The development and cognitive testing of a Patient Reported Experience Measure for patients with chronic pain of temporomandibular disorders

Dina Taimeh [1,2], Richeal NiRiordain [1,3], Stefano Fedele [1,4,5], Rachel Leeson [1].

1. Department of Maxillofacial Medicine and Surgery, UCL Eastman Dental Institute, University College London. London, UK
2. Department of Oral and Maxillofacial Surgery, Oral Medicine and Periodontology, Faculty of Dentistry, University of Jordan. Amman, Jordan
3. Oral Medicine Unit, Cork University Dental School and Hospital, Ireland.
4. Oral Medicine Unit, Eastman Dental Hospital, University College London Hospitals Trust. London, UK
5. NIHR University College London Hospitals Biomedical Research Centre. London, UK

Corresponding author: Dina Taimeh, UCL Eastman Dental Institute, University College London, Rockefeller Building, 20 University Street, London WC1E 6DE, UK and School of Dentistry, University of Jordan, Queen Rania Street, 11972, Amman, Jordan.

Dina.taimeh.17@ucl.ac.uk

Funding information

Financial support was provided by the University of Jordan in the form of a PhD student sponsorship awarded to DT.

Conflict of interest statement

The researchers declare no conflict of interest.

Data availability statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Abstract

Introduction: the importance of the patients' clinical experience has been reinforced several times over the last decade by healthcare organisations and policy makers. Routine gathering of experience data can help in enhancing patient centred care and provide guidance to quality improvement schemes. Patient Reported Experience Measures (PREMs) can help to that end. The aim of this study was to develop a patient reported experience measure to evaluate the experience of patients with temporomandibular disorders while receiving healthcare. **Methods**: input from several sources was utilised to develop the tool; previous literature, patients with temporomandibular disorders, and experts in the field. A qualitative study was conducted following the COnsensus-based Standards for the selection of health Measurement Instruments (COSMIN) guidance to generate the items of the questionnaire, which subsequently underwent cognitive testing. **Results**: 17 patients took part in the qualitative study, in addition to six healthcare professionals. The preliminary questionnaire consisted of 28 questions with six response options. **Conclusions**: this patient reported experience measure is a brief tool to evaluate the clinical experience of patients with temporomandibular disorders. Patients' involvement ensured face and content validity of the questionnaire, in addition to the relevance, comprehensibility and comprehensiveness of the items.

Key words: temporomandibular disorders, patient reported experience measures, validity, interviews, qualitative research.

1. Introduction

Temporomandibular disorder is an umbrella term which encompasses a group of conditions that affect the temporomandibular joint, associated musculature or both [1]. Clinical manifestations include pain in the jaw, joint noises, limitations to the range of mandibular movements, earache and headache. After pain from odontogenic origins, TMD is the one of the most common causes of pain in the orofacial region and could potentially progress to become a chronic pain condition [2] . Similar to other chronic pain conditions, TMD could have

profound impact on the patients' quality of life, with associated behavioural, psychological, and psychosocial challenges [3 4].

The importance of the clinical experience for patients has been reinforced in the UK's National Health Service (NHS) and elsewhere several times over the last decade through multiple reviews and polices [5 6]. It is perceived as a major part of the journey of chronic pain patients in particular, hence, it is important that it is a positive one for them [7].

Patient Reported Experience Measures (PREMs) are validated tools which gather the views and experiences of a particular group of patients while they are receiving healthcare [8]. The data gathered from such questionnaires help not only in improving patient-centred care but also grant vital feedback to care providers about patients' impressions, and provide a reliable tool for clinical research, audits and quality improvement schemes [8]. A questionnaire that is patient centred should encompass the values and aspects as prioritised by the target population [9]. Therefore, their involvement in the development process is necessary [10], and could be in the form of focus groups and cognitive interviews [9]. Focus groups are useful in exploring the wider aspects of the construct and generating the items of the questionnaires, while cognitive interviews are more focused on assessing the suitability and readability of the newly developed tool [9,11].

Following a literature search, no PREMs were identified for patients with TMD, or indeed chronic facial pain. This qualitative study was conducted as part of a project to develop and validate a Patient Reported Experience Measure for patients with pain related TMD. The focus groups aimed to discover the important aspects of clinical experience for patients with TMD and to explore their journey within the healthcare services in England, starting from primary care all the way to a specialised facial pain unit in a tertiary care centre. The Items generated from the focus groups were used to construct the new questionnaire. The cognitive interviews subsequently aimed to test the readability, relevance, comprehensibility, and comprehensiveness of the newly developed PREM.

2. Materials and methods

2.1. Study design

This was a qualitative study conducted as part of a project to develop a PREM for patients with TMD. In preparation for the project, a qualitative evidence synthesis was conducted to obtain input from the literature regarding the experience of patients with TMD with healthcare services [12]. Subsequently, a qualitative study was conducted to develop the items of the PREM, in the form of focus groups and individual interviews [13]. The research team used the NHS patient experience framework as a basis of the PREM as it consists of a comprehensive list of domains which are important to patients [14,15]. These domains were inspired by the Picker's Institute principles for patient-centred care [6] and were used as a basis of other PREMs such as the patient-reported experience measure for patients with Rheumatoid Arthritis and other rheumatic conditions [15]. Patient experience has several definitions such as 'what the process of receiving care feels like for the patient, their family and carers' [16], or the 'feedback from patients on what actually happened in the course of receiving care or treatment, both the objective facts and their subjective views of it' [17]. It is the construct intended for this instrument.

The study received ethical approval from the Southeast Scotland Research Committee 1 (REC reference: 19/SS/0130) and the Health Research Authority (HRA) prior to data collection. It was conducted in accordance with the Declaration of Helsinki.

2.2. Participants

The participants were patients ≥18 years old, with symptoms of painful TMD diagnosed by specialists in a facial pain unit. The patients were later classified according to the Diagnostic Criteria for TMD (DC/TMD) by the research team. They were competent in the English language and had at least one clinical visit to the specialist facial pain unit.

Participants for both the focus groups and individual interviews were first screened and approached during their routine clinical visits where they were given oral and written information about the study. Informed consent was obtained remotely, while adhering to the

guidance of the HRA for e-consents. Once written consent was obtained, the participants were booked to participate in a focus group, or later in an individual cognitive interview.

2.3. Focus groups and item generation

The focus groups were conducted by RNR and DT, using an online platform. Semi-structured interviews were utilised to elicit the data from 15 participants with the use of a topic guide. The questions explored the experiences of patients with TMD within the healthcare system within the UK, starting from primary care all the way to a specialist facial pain unit in a tertiary care centre. The participants were also invited to comment on the NHS patient experience framework and make suggestions on how to make it more suited to the experience of patients with TMD. Data saturation was reached after holding three group discussions as no new themes emerged in the third interview. The interviews were audiotaped for verbatim transcription.

Data analysis followed the framework analysis approach developed by Jane Ritchie and Liz Spencer [18]. It consists of seven steps: transcription, familiarisation with the interviews, coding of the data, developing a working analytical framework, applying the analytical framework, charting data into the framework matrix, and finally interpreting the data. The natural categories which emerged from the data, interestingly matched to a great extent the domains of the NHS framework. So, the emerging themes were then matched under the overarching themes (domains) of the NHS framework, which was modified slightly to better represent the experience of TMD patients. A combination of a priori aspects and emergent issues were used to develop the categories which best fit the data and answered the research question. A full description of the focus groups and the results may be found elsewhere [13].

The findings from this series of focus groups, in addition to input form the literature, were used to generate the priority items for the new PREM. Multiple questions were generated for each domain to address the patients' concerns and to capture the important aspects of care for them.

2.4. Item improvement (expert input and cognitive interviews)

2.4.1. Expert input

The list of candidate questions was circulated to six healthcare professionals who manage TMD patients regularly for comments about the suitability, relevance, comprehensiveness of the items, and the general format of the questionnaire. Several discussions were held where suggestions were made to the length of the questionnaire and the wording of some items.

2.4.2. Cognitive interviews

Following the recommendations of the COnsensus-based Standards for the selection of health Measurement Instruments (COSMIN), seven participants were enrolled at this stage to give feedback regarding the readability, relevance, comprehensiveness and comprehensibility of the questionnaire. In each interview, the participants were asked to read the questionnaire, and think aloud. The purpose of this exercise was to ensure that participants interpret the questions similarly and as intended by the research team. In addition, they were invited to assess the acceptability and readability of the questions and suggest any missing items. The participants were also asked to mark the importance of each question on a five-point likert scale ranging from ‘very important’ to ‘not important at all’.

Bristowe et al [19] reported in their study to develop a PROM which reflects the breadth of concern for patients with HIV, that participants with HIV preferred questionnaires no longer than two pages (up to four sides) or no longer than 25 questions long. Therefore, the questions with the highest mean importance score were selected for inclusion with a view of keeping the list close to 25 questions without compromising important questions, and hence the content validity.

After selecting the items and implementing the participants’ comments, one participant was shown the modified version of the PREM to ensure that the changes were acceptable and important items were not removed.

Further refinement and item reduction is expected at the later stages of development, such as during the statistical validation and reliability testing.

3. Results

3.1. Focus groups and item generation

24 participants (20 females, 4 males) were invited to join the focus groups and cognitive interviews. Due to scheduling conflicts and reluctance to use online platforms, 15 patients agreed to join the focus groups. Five of these participants later took part in the cognitive interviews, in addition to 2 other participants who only participated in the cognitive interviews. The participants ages ranged from 19-79 years. See table 1 for the participants' details.

The findings of the focus groups described the experiences of patients within the healthcare system in England as patients with TMD. The full findings can be found elsewhere [13]. The patients confirmed the suitability of the NHS experience framework to their own experience, but also suggested some modifications. One domain under discussion was the importance of family and friends' involvement in healthcare. Interestingly, their involvement was not crucial to this group of participants. They mentioned that they may not necessarily involve them in their care, as most of them attend to their appointments alone anyway. They did acknowledge, however, that it may be crucial for other patients who need support, so were careful not to dismiss this area as an important part of the clinical experience. Therefore, this domain was kept for the time being.

The findings of the focus groups, in addition to input from previous literature, informed the generation of a preliminary list of 50 questions.

3.2. Item improvement (expert input and cognitive interviews)

3.2.1. Expert opinion

The candidate list of questions was presented to six healthcare professionals who deal regularly with patients with TMD. They suggested some amendments to the wording of some

items to make them clearer and easier to read. Additionally, they recommended the omission of 10 items, which were deemed too similar to others.

3.2.2. Cognitive interviews

The remote interviews ranged from 30-60 minutes in length each. The participants found most of the questions clear and understandable. None of the questions were found to be offensive or uncomfortable to answer. The mean importance score was calculated for each item to determine the most important questions. The questions with the highest importance score were selected for inclusion with a view of keeping the list close to 25 questions without compromising important questions.

The list was further refined by considering the comments and suggestions of the participants, for example vague wording or repetitive items. Five items with low importance scores were also selected from the original list because they were strongly emphasised in the literature and in the focus groups. These items could be deleted at a later stage, but if they were deleted at this stage, it would be difficult to restore them later.

The modified version of the PREM was then shown to a participant. Minor changes were suggested to the wording of some items, and no additional items were suggested. The final list of questions consisted of 28 questions, with six response options (strongly agree, agree, neutral, disagree, strongly disagree, and not applicable), in addition to one question assessing the overall satisfaction with the experience. This initial list of questions could be found in the supplementary material.

4. Discussion

Findings from this qualitative study, both focus groups and cognitive interviews, provide valuable information about the important aspects of care for patients with temporomandibular disorders. These findings, in addition to input form the literature, were used to develop a new

tool for the routine assessment of the clinical experience of these patients. Measuring the clinical experience and obtaining feedback offers meaningful insight into what matters most to patients. Over the past few decades, hospital experience has increasingly become crucial to clinical quality. The delivery of a clinically effective intervention may no longer be viewed as a successful clinical experience for patients if it was not delivered in a timely manner, in poor clinical conditions or from uncompassionate clinicians [17]. Therefore, healthcare services in England now review patient experience as part of quality assessments, and funding to some services is tied to improvements to patient experience [20]. The assessment of patients' feedback could also be used meaningfully to understand the problems faced when delivering care to patients, compare organisations for performance assessment and informing referring clinicians about the quality of services. Furthermore, there is some evidence linking a positive experience to better patient outcomes due to better adherence to treatment instructions and better use of preventive services [21]. Experience has traditionally been measured by satisfaction surveys. These are useful sources for public accountability purposes and to give an impression of the 'bigger picture'. However, they could be insensitive to some problems faced in healthcare. Additionally, satisfaction is subjective and possibly influenced by the users, their past experiences, age, and social class [22]. This leads to the idea of measuring patient-reported experience. Rather than asking service users to give subjective ratings of their satisfaction, PREMs give more focus to objective and measurable experiences. This approach provides more interpretable and actionable data.[23]

The experience of chronic pain patients with healthcare services seems to be of particular importance. Several qualitative systematic reviews of chronic pain conditions have mentioned in one way or another its significance as a major part of their lives [7,24]. Therefore, if a questionnaire was developed to capture this experience, patient involvement would be prudent [9,10]. It gives important insight into the relevance of the questions and ensures that the questionnaire is easy to complete by the target population [10]. Lack of patient input may compromise the validity, sensitivity and response of a questionnaire [10,25]. A major drawback

to patient involvement is the logistics behind it; it adds to the cost, time and complexity of the research [10]. These challenges might discourage developers form involving patients. However, this might not be the case for much longer, as patient involvement is increasingly required by official organisations such as the American Food and Drug Administration (FDA) [26].

According to the COSMIN guidance, the content validity is the degree to which the content of an instrument is an adequate reflection of the construct to be measured. It is assessed by asking the patients and professionals about the relevance, comprehensiveness, and comprehensibility of the items and the suitability of the response options [27]. Content validity is often considered one of the most important measurement properties of a patient reported measure, and lack thereof, could affect most of them negatively [27]. Irrelevant questions may decrease the internal validity and interpretability of the patient reported measure. Moreover, it could lead to low response rates if patients feel that they are being asked irrelevant questions or frustrated that important questions are being missed [27]. This series of cognitive interviews therefore provided the opportunity to check the relevance, acceptability, content and face validity of the questionnaire.

The length of the questionnaire also plays an important role; it affects the response rates, the quality of the data, and completion rates [28]. Therefore, it was important to balance the number of items with the possibility of respondent burden. The length of the questionnaire at this point was 28 questions. However, this is not the final version. It is anticipated that with further psychometric testing, some items will be omitted. Therefore, it is important to emphasise that this instrument is still under development and further testing is needed before future use.

Patient input ideally reflects the different manifestations of the construct. The researchers ensured including participants with negative aspects to their experience as well as participants with a positive experience. A purposive sample of participants was also chosen to best represent participants in different stages of care at the tertiary care centre, duration of symptoms, a wide age range and with different ethnic backgrounds. The participating dental

hospital is tertiary centre for facial pain cases, with referrals coming in from all over England. In many cases, English is not the first language for many patients. In order to make sure that the phrasing of the items is appropriate for all patient backgrounds, two participants were invited to take part with non-English first languages. They both confirmed the understandability and readability.

Strengths and limitations

Major strengths for the study were the involvement of patients in developing the PREM, which ensures the relevance of the questions to this cluster of patients, and the methodological rigor with which the study was conducted. Data triangulation was also ensured by having input from the literature as well as from patients. A qualitative evidence synthesis was carried out in preparation for this study, to complement the data gathered form the focus groups and make sure that important aspects of care are noted [12].

The limitations to this piece of research include the inherent limitations associated with online focus groups and interviews. The research design had to be amended in response to the SARS-CoV-2 (COVID-19) outbreak in the UK at the time of conducting this study to ensure the safety of the participants and the research team. These limitations include a change in the dynamic of the group discussion when compared to that of a traditional face to face meeting. Additionally, they require internet access with users who are adept at online technology. This may have discouraged some patients from taking part. All the enrolled participants, however, were comfortable navigating the online platform.

The overall sample size used in the focus groups and cognitive interviews consisted of 15 females and 2 males. This may have affected the generalisability of the results as males were underrepresented. It is worth noting however, that females are more likely to develop persistent TMD [29], with a female: male ratio reported up to 4:1 in a clinical environment [30]. This may have skewed the sample in favour of female patients.

5. Conclusions

The patient reported experience measure for patients with TMD is a brief questionnaire which aims to provide healthcare services with a means to evaluate their performance and measure the impact of implemented changes to the care of patients with TMD. The next step for validation of the new tool will be a quantitative pilot study at a specialist facial pain unit to evaluate its psychometric properties. Further refinement of the questions is expected at this stage. Consideration will also be given to undetected problems which might arise after the questionnaire is applied to a larger sample size.

Table 1. Participants' details

Number	Sex	DC/TMD classification	Participation
1	F	Myalgia, DDwR†.	Focus group + cognitive interview
2	F	Myalgia, arthralgia	Focus group + cognitive interview
3	F	Myalgia, headache attributed to TMD.	Focus group + cognitive interview
4	M	Myalgia, DDwR†.	Focus group
5	F	Arthralgia, DDwR†.	Focus group
6	F	Myalgia.	Focus group
7	F	Myalgia, DDwR† with intermittent locking.	Focus group + cognitive interview
8	F	Myalgia.	Focus group
9	F	Myalgia, DDwR† with intermittent locking.	Focus group
10	F	Myalgia.	Focus group
11	F	Myalgia and arthralgia.	Focus group
12	F	Myalgia and Headache attributed to TMD.	Focus group + cognitive interview
13	F	Myalgia	Focus group + cognitive interview
14	F	Myalgia	Focus group
15	F	Myalgia	Focus group
16	M	Myalgia, DDwR†.	Cognitive interview
17	F	Myalgia	Cognitive interview

†: Disc displacement with reduction

References

1. Leeuw Rd. American Academy of Orofacial Pain Guidelines for Assessment, Diagnosis, and Management. 2013.
2. Dworkin SF, Massoth DL. Temporomandibular disorders and chronic pain: disease or illness? *J Prosthet Dent.* 1994;72(1):29-38.
3. Dahlstrom L, Carlsson GE. Temporomandibular disorders and oral health-related quality of life. A systematic review. *Acta Odontologica Scandinavica.* 2010;68(2):80-85.
4. Parker MW, Holmes EK, Terezhalmy GT. Personality characteristics of patients with temporomandibular disorders: diagnostic and therapeutic implications. *J Orofac Pain.* 1993;7(4):337-344.
5. Raleigh V, Graham C, Thompson J, Sizmur S, Jabbal J, Coulter A. Patients' experience of using hospital services: An analysis of trends in inpatient surveys in NHS acute trusts in England, 2005–13. In: The king's Fund, Picker Institute Europe; 2015.
6. Paparella G. Person-centred care in Europe: a cross-country comparison of health system performance, strategies and structures. 2016.
7. Toye F, Seers K, Barker KL. Living life precariously with rheumatoid arthritis - a mega-ethnography of nine qualitative evidence syntheses. *BMC Rheumatology.* 2019;3(1):5.
8. Kingsley C, Patel S. Patient-reported outcome measures and patient-reported experience measures. *BJA Education.* 2017;17(4):137-144.
9. Paterson C. Seeking the patient's perspective: a qualitative assessment of EuroQol, COOP-WONCA charts and MYMOP. *Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation.* 2004;13(5):871-881.
10. Wiering B, de Boer D, Delnoij D. Patient involvement in the development of patient-reported outcome measures: The developers' perspective. *BMC Health Serv Res.* 2017;17(1):635.
11. Jobe JB, Mingay DJ. Cognitive research improves questionnaires. *Am J Public Health.* 1989;79(8):1053-1055.
12. Taimeh D, Leeson R, Fedele S, Riordain RN. A Meta-Synthesis of the Experience of Chronic Temporomandibular Disorder Patients Within Health Care Services. *J Oral Facial Pain Headache.* 2023;37(1):57-75.
13. Taimeh D, Riordain RN, Fedele S, Leeson R. Healthcare priorities in patients with chronic facial pain of temporomandibular disorders. *Oral Dis.* 2022.
14. NHSEngland. NHS Patient Experience Framework. In: Care DoHaS, ed2011.
15. Bosworth A, Cox M, O'Brien A, et al. Development and Validation of a Patient Reported Experience Measure (PREM) for Patients with Rheumatoid Arthritis (RA) and other Rheumatic Conditions. *Curr Rheumatol Rev.* 2015;11(1):1-7.
16. The Patient Experience Book. In: Improvement NIfIa, ed: NHS Institute for Innovation and Improvement, i-House, University of Warwick Science Park, Millburn Hill Road, COVENTRY, CV4 7HS. ; 2013.
17. Patient Experience Framework (2012/13 and beyond). "Achieving our vision to commission a positive patient experience". In: NHS Wakefield Clinical Commissioning Group; 2012.
18. Ritchie J, Lewis J. *Qualitative Research Practice: A Guide for Social Science Students and Researchers.* SAGE Publications; 2003.
19. Bristowe K, Murtagh FEM, Clift P, et al. The development and cognitive testing of the positive outcomes HIV PROM: a brief novel patient-reported outcome measure for adults living with HIV. *Health Qual Life Outcomes.* 2020;18(1):214.
20. Using the Commissioning for Quality and Innovation (CQUIN) payment framework. Guidance on new national goals for 2012-13. In. London, UK: Department of Health; 2012.
21. Doyle C, Lennox L, Bell D. A systematic review of evidence on the links between patient experience and clinical safety and effectiveness. *BMJ Open.* 2013;3(1).

22. Fitzpatrick R, Hopkins A. Problems in the conceptual framework of patient satisfaction research: an empirical exploration. *Sociology of health & illness.* 1983;5(3):297-311.
23. Skipper E. National COPD Audit Programme: Patient Reported Experience Measures (PREMs) Development Work & Feasibility Report. 2018.
24. Toye F, Seers K, Allcock N, et al. Patients' experiences of chronic non-malignant musculoskeletal pain: a qualitative systematic review. *Br J Gen Pract.* 2013;63(617):e829-841.
25. Meadows KA. Patient-reported outcome measures: an overview. *Br J Community Nurs.* 2011;16(3):146-151.
26. Guidance for Industry on Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims. In: Administration UDoHaHSFaD, ed. Washington: Food and Drug Administration US; 2009.
27. Terwee CB, Prinsen CAC, Chiarotto A, et al. COSMIN methodology for evaluating the content validity of patient-reported outcome measures: a Delphi study. *Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation.* 2018;27(5):1159-1170.
28. Sharma H. How short or long should be a questionnaire for any research? Researchers dilemma in deciding the appropriate questionnaire length. *Saudi J Anaesth.* 2022;16(1):65-68.
29. Slade GD, Bair E, Greenspan JD, et al. Signs and symptoms of first-onset TMD and sociodemographic predictors of its development: the OPPERA prospective cohort study. *J Pain.* 2013;14(12 Suppl):T20-32.e21-23.
30. Durham J, Aggarwal V, Davies S, et al. Tempromandibular disorders (TMDs): an update and mangement guidance for primary care from the UK specialist interest group in rorfacial pain and TMDs (USOT). *Royal College of Surgeons England.* 2013.