



NAIL-Q[®]

A User's Guide for Researchers and Clinicians

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1. What is the NAIL-Q?

Nail conditions are common in the population and affect people of all ages. Nail conditions can cause substantial distress due to their appearance, symptoms (e.g., pain), impact on function and mobility, and reduced health-related quality of life (HRQL). Our team developed the NAIL-Q to provide a PROM that could be used across all types of fingernail and toenail conditions, as no such PROM exists. The NAIL-Q is a rigorously developed patient-reported outcome measure (PROM) that can be used in research and clinical care to measure outcomes of patients. The NAIL-Q includes a scale about nail appearance, five scales measuring health-related quality of life (HRQOL), and a scale on treatment outcome.

2. How was the NAIL-Q Developed and Validated?

The NAIL-Q represents a new generation of PROMs developed using a modern psychometric approach called Rasch Measurement Theory (RMT). In RMT, scales that compose a PROM are each designed to measure and score a unidimensional construct. In scale development, data that meet the requirement of the Rasch model provide interval-level measurement. When a scale has high content validity and is targeted to measure a concept as experienced by a sample, accurate tracking of clinical change can be achieved. In addition to their use in research studies, NAIL-Q scales can be used with individual patients to inform clinical care.

To create the NAIL-Q, we followed internationally recommended guidelines for PROM development. Figure 1 shows an example of the multiphase mixed methods approach that our team follows to develop a PROM. Concepts for the NAIL-Q scales were elicited during qualitative interviews with 23 adult patients with a broad range of fingernail and toenail conditions. Scales were refined with input from 7 patients and 11 clinical experts. The scales were then field-tested using Prolific Academic, an online crowd working platform. The sample included 555 people from 23 countries who ranged in age from 18 to 80 years. Out of the 555 participants, 441 had toenail conditions and 186 had fingernail conditions, with 72 participants having both fingernail and toenail conditions. Sample characteristics are shown in Tables 1-2.

Figure 2 shows the NAIL-Q conceptual framework. Each aspect of the framework is measured by a NAIL-Q scale. RMT analyses for the 7 scales provided evidence of reliability and validity. Data fit the Rasch model for six scales, with slight misfit for Strength: Fingernails ($p=0.02$). Reliability statistics with and without extremes for the Person Separation Index were ≥ 0.79 and Cronbach's alpha were ≥ 0.83 . Based on a test-retest sample, intraclass correlation coefficients were ≥ 0.81 . In an evaluation at the end of the survey, most participants agreed that the NAIL-Q was easy to understand, asked relevant and important questions in a respectful way, and thought that it should be used to inform clinical care. Further psychometric evidence is available in our publication [1].

Figure 1: The multiphase mixed methods approach our team follows to develop a PRO measure. (Reprinted from Riff KW, Tsangaris E, Goodacre T, et al.) International multiphase mixed methods study protocol to develop a cross-cultural patient-reported outcome instrument for children and young adults with cleft lip and/or palate (CLEFT-Q). *BMJ Open* 2017;7(1):015467.)

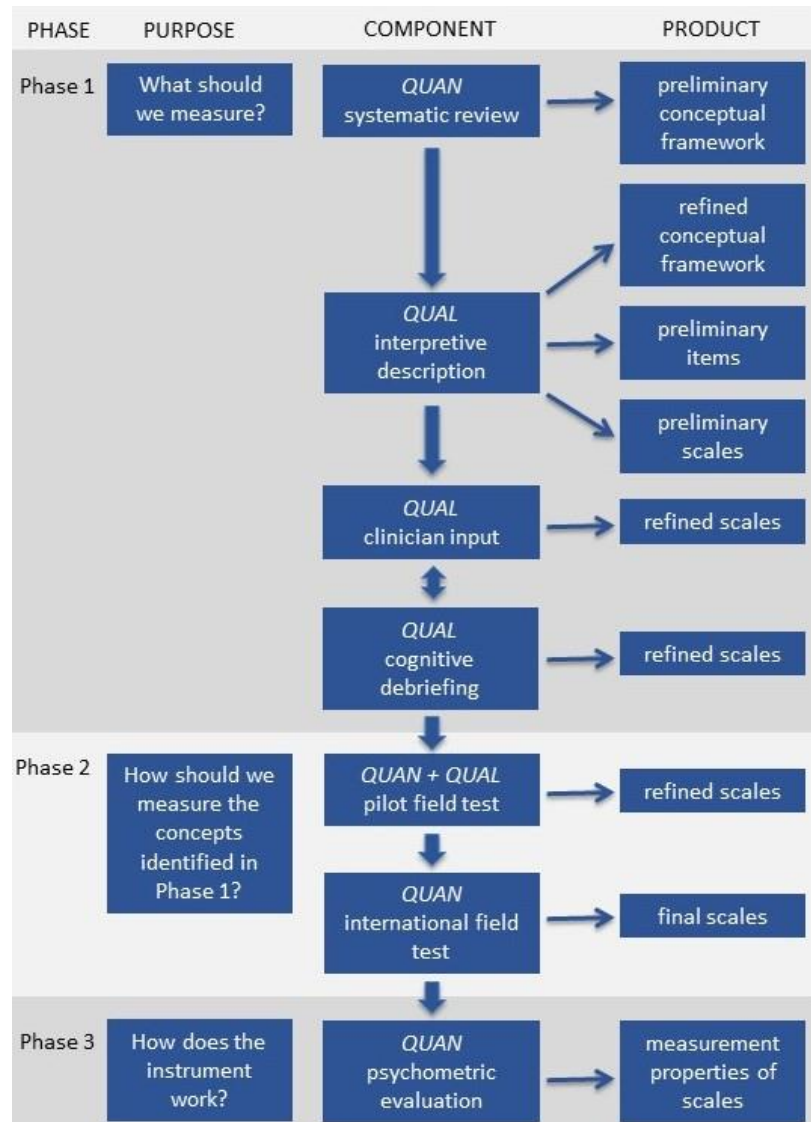


Figure 2: NAIL-Q Conceptual Framework

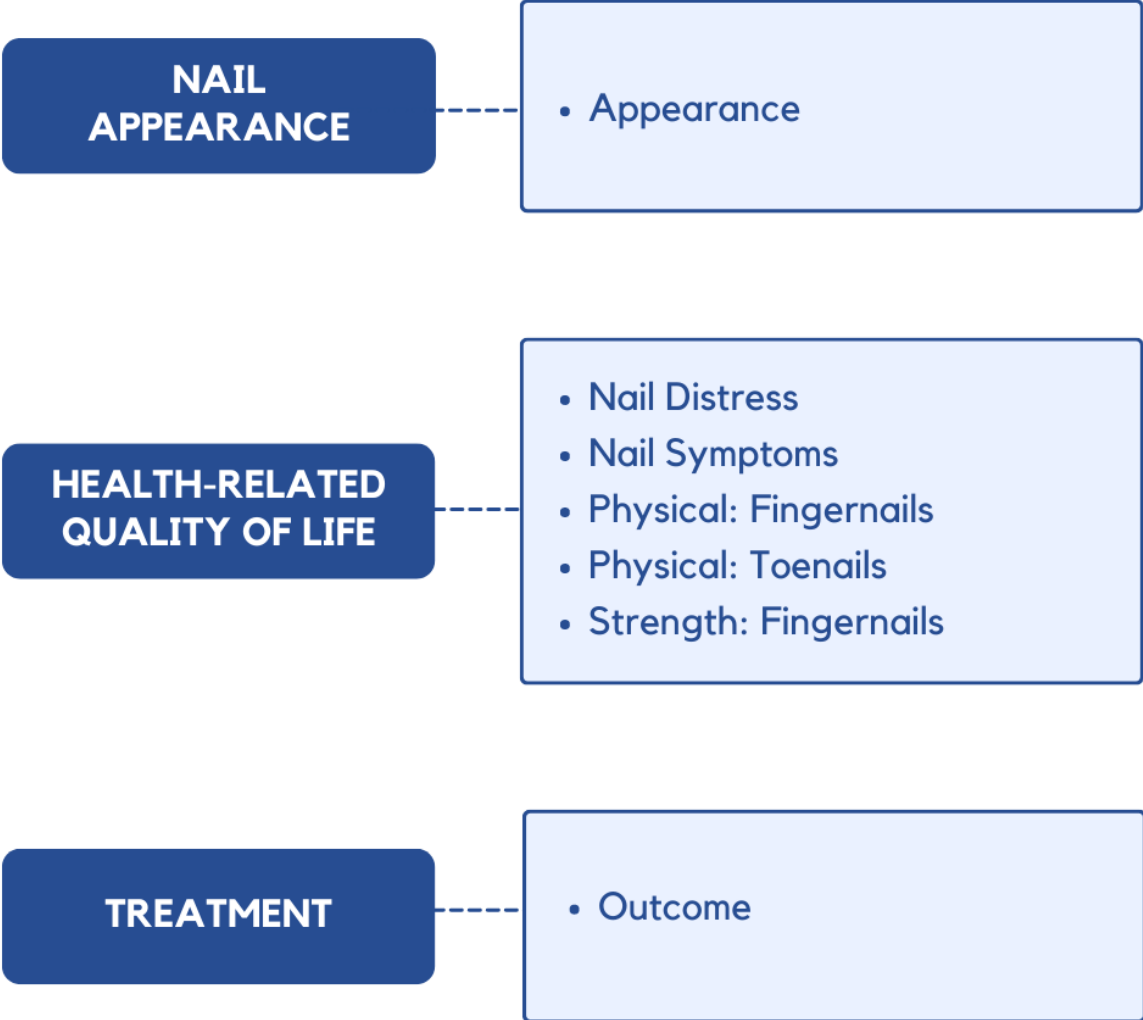


Table 1: Characteristics for the 555 participants who completed the NAIL-Q

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	43.2
	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
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

Table 2: Clinical characteristics for the 555 participants in the study sample

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
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

3. NAIL-Q Scales

Table 3 shows the NAIL-Q scales, including the number of items, response options, recall period, scoring, and Flesch-Kincaid (FK) grade reading level. Below the table is a brief description of the content of each scale.

Table 3: Description of NAIL-Q scales

Name	Items	Response options	Recall	Scoring	FK
Nail Appearance					
Appearance*	10	extremely dissatisfied → extremely satisfied	now	0-100	0.7
Health-Related Quality of Life					
Nail Distress*	7	always → never	1 week	0-100	4.9
Nail Symptoms*	6	extremely concerned → not at all concerned	1 week	0-100	2.9
Physical: Fingernails	6	always → never	1 week	0-100	10.7
Physical: Toenails	5	always → never	1 week	0-100	6.7
Strength: Fingernails	4	extremely concerned → not at all concerned	1 week	0-100	3.4
Treatment					
Outcome	7	strongly disagree → strongly agree	most recent	0-100	4.7

*A version of this scale is available for fingernails and one for toenails. The content and their scoring tables are identical, but the instructions differ and are specific to either toenails or fingernails.

NAIL APPEARANCE

Appearance (Fingernail or Toenail): This 10-item scale measures satisfaction with current nail appearance using 6 response options that range from extremely dissatisfied to extremely satisfied. Items ask how clear the nails look, how strong they are, how smooth the surface looks, and how they look compared with other people’s nails.

HEALTH-RELATED QUALITY OF LIFE

Nail Distress (Fingernail or Toenail): This 7-item scale measures how often (always, often, sometimes, rarely, never) someone experienced nail-related distress in the past week. Items ask about psychosocial concerns such as being aware of the nail condition around

other people, avoiding photos that show the nails, and feeling self-conscious, upset, and frustrated by the nail condition.

Nail Symptoms (Fingernail or Toenail): This 6-item scale measures how concerned (extremely, very, somewhat, a little, not at all) someone has been about their nail condition in the past week. Items ask about skin that bleeds and looks red, as well as nails that throb and cause pain.

Physical: Fingernails: This 6-item scale measures fingernail function in terms of how often (always, often, sometimes, rarely, never) someone's nail condition has interfered with activities in the past week. Items ask about buttoning a shirt or coat, personal grooming, doing chores around the house and putting on or taking off clothes.

Physical: Toenails: This 5-item scale measures toenail function in terms of how often (always, often, sometimes, rarely, never) someone's nail condition has interfered with activities in the past week. Items ask about their ability to walk or move around, doing one's usual daily activities, and being physically active.

Strength: Fingernails: This 4-item scale measures how concerned (extremely, very, somewhat, a little, not at all) someone has been about the strength of their fingernails in the past week. Items ask about nails that peel, split, chip, and break.

TREATMENT

Outcome: This 7-item scale measures how much the person agrees or disagrees using 6 response options with statements about the outcome of the most recent treatment for their nail condition. Items ask whether the treatment met with their expectations, was worthwhile having, and whether they would recommend it to other people with their nail condition.

4. Administration of the NAIL-Q

The NAIL-Q is designed to be completed by adult patients on their own (self-report). Each scale is independently functioning, which means that only scales relevant to the clinical situation or research question should be completed. Brief instructions and the timeframe for reporting are provided at the start of each scale. The NAIL-Q was field-tested using Research Electronic Data Capture System (REDCap). You may use a paper and pencil format or create an online version for ease of administration in non-profit academic research (e.g., REDCap) and in clinical care (e.g., hospital EMR such as Epic). If you plan to have an ePRO company capture and manage NAIL-Q data collection, the ePRO company may need a license. If you have had NAIL-Q scales converted into an electronic format, you will require an e-conversion review and certificate. Please email qportfolioteam@gmail.com for more information.

5. Scoring the NAIL-Q

There is no overall or total NAIL-Q score. Instead, the NAIL-Q is composed of independently functioning scales.

To score a scale, the raw scores for the set of items in a scale are added together to produce a total raw score. If missing data is less than 50% of the scale's items, the within person mean for the completed items can be imputed for the missing items prior to computing a total raw score. For example, if there is a 10-item scale and someone has not responded to all the items, but has responded to ≥ 5 items, all other items for that person can be imputed with a within-person mean (rounded to the nearest integer), and a summed score can be calculated. Alternatively, for a 10-item scale, if someone has responded to ≤ 4 items, the summed score for this person cannot be computed and is classified as missing data. Importantly, the Conversion Tables are only valid with complete data (i.e., when a person has $\geq 50\%$ completed responses). Once a total raw score for the scale is computed, the Conversion Table can be used to convert the raw score into a score that ranges from 0 (worst) to 100 (best). The conversion, which linearizes the scores, is based on the findings from the Rasch analysis. Higher scores for NAIL-Q scales reflect a better outcome. The Conversion Tables for changing raw scores into 0 to 100 scores are available after a licensing agreement is signed.

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- You will not sell, sublicense, rent, loan, or transfer the NAIL-Q to anyone.
- You will not reproduce any NAIL-Q scales in publications or other materials.
- You will not translate the NAIL-Q without permission from our team.

For questions regarding study design and optimal use of NAIL-Q scales, please contact:

Anne Klassen, DPhil (Oxon)
McMaster University
Hamilton, Ontario
Canada
aklass@mcmaster.ca

7. Frequently Asked Questions

Do I need to use all the scales?

Each scale functions independently; therefore, patients can be asked to complete one or more scales. It is not necessary for a patient to complete all of the scales as there is no overall or total NAIL-Q score. A researcher or clinician may, therefore, select a subset of scales depending on the particular purpose of the study or use.

Can I use any full items of the NAIL-Q in my publication?

According to the licensing agreement, you cannot reproduce the content of NAIL-Q scales verbatim in a publication. However, it is possible to show shortened versions of items. The short forms of items that can be used in a publication are shown in Table 4 below and in the psychometric publication for the NAIL-Q Table S5 [1].

Table 4: Shortened items for NAIL-Q scales to use in publications

APPEARANCE	DISTRESS	PHYSICAL: FINGERNAILS	STRENGTH: FINGERNAILS
clear	aware with others	button	peel
hard	avoid photos	groom	split
strong	upset	type	chip
thickness	frustrated	daily activities	break
smooth	people look	chores	OUTCOME
even surface	self-conscious	clothes	glad had it
normal	dislike	PHYSICAL: TOENAILS	would recommend
healthy	SYMPTOMS	independent	worthwhile
compared	skin bleeds	daily activities	time and effort
up close	nails throb	walk or move	treatment worked
	skin red	activities enjoy	pleased
	skin swollen	physically active	better than expected
	pain in tips		
	nails cause pain		

Can I delete or add or change any items or response options of the NAIL-Q?

You cannot delete or add or change the wording of any items or response options of the NAIL-Q. Any modification to the content of the NAIL-Q is prohibited under copyright laws. Also, making any changes to NAIL-Q scales would invalidate their psychometric properties.

Can I translate the NAIL-Q into a new language?

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Are there specific time points when patients complete the scales?

A researcher or clinician can decide the time points they would like to administer the scales.

Does it cost money to use the NAIL-Q?

Use of NAIL-Q scales is free for non-profit users, including use by hospitals. For-profit users should contact McMaster University for information about fees: milo@mcmaster.ca.

8. Publications Related to NAIL-Q Development and Validation

1. Klassen AF, Rae C, O'Malley M, Breitkopf T, Algu L, Mansouri J, Brown CR, Wang Y, Lipner SR. Development and Validation of a Patient-Reported Outcome Measure for Fingernail and Toenail Conditions: the NAIL-Q. *Clin Cosmet Investig Dermatol*. 2023 Oct 27;16:3091-3105.
2. Abid K, Algu L, Kamran R, Leveille CF, Rae C, Lipner SR, Klassen AF. Content Analysis of Patient-Reported Outcome Measures Used in Patients With Nail Conditions: A Systematic Review. *JAMA Dermatol*. 2021 Dec 1;157(12):1509–1511.