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Development of a patient-reported outcome measure for hand conditions: The HAND-Q

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Complete List of Authors:	Sierakowski, Kyra; Flinders Medical Centre, Plastic & Reconstructive Surgery Kaur, Manraj; McMaster University, School of Rehabilitation Science Sanchez, Kathleen; Flinders University Bain , Gregory; Flinders University Cano, Stefan; Modus Outcomes Griffin, Philip; Flinders University Klassen, Anne; McMaster University, Pediatrics Pusic, Andrea; Brigham and Women's Hospital Biomedical Research Institute Lalonde, Don; Dalhousie University Dean, Nicola; Flinders University, College of Medicine & Public Health; Flinders Medical Centre, Plastic & Reconstructive Surgery
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TITLE: Development of a patient-reported outcome measure for hand conditions: The HAND-Q

AUTHORS:**

1. Kyra L. Sierakowski MD, PhD, Department of Plastic & Reconstructive Surgery, College of Medicine and Public Health, Flinders University, Adelaide, South Australia, Australia
2. Manraj N. Kaur PT, PhD, Department of Surgery, Patient-Reported Outcome, Value and Experience (PROVE) Center, Harvard Medical School, Brigham and Women's Hospital, Boston, Massachusetts, United States
3. Kathleen Evans Sanchez MD, Department of Plastic & Reconstructive Surgery, College of Medicine and Public Health, Flinders University, Adelaide, South Australia, Australia
4. Gregory I. Bain MBBS, PhD, Department of Orthopaedic Surgery, Flinders University, Adelaide, South Australia, Australia,
5. Stefan Cano PhD, Modus Outcomes, Letchworth Garden City, United Kingdom
6. Philip A. Griffin MBBS, FRACS, Department of Plastic & Reconstructive Surgery, Flinders Medical Centre, Adelaide, South Australia, Australia
7. Anne Klassen DPhil, Faculty of Health Sciences, McMaster University, Hamilton, Ontario, Canada
8. Andrea Pusic, MD, MHS, Department of Surgery, Patient-Reported Outcome, Value and Experience (PROVE) Center, Harvard Medical School, Brigham and Women's Hospital, Boston, Massachusetts, United States
9. Don Lalonde MD, Department of Plastic Surgery, Dalhousie University, Saint John, New Brunswick, Canada
10. Nicola R. Dean MBChB, PhD, Department of Plastic & Reconstructive Surgery, College of Medicine and Public Health, Flinders University, Adelaide, South Australia, Australia

**Drs. Sierakowski and Kaur share the first authorship of this manuscript

CORRESPONDING AUTHOR: Kyra L. Sierakowski, Department of Plastic & Reconstructive Surgery, College of Medicine and Public Health, Flinders University, Adelaide, South Australia, Australia, kyra.sierakowski@flinders.edu.au

RUNNING HEAD: Development of the HAND-Q

KEYWORDS: Hand conditions, patient-reported outcomes, patient-reported outcome instrument, HAND-Q

ETHICS APPROVAL STATEMENT: Ethics approval for this study was obtained at all of the participating sites: Australia, Southern Adelaide Clinical Human Research Ethics Committee (Reference Number 003.17 HREC/17/SAC/5); Canada and the US, Horizon Health Network Research Ethics Board (File # RS-2017-2499).

ABSTRACT

Objectives: The purpose of this study was to identify and understand the issues that are relevant to patients with hand conditions. Data from qualitative interviews were used to develop a patient-reported outcome measure for adults with hand conditions, the HAND-Q.

Setting: Purposive, heterogeneous sample of participants who had received surgery for a hand condition was recruited from tertiary hand clinics in Canada and Australia. Interviews were conducted in person or over the telephone depending on participant preference.

Participants: A total of 62 qualitative interviews were performed with 34 females and 28 males, mean age 65 years. Selection criteria for participants were the ability to comprehend the study and provide consent.

Primary & Secondary Outcome Measures: An interview guide was used to conduct in-depth, semi-structured interviews. All interviews were audio-recorded and transcribed verbatim. Data were analyzed using a line-by-line approach, constant comparison was used to develop the conceptual framework. Participants' quotes were used to create an item bank and draft scales were formed. The scales were pilot tested using cognitive debriefing interviews with patients from Canada, Australia, and the United States, and an online survey with clinical experts. The scales were refined iteratively based on patient and expert feedback.

Results: Qualitative data analysis resulted in 3008 unique codes, which were organized into two top-level domains of HRQOL and satisfaction with treatment outcomes. HAND-Q scales were developed and refined through patient interviews (n=15) and feedback from experts (n=25). The resulting field test version of the HAND-Q consisted of 319 unique items organized into 20 independently functioning scales.

Conclusions: The HAND-Q is a comprehensive PROM developed using extensive patient and expert input and established guidelines for PROM development and validation. Once the psychometric properties of the HAND-Q are established in an international field test, it could be used in clinical research and practice.

ARTICLE SUMMARY

Strengths and limitations

- The HAND-Q, a patient-reported outcome measure (PROM) for hand conditions, was developed and refined with input from a heterogeneous, international sample of patients with diverse hand conditions and clinician experts.
- The HAND-Q is a modular PROM. It consists of independently functioning scales that measure health-related quality of life and satisfaction with experience of care and hand splints or braces.
- In phase 2, an international field test will be conducted to assess the psychometric performance of HAND-Q scales, following which it will be made available at no charge for clinical practice and research.
- The HAND-Q development sample included participants from English-speaking, high-income countries. Future work will be required to translate and culturally adapt the HAND-Q.

INTRODUCTION

Any condition or injury of the hand can significantly impact the health-related quality of life (HRQOL) of an individual. While several objective and performance-based measures exist to assess the impact of hand conditions and their treatment on the range of motion, strength, dexterity, sensation, and functional impairment, the impact on an individual's HRQOL is best assessed by asking patients directly. Patient-reported outcome measures (PROMs) are questionnaires that are used to assess HRQOL in clinical practice and research. The data collected from PROMs can be used to understand, monitor, and communicate the impact of a condition on patients and enhance shared decision-making, resulting in better treatment outcomes overall (1).

A recent systematic review designed to identify all PROMs relevant to the field of hand surgery identified 24 PROMs for upper extremity conditions (2). Most commonly used PROMs in hand conditions included the Disabilities of the Arm, Shoulder and Hand (DASH), the Michigan Hand Outcomes Questionnaire (MHQ), and the Patient-rated Wrist/Hand Evaluation (PRWHE). However, these three PROMs have important limitations. The DASH, MHQ, and PRWHE were developed in the 1990s using the traditional classical test theory (CTT) approach. Importantly, qualitative interviews with patients with hand conditions were not a part of these instruments' development, which countermands the recommendations of the Medical Outcomes Trust and the United States Food and Drug Administration (3-5). Further, increasingly modern psychometric methods that involve Rasch Measurement Theory (RMT) or Item Response Theory analysis are used to develop scales that form clinical hierarchies and have interval level measurement properties. Modern approaches to scale development allow for meaningful and interpretable measurement of change in patient status, which is difficult for scales developed using the CTT approach.

To overcome the limitations of existing instruments, our team developed a PROM for hand conditions called the HAND-Q. The detailed study protocol for the development of HAND-Q is published

elsewhere (6). This paper aims to describe the results of the qualitative Phase 1 study to develop and refine the HAND-Q scales, which will be tested in a subsequent international field-test study.

METHODS

The ethics approvals for this study were obtained from the Southern Adelaide Clinical Human Research Ethics Committee (Australia) and the Horizon Health Network Research Ethics Board (Canada). Phase 1 of the HAND-Q development was completed in three steps: 1) development of the conceptual framework, 2) scales formation, and 3) pilot testing to establish content validity with feedback from patients and experts.

Approach

We used the applied health services approach of interpretive description (7) to design, conduct, and analyse the qualitative study results. Interpretive description acknowledges pre-existing theoretical and clinical knowledge informing a study, which was appropriate in our study given that much is known already about the impact of hand condition on individual's HRQOL. This approach also aims to produce knowledge relevant to the clinical context with the provision that a patient's understanding of a concept is of the most significant importance, regardless of the clinical or theoretical explanation (8).

Stage 1: Development of the conceptual framework

Study participants and recruitment

English-speaking adults (18 years or older) who had had surgery on one or both hands in the preceding 12 months and were at least four weeks post-hand surgery were recruited from tertiary healthcare centers in Adelaide, Australia, and Saint John, New Brunswick, Canada. Patients who were unable to provide informed consent due to a language barrier or cognitive impairments were excluded. The recruitment followed a purposive sampling strategy to ensure heterogeneity by targeting key demographic (age, gender) and clinical variables (hand condition), surgical setting (hospital operating

room versus in-office surgery), funding (public versus private), and type of anesthesia used for surgery (general anesthesia, sedation, or local anesthesia). Patients were screened for eligibility by treating clinician(s) or the clinic's administrative staff and informed of the study objectives and procedures by a member within their clinical circle of care. The contact information for patients who expressed an interest in participation was shared with the study research coordinator, who then contacted the patient, explained the study in detail, answered study-specific questions, and obtained written consent for participation.

Data collection

A semi-structured interview guide was developed to elicit in-depth information on the treatment and experience of living with their hand condition, specifically concerning HRQOL (physical, psychological, social, and sexual well-being) and satisfaction (appearance and process of care). Interview probes were used to guide the patient's description of the treatment outcomes or to elicit detailed answers. The probes were informed by the clinical expertise of the study team and the concepts identified in the systematic review. (6, 9). In-depth, qualitative interviews were conducted in-person or over the telephone by an experienced qualitative interviewer using the interview guide (5). The participants were asked to describe their experiences of living with their hand condition, including any treatments. The interviews were audio-recorded and transcribed verbatim, with identifying information removed.

Data analysis and rigor

The data collection and analysis took place concurrently to explore the relevance and importance of the emerging concepts identified during the interviews. Content analysis of the interview transcripts was completed using a 'line-by-line' approach in Microsoft Word, Version 2019 (Microsoft Corp., WA, USA). Participants' quotes about any aspect of outcome or experience of care were copied into a Microsoft Excel spreadsheet Version 2019 (Microsoft Corp., WA, USA), along with demographic and clinical information. Constant comparison was used to identify common concepts of interest, and the data were categorized into conceptual top domains, sub-domains, and major and minor themes (10).

The interviews were coded by one experienced qualitative researcher and checked by another team member. Codes were confirmed after discussion with the senior author (AK), who oversaw the analysis. To ensure rigor, the data analysis results were reviewed with the members of the study team throughout the study (11). Interviews continued until saturation was achieved; that is, no new concepts were identified in subsequent interviews (12).

Stage 2: HAND-Q scale formation

The conceptual framework and the coded data developed in Stage 1 were used to create items for the identified domains. For item development, efforts were made to retain the participants' language as much as possible. To ensure that the items were clear, easy to understand, and resonated with patients, we avoided double-barrelled items, or items with technical jargon or slang. For scale development, the theoretical underpinnings of the Rasch Measurement Theory were adopted (13). The RMT approach to scale development requires that the items map out a concept of interest through a clinical hierarchy (measuring from a little to a lot of a concept). Therefore, each item was designed to measure the concept of interest in varying amounts. For example, in the Physical Function scale, the items range from those that would be easy to endorse for most people with a hand problem (e.g., eating with your hand(s)) to more challenging (e.g., eating with cutlery) to the most difficult to endorse (e.g., opening a jar).

The response options for the HAND-Q scales were limited to four options for simplicity and per recommended guidelines (14). We deliberately did not include a neutral response option. The amount of the construct measured by a neutral option is unclear and does not fit the mathematical model of RMT.

Stage 3: Pilot testing of HAND-Q scales for content validity

Patient input – cognitive interview

A new sample of patients with hand conditions using the same eligibility criteria and recruitment strategy from Stage 1 was recruited from Allentown, Pennsylvania, United States. Ethics approval was obtained from the Lehigh Valley Health Network Institutional Review Board. Participants from Australia and Canada who took part in Stage 1 were also invited to participate in cognitive interviews. Relevant HAND-Q scales were sent to the participants before the interview. An interview guide was used, and the interviews were conducted by an experienced qualitative interviewer by telephone. The 'think aloud' technique (15, 16) was used, whereby the scales were reviewed item-by-item, and the participants were asked to comment on the clarity, ease of understanding, and relevance of the title, instructions, timeframe, response options, and items. Where appropriate, participants were asked to paraphrase the items in their own words and provide examples from their treatment experience. Participants were also asked to nominate missing items (if any) and comment on the comprehensiveness of each scale.

The interviews were conducted in three consecutive rounds to allow for changes to be made to the scales in-between the rounds. The interviews were audio-recorded and transcribed verbatim, with identifying information removed. The interview transcripts were analysed descriptively by one experienced qualitative researcher and checked by another team member. Relevant participant quotes pertaining to items were copied and pasted into a Microsoft Excel spreadsheet. An item tracking matrix (17) was used to document the changes made to the items between rounds of interviews. Data saturation was thought to be reached when participants did not recommend any further changes to the HAND-Q scales.

Expert Opinion – Online survey

We sought feedback from healthcare professionals with expertise in treating hand conditions (hereafter referred to as "experts") to ensure buy-in and affirm that the HAND-Q scales comprehensively explored clinically important issues. A multidisciplinary team of experts was identified through the professional networks of the study investigator team and invited via email to

participate in an online Research Electronic Data Capture (REDCap) (18) survey. The experts were asked to review scales one at a time and comment on the relevance, comprehension, and comprehensibility of its content. Non-respondents were sent a reminder one week later. Two rounds of expert surveys were completed between the first and second rounds of patient cognitive interviews. The feedback from experts was analysed descriptively by one experienced qualitative researcher and checked by another member of the team and used to refine the HAND-Q scales.

Patient and public involvement

An international group of patients and healthcare providers were engaged in all stages of the development of the HAND-Q. The input of patients in stage 1 was fundamental to the scale formation and the feedback from patients and healthcare providers in stage 3 helped us refine the scales. Regular team de-briefs were conducted with the team members throughout the three stages.

RESULTS

Stage 1: Development of the conceptual framework

The qualitative interviews took place between June and November 2017; the mean interview time was 34 minutes (range 12 to 61). A total of 62 (females, n=34, 55%) in-depth qualitative interviews with 40 participants in Australia and 22 in Canada were conducted. The mean age of the participants was 65 ± 11 years (range, 28 to 86). The participants' diagnoses included;carpal tunnel (n=20), Dupuytren's contracture (n=14), trigger finger (n=8), osteoarthritis (n=8), trauma (n=7) and other less common conditions (n=4). An example of how the interview data were coded and categorized into domains and themes is shown in Appendix 1.

The analysis of the interview data resulted in 3008 unique codes, which were organized into top-level domains of HRQOL and satisfaction with treatment outcomes (Figure 1). The HRQOL top-level domain (n=1498 unique codes) was categorized into the sub-domains of physical well-being (943 codes),

psychological well-being (324 codes), and social well-being (231 codes). The satisfaction top domain included sub-domains of satisfaction with appearance (385 codes), overall outcome (36 codes), process of care (486 codes), anesthesia (258 codes), and hand splint or brace (22 codes). Table 1 shows the conceptual framework of the HAND-Q with supportive data from the qualitative interviews.

Stage 2: Scales formation

The conceptual framework was used to develop the first draft of the HAND-Q scales. A total of 20 scales were developed to measure the concepts identified in Stage 1. The full list of scales is shown in Table 2.

Stage 3: Pilot testing of HAND-Q scales for content validity

A total of 20 cognitive interviews in three rounds were performed with patients between January 1, 2018, and February 28, 2018. Participants were in Australia (n=9), Canada (n=7), and the United States (n=4). The majority of the participants were females (n=13, 65%), and the mean age of the sample was 60 ± 12 years (range, 32 to 76 years). Participants were seeking or had received treatments for a range of hand conditions, including carpal tunnel (n=9), Dupuytren's contracture (n=3), trigger finger (n=3), osteoarthritis (n=7), trauma (n=5), and other less common conditions (n=3). Further, a total of 25 experts provided input in two rounds (round 1, n=14) on the content of the HAND-Q scales. Figure 2 shows the composition of experts for each round. A summary of the number of items that were added, retained, revised, or dropped is shown in Table 2.

The field-test version of the HAND-Q consists of a total of 319 unique items organized into 20 independently functioning scales.

DISCUSSION

In-depth qualitative interviews were conducted with an international sample of patients with hand conditions to gain a comprehensive understanding of the range of treatment outcomes and

experience of care-related concepts. The qualitative data were used to develop a conceptual framework, which was used to develop a draft of the HAND-Q, a comprehensive PROM for patients with hand conditions. The draft version of HAND-Q was refined through patient and expert feedback, and content validity was demonstrated.

We adopted a patient-centered approach for this study, where patients were engaged in content generation and refining of the HAND scales. Measuring what matters to patients is fundamental to understanding the burden of hand conditions and providing effective and efficient care that aligns with patients' treatment preferences and values. Due to HAND-Q's "bottom-up" approach, we were able to identify and develop scales for concepts that are either missing or incompletely assessed in the existing hand-specific PROMs to-date (2). For example, the HAND-Q has a unique scale that measures the impact of hand condition on someone's sexual life. Items in this scale ask about the had problem being a distraction during sexual activity or interfering with the ability to give pleasure. Since hands are a part of the body that are difficult to hide, participants in our study described feeling embarrassed and self-conscious about their hand condition. The HAND-Q measures appearance of hands (e.g., size, shape of fingers and thumbs, how the hands look when holding a glass or resting the palms on a table) to provide a means to evaluate treatments that change how the hand looks. Another unique strength of the HAND-Q is that the development of the scales was embedded within the principles of a modern psychometric approach (i.e., RMT), resulting in independently functioning scales. To elaborate, the negative impact of injuries and conditions of the hand on psychological well-being has been well-established in the literature (19-21). Existing PROMs, such as the DASH (22), PRWHE (23), and the (MHQ) (24), measure the impact of condition or treatment on psychological well-being with the help of a single item rather than a scale. When the raw score for the single item on psychological well-being is added to raw item scores of unrelated constructs to produce a total score, it makes it impossible to ascertain the impact of the condition or treatment on patients' psychological well-being. Further, it makes it challenging for clinicians and researchers to interpret the total score, discouraging them from using PROMs. In contrast, the HAND-Q includes one independently

functioning scale with items that measure only one construct – psychological function – resulting in more targeted measurement. The modular design allows the clinicians to choose the scales that are most relevant to their clinical practice or research question, reducing patient burden. Additionally, as the field of hand surgery evolves and new concepts of interest are identified, the modular design allows for new scales to be added to the HAND-Q, keeping it relevant ("fit for purpose") over time.

Our study is not without limitations. The study sample is not representative of the full breadth of hand conditions seen in the clinical practice. While the common conditions such as carpal tunnel and trigger finger were included, rarer hand deformities and amputation due to congenital or traumatic causes were not. Further qualitative work would be required to examine the content validity and other psychometric properties of the HAND-Q scales in the clinical populations not included in this study. Further, we only included English-speaking participants from three developed countries with similar economic and cultural environments. To ensure that the HAND-Q scales are relevant globally, the scales have been translated and culturally adapted to a number of languages in preparation for an international field-test study. RMT analysis will be used to examine differential item functioning by language to determine if the HAND-Q works the same across country.

The next phase of HAND-Q development is an international field test that is currently underway in Australia, Canada, Finland, France and the United States. The data from the field test will be analysed using RMT analysis, and the psychometric properties of reliability and validity will be examined. Once the scales are finalized, they will be made available at no charge for not-for-profit clinical and research use through www.qportfolio.org.

CONCLUSION

The HAND-Q is a comprehensive PROM that was developed with extensive patient and expert input. The content validity of the HAND-Q was demonstrated, and the scales were found to be relevant, comprehensive, and comprehensible. The measurement properties of reliability and validity will be examined following an international field test study that includes patients with diverse hand

conditions. Once the HAND-Q is finalized, we anticipate that it will be implemented in clinical practice, research, and quality improvement initiatives to examine the clinical effectiveness of hand-related interventions, improve patient-clinician interactions, inform patient education, ultimately enhancing patient-centered care.

FIGURE LEGEND

Figure 1: Conceptual framework of the HAND-Q (n= 3008 unique codes)

Figure 2: Composition of expert panel in the rounds of refining of the scale

TABLE 1: Conceptual Framework of the HAND-Q with supportive participant quotes and examples

HAND -Q CONCEPTUAL FRAMEWORK	Top-level domain	Subdomain	Major Theme	Minor theme	Categories (where applicable) and participant words and examples
	Health-related quality of life	Physical (943 codes)	Symptoms	Pain	Intensity ("mild", "severe")
					Frequency ("all the time", "on and off"
					Type ("ache", "stinging", "burning", "cramp", "discomfort", "sore", "tender", or "throbbing")
					Aggravating Factors (e.g., during activities, at rest, when touched, weather fluctuations)
				Sensation	Lack of Sensation ("numb", "dead feeling")
					Abnormal Sensation ("buzzing", "going to sleep", "pins and needles", "prickly", "tingly", "twitching")
					Excessive Sensation ("sensitive")
				Weakness	("weak", "feeling tired")

			Function	Experience	Impaired mobility ("cannot make a fist", "unable to flatten fingers", fingers getting stuck in certain positions)
					Sleep ("pain drives me insane night")
					Power grip (e.g., holding mug or glass, carrying bags, turning a tap, opening jars, operating a computer mouse, shaking hands)
					Pinch grip (e.g., using cutlery, turning key, picking up fine objects, holding pen)
				Impact	Hygiene (e.g., wiping after using the toilet, showering, using a towel after a shower, brushing teeth, doing hair, clipping nails)
					Chores (e.g., preparing food, washing dishes, folding laundry, vacuuming)
					Dressing (e.g., doing up bra, buttoning a shirt, tucking shirt, tying shoelaces)
					Recreational activities (e.g., crochet, knitting, gardening, playing a musical instrument, sewing, painting)
		Psychological (324 codes)	Emotional distress	Irritation - Frustration	I have to go get help with simple things", "...it does get a bit frustrating that it is ongoing"
				Being down – Upset, Sad	"sick of the same things", "can't take it anymore"
				Overwhelmed	t has demolished me", "I can't go through this again"
				Self-conscious	would hide my hands under the table", "I used to wear hoodies and long sleeves because I didn't want people to know I was wearing a splint"
			Acceptance	Accept	"it is what it is"

		Social (231 codes)	Isolation	Conceal – hand	"I don't like going out because I can't cut food", "I feel self-conscious at the shops handing over money", "… sometimes when you put your hand out for a handshake some people look and think what on earth is wrong there..."
			Function (incl. work)	Job loss/leave profession	"I'd lost my typing role", "doctors deemed me unfit for work", "cannot pick up slack"
				Task modification	"I just run the machinery instead of using it"
			Relationships		"Spouse too me to appointments", "Spouse helped with chores"
	Satisfaction	Appearance (385 codes)	Hand region (i.e., fingers, thumb, palm, knuckles, skin, nails, scar)	Size	"fat", "pudgy", "swollen", "large", "big", "skinny"
				Shape	"curled", "deformed", "misshaped"
				Colour	"red", "white", "pink"
				Contour	"distorted", "twisted", "stuck out", "curled", "crooked"
				Similarity	"match"
				Smoothness	"bumps", "lumps"
				Scenarios	"up close", "far away", "when waving hands", "in photographs"

				Age	old", "wrinkled", "age spots", "veins stick out"
				Skin (esp. on back of hand)	"tight", "taut"
				Qualitative descriptions	ot right", "abnormal", "ugly", "imperfect"
		Outcome (36 codes)	Appraisal	glad", "pleased", "satisfied", "changed my life", "met expectations", "would recommend to others", "worth it", "great", "would have the treatment again without hesitation"	
		Experience of Care (468 codes)	Pre-procedure information	Amount	"enough", "knew what to expect", "more needed"
				Format of delivery	"written", "might be more visual", "pamphlet", "information package", "diagrams"
				Accessibility	"easy to understand", "sufficient time to review"

				Nature of information	e.g., details of the procedure, type of anesthesia, what to do in case of a complication, precautions, recovery, and outcomes to be expected
			Satisfaction with care – Hand surgeon and hand therapist	Description	professional", "kind", "friendly", "attentive", "easy to talk to", "caring", "inspiring", "thorough", "knowledgeable
				Nature of appointment	feeling heard", "feeling unrushed", "being included in decisions about treatment"
			Satisfaction with care – Hand Clinic	Overall	nice atmosphere", "clean", "sterile", "ease of booking appointment
			Satisfaction with care – Clinic office staff	Overall	on schedule", "worked as a team", "made me feel welcomed"

		Anesthesia (258 codes)	Experience	Worry – anesthesia not working	amount of anesthetic not being enough", "feeling pain or other sensations" during the procedure
				Worry – recovery from anesthesia	eg, impact on daily activities
			Severity of post-anesthesia symptoms	Type and experience	nausea, vomiting, constipation, diarrhea, and difficulty passing urine. "feeling sleepy", "tired", "down", "Irritable", "unwell", "confused", "forgetful"
			Awake procedure	Feelings when administered	"pain", "tingly", "warm"
				Sensation at the site	"pain"
				Distress – seeing blood or surgical equipment	"worried", "anxious"
				Environment of operating room	"comfortable", "clean", "sterile"
				Ability to ask questions	
		Hand Splint or Brace (22 codes)	Appearance of hand with splint or brace	Qualitative	"people don't look at the hand as much", "splint made my hand look normal"
			Cleaning the splint or brace	Qualitative	t looks filthy because you cannot clean it"

			Donning and doffing	"cumbersome", "irritating", "uncomfortable", "pain", "fingers getting stuck", "spasm in fingers and hand"	
			Ability to perform daily activities	e.g., being physically active, sleep, socialize, dress, and care for hand	
			Financial burden	"Expensive"	

TABLE 2: Summary of the number of items that were added, retained, revised, or dropped during the refining of the HAND-Q scales

	Response options	Recall period	Initial items	Items added	Items revised	Items dropped	Items for field-test
Health-Related Quality of Life scales							
Appearance	Satisfaction	Now	29	1	10	0	30
Function	Difficulty	Past week	34	3	14	2	35
Symptoms	Severity	Past week	18	6	17	2	22
Psychological	Frequency	Past week	16	3	0	0	19
Life impact	Severity	Past week	9	2	1	0	11
Sleep	Frequency	Past week	8	1	3	1	8
Social	Agree/Disagree	Past week	13	0	4	0	13
Sexual	Bothered	None	9	0	0	0	9
Work	Agree/Disagree	None	9	2	3	0	11
Acceptance	Agree/Disagree	None	7	0	6	0	7
Satisfaction scales							
Anesthesia	Bothered	None	17	0	5	3	14
Post-anesthesia symptoms	Severity	None	12	2	0	1	13
Awake procedure	Satisfaction	None	17	1	8	1	17
Information	Satisfaction	None	21	1	7	2	20
Surgeon	Agree/Disagree	Recent appointments	25	1	8	1	25
Hand therapist	Agree/Disagree	Recent appointments	20	1	4	2	19
Hand clinic	Agree/Disagree	Recent appointments	14	0	3	1	13
Overall outcome	Agree/Disagree	Most recent treatment	10	0	13	1	9
Office staff	Agree/Disagree	Recent appointments	13	1	2	0	14
Splint	Satisfaction	Most recent splint	11	2	1	1	12
Total			312	28	109	15	319

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CONTRIBUTION STATEMENT: KLS, ND, AFK and ALP conceptualized the study; AFK, ALP and SJC developed the methodology used for the development of the HAND-Q; KLS and KES conducted the interviews; KLS, KES, and AFK analysed the data, AFK led the development and refinement of the scales with assistance from all listed co-authors; KLS and MNK wrote the manuscript, which was approved for submission by all listed co-authors.

COMPETING INTERESTS: Drs. Sierakowski, Dean, Pusic and Klassen are co-developers of the HAND-Q and receive a share of any license revenue on the inventor sharing policies of the institutions that they are associated with. The remaining authors have no conflict of interest to declare.

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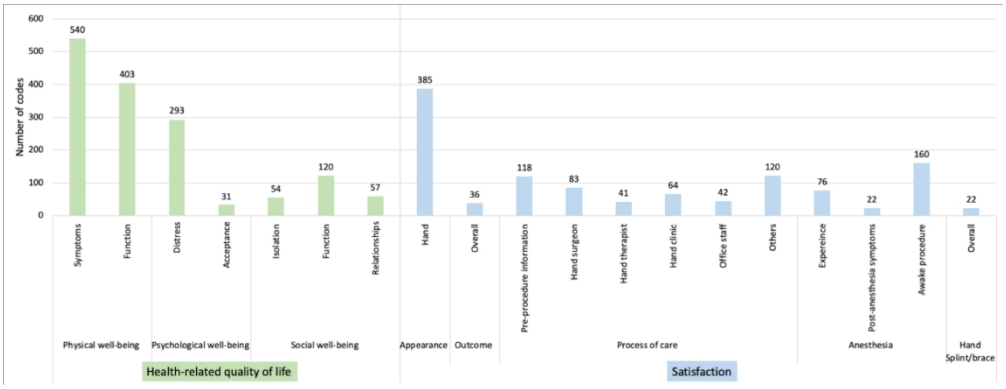

Figure 1

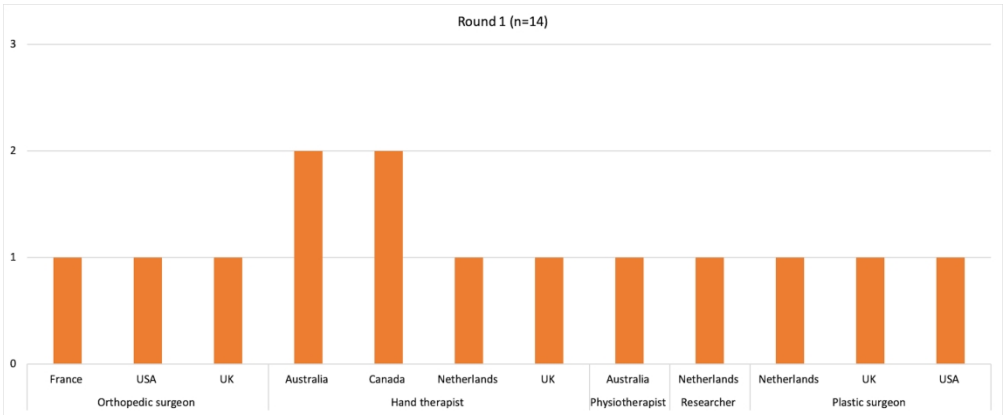

Figure 2 - Round 1

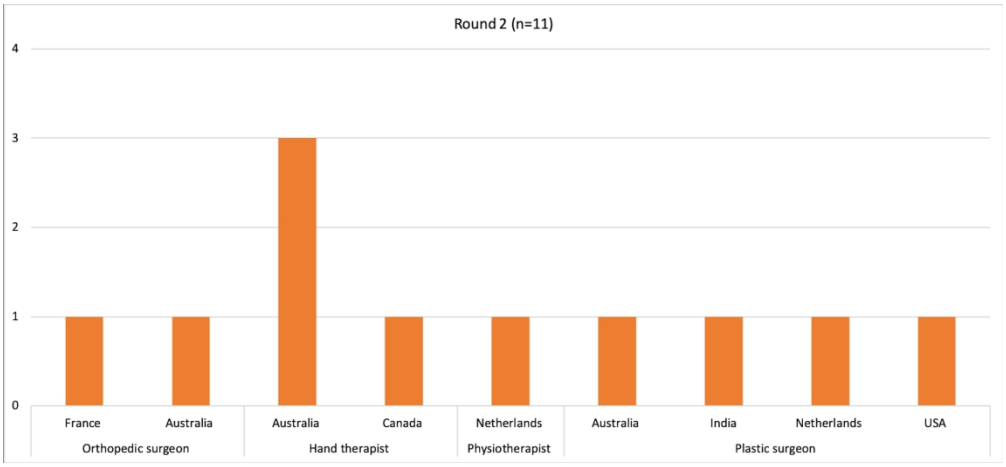

Figure 2 - Round 2

APPENDIX 1: Examples of coding schema of the Stage 1 concept elicitation interviews

Participant quote	**Item**	**Top-level domain**	**Sub-domain**	**Theme**	**Sub-theme**
This one has been a real pain in the proverbial here, it's still aching, it has not stopped aching, it drives me insane at night because it, during the day I don't seem to notice it but at night it aches and it's still aching, it's aching up here today (Participant with osteoarthritis)	My hand has not stopped aching	Physical	Symptom	Pain	Type – ache
	My hand pain drives me insane at night	Physical	Function – experience	Sleep	Disturbed
Well in my hands it causes me disability, being unable to clothe myself, I have to have special knives and forks. I find that I find it difficult to do up buttons. I like writing and I find it difficult to write, but I do write (Participant with rheumatoid arthritis)	I have been unable to clothe myself	Physical	Function - Impact	ADL	Dressing
	I have special knives and forks	Physical	Function - Impact	Accommodation	Special knives, forks
	I find it difficult to do up buttons	Physical	Function - Impact	ADL	Dressing – buttons
	I find it difficult to write	Physical	Function - Impact	IADL	Writing
It's just I'm aware that it's going to hurt, and I don't like it. I uh, it saddens me, it depresses me, it's frustrating and it can be embarrassing (Participant with	It saddens me that my hand is going to hurt	Psychological	Distress	Being down	Sad
	My hand pain depresses me	Psychological	Distress	Being down	Depressed

carpal tunnel syndrome)	My hand pain is frustrating	Psychological	Distress	Irritation	Frustration
	My hand pain can be embarrassing	Psychological	Distress	Self-conscious	Embarrassing

ADL, activities of daily living; IADL, instrumental activities of daily living

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TITLE: A qualitative study informing the development and content validity of the HAND-Q - a modular patient-reported outcome measure for hand conditions

AUTHORS:**

1. Kyra L. Sierakowski MD, PhD, Department of Plastic & Reconstructive Surgery, College of Medicine and Public Health, Flinders University, Adelaide, South Australia, Australia
2. Manraj N. Kaur PT, PhD, Department of Surgery, Patient-Reported Outcome, Value and Experience (PROVE) Center, Harvard Medical School, Brigham and Women's Hospital, Boston, Massachusetts, United States
3. Kathleen Evans Sanchez MD, Department of Plastic & Reconstructive Surgery, College of Medicine and Public Health, Flinders University, Adelaide, South Australia, Australia
4. Gregory I. Bain MBBS, PhD, Department of Orthopaedic Surgery, Flinders University, Adelaide, South Australia, Australia,
5. Stefan Cano PhD, Modus Outcomes, Letchworth Garden City, United Kingdom
6. Philip A. Griffin MBBS, FRACS, Department of Plastic & Reconstructive Surgery, Flinders Medical Centre, Adelaide, South Australia, Australia
7. Anne Klassen DPhil, Faculty of Health Sciences, McMaster University, Hamilton, Ontario, Canada
8. Andrea Pusic, MD, MHS, Department of Surgery, Patient-Reported Outcome, Value and Experience (PROVE) Center, Harvard Medical School, Brigham and Women's Hospital, Boston, Massachusetts, United States
9. Don Lalonde MD, Department of Plastic Surgery, Dalhousie University, Saint John, New Brunswick, Canada
10. Nicola R. Dean MBChB, PhD, Department of Plastic & Reconstructive Surgery, College of Medicine and Public Health, Flinders University, Adelaide, South Australia, Australia

**Drs. Sierakowski and Kaur share the first authorship of this manuscript

CORRESPONDING AUTHOR: Kyra L. Sierakowski, Department of Plastic & Reconstructive Surgery, College of Medicine and Public Health, Flinders University, Adelaide, South Australia, Australia, kyra.sierakowski@flinders.edu.au

RUNNING HEAD: Development of the HAND-Q

KEYWORDS: Hand conditions, patient-reported outcomes, patient-reported outcome instrument, HAND-Q

ETHICS APPROVAL STATEMENT: Ethics approval for this study was obtained at all of the participating sites: Australia, Southern Adelaide Clinical Human Research Ethics Committee (Reference Number 003.17 HREC/17/SAC/5); Canada, Horizon Health Network Research Ethics Board (File # RS-2017-2499) the US, Office of Research and Innovation, Lehigh Valley Health Network, Allentown, Pennsylvania (United States, Reference STUDY00000046).

ABSTRACT

Objectives: The purpose of this study was to identify and understand the issues that are relevant to patients with hand conditions. The data were used to develop a patient-reported outcome measure (PROM) for adults with hand conditions (HAND-Q) and refine it with input from patients and clinician experts.

Design: Semi-structured qualitative interviews were used to understand what matters to patients. Cognitive debriefing was used to refine preliminary HAND-Q scales.

Setting: Hand clinics in tertiary healthcare centres in Canada, Australia, and United States.

Participants: Eligible participants were English-speaking adults who were able to provide informed consent and had hand surgery in the preceding 12 months and at least 4 weeks had passed since their hand surgery. A total of 62 in-depth interviews (females, n=24; mean age = 65 years) were conducted to develop an item pool and draft the HAND-Q scales. The preliminary scales were refined through cognitive debriefing interviews with 20 participants and feedback from 25 clinician experts. All interviews were audio-recorded, transcribed verbatim and coded using a line-by-line approach.

Results: Qualitative data analysis resulted in 3008 unique codes, which were organized into two top-level domains of HRQL and satisfaction with treatment outcomes. The scales were refined iteratively, and the field-test version included 319 unique items and 20 independently functioning scales.

Conclusions: The HAND-Q is a comprehensive PROM developed using extensive patient and expert input and established guidelines for PROM development and validation. In the next phase, the psychometric properties of the HAND-Q will be established in an international field

test, following which the HAND-Q will be available for use in clinical research and practice at no charge.

ARTICLE SUMMARY

Strengths and limitations

- The development of HAND-Q included in-depth input from a heterogeneous, international sample of adult patients with diverse hand conditions.
- The comprehensibility, comprehensiveness, and relevance of the field-test version of the HAND-Q was established using extensive feedback from patients with hand conditions and clinician experts.
- Patients with rare hand conditions (e.g., congenital deformities, hand amputation or brachial plexus injuries) were not included in the development of the HAND-Q, and further validation work will be required.
- Only English-speaking patients from high income countries were included and the scales will need to be examined for content validity and psychometrics in diverse patient populations.

INTRODUCTION

Any condition or injury of the hand can significantly impact the health-related quality of life (HRQL) of an individual. While several objective and performance-based measures exist to assess the impact of hand conditions and their treatment on the range of motion, strength, dexterity, sensation, and functional impairment, the impact on an individual's HRQL is best assessed by asking patients directly. Patient-reported outcome measures (PROMs) are questionnaires that are used to assess HRQL in clinical practice and research. The data collected from PROMs can be used to understand, monitor, and communicate the impact of a condition on patients and enhance shared decision-making, resulting in better treatment outcomes overall (1).

A recent systematic review designed to identify all PROMs relevant to the field of hand surgery identified 24 PROMs for upper extremity conditions (2). Most commonly used PROMs in hand conditions included the Disabilities of the Arm, Shoulder and Hand (DASH), the Michigan Hand Outcomes Questionnaire (MHQ), and the Patient-rated Wrist/Hand Evaluation (PRWHE). However, these three PROMs have important limitations. The DASH, MHQ, and PRWHE were developed in the 1990s using the traditional classical test theory (CTT) approach. Importantly, qualitative interviews with patients with hand conditions were not a part of these instruments' development, which countermands the recommendations of the Medical Outcomes Trust and the United States Food and Drug Administration (3-5). Further, increasingly modern psychometric methods that involve Rasch Measurement Theory (RMT) or Item Response Theory analysis are used to develop scales that form clinical hierarchies and have interval level measurement properties. Modern approaches to scale development allow for meaningful and interpretable measurement of change in patient status, which is difficult for scales developed using the CTT approach.

To overcome the limitations of existing instruments, our team developed a PROM for hand conditions called the HAND-Q. The HAND-Q is intended to be used in clinical care, research and quality improvement initiatives in acute and chronic care of adults with hand conditions. The modular

construction of the HAND-Q means that the practitioner can choose the scales of relevance for a particular application. It is anticipated that the HAND-Q will be implemented in hospital and private hand clinics that manage hand conditions surgically and non-surgically. The detailed study protocol for the development of HAND-Q is published elsewhere (6). This paper aims to describe the results of the first phase of the development of the HAND-Q - a qualitative study to develop and refine the HAND-Q scales - which will be tested psychometrically in a subsequent international field-test study.

METHODS

The ethics approvals for this study were obtained from the Southern Adelaide Clinical Human Research Ethics Committee (Australia, Reference HREC/17/SAC/5), Horizon Health Network Research Ethics Board (Canada, Reference 2017-2499) and Office of Research and Innovation, Lehigh Valley Health Network, Allentown, Pennsylvania (United States, Reference STUDY00000046). The first phase of the HAND-Q development was completed in three steps: 1) development of the conceptual framework, 2) scales formation, and 3) pilot testing to establish content validity with feedback from patients and experts. The COnsolidated criteria for REporting Qualitative research(COREQ) Checklist (7) was used to report the results.

Approach

We used the applied health services approach of interpretive description (8) to design, conduct, and analyse the qualitative study results. Interpretive description acknowledges pre-existing theoretical and clinical knowledge informing a study, which was appropriate in our study given that much is known already about the impact of hand condition on individual's HRQL. This approach also aims to produce knowledge relevant to the clinical context with the provision that a patient's understanding of a concept is of the most significant importance, regardless of the clinical or theoretical explanation (9).

Stage 1: Development of the conceptual framework

Study participants and recruitment

English-speaking adults (18 years or older) who had had surgery on one or both hands in the preceding 12 months and were at least four weeks post-hand surgery were recruited from tertiary healthcare centers in Adelaide, Australia, and Saint John, New Brunswick, Canada. The limit of 12 months was imposed to ensure that the HRQL issues were relevant and there was minimal recall bias. Although the HAND-Q is designed to be used for all patients with hand conditions (and not just those who have surgical treatment for their condition) the experience of surgery themes to be explored in the interviews required that participants had experienced surgical management. Patients who were unable to provide informed consent due to a language barrier or cognitive impairments were excluded. The recruitment followed a purposive sampling strategy to ensure heterogeneity by targeting key demographic (age, gender) and clinical variables (hand condition), funding (public versus private), and type of anesthesia used for surgery (general anesthesia /sedation, or local anesthesia). Patients were screened for eligibility by treating clinician(s) or the clinic's administrative staff and informed of the study objectives and procedures by a member within their clinical circle of care. The contact information for patients who expressed an interest in participation was shared with the study research coordinator, who then contacted the patient, explained the study in detail including the credentials of the interviewer, answered study-specific questions, and obtained written consent for participation.

Data collection

A semi-structured interview guide was developed to elicit in-depth information on the treatment and experience of living with their hand condition, specifically concerning HRQL (physical, psychological, social, and sexual well-being) and satisfaction (appearance and process of care). Interview probes were used to guide the patient's description of the treatment outcomes or to elicit detailed answers. The probes were informed by the clinical expertise of the study team and the concepts identified in the systematic review. (6, 10). In-depth, qualitative interviews were conducted in-person or over the

telephone by an experienced qualitative interviewer (KS, cisfemale) with no relationship to the participants using the interview guide (5). The participants were asked to describe their experiences of living with their hand condition, including any treatments. The interviews were audio-recorded and transcribed verbatim, with identifying information removed.

Data analysis and rigor

The data collection and analysis took place concurrently to explore the relevance and importance of the emerging concepts identified during the interviews. Inductive content analysis of the interview transcripts was completed using a 'line-by-line' approach in Microsoft Word, Version 2019 (Microsoft Corp., WA, USA). Participants' quotes about any aspect of outcome or experience of care were copied into a Microsoft Excel spreadsheet Version 2019 (Microsoft Corp., WA, USA), along with demographic and clinical information. Constant comparison was used to identify common concepts of interest, and the data were categorized into conceptual top domains, sub-domains, and major and minor themes (11). The interviews were coded by one experienced qualitative researcher and checked by another team member. Codes were confirmed after discussion with the senior author (AK), who oversaw the analysis. To ensure rigor, the data analysis results were reviewed with the members of the study team throughout the study (12). Interviews continued until saturation was achieved; that is, no new concepts were identified in subsequent interviews (13).

Stage 2: HAND-Q scale formation

The conceptual framework and the coded data developed in Stage 1 were used to create items for the identified domains. For item development, efforts were made to retain the participants' language as much as possible. To ensure that the items were clear, easy to understand, and resonated with patients, we avoided double-barrelled items, or items with technical jargon or slang. For scale development, the theoretical underpinnings of the Rasch Measurement Theory were adopted (14). The RMT approach to scale development requires that the items map out a concept of interest through a clinical hierarchy (measuring from a little to a lot of a concept). Therefore, each item was

designed to measure the concept of interest in varying amounts. For example, in the Physical Function scale, the items range from those that would be easy to endorse for most people with a hand problem (e.g., eating with your hand(s)) to more challenging (e.g., eating with cutlery) to the most difficult to endorse (e.g., opening a jar).

The response options for the HAND-Q scales were limited to four options for simplicity and per recommended guidelines (15). We deliberately did not include a neutral response option. The amount of the construct measured by a neutral option is unclear and does not fit the mathematical model of RMT.

Stage 3: Pilot testing of HAND-Q scales for content validity

Patient input – cognitive interview

A new sample of patients with hand conditions using the same eligibility criteria and recruitment strategy from Stage 1 was recruited from Allentown, Pennsylvania, United States. Ethics approval was obtained from the Lehigh Valley Health Network Institutional Review Board. Participants from Australia and Canada who took part in Stage 1 were also invited to participate in cognitive interviews. Relevant HAND-Q scales were sent to the participants before the interview. An interview guide was used, and the interviews were conducted by an experienced qualitative interviewer by telephone. The 'think aloud' technique (16, 17) was used, whereby the scales were reviewed item-by-item, and the participants were asked to comment on the clarity, ease of understanding, and relevance of the title, instructions, timeframe, response options, and items. Where appropriate, participants were asked to paraphrase the items in their own words and provide examples from their treatment experience. Participants were also asked to nominate missing items (if any) and comment on the comprehensiveness of each scale.

The interviews were conducted in three consecutive rounds to allow for changes to be made to the scales in-between the rounds. The interviews were audio-recorded and transcribed verbatim, with

identifying information removed. The interview transcripts were analysed descriptively by one experienced qualitative researcher and checked by another team member. Relevant participant quotes pertaining to items were copied and pasted into a Microsoft Excel spreadsheet. An item tracking matrix (18) was used to document the changes made to the items between rounds of interviews. Data saturation was thought to be reached when participants did not recommend any further changes to the HAND-Q scales.

Expert Opinion – Online survey

We sought feedback from healthcare professionals with expertise in treating hand conditions (hereafter referred to as "experts") to ensure buy-in and affirm that the HAND-Q scales comprehensively explored clinically important issues. A multidisciplinary team of experts was identified through the professional networks of the study investigator team and invited via email to participate in an online Research Electronic Data Capture (REDCap) (19) survey. The experts were asked to review scales one at a time and comment on the relevance, comprehension, and comprehensibility of its content. Non-respondents were sent a reminder one week later. Two rounds of expert surveys were completed between the first and second rounds of patient cognitive interviews. The feedback from experts was analysed descriptively by one experienced qualitative researcher and checked by another member of the team and used to refine the HAND-Q scales.

Patient and public involvement

The HAND-Q has been developed with patients as central focus and with patient input vital throughout the development process. An international group of patients were engaged in all stages of the development of the HAND-Q. The input of patients in stage 1 qualitative interviews was fundamental to the scale formation, with patients' words providing the content for the item development in stage 2. Feedback from patients in stage 3 helped to refine the scales. Regular team de-briefs were conducted with the team members throughout the three stages.

RESULTS

Stage 1: Development of the conceptual framework

The qualitative interviews took place between June and November 2017; the mean interview time was 34 minutes (range 12 to 61). A total of 62 (females, n=34, 55%) in-depth qualitative interviews with 40 participants in Australia and 22 in Canada were conducted. The mean age of the participants was 65 ± 11 years (range, 28 to 86). The participants' diagnoses included; carpal tunnel (n=20), Dupuytren's contracture (n=14), trigger finger (n=8), osteoarthritis (n=8), trauma (n=7) and other less common conditions (n=4). Further demographic information available in Table 1. An example of how the interview data were coded and categorized into domains and themes is shown in Appendix 1.

The analysis of the interview data resulted in 3008 unique codes, which were organized into top-level domains of HRQL and satisfaction with treatment outcomes (Figure 1). The HRQL top-level domain (n=1498 unique codes) was categorized into the sub-domains of physical well-being (943 codes), psychological well-being (324 codes), and social well-being (231 codes). The satisfaction top domain included sub-domains of satisfaction with appearance (385 codes), overall outcome (36 codes), process of care (486 codes), anesthesia (258 codes), and hand splint or brace (22 codes). Table 2 shows the conceptual framework of the HAND-Q with supportive data from the qualitative interviews.

Stage 2: Scales formation

The conceptual framework was used to develop the first draft of the HAND-Q scales. Item generation was based on content from participant interviews and the participants' wording was maintained as much as possible. A total of 20 scales were developed to measure the concepts identified in Stage 1. The full list of scales is shown in Table 3.

Stage 3: Pilot testing of HAND-Q scales for content validity

Cognitive interviews were conducted to review draft scales with patients. The draft scales were reviewed and discussed in detail to ensure that the scales were measuring the concepts important to patients in an easy-to-understand format. Any instructions or items that caused confusion were subsequently altered to improve the interpretability of the scales. A total of 20 cognitive interviews in three rounds were performed with patients between January 1, 2018, and February 28, 2018. Participants were in Australia (n=9), Canada (n=7), and the United States (n=4). The majority of the participants were females (n=13, 65%), and the mean age of the sample was 60 ± 12 years (range, 32 to 76 years). Participants were seeking or had received treatments for a range of hand conditions, including carpal tunnel (n=9), Dupuytren's contracture (n=3), trigger finger (n=3), osteoarthritis (n=7), trauma (n=5), and other less common conditions (n=3). Further demographic information is available in Table 4.

A total of 25 experts provided input in two rounds (round 1, n=14) on the content of the HAND-Q scales. Figure 2 shows the composition of experts for each round. A summary of the number of items that were added, retained, revised, or dropped is shown in Table 3. The field-test version of the HAND-Q consists of a total of 319 unique items organized into 20 independently functioning scales.

DISCUSSION

In-depth qualitative interviews were conducted with an international sample of patients with hand conditions to gain a comprehensive understanding of the range of treatment outcomes and experience of care-related concepts. The qualitative data were used to develop a conceptual framework, which was used to develop a draft of the HAND-Q, a comprehensive PROM for patients with hand conditions. The draft version of HAND-Q was refined through patient and expert feedback, and content validity was demonstrated.

We adopted a patient-centered approach for this study, where patients were engaged in content generation and refining of the HAND scales. Measuring what matters to patients is fundamental to understanding the burden of hand conditions and providing effective and efficient care that aligns with patients' treatment preferences and values. Due to HAND-Q's "bottom-up" approach, we were able to identify and develop scales for concepts that are either missing or incompletely assessed in the existing hand-specific PROMs to-date (2). For example, the HAND-Q has a unique scale that measures the impact of hand condition on someone's sexual life. Items in this scale ask about the had problem being a distraction during sexual activity or interfering with the ability to give pleasure. Since hands are a part of the body that are difficult to hide, participants in our study described feeling embarrassed and self-conscious about their hand condition. The HAND-Q measures appearance of hands (e.g., size, shape of fingers and thumbs, how the hands look when holding a glass or resting the palms on a table) to provide a means to evaluate treatments that change how the hand looks.

Another unique strength of the HAND-Q is that the development of the scales was embedded within the principles of a modern psychometric approach (i.e., RMT), resulting in independently functioning scales. To elaborate, the negative impact of injuries and conditions of the hand on psychological well-being has been well-established in the literature (20-22). Existing PROMs, such as the DASH (23), PRWHE (24), and the (MHQ) (25), measure the impact of condition or treatment on psychological well-being with the help of a single item rather than a scale. When the raw score for the single item on psychological well-being is added to raw item scores of unrelated constructs to produce a total score, it makes it impossible to ascertain the impact of the condition or treatment on patients' psychological well-being. Further, it makes it challenging for clinicians and researchers to interpret the total score, discouraging them from using PROMs. In contrast, the HAND-Q includes one independently functioning scale with items that measure only one construct – psychological function – resulting in more targeted measurement. The modular design allows the clinicians to choose the scales that are

most relevant to their clinical practice or research question, reducing patient burden. Additionally, as the field of hand surgery evolves and new concepts of interest are identified, the modular design allows for new scales to be added to the HAND-Q, keeping it relevant ("fit for purpose") over time.

Our study is not without limitations. The study sample is not representative of the full breadth of hand conditions seen in the clinical practice. While the common conditions such as carpal tunnel syndrome, Dupuytren's contracture and trigger finger were included, rarer hand conditions such as congenital anomalies or brachial plexus injury were not. Non-surgical patients were excluded from the study; however, this was strategic as post-operative patients are able to describe their pre-operative (i.e., non-surgical) and post-operative experience with the hand condition and it's HRQL impact. Further qualitative work would be required to examine the content validity and other psychometric properties of the HAND-Q scales in the clinical populations not included in this study. Further, we only included English-speaking participants from three developed countries with similar economic and cultural environments. To ensure that the HAND-Q scales are relevant globally, the scales have been translated and culturally adapted to a number of languages in preparation for an international field-test study. RMT analysis will be used to examine differential item functioning by language to determine if the HAND-Q works the same across country.

The next phase of HAND-Q development is an international field test that is currently underway in Australia, Canada, Finland, France and the United States. The data from the field test will be analysed using RMT analysis, and the psychometric properties of reliability and validity will be examined. Once the scales are finalized, they will be made available at no charge for not-for-profit clinical and research use through www.qportfolio.org.

CONCLUSION

The HAND-Q is a comprehensive PROM that was developed with extensive patient and expert input. The content validity of the HAND-Q was demonstrated, and the scales were found to be relevant, comprehensive, and comprehensible. The measurement properties of reliability and validity will be

examined following an international field test study that includes patients with diverse hand conditions. Once the HAND-Q is finalized, we anticipate that it will be implemented in clinical practice, research, and quality improvement initiatives to examine the clinical effectiveness of hand-related interventions, improve patient-clinician interactions, inform patient education, ultimately enhancing patient-centered care.

FIGURE LEGEND

Figure 1: Conceptual framework of the HAND-Q (n= 3008 unique codes)

Figure 2: Composition of expert panel in the rounds of refining of the scale

TABLE 1: Demographics of participants in Qualitative Interviews

		Australian	Canadian	Total
Number of participants		40	22	62
Age				
	Average	63	67	65
	Range	38 - 78	27 - 85	27 - 85
Gender				
	Male	18	10	28
	Female	22	12	34
Hand condition				
	Trigger finger	4	4	8
	OA	8	0	8
	RA	1	0	1
	CTS	8	12	20
	Trauma	6	1	7
	Dupuytren's	11	3	14
	Other	2	2	4
Funding				
	Public	17	22	39
	Private	23	0	23
Anaesthesia				
	Local only	7	21	28
	Sedation, GA	33	1	34

TABLE 2: Conceptual Framework of the HAND-Q with supportive participant quotes and examples

Top level domain	Subdomain	Major Theme	Minor theme	Categories (where applicable) and participant words and
Health-related quality of life	Physical (943 codes)	Symptoms	Pain	Intensity ("mild", "severe")
				Frequency ("all the time", "on and off"
				Type ("ache", "stinging", "burning", "cramp") "discomfort",
				Aggravating Factors (e.g., during activities, at rest, when
			Sensation	Lack of Sensation ("numb", "dead feeling")
				Abnormal Sensation ("buzzing", "going to sleep", "pins and
				Excessive Sensation ("sensitive")
			Weakness	("weak", "feeling tired")
		Function	Experience	Impaired mobility ("cannot make a fist", "unable to flatten
				Sleep ("pain drives me insane night")
				Power grip (e.g., holding mug or glass, carrying bags, turning
				Pinch grip (e.g., using cutlery, turning key, picking up fine
			Impact	Hygiene (e.g., wiping after using the toilet, using a towel after
				Chores (e.g., washing dishes, folding laundry, vacuuming)
				Dressing (e.g., doing up bra, buttoning a shirt, tying
				Recreational activities (e.g., crochet, gardening)
	Psychological (324 codes)	Emotional distress	Irritation	"…it does get a bit frustrating that it is ongoing"
			Being down	"sick of the same things", "can't take it anymore"
			Overwhelmed	"it has demolished me", "I can't go through this again"
			Self-conscious	"hide my hands", "I didn't want people to know I was wearing
		Acceptance	Accept	"it is what it is"
	Social (231 codes)	Isolation	Conceal – hand	"I don't like going out because I can't cut food"
		Function (incl. work)	Job loss	"I'd lost my typing role", "doctors deemed me unfit for work"
			Modify work	"I just run the machinery instead of using it"
		Relationships		"spouse took me to appointments", "spouse helped with
Appearance	Appearance (385 codes)	Hand region (i.e., fingers, thumb, palm, knuckles, skin, nails,	Size	"fat", "pudgy", "swollen", "large", "big", "skinny"
			Shape	"curled", "deformed", "misshaped"
			Colour	"red", "white", "pink"

			Contour	"distorted", "twisted", "stuck out", "curled", "crooked"
			Similarity	"match"
			Smoothness	"bumps", "lumps"
			Scenarios	"up close", "far away", "when waving hands", "in
			Age	"old", "wrinkled", "age spots", "veins stick out"
			Skin	"tight", "taut"
			Qualitative	not right", "abnormal", "ugly", "imperfect"
Experience of care	Experience of Care (468 codes)	Pre-procedure information	Amount	"enough", "knew what to expect", "more needed"
			Format of delivery	"written", "might be more visual", "pamphlet", "information
			Accessibility	"easy to understand", "sufficient time to review"
			Nature of	e.g., details of the procedure, type of anesthesia, what to do
		Satisfaction- Hand	Description	professional", "kind", "friendly", "attentive", "easy to talk to",
			Nature of	"feeling heard", "feeling unrushed", " included in decisions"
		Satisfaction - Hand	Overall	"nice atmosphere", "clean", "sterile", "ease of booking
		Satisfaction - Office	Overall	"on schedule", "worked as a team", "made me feel
Anesthesia	Anesthesia (258 codes)	Experience	Worry – not	"amount of anesthetic not being enough", "feeling pain"
			Worry – recovery	eg, impact on daily activities
		Post-anesthesia	Type and	"feeling sleepy", "tired", "down", "Irritable", "unwell",
		Awake procedure	Administration	"pain", "tingly", "warm"
			Sensation at the	"pain"
			Distress	Seeing blood or surgical equipment - "worried", "anxious"
			Environment	Operating room - "comfortable", "clean", "sterile"
			Ability to ask	
Treatment	Hand Splint or Brace (22 codes)	Appearance of hand	Qualitative	"people don't look at the hand", " made my hand look
		Cleaning splint or	Qualitative	"it looks filthy because you cannot clean it"
		Donning and doffing		"cumbersome", "irritating", "uncomfortable", "pain", “stuck”
		Perform daily activities		e.g., being physically active, sleep, socialize, dress, and care
		Financial burden		"Expensive"
	Outcome (36 codes)	Appraisal		glad", "pleased", "satisfied", "changed my life", "met expectations"

TABLE 3: Summary of the number of items that were added, retained, revised, or dropped during the refining of the HAND-Q scales

	Response	Recall	Initial	Items	Items	Items	Items
Health-Related Quality of Life scales							
Function	Difficulty	Past week	34	3	14	2	35
Symptoms	Severity	Past week	18	6	17	2	22
Psychological	Frequency	Past week	16	3	0	0	19
Life impact	Severity	Past week	9	2	1	0	11
Sleep	Frequency	Past week	8	1	3	1	8
Social	Agree/Disagree	Past week	13	0	4	0	13
Sexual	Bothered	None	9	0	0	0	9
Work	Agree/Disagree	None	9	2	3	0	11
Acceptance	Agree/Disagree	None	7	0	6	0	7
Appearance scale							
Appearance	Satisfaction	Now	29	1	10	0	30
Experience of care scales							
Anesthesia	Bothered	None	17	0	5	3	14
Post-anesthesia	Severity	None	12	2	0	1	13
Awake procedure	Satisfaction	None	17	1	8	1	17
Information	Satisfaction	None	21	1	7	2	20
Surgeon	Agree/Disagree	Recent	25	1	8	1	25
Hand therapist	Agree/Disagree	Recent	20	1	4	2	19
Hand clinic	Agree/Disagree	Recent	14	0	3	1	13
Office staff	Agree/Disagree	Recent	13	1	2	0	14
Hand treatment scales							
Overall outcome	Agree/Disagree	Most recent	10	0	13	1	9
Splint	Satisfaction	Most recent	11	2	1	1	12
Total			312	28	109	15	319

TABLE 4: Demographics of participants in Cognitive Interviews

		Australian	Canadian	American	Total
Number of participants		9	7	4	20
Age					
	Average	61	64	56	60
	Range	47 - 76	55 - 76	32 - 76	32-76
Sex					
	Male	3	2	2	7
	Female	6	5	2	13
Hand condition					
	Trigger finger	1	1	2	3
	OA	4	2	3	7
	RA	1	0	0	1
	CTS	2	5	7	9
	Trauma	2	2	3	5
	Dupuytren's	2	1	1	3
	Other	1	1	2	3

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CONTRIBUTION STATEMENT: KLS, ND, AFK and ALP conceptualized the study; AFK, ALP and SJC developed the methodology used for the development of the HAND-Q; KLS and KES conducted the interviews; KLS, KES, and AFK analysed the data, AFK led the development and refinement of the scales with assistance from all listed co-authors; GB,PG and DL helped with recruitment and provided content expertise, KLS and MNK wrote the manuscript, which was approved for submission by all listed co-authors.

COMPETING INTERESTS: Drs. Sierakowski, Dean, Pusic and Klassen are co-developers of the HAND-Q and receive a share of any license revenue on the inventor sharing policies of the institutions that they are associated with. Anne Klassen is an owner of EVENTUM Research which provides consulting services to the pharmaceutical industry. The remaining authors have no conflict of interest to declare.

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DATA SHARING STATEMENT: De-identified data available from KLS upon reasonable request.

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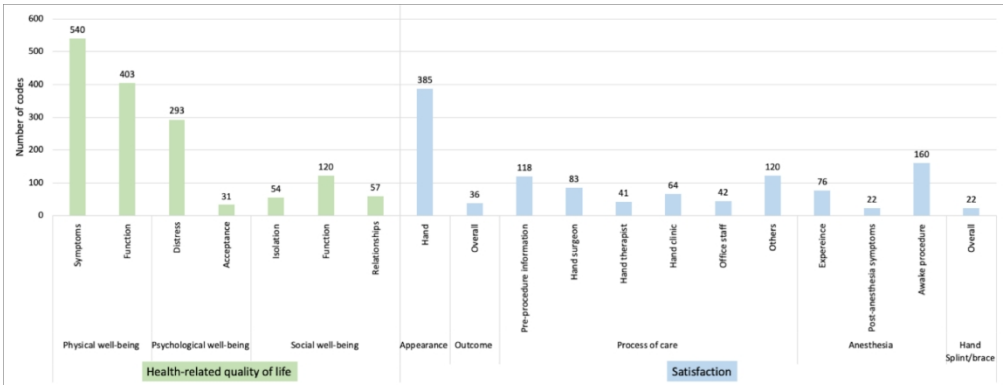

Figure 1

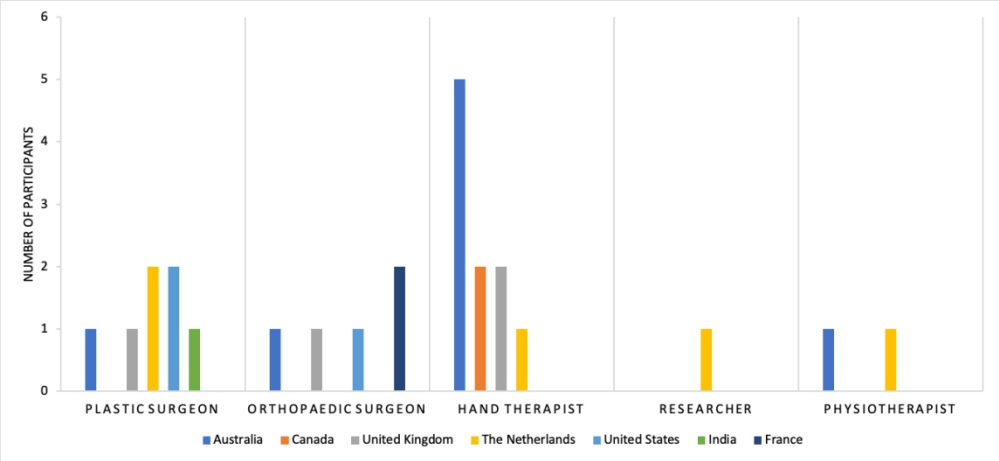

Figure 2: Composition of expert panel in the rounds of refining of the scale (Rounds 1 and 2)

228x105mm (150 x 150 DPI)

Supplementary material

Appendix 1
Interview Guide for qualitative interviews performed in phase 1

Experience of care

1. What treatments have you had for your condition?
2. What was good or bad about the treatment?
3. If the participant has had surgery:
    a. What was your experience of the anaesthetic used? Probe: general anaesthetic, block, local
    b. Would you have considered having treatment under local anaesthetic? Probe: why, why not
4. Who do you see when you come to the hospital clinic? Probe: receptionist, nurse, doctor, occupational therapist
5. What are the people like who care for you? Probe: friendly, made you feel comfortable, easy to talk to, listened to you
6. What kind of verbal and written information did they give you? Probe: gave enough information, let you ask questions, answered your questions, provided information about recovery

Physical function

1. Does your condition create any functional problems? Probe: work, personal care, hobbies
2. What specific things do you have difficulty with due to your hand problem? Probe: getting dressed, cooking, typing, sport
3. Do you experience any symptoms related to your functional problem? Probe: pain, discomfort, embarrassment, mood disturbance

Psychological well-being

1. How does your hand problem make you feel? Probe: frustrated, angry, upset, worried, stressed
2. How does your hand problem make you feel about yourself? Probe: self esteem, body image, confidence, self-conscious, different from others

Appearance

1. How would you describe the appearance of your hand/s? Probe: from close up, from far away, symmetry, texture, attractiveness
2. How has your hand appearance changed since your treatment? Probe: scarring, descriptive detail
3. What do you like or dislike about your hand appearance?
4. Is there anything about your hand appearance that you would like to change? Probe: for details
5. Do you ever hide your hands? How do you do this?

6. How important is the appearance of your hands to you?

Other

1. Is there anything I have not asked you that you think it is important for me to know?
2. Would you like to receive a copy of the transcript from today's discussion?
3. Would you be interested in participating in Cognitive Interview?

APPENDIX 2: COREQ: Consolidated criteria for reporting qualitative research: a 32-item checklist for interviews and focus groups

Section/Topic	Item No	Checklist item	Reported on page No
Domain 1: Research team and reflexivity			
Personal Characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?Interviewer/facilitator	7
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	Title page
Occupation	3	What was their occupation at the time of the study?	Title page
Gender	4	Was the researcher male or female?	Not relevant
Experience and training	5	What experience or training did the researcher have? Relationship with participants	7
Relationship with participants			
Relationship established	6	Was a relationship established prior to study commencement?	7
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	7
Interviewer characteristics	8	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	7
Domain 2: study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	6
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	6
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	6-7
Sample size	12	How many participants were in the study?	10
Non-participation	13	How many people refused to participate or dropped out? Reasons?	10
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	10
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	-
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	10
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Supplementary material
Repeat interviews	18	Were repeat interviews carried out? If yes, how many?	
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	7
Field notes	20	Were field notes made during and/or after the interview or focus group?	7
Duration	21	What was the duration of the interviews or focus group?	10
Data saturation	22	Was data saturation discussed?	8
Transcripts returned	23	Were transcripts returned to participants for comment and/or	-

		correction?	
Domain 3: analysis and findings Data analysis			
Number of data coders	24	How many data coders coded the data?	8
Description of the coding tree	25	Did authors provide a description of the coding tree?	10-11
Derivation of themes	26	Were themes identified in advance or derived from the data?	7
Software	27	What software, if applicable, was used to manage the data?	7
Participant checking	28	Did participants provide feedback on the findings?	8-9
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? e.g. participant number	Table 1
Data and findings consistent	30	Was there consistency between the data presented and the findings?	Table 1
Clarity of major themes	31	Were major themes clearly presented in the findings?	10, Table 1
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	10-11, Table1,2

APPENDIX 3: Examples of coding schema of the Stage 1 concept elicitation interviews

Participant quote	**Item**	**Top-level domain**	**Sub-domain**	**Theme**	**Sub-theme**
This one has been a real pain in the proverbial here, it's still aching, it has not stopped aching, it drives me insane at night because it, during the day I don't seem to notice it but at night it aches and it's still aching, it's aching up here today (Participant with osteoarthritis)	My hand has not stopped aching	Physical	Symptom	Pain	Type – ache
	My hand pain drives me insane at night	Physical	Function – experience	Sleep	Disturbed
Well in my hands it causes me disability, being unable to clothe myself, I have to have special knives and forks. I find that I find it difficult to do up buttons. I like writing and I find it difficult to write, but I do write (Participant with rheumatoid arthritis)	I have been unable to clothe myself	Physical	Function - Impact	ADL	Dressing
	I have special knives and forks	Physical	Function - Impact	Accommodation	Special knives, forks
	I find it difficult to do up buttons	Physical	Function - Impact	ADL	Dressing – buttons
	I find it difficult to write	Physical	Function - Impact	IADL	Writing
It's just I'm aware that it's going to hurt, and I don't like it. I uh, it saddens me, it depresses me, it's frustrating and it can be embarrassing (Participant with	It saddens me that my hand is going to hurt	Psychological	Distress	Being down	Sad
	My hand pain depresses me	Psychological	Distress	Being down	Depressed

carpal tunnel syndrome)	My hand pain is frustrating	Psychological	Distress	Irritation	Frustration
	My hand pain can be embarrassing	Psychological	Distress	Self-conscious	Embarrassing

ADL, activities of daily living; IADL, instrumental activities of daily living

APPENDIX 2: COREQ: Consolidated criteria for reporting qualitative research: a 32-item checklist for interviews and focus groups

Section/Topic	Item No	Checklist item	Reported on page No
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Domain 2: study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	6
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	6
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	6-7
Sample size	12	How many participants were in the study?	10
Non-participation	13	How many people refused to participate or dropped out? Reasons?	10
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	10
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	-
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	10
Data collection			
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Repeat interviews	18	Were repeat interviews carried out? If yes, how many?	
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	7
Field notes	20	Were field notes made during and/or after the interview or focus group?	7
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BMJ Open

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Complete List of Authors:	Sierakowski, Kyra; Flinders Medical Centre, Plastic & Reconstructive Surgery Kaur, Manraj; McMaster University, School of Rehabilitation Science Sanchez, Kathleen; Flinders University Bain , Gregory; Flinders University Cano, Stefan; Modus Outcomes Griffin, Philip; Flinders University Klassen, Anne; McMaster University, Pediatrics Pusic, Andrea; Brigham and Women's Hospital Biomedical Research Institute Lalonde, Don; Dalhousie University Dean, Nicola; Flinders University, College of Medicine & Public Health; Flinders Medical Centre, Plastic & Reconstructive Surgery
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A qualitative study informing the development and content validity of the HAND-Q: a modular patient-reported outcome measure for hand conditions

AUTHORS:**

1. Kyra L. Sierakowski MD, PhD, Department of Plastic & Reconstructive Surgery, College of Medicine and Public Health, Flinders University, Adelaide, South Australia, Australia
2. Manraj N. Kaur PT, PhD, Department of Surgery, Patient-Reported Outcome, Value and Experience (PROVE) Center, Harvard Medical School, Brigham and Women's Hospital, Boston, Massachusetts, United States
3. Kathleen Evans Sanchez MD, Department of Plastic & Reconstructive Surgery, College of Medicine and Public Health, Flinders University, Adelaide, South Australia, Australia
4. Gregory I. Bain MBBS, PhD, Department of Orthopaedic Surgery, Flinders University, Adelaide, South Australia, Australia
5. Stefan Cano PhD, Modus Outcomes, Letchworth Garden City, United Kingdom
6. Philip A. Griffin MBBS, FRACS, Department of Plastic & Reconstructive Surgery, Flinders Medical Centre, Adelaide, South Australia, Australia
7. Anne Klassen DPhil, Faculty of Health Sciences, McMaster University, Hamilton, Ontario, Canada
8. Andrea Pusic, MD, MHS, Department of Surgery, Patient-Reported Outcome, Value and Experience (PROVE) Center, Harvard Medical School, Brigham and Women's Hospital, Boston, Massachusetts, United States
9. Don Lalonde MD, Department of Plastic Surgery, Dalhousie University, Saint John, New Brunswick, Canada
10. Nicola R. Dean MBChB, PhD, Department of Plastic & Reconstructive Surgery, College of Medicine and Public Health, Flinders University, Adelaide, South Australia, Australia

**Drs. Sierakowski and Kaur share the first authorship of this manuscript

CORRESPONDING AUTHOR: Kyra L. Sierakowski, Department of Plastic & Reconstructive Surgery, College of Medicine and Public Health, Flinders University, Adelaide, South Australia, Australia, kyra.sierakowski@flinders.edu.au

RUNNING HEAD: Development of the HAND-Q

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ETHICS APPROVAL STATEMENT: Ethics approval for this study was obtained at all of the participating sites: Australia, Southern Adelaide Clinical Human Research Ethics Committee (Reference Number 003.17 HREC/17/SAC/5); Canada, Horizon Health Network Research Ethics Board (File # RS-2017-2499) the US, Office of Research and Innovation, Lehigh Valley Health Network, Allentown, Pennsylvania (United States, Reference STUDY00000046).

ABSTRACT

Objectives: The purpose of this study was to identify and understand the issues that are relevant to patients with hand conditions. The data were used to develop a patient-reported outcome measure (PROM) for adults with hand conditions (HAND-Q) and refine it with input from patients and clinician experts.

Design: Semi-structured qualitative interviews were used to understand what matters to patients. Cognitive debriefing was used to refine preliminary HAND-Q scales.

Setting: Hand clinics in tertiary healthcare centres in Canada, Australia, and United States.

Participants: Eligible participants were English-speaking adults who were able to provide informed consent and had hand surgery in the preceding 12 months and at least 4 weeks had passed since their hand surgery. A total of 62 in-depth interviews (females, n=24; mean age = 65 years) were conducted to develop an item pool and draft the HAND-Q scales. The preliminary scales were refined through cognitive debriefing interviews with 20 participants and feedback from 25 clinician experts. All interviews were audio-recorded, transcribed verbatim and coded using a line-by-line approach.

Results: Qualitative data analysis resulted in 3008 unique codes, which were organized into two top-level domains of HRQL and satisfaction with treatment outcomes. The scales were refined iteratively, and the field-test version included 319 unique items and 20 independently functioning scales.

Conclusions: The HAND-Q is a comprehensive PROM developed using extensive patient and expert input and established guidelines for PROM development and validation. In the next phase, the psychometric properties of the HAND-Q will be established in an international field

test, following which the HAND-Q will be available for use in clinical research and practice at no charge.

ARTICLE SUMMARY

Strengths and limitations

- The development of HAND-Q included in-depth input from a heterogeneous, international sample of adult patients with diverse hand conditions.
- The comprehensibility, comprehensiveness, and relevance of the field-test version of the HAND-Q was established using extensive feedback from patients with hand conditions and clinician experts.
- Patients with rare hand conditions (e.g., congenital deformities, hand amputation or brachial plexus injuries) were not included in the development of the HAND-Q, and further validation work will be required.
- Only English-speaking patients from high income countries were included and the scales will need to be examined for content validity and psychometrics in diverse patient populations.

INTRODUCTION

Any condition or injury of the hand can significantly impact the health-related quality of life (HRQL) of an individual. While several objective and performance-based measures exist to assess the impact of hand conditions and their treatment on the range of motion, strength, dexterity, sensation, and functional impairment, the impact on an individual's HRQL is best assessed by asking patients directly. Patient-reported outcome measures (PROMs) are questionnaires that are used to assess HRQL in clinical practice and research. The data collected from PROMs can be used to understand, monitor, and communicate the impact of a condition on patients and enhance shared decision-making, resulting in better treatment outcomes overall (1).

A recent systematic review designed to identify all PROMs relevant to the field of hand surgery identified 24 PROMs for upper extremity conditions (2). Most commonly used PROMs in hand conditions included the Disabilities of the Arm, Shoulder and Hand (DASH), the Michigan Hand Outcomes Questionnaire (MHQ), and the Patient-rated Wrist/Hand Evaluation (PRWHE). However, these three PROMs have important limitations. The DASH, MHQ, and PRWHE were developed in the 1990s using the traditional classical test theory (CTT) approach. Importantly, qualitative interviews with patients with hand conditions were not a part of these instruments' development, which countermands the recommendations of the Medical Outcomes Trust and the United States Food and Drug Administration (3-5). Further, increasingly modern psychometric methods that involve Rasch Measurement Theory (RMT) or Item Response Theory analysis are used to develop scales that form clinical hierarchies and have interval level measurement properties. Modern approaches to scale development allow for meaningful and interpretable measurement of change in patient status, which is difficult for scales developed using the CTT approach.

To overcome the limitations of existing instruments, our team developed a PROM for hand conditions called the HAND-Q. The HAND-Q is intended to be used in clinical care, research and quality improvement initiatives in acute and chronic care of adults with hand conditions. The modular

construction of the HAND-Q means that the practitioner can choose the scales of relevance for a particular application. It is anticipated that the HAND-Q will be implemented in hospital and private hand clinics that manage hand conditions surgically and non-surgically. The detailed study protocol for the development of HAND-Q is published elsewhere (6). This paper aims to describe the results of the first phase of the development of the HAND-Q - a qualitative study to develop and refine the HAND-Q scales - which will be tested psychometrically in a subsequent international field-test study.

METHODS

The ethics approvals for this study were obtained from the Southern Adelaide Clinical Human Research Ethics Committee (Australia, Reference HREC/17/SAC/5), Horizon Health Network Research Ethics Board (Canada, Reference 2017-2499) and Office of Research and Innovation, Lehigh Valley Health Network, Allentown, Pennsylvania (United States, Reference STUDY00000046). The first phase of the HAND-Q development was completed in three steps: 1) development of the conceptual framework, 2) scales formation, and 3) pilot testing to establish content validity with feedback from patients and experts. The COnsolidated criteria for REporting Qualitative research (COREQ) Checklist (7) was used to report the results.

Approach

We used the applied health services approach of interpretive description (8) to design, conduct, and analyse the qualitative study results. Interpretive description acknowledges pre-existing theoretical and clinical knowledge informing a study, which was appropriate in our study given that much is known already about the impact of hand condition on individual's HRQL. This approach also aims to produce knowledge relevant to the clinical context with the provision that a patient's understanding of a concept is of the most significant importance, regardless of the clinical or theoretical explanation (9).

Stage 1: Development of the conceptual framework

Study participants and recruitment

English-speaking adults (18 years or older) who had had surgery on one or both hands in the preceding 12 months and were at least four weeks post-hand surgery were recruited from tertiary healthcare centres in Adelaide, Australia, and Saint John, New Brunswick, Canada. The limit of 12 months was imposed to ensure that the HRQL issues were relevant and there was minimal recall bias. Although the HAND-Q is designed to be used for all patients with hand conditions (and not just those who have surgical treatment for their condition) the experience of surgery themes to be explored in the interviews required that participants had experienced surgical management. Patients who were unable to provide informed consent due to a language barrier or cognitive impairments were excluded. The recruitment followed a purposive sampling strategy to ensure heterogeneity by targeting key demographic (age, gender) and clinical variables (hand condition), funding (public versus private), and type of anesthesia used for surgery (general anesthesia /sedation, or local anesthesia). Patients were screened for eligibility by treating clinician(s) or the clinic's administrative staff and informed of the study objectives and procedures by a member within their clinical circle of care. The contact information for patients who expressed an interest in participation was shared with the study research coordinator, who then contacted the patient, explained the study in detail including the credentials of the interviewer, answered study-specific questions, and obtained written consent for participation.

Data collection

A semi-structured interview guide (Supplementary materials, Appendix 1) was developed to elicit in-depth information on the treatment and experience of living with their hand condition, specifically concerning HRQL (physical, psychological, social, and sexual well-being) and satisfaction (appearance and process of care). Interview probes were used to guide the patient's description of the treatment outcomes or to elicit detailed answers. The probes were informed by the clinical expertise of the study team and the concepts identified in the systematic review. (6, 10). In-depth, qualitative interviews

were conducted in-person or over the telephone by an experienced qualitative interviewer (KS, cisfemale) with no relationship to the participants using the interview guide (5). The participants were asked to describe their experiences of living with their hand condition, including any treatments. The interviews were audio-recorded and transcribed verbatim, with identifying information removed.

Data analysis and rigor

The data collection and analysis took place concurrently to explore the relevance and importance of the emerging concepts identified during the interviews. Inductive content analysis of the interview transcripts was completed using a 'line-by-line' approach in Microsoft Word, Version 2019 (Microsoft Corp., WA, USA). Participants' quotes about any aspect of outcome or experience of care were copied into a Microsoft Excel spreadsheet Version 2019 (Microsoft Corp., WA, USA), along with demographic and clinical information. Constant comparison was used to identify common concepts of interest, and the data were categorized into conceptual top domains, sub-domains, and major and minor themes (11). The interviews were coded by one experienced qualitative researcher and checked by another team member. Codes were confirmed after discussion with the senior author (AK), who oversaw the analysis. To ensure rigor, the data analysis results were reviewed with the members of the study team throughout the study (12). Interviews continued until saturation was achieved; that is, no new concepts were identified in subsequent interviews (13).

Stage 2: HAND-Q scale formation

The conceptual framework and the coded data developed in Stage 1 were used to create items for the identified domains. For item development, efforts were made to retain the participants' language as much as possible. To ensure that the items were clear, easy to understand, and resonated with patients, we avoided double-barrelled items, or items with technical jargon or slang. For scale development, the theoretical underpinnings of the Rasch Measurement Theory were adopted (14). The RMT approach to scale development requires that the items map out a concept of interest through a clinical hierarchy (measuring from a little to a lot of a concept). Therefore, each item was

designed to measure the concept of interest in varying amounts. For example, in the Physical Function scale, the items range from those that would be easy to endorse for most people with a hand problem (e.g., eating with your hand(s)) to more challenging (e.g., eating with cutlery) to the most difficult to endorse (e.g., opening a jar).

The response options for the HAND-Q scales were limited to four options for simplicity and per recommended guidelines (15). We deliberately did not include a neutral response option. The amount of the construct measured by a neutral option is unclear and does not fit the mathematical model of RMT.

Stage 3: Pilot testing of HAND-Q scales for content validity

Patient input – cognitive interview

A new sample of patients with hand conditions using the same eligibility criteria and recruitment strategy from Stage 1 was recruited from Allentown, Pennsylvania, United States. Ethics approval was obtained from the Lehigh Valley Health Network Institutional Review Board. Participants from Australia and Canada who took part in Stage 1 were also invited to participate in cognitive interviews. Relevant HAND-Q scales were sent to the participants before the interview. An interview guide was used, and the interviews were conducted by an experienced qualitative interviewer by telephone. The 'think aloud' technique (16, 17) was used, whereby the scales were reviewed item-by-item, and the participants were asked to comment on the clarity, ease of understanding, and relevance of the title, instructions, timeframe, response options, and items. Where appropriate, participants were asked to paraphrase the items in their own words and provide examples from their treatment experience. Participants were also asked to nominate missing items (if any) and comment on the comprehensiveness of each scale.

The interviews were conducted in three consecutive rounds to allow for changes to be made to the scales in-between the rounds. The interviews were audio-recorded and transcribed verbatim, with

identifying information removed. The interview transcripts were analysed descriptively by one experienced qualitative researcher and checked by another team member. Relevant participant quotes pertaining to items were copied and pasted into a Microsoft Excel spreadsheet. An item tracking matrix (18) was used to document the changes made to the items between rounds of interviews. Data saturation was thought to be reached when participants did not recommend any further changes to the HAND-Q scales.

Expert Opinion – Online survey

We sought feedback from healthcare professionals with expertise in treating hand conditions (hereafter referred to as "experts") to ensure buy-in and affirm that the HAND-Q scales comprehensively explored clinically important issues. A multidisciplinary team of experts was identified through the professional networks of the study investigator team and invited via email to participate in an online Research Electronic Data Capture (REDCap) (19) survey. The experts were asked to review scales one at a time and comment on the relevance, comprehension, and comprehensibility of its content. Non-respondents were sent a reminder one week later. Two rounds of expert surveys were completed between the first and second rounds of patient cognitive interviews. The feedback from experts was analysed descriptively by one experienced qualitative researcher and checked by another member of the team and used to refine the HAND-Q scales.

Patient and public involvement

The HAND-Q has been developed with patients as central focus and with patient input vital throughout the development process. An international group of patients were engaged in all stages of the development of the HAND-Q. The input of patients in stage 1 qualitative interviews was fundamental to the scale formation, with patients' words providing the content for the item development in stage 2. Feedback from patients in stage 3 helped to refine the scales. Regular team de-briefs were conducted with the team members throughout the three stages.

RESULTS

Stage 1: Development of the conceptual framework

The qualitative interviews took place between June and November 2017; the mean interview time was 34 minutes (range 12 to 61). A total of 62 (females, n=34, 55%) in-depth qualitative interviews with 40 participants in Australia and 22 in Canada were conducted. The mean age of the participants was 65 ± 11 years (range, 28 to 86). The participants' diagnoses included carpal tunnel (n=20), Dupuytren's contracture (n=14), trigger finger (n=8), osteoarthritis (n=8), trauma (n=7) and other less common conditions (n=4). Further demographic information available in Table 1. The completed COREQ checklist is provided in the Supplementary materials (Appendix 2). The Supplementary materials also include an example of how the interview data were coded and categorized into domains and themes (Appendix 3).

The analysis of the interview data resulted in 3008 unique codes, which were organized into top-level domains of HRQL and satisfaction with treatment outcomes (Figure 1). The HRQL top-level domain (n=1498 unique codes) was categorized into the sub-domains of physical well-being (943 codes), psychological well-being (324 codes), and social well-being (231 codes). The satisfaction top domain included sub-domains of satisfaction with appearance (385 codes), overall outcome (36 codes), process of care (486 codes), anesthesia (258 codes), and hand splint or brace (22 codes). Table 2 shows the conceptual framework of the HAND-Q with supportive data from the qualitative interviews.

Stage 2: Scales formation

The conceptual framework was used to develop the first draft of the HAND-Q scales. Item generation was based on content from participant interviews and the participants' wording was maintained as much as possible. A total of 20 scales were developed to measure the concepts identified in Stage 1. The full list of scales is shown in Table 3.

Stage 3: Pilot testing of HAND-Q scales for content validity

Cognitive interviews were conducted to review draft scales with patients. The draft scales were reviewed and discussed in detail to ensure that the scales were measuring the concepts important to patients in an easy-to-understand format. Any instructions or items that caused confusion were subsequently altered to improve the interpretability of the scales. A total of 20 cognitive interviews in three rounds were performed with patients between January 1, 2018, and February 28, 2018. Participants were in Australia (n=9), Canada (n=7), and the United States (n=4). The majority of the participants were females (n=13, 65%), and the mean age of the sample was 60 ± 12 years (range, 32 to 76 years). Participants were seeking or had received treatments for a range of hand conditions, including carpal tunnel (n=9), Dupuytren's contracture (n=3), trigger finger (n=3), osteoarthritis (n=7), trauma (n=5), and other less common conditions (n=3). Further demographic information is available in Table 4.

A total of 25 experts provided input in two rounds (round 1, n=14) on the content of the HAND-Q scales. Figure 2 shows the composition of experts for each round. A summary of the number of items that were added, retained, revised, or dropped is shown in Table 3. The field-test version of the HAND-Q consists of a total of 319 unique items organized into 20 independently functioning scales (Supplementary materials, Appendix 4).

DISCUSSION

In-depth qualitative interviews were conducted with an international sample of patients with hand conditions to gain a comprehensive understanding of the range of treatment outcomes and experience of care-related concepts. The qualitative data were used to develop a conceptual framework, which was used to develop a draft of the HAND-Q, a comprehensive PROM for patients

with hand conditions. The draft version of HAND-Q was refined through patient and expert feedback, and content validity was demonstrated.

We adopted a patient-centred approach for this study, where patients were engaged in content generation and refining of the HAND scales. Measuring what matters to patients is fundamental to understanding the burden of hand conditions and providing effective and efficient care that aligns with patients' treatment preferences and values. Due to HAND-Q's "bottom-up" approach, we were able to identify and develop scales for concepts that are either missing or incompletely assessed in the existing hand-specific PROMs to-date (2). For example, the HAND-Q has a unique scale that measures the impact of hand condition on someone's sexual life. Items in this scale ask about the had problem being a distraction during sexual activity or interfering with the ability to give pleasure. Since hands are a part of the body that are difficult to hide, participants in our study described feeling embarrassed and self-conscious about their hand condition. The HAND-Q measures appearance of hands (e.g., size, shape of fingers and thumbs, how the hands look when holding a glass or resting the palms on a table) to provide a means to evaluate treatments that change how the hand looks.

Another unique strength of the HAND-Q is that the development of the scales was embedded within the principles of a modern psychometric approach (i.e., RMT), resulting in independently functioning scales. To elaborate, the negative impact of injuries and conditions of the hand on psychological well-being has been well-established in the literature (20-22). Existing PROMs, such as the DASH (23), PRWHE (24), and the (MHQ) (25), measure the impact of condition or treatment on psychological well-being with the help of a single item rather than a scale. When the raw score for the single item on psychological well-being is added to raw item scores of unrelated constructs to produce a total score, it makes it impossible to ascertain the impact of the condition or treatment on patients' psychological well-being. Further, it makes it challenging for clinicians and researchers to interpret the total score, discouraging them from using PROMs. In contrast, the HAND-Q includes one independently

functioning scale with items that measure only one construct – psychological function – resulting in more targeted measurement. The modular design allows the clinicians to choose the scales that are most relevant to their clinical practice or research question, reducing patient burden. Additionally, as the field of hand surgery evolves and new concepts of interest are identified, the modular design allows for new scales to be added to the HAND-Q, keeping it relevant ("fit for purpose") over time.

Our study is not without limitations. The study sample is not representative of the full breadth of hand conditions seen in the clinical practice. While the common conditions such as carpal tunnel syndrome, Dupuytren's contracture and trigger finger were included, rarer hand conditions such as congenital anomalies or brachial plexus injury were not. Non-surgical patients were excluded from the study; however, this was strategic as post-operative patients are able to describe their pre-operative (i.e., non-surgical) and post-operative experience with the hand condition and it's HRQL impact. Further qualitative work would be required to examine the content validity and other psychometric properties of the HAND-Q scales in the clinical populations not included in this study. Further, we only included English-speaking participants from three developed countries with similar economic and cultural environments. To ensure that the HAND-Q scales are relevant globally, the scales have been translated and culturally adapted to a number of languages in preparation for an international field-test study. RMT analysis will be used to examine differential item functioning by language to determine if the HAND-Q works the same across country.

The next phase of HAND-Q development is an international field test that is currently underway in Australia, Canada, Finland, France and the United States. The data from the field test will be analysed using RMT analysis, and the psychometric properties of reliability and validity will be examined. Once the scales are finalized, they will be made available at no charge for not-for-profit clinical and research use through www.qportfolio.org.

CONCLUSION

The HAND-Q is a comprehensive PROM that was developed with extensive patient and expert input. The content validity of the HAND-Q was demonstrated, and the scales were found to be relevant, comprehensive, and comprehensible. The measurement properties of reliability and validity will be examined following an international field test study that includes patients with diverse hand conditions. Once the HAND-Q is finalized, we anticipate that it will be implemented in clinical practice, research, and quality improvement initiatives to examine the clinical effectiveness of hand-related interventions, improve patient-clinician interactions, inform patient education, ultimately enhancing patient-centred care.

FIGURE LEGEND

Figure 1: Conceptual framework of the HAND-Q (n= 3008 unique codes)

Figure 2: Composition of expert panel in the rounds of refining of the scale

TABLE 1: Demographics of participants in Qualitative Interviews

		Australian	Canadian	Total
Number of participants		40	22	62
Age				
	Average	63	67	65
	Range	38 - 78	27 - 85	27 - 85
Gender				
	Male	18	10	28
	Female	22	12	34
Hand condition				
	Trigger finger	4	4	8
	OA	8	0	8
	RA	1	0	1
	CTS	8	12	20
	Trauma	6	1	7
	Dupuytren's	11	3	14
	Other	2	2	4
Funding				
	Public	17	22	39
	Private	23	0	23
Anaesthesia				
	Local only	7	21	28
	Sedation, GA	33	1	34

TABLE 2: Conceptual Framework of the HAND-Q with supportive participant quotes and examples

Top level domain	Subdomain	Major Theme	Minor theme	Categories (where applicable) and participant words and
Health-related quality of life	Physical (943 codes)	Symptoms	Pain	Intensity ("mild", "severe")
				Frequency ("all the time", "on and off"
				Type ("ache", "stinging", "burning", "cramp") "discomfort",
				Aggravating Factors (e.g., during activities, at rest, when
			Sensation	Lack of Sensation ("numb", "dead feeling")
				Abnormal Sensation ("buzzing", "going to sleep", "pins and
				Excessive Sensation ("sensitive")
			Weakness	("weak", "feeling tired")
		Function	Experience	Impaired mobility ("cannot make a fist", "unable to flatten
				Sleep ("pain drives me insane night")
				Power grip (e.g., holding mug or glass, carrying bags, turning
				Pinch grip (e.g., using cutlery, turning key, picking up fine
			Impact	Hygiene (e.g., wiping after using the toilet, using a towel after
				Chores (e.g., washing dishes, folding laundry, vacuuming)
				Dressing (e.g., doing up bra, buttoning a shirt, tying
				Recreational activities (e.g., crochet, gardening)
	Psychological (324 codes)	Emotional distress	Irritation	"…it does get a bit frustrating that it is ongoing"
			Being down	"sick of the same things", "can't take it anymore"
			Overwhelmed	"it has demolished me", "I can't go through this again"
			Self-conscious	"hide my hands", "I didn't want people to know I was wearing
		Acceptance	Accept	"it is what it is"
	Social (231 codes)	Isolation	Conceal – hand	"I don't like going out because I can't cut food"
		Function (incl. work)	Job loss	"I'd lost my typing role", "doctors deemed me unfit for work"
			Modify work	"I just run the machinery instead of using it"
		Relationships		"spouse took me to appointments", "spouse helped with
Appearance	Appearance (385 codes)	Hand region (i.e., fingers, thumb, palm, knuckles, skin, nails,	Size	"fat", "pudgy", "swollen", "large", "big", "skinny"
			Shape	"curled", "deformed", "misshaped"
			Colour	"red", "white", "pink"

			Contour	"distorted", "twisted", "stuck out", "curled", "crooked"
			Similarity	"match"
			Smoothness	"bumps", "lumps"
			Scenarios	"up close", "far away", "when waving hands", "in
			Age	"old", "wrinkled", "age spots", "veins stick out"
			Skin	"tight", "taut"
			Qualitative	not right", "abnormal", "ugly", "imperfect"
Experience of care	Experience of Care (468 codes)	Pre-procedure information	Amount	"enough", "knew what to expect", "more needed"
			Format of delivery	"written", "might be more visual", "pamphlet", "information
			Accessibility	"easy to understand", "sufficient time to review"
			Nature of	e.g., details of the procedure, type of anesthesia, what to do
		Satisfaction- Hand	Description	professional", "kind", "friendly", "attentive", "easy to talk to",
			Nature of	"feeling heard", "feeling unrushed", " included in decisions"
		Satisfaction - Hand	Overall	"nice atmosphere", "clean", "sterile", "ease of booking
		Satisfaction - Office	Overall	"on schedule", "worked as a team", "made me feel
Anesthesia	Anesthesia (258 codes)	Experience	Worry – not	"amount of anesthetic not being enough", "feeling pain"
			Worry – recovery	e.g., impact on daily activities
		Post-anesthesia	Type and	"feeling sleepy", "tired", "down", "Irritable", "unwell",
		Awake procedure	Administration	"pain", "tingly", "warm"
			Sensation at the	"pain"
			Distress	Seeing blood or surgical equipment - "worried", "anxious"
			Environment	Operating room - "comfortable", "clean", "sterile"
			Ability to ask	
Treatment	Hand Splint or Brace (22 codes)	Appearance of hand	Qualitative	"people don't look at the hand", " made my hand look
		Cleaning splint or	Qualitative	"it looks filthy because you cannot clean it"
		Donning and doffing		"cumbersome", "irritating", "uncomfortable", "pain", “stuck”
		Perform daily activities		e.g., being physically active, sleep, socialize, dress, and care
		Financial burden		"Expensive"
	Outcome (36 codes)	Appraisal		glad", "pleased", "satisfied", "changed my life", "met expectations"

TABLE 3: Summary of the number of items that were added, retained, revised, or dropped during the refining of the HAND-Q scales

	Response	Recall	Initial	Items	Items	Items	Items
Health-Related Quality of Life scales							
Function	Difficulty	Past week	34	3	14	2	35
Symptoms	Severity	Past week	18	6	17	2	22
Psychological	Frequency	Past week	16	3	0	0	19
Life impact	Severity	Past week	9	2	1	0	11
Sleep	Frequency	Past week	8	1	3	1	8
Social	Agree/Disagree	Past week	13	0	4	0	13
Sexual	Bothered	None	9	0	0	0	9
Work	Agree/Disagree	None	9	2	3	0	11
Acceptance	Agree/Disagree	None	7	0	6	0	7
Appearance scale							
Appearance	Satisfaction	Now	29	1	10	0	30
Experience of care scales							
Anesthesia	Bothered	None	17	0	5	3	14
Post-anesthesia	Severity	None	12	2	0	1	13
Awake procedure	Satisfaction	None	17	1	8	1	17
Information	Satisfaction	None	21	1	7	2	20
Surgeon	Agree/Disagree	Recent	25	1	8	1	25
Hand therapist	Agree/Disagree	Recent	20	1	4	2	19
Hand clinic	Agree/Disagree	Recent	14	0	3	1	13
Office staff	Agree/Disagree	Recent	13	1	2	0	14
Hand treatment scales							
Overall outcome	Agree/Disagree	Most recent	10	0	13	1	9
Splint	Satisfaction	Most recent	11	2	1	1	12
Total			312	28	109	15	319

TABLE 4: Demographics of participants in Cognitive Interviews

		Australian	Canadian	American	Total
Number of participants		9	7	4	20
Age					
	Average	61	64	56	60
	Range	47 - 76	55 - 76	32 - 76	32-76
Sex					
	Male	3	2	2	7
	Female	6	5	2	13
Hand condition					
	Trigger finger	1	1	2	3
	OA	4	2	3	7
	RA	1	0	0	1
	CTS	2	5	7	9
	Trauma	2	2	3	5
	Dupuytren's	2	1	1	3
	Other	1	1	2	3

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CONTRIBUTORS: KLS, ND, AFK and ALP conceptualized the study; AFK, ALP and SJC developed the methodology used for the development of the HAND-Q; KLS and KES conducted the interviews; KLS, KES, and AFK analysed the data, AFK led the development and refinement of the scales with assistance from all listed co-authors; GB,PG and DL helped with recruitment and provided content expertise, KLS and MNK wrote the manuscript, which was approved for submission by all listed co-authors.

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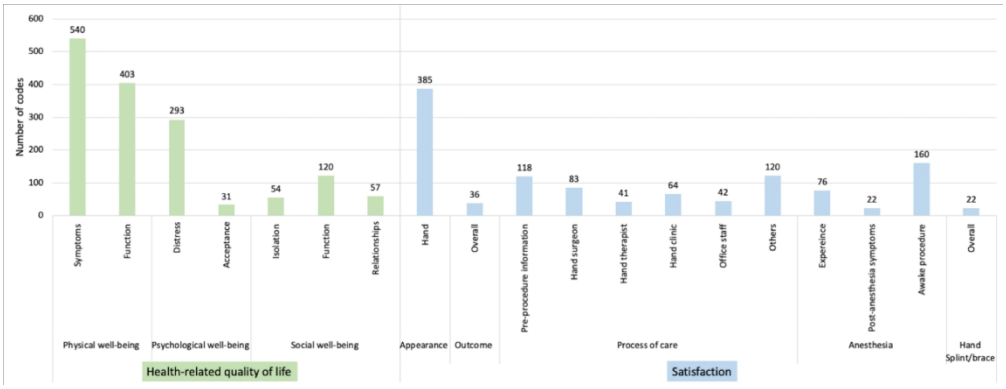
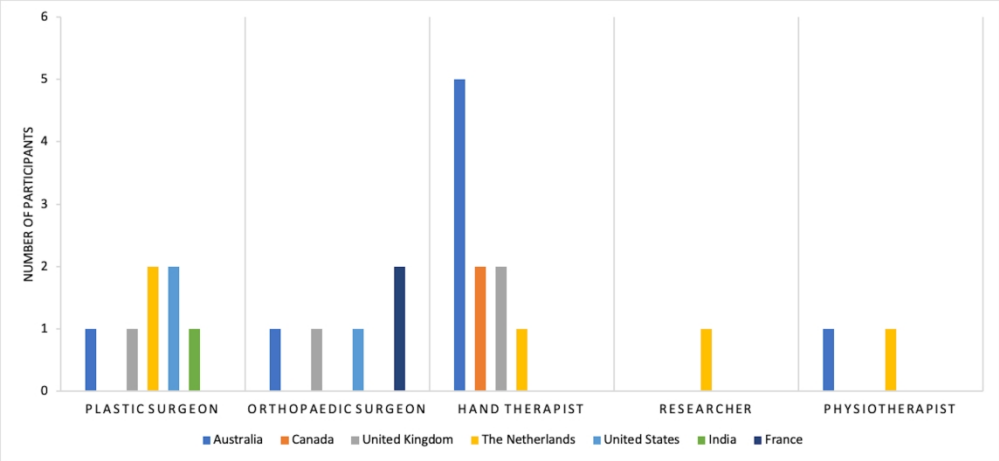


Figure 1: Conceptual framework of the HAND-Q (n= 3008 unique codes)

274x104mm (300 x 300 DPI)



Caption : Figure 2: Composition of expert panel in the rounds of refining of the scale (Rounds 1 and 2)

228x105mm (300 x 300 DPI)

Supplementary material

Appendix 1
Interview Guide for qualitative interviews performed in phase 1

Experience of care

1. What treatments have you had for your condition?
2. What was good or bad about the treatment?
3. If the participant has had surgery:
    a. What was your experience of the anaesthetic used? Probe: general anaesthetic, block, local
    b. Would you have considered having treatment under local anaesthetic? Probe: why, why not
4. Who do you see when you come to the hospital clinic? Probe: receptionist, nurse, doctor, occupational therapist
5. What are the people like who care for you? Probe: friendly, made you feel comfortable, easy to talk to, listened to you
6. What kind of verbal and written information did they give you? Probe: gave enough information, let you ask questions, answered your questions, provided information about recovery

Physical function

1. Does your condition create any functional problems? Probe: work, personal care, hobbies
2. What specific things do you have difficulty with due to your hand problem? Probe: getting dressed, cooking, typing, sport
3. Do you experience any symptoms related to your functional problem? Probe: pain, discomfort, embarrassment, mood disturbance

Psychological well-being

1. How does your hand problem make you feel? Probe: frustrated, angry, upset, worried, stressed
2. How does your hand problem make you feel about yourself? Probe: self esteem, body image, confidence, self-conscious, different from others

Appearance

1. How would you describe the appearance of your hand/s? Probe: from close up, from far away, symmetry, texture, attractiveness
2. How has your hand appearance changed since your treatment? Probe: scarring, descriptive detail
3. What do you like or dislike about your hand appearance?
4. Is there anything about your hand appearance that you would like to change? Probe: for details
5. Do you ever hide your hands? How do you do this?

6. How important is the appearance of your hands to you?

Other

1. Is there anything I have not asked you that you think it is important for me to know?
2. Would you like to receive a copy of the transcript from today's discussion?
3. Would you be interested in participating in Cognitive Interview?

APPENDIX 2: COREQ: Consolidated criteria for reporting qualitative research: a 32-item checklist for interviews and focus groups

Section/Topic	Item No	Checklist item	Reported on page No
Domain 1: Research team and reflexivity			
Personal Characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?Interviewer/facilitator	7
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	Title page
Occupation	3	What was their occupation at the time of the study?	Title page
Gender	4	Was the researcher male or female?	Not relevant
Experience and training	5	What experience or training did the researcher have? Relationship with participants	7
Relationship with participants			
Relationship established	6	Was a relationship established prior to study commencement?	7
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	7
Interviewer characteristics	8	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	7
Domain 2: study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	6
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	6
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	6-7
Sample size	12	How many participants were in the study?	10
Non-participation	13	How many people refused to participate or dropped out? Reasons?	10
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	10
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	-
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	10
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Supplementary material
Repeat interviews	18	Were repeat interviews carried out? If yes, how many?	
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	7
Field notes	20	Were field notes made during and/or after the interview or focus group?	7
Duration	21	What was the duration of the interviews or focus group?	10
Data saturation	22	Was data saturation discussed?	8
Transcripts returned	23	Were transcripts returned to participants for comment and/or	-

		correction?	
Domain 3: analysis and findings Data analysis			
Number of data coders	24	How many data coders coded the data?	8
Description of the coding tree	25	Did authors provide a description of the coding tree?	10-11
Derivation of themes	26	Were themes identified in advance or derived from the data?	7
Software	27	What software, if applicable, was used to manage the data?	7
Participant checking	28	Did participants provide feedback on the findings?	8-9
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? e.g. participant number	Table 1
Data and findings consistent	30	Was there consistency between the data presented and the findings?	Table 1
Clarity of major themes	31	Were major themes clearly presented in the findings?	10, Table 1
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	10-11, Table1,2

APPENDIX 3: Examples of coding schema of the Stage 1 concept elicitation interviews

Participant quote	**Item**	**Top-level domain**	**Sub-domain**	**Theme**	**Sub-theme**
This one has been a real pain in the proverbial here, it's still aching, it has not stopped aching, it drives me insane at night because it, during the day I don't seem to notice it but at night it aches and it's still aching, it's aching up here today (Participant with osteoarthritis)	My hand has not stopped aching	Physical	Symptom	Pain	Type – ache
	My hand pain drives me insane at night	Physical	Function – experience	Sleep	Disturbed
Well in my hands it causes me disability, being unable to clothe myself, I have to have special knives and forks. I find that I find it difficult to do up buttons. I like writing and I find it difficult to write, but I do write (Participant with rheumatoid arthritis)	I have been unable to clothe myself	Physical	Function - Impact	ADL	Dressing
	I have special knives and forks	Physical	Function - Impact	Accommodation	Special knives, forks
	I find it difficult to do up buttons	Physical	Function - Impact	ADL	Dressing – buttons
	I find it difficult to write	Physical	Function - Impact	IADL	Writing
It's just I'm aware that it's going to hurt, and I don't like it. I uh, it saddens me, it depresses me, it's frustrating and it can be embarrassing (Participant with	It saddens me that my hand is going to hurt	Psychological	Distress	Being down	Sad
	My hand pain depresses me	Psychological	Distress	Being down	Depressed

carpal tunnel syndrome)	My hand pain is frustrating	Psychological	Distress	Irritation	Frustration
	My hand pain can be embarrassing	Psychological	Distress	Self-conscious	Embarrassing

ADL, activities of daily living; IADL, instrumental activities of daily living

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Appendix 4: HAND-Q© - FIELDTEST VERSION

APPEARANCE

	Very dissatisfied	Somewhat dissatisfied	Somewhat satisfied	Very satisfied
1. How your hands look from far away?	1	2	3	4
2. How the palms of your hands look?	1	2	3	4
3. How straight your fingers and thumbs look?	1	2	3	4
4. The size of your fingers and thumbs?	1	2	3	4
5. The shape of your fingers and thumbs?	1	2	3	4
6. How your fingers and thumbs line up with each other?	1	2	3	4
7. How well your fingers match each other?	1	2	3	4
8. How your fingernails look?	1	2	3	4
9. How your knuckles look?	1	2	3	4
10. The size of your knuckles?	1	2	3	4
11. The shape of your knuckles?	1	2	3	4
12. How your hands look when you rest your palms on a table?	1	2	3	4
13. How your hands look when you wave at someone?	1	2	3	4
14. How your hands look when you hold a glass?	1	2	3	4
15. How your hands look compared with other people's hands?	1	2	3	4
16. How normal your hands look?	1	2	3	4
17. How masculine or feminine your hands look?	1	2	3	4
18. How well proportioned your hands look (ie, all parts look the right size and shape)?	1	2	3	4
19. How the veins on the back of your hands look?	1	2	3	4
20. How noticeable the veins on the back of your hands are?	1	2	3	4
21. How the tendons on the back of your hands look?	1	2	3	4
22. How visible the tendons on the back of your hands are?	1	2	3	4
23. How the skin on your hands looks?	1	2	3	4
24. How taut (ie, firm) the skin on the back of your hands looks?	1	2	3	4
25. How smooth the skin on the back of your hands looks?	1	2	3	4
26. How blemish-free the skin on the back of your hands looks?	1	2	3	4
27. How youthful your hands look?	1	2	3	4
28. The age your hands look?	1	2	3	4
29. How your hands look from close up?	1	2	3	4
30. How your hands look overall?	1	2	3	4

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FUNCTION

	Not at all difficult	A little difficult	Moderately difficult	Extremely difficult
1. Placing your palms flat on a table?	1	2	3	4
2. Making a fist with your hand(s)?	1	2	3	4
3. Shaking someone's hand?	1	2	3	4
4. Clapping your hands?	1	2	3	4
5. Holding a phone to your ear?	1	2	3	4
6. Holding a book to read?	1	2	3	4
7. Holding a bag of groceries?	1	2	3	4
8. Plugging a cord into a socket?	1	2	3	4
9. Using a TV remote control?	1	2	3	4
10. Gripping handles (eg, tennis racket, golf club, broom)?	1	2	3	4
11. Picking up a coin?	1	2	3	4
12. Taking things out of a pocket?	1	2	3	4
13. Turning a door knob?	1	2	3	4
14. Turning a key in a lock?	1	2	3	4
15. Turning a tap (ie, faucet)?	1	2	3	4
16. Writing with a pen or pencil?	1	2	3	4
17. Typing?	1	2	3	4
18. Opening a jar?	1	2	3	4
19. Opening a small lid (eg, water or other beverage bottle)?	1	2	3	4
20. Washing the dishes?	1	2	3	4
21. Preparing food (eg, peeling, cutting)?	1	2	3	4
22. Eating with cutlery (eg, fork, spoon, knife)?	1	2	3	4
23. Eating with yours hand(s)?	1	2	3	4
24. Holding a glass?	1	2	3	4
25. Scratching an itch?	1	2	3	4
26. Washing your hands?	1	2	3	4
27. Brushing your teeth?	1	2	3	4
28. Clipping your fingernails?	1	2	3	4
29. Buttoning a shirt or coat?	1	2	3	4
30. Doing up a zipper?	1	2	3	4
31. Tying shoelaces?	1	2	3	4
32. Cleaning (eg, wiping) yourself after a bowel movement?	1	2	3	4
33. Putting on or taking off clothes?	1	2	3	4
34. Showering?	1	2	3	4
35. Personal grooming (eg, shaving, putting on make-up)?	1	2	3	4

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SYMPTOMS

	None	Mild	Moderate	Severe
1. Hands feeling itchy?	1	2	3	4
2. Hands feeling numb (ie, less feeling)?	1	2	3	4
3. Tingling in your hands (ie, pins and needles feeling)?	1	2	3	4
4. Hands feeling sensitive (ie, too much feeling)?	1	2	3	4
5. Hands feeling stiff?	1	2	3	4
6. Swelling or puffiness?	1	2	3	4
7. Cramping in your hands?	1	2	3	4
8. Hands feeling hotter or colder than normal?	1	2	3	4
9. Hands feeling weak (ie, lack of strength)?	1	2	3	4
10. Hands feeling achy?	1	2	3	4
11. Throbbing pain in your hands?	1	2	3	4
12. Stinging or burning pain in your hands?	1	2	3	4
13. Pain when you use your hands?	1	2	3	4
14. Pain when your hands are at rest?	1	2	3	4
15. Pain when your hands are touched?	1	2	3	4
16. Pain when the weather changes?	1	2	3	4
17. Hands feeling dry?	1	2	3	4
18. Hands feeling moist?	1	2	3	4
19. Clumsiness (eg, dropping or spilling things)?	1	2	3	4
20. Hand tremors (ie, shaking)?	1	2	3	4
21. Hand symptoms (eg, pain, numbness) disturbing your sleep?	1	2	3	4
22. Hands that are worse in cold weather?	1	2	3	4

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PSYCHOLOGICAL

	Never	Sometimes	Often	Always
1. Frustrated?	1	2	3	4
2. Upset?	1	2	3	4
3. Worried?	1	2	3	4
4. Concerned?	1	2	3	4
5. Sorry for yourself?	1	2	3	4
6. Depressed?	1	2	3	4
7. Irritated?	1	2	3	4
8. Angry?	1	2	3	4
9. Embarrassed?	1	2	3	4
10. Self-conscious?	1	2	3	4
11. Anxious?	1	2	3	4
12. Fed-up?	1	2	3	4
13. Overwhelmed?	1	2	3	4
14. Annoyed?	1	2	3	4
15. Stressed?	1	2	3	4
16. Unattractive?	1	2	3	4
17. Useless?	1	2	3	4
18. Hopeless?	1	2	3	4
19. Desperate?	1	2	3	4

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LIFE IMPACT

	Not at all	A little bit	Quite a bit	Very much
1. Being physically active?	1	2	3	4
2. Taking a bath or shower?	1	2	3	4
3. Being able to relax?	1	2	3	4
4. Sleeping at night?	1	2	3	4
5. Doing activities you enjoy?	1	2	3	4
6. Your emotional wellbeing?	1	2	3	4
7. Your mood?	1	2	3	4
8. Your ability to enjoy life?	1	2	3	4
9. Your social life?	1	2	3	4
10. Your close relationships?	1	2	3	4
11. Your ability to be independent?	1	2	3	4

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SLEEP

	Never	Sometimes	Often	Always
1. Had trouble falling asleep?	1	2	3	4
2. Had trouble staying asleep?	1	2	3	4
3. Had trouble finding a comfortable position to sleep in?	1	2	3	4
4. Woken up at night?	1	2	3	4
5. Not had enough sleep?	1	2	3	4
6. Taken medication to help you sleep?	1	2	3	4
7. Had symptoms (eg, pain, numbness) from your hands disturb your sleep?	1	2	3	4
8. Felt tired during the day?	1	2	3	4

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SOCIAL

	Definitely disagree	Somewhat disagree	Somewhat agree	Definitely agree
1. I stayed at home more than I would have liked.	1	2	3	4
2. I found it hard to get out and meet people.	1	2	3	4
3. I felt embarrassed about my hands.	1	2	3	4
4. I cut down on social activities I enjoy.	1	2	3	4
5. I saw friends less than I would have liked.	1	2	3	4
6. I missed out on social events.	1	2	3	4
7. I felt like I was a burden to family or friends.	1	2	3	4
8. I felt isolated from family or friends.	1	2	3	4
9. I felt that people did not understand what I go through with my hand problem.	1	2	3	4
10. I covered up or hid my hand(s).	1	2	3	4
11. My hand problem interfered with my ability to enjoy life.	1	2	3	4
12. I felt self-conscious about my hands around other people.	1	2	3	4
13. I avoided greetings (eg, waving or shaking hands).	1	2	3	4

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SEXUAL

	Not at all bothered	A little bothered	Moderately bothered	Extremely bothered
1. How your hands look?	1	2	3	4
2. Being able to use your hands in tender ways (eg, touch, hold)?	1	2	3	4
3. Limitations in hand function that can interfere with sexual activity (eg, grip, strength)?	1	2	3	4
4. Symptoms you feel in your hands that can interfere with sexual activity (eg, pain, numbness, tingling)?	1	2	3	4
5. Being aware of your hands during sexual activity?	1	2	3	4
6. Your hand problem affecting how much you enjoy sexual activity?	1	2	3	4
7. Your hand problem being a distraction during sexual activity?	1	2	3	4
8. Your hand problem interfering with your ability to give pleasure?	1	2	3	4
9. Your partner seeing your hands during sexual activity?	1	2	3	4

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WORK

	Definitely disagree	Somewhat disagree	Somewhat agree	Definitely agree
1. I was conscious of my hand(s) at work.	1	2	3	4
2. I worried about missing work.	1	2	3	4
3. I had to reduce the amount of work I do in a day.	1	2	3	4
4. It was hard for me to keep up with my work.	1	2	3	4
5. I had trouble performing my job.	1	2	3	4
6. I had to change how I do my job.	1	2	3	4
7. My work made my hand(s) worse.	1	2	3	4
8. I worried about losing my job.	1	2	3	4
9. The quality of my work has gone down.	1	2	3	4
10. I thought about quitting work.	1	2	3	4
11. I was not able to do my job.	1	2	3	4

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ACCEPTANCE

	Definitely disagree	Somewhat disagree	Somewhat agree	Definitely agree
1. I have learned to live with my hand problem.	1	2	3	4
2. My hand problem has become part of my life.	1	2	3	4
3. I have accepted my hand problem.	1	2	3	4
4. I get on with my life as best I can.	1	2	3	4
5. If my hand problem does not improve, I will be okay.	1	2	3	4
6. I have a positive attitude towards my hand problem.	1	2	3	4
7. I am fine with my hand problem.	1	2	3	4

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ANESTHESIA

	Not at all bothered	A little bothered	Moderately bothered	Extremely bothered
1. Time spent to prepare for the anaesthesia (eg, tests or appointments, forms, travel)?	1	2	3	4
2. Any pre-operative anxiety about having an anaesthetic?	1	2	3	4
3. Thoughts of embarrassing yourself during anaesthesia (eg, saying something inappropriate)?	1	2	3	4
4. The amount of anaesthetic you might be given (eg, if the operation took longer than normal)?	1	2	3	4
5. The chance that something could go wrong during the anaesthesia?	1	2	3	4
6. That you might feel pain during surgery (ie, if the anaesthetic is not effective)?	1	2	3	4
7. The affect the anaesthesia might have on your health?	1	2	3	4
8. The number of needles you had in total (ie, for blood tests and anaesthetic needles you felt during surgery)?	1	2	3	4
9. Any pain caused by the needle(s) used to give you the anaesthetic?	1	2	3	4
10. Any discomfort caused by the tight armband used during surgery (ie, tourniquet)?	1	2	3	4
11. How long it took to recover from the anaesthetic?	1	2	3	4
12. How long you had to wait in total at the hospital or clinic on the day of your surgery?	1	2	3	4
13. The impact of the anaesthesia on your productivity that day?	1	2	3	4
14. The impact of the anaesthesia on your ability to do your usual activities that day?	1	2	3	4

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POST-ANESTHESIA SYMPTOMS

	None	Mild	Moderate	Extreme
1. Nausea?	1	2	3	4
2. Vomiting?	1	2	3	4
3. Difficulty passing urine?	1	2	3	4
4. Constipation or diarrhoea?	1	2	3	4
5. Feeling sleepy?	1	2	3	4
6. Feeling tired or exhausted?	1	2	3	4
7. Feeling down or depressed?	1	2	3	4
8. Feeling irritable?	1	2	3	4
9. Feeling unwell?	1	2	3	4
10. Problems thinking clearly?	1	2	3	4
11. Trouble remembering?	1	2	3	4
12. Pain caused by the anaesthesia (eg, use of needles, breathing tube, arm or leg band)?	1	2	3	4
13. Numbness of the arm?	1	2	3	4

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AWAKE PROCEDURE

	Very dissatisfied	Somewhat dissatisfied	Somewhat satisfied	Very satisfied
1. Information you were given about how your surgery would be done?	1	2	3	4
2. Being awake during your surgery?	1	2	3	4
3. How the local anaesthetic injection(s) felt?	1	2	3	4
4. How good the local aneasthetic was at preventing pain?	1	2	3	4
5. How your surgery felt while it was taking place?	1	2	3	4
6. Being able to ask questions during your surgery?	1	2	3	4
7. Being able to take part in conversation during your surgery?	1	2	3	4
8. Noises from your surgery (eg, cutting into the hand)?	1	2	3	4
9. The amount of blood you saw?	1	2	3	4
10. How comfortable the surgical team made you feel?	1	2	3	4
11. The confidence you felt in the surgical team?	1	2	3	4
12. The room where you had your surgery (eg, sterile, comfortable)?	1	2	3	4
13. How long your surgery took?	1	2	3	4
14. How long you had to wait after your surgery before you could leave the hospital or clinic?	1	2	3	4
15. The total amount of time you spent at the clinic or hospital on the day of your surgery?	1	2	3	4
16. How long it took for the local anaesthetic to wear off?	1	2	3	4
17. Information you were given about how to care for your hand at home?	1	2	3	4

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INFORMATION

	Very dissatisfied	Somewhat dissatisfied	Somewhat satisfied	Very satisfied
1. Options for how the surgery could be done?	1	2	3	4
2. Who would be involved in your care (eg, doctor, nurse, hand therapist)?	1	2	3	4
3. How much pain you might feel during your recovery?	1	2	3	4
4. What to do if you have a complication (eg, infection, bleeding)?	1	2	3	4
5. How to care for your hand(s) when you bathe or shower?	1	2	3	4
6. How your surgery would be done?	1	2	3	4
7. The amount of time it would take to heal and recover?	1	2	3	4
8. How much you could use your hands during your recovery?	1	2	3	4
9. Knowing what activities you should avoid (eg, vigorous activity)?	1	2	3	4
10. How much your hands would change with surgery?	1	2	3	4
11. How to change behaviours that affect hand healing (eg, smoking, diet)?	1	2	3	4
12. How well your questions were answered?	1	2	3	4
13. The written information you were given?	1	2	3	4
14. How easy it was for you to ask questions?	1	2	3	4
15. How easy it was to understand the information you were given?	1	2	3	4
16. The timing of when you were given information (ie, told you what you needed to know at the right time)?	1	2	3	4
17. How likely the surgery would help you to achieve the goals you have for your hands?	1	2	3	4
18. The amount of time you had to discuss the information you were given?	1	2	3	4
19. That the information you were given by different members of the healthcare team was the same (ie, did not contradict each other)?	1	2	3	4
20. That the information given to you helped you to have realistic expectations about how your hands would change after surgery?	1	2	3	4

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SURGEON

	Definitely disagree	Somewhat disagree	Somewhat agree	Definitely agree
1. Made you feel comfortable?	1	2	3	4
2. Acted in a professional manner?	1	2	3	4
3. Was friendly and kind?	1	2	3	4
4. Was easy to talk to?	1	2	3	4
5. Talked to you in a way that was easy to understand?	1	2	3	4
6. Answered all your questions?	1	2	3	4
7. Treated you with respect?	1	2	3	4
8. Listened to you and understood your concerns?	1	2	3	4
9. Involved you in the decisions about your treatment?	1	2	3	4
10. Was attentive to your needs?	1	2	3	4
11. Tailored treatment to address your concerns?	1	2	3	4
12. Helped you figure out what was best for you?	1	2	3	4
13. Was available when you had concerns?	1	2	3	4
14. Spent enough time with you?	1	2	3	4
15. Made sure to protect your privacy?	1	2	3	4
16. Really cared about you?	1	2	3	4
17. Looked after your hand(s) carefully?	1	2	3	4
18. Knew your medical history?	1	2	3	4
19. Knew the history of your hand problem?	1	2	3	4
20. Was knowledgeable about hand problems?	1	2	3	4
21. Had the right amount of experience?	1	2	3	4
22. Knew what they were doing?	1	2	3	4
23. Inspired hope that your hand problem would improve with treatment?	1	2	3	4
24. Shared your information with other members of the healthcare team who needed it (eg, hand therapists, nurses)?	1	2	3	4
25. Consistently provided a high level of care?	1	2	3	4

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OFFICE STAFF

	Definitely disagree	Somewhat disagree	Somewhat agree	Definitely agree
1. Treated you with respect?	1	2	3	4
2. Made you feel comfortable?	1	2	3	4
3. Were knowledgeable?	1	2	3	4
4. Were attentive to your needs?	1	2	3	4
5. Were thorough?	1	2	3	4
6. Worked together as a team?	1	2	3	4
7. Welcomed you at the front desk?	1	2	3	4
8. Answered all your questions?	1	2	3	4
9. Were available when you had concerns?	1	2	3	4
10. Were friendly and kind?	1	2	3	4
11. Acted in a professional manner?	1	2	3	4
12. Treated you with respect over the phone?	1	2	3	4
13. Made sure to protect your privacy?	1	2	3	4
14. Were caring?	1	2	3	4

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HAND CLINIC

	Definitely disagree	Somewhat disagree	Somewhat agree	Definitely agree
1. Had a nice atmosphere (eg, welcoming, calm)?	1	2	3	4
2. Welcomed you at the front desk?	1	2	3	4
3. Was clean and sterile?	1	2	3	4
4. Was well organized?	1	2	3	4
5. Made it easy to book an appointment?	1	2	3	4
6. Kept your appointment as scheduled (ie, did not cancel or change)?	1	2	3	4
7. Was on time (ie, did not make you wait)?	1	2	3	4
8. Had enough healthcare staff?	1	2	3	4
9. Had consistent healthcare staff (ie, not constantly changing)?	1	2	3	4
10. Had healthcare staff that were knowledgeable about hand problems?	1	2	3	4
11. Was a place you would recommend to other people with hand problems?	1	2	3	4
12. Protected your healthcare information?	1	2	3	4
13. Provided a phone number you could use outside of office hours?	1	2	3	4

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HAND THERAPIST

	Definitely disagree	Somewhat disagree	Somewhat agree	Definitely agree
1. Acted in a professional manner?	1	2	3	4
2. Were friendly and kind?	1	2	3	4
3. Were easy to talk to?	1	2	3	4
4. Talked to you in a way that was easy to understand?	1	2	3	4
5. Listened to you and understood your concerns?	1	2	3	4
6. Answered all your questions?	1	2	3	4
7. Treated you with respect?	1	2	3	4
8. Spent enough time with you?	1	2	3	4
9. Involved you in the decisions about your treatment?	1	2	3	4
10. Were attentive to your needs?	1	2	3	4
11. Were caring?	1	2	3	4
12. Were knowledgeable about hand problems?	1	2	3	4
13. Had the right amount of experience?	1	2	3	4
14. Knew what they were doing?	1	2	3	4
15. Saw you at the scheduled time?	1	2	3	4
16. Looked after your hand(s) carefully?	1	2	3	4
17. Inspired hope that your hand problem would improve with treatment?	1	2	3	4
18. Knew the history of your hand problem?	1	2	3	4
19. Consistently provided a high level of care?	1	2	3	4

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OUTCOME

	Definitely disagree	Somewhat disagree	Somewhat agree	Definitely agree
1. I am glad that I had the hand treatment.	1	2	3	4
2. I am satisfied with the results.	1	2	3	4
3. Having the hand treatment changed my life for the better.	1	2	3	4
4. The outcome of my hand treatment met my expectations.	1	2	3	4
5. I would recommend the hand treatment I had to others.	1	2	3	4
6. The hand treatment was worth the time and effort it took.	1	2	3	4
7. The results of my hand treatment turned out great.	1	2	3	4
8. If necessary I would have this hand treatment again without any hesitation.	1	2	3	4
9. I am pleased with the outcome of my hand treatment.	1	2	3	4

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SPLINT

	Very dissatisfied	Somewhat dissatisfied	Somewhat satisfied	Very satisfied
1. How comfortable the splint was to wear?	1	2	3	4
2. How easy the splint was to put on?	1	2	3	4
3. How easy the splint was to remove?	1	2	3	4
4. How often you needed to replace the splint?	1	2	3	4
5. How the splint looked?	1	2	3	4
6. How much the splint cost?	1	2	3	4
7. Your ability to be physically active with the splint on?	1	2	3	4
8. Your ability to sleep with the splint on?	1	2	3	4
9. Your ability to socialize with the splint on?	1	2	3	4
10. Your ability to enjoy life with the splint on?	1	2	3	4
11. Your ability to dress yourself with the splint on?	1	2	3	4
12. Your ability to care for your hand with the splint on?	1	2	3	4

APPENDIX 2: COREQ: Consolidated criteria for reporting qualitative research: a 32-item checklist for interviews and focus groups

Section/Topic	Item No	Checklist item	Reported on page No
Domain 1: Research team and reflexivity			
Personal Characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?Interviewer/facilitator	7
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	Title page
Occupation	3	What was their occupation at the time of the study?	Title page
Gender	4	Was the researcher male or female?	Not relevant
Experience and training	5	What experience or training did the researcher have? Relationship with participants	7
Relationship with participants			
Relationship established	6	Was a relationship established prior to study commencement?	7
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	7
Interviewer characteristics	8	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	7
Domain 2: study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	6
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	6
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	6-7
Sample size	12	How many participants were in the study?	10
Non-participation	13	How many people refused to participate or dropped out? Reasons?	10
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	10
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	-
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	10
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Supplementary material
Repeat interviews	18	Were repeat interviews carried out? If yes, how many?	
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	7
Field notes	20	Were field notes made during and/or after the interview or focus group?	7
Duration	21	What was the duration of the interviews or focus group?	10
Data saturation	22	Was data saturation discussed?	8
Transcripts returned	23	Were transcripts returned to participants for comment and/or	-

		correction?	
Domain 3: analysis and findings Data analysis			
Number of data coders	24	How many data coders coded the data?	8
Description of the coding tree	25	Did authors provide a description of the coding tree?	10-11
Derivation of themes	26	Were themes identified in advance or derived from the data?	7
Software	27	What software, if applicable, was used to manage the data?	7
Participant checking	28	Did participants provide feedback on the findings?	8-9
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? e.g. participant number	Table 1
Data and findings consistent	30	Was there consistency between the data presented and the findings?	Table 1
Clarity of major themes	31	Were major themes clearly presented in the findings?	10, Table 1
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	10-11, Table1,2