




Development and Validation of a Patient-Reported Outcome Measure for Fingernail and Toenail Conditions: The NAIL-Q

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Background: Patient-reported outcome measures (PROMs) are needed to measure outcomes that matter to people with nail conditions, from their perspective.

Objective: To design a comprehensive new PROM (NAIL-Q) to measure outcomes important in toenail and fingernail conditions.

Methods: A mixed methods iterative approach was used. Phase 1 involved concept elicitation interviews that were audio-recorded, transcribed, and coded line-by-line. Concepts were developed into scales and refined through cognitive debriefing interviews with patients and expert input. Data was then collected from an international sample using a crowdsourcing platform. Eligible participants were aged ≥ 18 years with a nail condition for at least 3 months. Rasch Measurement Theory (RMT) analysis was used to examine item and scale performance. Other psychometric tests included test-retest reliability, and convergent and construct validity.

Results: Phase 1 interviews involved 23 patients with 10 nail conditions and input from 11 dermatologists. The analysis led to the development of 84 items for field-testing. In Phase 2, 555 participants completed the survey. Toenail conditions ($n = 441$) were more common than fingernail conditions ($n = 186$). The RMT analysis reduced the number of items tested to 45 in 7 scales measuring nail appearance, health-related quality of life concerns, and treatment outcomes. All items had ordered thresholds and nonsignificant chi-square p values. Reliability statistics with and without extremes for the Person Separation Index were ≥ 0.79 and Cronbach's alpha were ≥ 0.83 , and for intraclass correlation coefficients were ≥ 0.81 . Construct validity was further supported in that most participants agreed that the NAIL-Q was easy to understand, asked relevant and important questions in a respectful way, and that it should be used to inform clinical care.

Conclusion: The NAIL-Q is a rigorously designed and tested PROM that measures nail appearance, health-related quality of life and treatment outcomes. This PROM can be used in clinical practice to inform patient care and to include the patient perspective in research.

Keywords: validity, reliability, psychometrics, health-related quality of life

Introduction

Nail conditions are common in the population, affect people of all ages, and have a broad differential diagnosis.¹⁻⁷ Nail conditions can cause distress due to their cosmetic appearance, symptoms such as pain, reduced function and mobility, reducing one's health-related quality of life (HRQL).⁸⁻¹¹ Patient reported outcome measures (PROMs) are valuable tools that can be used to measure these concepts from the patient perspective.¹² PROMs are increasingly used in research studies to inform clinical care and improve health care quality.¹³⁻¹⁸

There are currently seven published PROMs for nail conditions.¹⁹⁻²⁵ Five PROMs were developed for onychomycosis, including the Onychomycosis-Specific Questionnaire,¹⁹ Health-Related Quality of Life Measure for Onychomycosis,²⁰ Onychomycosis Disease-Specific Questionnaire (ODSQ),²¹ NAILQoL,²² and the OnyCOE-t.²³ Two

PROMs were developed for nail psoriasis, including the Psoriasis Quality of Life Scale (NPQ10)²⁴ and the Nail Assessment in Psoriasis and Psoriatic Arthritis QOL (NAPPA-QOL).²⁵ A review that applied Consensus-based Standards for the selection of health Measurement Instruments (COSMIN) guidelines^{26,27} concluded that these seven PROMs had limited evidence supporting validity, reliability, and responsiveness.²⁸

A new PROM is needed to provide evidence about the impact and effectiveness of treatments for all types of nail conditions from the patient perspective. The aim of our study was to develop the NAIL-Q for use with patients with any type of fingernail or toenail condition using the Rasch Measurement Theory (RMT) approach.^{29,30}

Patients and Methods

Ethics Statement

Ethics board approval was obtained from the Hamilton Integrated Research Ethics Board approvals #7370 and #14622 and from Weill Cornell Medicine (New York, NY, USA).

Approach

We used a mixed methods approach³¹ and adhered to best practices guidelines for PROM development.¹²

Phase 1: Qualitative

In phase 1, Interpretative Description³² was used to generate knowledge relevant to a clinical context. Participants were recruited from a dermatology clinic in Canada and one in the USA and provided with a thank-you gift card for each task they helped with (ie, initial, cognitive, and final review), as described below. Research staff were asked to recruit a purposive sample of English-speaking adults who varied by age, gender, ethnicity, and nail conditions. Informed consent was obtained, and interviews were conducted by phone by a skilled qualitative researcher. A semi-structured interview guide was used and updated as new concepts were elicited ([Table S1](#)).

Interviews were audio-recorded, transcribed verbatim et literatim, and coded using a line-by-line approach. Concepts were labelled with a domain and major/minor theme using constant comparison to refine categories and form a conceptual framework.³³ Interviews continued until redundancy of concepts was reached.³⁴ Codes were used to develop items to form NAIL-Q scales. Scales were assigned instructions, a time frame for answering, and response options.

A series of cognitive debriefing interviews with patients were performed by phone/Zoom by two skilled qualitative interviewers. The think aloud method^{35,36} was used to determine if participants found the instructions, response options, and scale content easy to understand, relevant, and comprehensive.

Interviews were audio-recorded, transcribed verbatim et literatim, and coded. The scales were revised based on patient feedback and included in a REDCap survey³⁷ to which dermatologists with nail expertise were invited by email to review. To establish content validity, experts were asked to identify any content that they deemed would be hard to understand, not relevant to nail conditions, or missing.

To ensure changes suggested by experts were acceptable to patients, a REDCap survey was sent to the cognitive debriefing sample via email. Participants were asked to review the scale and identify any items that were hard to understand, not relevant or missing. Nonrespondents were emailed after one week, followed by a phone call one week later. Feedback was used to finalize the NAIL-Q field-test version.

Phase 2: Quantitative

Data for this phase were collected from Prolific Academic (www.prolific.co), an online crowd working platform. Participants were paid the equivalent of 10.50 sterling per hour. A short pre-screen survey was directed to Prolific participants fluent in English. Instructions asked people to complete the pre-screen if they had a fingernail and/or toenail condition for 3 months or longer for which they had seen a health professional in the past. Six images depicting common nail conditions were included, and people were asked to identify their nail condition from the images, or to indicate “other” or “not sure” ([Figure S1](#)).

Participants with any of the six nail conditions were invited to complete the full survey. This survey included demographics (age, gender, race, marital status, education, daily activity, and country) and clinical questions, including severity, sides and number of nails affected, and how long the condition had lasted. Single items asked about pain,

embarrassment, and activity interference. Participants were asked when they last saw a healthcare professional for their nail condition, and the number of appointments in the past 2 years. For seven treatments (topical medications, oral medications, biologics, laser, surgery, taping, injections, and clipping nails) participants were asked to indicate their status (ie, do not need, need, currently having, have had, had and need more). Those who had treatment were asked when they had treatment, and if the treatment made their condition better, the same, or worse.

For the NAIL-Q, participants whose nail condition affected fingernails and toenails completed the Appearance, Distress and Symptoms scales twice. The Outcome scale was completed by participants who had or were having treatment. The NAIL-Q was followed by six evaluation questions with disagree/agree response options: (1) asked questions in a respectful way, (2) was easy to understand, (3) was thorough, (4) asked questions that are important to me, (5) should be used by doctors treating people with nail conditions, and (6) would help my doctor better understand my nail condition. Finally, participants completed the generic EQ-5D-5L health-related quality of life utility PROM, which was scored using the USA normative values.³⁸ EQ-5D-5L includes 5 items (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) with five response options that range from one (no problem) to five (unable to/extreme problem).

At the end of the survey, participants were asked to participate in a test–retest (TRT) study. Late respondents (less than seven days from the initial survey) and those with missing scale data were not invited. We asked if there had been a change in their nail condition and if treatment had been initiated since the initial survey. We aimed to include 100 participants per scale.

The RMT analysis used RUMM2030 software and the unrestricted Rasch model for polytomous data (RUMM version 2030, RUMM Laboratory Pty Ltd, Duncraig, Western Australia, Australia, 1998–2021). Our goal was to identify the best subset of items to retain in each scale. The RMT analysis is described in detail elsewhere.²⁹ Briefly, we performed a range of statistical and graphical tests to examine if the data fit the Rasch model. We adjusted the sample size to 500 for tests that used a X^2 analysis. We examined: (1) item response categories to determine if item responses were properly ordered; (2) item fit statistics to determine if scale items mapped out an item difficulty continuum; (3) local dependency to determine if item residuals were too closely related to each other and performed subtests if residual correlations were ≥ 0.20 ; (4) targeting to determine how well a scale measured the experience of the sample; (5) Person Separation Index and Cronbach's alpha values³⁹ to determine scale reliability using criteria that values should be ≥ 0.70 ;^{26,40} and (6) Differential Item Functioning (DIF) to determine if items in a scale behaved the same for age (<30 vs ≥ 30 years), gender (man vs woman), country (UK vs USA), education (completed college/trade school or university yes/no), and location (toenail vs fingernail). DIF analysis was performed with random samples to ensure subgroups were equivalent in size and repeated three times. We only performed DIF if there were at least 150 participants in the analysis. Any items with DIF were split on the characteristic, and person locations from the original and split analyses were correlated to inspect the impact of DIF on scale scoring.

In SPSS Version 28, we performed Principal Component Analysis and hypothesized that scale items would load ≥ 0.70 providing evidence that the items were part of the latent variable.⁴¹ Scale scores were transformed from 0 (worst) to 100 (best) based on person locations. For the TRT data, anyone who reported their nail condition had changed, or they had initiated treatment, were excluded. Intra-class correlation coefficients (ICC) were computed with a two-way random effects model; values should be ≥ 0.70 .^{26,40}

For convergent validity, NAIL-Q scales were correlated with the EQ-5D-5L scores. COSMIN criteria stipulate that the correlations should be ≥ 0.50 between scales measuring similar constructs, 0.30 – 0.50 between scales measuring related but dissimilar constructs, and <0.30 between scales measuring unrelated constructs.²⁶ We hypothesized that with EQ-5D-5L, the NAIL-Q's Appearance and Outcome scales represent dissimilar constructs, and the NAIL-Q's HRQL scales represent related but dissimilar constructions. In terms of construct validity, we tested six hypotheses of known group differences (Table 1).

Parametric and nonparametric tests were used based on whether the scale data were normally distributed assessed by Skewness and Kurtosis values.⁴² Categorical variables with small cell sizes were combined for analyses. P-values of <0.05 were considered statistically significant.

Table 1 Construct Validation Hypotheses and Results

	Nail Appearance	Nail Distress	Nail Symptoms	Strength: Fingernail	Physical: Fingernails	Physical: Toenails	Treatment Outcome
1. As condition severity increases NAIL-Q scores	Decrease**	Decrease**	Decrease**	Decrease*	Decrease**	Decrease**	NA
2. As level of pain increases NAIL-Q scores ...	NA	NA	Decrease**	NA	NA	NA	NA
3. As person reports more embarrassment NAIL-Q scores ...	Decrease**	Decrease**	Decrease**	NA	NA	NA	NA
4. As person reports more interference with activities NAIL-Q scores	NA	Decrease**	Decrease**	Decrease**	Decrease**	Decrease**	NA
5. Both side involvement will have NAIL-Q scores that are...	Lower**	Lower*	NA	NA	NA	NA	NA
6. With improvement with treatment NAIL-Q scores ...	NA	NA	NA	NA	NA	NA	Increase**

Note: *p < 0.05; **p < 0.001. NA= Not applicable

Results

Phase 1: Qualitative Study

Interviews with 19 women and four men were conducted between October 2019 and November 2020. [Table S2](#) shows sample characteristics.

Participants described a range of outcomes that mattered to them. Participants were concerned about having weak nails that chip, break, crack, split, peel, loosen, and fall off [“Well they are also splitting and cracking and peeling off”]. Pain was a common symptom [“I will get an ingrown nail on my finger, and it swells up. It gets painful, extremely painful”]. Some participants described trouble using their hands [“I need to remember that, oh, I need to grip that differently or hold that differently”], and feet [“...I started to feel it every time I was walking”]. Nail appearance was typically described negatively [“unattractive”, “ugly”, “not normal”, “bad”]. Specific problems included pits, indents, or nails that were uneven, thin, or discolored (eg, spots or stripes). Participants generally disliked their nails [“It was terribly embarrassing”], and participants felt self-conscious of their nails [“... when I used to take the train, holding onto a pole, I’m conscious then of it...you know, being messed up”]. Many participants described concealment behaviors [“I keep my polish on my nails all the time. If I don’t, I put Band-Aids over them”].

The first draft of NAIL-Q included six scales with 89 items. Changes made in each round are shown in [Table S3](#) and summarized in [Table S4](#). Revisions took place between June 2021 and January 2022. Round 1 included seven cognitive debriefing interviews. Based on this round, 16 items were revised, 20 items dropped, and two items added. NAIL-Q had 71 items after Round 1. In Round 2, 35 clinical experts were invited to review the NAIL-Q and 11 (five men, six women) complied. Experts were from the USA (n = 5), Canada (n = 4), Brazil (n = 1) and Switzerland (n = 1). All experts were dermatologists; five had intermediate and six had advanced expertise in nail conditions. Based on this round, two items were revised, one item dropped, and 13 items added. At the end of Round 2, NAIL-Q had 83 items. In Round 3, the seven cognitive interview participants were invited to review the NAIL-Q and five participated. Based on this round, one item was revised, and one item added. The final field-test version included 84 items.

Phase 2: Quantitative Study

The field-test study took place in June and July 2022. The recruitment process is shown in [Figure 1](#). The screen, full survey, and TRT took participants 3 (SD = 2.4), 12.8 (SD = 6.4) and 8.5 (SD = 5.7) minutes on average to complete, respectively.

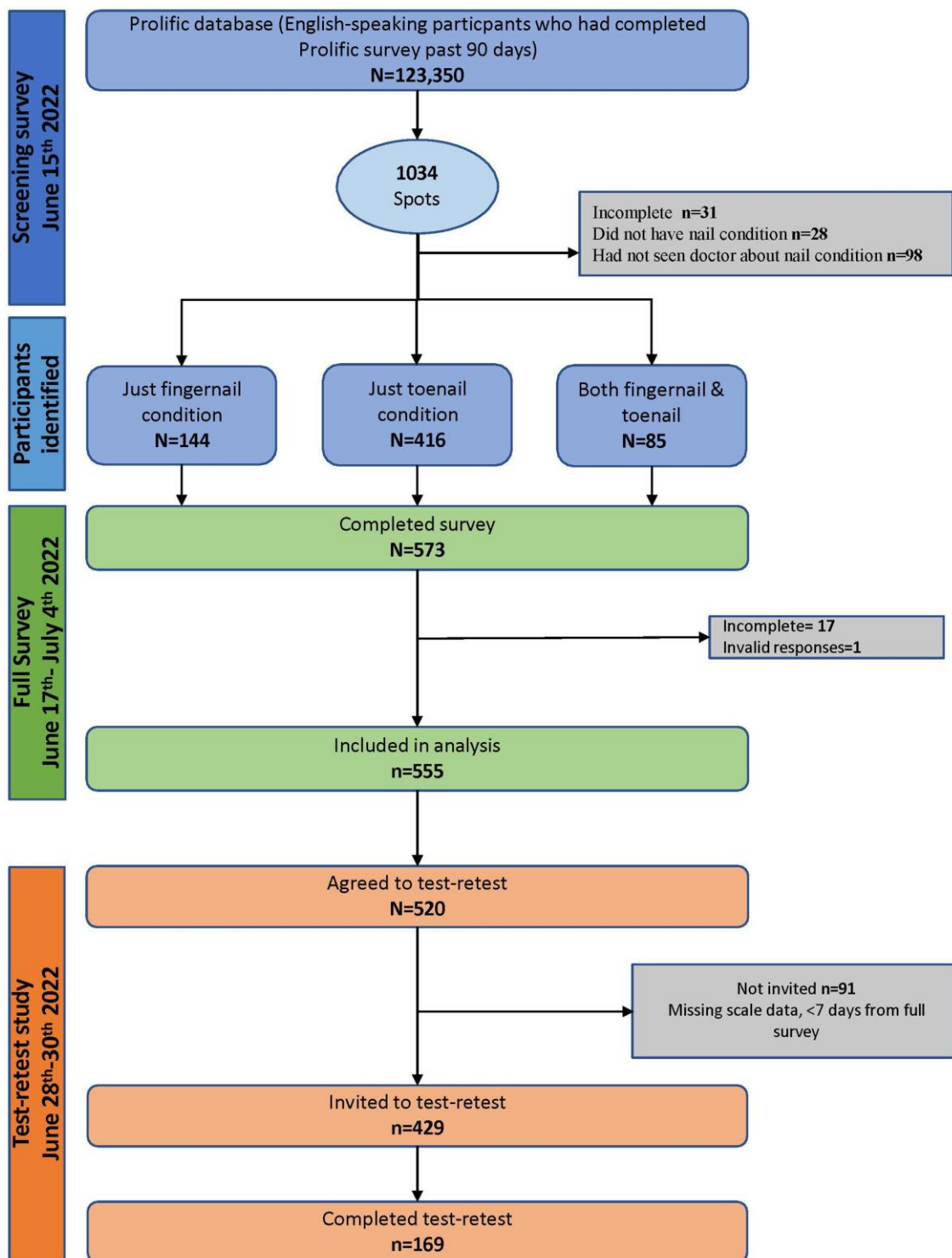


Figure 1 Recruitment flow diagram.

Table 2 and 3 show the sample demographic and clinical characteristics, respectively. The 555 participants came from 23 countries and ranged in age from 18 to 80 years (Mean 36.7; SD = 13.9). Toenail conditions were more common ($n = 441$) than fingernail conditions ($n = 186$). A small sample (72, 13%) had both fingernail and toenail conditions. Most participants ($n = 325$, 58.6%) had seen a healthcare professional about their nails 1 or 2 times in the past 2 years.

The RMT analysis reduced the NAIL-Q to 45 items. Figure 2 shows the final conceptual framework. Each aspect of the framework is measured by a NAIL-Q scale. The scales include five or six response options that measure satisfaction (Nail Appearance), frequency (Nail Distress, Physical: Fingernails, Physical: Toenails), concern (Nail Symptoms; Strength: Fingernails), and agreement (Treatment Outcome). Item-level fit statistics and DIF results are shown in Table S5. All 45 items had ordered thresholds and non-significant $X^2 P$ values after Bonferroni adjustment.

Table 2 Sample Demographic Characteristics for 555 Participants

Characteristics		n	%
Country	USA	186	33.5
	UK	170	30.6
	South Africa	53	9.5
	Portugal	36	6.5
	Poland	25	4.5
	Mexico	21	3.8
	Italy	18	3.2
	Spain	14	2.5
	Other	32	5.8
Gender	Woman	299	53.9
	Man	243	43.8
	Other gender	13	2.3
Age	18–29	240	43.3
	30–39	130	23.4
	40–49	77	13.9
	50–59	67	12.1
	60+	41	7.4
Race	White	383	69.0
	Black	69	12.4
	Latin American	35	6.3
	South Asian	18	3.2
	East Asian	8	1.4
	Middle Eastern	7	1.3
	Southeast Asian	5	0.9
	Other	30	5.4

(Continued)

Table 2 (Continued).

Characteristics		n	%
Marital status	Never married	291	52.4
	Separated	13	2.3
	Divorced	24	4.3
	Widowed	4	0.7
	Living common-law	55	9.9
	Married	149	26.8
	Other	11	2.0
	Prefer not to answer	8	1.4
Highest education	Some high school	5	0.9
	Completed high school	71	12.8
	Some college/trade school/university	120	21.6
	Completed college/trade school/university degree	240	43.2
	Some Masters or Doctoral degree	41	7.4
	Completed Masters or Doctoral degree	73	13.2
	Prefer not to answer	5	0.9
Daily activity	Working full time	289	52.1
	Working part-time	92	16.6
	Not working/not looking for work	16	2.9
	Unemployed and looking for work	36	6.5
	Retired	23	4.1
	Disabled/unable to work	10	1.8
	Currently in school	70	12.6
	Other	13	2.3
	Prefer not to answer	6	1.1

Item fit was within +2.5 for 37 items. DIF was identified for 14 items including 2 of 35 tested for country, 4 of 45 tested for age, 4 of 35 tested for gender, and 9 of 23 tested for location. Pearson correlations between person locations for items before and after item split for DIF indicated marginal impact of DIF on scoring, with all correlations ≥ 0.996 .

Scale-level results are shown in Table 4. The data fit the Rasch model for six scales with a slight misfit for Strength: Fingernails ($p = 0.02$). PSI values were ≥ 0.79 , and Cronbach's alpha values were ≥ 0.83 with and without extremes. Three pairs of items in the Appearance scale and one pair in the Outcome scale evidenced local dependency. Subtests to examine their impact on reliability showed a drop in PSI values of ≤ 0.01 . The proportion of patients to score on the scale ranged from 76.5% to 96%. While two scales evidenced some ceiling effect, it should be noted that 80% (Physical: Fingernails) and 83% (Physical: Toenails), of those to score at the ceiling chose "Not at all" when asked: "How much

Table 3 Sample Clinical Characteristics

Characteristics		Fingernails		Toenails	
		n	%	n	%
Condition*	Onychomycosis	18	–	150	–
	Psoriasis	22	–	15	–
	Ingrown	48	–	232	–
	Brittle	98	–	42	–
	Onycholysis	31	–	53	–
	Paronychia	18	–	20	–
	Other	3	–	1	–
Self-reported severity	Mild	72	38.7	156	35.7
	Moderate	101	54.3	238	54.5
	Severe	12	6.5	36	8.2
	Very severe	1	0.5	7	1.6
Sides affected	One side	71	38.2	201	25.9
	Both sides	115	61.8	236	54.0
Number of nails affected	1	43	23.1	135	24.4
	2	28	15.1	156	28.1
	3	16	8.6	44	7.9
	4	16	8.6	35	6.3
	5	11	5.9	17	3.1
	6	6	3.2	12	2.2
	7	9	4.8	4	0.7
	8	9	4.8	5	0.9
	9	1	0.5	4	0.7
	10	46	24.7	25	4.5
Time had condition	≤6 months	56	30.1	144	33.3
	6–12 months	29	15.6	64	14.6
	1–5 years	60	32.3	120	27.5
	>5 years	41	22.0	109	24.9
Treatment status	Do not require	27	14.8	20	4.6
	Need	29	15.9	59	13.6
	Currently having	50	27.5	129	29.7
	Had and need more	32	17.6	127	29.3
	Completed	44	24.2	99	22.8

(Continued)

Table 3 (Continued).

Characteristics		Fingernails		Toenails	
		n	%	n	%
Compared with before treatment	Worse	5	3.0	18	5.0
	About the same	37	29.4	96	26.4
	A little better	59	46.8	163	44.9
	A lot better	25	19.8	86	23.7

Notes: *43 (23.1%) reported more than 1 fingernail condition and 61 (14%) reported more than 1 toenail condition.

does your nail condition interfere with doing your usual daily activities?” Targeting can be seen graphically in the person-item threshold distributions ([Figure S2](#)). The item thresholds distributions (blue histogram) were spread over a reasonable range that matched the sample (pink histograms).

TRT data for toenails ($n = 95$) and fingernails ($n = 97$) provided 192 assessments for the Appearance, Distress, and Symptoms scales, 140 for the Outcomes scale, 95 for the Physical: Toenails, and 97 for the Physical: Fingernails and Strength: Fingernails scales. TRT participants who reported a change in their nail condition ($n = 12$) or started a treatment ($n = 18$) were excluded. The ICC values for all NAIL-Q scales were ≥ 0.81 , which exceeded the COSMIN criteria (see [Table 4](#)).

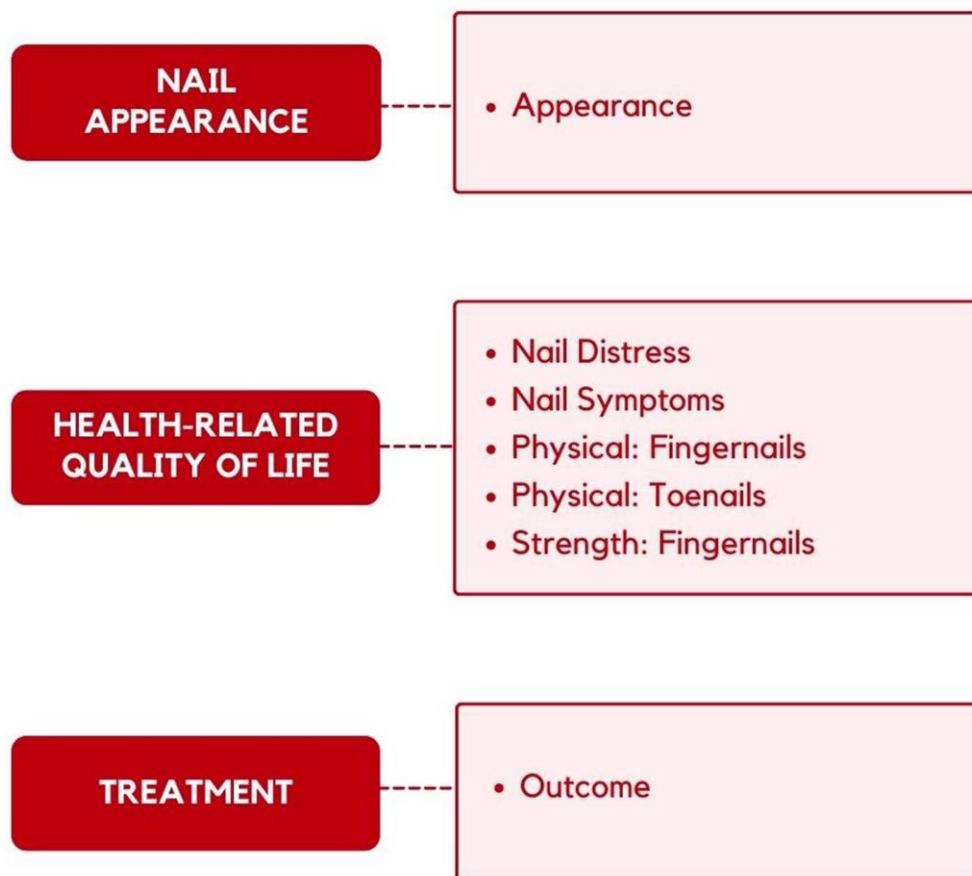
**Figure 2** Framework for the NAIL-Q.

Table 4 RMT Scale-Level Statistics and Other Scale Findings

Scale	RMT Analysis										Test-Retest Analysis			Floor		Ceiling	
	Sample n	RMT n	Scored on Scale %	χ^2	DF	p-value	PSI +extr	PSI -extr	α +extr	α -extr	ICC	95% LB	95% UB	n	%	n	%
NAIL APPEARANCE	623	598	96.0	108.1	90	0.09	0.93	0.93	0.95	0.94	0.81	0.74	0.86	22	3.5	1	0.2
NAIL DISTRESS	619	589	95.2	67.8	56	0.13	0.89	0.88	0.91	0.90	0.86	0.81	0.89	26	4.2	4	0.6
NAIL SYMPTOMS	622	516	83.0	53.2	24	0.12	0.87	0.86	0.93	0.90	0.84	0.78	0.88	19	3.1	84	13.5
STRENGTH: FINGERNAILS	186	166	89.2	18.5	8	0.02	0.84	0.80	0.89	0.83	0.84	0.76	0.90	10	5.4	9	4.8
PHYSICAL: FINGERNAILS	183	140	76.5	9.2	12	0.69	0.85	0.85	0.93	0.88	0.82	0.73	0.88	1	0.5	40	21.9
PHYSICAL: TOENAILS	435	296	68.1	23.0	15	0.09	0.79	0.79	0.91	0.84	0.89	0.84	0.93	4	0.9	133	30.6
OUTCOME	427	379	88.8	30.2	35	0.70	0.95	0.94	0.97	0.95	0.84	0.77	0.89	26	6.1	21	4.9

Abbreviations: χ^2 , chi square; DF, degrees of freedom; PSI±extr, Person Separation Index with and without extremes; α ±extr, Cronbach alpha with and without extremes; ICC, intraclass correlation coefficient; LB, lower bound; UB, upper bound; floor, % to score at 0 (lowest score); ceiling, % to score 100 (highest score).

Table 5 Participants to Disagree/Agree to NAIL-Q Evaluation Questions

	Disagree		Slightly Agree		Mostly Agree		Strongly Agree		Missing	
	n	%	n	%	n	%	n	%	n	%
1. Asked questions in a respectful way.	11	2.0	33	5.9	135	24.3	363	65.4	13	2.3
2. Easy to understand.	12	2.2	45	8.1	158	28.5	327	58.9	13	2.3
3. Was thorough.	34	6.1	63	11.4	189	34.1	260	46.8	9	1.6
4. Asked questions that are important to me.	57	10.3	107	19.3	176	31.7	203	36.6	12	2.2
5. Should be used by doctors treating people with nail conditions.	48	8.6	139	25.0	179	32.3	181	32.6	8	1.4
6. Would help my doctor better understand my nail condition.	69	12.4	119	21.4	195	35.1	160	28.8	12	2.2

Principal Component Analysis supported a single factor for all 7 scales, with factor loadings ≥ 0.78 to 0.94. Pearson correlations between NAIL-Q scales and the EQ-5D-5L scores met the COSMIN criteria for five scales Appearance ($r = 0.18$, $n = 615$), Distress ($r = 0.31$, $n = 614$), Physical: Fingernails ($r = 0.30$, $n = 182$), Physical: Toenails ($r = 0.40$, $n = 433$), and Outcome ($r = 0.10$, $n = 427$). The two remaining scales had correlations that were weaker than hypothesized (Symptoms, $r = 0.26$, $n = 615$; Strength: Fingernails, $r = 0.10$, $n = 182$).

Table 1 summarizes the construct validity findings, and Tables S6–S11 provide the detailed results. All 6 hypotheses were supported by the data. As nail condition severity increased, NAIL-Q scores were incrementally lower (see Table S6). Those with a nail condition that affected both sides reported lower scores than those whose nail condition was on one side (see Table S7). As pain increased, symptom scale scores decreased (see Table S8). Participants who reported feeling more embarrassed about their nail condition reported worse NAIL-Q scores (see Table S9). Additionally, as interference with activities increased, scores on the NAIL-Q scales decreased (see Table S10). Finally, following treatment, scores on the Outcome scale were higher for those who reported their nail condition as better compared with those whose condition was the same or worse following treatment (see Table S11).

Finally, Table 5 shows the proportion of participants to agree/disagree with the six evaluation questions. Most participants agreed that the NAIL-Q asked questions in a respectful way, was easy to understand, was thorough, asked important questions, should be used by doctors treating people with nail conditions, and would help doctors better understand nail conditions.

Discussion

Nail disorders are common and comprise approximately 10% of all dermatological conditions.⁴³ The NAIL-Q is a rigorously developed and tested PROM that can be used in research and clinical care to measure outcomes that matter to people with nail conditions. The NAIL-Q was developed using a patient-centred approach in line with guidelines for PROM development.¹² Our analysis refined a set of independently functioning scales with strong psychometric properties. The evaluation questions provided additional evidence of content validity by showing the NAIL-Q was easy to understand, asked relevant and important questions in a respectful way, and should be used to inform clinical care.

A recent review assessed the content measured by seven nail-specific PROMs.^{19–25,44} Most items in existing PROMs measure physical and psychological concerns.⁴⁴ While the NAIL-Q includes such concerns, it also covers additional concepts, including a scale to measure satisfaction with nail appearance. In clinical trials of treatments for nail conditions, how the nail looks (eg, how thick, clear, even, healthy it looks) represents a proximal outcome important to patients but is largely overlooked in existing PROMs.⁴⁴ Although, five of the seven existing nail-specific PROMs measure nail appearance,^{19–21,23,25} only the onychomycosis-specific PROM from Lubek et al²⁰ and the OnyCOE- τ ^{TM23} provide a separate score for this construct.^{28,44} While such a concept could be measured using objective measures, today it is important in clinical trials to also measure outcomes from the patient perspective.⁴⁴ In addition to outcomes,

measuring patients' experience of care is integral to providing patient-centered care. Previously developed nail-specific PROMs include only a limited number of items that address treatment outcomes,⁴⁴ with only the psoriasis-specific NAPPA-PBI and onychomycosis-specific Lubek et al²⁰ instrument scoring this construct.²⁵ The NAIL-Q, in contrast, includes a scale that can be used post-treatment for any nail condition to evaluate satisfaction with nail treatment (eg, pleased with result, worth the time/effort, would recommend to others, better than expected). We expect this scale will provide useful feedback to physicians and researchers about different nail treatments from the patient perspective.

An important advantage of the NAIL-Q is that its scales were designed to be used across all nail conditions, with most scales applicable to both fingernails and toenails. Other nail-specific PROMs were designed for use in psoriasis and onychomycosis.^{28,44} Using standardized PROM measurements across nail conditions will allow comparability of results between conditions and across studies and could also help facilitate the implementation of PROMs into clinical practice for purposes such as benchmarking, value-based payment, and shared decision-making.^{18,45-47}

Limitations

Our phase 1 study included only four males. However, this limitation was addressed in our phase 2 study, which included more gender diversity; 43.8% identified as male, and 2.3% identified as nonbinary. Furthermore, the DIF analysis by gender showed that items with DIF had negligible impact on scoring. The qualitative sample to develop the NAIL-Q only included people from Canada and the USA. The field-test sample, on the other hand, was open to anyone fluent in English on the Prolific platform. While a strength of the study was the testing of NAIL-Q in people from multiple countries, a limitation is that we were only able to examine DIF by country for the UK and USA. Additional research to explore the psychometric performance of the NAIL-Q in countries where our sample was limited in size is warranted. Another limitation is that since the phase 2 sample was community-based, it was not possible to confirm nail diagnoses clinically, nor the severity ratings, as both variables were self-reported. Future research could examine the psychometric performance of the NAIL-Q in a clinic-based sample with confirmed diagnoses and objective measures of nail severity. Future research to measure responsiveness (ability to measure change) and to determine minimally important differences for NAIL-Q scales is also needed.

There are many advantages to recruiting research participants using online platforms such as Prolific. Such studies can accrue large diverse international samples quickly and at low cost. Online platforms are ideal for TRT studies as it is possible to control the collection of retest data on a specific day and for a specific number of participants. While crowdsourcing platforms may be a useful means to engage research participants, there are limitations. Many factors can affect data quality, including lack of attention, comprehension, honesty, and reliability.⁴⁸ We used Prolific as it has been shown to provide high-quality data compared to other similar platforms.⁴⁸

Conclusion

The NAIL-Q is a rigorously designed nail-specific PROM developed using a modern psychometric approach.¹² The NAIL-Q can be used to measure outcomes for adults with any fingernail or toenail condition. The NAIL-Q is available on the following website: www.qportfolio.org/nail-q/.

Key Points

- The NAIL-Q was carefully designed using a modern psychometric approach (Rasch Measurement Theory) to measure concepts that are relevant to people with nail conditions.
- Most participants found that the NAIL-Q was easy to understand, asked relevant and important questions in a respectful way, and thought it should be used to inform clinical care.
- The NAIL-Q provides seven independently functioning scales that measure nail appearance, physical and psychosocial concerns, and satisfaction with the treatment that can be used to inform clinical trials, research, and patient care.

Data Sharing Statement

The datasets generated during and/or analysed during the current study are not publicly available due to participant privacy, and legal requirements under data transfer agreements.

Ethics Approval

This study was approved by the Hamilton Integrated Research Ethics Board approvals #7370 and #14622 and from Weill Cornell Medicine (New York, NY, USA) and we certify that the study was performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

Consent for Participation

All participants provided electronic informed consent at the start of the online survey.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The NAIL-Q is owned by McMaster University and Weill Cornell Medicine. The developers could potentially receive a share of any license revenues as royalties based on their institutions' inventor sharing policy. Anne Klassen provides research consulting services to the pharmaceutical industry through EVENTUM Research. The other authors have no conflicts of interest to report for this work.

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SUPPORTIVE INFORMATION

Title: Development and Validation of a Patient-Reported Outcome Measure for Fingernail and Toenail Conditions: the NAIL-Q

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Table S1: Semi-structured interview guide

NAIL CONDITION
<ol style="list-style-type: none"> 1. Can you describe your nail condition to me? 2. How long have you had this condition? 3. What kinds of treatments have you had/will you have in the future for your nail condition? 4. How happy/satisfied have you been with each treatment(s)?
SYMPTOMS/FUNCTION
<ol style="list-style-type: none"> 5. Can you describe any symptoms and sensations you experience with your nail condition? <u>Probe as needed</u>: pain, swelling, numbness, itch, odor etc. For each symptom/sensation, how bad is it (eg, intensity/severity/frequency). For each symptom/sensation, how does it interfere in your daily life? 6. Can you describe any functional problems you have using your hands/feet? <u>Probe</u>: activities of daily living, self-care, walk, exercise, range of motion etc. 7. Do you use any accommodations such as special footwear, gloves, etc? 8. What issues do you experience with regards to taking care of your nails?
APPEARANCE
<ol style="list-style-type: none"> 9. How would you describe how your nails looks? <u>Probe</u>: before and after treatment for contour, colour, shape, scenarios, size, shape, qualitative, surrounding skin, symmetry, visibility. 10. How have your toenails affected what kind of shoes you wear? 11. What do you like/dislike about the appearance of your nails? 12. What would you like to change about the appearance of your nails?
PSYCHOLOGICAL
<ol style="list-style-type: none"> 13. Can you describe if/how your nails (how it looks and feels) affects you emotionally? <u>Probe as needed</u>: negative (distress, feel down, irritation) and positive (happy, vibrant) emotions; negative (self-conscious, embarrassed) and positive (confident, attractive) body image concerns; concealment behaviours (gloves, shoes, makeup, polish). 14. For any nail treatments you have had, can you describe any changes in your psychological wellbeing and how you feel about yourself? <u>Probe as needed</u>: for positive (feel better, happier, more confident, attractive) and negative (feel worse, self-conscious, unattractive) 15. How big were these changes and how long did they last?
SOCIAL
<ol style="list-style-type: none"> 16. Thinking about your nails (how it looks/feels), can you describe any impacts on social interactions with people? <u>Probe as needed</u>: positive (more confident, go out more, making friends, recreation, shake hands, dating) and negative (isolation, stay in, stigmatized, avoidance) 17. Do people stare or notice your nails? 18. How have you felt supported or not supported by people in your life? 19. Does your nail condition (how it looks/feels) have any impact on your work life? Please describe these.
GENERAL
<ol style="list-style-type: none"> 20. Can you describe any other concerns or issues you experienced that we have not already covered? 21. Thinking back over what you have talked about in this interview, what would you say are the most/least important concerns in relation to your nail condition?

Figure S1 REDCap survey images to aid participants in identifying nail condition**1. Onychomycosis**
(fungal infection)**2. Nail psoriasis**
(nails thicken and develop holes)**3. Ingrown nails**
(nails grow into flesh at corner/sides)**4. Brittle nails**
(nails too dry and thin)**5. Onycholysis**
(nails separate from the nail bed)**6. Paronychia**
(inflammation in the nail folds)

Table S2: Sample characteristics for phase 1 qualitative study

		Number
COUNTRY	Canada	5
	USA	18
AGE	<49	6
	50-59	3
	60-69	6
	≥70	8
GENDER	Woman	19
	Man	4
RACE	White	16
	Black / African American	2
	Hispanic / Latino1	4
	Other	1
CONDITION	Brittle nails	4
	Dystrophy	1
	Ingrown toenails	1
	Lichen Planus	3
	Onychomycosis	8
	Onychopapilloma	1
	Onychophagia	1
	Onychorrhexis	1
	Psoriasis	3
	Trachyonychia	1
	Trauma	1
SEVERITY BEFORE TREATMENT	Mild	6
	Moderate	8
	Severe	11
TIME SINCE DIAGNOSIS, YEARS*	<1	2
	1-5	13
	>5	10
NAILS AFFECTED	Fingernails	21
	Toenails	9
	Both	7
NUMBER FINGERNAILS AFFECTED*	One	5
	Some	7
	All	8
NUMBER TOENAILS AFFECTED*	One	0
	Some	6
	All	2

Note: 2 participants had 2 nail conditions; * data missing for 1 participant

Table S3: Item revision during each round

ROUND 1	Decision	ROUND 2	Decision	ROUND 3	Decision	FIELD-TEST	FINAL
APPEARANCE							
How smooth the surface of your nails look (no ridges, indents or pits)?	retain		retain		retain		retain
The thickness of your nails?	retain		retain		retain		retain
How even the surface of the nails looks?	retain		retain		retain		retain
How your nails look up close?	retain		retain		retain		retain
How clear your nails look (no spots or stripes)?	retain		retain		retain		retain
How strong your nails are?	retain		retain		retain		retain
How hard your nails are?	retain		retain		retain		retain
How normal your nails look?	retain		retain		retain		retain
How healthy your nails are?	retain		retain		retain		retain
The color of your nails?	retain		retain		retain		drop
How even colored your nails look?	retain		retain		retain		drop
How your nails look under a bright light?	retain		retain		retain		drop
How your nails look when you are using your hands (eg, eating, playing cards)?	retain		retain		retain		drop
How attractive your nails look?	retain		retain		retain		drop
How fast your nails grow?	retain		retain		retain		drop
How your nails look if you rest your palms on a table?	retain		retain		retain		drop
The length of your nails?	retain		retain		retain		drop
How your nails look compared with other people?	revise	How your nails look compared with other people's nails?	retain		retain		retain
How securely attached your nails are to the nailbed?	revise	How tightly attached your nail(s) are to the nailbed?	retain		retain		drop
How the cuticle/skin around your nails looks?	retain		revise	How the skin around your nails looks?	retain		drop
How clean your nail condition makes your nails look?	drop						
The shape of your nails?	drop						
The size of your nails?	drop						
How well your nails match each other?	drop						
How your nails look when you hold a glass?	drop						
			add	How your nails look in photos?	retain		
			add	How your cuticles look (ie, the skin at the bottom edge of your nails)?	retain	How your cuticles look?	
NAIL DISTRESS							
I get upset about my nail condition.	retain		retain		retain		retain
I dislike when people look at my nails.	retain		retain		retain		retain
I dislike how my nails look.	retain		retain		retain		retain
I am self-conscious of my nail condition.	retain		retain		retain		retain
I am embarrassed about my nail	retain		retain		retain		drop

condition.							
My nail condition interferes with my ability to enjoy life.	retain		retain		retain		drop
I worry about having to greet people (eg, shake hands or wave).	retain		retain		retain		drop
I worry people might think my nail condition is contagious.	retain		retain		retain		drop
I avoid having my nails done (eg, manicure, pedicure).	retain		retain		retain		drop
I hide my nails when I am with other people (eg, gloves, keep hands in pocket).	revise	I hide my nails when I am with other people (eg, gloves, shoes, keep hands in pocket).	retain		retain		drop
I am conscious of my nail condition when I am with other people (eg, restaurant, beach).	revise	I am aware of my nail condition when I am with other people (eg, restaurant, beach).	retain		retain		retain
I cover my nails when I go out (eg, nail polish, artificial nails).	drop						
I dislike when people ask about my nails.	drop						
I avoid some activities that show my nails.	drop						
			add	I avoid having photos taken that show my nails.	retain		retain
					add	My nail condition makes me feel frustrated.	retain
NAIL SYMPTOMS							
Nails that break?	retain		retain		retain		retain
Nails that peel (layers)?	retain		retain		retain		retain
Nails that split?	retain		retain		retain		retain
Nails that chip?	revise	Nails that chip (ie, little pieces come off)?	retain		retain		retain
Skin around the nails that looks swollen?	retain		retain		retain		retain
Skin around the nails that bleeds?	retain		retain		retain		retain
Nails that cause pain?	retain		retain		retain		retain
Nails that come off?	retain		retain		retain		drop
Nails and surrounding skin that are infected?	retain		retain		retain		drop
Nails that are loose or lifted from the nailbed?	retain		retain		retain		drop
Nails that smell?	retain		retain		retain		drop
Nails that crack?	drop						
Skin around the nails that looks inflamed?	drop						
Nails that are dry?	drop						
Nails that cause sensitivity?	drop						
			add	Nails that throb?	retain		retain
			add	Skin around the nails that look red?	retain		retain
			add	Nails that cause pain in the tips of your fingers or toes?	retain		retain

			add	Nails that do not grow as fast as you would like?	retain		drop
PHYSICAL: FINGERNAILS							
Buttoning a shirt or coat?	retain		retain		retain		retain
Putting on or taking off clothes?	retain		retain		retain		retain
Personal grooming (eg, shaving, putting on make-up)?	retain		retain		retain		retain
Typing?	retain		retain		retain		retain
Preparing food (eg, peeling, cutting)?	retain		retain		retain		drop
Gripping handles (eg, tennis racket, golf club, broom)?	retain		retain		retain		drop
Writing with a pen or pencil?	retain		retain		retain		drop
Scratching an itch?	revise	Using your nails to scratch an itch?	retain		retain		drop
Picking up a coin?	revise	Picking up a small item (eg, coin, pill, button)?	retain		retain		drop
Clipping your fingernails?	revise	Looking after your nails (eg, clip, clean)?	retain		retain		drop
Eating with cutlery (eg, fork, spoon, knife)?	drop						
Opening a jar?	drop						
Turning a key in a lock?	drop						
	add	Doing chores around the house?	retain		retain		retain
	add	Being able to get your hands wet (eg, do dishes, wash hands)?	retain		retain		drop
			add	Doing your usual daily activities (eg, work, school)?	retain		retain
PHYSICAL: TOENAILS							
Being physically active?	retain		retain		retain		retain
Your ability to be independent?	retain		retain		retain		retain
Putting on or taking off socks?	retain		retain		retain		drop
Your ability to move around?	revise	Your ability to walk or move around?	retain		retain		retain
Your ability to do your usual activities (eg, work, school)?	revise	Doing your usual daily activities (eg, work, school)?	retain		retain		retain
Being able to wear shoes you like?	revise	Being able to wear shoes that cover your toes?	retain		retain		drop
Your ability to do chores around the house?	revise	Doing chores around the house?	retain		retain		drop
Doing activities you enjoy?	revise	Doing activities that you enjoy?	retain		retain		retain
Your ability to clean your nails?	revise	Looking after your nails (eg, clip, clean)?	retain		retain		drop
Putting on or taking off clothes (eg, nails catch or snag)?	drop						
Your ability to enjoy life?	drop						

Your social life?	drop						
Your self-confidence?	drop						
Your ability to clip your nails?	drop						
TREATMENT OUTCOME							
I wish I had the nail treatment sooner.	retain		retain		retain		drop
The results of the nail treatment are great.	retain		retain		retain		drop
My nail condition has improved with treatment.	retain		retain		retain		drop
I am pleased with the results of the nail treatment.	retain		retain		retain		retain
It was worthwhile having the nail treatment.	retain		retain		retain		retain
The results of the nail treatment are better than I expected.	retain		retain		retain		retain
I am happy with the nail treatment.	revise	I am happy with the result of the nail treatment.	revise	I am glad I had the nail treatment.	retain		retain
My nails are much better than before the nail treatment.	revise	My nails are better than before the nail treatment.	drop				drop
			add	The treatment worked for my nail condition.	retain		retain
			add	The treatment was worth the time and effort.	retain		retain
			add	I am happy with how fast the nail treatment worked.	retain		drop
			add	I would have the nail treatment again if I needed to.	retain		drop
			add	I would recommend the nail treatment to other people with my condition.	retain		retain

Table S4: Item revision during 3 rounds of participant and expert input

Scales	Decisions	Round 1 – participants	Round 2 - experts	Round 3 - participants	Field-test version
NAIL APPEARANCE		n=25	n =20	n=22	n=22
	Retain	18	19	21	
	Revise	2	1	1	
	Drop	5	0	0	
	Add	0	2	0	
NAIL DISTRESS		n =14	n=11	n=12	n=13
	Retain	9	11	12	
	Revise	2	0	0	
	Drop	3	0	0	
	Add	0	1	1	
NAIL SYMPTOMS		n=15	n=11	n=15	n=15
	Retain	10	11	15	
	Revise	1	0	0	
	Drop	4	0	0	
	Add	0	4	0	
PHYSICAL: FINGERNAILS		n =13	n=12	n=13	n=13
	Retain	7	12	13	
	Revise	3	0	0	
	Drop	3	0	0	
	Add	2	1	0	
PHYSICAL: TOENAILS		n =14	n=9	n=9	n=9
	Retain	3	9	9	
	Revise	6	0	0	
	Drop	5	0	0	
	Add	0	0	0	
TREATMENT OUTCOME		n=8	n=8	n=12	n=12
	Retain	6	6	12	
	Revise	2	1	0	
	Drop	0	1	0	
	Add	0	5	0	
TOTAL		89	71	83	84

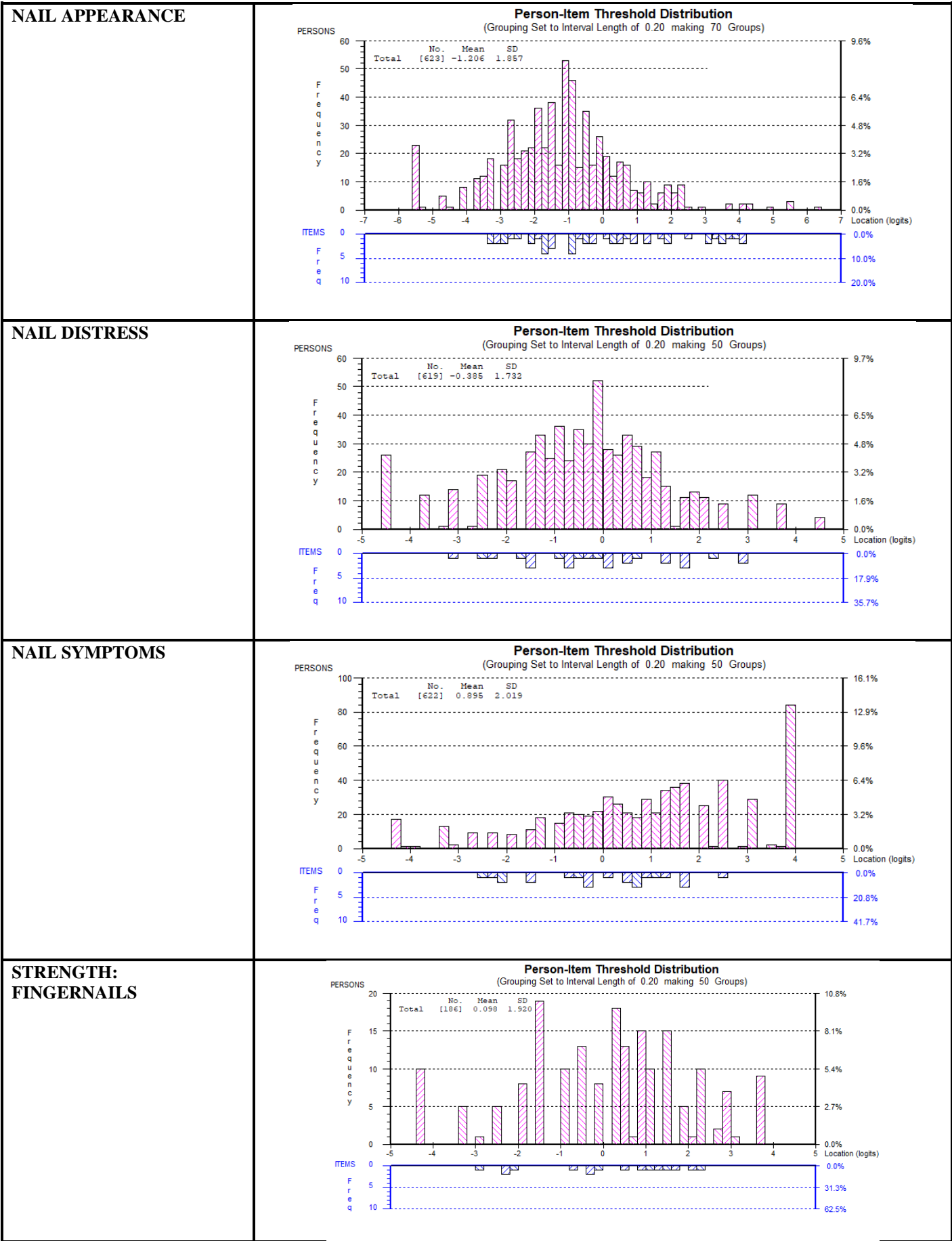
Table S5: RMT item level fit statistics and differential item function results

Scales	Item Fit Statistics							Differential Item Function*				
Item	Location	SE	Fit Residual	DF	χ^2	DF	p-value	Country	Age	Gender	Education	Location
NAIL APPEARANCE												
Clear	-0.47	0.05	4.89	529.4	15.0	9	0.09	no	no	1,2,3	no	1,2
Hard	-0.42	0.05	1.90	520.4	12.9	9	0.17	no	no	no	no	1,2,3
Strong	-0.41	0.05	3.42	530.3	14.8	9	0.10	no	no	no	no	1,2,3
Thickness	-0.14	0.05	0.41	531.2	8.6	9	0.47	no	no	1,3	no	no
Smooth	-0.10	0.05	0.43	532.0	5.1	9	0.83	no	no	no	no	no
Even surface	-0.03	0.05	-1.05	530.3	10.3	9	0.33	no	no	no	no	no
Normal	0.11	0.05	-1.80	531.2	8.8	9	0.45	no	no	no	no	1,2,3
Healthy	0.29	0.06	-3.48	532.9	15.4	9	0.08	no	no	no	no	no
Compared	0.50	0.05	0.98	531.2	3.4	9	0.95	no	no	no	no	no
Up close	0.66	0.05	-0.96	530.3	13.8	9	0.13	no	no	no	no	3
NAIL DISTRESS												
Aware with others	-0.61	0.05	3.60	498.0	17.4	8	0.03	no	no	1,2,3	no	no
Avoid photos	-0.49	0.05	-0.20	497.1	9.7	8	0.29	no	1	no	no	1,2,3
Upset	-0.28	0.06	1.74	496.3	5.1	8	0.75	1,2,3	no	no	no	3
Frustrated	-0.23	0.05	-1.11	499.7	15.9	8	0.04	no	no	no	no	no
People look	0.28	0.05	-1.40	496.3	16.6	8	0.03	no	no	no	no	2
Self-conscious	0.65	0.06	0.13	498.8	4.8	8	0.78	no	no	no	no	no
Dislike	0.69	0.06	-0.39	498.8	10.5	8	0.23	1,2,3	1,2,3	no	no	no
NAIL SYMPTOMS												
Skin bleeds	-0.41	0.06	-0.88	421.4	12.3	7	0.09	no	1,2,	no	no	1,2,3
Nails throb	-0.35	0.06	2.90	419.8	7.0	7	0.42	no	1,2,3	no	no	no
Skin red	-0.09	0.06	-0.63	423.9	12.2	7	0.09	no	no	no	no	no
Skin swollen	0.04	0.06	-0.79	423.1	7.0	7	0.43	no	no	no	no	no
Pain in tips	0.17	0.05	-0.01	423.1	6.4	7	0.49	no	no	no	no	no
Nails cause pain	0.64	0.06	0.22	423.9	8.1	7	0.32	no	no	no	no	
STRENGTH: FINGERNAILS												
Peel	-0.05	0.10	2.99	116.6	7.6	2	0.02	N/A	no	N/A	N/A	N/A

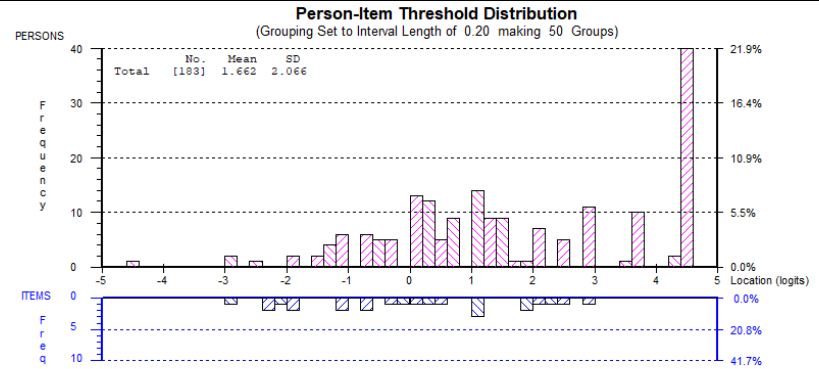
Split	-0.03	0.1 1	-0.84	118. 8	5.4	2	0.07	N/A	no	N/A	N/A	N/A
Chip	0.00	0.1 0	0.66	120. 2	0.7	2	0.71	N/A	no	N/A	N/A	N/A
Break	0.08	0.1 0	-1.67	119. 5	4.8	2	0.09	N/A	no	N/A	N/A	N/A
PHYSICAL: FINGERNAILS												
Button	-0.30	0.1 2	-0.72	112. 7	3.0	2	0.23	N/A	no	N/A	N/A	N/A
Groom	-0.23	0.1 2	0.68	111. 1	2.2	2	0.33	N/A	no	N/A	N/A	N/A
Type	-0.07	0.1 2	0.74	111. 1	1.3	2	0.53	N/A	no	N/A	N/A	N/A
Daily activities	0.12	0.1 2	-0.90	112. 7	1.4	2	0.49	N/A	no	N/A	N/A	N/A
Chores	0.18	0.1 1	0.63	111. 9	0.9	2	0.64	N/A	no	N/A	N/A	N/A
Clothes	0.30	0.1 1	1.76	112. 7	0.4	2	0.83	N/A	no	N/A	N/A	N/A
PHYSICAL: TOENAILS												
Independent	-0.85	0.0 9	0.34	231. 8	4.1	3	0.25	no	no	no	no	N/A
Daily activities	-0.40	0.0 8	-2.53	231. 0	10. 7	3	0.01	no	no	no	no	N/A
Walk or move	0.10	0.0 8	-0.85	232. 6	3.3	3	0.35	no	no	no	no	N/A
Activities enjoy	0.49	0.0 8	0.86	228. 7	1.5	3	0.67	no	no	no	no	N/A
Physically active	0.67	0.0 8	2.15	231. 8	3.3	3	0.34	no	no	no	no	N/A
TREATMENT OUTCOME												
Glad had it	-0.85	0.0 8	-0.09	319. 9	5.8	5	0.32	no	no	1,2	N/A	N/A
Would recommend	-0.59	0.0 7	1.34	319. 9	2.5	5	0.78	no	no	no	N/A	N/A
Worthwhile	-0.35	0.0 8	-0.60	320. 8	2.9	5	0.72	no	no	no	N/A	N/A
Time and effort	-0.15	0.0 8	-1.82	318. 2	2.5	5	0.77	no	no	no	N/A	N/A
Treatment worked	0.35	0.0 8	-2.30	319. 9	8.5	5	0.13	no	no	no	N/A	N/A
Pleased	0.54	0.0 8	-1.15	317. 4	1.5	5	0.92	no	no	no	N/A	N/A
Better than expected	1.04	0.0 8	3.24	320. 8	6.6	5	0.26	no	no	no	N/A	N/A

*In DIF analysis, 1 = random sample 1 was significant; 2 = random sample 2 was significant; 3 = random sample 3 was significant

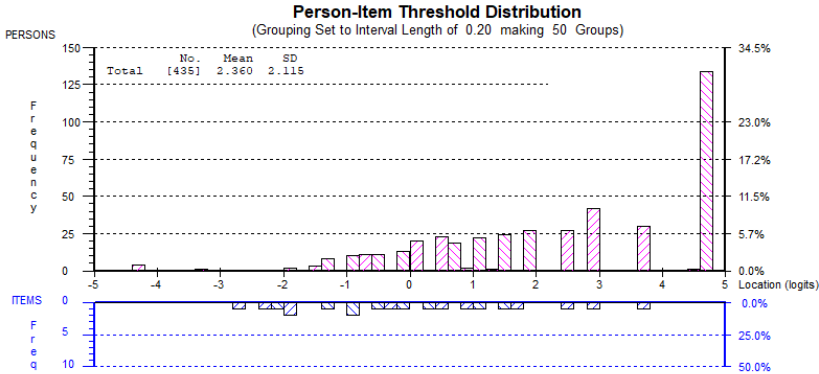
Figure S2: Person-item threshold distributions for each NAIL-Q scale from RMT analysis



PHYSICAL: FINGERNAILS



PHYSICAL: TOENAILS



TREATMENT OUTCOME

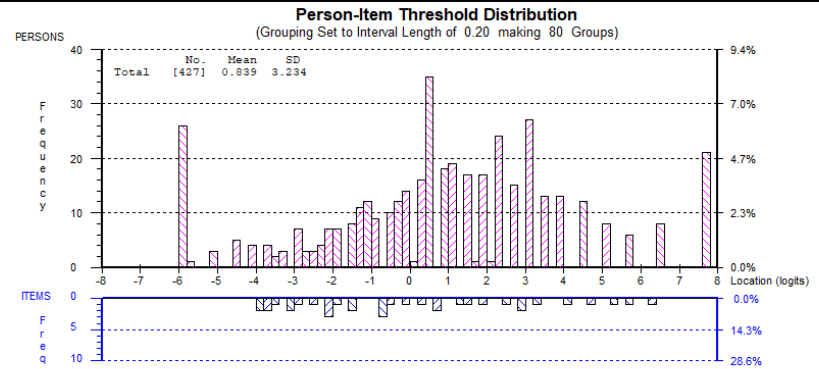


Table S6: How would you describe the SEVERITY of your nail condition?

Scale		Mean	SD	95% CI		N	P-value
				Lower Bound	Upper Bound		
APPEARANCE	Mild	46	12	44	47	228	p<0.001
	Moderate	39	15	37	41	339	
	Severe/Very severe	26	16	22	30	56	
DISTRESS	Mild	55	17	53	57	227	p<0.001
	Moderate	43	17	41	44	336	
	Severe/Very severe	27	17	23	31	56	
SYMPTOMS	Mild	71	23	68	74	228	p<0.001
	Moderate	58	24	55	60	338	
	Severe/Very severe	47	28	39	54	56	
STRENGTH: FINGERNAILS	Mild	57	24	52	63	72	P=0.045
	Moderate	49	26	44	54	101	
	Severe/Very severe	43	28	26	59	13	
PHYSICAL: FINGERNAIL	Mild	78	21	73	83	72	p<0.001
	Moderate	64	21	60	68	98	
	Severe/Very severe	47	27	30	63	13	
PHYSICAL: TOENAILS	Mild	84	19	81	87	155	p<0.001
	Moderate	71	21	68	74	237	
	Severe/Very severe	60	27	52	69	43	

Table S7: What side is your nail condition on?

Scale		Mean	Std. Deviation	N	P-value
APPEARANCE	one side	43	14	272	p<0.001
	both sides	38	16	351	
DISTRESS	one side	48	17	269	p=0.027
	both sides	44	21	350	

Table S8: How PAINFUL is your nail condition?

Scale	Response Options	Mean	Std. Deviation	95% CI		N	P-value
SYMPTOMS				Lower Bound	Upper Bound		
	No pain	77	24	74	80	227	p<0.001
	Mild	59	20	56	61	234	
	Moderate	46	20	43	49	139	
	Severe/Very severe	29	26	18	41	22	

Table S9: How EMBARRASSING is your nail condition?

Scale	Response Options	Mean	Std. Deviation	95% CI		N	P-value
				Lower Bound	Upper Bound		
APPEARANCE	Not at all	51	14	48	53	116	p<0.001
	A little	42	12	41	44	276	
	Moderately	37	15	34	39	146	
	Extremely	25	15	22	29	85	
DISTRESS	Not at all	64	16	61	67	115	p<0.001
	A little	50	14	48	51	274	
	Moderately	38	13	35	40	145	
	Extremely	22	15	19	25	85	
SYMPTOMS	Not at all	70	23	65	74	116	p<0.001
	A little	64	24	61	67	275	
	Moderately	57	24	53	61	146	
	Extremely	50	29	44	57	85	

Table S10: How much does your NAIL condition INTERFERE with doing your usual daily activities?

Scale	Response Options	Mean	Std. Deviation	95% CI		N	P-value
				Lower Bound	Upper Bound		
DISTRESS	Not at all	53	19	50	55	231	p<0.001
	Little bit	45	17	43	47	316	
	Quite a bit/ Very much	28	17	24	32	72	
SYMPTOMS	Not at all	75	24	72	78	232	p<0.001
	Little bit	58	21	55	60	317	
	Quite a bit/ Very much	35	25	30	41	73	
PHYSICAL: FINGERNAILS	Not at all	89	15	86	93	61	p<0.001
	Little bit	62	18	58	65	100	
	Quite a bit/ Very much	42	15	36	49	22	
STRENGTH: FINGERNAILS	Not at all	66	22	60	71	62	p<0.001
	Little bit	46	24	41	50	101	
	Quite a bit/ Very much	43	29	30	55	23	
PHYSICAL: TOENAILS	Not at all	91	14	89	93	169	p<0.001
	Little bit	68	19	66	71	216	
	Quite a bit/ Very much	46	18	41	52	50	

Table S11: How much worse or better is your NAIL condition now compared with before you had the treatment?

Scale	Response Options	Mean	Std. Deviation	95% CI		N	P-value
				Lower Bound	Upper Bound		
OUTCOME	A lot / A little worse	28	22	18	38	21	p<0.001
	Same	36	21	32	40	134	
	A little better	58	13	56	60	222	
	A lot better	77	16	74	80	103	

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