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Development of a PROM to measure patient-centredness in chronic care consultations in primary care

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Abstract

Introduction Validated patient-reported outcome measures (PROMs) are crucial for assessing patients' experiences in the healthcare system. Both clinically and theoretically, patient-centered consultations are essential in patient-care, and are often suggested as the optimal strategy in caring for patients with multimorbidity.

Aim To either identify or develop and validate a patient-reported outcome measure (PROM) to assess patient-centredness in consultations for patients with multimorbidity in general practice.

Methods We attempted to identify an existing PROM through a systematic literature review. If a suitable PROM was not identified, we planned to (1) construct a draft PROM based on items from existing PROMs, (2) conduct group and individual interviews among members of the target population to ensure comprehensibility, comprehensiveness and relevance, and (3) perform a psychometric validation in a broad sample of patients from primary care.

Results We did not identify an eligible PROM in the literature review. The item extraction and face validity meetings resulted in a new PROM consisting of 47 items divided into five domains: biopsychosocial perspective; `patient-as-person'; sharing power and responsibility; therapeutic alliance; and coordinated care. The interviews resulted in a number of changes to the layout and phrasing as well as the deletion of items. The PROM used in the psychometric validation consisted of 28 items. Psychometric validation showed high internal consistency, overall high reliability, and moderate fit indices in the confirmatory factor analysis for all five domains. Few items demonstrated differential item functioning concerning variables such as age, sex, and education.

Conclusions This study successfully developed and validated a PROM to measure patient-centredness in consultations for patients with multimorbidity. The five domains demonstrated high reliability and validity, making it a valuable tool for measuring patient-centredness of consultations in general practice.

Trial registration Trial registration number (data for psychometric validation): https://clinicaltrials.gov: NCT05676541 Registration Date: 2022-12-16.

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Keywords Patient-reported outcome measures, Patient-centredness, General practice, Chronic disease, Multimorbidity, Primary care

Background

Having multiple chronic conditions, often referred to as multimorbidity, is increasingly common and linked to various health issues [1, 2]. Patients with multimorbidity face challenges such as multiple appointments, complex treatment schedules, and conflicting advice. Patient-centred consultations are often suggested as an optimal strategy when caring for patients with multimorbidity in general practice [3–5].

Despite widespread advocacy for and education on the patient-centred model (PCM) of consultations in general practice, a lack of consensus regarding its precise definition remains [6–8]. The definition originally emphasized recognizing patients as unique individuals and paying attention to both the patient's and the general practitioner's (GP's) agenda, but it is used in various ways [9, 10]. Shared decision-making is a prominent example of an aspect of patient–physician interaction that has been developed from the PCM [11]. Stewart et al. provided a comprehensive model of PCM, identifying six components, including exploring the patient's experience and enhancing the doctor–patient relationship [12]. This conceptual framework was further developed by Mead and Bower, who presented a framework consisting of five conceptual dimensions: biopsychosocial perspective; `patient-as-person'; sharing power and responsibility; therapeutic alliance; and `doctor-as-person' [13]. Langberg et al. added the dimension "Coordinated care" and argued, the six domains represented three main elements; understanding the patient's situation, developing the doctor-patient relationship and managing coordination of care in the organisational framework of the health care system [14].

Patient-reported outcome measures (PROMs) are as outcomes essential for structurally assessing patients' experiences in the healthcare system [15–17]. PROMs must undergo face and content validation to ensure relevance and coverage of the measured construct as well as the clarity and understanding in the target population [18]. If the PROM encompasses items that are qualitatively indicated to measure different nuances of the same domain, these should be psychometrically validated in a larger sample to ensure the adequateness of the measurement properties so that a sum score of these items can be scientifically justified [19, 20]. These criteria are summarised in the Consensus- based standards for the selection of health status measurement instruments (COSMIN) checklist [21].

In preparing a randomized clinical trial evaluating extended and dedicated consultations for patients with multimorbidity, we aimed to measure patient-experienced patient-centredness in the consultations. We decided to use the conceptual framework presented by Mead and Bower and further developed by Langberg et al. to define the concept of patient-centredness [13, 14]. However, to measure the concept of patient-centredness, we had to either identify or develop a suitable PROM.

Hence, the first aim of this study was to identify one or more PROMs to measure patient-centredness in consultations concerning chronic conditions in patients with multimorbidity according to the chosen theoretical framework with adequate validity to use unaltered. If a PROM with adequate validity could not be identified, we proceeded to the second aim, which was to develop and validate a new PROM to measure patient-centredness in consultations concerning chronic conditions in patients with multimorbidity.

Methods

The validation process consisted of five steps: The first step was to choose the theoretical framework to define patient-centredness in consultations. The second step was to conduct a literature search to identify PROMs measuring patient-centredness in consultations and quality-assess these PROMs. The main aim of the literature search was to identify a PROM which could be used unaltered. If no such PROM was identified, we proceeded to step three, which was to extract domains or items from the identified PROMs if they measured aspects of patient-centredness according to the chosen theoretical framework and construct a draft PROM with high face validity. In step four, the draft PROM was tested and modified in group and individual interviews among the target population. When the content validation procedure had resulted in a PROM with high content validity, we proceeded to step five, the psychometric validation. The steps in the development and validation of the PROM are outlined in Fig. 1.

Step 1: Theoretical framework

We selected the theoretical framework presented by Langberg et al. to define patient-centredness in consultations [14]. This framework was developed based on the original framework by Mead and Bower [13] and

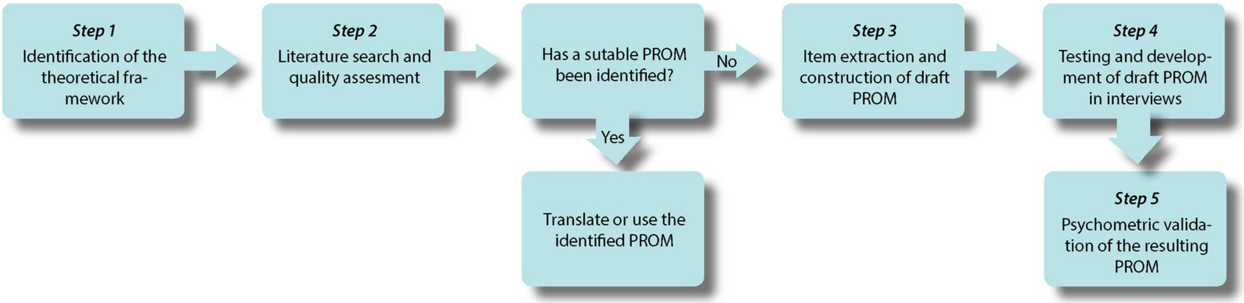

Fig. 1 The steps in the development and validation of the PROM

further developed through a systematic review of the literature, in which the authors explored whether the original domains were still relevant and covered the patients' experiences of patient-centredness. The definition of the concept of patient-centredness is highly debated and a number of different concepts are used [22, 23]. We chose this particular framework based on three main reasons: Firstly, it was built upon a widely recognized framework building on solid qualitative work. Secondly, it aimed to encompass the patient's perspective on patient-centrednes, although not strictly only in consultations. Finally, the expert on patient-centredness in consultations in our group had extensive experience with this framework. The framework consists of six conceptual dimensions: biopsychosocial perspective; `patient-as-person'; sharing power and responsibility; therapeutic alliance; `doctor-as-person' and "coordinated care". After careful consideration, we omitted the domain; 'doctor-as-person' since this domain was difficult to assess from a patient-perspective.

The biopsychosocial perspective emphasizes holistically viewing the patient's illness, beyond just the biomedical aspects, to include health promotion and the doctor's responsibility for non-medical concerns. The "patient-as-person" approach focuses on understanding the patient's illness within the context of their unique life story, recognizing the personal meaning of the illness and the broader life circumstances. Sharing power and responsibility focuses on a shared and egalitarian doctor-patient relationship, emphasizing mutual participation. This means treating the patient with respect and ensuring active involvement in decision-making, while fostering patient empowerment. The therapeutic alliance means prioritising the doctor-patient relationship, with the doctor being perceived as caring, sensitive, and empathic. It should also involve a shared understanding and agreement on treatment goals. Finally, "coordinated care", the newest dimension added by Langberg et al., focuses on the need for coordination and integration across various aspects of a patient's care plan. The goal is to create a more seamless, healing, and hassle-free experience for the patient throughout their care journey. Enhancing this dimension is expected to reduce unnecessary use of healthcare resources, making care more integrated, accessible, and cost-effective.

Step 2: Literature search and quality assessment

We included studies on PROM development and validation conducted in primary care, which aimed to measure patient-centredness in consultations. They should be intended to be completed by and validated among patients with at least two unselected chronic conditions. Thus, we did not include PROMs developed specifically for patients with, for example, diabetes and co-morbidity. We searched PubMed using the following search string: (patient-reported outcome measure[TiAb] OR PROM[TiAb] OR instrument[TiAb] OR validation[TiAb]) AND (multimorbid* OR (chronic AND (illness OR disease OR condition?))) AND (patient-centered* OR person-centered*). We did not include a search term regarding primary care since this tends to lower the sensitivity. The search string was constructed by AH, who has expertise within the area, with input from the group. A librarian was not consulted. We searched for validation studies published in Danish, Swedish, Norwegian or English published before the 1st of October 2022, when the search was performed. Titles and abstracts were screened by two authors (AH and SFB) and full-text articles were retrieved on potentially relevant manuscripts. Full-text articles were reviewed for eligibility by two authors (AH and SFB) and a third author (KB) was consulted in case of disagreement.

To be eligible for risk of bias assessment and item extraction, the PROM had to: (1) measure one or more aspects of the concept of patient-centredness in consultations, and (2) be intended for use in and validated among patients with at least two unselected chronic conditions. The COSMIN Risk of Bias checklist boxes 1–4 (PROM development, content validity, structural validity, and internal consistency) was used for risk of bias assessment [24]. The risk of bias was assessed by two authors (AH and AM). To be eligible for the use of the full PROM, the PROM had to have at least good quality in domains 1–4 in the COSMIN checklist.

Step 3: Content validation 1, item extraction, construction of a draft PROM and face validity

The process of content validation involved two primary components: (1) extracting items and constructing a draft of the PROM and (2) conducting focus group and individual interviews with patients with multimorbidity. If no PROM was eligible for use in our trial in unaltered form by fulfilling both the criteria for item extraction and having at least good quality according to boxes 1–4 in the COSMIN checklist, we planned to extract items from PROMs fulfilling the criteria for item extraction if they corresponded to one of the dimensions in the chosen theoretical framework and design a new PROM.

The item extraction process consisted of a manual extraction of all items from the identified PROMs and a grouping of these items into the five domains: biopsychosocial perspective; `patient-as-person'; sharing power and responsibility; therapeutic alliance; and "coordinated care". Items were extracted by a student employee and ADG helped organize the items into the five domains.

Four of the authors (AH, ABL, JBB and ADG) ensured face validity of the draft PROM as well as the subsequent versions of the PROM emerging after each interview by critically examining each theoretical domain and the corresponding items. Members of the author group represented different geographical regions in Denmark and were consulted to clarify regional perspectives when needed. SFB represented the Southern Region, JKK, The Northern Region, AM and MATK, Region Zealand, AP, The Central Region and ZKJ and SB, The Capital Region.

Step 4: Content validation 2, group and individual interviews

Focus group interviews

Focus group interviews were conducted with patients with multimorbidity. The patients were recruited through their GP, who were asked to invite five patients with multimorbidity for each group interview through purposive sampling. The GPs were recruited through the authors' network. Seven GPs (six practices) participated in recruiting patients. The limit of five patients was chosen since we wanted a dynamic group, but also with the possibility to share some private experiences. We also anticipated some not showing up due to health reasons. The PROM was intended to be used in a trial evaluating extended consultations among patients with multimorbidity [25]. Multimorbidity in this trial was defined as experiencing significant problems in one's daily life due to multimorbidity. Since we wanted to ensure high content validity among the patients included in the trial and we wanted to identify patients, who might experience problems with fragmentation of care and lack of patient-centredness in consultations, we used a quite extensive definition of multimorbidity, which had been used in a content validation procedure previously and proven effective in identifying patients with some degree of problems in their daily life and experience of inequality in health [26]. The patients had to fulfil the following inclusion criteria: age over 18 years, had two or more chronic conditions, and experienced significant problems concerning their life and health due to their multimorbidity. To clarify the concept of multimorbidity, we specified that patients' problems could be either biomedical or psychosocial: (1) having several chronic conditions from different organ systems, (2) having one or more of the conditions newly diagnosed or poorly regulated, (3) lacking social network, (4) being anxious or nervous, and (5) feeling limited physically and socially by their conditions or (6) having problem in relation to the healthcare system.

The focus group interviews were semistructured and lasted approximately two hours. They aimed to investigate whether the draft version of the PROM had content relevance, content coverage, and functionality and whether new items and domains were understandable for the patients. We chose focus group interviews to ensure the possibility for generation of new items, and to facilitate an open discussion about the content and layout of the drafted PROM. The first and second focus group interview were moderated by JBB, who is very experienced in content validation procedures and assisted by ABL, who was not experienced at the time. The third focus group interview was moderated by ABL and assisted by JBB. The interviews were audio-recorded, transcribed and both moderators took notes for later analysis. The transcriptions served to identify new meaningful items.

During the group interviews, the participants were presented with the draft version of the PROM and were asked to complete it. The participants were encouraged to note wording, ease of completion, and eventual challenges when completing the PROM. Thereafter, the moderator addressed content, relevance, content coverage, and understandability on an item-to-item basis. When items were mentioned, the moderator facilitated a discussion on how to improve the items, and the suggestions were noted. Furthermore, the participants were encouraged to discuss areas not covered by the drafted PROM. Finally, if new items and/or domains were generated, the interviewees were asked about the comprehension and relevance of the new domains and items. The iterative process was continued until the interviewees had no further comments. Special care was taken to avoid professional jargon and ambiguous wording when generating new or adapted items. The theoretical foundation for this technique has been outlined previously [27].

JBB, ABL, and AH participated in the content analysis of the interviews. If agreement among the authors could not be reached, the transcriptions were re-visited or the audio-recording and the participants' replies were reaudited and reanalysed until a consensus was reached. We pre-planned three focus groups in three geographically diverse locations in Denmark and had the opportunity to plan additional focus groups until no further new themes emerged. The individual interviews were conducted after the last group interview.

Individual interviews

The purpose of the individual interviews was to ensure functionality and correct minor errors that had not been identified in the focus group interviews. The participants were recruited in the same way as in the group interviews, but from different geographical locations and practices. The interviews entailed think-aloud techniques and verbal probing, for example by asking the informant to elaborate on item meaning and relevance on an item-to-item basis to further test the participants' understanding, the structure of the response category, and the PROM layout. Participants were asked to read the entire PROM aloud and to verbalize their thoughts while completing the PROM. If the participants had difficulties understanding or answering the items or offered critical comments, the interviewer probed the nature of the problem. The individual interviews took between 30 and 60 min and were conducted by ABL and SFB. The interviews were audio-recorded, and the interviewer took notes. The individual interviews were not transcribed since it was not their primary aim to identify new meaningful items but rather to ensure functionality. The audio-recordings, the participants' replies to the PROM, and the interview notes were discussed by the authors. Based on these discussions, the items were modified and tested in subsequent interviews. The individual interviews were repeated until no new information or problems emerged.

Step 5: Psychometric validation

The data for the psychometric validation were collected in a questionnaire baseline-survey connected to a cluster-randomized trial (the MM600 trial) in which 250 general practices in Denmark participated [25]. The draft PROM was sent in March 2023 via an online secured connection to all patients > 18 years listed at participating practices who had attended at least consultation concerning chronic disease in 2022. In Denmark, GPs can allocate additional time to perform a yearly check-up for most chronic conditions.

The analysis aimed at exploring whether the five theoretical domains (biopsychosocial perspective; `patient-as-person'; sharing power and responsibility; therapeutic alliance; and coordinated care) were consistent, reliable, unidimensional and whether the scales had differential item functioning (DIF). The domains were assessed for internal consistency using Cronbach's Alpha and reliability using the Total Reliability Coefficient (TRC) [28]. Ceiling and floor effects were assessed by the number and percentage of participants scoring maximum resp. minimum on the corresponding scale. Confirmatory factor analysis CFA model fit was used to determine whether the domains were unidimensional and was assessed with the goodness of fit index (GFI) > 0.95; root mean square error of approximation (RMSEA) < 0.06; standardized root mean square residual (SRMR) < 0.06; and the Comparative Fit Index (CFI) > 0.95 [29, 30]. The items were assessed for differential item functioning (DIF) concerning age, sex, geographical region, living alone, education, occupation, self-rated health, number of chronic conditions, number of medicines and variables related to the type of consultation, separately for the five domains, with partial gamma coefficients between the item and the covariate conditional on the scale score [31]; for the geographical region covariate, which was not ordinal, a partial p-gamma coefficient was used [32]. The absolute value of these partial gamma coefficients were then plotted in a half-normal plot; instances of DIF, assuming these are a minority, then fall clearly off the line extrapolating the smaller partial gamma coefficients, in a method attributed to Daniel [33]. The scores for each domain is the sum of the scores for the items included in the domain. Each item scores from 0 (lowest) to 3 (highest), hence, the range of the domain is dependent on and can be determined from the number of items in the domain. Statistical analyses were performed in SAS, R and DIGRAM.

All data management procedures adhered to established rules and regulations, including GDPR compliance. Data collection, storage, and analysis complied with institutional guidelines and relevant legal requirements to ensure data integrity and confidentiality. Access to data was restricted to authorized personnel only. Data was securely stored using encrypted drives, and regular backups were conducted to prevent data loss.

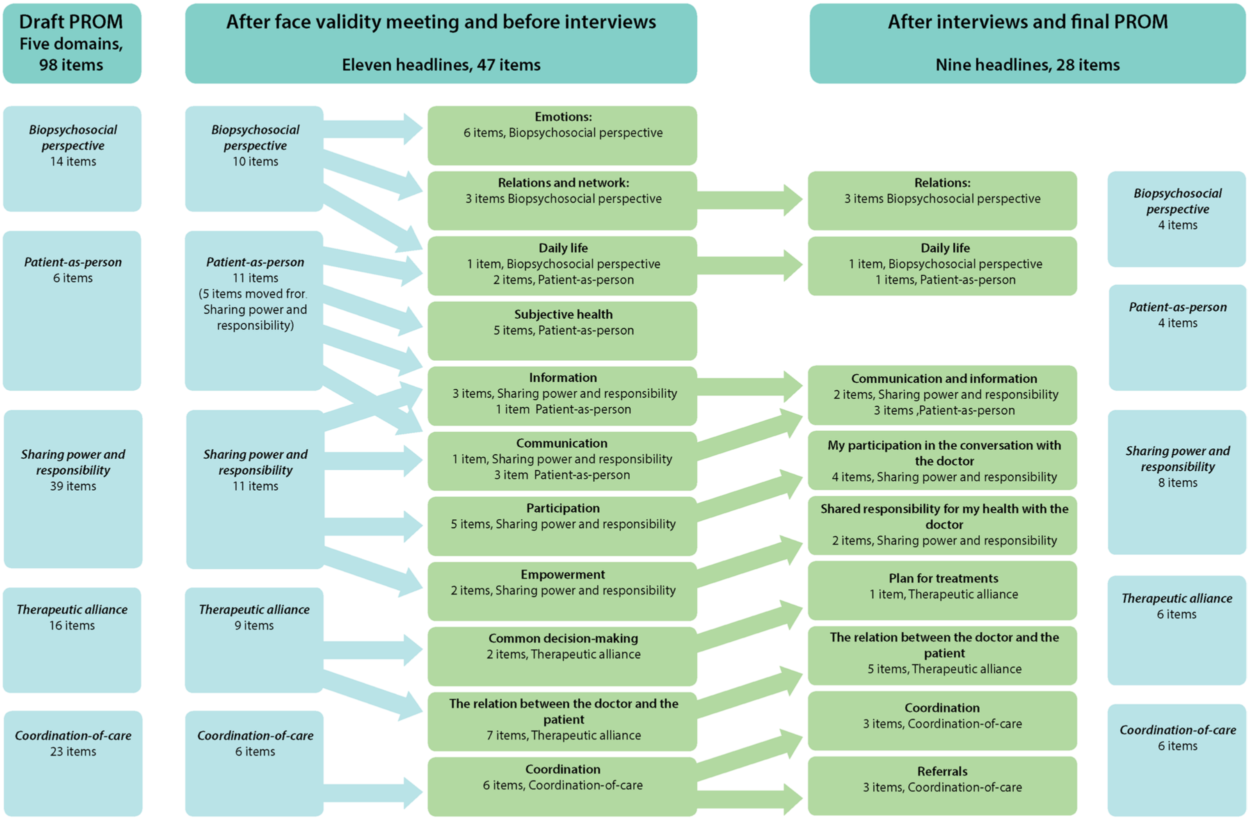

Fig. 2 Content validation procedure visualized. PROM: patient-reported outcome measure

Results

Literature search

The initial search in PubMed yielded 225 results. After screening the titles and abstracts, eight studies from the search and one additional study from a systematic review [34] identified in the search were selected for full-text reading. The screening of references did not identify additional eligible studies. After full-text reading, one study was excluded because it was not a PROM validation study [35], six studies were excluded because they aimed to measure patient-centredness of care rather than patient-centredness of consultations [36–41], and the remaining two studies were excluded because they targeted the wrong patient population [42–44]. More detail available in Appendix 1 (PRISMA flow chart) and Appendix 2 (reasons for exclusion). Since none of the identified PROMs were eligible for quality assessment and thus none could be used for our purpose in their full version, we omitted this step.

Content validation 1: Item extraction, construction of a draft PROM and face validity Although no PROMs were eligible for full item extraction, the identified PROMs were reviewed for relevant items or domains concerning our selected framework [14]. Six PROMs had one or more items eligible for extraction [36, 38, 39, 41–44]. We extracted 102 items and sorted them into the five remaining domains in the selected framework. Four items could not be allocated to a domain and were excluded, leaving 98 items. The biopsychosocial perspective domain contained 14 items, the patient-as-person domain contained 6 items, the sharing power and responsibility domain contained 39 items, therapeutic alliance domain contained 16 items, the coordination-of-care domain contained 23 items. Figure 2 gives an overview of the allocation of items during the face and content validity procedure.

After the initial extraction of items, a draft version of the PROM was constructed. The draft version of the PROM was reviewed for face validity by a panel consisting of ADG (experienced qualitative researcher), AH (some experience in content validation), ABL (some experience in qualitative research) and JBB (extensive experience in content validation). The items were regrouped under new headlines presumed more relevant and understandable to the patients based on the panel's experience. Redundant items were removed. The resulting PROM contained 47 items grouped into new headlines; "The relation between the doctor and the patient", "information", "participation", "empowerment", "communication", "common decision-making", "coordination", "relations and network", "daily life", "subjective health" and "emotions". We did not expect these headlines to represent a new theoretical framework but merely to enhance the comprehensibility of the PROM. Also, the headlines did not correspond directly to the domains in the theoretical framework. Four response categories were added: (no, not at all), 1 (yes, a little), 2 (yes, some), 3 (yes, a lot). After careful consideration, we chose positive phrasing of items, for example; "the doctor listened to my problems" instead of the opposite. We decided on the positive phrasing since it was the most common in the extracted items and we anticipated, a negative phrasing could antagonize both patients and doctors participating in data collections using the PROM. We also decided to explore further in the interviews whether, patients agreed with this decision.

Content validation 2, group and individual interviews

Three focus group interviews were conducted: one with four women and one man, one with three women and two men, and one with three women and two men in three different regions of Denmark. Each group was presented with a draft version of the PROM, which was adjusted by the expert panel consisting of ADG, AH, and JBB after each session based on participant feedback.

The first two focus groups and the subsequent expert panel review resulted in extensive removal of items, changes to the layout of the questionnaire and regrouping of items under new headlines. Two entire headlines including their related items were removed; "Emotions" and "Subjective health". Both were considered irrelevant for most consultations about chronic conditions. The items, that were considered relevant, were already encompassed in the other headlines. No new items were generated. The PROM presented in the third focus group consisted of 32 items grouped under nine headlines "The relation between the doctor and the patient" (5 items), "My participation in the conversation with the doctor" (5 items), "Shared responsibility for my health with the doctor" (2 items), "Communication and information" (6 items), "Plan for treatments" (1 item), "Relations" (3 items), "Daily life" (2 items"), "Coordination" (3 items) and "Referrals" (5 items). In the third focus group, no new items were generated, but one item regarding "My participation in the conversation with the doctor", one item regarding "communication and information", and two items regarding "referrals" were removed, resulting in a 28-item PROM. The informants needed a fifth response category; (not applicable/ do not know), which was added to all items.

Subsequently, 12 individual interviews with patients fulfilling the inclusion criteria were conducted, involving eight women and four men aged 53 to 81 years. These interviews led to minor corrections in phrasing and layout, with no new items generated and none removed.

A number of headlines and items were changed or removed due to lack of comprehensibility. For example, for a number of participants, a domain named "Take control and shared responsibility regarding decisions about my health" was unclear. The participants were encouraged to suggest rephrasing for better clarity and suggested "Shared responsibility for my health with the doctor". Some participants also expressed an unclear understanding of the item "I know who coordinates my treatments" in the coordination domain. They suggested rephrasing it to "I know who to ask when I have questions about my treatment". The domain regarding "Have you been referred to treatment by anyone other than your doctor?" was also unclear as to when in time the question was regarding. Rephrasing and setting a timeline for the question were suggested, calling it "In the past year, have you been referred to another treatment by your doctor?". The item in the "Daily life" domain asked, "I felt that the doctor saw me as a whole person"; several of the participants were unsure what the meaning of "a whole person" meant. A clarification text below the item was added and accepted in the subsequent interviews.

To assess comprehensiveness, the participants were asked if they found the PROM comprehensive in addressing their experience with patient-centeredness. To frame the concept of patient-centeredness to the patients, we used Langbergs three elements; the doctors ability to understand the patient's situation, develop the doctor-patient relationship and manage coordination of care in the organisational framework of the health care system. None of the participants felt that additional questions needed to be included in the PROM to cover their experience with patient-centeredness in chronic care consultations or that any questions were missing and therefore, no further items or domains were added.

All interviewed patients were asked about the relevance of the questionnaire. They unanimously agreed that it was pertinent, although some indicated that certain questions seemed implicit during visits to a GP. For instance, the item "The doctor seemed interested in why I had come" in the "My participation in the conversation with the doctor" domain was considered inherent when consulting a doctor by many patients. Conversely, other participants noted that this was not necessarily the case, when they consulted their GPs. This reflection

Table 1 The characteristics of the respondents to the PROM compared to all the respondents to the questionnaire and the full population, who received the questionnaire

Variable	Respondents patient-centredness in consultations PROM *N* (%)	Respondents of full questionnaire *N* (%)	Full population *N* (%)
Female	12,328 (51.67%)	18,665 (51.88%)	84,178 (52.42%)
Age			
< 40 years	938 (3.93%)	1595 (4.43%)	12,722 (7.92%)
40–49 years	1,533 (6.42%)	2263 (6.29%)	14,260 (8.88%)
50–59 years	4,051 (16.98%)	6045 (16.80%)	30,262 (18.84%)
60–69 years	7,239 (30.34%)	10,499 (29.18%)	42,366 (26.38%)
70 or older	10,099 (42.33%)	15,575 (43.29%)	60,974 (37.97%)
Education			
Basic schooling	1,382 (5.80%)	2289 (6.92%)	-
High school or courses	10,540 (44.26%)	15,166 (45.86%)	-
Higher education 2 years	2,461 (10.33%)	3361 (10.16%)	-
Higher education 3–4 years	6,692 (28.10%)	8737 (26.42%)	-
Higher education 5–6 years	2,734 (11.48%)	3515 (10.63%)	-
Chronic conditions			
0–1 chronic condition	4,055 (17.01%)	7844 (22.14%)	-
2–3 chronic conditions	10,814 (45.35%)	15,662 (44.20%)	-
4–5 chronic conditions	6,796 (28.50%)	9054 (25.55%)	-
6 or more chronic conditions	2,180 (9.14%)	2876 (8.12%)	-

highlighted both the relevance of the item and the varied experiences within the healthcare setting.

The result of the content validation was a PROM with 28 items grouped under nine headlines regarding the experienced patient-centeredness in primary care consultations regarding chronic conditions.

Psychometric validation

The PROM was distributed to 160,584 people (159,619 digitally 965 by post) as part of an ongoing trial [25]. 35,977 responded to the survey (response rate 0.22). The patient-centeredness in consultations PROM was optional and placed last, 24,064 agreed to respond (response rate 0.67). A total of 23,860 people completed the PROM (completion rate 0.99) and were included in the present analysis. The details of the full questionnaire study will be described in a separate publication.

The characteristics of the respondents to the PROM compared to all the respondents and the full population are presented in Table 1. 51.67% of the respondents to the PROM were female compared to 51.88% of all the respondents and 52.42% in the full population. The majority were 60 years or older in all populations with a higher drop-out of younger patients both from the full population to the full questionnaire and from the full questionnaire to the PROM. Educational level and conditions could only be compared among the respondents. About half the respondents in both populations had education beyond high school with a slightly higher drop-out among people with shorter education. The majority of patients reported having between 2 and 5 chronic conditions with a higher dropout among those with few chronic conditions.

The respondents were asked to think about a consultation with their GP about their chronic conditions and provide information on the consultation they were thinking about. 83% thought about a type of chronic care consultation, while the rest thought about other types of consultations. 47% of the consultations had taken place within the past 3 months, while 22% had taken place more than 6 months prior. In 74% of the consultations, regular GPs were present. The distribution of all the covariates in the population used in the psychometric analysis can be seen in Appendix 3.

The psychometric properties of the original domains are shown in Table 2. The domains “biopsychosocial” and “coordinated care” had a high number of missing values due to some of the items concerning support from relatives, which is not always relevant, and referrals, which did not always occur at the consultation. All of the domains showed good internal consistency (Cronbach’s alpha ranging from 0.87 to 0.95), and overall reliability (TRC ranging from 0.89 to 0.95). The fit of the models in the confirmatory factor analysis was good, with an SRMR ranging from 0.003 to 0.068, a GFI ranging from 0.81 to

Table 2 Psychometric properties of the five domains. # min and # max represents the number and proportion of patients responding with either the lowest (0) or highest (3) possible score in each domain. Cronbach's alpha measures the average correlation among items within a test, indicating how well they measure the same underlying construct. The values range from 0 to 1, with higher values indicating better internal consistency. The total reliability coefficient (TRC) is an overarching measure of reliability, encompassing various sources of error variance. Higher values indicate better reliability. The goodness-of-fit index (GFI) compares the fit of the specified model to that of a null model (one with no relationships among variables). The values range from 0 to 1, with higher values indicating a better fit. The root mean square error of approximation (RMSEA) measures how well the model approximates the population covariance matrix per degree of freedom. Lower values indicate a better fit. The standardized root mean squared residual (SRMR) is a measure of the difference between observed and predicted correlations. The values range from 0 to 1, with lower values indicating a better fit. The comparative fit index (CFI) compares the fit of the specified model to an independent (null) model. The values range from 0 to 1, with higher values indicating a better fit

Scale Name			**Ceiling effect**		**Internal consistency**		**CFA model fit**			
Scale Name	***N* Items**	***N***	**# min**	**# max**	**Cronbach's alpha**	**TRC**	**GFI**	**RMSEA**	**SRMR**	**CFI**
Biopsycosocial	4	7543	486 (0.064)	1932 (0.256)	0.891	0.910	0.978	0.147	0.025	0.986
Patient as a person	4	18,164	301 (0.017)	7694 (0.424)	0.906	0.900	0.999	0.025	0.003	1.000
Sharing power and responsibility	8	18,139	57 (0.003)	7918 (0.437)	0.930	0.940	0.934	0.116	0.028	0.957
Therapeutic alliance	6	19,021	150 (0.008)	10,116 (0.532)	0.950	0.950	0.936	0.147	0.020	0.970
Coordinated care	6	8756	5 (0.000)	3702 (0.423)	0.875	0.890	0.871	0.201	0.068	0.881

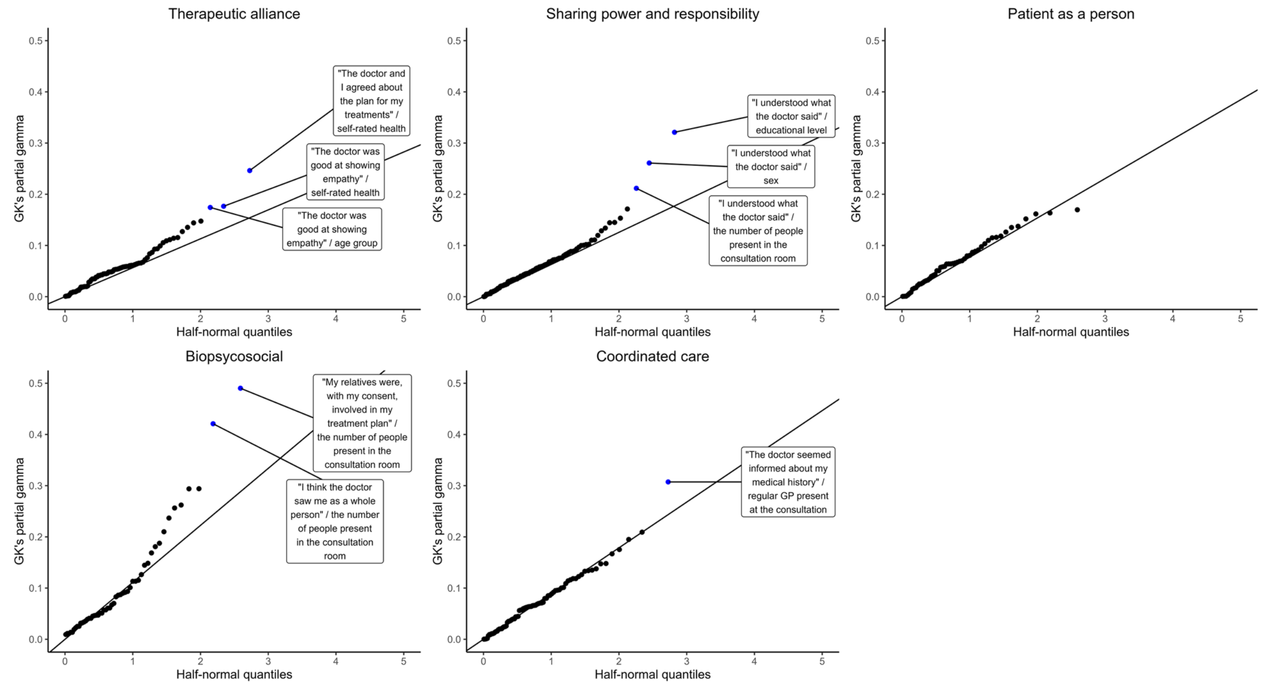

Fig. 3 Differential Item Functioning (DIF) analysis for each of the five domains

1.00 and a CFI ranging from 0.88 to 1.00. The domain "coordinated care" had the poorest fit.

The DIF analysis is shown in Fig. 3. The items "the doctor and I agreed about the plan for my treatments" and "the doctor was good at showing empathy" showed DIF concerning self-rated health. The item "the doctor was good at showing empathy" also showed DIF concerning age group. The item "I understood what the doctor said" showed DIF concerning educational level, sex and the number of people present in the consultation room. The items "My relatives were, with my consent, involved in my treatment plan" and "I think the doctor saw me as a whole person" also showed DIF concerning the number of people present in the consultation room. The item regarding coordination at referrals "The doctor seemed informed about my medical history" showed DIF with regard to the covariate "Regular GP present at the consultation".

Discussion

This study aimed to identify or develop and validate a patient-reported outcome measure (PROM) to assess patient-experienced patient-centredness in consultations for patients with multimorbidity. No existing PROMs were found in the systematic search, and therefore a new PROM was developed. Based on items from six existing PROMs, face and content validity evaluation through interviews we developed a new PROM with 28 items grouped under new headlines. In the psychometric validation, four of the five original, theoretical domains; biopsychosocial perspective, patient-as-person, sharing power and responsibility, and therapeutic alliance showed acceptable internal consistency, overall reliability, and acceptable fit indices in the confirmatory factor analysis while the fifth domain, coordinated care showed a poorer fit to the model. All domains except the biopsychosocial domain had a high ceiling effect.

This study employed a rigorous, multistep validation process, including a literature review, item extraction, focus group interviews, individual interviews, and psychometric testing, in a broad sample from primary care. However, the study also has limitations. The systematic review excluded non-PubMed Databases such as PsychInfo and Embase since a previous systematic review with a related focus did not identify additional PROMs searching these databases [45]. As we did not identify any fully eligible PROMs for item extraction, we had to use PROMs developed for other target groups. In our content validation procedure, the study was confined to a GP setting in Denmark, potentially limiting the applicability of the PROM in different cultural and healthcare settings. The initial focus group interviews were performed by an interviewer experienced in content validation. However, the subsequent interviews were conducted by a qualitative researcher with limited experience in content validation. Additionally, we did not interview experts in the field about the relevance of the items as recommended in the COSMIN risk of bias checklist. In our psychometric validation, we used CFA to determine whether the domains were unidimensional. While the CFA suggested unidimensionality, the TRC requires fit to a Rasch model. Therefore, this measure should be interpreted with some caution. According to the psychometric validation, the "coordinated care" domain had poorer psychometric properties compared to the other domains. This could be because this domain is the "newest" domain in the theoretical framework and may need further exploration. Some of the domains had high alpha coefficients suggesting some redundancy among items. In our content validation, we ensured that the informants did not consider the items redundant. However, this aspect requires further exploration in the future. Some items showed DIF, indicating that responses varied between individuals based on factors such as age, sex, and education. However, the findings regarding DIF were mostly not surprising. For example, understanding what the doctor said differed based on educational level, sex and whether a third person was present in the consultation. The PROM had a substantial ceiling effect in four out of five domains indicating a high degree of experienced patient-centredness according to this PROM in our sample. However, whether this is also the case in other settings, remains to be investigated. Although the PROM was developed for, and content validated among patients with multimorbidity, the psychometric analysis was performed in a sample of patients with any chronic disease. The PROM may have seemed less relevant for patients with only one or two chronic conditions, explaining the higher drop-out in these groups. However, it did not show DIF based on the number of conditions.

The conceptual framework for patient-centredness used in this study was based on models established by Mead and Bower [13] and further developments by Langberg et al. [14], emphasizing dimensions such as the biopsychosocial perspective, patient-as-person, and therapeutic alliance. Mead and Bower also attempted to measure patient-centredness, but with measures developed for an external assessor and not for the patient [46]. They found limited validity of the included measures, and doubted whether a common construct was measured. Patients' views on patient-centeredness are crucial and a necessary part of a new PROM's construct, which is also emphasized in the COSMIN checklist, yet the concept is defined by professionals, also in this study. The theoretical framework in our study differs substantially from the framework used in some well-known measures, such as the PACIC measure [37]. While the PACIC measure is based on the Chronic Care Model and measures different aspects of patients' experience with chronic care, such as involvement and goal setting, our PROM aims to measure patients' experience in individual consultations. Thus, such measures are not mutually exclusive but rather supplemental.

Conclusions

This study successfully developed and validated a PROM to measure patient-centredness in consultations for patients with multimorbidity by measuring the following five domains: biopsychosocial perspective, patient-as-person, sharing power and responsibility, therapeutic alliance, and coordinated care. The domains in the resulting PROM demonstrated acceptable reliability and validity, making it a valuable tool for assessing and improving patient-centredness of consultations in general practice. Future research should focus on further refining the PROM to address DIF issues and validating its applicability in different cultural and healthcare contexts. Also, further psychometric validation using item response theory models is needed to ensure unidimensionality of the domains. Implementing this PROM in clinical research could enhance the understanding of patient experiences and inform strategies to optimize care for patients with multimorbidity.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12955-024-02327-x.

Supplementary Material 1.

Supplementary Material 2.

Supplementary Material 3.

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Authors' contributions

AH, SFB, KB and AM conducted the systematic review. SFB, JKK, AM, MATK, AP, ZKJ and SB provided regional perspectives for the expert panel consisting of AH, ABL, JBB and ADG and they invited patients for the interviews. JBB and ABL conducted and analyzed the interviews. AH, AWP and VS performed the psychometric validation with supervision from JBB. The manuscript was drafted by AH and ABL and critically revised by all other authors.

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Data availability

The datasets generated during the current study are not publicly available due to individual privacy, but can under some circumstances be made available from the corresponding author upon reasonable request. However, the data for this study is part of an ongoing trial and cannot be shared until completion of the trial. The PROM can be made available by contacting the corresponding author.

Declarations

Ethics approval and consent to participate

The study was conducted in accordance with the protocol and the Helsinki Declaration in its most recent form. Good clinical practice guidelines was followed as well as rules for informed consent. According to Sect. 2 of the Danish Act on Research Ethics of Research Projects, this project does not constitute a health research project but is rather considered a quality improvement project. The protocols for the studies included in this manuscript was presented to Denmark's Capital Region's Ethical Committee for confirmation (ref: H- 22041229). All patients gave informed consent for the interviews and before completing the questionnaire.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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