionals in areas with lower accessibility to medical  
12 services (such as island areas) may have to provide services to patients with higher complexity caused  
13 by underlying factors, including lower educational background. Therefore, they may need training to  
14 appropriately assess patients’ biopsychosocial needs.

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

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

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

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

7 The PCAM might be able to improve long-term care services in communities in island areas.  
8 Japan is experiencing unprecedented aging of the population, a phenomenon that has been termed the  
9 “super-aged” society.[47] Moreover, island areas were reported to have a substantially higher  
10 percentage of population aging on average (34.2%[48]) compared with the national average  
11 (26.6%)[17] in 2015. To address the challenge of population aging, Japan has established the  
12 “Community-based Integrated Care System,” which comprehensively ensures the provision of health  
13 care, nursing care, preventive long-term care, housing, and livelihood support.[49] However, in areas  
14 isolated from their surroundings, such as remote islands, these services are not usually well  
15 developed.[50] The PCAM can be helpful for identifying and highlighting the services that are  
16 necessary but lacking in communities. Based on these assessments, small communities may be able to  
17 address problems and improve services in a quick and flexible manner, with closer relationships among  
18 organizations including medical institutions, local governments, and the private sector, related to the  
19 Community-based Integrated Care System.[50]

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

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3 1 which could have led to underestimation of PCAM scores. Third, although we included study  
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5 2 participants consecutively, 16.7% of eligible participants were excluded. Nine patients were excluded  
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7 3 because their participation was judged to have an unfavorable influence on the patient–physician  
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9 4 relationships. The main reason was that they had confirmed or suspected mental or personality disorders,  
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11 5 which is likely to cause high psychological complexity. Exclusion of these possible participants might  
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13 6 have resulted in underestimation of PCAM scores. Additionally, the primary investigator was unable to  
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15 7 obtain informed consent from two patients because he was out of office, and from a further 32 patients  
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17 8 because many patients were in the waiting room at that time. These patients visited the clinic only once  
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19 9 during the inclusion period and therefore could not be enrolled in this study during a subsequent visit.  
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21 10 These patients usually had mild acute diseases, such as upper respiratory tract inflammation or  
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23 11 gastroenteritis, and were otherwise healthy, which meant their patient complexity was likely to be low.  
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25 12 Exclusion of these possible participants might have resulted in overestimation of PCAM scores.  
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## 33 **CONCLUSION**

34  
35 16 In this study, confirmatory factor analysis found that the data did not fit sufficiently using the  
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37 17 previously reported two- and three- factor structures. Instead, exploratory factor analysis revealed a  
38  
39 18 new two-factor structure, for which the Cronbach’s alpha values exceeded the threshold level. Therefore,  
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41 19 the structural validity and internal consistency of the English version of the PCAM were verified in a  
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43 20 primary care setting in a Japanese island area.  
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53  
54 25 [services.edanz.com/ac](https://en-author-services.edanz.com/ac)) for editing a draft of this manuscript.  
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56  
57

## 58 **Contributors**



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

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## 10 **Disclaimer**

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

## 15 **Competing interests**

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

## 24 **Ethics approval**

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

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1     **Data sharing statement**

2     No additional data are available.

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

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4 **Figure 2. Distribution of PCAM scores**

5 PCAM, the Patient Centered Assessment Method.

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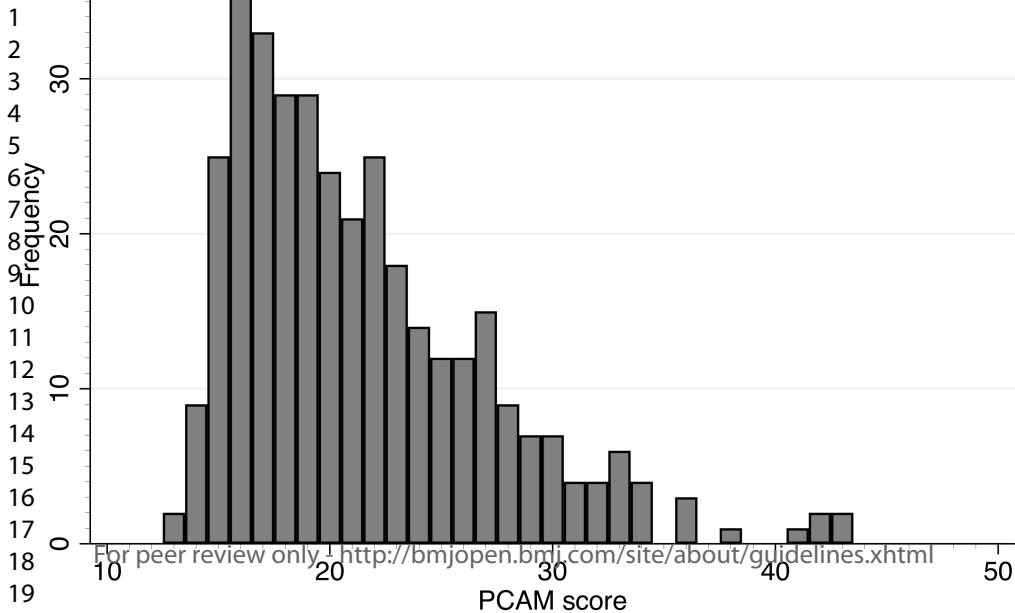
1 Visited Tarama Clinic  
from 1 April 2018 to 30 June 2018  
( n = 521 )

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4 Not meet the eligibility criteria ( n = 95 )  
5 • Not lived on the island ( n = 13 )  
6 • Aged less than 20 years ( n = 57 )  
7 • Lacked decision-making capacity ( n = 25 )  
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11 Eligible participants  
12 ( n = 426 )  
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15 Excluded ( n = 91 )  
16 • Refused to participate ( n = 28 )  
17 • Judged to have unfavourable influences on  
18 the patient-physician relationships ( n = 9 )  
19 • Informed consent not obtained  
20 i. the principal investigator was out of the office ( n = 2 )  
21 ii. too many patients in the waiting-room ( n = 32 )  
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24  
25 Included in this study  
26 ( n = 355 )  
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# 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 sectional reporting guidelines, and cite them as:

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

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

1	Eligibility criteria	<a href="#">#6a</a>	Give the eligibility criteria, and the sources and methods of selection of participants.	7
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5		<a href="#">#7</a>	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8, 9
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10	Data sources /	<a href="#">#8</a>	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
11	measurement			
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18	Bias	<a href="#">#9</a>	Describe any efforts to address potential sources of bias	7
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21	Study size	<a href="#">#10</a>	Explain how the study size was arrived at	9
22				
23	Quantitative	<a href="#">#11</a>	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why	9–11
24	variables			
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27	Statistical	<a href="#">#12a</a>	Describe all statistical methods, including those used to control for confounding	9–11
28	methods			
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31	Statistical	<a href="#">#12b</a>	Describe any methods used to examine subgroups and interactions	n/a
32	methods			
33				
34	Statistical	<a href="#">#12c</a>	Explain how missing data were addressed	11
35	methods			
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37				
38	Statistical	<a href="#">#12d</a>	If applicable, describe analytical methods taking account of sampling strategy	n/a
39	methods			
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42	Statistical	<a href="#">#12e</a>	Describe any sensitivity analyses	Sensitivity analyses were not performed.
43	methods			
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47	<b>Results</b>			
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50	Participants	<a href="#">#13a</a>	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
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58	Participants	<a href="#">#13b</a>	Give reasons for non-participation at each stage	11
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1	Participants	<a href="#">#13c</a>	Consider use of a flow diagram	26
2				
3	Descriptive data	<a href="#">#14a</a>	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
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10	Descriptive data	<a href="#">#14b</a>	Indicate number of participants with missing data for each variable of interest	11
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14	Outcome data	<a href="#">#15</a>	Report numbers of outcome events or summary measures. Give information separately for exposed and unexposed groups if applicable.	11–13
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19	Main results	<a href="#">#16a</a>	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
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26	Main results	<a href="#">#16b</a>	Report category boundaries when continuous variables were categorized	n/a
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30	Main results	<a href="#">#16c</a>	If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
31				
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34	Other analyses	<a href="#">#17</a>	Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses	Other analyses were not performed
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39	<b>Discussion</b>			
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41	Key results	<a href="#">#18</a>	Summarise key results with reference to study objectives	14
42				
43				
44	Limitations	<a href="#">#19</a>	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
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49	Interpretation	<a href="#">#20</a>	Give a cautious overall interpretation considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence.	14–18
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54	Generalisability	<a href="#">#21</a>	Discuss the generalisability (external validity) of the study results	17
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58	<b>Other</b>			

**Information**

1  
2  
3 Funding [#22](#) Give the source of funding and the role of the funders for the 19  
4 present study and, if applicable, for the original study on which  
5 the present article is based  
6

7  
8 None The STROBE checklist is distributed under the terms of the Creative Commons Attribution License CC-  
9 BY. This checklist can be completed online using <https://www.goodreports.org/>, a tool made by the [EQUATOR](#)  
10 [Network](#) in collaboration with [Penelope.ai](#)  
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