



WOUND-Q®

A User's Guide for Researchers and Clinicians

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1. What is the WOUND-Q?

The WOUND-Q is a rigorously developed patient-reported outcome measure (PROM) that measures outcomes important to patients with any type of chronic wound located in any anatomical location. The WOUND-Q can be used to measure outcomes in research and clinical practice from the perspective of patients.

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

The WOUND-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, WOUND-Q scales can be used with individual patients to inform clinical care.

Figure 1 shows the multiphase mixed-methods approach we use to develop Q-Portfolio instruments. We followed internationally recommended guidelines for PROM development to ensure that the WOUND-Q meets requirements of regulatory bodies. A detailed description of the protocol followed to develop the WOUND-Q has been published [1].

The qualitative phase took place between January 2016 and March 2017. Table 1 shows characteristics of the qualitative study sample. We conducted 60 interviews with patients with more than 11 different types of wounds that had lasted 3 months to 25 years. Analysis led to the development of a conceptual framework and a set of scales that measure concepts important to patients. The qualitative dataset included 2776 codes that covered four top-level domains: wound (726 codes); health-related quality of life (510 physical codes, 329 social codes, and 257 psychological codes); experience of care (572 codes); and treatment (382 codes). Figure 2 shows the WOUND-Q conceptual framework. A set of independently functioning scales was developed from the coded material.

Content validity for WOUND-Q scales was established through 20 cognitive debriefing interviews with people with chronic wounds. These interviews were conducted between September 2017 and March 2018. The scales were also shown to 12 plastic surgeons, four vascular surgeons, two general surgeons, and three nurse practitioners. Experts were based in Australia, Belgium, Canada, Denmark, Germany, the Netherlands, the USA, and the UK. An additional five plastic surgeons attending a wound conference took part in one-on-one interviews. Based on patient and expert input, the scales were further refined.

Teams in Denmark and the Netherlands performed translation and cultural adaptations of the WOUND-Q in preparation for data collection. The field-test study took place in Canada, Denmark, the Netherlands, and the USA between August 2018 and May 2020. Data were collected from 881 patients with a broad range of chronic wounds. The sample provided 1020 WOUND-Q assessments. Research Electronic Data Capture System (REDCap) was used for data entry in Canada, Denmark, and the USA. Data collection in the Netherlands used the Castor database. Some data were collected using paper booklets. Table 1 shows characteristics for the field-test sample. Most participants reported having drainage from their wound in the past week, and many reported their wound smelled in the past week.

The WOUND-Q (see Table 2) measures 4 domains: wound; health-related quality of life; experience of healthcare; and treatment. Each domain has multiple independently functioning scales. RMT analysis provided evidence of reliability and validity for 13 scales. Details about the development and validation of the WOUND-Q are available in our publications [1-4].

Figure 1: The multiphase mixed-methods approach our team follows to develop PRO measures (Reprinted from Klassen A, van Haren ELWG, Cross K, et al. International multiphase mixed methods study protocol to develop a patient-reported outcome measure for all types of chronic wounds (the WOUND-Q). *BMJ Open*. 2020;10:e032332. doi:10.1136/bmjopen-2019-032332)

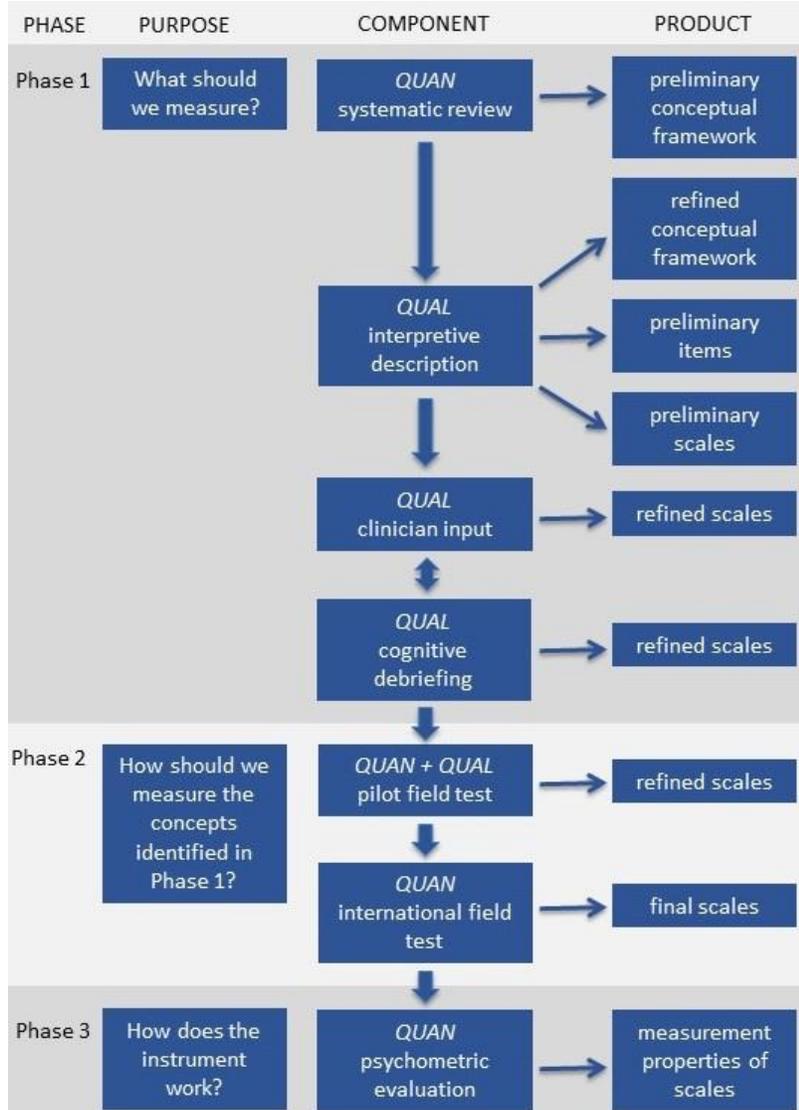
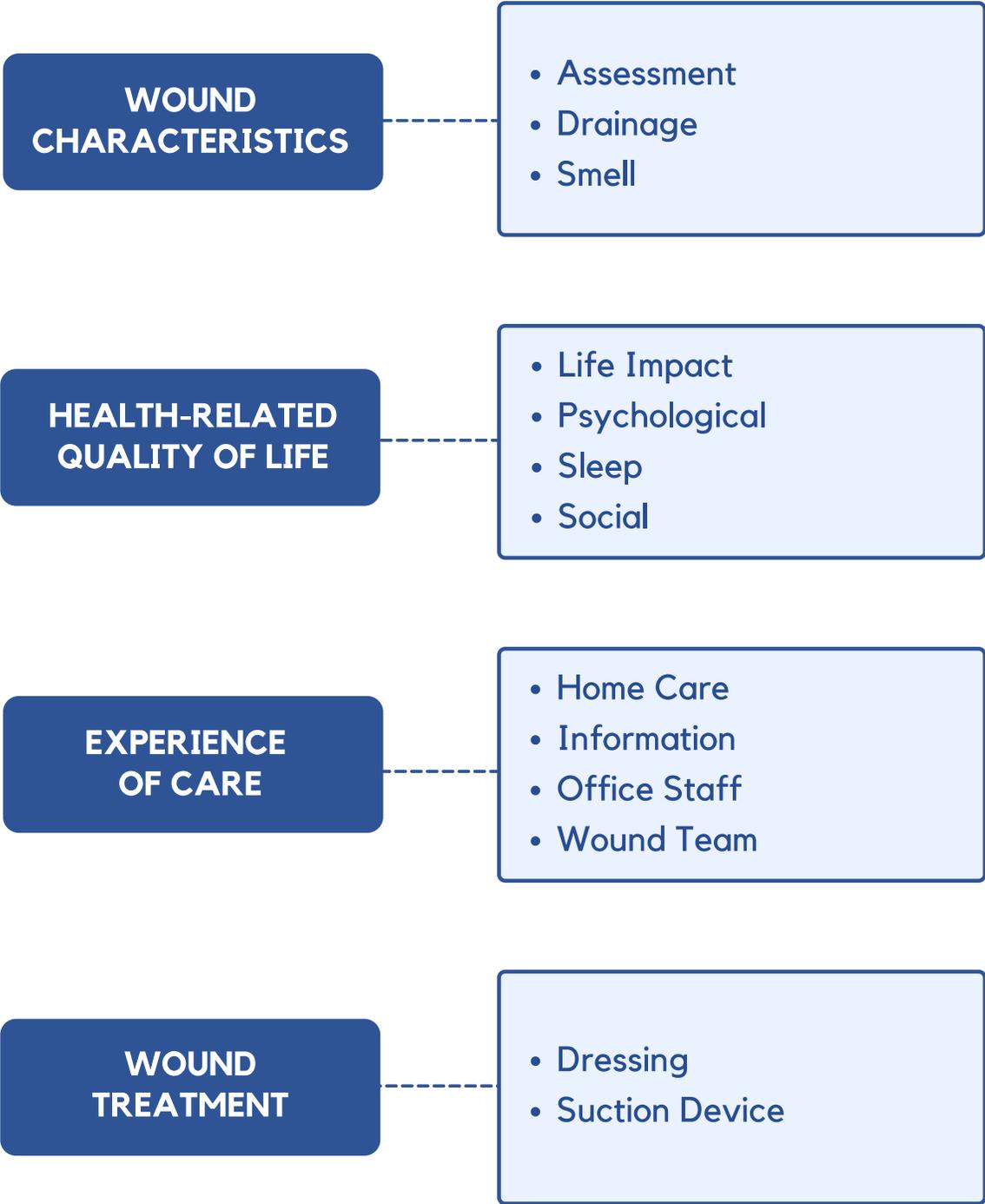


Table 1: Characteristics of participants in phase 1 (N=60) and phase 2 (N=881)

		Phase 1		Phase 2	
		N	%	N	%
Country	Canada	21	35	128	14.5
	Denmark	12	20	299	33.9
	The Netherlands	15	25	221	25.1
	USA	12	20	233	26.4
Gender	Male	35	58	519	58.9
	Female	25	42	357	40.5
	Other	0	0	2	0.2
	Missing	0	0	3	0.3
Age in years	18-49	17	28	145	16.5
	50-59	13	22	183	20.8
	60-69	15	25	243	27.6
	70-79	15	25	207	23.5
	80-95	0	0	102	11.6
	Missing	0	0	1	0.1
BMI	Under/normal weight	15	25	263	29.9
	Overweight	24	40	257	29.2
	Obese	14	23	328	37.2
	Missing	7	12	33	3.7
Number of wounds	Healed	0	0	11	1.2
	1	40	67	553	62.8
	2	10	17	162	18.4
	3+	10	17	155	17.6
Wound type or cause	Diabetic foot ulcer	8	14	152	17.3
	Pressure ulcer	15	25	130	14.8
	Surgical wound	9	15	142	16.1
	Venous Ulcer	12	20	111	12.6
	Trauma/injury	1	2	96	10.9
	Arterial ulcer	0	0	31	3.5
	Hidradenitis	5	8	23	2.6
	Radiation necrosis	2	3	14	1.6
	Infection	0	0	9	1.0
	Cancer	1	2	7	0.8
	Pyoderma gangrenosum	0	0	6	0.7
	Pilonidal abscess	2	3	6	0.7
	Other/unknown	3	5	136	15.5
	Multiple	2	3	10	1.1
Missing	0	0	8	0.9	

		Phase 1		Phase 2	
		N	%	N	%
Location of wound	Leg or knee	17	28	270	30.6
	Foot, ankle	14	24	227	25.8
	Toe(s)	0	0	70	7.9
	Buttocks	12	20	62	7.0
	Abdomen, genitals, chest, back	4	8	59	6.7
	Arm, shoulder, armpit, hand	0	0	18	2.1
	Face or neck	0	0	6	0.7
	Other	0	0	5	0.6
	Multiple	0	0	121	13.7
	Missing	0	0	43	4.9
Age of wound	3 to 6 months	14	23	318	36.1
	7 to 12 months	13	22	166	18.9
	1 to 2 years	16	27	181	20.5
	3 to 4 years	6	10	88	10.0
	5 to 10 years	5	8	49	5.6
	More than 10 years	6	10	36	4.1
	Missing	0	0	43	5.0
Wound size, cm length x width	<0.1	7	12	206	23.4
	1 to 2.4	15	25	146	16.6
	2.5 to 4.9	10	17	98	11.1
	5 to 9.9	14	24	94	10.7
	10 to 24.9	10	17	136	15.4
	≥25	0	0	138	15.7
	Missing	3	5	63	7.2

Figure 2: WOUND-Q conceptual framework



3. WOUND-Q Scales

Table 2 shows the WOUND-Q scales including number of items, response options, recall period, and Flesch-Kincaid (FK) grade reading level. Below the Table 2 is a brief description of the content of each scale.

Table 2: Description of WOUND-Q scales

Name of scale	Items	Response options	Recall period	FK
Wound				
Assessment	11	very much → not at all	past week	1.5
Drainage	8	very much → not at all	past week	4.6
Smell	8	very much → not at all	past week	4.0
Health-Related Quality of Life				
Life Impact	8	very much → not at all	past week	8.6
Psychological	10	always → never	past week	12.0
Sleep	5	always → never	past week	5.2
Social	5	agree → disagree	past week	7.5
Patient Experience				
Information	10	dissatisfied → satisfied	n/a	6.8
Home Care	10	disagree → agree	most recent	4.6
Wound Team	10	disagree → agree	most recent	5.5
Office Staff	8	disagree → agree	most recent	5.1
Treatment				
Dressing	9	dissatisfied → satisfied	most recent	4.7
Suction Device	9	dissatisfied → satisfied	most recent	5.6

WOUND

Assessment: This 11-item scale measures how concerned (very much, quite a bit, a little bit, not at all) someone has been with their wound(s) over the past week. If a person has more than one chronic wound, they are asked to answer based on the wound that concerns them the most. Items ask about the wound in terms of its size, shape, how it smells, and the amount of drainage, as well as specific symptoms including pain, burning, swelling, and bleeding.

Drainage: This 8-item scale measures how bothered (not at all, a little bit, quite a bit, very much) someone has been in the past week by drainage from their wound(s). If a person has more than one chronic wound, they are asked to answer based on the wound that bothers them the most. Items ask about the color, thickness, smell, and amount of drainage, as well as how noticeable the drainage is, how often dressings need to be changed, and how much the drainage interferes with their ability to enjoy life.

Smell: This 8-item scale measures how bothered (not at all, a little bit, quite a bit, very much) someone has been in the past week by the smell from their wound(s). If a person has more than one chronic wound, they are asked to answer based on the wound that smells the worst. Items ask about the smell itself, i.e., how unpleasant it is and how strong it is with and without a dressing. Other items ask about any impact on social life, close relationships, and people commenting on the smell.

HEALTH-RELATED QUALITY OF LIFE

Life Impact: This 8-item scale measures how much (not at all, a little bit, quite a bit, very much) in the past week someone's quality of life has been affected by their wound(s). Items ask about close relationships, emotional wellbeing, social life, ability to be independent, etc.

Psychological: This 10-item scale measures how often (never, sometimes, often, always) in the past week someone's wound(s) has affected their psychological function. Items ask about feeling hopeless, depressed, anxious, self-conscious, frustrated, etc.

Sleep: This 5-item scale measures how often (never, sometimes, often, always) in the past week someone's wound(s) has affected their sleep. Items ask about trouble falling asleep, finding a comfortable position to sleep in, staying asleep, etc.

Social: This 5-item scale measures the impact of a person's wound(s) on their social life. The scale is based on the past week and items ask respondents to indicate how much they agree/disagree that they felt isolated, found it hard to get out, missed out on social events, etc.

EXPERIENCE OF CARE

Information: This 10-item scale measures satisfaction with information a person has received about chronic wounds from the wound care team and how it was given. Items ask about who would be involved in their care, how easy it was to understand the information, what they could do to promote healing, etc.

Home Care: This 10-item scale measures satisfaction with wound care delivered by homecare nurses. Items ask respondents to indicate how much they agree/disagree that the nurses treated them with respect, made them feel comfortable, were attentive, had the right amount of experience, etc.

Wound Team: This 10-item scale measures satisfaction with members of the wound care team (e.g., doctors, nurses). Items ask respondents to indicate how much they agree/disagree that the wound team treated them with respect, talked to them in a way that was easy to understand, worked together as a team, etc.

Office Staff: This 8-item scale measures satisfaction with members of the office staff (e.g., secretaries, receptionists). Items ask respondents to indicate how much they

agree/disagree that the office staff treated them with respect, were attentive to their needs, were available when they had concerns, etc.

TREATMENT

Dressing: This 9-item scale measures satisfaction with wound dressing. Items ask about how easy the dressing was to put on and remove, how often it needed to be changed, how comfortable it was to wear, etc.

Suction Device: This 9-item scale measures satisfaction with the use of a suction device (e.g., vacuum pump device, negative pressure therapy dressing). Items ask about how well the device removed drainage, how much noise it made, and the ability to socialize, enjoy life and be physically active when the device was used, etc.

4. Administration of the WOUND-Q

The WOUND-Q was designed for patients with chronic wounds to complete on their own (self-report). Each scale is independently functioning, which means that only scales relevant to the clinical situation or research question need be completed. Patients can thus be asked to complete a subset of scales relevant to their situation. Brief instructions are provided at the start of each scale. The WOUND-Q was field-tested using two modes of data collection, i.e., online data collection using Research Electronic Data Capture System (REDCap) and paper-and-pencil. You may use the 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 WOUND-Q data collection, the ePRO company may need a license. If you have had WOUND-Q scales converted into an electronic format and require an e-conversion review and certificate, please email gportfolioteam@gmail.com.

5. Scoring the WOUND-Q

There is no overall or total WOUND-Q score. The WOUND-Q is composed of independently functioning scales that are scored separately. 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 WOUND-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.

6. Conditions of Use

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Use of the WOUND-Q questionnaire requires completion of a licensing agreement. The use of the WOUND-Q and its modules in non-profit academic research and in clinical care is free of charge. The use of the WOUND-Q by ‘for-profit’ organizations (e.g., pharmaceutical companies, contract research organizations, ePRO companies) is subject to a licensing fee.

Non-profit users can access the WOUND-Q using the following link:

<https://qteam.mcmaster.ca/surveys/?s=9X73E834MCH4LPY3>

For questions regarding fees to be paid by ‘for-profit’ organizations, please contact:

Licensing Manager
Office of Technology Development
Memorial Sloan Kettering Cancer Center
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gotdtrm@mskcc.org

PLEASE NOTE

When you sign a WOUND-Q license, you agree to the following terms:

- You will not modify, adapt, or create another derivative work from the WOUND-Q
- You will not sell, sublicense, rent, loan, or transfer the WOUND-Q to anyone
- You will not reproduce any WOUND-Q scales in publications or other materials
- You will not translate the WOUND-Q without permission from our team

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

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7. Frequently Asked Questions

Do I have to use all the scales?

Each scale functions independently; therefore, patients can be asked to complete some or all the WOUND-Q scales. It is not necessary for a patient to complete all of the scales as there is no overall or total WOUND-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 delete or add or change any items or response options of the WOUND-Q?

You cannot delete or add or change the wording of any items or response options of the WOUND-Q. Any modification to the content of the WOUND-Q is prohibited under copyright laws. Making changes to the WOUND-Q would invalidate its psychometric properties.

Can I reproduce WOUND-Q scales in a publication or other public document (e.g., PhD thesis)?

According to the licensing agreement, you cannot reproduce the content of WOUND-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 3 below. These short forms are from the publication that described the international WOUND-Q field-test study [3].

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

Yes, with permission, you can translate the WOUND-Q into different languages. Before starting a translation, check our translations list on www.qportfolio.org to see if there is a translation in the language you need. If there is not a translation in the language you need, you will need to obtain permission from our team, sign a translation licensing agreement, and receive information on the method you need to follow. Email us at qportfolioteam@gmail.com for more information. Please note that the developers of the WOUND-Q own the copyright of all translations of the WOUND-Q.

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 WOUND-Q?

Use of WOUND-Q scales is free for non-profit users, including the use by hospitals in patient care. For-profit users should contact Memorial Sloan Kettering Cancer Center for information about fees (gotdtrm@mskcc.org).

Table 3: Shortened items for WOUND-Q scales to use in a publication

ASSESSMENT	relax	team members	OFFICE STAFF
bleeding	emotional	easy to understand	respect
smell	social life	time to discuss	comfortable
burning	independence	written information	caring
holes	move around	promote healing	professional
swelling	activities enjoy	wound products	thorough
edges	physically active	timing of information	attentive
colour	PSYCHOLOGICAL	consistent	questions
drainage	hopeless	expectations	available
pain	desperate	HOME CARE	DRESSING
deep	overwhelmed	respect	put on
size	sorry for self	spent time	looks
DRAINAGE	depressed	attentive	absorb
colour	self-conscious	careful	smell
thick	anxious	decisions	remove – easy
smell	irritated	professional	change
noticing	frustrated	questions	comfortable
clothes	worried	right experience	remove – felt
enjoy life	SLEEP	knowledgeable	active
amount	falling asleep	knew what to do	SUCTION DEVICE
dressing	enough sleep	WOUND TEAM	drainage
SMELL	staying asleep	respect	looks
relationships	position	understand	sleep
comments	woken up	professional	noise
social life	SOCIAL	questions	carry
dressing on	isolated	knowledgeable	comfortable
noticing	meet people	right experience	socialize
stopping	missed out	worked together	enjoy life
unpleasant	cut down	high level care	active
dressing off	enjoy life	decisions	
LIFE IMPACT	INFORMATION	available	
relationships	ask questions		

8. Acknowledgements

Development of the WOUND-Q has involved hundreds of people with chronic wounds and the collaboration of numerous health care professionals and researchers around the world. We are truly grateful for their dedication and help with our research. The WOUND-Q study has been generously funded by the following grants:

Qualitative Phase: Pusic A, Klassen A, (co-PI). A Qualitative Phase I Study to Develop a New Patient-Reported Outcome Instrument for Acute and Chronic Wounds: The WOUND-Q. The Plastic Surgery Foundation, January 2016 – July 2017.

Quantitative Phase: Pusic A, Klassen A, (co-PI). Development and Validation of a New Patient-Reported Outcome Instrument for Chronic Wounds: The WOUND-Q Phase II study. The Plastic Surgery Foundation, March 2018 – February 2020.

9. Publications Related to WOUND-Q Development and Validation

1. Klassen AF, Cross K, Gibbons C, Hoogbergen MM, Longmire N, Poulsen L, Squitieri L, Tsangaris E, van Alphen T, van Haren ELWG, Pusic AL. International mixed methods study protocol to develop a patient-reported outcome instrument for all types of chronic wounds: The WOUND-Q. *BMJ Open*. 2019; 10(3):e032332. doi: 10.1136/bmjopen-2019-032332.
2. Squitieri L, Tsangaris E, Klassen AF, van Haren ELWG, Poulsen L, Longmire NM, van Alphen TC, Hoogbergen MM, Sorensen JA, Cross K, Pusic AL. Patient-reported experience measures are essential to improving quality of care for chronic wounds: an international qualitative study. *Int Wound J*. 2020; 17(4):1052-1061. doi: 10.1111/iwj.13374.
3. Klassen AF, van Haren ELWG, van Alphen TC, Cano S, Cross KM, van Dishoeck A, Fan KL, Hoogbergen MM, Orgill D, Poulsen L, Sørensen JA, Squitieri L, Tsangaris E, Vasilic D, Pusic AL. International Study to Develop the WOUND-Q Patient-Reported Outcome Measure for all Types of Chronic Wounds. *Int Wound J*. 2021; 1-23. doi.org/10.1111/iwj.13549.
4. van Alphen T, Poulsen L, van Haren E, Lind Jacobsen A, Tsangaris E, Sørensen JA, Hoogbergen M, van der Hulst R, Pusic A, Klassen A. Danish and Dutch linguistic validation and cultural adaptation of the WOUND-Q, a PROM for chronic wounds. *Eur J Plast Surg*. 2019; 10:1-0. doi.org/10.1007/s00238-019-01529-7