

The Development and Validation of the CARE Burn Scale—Adult Form: A Patient-Reported Outcome Measure (PROM) to Assess Quality of Life for Adults Living with a Burn Injury

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Patient-Reported Outcome Measures (PROMs) identify vital information about patient needs and therapeutic progress. This paper outlines the development and validation of the CARE Burn Scale—Adult Form: a PROM that assesses quality of life in adults living with a burn injury. Eleven patients, 10 family members and 4 health professional interviews, and a systematic review informed the development of a conceptual framework and a draft measure. Cognitive debriefing interviews conducted with three adult burn patients, one family member, and eight health professionals provided feedback to ascertain content validity of the measure. The measure was then field tested with 304 adult burn patients. Rasch psychometric analysis was conducted for scale reduction, and traditional psychometric analyses provided a comparison with other measures. Further psychometric testing with an additional 118 adult burn patients tested the shortened CARE Burn Scale in relation to other quality of life PROMs. The conceptual framework outlined 14 domains; 12 of which fulfilled Rasch and traditional psychometric analyses. Two individual scales did not fulfill the Rasch criteria and were retained as checklists. Individual CARE Burn Scales correlated moderately-to-highly with other quality of life scales measuring similar constructs, and had low-to-no correlations with dissimilar constructs and the majority of sociodemographic factors, indicating evidence of concurrent and divergent validity. The CARE Burn Scale—Adult Form can help identify patient needs and provides burns-specialist health professionals with a tool to assess quality of life and therapeutic progress after a burn event and related treatment.

In the United Kingdom, approximately 250,000 individuals sustain burn injuries every year, with 7634 patients requiring specialist treatments in 2011.^{1,2} The needs of burn patients are complex and wide-ranging. Burn wounds and scarring can cause severe pain and itching and limit range of movement.^{3,4} These factors, along with potentially significant time spent attending scar management, physiotherapy, and other clinical appointments, can also impact an individual's ability to engage with work and activities of daily living.⁵

A number of psychosocial difficulties such as depression,^{6–11} anxiety,^{6,9,12,13} difficulties sleeping,¹⁴ and trauma

symptoms^{5,6,8,9,15} can also accompany the physical impact of a burn. Patients with burn scarring can also encounter unwanted questions or staring from others which can lead to avoidance of activities which could draw attention to their scars, fear of being judged negatively by others, low social self-esteem, and withdrawal from romantic relationships.^{16–18} Consequently, social support from friends, family, and health professionals is paramount when adapting to the impact of a burn.^{19,20}

Given the complex and varying needs of burn patients, it is essential that health professionals are able to comprehensively assess postburn adjustment, in order to identify individual support needs. While many adjust well,^{9,21} and some report posttraumatic growth following the injury,²² others experience significant difficulties.²³ For some, psychosocial adjustment is harder to manage than the physical symptoms.²⁴ Furthermore, psychosocial difficulty is not predicted by the size, location, or depth of a burn²⁵ and many patients encounter new challenges as they progress through their treatment and recovery.⁵ It is, therefore, important to assess the needs of all patients rather than focusing on those with more physically serious or visible injuries, and not to focus solely on the acute recovery period.

However, psychosocial health professionals working in U.K. NHS (National Health Service) Burn Services, often lack time and resources to assess all patients, or rely on information from staff who do not have specialist training when deciding who would benefit from psychosocial support.⁵ Patient-Reported

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Outcome Measures (PROMs) offer a potential solution to issues of assessment in burn services. PROMs, which are standardized, rigorously tested health-related questionnaires, enable health professionals to identify the needs of their patients, and assess their therapeutic progress throughout the treatment pathway.²⁶ Furthermore, communicating the status of one's own health can be an empowering experience for patients; putting them at the center of their own care.²⁷ Although the use of PROMs within the United Kingdom was recommended by The NHS Next Stage Review,²⁸ the National Burn Care Review concluded that PROMs are not consistently used within U.K. Burn Services and identified a lack of PROMs designed to assess the needs of burn patients being treated within this system.²⁹ For this reason, the need to develop burn-specific U.K. PROMs and the importance of rigorous outcome measurement within U.K. burn care have been highlighted.^{1,27}

A recent systematic review of PROMs used in adult burn research identified 77 different PROMs being used, however only 4 were burn-specific.³⁰ While generic PROMs can be useful for detecting general health outcomes, condition-specific PROMs often have better face validity and can be more sensitive to condition-specific health needs and detecting therapeutic changes.³¹ Although the level of psychometric evaluation was considered strong overall, Griffiths et al's review concluded that most PROMs had not been validated with an adult burn population, and only a small number had been developed in collaboration with adult burn patients.

Positively, a small number of validated burn-specific PROMs, assessing quality of life in adult burn patients, are available. These include the Burn-Specific Health Scale-Abbreviated (BSHS-A)³² and Burn-Specific Health Scale-Brief (BSHS-B),³³ the Adult Burn Outcome Questionnaire Short Form (ABOQ),³⁴ the Young Adult Burn Outcome Questionnaire (YABOQ),³⁵ the Brisbane Burn Scar Impact Profile (BBSIP) for Adults,³⁶ and the Life Impact Burn Recovery Evaluation (LIBRE) Profile.³⁷ However, there are currently no PROMs which have been designed for, or developed in collaboration with, adult burn patients in the United Kingdom. Additionally, current PROMs do not include all aspects of quality of life affected by burns (eg, positive growth) or both the wound and scar phases after injury. This has led health professionals to rely on large batteries of different measures, which can be time consuming and burdensome for patients.⁵ In summary, it is important that Burn Services in the United Kingdom have access to a quality of life PROM for adults affected by burns which assesses all aspects of burn injuries, and can be used at any stage of recovery.

The present study therefore followed the PROM development guidelines from the Scientific Advisory Committee of the Medical Outcomes Trust (2002)³⁸ and Cano et al,³⁹ to rigorously develop and psychometrically evaluate a burn-specific PROM to assess the needs of U.K. adult burn patients.

METHODS

All necessary University and NHS ethics approvals were obtained.

The CARE Burn Scale—Adult Form was developed following an established development and validation process, identified as the gold standard for developing and evaluating

PROMs.^{38,39} This involved item generation (developing a conceptual framework using a literature review, qualitative interviews with patients, and expert opinion), item reduction (using psychometric criteria such as Rasch analysis), and psychometric evaluation (using psychometric criteria).

Stage 1.1: Conceptual Framework Development

The conceptual framework of a PROM outlines the concepts/domains that it measures and the scale items are then developed based on this framework.³⁸ Historically, "top down" methods have often been used in which the conceptual framework and related items are developed based on the reviews of the literature or existing measures or conceptual frameworks.⁴⁰ Developing injury-specific measures (such as burn-specific PROMs) using these "top down" methods alone and not involving the patient population that the PROM is intended for, increases the likelihood that key experiences related to the impact of the injury on health outcomes will be missed.⁴¹ This in turn can reduce the content validity and the potential responsiveness of the PROM if it fails to measure key health domains that are important to the patient population.⁴⁰

More recently, a number of PROM development guidelines recommend using qualitative interviews or focus groups with patients to inform the conceptual framework and related items to increase the content validity of the PROM being developed.^{38,42,43} The Cochrane Handbook of Systematic Reviews⁴² in particular recommends that the conceptual framework (ie, the outline of the domains that a PROM measures) should be elicited from qualitative interviews with patients from the target population (in this case adult burn patients) and patients should be involved in generating the items that each domain measures to ensure that all relevant aspects of the domain are measured. The involvement of patients at the conceptual framework and item development stage is deemed essential to the content validity of the measure.⁴²

Similarly, Cano et al^{39,44,45} recommend that the conceptual framework of a PROM should be based on in-depth qualitative interviews with the target population, expert opinions, and a review of the literature. The current study followed this method to develop the conceptual framework and PROM items in the CARE Burn Scale—Adult Form.

Semistructured interviews were conducted with adult burn patients and burns-specialist health professionals to explore, in-depth, patients' experiences of living with a burn injury and its impact on quality of life. Recruitment aimed to include patients with different types of burn and from different age groups. Interviews took place face-to-face and over the telephone between April 2013 and October 2013. They were tape recorded, transcribed verbatim, and subjected to a thematic analysis.⁴⁶ These findings informed a conceptual framework to outline the key aspects of well-being that are influenced when living with a burn injury, and the domains that the CARE Burn Scale would measure.

Stage 1.2: Item Generation, Initial Scale Formation, and Pretesting

An extensive list of potential items was created for each domain in the conceptual framework, based on the patient interview data. When possible, patients' own words or

phrases were incorporated to increase the content validity of the items. A systematic review of PROM used in adult burn care research was also conducted³⁰ and from this review relevant quality of life scales were obtained and reviewed. Any new items identified in these scales that were not discussed in the interviews were added to the relevant CARE Burn Scale domain. Lastly, psychologists, counselors, and nurses from NHS Burn Services across the United Kingdom reviewed the draft measure and provided feedback to ensure it was as comprehensive as possible, acceptable to its potential users and suggested new items that were thought missing.

Cognitive debriefing interview techniques, a recommended part of the PROM development process,^{44,47} were then conducted with adult burn patients who were asked to review the draft scale to explain their understanding of the items, identify any that were unclear or hard to understand, provide feedback on the response categories, and suggest any new items that they felt were missing.⁴⁵

Stage 2: Item Reduction

Field-test versions of the CARE Burn Scale were handed out in burn clinics and posted to adult burn patients from 11 NHS Burn Services throughout the United Kingdom. Eligible participants were adults aged 18 years and over who had sustained a burn injury, had received treatment from an NHS Burn Service, and were able to read English in order to complete the questionnaire.

Rasch Measurement Model and Analyses. For the purpose of the Rasch Analyses, the raw scores were transformed into logits and then translated into a linear scoring system, using summated scales as described in [Supplementary Appendix B](#). The Rasch measurement model⁴⁸⁻⁵⁰ and analyses⁵¹⁻⁵³ were used for item reduction using RUMM2030.⁵⁴ The data collected for each domain of the conceptual framework was analyzed against the Rasch measurement criteria described below during the item reduction phase.

Item Fit Statistics. Rasch analysis involves assessing whether the observed data is consistent with the responses predicted by the Rasch mathematical model. Two indicators were examined: 1) item-trait interaction where a nonsignificant chi-square value ($P > .05$) indicates negligible deviation between observed data and expectations of the model; 2) the standardized residual, for each item in the range -2.5 to $+2.5$ indicates good fit, and should also have nonsignificant chi-square values (Bonferroni adjusted significance level of 0.01).

Person Separation Index (PSI). The PSI measures whether the measurement of patients in this sample are reliably separated. Higher scores reflect stronger reliability. The value of 0.7 indicated the possibility to distinguish at least two groups of patients. The PSI is similar to Cronbach's alpha which is commonly used to measure reliability.^{55,56}

Local Dependency. For each pair of items within a scale, a residual correlation >0.3 above the mean residual correlation (of all item pairs for that scale)⁵⁷ indicates a problem with fit,

suggesting the existence of extraordinary association within the set of items.

Unidimensionality. Unidimensionality assumption was checked by application of Smith's procedure⁵⁸ based on paired t -tests to see if the person estimates derived from most diverse subsets of items are significantly different. Unidimensionality is supported if the percentage, or the lower bound of the 95% binomial confidence interval, of significant t -tests ($P < .05$) is less than 5%.

Differential Item Functioning. To assess the extent to which item parameters remain invariant across different groups of patients we used Differential Item Functioning analysis (DIF).⁵⁹ We compared item difficulties given the level of the trait across the following: age (split based on median: ≤ 41 , >41), gender, ethnicity (White-British, Other), cause of burn (flame or liquid, contact, electricity, chemical, acid or other), wound healing status (burn scar, burn wound, both wound and scar, no wound or scar, other), and body part affected (usually visible to others [eg, head, neck, face, hands] or non-visible [eg, back, legs, bottom]). By this check, we explored the issue of possible bias that might be resulting in misfit of the data to model. Uniform and nonuniform DIF were investigated graphically (inspection of item characteristic curves [ICCs] for different groups) and by results of analysis of variance (Bonferroni adjusted significance level of 0.05).

Targeting and Item Locations. Distributions of item and person locations were graphically compared to determine whether they covered more or less on the same areas of Rasch continuum. Large floor and ceiling effects would indicate the existence of the problem.

Item Thresholds. For each item, the use of response categories scored with successive integer scores indicated a continuum of increasing impact. This assumption was tested by ordering the thresholds (or points of crossover between two adjacent response categories) specified by the Rasch analysis.

Traditional Psychometric Analysis (Classical Test Theory). Traditional psychometric analysis via classical test theory (CTT) was also conducted on the data to show how the scale operates based on the CTT criteria: Cronbach's alphas (for each scale domain) and item-total correlations. Analyses were undertaken using IBM SPSS Statistics 23.⁶⁰

Stage 3: Further Psychometric Evaluation

The final version of the CARE Burn Scale was then tested in comparison to other validated quality of life questionnaires in a different sample of adult burn patients to ascertain evidence of concurrent and discriminant validity, following recommended PROM development guidelines and criteria.⁶¹ Questionnaires were handed out in burn clinics and posted out to adult burn patients recruited from 11 NHS Burn Services throughout the United Kingdom. Eligible participants were adults aged 18 years and over who had sustained a burn injury and received treatment from an NHS Burn Service. Patients needed to be able to read English fluently in order to complete the questionnaire.

All statistical analyses were performed in Stata v.15.1.⁶² In addition to tests of data quality and scaling assumptions, the following properties relating to validity and reliability were examined:

1. Concurrent and discriminant validity: The final version of the CARE Burn Scale—Adult Form was compared with existing health PROMs, which measure similar constructs (the Burn Specific Health Scale Abbreviated (BSHS-A),³² EQ5ED,⁶³ PTSD CheckList—Civilian Version (PCL),⁶⁴ and the Post-traumatic Growth Inventory.⁶⁵ It was hypothesized that the CARE Burn Scale—Adult Form subscales would have moderate/high significant correlations with related constructs and low/no significant correlations with dissimilar constructs. Criteria were used as guides in terms of the magnitude of correlations, as opposed to pass/fail benchmarks (high correlation, $r > .70$; and moderate correlation, $r = .30-.70$).

Specifically, regarding the various subscales of the CARE Burn Scale—Adult Form (described in the results section, below), it was hypothesized that:

- *Wound/Scar Discomfort* and *Physical Well-being* would moderately correlate with the BSHS Physical Health scales.
- *Social Situations* would moderately correlated with the BSHS Social Health total score.
- *Friend Support* would moderately correlate with the BSHS Social Friends subscale.
- *Work Life* and *Family Support* would moderately correlate with the BSHS Social Health total score.
- *Wound/Scar Dissatisfaction* would moderately correlate with the BSHS Body Image subscale.
- *Trauma Symptoms*, *Negative Mood* and *Self-worth* would moderately correlate with the BSHS Mental Health total score and BSHS Mental Affect subscale.
- *Intimacy* would moderately correlate with the BSHS Social Sexual subscale.
- The Post Traumatic Growth Inventory would moderately correlate with *Positive Growth* and have low/no correlations with the other CARE Burn Scales since they are dissimilar constructs.

- *Trauma Symptoms* would moderately correlate with the PTSD CheckList—Civilian Version (PCL).
- The EQ-5D-5L would have low/moderate correlations with the individual CARE Burn Scale subscales since it is a general quality of life measure.

Traditional psychometric measurement properties were also examined: acceptability (percentage of missing data; <10%), and reliability (Cronbach’s alpha coefficients; >0.70), and acceptable item–total correlations; >0.30).

The relationship between CARE Burn Scale subscales and sociodemographic variables (age, gender, time since burn, ethnicity, marital status, and cause of burn) were also examined using regression analyses to determine the extent to which scores were influenced by these variables.

RESULTS

Stage 1.1: Conceptual Framework Formation

Eleven adult burn patients (4 female, 7 male, aged 27–78, $M = 51.90$, $SD = 18.68$; Table 1) and 10 of their family members (7 partners, 2 mothers, and 1 daughter, 7 female, 3 male, aged 42–78, $M = 57.00$, $SD = 13.09$) were interviewed. Four clinical psychologists who worked with adults with a burn were also interviewed (in-depth analysis of the health professionals’ interviews is reported in Guest et al⁵ and patient interview analysis is reported in Griffiths⁶⁶). Thematic analysis identified a range of themes which reflected patients’ experiences of living with a burn injury and its impact on quality of life. Informed by these interviews, expert opinions and the systematic review³⁰, 14 key domains formed the conceptual framework of adult burn patients’ experiences of living with a burn (Figure 1):

1. *Wound/Scar Discomfort*: the extent to which patients feel discomfort or pain in relation to their burn wound/scar.
2. *Physical Well-being*: patients’ physical health and their physical abilities.
3. *Wound/Scar Treatment*: the extent to which patients feel bothered by a range of different wound/scar treatments such as dressing/bandage changes, washing and dressing and physiotherapy exercises.

Table 1. Stage 1: Interview study participants

Ref	Age	Ethnicity	Burn Type	Body Part(s) Affected by Burn	Time Since Burn
P1	40	White	Flame	Hands, chest, breasts, abdomen, thighs	1.5 years
P2	35	White	Flame	Arms, face	2.5 years
P3	63	White	Flame	Arms, face	7 years
P4	71	White	Contact	Leg	3 years
P5	65	White	Flame	Leg, arms, face, stomach, hair	7 years
P6	59	White	Electrical	Feet, legs, hands, arm, head	2 years
P7	47	White	Flame	Arms, hands, torso (front and back), face, neck.	5 years
P8	52	White	Electrical	Face, hands, chest	4 years
P9	78	White	Liquid	Legs	3 years
P10	27	White	Flame	Legs, bottom, stomach	3 years
P11	34	Asian	Flame	Neck, face, arm.	1 year



Figure 1. Conceptual framework

4. *Social Situations*: patient confidence in challenging social situations in which other people may look, touch or ask questions about their burn wounds/scarring.
5. *Avoidance Behaviors*: the extent to which patients avoid looking at their burn or avoid activities or situations because of how their burn wounds/scars look.
6. *Self-worth*: the extent to which a patient has positive feelings about themselves.
7. *Negative Mood*: the extent to which a patient reports low/negative mood.
8. *Wound/Scar Dissatisfaction*: how bothered patients feel about the look of their burn wound/scarring.
9. *Work Life*: patients' perceptions of the quality of their work life.
10. *Family Support*: patients' perceptions of the quality of their family relationships.
11. *Friend Support*: patient perceptions of the quality of their friendships.
12. *Intimacy*: the extent to which patients' feel attractive to others and confident about showing their burn wounds/scars in intimate situations.
13. *Trauma Symptoms*: negative psychological and behavioral symptoms related to the patient's burn injury, such as flashbacks, bad dreams and anxiety.
14. *Positive Growth*: the extent to which patients report positive outcomes/personal development after living with a burn injury.

Stage 1.2: Item Generation, Initial Scale Formation, and Pretesting

Initial items ($n = 110$) were generated, covering all 14 domains of the conceptual framework. Cognitive debriefing interviews were then conducted with three adult burn patients and one family member, and feedback was also obtained from seven health professionals (four clinical psychologists, one counselor, one psychotherapist, and one physiotherapist) and one international PROM development expert. This resulted in minor changes to items (changes to wording, providing more burn-specific examples, more simple language) and a further 99 items being added to the existing domains, resulting in 209 items in the scale that was field tested.

The domains in which increasingly higher scores reflect increasingly poorer outcomes are: *Burn Wound/Scar Discomfort*, *Wound/Scar Treatments*, *Wound/Scar Dissatisfaction*, *Avoidance Behaviors*, *Trauma Symptoms*, and *Negative Mood*. The domains in which increasingly higher scores reflect increasingly better outcomes are: *Physical*

Well-being, Confidence in Social Situations, Friendships, Family Life, Work Life, Intimacy, Self-Worth, and Positive Growth.

Stage 2: Item Reduction Phase

Sample. A total of 304 participants completed the CARE Burn Scale—Adult Form. Participant characteristics are shown in Table 2. The largely supported rule of thumb is that in order to perform an accurate and precise Rasch analysis to >99% confidence and with item calibrations within ± 0.5 logits, the advised sample size is 250⁶⁷.

Item Reduction. The raw scores were transformed into logits for the purpose of Rasch analyses, which are translated into a linear scoring system (see Supplementary Appendix).

Of the 14 scales tested, a Rasch solution was found for 12 (Table 3). This was not the case for the *Discomfort with*

Burn Wound/Scar Treatment and *Avoidance Behaviors*, which are reported as checklists. For *Discomfort with Burn Wound/Scar Treatment*, the items occupied mostly the same space on the Rasch continuum, meaning that there is no requirement for multiple items and thus a scale cannot be formed. For *Avoidance Behaviors*, multiple items had multiple issues with combinations of model fit, local independence and differential item functioning on gender and scar visibility. Despite all various attempts to find a solution, none could be found to satisfy the criteria of the Rasch measurement model.

Overall, using the Rasch Measurement Model and Analyses (previously described in the Methods section), the initial 194 items across the 12 scales were reduced to 45 items (Table 3). Scale reliability was generally supported by high PSI, with only *Low Mood* and *Positive Growth* exhibiting PSI < 0.70 (0.62–0.69, respectively). Fit to the Rasch model was good, with all item–trait interactions nonsignificant and no items with fit residuals out of range or presenting significant χ^2 values. All final scale solutions contain no items with reversed thresholds. However, all but *Positive Growth* required response thresholds to be collapsed for this to be the case. For *Wound/Scar Discomfort*, *Wound/Scar Dissatisfaction*, *Trauma Symptoms*, and *Low Mood*, the second and third categories were collapsed. For *Physical Well-being*, *Social Situations*, *Friend Support*, *Work Life*, *Family Support*, *Self-worth*, and *Intimacy*, the third and fourth categories were collapsed. All pairs of items within each scale had a residual correlation less than .3 above the mean residual correlation (of all item pairs for that scale), supporting local independence amongst items. The vast majority of items did not exhibit DIF, suggesting that items remain invariant across different groups of patients. Unidimensionality was confirmed via Smith’s procedure⁵⁸ for all 12 scale solutions.

Despite finding 12 solutions, all had gaps in the person location and item threshold distributions, meaning that it is not possible to wholly reflect the range of the continuum (Supplementary Appendix A). *Physical Well-being*, *Social Situations*, *Friendship*, *Work Life*, *Family Life*, *Burn Wound/Scar Dissatisfaction*, and *Trauma Symptoms* had ceiling effects in their person distributions. Also *Social Situations*, *Self-worth*, and *Low Mood* had items with DIF issues. However, the evidence for these DIF issues is weak (*P*-value just less than the $\alpha = 0.05$ Bonferroni-corrected level) but are reported for full disclosure.

See Supplementary Appendix B for a list of the final scale items.

Traditional Psychometric Analyses (Classical Test Theory). All scales with Rasch solutions passed criteria for acceptability, reliability, and validity (Table 3): Cronbach’s alpha > 0.80 and all item-total correlation coefficients > 0.70.

Checklists. Based on theoretical insight, scales for which a Rasch model solution could not be found were kept (with all original items) as checklists. For all items of the *Wound/Scar Treatment* scale, “Not a lot” was the most commonly endorsed category. Similarly, for items of *Avoidance Behaviors*, “Never” was the most commonly endorsed category (Table 4).

Table 2. Stage 2: Participant characteristics (*n* = 304)

		N	%	
	Mean 43.2 years (SD 15.87)			
Age	Range 18– 81 years			
Gender	Male	139	45.7	
	Female	159	52.3	
Ethnicity	White	242	79.6	
	Mixed	1	0.3	
	Asian (Indian, Pakistani, Bangladeshi)	10	3.3	
	Black	5	1.6	
	Chinese	5	1.6	
	Other	19	6.3	
	Rather not say	1	0.3	
Cause of burn	None	1	0.3	
	Flame	64	21.1	
	Liquid	138	45.4	
	Contact	15	4.9	
	Electricity	21	6.9	
	Chemical or acid	24	7.9	
Injury status	Other	35	11.5	
	Burn wound	37	12.2	
	Burn scar	156	51.3	
	Both wound and scar	85	28.0	
Body part affected	No wound scar	16	5.3	
	Head or face	65	21.4	
	Neck	47	15.5	
	Chest	61	20.1	
	Back	39	12.8	
	Lower arms	77	25.3	
	Upper arms	62	20.4	
	Hands	114	37.5	
	Bottom	31	10.2	
	Upper legs	74	24.3	
	Lower legs	61	20.1	
	Feet	48	15.8	
	Time in full years since burn	Median 1.0 (Interquartile range 6.0), range 0–60		

Percentages in the above table may not sum to 100% as they show the share of given group in the whole sample of 304 burn patients.

Table 3. Stage 2: Summary of CARE Burn Scale—Adult Form psychometric analyses

CARE Burn Scale	Rasch analyses										Traditional Psychometric Analyses	
	Number of items retained in final version	Item-trait interaction χ^2 ; df; <i>P</i>	Person Separation Index	Number of items with fit residuals outside the band of -2.5, +2.5	Items with significant χ^2 value*	Number of items with thresholds reversed	Number of pairs of items with residual correlation >0.3	Number of items with DIF***	Unidimensionality tests: Highest eigenvalue** (proportion of significant <i>t</i> -tests***)	Item locations Logits (range of items category thresholds)	Person location logits (mean, SD) and Person Fit Residual (mean, SD)	Cronbach's alpha
Burn wound/scar discomfort	4	25.1; 16; 0.06	0.730	0	0	0	0	1.588 (3%)	(-0.255; 0.190) (-2.542; 2.110)	(0.901, 1.706) (-0.505, 1.351)	0.837	0.815 (0.776-0.846)
Physical well-being	2	4.8; 8; 0.77	0.733	0	0	0	0	1.981 (2%)	(-0.262; 0.262) (-3.714; 4.305)	(1.509, 3.248) (-0.808, 1.039)	0.922	0.961 (0.961-0.961)
Social situations	4	15.6; 16; 0.48	0.745	0	0	0	1	1.637 (1%)	(-1.193; 0.516) (-1.790; 1.818)	(0.408, 1.809) (-0.312, 0.913)	0.878	0.842 (0.762-0.883)
Friendship	4	24.3; 16; 0.08	0.780	0	0	0	0	1.515 (3%)	(-0.831; 0.739) (-2.677; 2.451)	(1.161, 2.224) (-0.341, 0.962)	0.913	0.889 (0.869-0.924)
Work life	2	2.9; 4; 0.57	0.730	0	0	0	0	1.997 (1%)	(-0.026; 0.026) (-3.370; 3.590)	(1.844, 2.914) (-0.735, 0.934)	0.928	0.957 (0.952-0.963)
Family Life	4	17.2; 12; 0.14	0.780	0	0	0	0	1.559 (1%)	(-0.522; 0.652) (-3.268; 4.337)	(2.995, 2.835) (-0.393, 1.039)	0.944	0.906 (0.859-0.926)
Self-worth	4	19.2; 16; 0.26	0.860	0	0	0	1	1.565 (3%)	(-0.762; 0.532) (-4.963; 5.075)	(0.141, 2.744) (-0.483, 1.103)	0.936	0.914 (0.892-0.937)
Burn wound/scar dissatisfaction	3	16.6; 12; 0.17	0.774	0	0	0	0	1.744 (3%)	(-0.085; 0.082) (-2.739; 2.714)	(0.582, 2.384) (-1.075, 1.726)	0.894	0.858 (0.771-0.922)
Intimacy	4	23.6; 16; 0.10	0.744	0	0	0	0	1.943 (3%)	(-0.700; 0.642) (-2.236; 3.229)	(0.409, 2.155) (-0.537, 1.147)	0.910	0.844 (0.775-0.882)
Trauma symptoms	6	29.7; 4; 0.19	0.747	0	0	0	0	1.913 (7%, 95% CI LB 4%)	(-0.682; 0.460) (-3.111; 2.590)	(1.924, 1.779) (-0.316, 1.142)	0.886	0.795 (0.729-0.832)
Low mood	4	19.5; 16; 0.24	0.619	0	0	0	1	1.538 (2%)	(-0.283; 0.268) (-1.848; 2.323)	(1.620, 1.593) (-0.393, 1.264)	0.818	0.800 (0.723-0.837)
Positive Growth	3	14.4; 12; 0.28	0.691	0	0	0	0	1.524 (1%)	(-0.476; 0.454) (-2.181; 1.854)	(-0.072, 1.767) (-0.465, 0.992)	0.815	0.843 (0.832-0.856)

*Baseline significance level was 0.01, which were after adjusted with Bonferroni correction for number of items.
 **Criterion of unidimensionality assumed was that highest eigenvalue for matrix of residual correlations should be <2.0.
 ***Criterion of unidimensionality acceptance is the proportion, or lower bound of 95% confidence interval (95% CI LB), is under 5%.
 ****Baseline significance level 0.05 Bonferroni adjusted.

Table 4. Stage 2: Number (%) of participants to endorse each response category of the symptom checklist

Scale/Item	Not a Lot		A Little		Quite a Bit		A Lot		N/A	
	N	%	N	%	N	%	N	%	N	%
Discomfort with treatment										
1. Dressing/bandage changes	107	34.5	61	19.7	21	6.8	22	7.1	87	28.1
2. Creaming	136	43.9	71	22.9	31	10.0	34	11.0	29	9.4
3. Massage	123	39.7	73	23.5	24	7.7	30	9.7	50	16.1
4. Physiotherapy exercises	112	36.1	73	23.5	15	4.8	15	4.8	77	24.8
5. Wearing pressure garments	99	31.9	56	18.1	17	5.5	28	9.0	94	30.3
6. Taking medication	127	41.0	51	16.5	10	3.2	18	5.8	93	30.0
7. Pain/discomfort	105	33.9	83	26.8	22	7.1	21	6.8	68	21.9
Avoidance behaviors										
Never										
Sometimes										
Often										
Always										
	N	%	N	%	N	%	N	%		
1. Avoid looking	165	53.2	99	31.9	21	6.8	15	4.8		
2. Avoid touching	172	55.5	92	29.7	17	5.5	18	5.8		
3. Cover with clothes/ makeup	109	35.2	85	27.4	40	12.9	60	19.4		
4. Try to hide	134	43.2	77	24.8	31	10.0	52	16.8		
5. Upsetting to look at myself in the mirror	158	51.0	93	30.0	13	4.2	31	10.0		
6. Feel ashamed	167	53.9	83	26.8	18	5.8	28	9.0		
7. Don't wear certain clothes	140	45.2	71	22.9	28	9.0	56	18.1		
8. Avoid certain situations or activities	135	43.5	83	26.8	16	5.2	60	19.4		

Stage 3: Further psychometric evaluation

Sample. Adult participants ($n = 118$; 78 women, 37 men, 3 gender not provided), aged 32–86 years (mean: 55.5 years, SD: 15.4 years) took part (Table 5). A sample size of $n = 95$ or larger will have in excess of 95% power to reject a correlation of 0.3 or lower compared to a correlation of 0.6 or higher. For sample sizes on $n = 115$ or larger, the asymmetric 95% confidence interval for correlation coefficients greater than 0.3 will have an absolute margin of error of no more than 0.166.

Traditional Psychometric Analyses

Tables 6 and 7 provide results of the traditional psychometric analysis. All scales exceeded criteria for validity and reliability. Scale reliability was supported by high Cronbach's alpha coefficients (>0.80), and appropriate item–total correlations (range of means, 0.62–0.80). Level of missing data was higher than 10% for 15 out of 45 items and tended to occur in the same domains (*Work Life*, *Intimacy*, *Trauma Symptoms*, and *Social Situations*). Missing data on these items ranged from 12 to 42%. A comparison of the results with and without missing data showed that the Cronbach's alphas remained unchanged which indicates that the missing data did not bias the results (Table 6).

Scale validity was supported by the correlations between the CARE Burn Scale subscales and the other validated quality of life/health psychometric measures (Table 8). Hypotheses relating to correlations between CARE Burn Scale subscales, the Burn Specific Health Scales,³² the EQ-5D-5L,⁶³ PTSD Checklist—Civilian Version (PCL),⁶⁴ and the Post Traumatic Growth Inventory⁶⁵ were widely supported through moderate

correlations with related constructs and low/no correlations with dissimilar constructs.

As predicted, the CARE Burn Scales correlated moderately/highly with many of the Burns Specific Health Scales. In particular, *Wound/ Scar Discomfort* and *Physical Well-being* moderately correlated with the all of the BSHS Physical Health subscales, *Social Situations* moderately correlated with the BSHS Social Health total score, *Friend Support* was highly correlated with the BSHS Social Health total score and the BSHS Social Friends subscale, *Work Life* and *Family Support* were moderately correlated with the BSHS Social Health Total Score. *Wound/Scar Dissatisfaction* was highly correlated with the BSHS Body Image subscale, *Trauma Symptoms* moderately correlated with the BSHS Mental Health total score and the BSHS Mental Affect subscale, *Negative Mood* was highly correlated with the BSHS Mental Health total score and the BSHS Mental Affective subscale. However, *Self-worth* did not significantly correlate with any of the BSHS Mental Health or Affect subscales and *Intimacy* did not correlate with the BSHS Sexual subscale which was not consistent with the predicted hypotheses.

As predicted, the Post Traumatic Growth Inventory showed significant moderate correlations with *Positive Growth* but not with any of the other CARE Burn Scale subscales. The PTSD Checklist—Civilian Version (PCL) was found to moderately correlate with *Trauma Symptoms* and *Negative Mood*. The EQ-5D-5L moderately correlated with all individual CARE Burn Scales apart from *Family Support*, *Self-worth*, *Intimacy*, and *Positive Growth*.

Regression analysis identified significant relationships between six of the individual CARE Burn Scale subscales and sociodemographic variables (ie, age, time since burn, gender,

Table 5. Stage 3: Patient characteristics study 2

Characteristics	Value
Age in years at time of participation (<i>n</i> = 115)	
Mean (SD)	56.0 (15.4)
Range	32.7–86.3
Age in years at time of burn (<i>n</i> = 115)	
Mean (SD)	34.2 (19.4)
Range	1–77
Time in years since burn (<i>n</i> = 108)	
Mean (SD)	23.6 (16.3)
Range	0.6–76.7
Gender (<i>n</i> = 115)	
Male	37 (32.2%)
Female	78 (67.8%)
Ethnicity (<i>n</i> = 118)	
White	91 (79.1%)
Mixed	1 (0.9%)
Asian (Indian, Pakistani, Bangladeshi)	5 (4.3%)
Black	3 (2.6%)
Chinese	4 (3.5%)
Other	11 (9.6%)
Rather not say	0 (0.0%)
None/missing	3 (2.6%)
Marital status (<i>n</i> = 115)	
Married/civil partnered	44 (38.3%)
Single	51 (44.3%)
Divorced/Separated	4 (3.5%)
Living with partner	15 (13.0%)
Widowed	1 (0.9%)
Cause of burn (<i>n</i> = 115)	
Flame	28 (24.4%)
Liquid	36 (31.3%)
Contact	14 (12.2%)
Electricity	8 (6.9%)
Chemical/acid	8 (6.9%)
Other	21 (18.3%)
Body part affected (<i>n</i> = 116; multiple responses possible)	
Head	34 (29.3%)
Neck	27 (23.3%)
Chest	37 (31.9%)
Back	17 (14.7%)
Lower arms	36 (31.0%)
Upper arms	38 (32.8%)
Hands	46 (39.7%)
Bottom	12 (10.3%)
Upper legs	35 (30.2%)
Lower legs	4 (3.5%)
Feet	17 (14.7%)

ethnicity, marital status, and cause of injury; [Table 9](#)). There was a significant effect of cause of burn, with nonliquid injuries being significantly associated with greater wound/scar discomfort compared with liquid injuries. Time since burn was significantly associated with greater work well-being. Women and those sustaining nonliquid burn injuries were more likely to report greater wound/scar dissatisfaction. Nonliquid injuries were also significantly associated with more negative mood and time since injury was associated

Table 6. Stage 3: Traditional psychometric analyses

Traditional Psychometric Analyses—Reliability				
Scale	N Items	Cronbach's alpha (all data)	Cronbach's alpha—no missing data	CITC (Mean, Range)*
Wound/Scar Discomfort	4	0.81	0.81	0.63, 0.48–0.77
Physical Well-being	2	0.90	0.90	-
Social Situations	4	0.87	0.87	0.72, 0.61–0.77
Friend Support	4	0.87	0.87	0.72, 0.57–0.82
Work	2	0.89	0.83	-
Family Support	4	0.89	0.89	0.75, 0.69–0.82
Self-Worth	4	0.91	0.91	0.80, 0.73–0.84
Wound/Scar Dissatisfaction	3	0.88	0.88	0.78, 0.73–0.82
Intimacy	4	0.88	0.87	0.74, 0.67–0.79
Trauma Symptoms	6	0.91	0.91	0.75, 0.64–0.82
Negative Mood	4	0.81	0.81	0.62, 0.51–0.67
Positive Growth	3	0.80	0.80	0.65, 0.56–0.71

*CITC = Corrected Item Total Correlation, only provided for scales with >2 subscales.

with greater positive growth. However, since the majority of regression coefficients (66/72) were nonsignificant, this provides evidence of discriminant validity.

DISCUSSION

The CARE Burn Scale—Adult Form was developed and validated with adult burn patients who had received treatment in the NHS Burn Service. They played a key, fundamental role in the development of this new PROM, informing item generation and reviewing and commenting on draft versions of the scale. The CARE Burn Scale—Adult Form therefore reflects key experiences that are pertinent to the quality of life of those living with a burn injury. Importantly, they highlighted the need to include both the wound and scar stages of injury recovery, and to ensure that the PROM could recognize trauma symptoms, avoidance behaviors, difficulties with wound/scar treatments, as well as positive outcomes and growth after living with a burn injury. The CARE Burn Scale—Adult Form is therefore the first burn-specific quality of life PROM to include reference to both the wound and scar stage of recovery and additional domains not captured in existing burn-specific PROMs.

The 12 scales with Rasch solutions showed good scale reliability was generally supported by high PSI values, and fit to the Rasch model was good. Evidence of reliability and validity based on traditional psychometric analyses was identified, as was concurrent and discriminate validity with other measures and sociodemographic factors. Overall, these findings indicate that the CARE Burn Scale—Adult Form is a valid and reliable scale to measure quality of life for adults living with a burn injury.

Table 7. Scaling assumptions and data quality

Scale and Items	Data Quality		Scaling Assumptions		
	Missing Data (%)	Possible Range	Actual Range	Mean Score (SD)	CITC*
Burn Wound/Scar Discomfort					
1. Uncomfortable	5	1-4	1-4	1.96 (0.94)	0.77
2. Sensitive to heat/cold	6	1-4	1-4	2.06 (1.08)	0.59
3. Sensitive nerve	3	1-4	1-4	1.88 (0.96)	0.69
4. Itchy	3	1-4	1-4	2.06 (0.94)	0.48
Physical Well-being					
1. Enough energy to do activities	5	1-4	1-4	3.12 (0.96)	-
2. Physical activities want to do	6	1-4	1-4	3.23 (0.93)	-
Social Situations					
1. Family members ask about wounds/scars	10	1-4	1-4	3.12 (1.12)	0.61
2. New people look at wounds/scars	15	1-4	1-4	2.69 (1.20)	0.77
3. Showing wounds/scar in public	15	1-4	1-4	2.56 (1.22)	0.76
4. Family members touching wounds/scars	15	1-4	1-4	2.70 (1.23)	0.72
Friend Support					
1. Can make new friends	7	1-4	1-4	3.12 (1.00)	0.74
2. Part of a group of friends	7	1-4	1-4	3.14 (1.01)	0.82
3. Accepted by friends	7	1-4	1-4	3.39 (0.87)	0.76
4. Talk to close friends	5	1-4	1-4	2.65 (1.14)	0.57
Work Life					
1. Respected at work	42	1-4	1-4	3.36 (0.84)	-
2. Treated same as others	42	1-4	1-4	3.49 (0.85)	-
Family Support					
1. Treated with respect	8	1-4	1-4	3.61 (0.73)	0.82
2. Listens to what I say	8	1-4	1-4	3.37 (0.80)	0.73
3. Practically supported	12	1-4	1-4	3.46 (0.88)	0.69
4. Emotionally supported	8	1-4	1-4	3.27 (0.97)	0.77
Self-worth					
1. Accept myself	7	1-4	1-4	2.89 (0.99)	0.73
2. Happy	8	1-4	1-4	2.71 (0.87)	0.78
3. Easy to concentrate	8	1-4	1-4	2.66 (0.90)	0.83
4. Confident	8	1-4	1-4	2.58 (0.97)	0.84
Burn Wound/Scar Dissatisfaction					
1. How wound/scars look when not covered	6	1-4	1-4	2.33 (1.08)	0.78
2. How noticeable wounds/scar are	7	1-4	1-4	2.56 (1.06)	0.73
3. How wound/scar look overall	7	1-4	1-4	2.45 (1.07)	0.82
Intimacy					
1. I feel attractive	14	1-4	1-4	2.29 (1.03)	0.67
2. Comfortable with own body	20	1-4	1-4	2.53 (1.10)	0.78
3. Romantic partner asks questions about wounds/scars	23	1-4	1-4	3.09 (1.09)	0.73
4. Romantic partner touches wounds/scars	21	1-4	1-4	2.75 (1.27)	0.79
Trauma Symptoms					
1. Difficult thinking of anything else	9	1-4	1-4	1.69 (0.86)	0.79
2. Difficult to let go of negative feelings	12	1-4	1-4	1.97 (0.94)	0.82
3. Get upset	12	1-4	1-4	1.95 (0.91)	0.82
4. Feel short-tempered	12	1-4	1-4	1.81 (0.95)	0.72
5. Bad dreams	11	1-4	1-4	1.51 (0.82)	0.7
6. Flashbacks	12	1-4	1-4	1.82 (0.96)	0.64
Negative Mood					
1. Difficult talking about burn injury event	8	1-4	1-4	1.65 (0.80)	0.51
2. Feel low	8	1-4	1-4	1.97 (0.80)	0.66
3. Feel angry with myself	8	1-4	1-4	1.83 (0.94)	0.65
4. Feel ashamed	8	1-4	1-4	1.75 (0.92)	0.67
Positive Growth					
6. I am a better person	8	1-4	1-4	2.39 (1.06)	0.68
7. More considerate to others	8	1-4	1-4	2.69 (1.02)	0.56
8. My life is more meaningful	8	1-4	1-4	2.27 (1.06)	0.71

*CITC = Corrected Item Total Correlation. Only reported for scales with >2 items.

Table 8. Stage 3 study: Correlations between the CARE Burn Scale—Adult Form and other validated quality of life psychometric measures

	CARE Burn Scale - Adult Form											
	Wound/ Scar Dis- comfort	Physical Well-being	Social Situations	Friendships	Work	Family	Self- worth	Wound/Scar Dissatisfac- tion	Intimacy	Trauma	Low Mood	Positive Growth
<i>BSHS</i>												
BSHS total	-0.46***	0.53***	0.36***	0.65***	0.50***	0.32***	0.17	-0.56***	0.26**	-0.65***	-0.78***	0.26**
Physical total	-0.47***	0.50***	0.17	0.39***	0.34**	0.15	-0.09	-0.33***	0.10	-0.53***	-0.42***	0.06
Physical mobility	-0.40***	0.44***	0.20*	0.34***	0.29**	0.11	-0.11	-0.23*	0.04	-0.41***	-0.32***	-0.02
Physical hand	-0.32***	0.41***	0.16	0.27**	0.26*	0.08	-0.09	-0.17	0.10	-0.39***	-0.24*	-0.04
Physical role	-0.51***	0.51***	0.19	0.46***	0.41***	0.17	-0.01	-0.41***	0.15	-0.56***	-0.50***	0.11
acti												
Mental health	-0.43***	0.52***	0.36***	0.66***	0.43***	0.34***	0.23*	-0.60***	0.28**	-0.62***	-0.80***	0.28**
total												
Mental body	-0.41***	0.44***	0.44***	0.57***	0.39***	0.22*	0.13	-0.74***	0.24*	-0.45***	-0.62***	0.07
image												
Mental	-0.42***	0.49***	0.29**	0.62***	0.41***	0.35***	0.24*	-0.54***	0.26*	-0.63***	-0.84***	0.32***
affective												
Social health	-0.35***	0.43***	0.36***	0.68***	0.42***	0.34***	0.24*	-0.50***	0.16	-0.53***	-0.74***	0.31**
total												
Social friends	-0.27**	0.42***	0.30**	0.66***	0.40***	0.36***	0.29**	-0.42***	0.21*	-0.51***	-0.72***	0.38***
Social sexual	-0.37***	0.34***	0.41***	0.50***	0.32**	0.20*	0.03	-0.51***	0.03	-0.52***	-0.64***	0.10
General total	-0.48***	0.53***	0.27**	0.60***	0.35**	0.30**	0.16	-0.50***	0.18	-0.56***	-0.77***	0.26**
EQ-5D-5L	0.51***	-0.56***	-0.32**	-0.58***	-0.39**	-0.14	-0.16	0.43***	-0.15	0.55***	0.63***	-0.19
total												
PTGI total	0.09	-0.06	-0.26**	0.03	-0.07	0.11	0.09	0.18	-0.10	0.13	0.12	0.53***
PCL total	0.31***	-0.39***	-0.22*	-0.32***	-0.13	-0.17	-0.17	0.42***	-0.05	0.42***	0.62***	-0.30**

* $P < .5$; ** $< .01$; *** $< .001$.

Table 9. Stage 3 study: Regression coefficients and resulting *P*-values for demographic variables and all the subscales

Subscales	Age at Participation (years)			Time Since Burn (years)			Gender (female)			Ethnicity (non-white)			Marital Status (not married/civil partnered)			Cause (nonliquid)		
	Coef.	95% CI	<i>P</i>	Coef.	95% CI	<i>P</i>	Coef.	95% CI	<i>P</i>	Coef.	95% CI	<i>P</i>	Coef.	95% CI	<i>P</i>	Coef.	95% CI	<i>P</i>
Wound/Scar Discomfort (<i>n</i> = 107)	0.15	-0.21, 0.51	.41	-0.03	-0.33, 0.27	.83	4.86	-6.10, 15.83	.38	-4.72	-16.14, 6.70	.41	2.41	-8.11, 12.93	.65	17.23	7.06, 27.40	.001*
Physical well-being (<i>n</i> = 105)	0.34	-0.11, 0.79	.14	0.23	-0.15, 0.61	.23	-4.84	-18.69, 9.02	.49	10.94	-3.61, 25.50	.14	-0.52	-13.79, 12.75	.94	-10.96	-23.84, 1.92	.09
Social Situations (<i>n</i> = 100)	0.28	-0.26, 0.82	.30	-0.19	-0.63, 0.26	.41	2.22	-13.79, 18.22	.78	13.32	-3.82, 30.46	.13	-8.40	-24.16, 7.37	.29	4.97	-9.99, 19.94	.51
Friend Support (<i>n</i> = 105)	-0.09	-0.51, 0.33	.68	0.04	-0.31, 0.38	.83	0.37	-12.26, 13.01	.95	9.66	-3.77, 23.10	.16	-4.20	-16.56, 8.16	.50	-10.28	-22.18, 1.63	.09
Work Life (<i>n</i> = 76)	0.01	-0.67, 0.68	.98	0.54	0.03, 1.06	.04*	-6.10	-26.77, 14.58	.56	10.56	-12.60, 33.73	.37	10.38	-8.20, 28.96	.27	-10.64	-29.06, 7.78	.25
Family Support (<i>n</i> = 103)	-0.08	-0.50, 0.33	.70	-0.05	-0.35, 0.34	.98	3.45	-9.30, 16.20	.59	-3.99	-17.43, 9.45	.56	-1.70	-13.87, 10.47	.78	-2.62	-14.65, 9.41	.67
Self-worth (<i>n</i> = 100)	-0.26	-0.70, 0.17	.23	0.26	-0.11, 0.63	.17	-1.00	-14.35, 12.35	.88	-6.62	-21.11, 7.87	.37	-10.78	-23.60, 2.04	.10	0.26	-12.23, 12.75	.97
Wound/Scar dis-satisfaction (<i>n</i> = 94)	0.07	-0.40, 0.54	.77	0.36	-0.03, 0.74	.07	15.54	1.31, 29.76	.03*	-0.22	-15.26, 14.82	.98	4.24	-9.69, 18.17	.55	20.85	7.52, 34.17	.002*
Intimacy	-0.13	-0.59, 0.34	.59	0.18	-0.20, 0.57	.35	2.06	-12.45, 16.57	.78	-4.97	-19.99, 10.04	.51	-9.90	-23.49, 3.69	.15	11.96	-1.30, 25.22	.08
Trauma Symptoms (<i>n</i> = 101)	0.10	-0.27, 0.46	.60	-0.14	-0.44, 0.16	.37	5.44	-5.72, 16.60	.34	-1.88	-13.37, 9.61	.75	6.37	-4.25, 16.99	.24	8.42	-1.94, 18.77	.11
Negative Mood (<i>n</i> = 103)	0.13	-0.19, 0.46	.41	-0.07	-0.34, 0.19	.59	4.69	-5.11, 14.49	.35	-0.33	-10.69, 10.04	.95	4.53	-5.05, 14.10	.35	9.65	0.45, 18.84	.04*
Positive Growth (<i>n</i> = 103)	-0.23	-0.64, 0.91	.28	0.38	0.04, 0.72	.03*	-0.35	-12.93, 12.23	.96	1.48	-11.83, 14.79	.83	-2.75	-15.05, 9.54	.66	4.76	-7.04, 16.56	.43

Significant values with *P* < .05 are marked with *.

*NB: ethnicity: non-white group included Asian, Black, Chinese, Mixed ethnic groups, "rather not say" and missing data; marital status: not married/civil partnership group included participants who were single, divorced/separated, living with partner and widowed; cause of injury: nonliquid group included flame, contact, electricity, and other burn injuries.

The item reduction stage was led by Rasch analysis which permits individual patient and subsample level measurement and produces interval level data that allows measurement invariance to be tested and valid total scores to be created. These increase the potential for the PROM to identify clinical change which will be of benefit to clinicians and researchers alike.⁶⁸ Burns research is increasingly using Rasch analysis in PROM development/validation papers, such as the Patient and Observer Scale (POSAS) and Lower Limb Index.^{69,70} Researchers developing new PROMs for use in adult burn care should consider using Rasch to ensure that the PROMS they develop are suitable for measuring the health of both individual patients and subgroups.

Comparing the CARE Burn Scale—Adult Form with Existing Burn-Specific PROMs

The CARE Burn Scale—Adult Form does cover domains that some existing burn-specific PROMs also measure such as *Wound/Scar Discomfort*^{34,35}, *Physical Abilities*^{32–35}, *Confidence in Social Situations*^{34,35,37}, *Friendships*^{32–35,37}, *Family*^{32–35,37}, *Work*^{33–35,37}, *Wound/Scar Dissatisfaction*^{32–35}, *Intimacy*^{32–35,37}, and *Negative Mood*^{32–35,37}.

However, the CARE Burn Scale—Adult Form has the advantage of including unique domains which are not measured by existing PROMs (such as the Abbreviated Burn Specific Health Scale (BSHS-A),³² the Burn Specific Health Scale—Brief (BSHS-B),³³ Young Adult Burn Outcome Questionnaire (YABOQ),³⁵ the Adult Burn Outcome Questionnaire (YABOQ) Short Form,³⁴ the Coping with Burns Questionnaire,⁷¹ and the Life Impact Burn Recovery Evaluation (LIBRE).³⁷ These unique domains are: *Trauma Symptoms* (ie, feeling upset, short tempered, experiencing bad dreams, or flashbacks/vivid memories), *Avoidance Behaviors* (ie, avoiding looking at or touching burn wounds/scars, covering up wounds/scars or avoiding certain social activities because of their wounds/scars), *Self-Worth* (ie, feeling confident, happy), *Wound/Scar Treatments* (ie, whether treatments such as dressing changes, creaming/massage and physiotherapy exercises bother patients), and *Positive Growth* (ie, life being more meaningful or feeling a better person after a burn injury). Using in-depth interviews with patients and health professionals to inform the conceptual framework and PROM items, rather than relying on existing PROMs or conceptual frameworks, led to these additional new domains which other scales do not cover. This further highlights the benefit of in-depth interviews when developing new PROMs to ensure that the scale measures the breadth of health outcomes that are most important to patients themselves.⁴²

Another advantage of the CARE Burn Scale—Adult Form is that it is freely available to download (via www.careburnscales.org.uk) for research and clinical purposes. Users are able to score the data themselves using the scoring sheets downloadable from the same website.

LIMITATIONS

Men typically outnumber women in the prevalence of burn injuries.² Yet there was a fairly even gender split in the Stage

2: Item reduction study. This might be explained by the fact that the data collection was part of a research project rather than routine clinical audit; women are significantly more likely to take part in research than men.⁷² In the current study, patients were simply invited to take part and were responsible for returning their questionnaire in the mail, or completed it online. Staff were not responsible for motivating/encouraging participants to take part or for collecting questionnaires, which is a different process to data collection in clinical audit which burn prevalence statistics are based on. The common gender differences in research participation may therefore have influenced the gender split in this study. Furthermore, the regression analysis showed that gender did not have a significant effect on any domains of the CARE Burn Scale, apart from *Wound/Scar Dissatisfaction* which showed women were more likely to be dissatisfied with their scarring compared to men. This is a typical finding in burns research.¹³ Therefore, the less typical gender split in the sample did not have a significant effect on the overall findings of the study.

The burn etiology in this study was comparable to other studies with adult burn patients in the United Kingdom; the current had 20.6% flame injuries compared with 21.12% reported by Stylianou et al (using the UK IBID database for adult injuries that occurred from 2003 to 2011).² The percentage of scald/liquid injuries was higher in the current study (44.8%) compared with 33.29% reported by Styliou et al, but since women are more likely to experience scalds compared with flame injuries, the higher rates of scald injuries in our sample could be related to our more even gender split compared with the male bias typical in burn injuries more generally.²

Another limitation of this study is the level of missing data identified in phase 3. Missing data is very common in questionnaire design studies and when collecting data in healthcare services, where less than 10% missing data is not thought to bias results.^{73,74} In the current study, the majority of items had less than 10% missing data, but for 15 out of 44 items this was 12–42% (mostly 10–15%). However two domains (*Work Life* and *Intimacy*) showed higher levels of missing data. This is not surprising since many adults delay returning to work after a burn and some might not feel comfortable answering questions about their intimate lives. A comparison of the Cronbach's alphas for each individual CARE Burn Scale using datasets with and without missing data indicated a negligible impact of missing data on the reliability of the scales and the dataset with missing data was therefore retained. In phase 3, participants completed a number of other PROMs at the same time as the CARE Burn Scale; therefore, missing data might reflect patient burden or fatigue from the longer survey length. Future research will test the final version of the CARE Burn Scale—Adult Form without the inclusion of other quality of life scales to gain a more accurate record of the level of missing data expected when completing it in routine clinical practice or research.

As with all psychometric scale development research, further ongoing validation work is needed. Test-retest reliability and responsiveness data are required to further validate the findings and explore the reliability of the CARE Burn Scale—Adult Form and its ability to detect clinical changes over time. This is necessary in order that suitably robust measures are available for longitudinal cohort studies within burns.

The CARE Burn Scale reported in this paper is only valid for adult burn patients. However, this scale is part of a suite of PROMs being developed by the authors, including measures for use in burn care with children under 8 years of age (parental report), young people aged 8–17 years and parents.^{75–77} Additionally, the CARE Burn Scale—Adult Form, has been tested with a U.K. population. Additional validation studies are warranted if they are to be used elsewhere, translation studies are needed if they are to be used with non-English speaking patients, and their value as a tool that can assess patient reported outcomes in different cultures needs to be explored.⁷⁸

CONCLUSIONS

The CARE Burn Scale—Adult Form measures key issues that adult patients have identified as being important to their well-being and quality of life after a burn injury. It was rigorously developed using gold standard guidelines and criteria for the development and review of PROM. The CARE Burn Scale—Adult Form is now available for clinical and research use to identify patients' needs and therapeutic progress, conduct service evaluation, and compare outcomes at different burn centers (see www.careburnscales.org.uk to access the full set of CARE Burn Scales).

SUPPLEMENTARY DATA

Supplementary data is available at *Journal of Burn Care & Research* online.

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CONTRIBUTORS

C.G. developed the study design, applied for ethics approvals, recruited participants, conducted the qualitative interviews and analysis, developed the conceptual framework,

created the CARE Burn Scale items, led the writing of the final paper, and approved the final article. E.G. recruited participants, prepared the datasets for analysis, and contributed to writing the paper and approved the final article. T.P. conducted the psychometric analysis and contributed to writing the paper and approved the final article. L.H. conducted the psychometric analysis, contributed to writing the paper, and approved the final article. M.G. conducted the psychometric analysis, contributed to writing the paper, and approved the final article. P.W. conducted the sample size calculations, contributed to writing the paper, and approved the final article. P.T. assisted with recruitment and contributed to writing the paper. D.H. developed the initial study design, contributed to writing the paper, and approved the final article.

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