

1 **The development and validation of the CARE Burn Scale - Adult Form: a Patient Reported Outcome**
2 **Measure (PROM) to assess quality of life for adults living with a burn injury**

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21 **Abstract**

22 *Introduction:* Patient Reported Outcome Measures (PROMs) identify vital information
23 about patient needs and therapeutic progress. This paper outlines the development and
24 validation of the CARE Burn Scale - Adult Form: a PROM that assesses quality of life in adults
25 living with a burn injury.

26 *Methods:* 11 patient, 10 family member and 4 health professional interviews, and a
27 systematic review were conducted to inform the development of a conceptual framework
28 and a draft measure. Cognitive debriefing interviews conducted with 3 adult burn patients,
29 1 family member and 8 health professionals provided feedback to ascertain content validity
30 of the measure. The measure was then field tested with 304 adult burn patients. Rasch
31 psychometric analysis was conducted for scale reduction, and traditional psychometric
32 analyses provided a comparison with other measures. Further psychometric testing with an
33 additional 118 adult burn patients tested the shortened CARE Burn Scale in relation to other
34 quality of life PROMs.

35 *Results:* The conceptual framework outlined 14 domains; 12 of which fulfilled Rasch and
36 traditional psychometric analyses. Two individual scales did not fulfil the Rasch criteria and
37 were retained as checklists. Individual CARE Burn Scales correlated moderately-to-highly
38 with other quality of life scales measuring similar constructs, and had low-to-no correlations
39 with dissimilar constructs and the majority of sociodemographic factors, indicating evidence
40 of concurrent and divergent validity.

41 *Conclusions:* The CARE Burn Scale – Adult Form can help identify patient needs and provides
42 burns-specialist health professionals with a tool to assess quality of life and therapeutic
43 progress after a burn event and related treatment.

44

45 **Keywords:** Patient-Reported Outcome Measure; PROM; Adult; Burn; Scar; Quality of Life

46 **Introduction**

47 In the UK, approximately 250,000 individuals sustain burn injuries every year, with 7,634
48 patients requiring specialist treatments in 2011 [1, 2]. The needs of burn patients are
49 complex and wide-ranging. Burn wounds and scarring can cause severe pain and itching and
50 limit range of movement [3, 4]. These factors, along with potentially significant time spent
51 attending scar management, physiotherapy and other clinical appointments, can also
52 impact an individual's ability to engage with work and activities of daily living [5].

53 A number of psychosocial difficulties such as depression [6-11], anxiety [6, 9, 12, 13],
54 difficulties sleeping [14], and trauma symptoms [5, 6, 8, 9, 15] can also accompany the
55 physical impact of a burn. Patients with burn scarring can also encounter unwanted
56 questions or staring from others which can lead to avoidance of activities which could draw
57 attention to their scars, fear of being judged negatively by others, low social self-esteem and
58 withdrawal from romantic relationships [16-18]. Consequently, social support from friends,
59 family and health professionals is paramount when adapting to the impact of a burn [19,
60 20].

61 Given the complex and varying needs of burn patients, it is essential that health
62 professionals are able to comprehensively assess post-burn adjustment, in order to identify
63 individual support needs. Whilst many adjust well [9, 21], and some report posttraumatic
64 growth following the injury [22], others experience significant difficulties [23]. For some,
65 psychosocial adjustment is harder to manage than the physical symptoms [24].
66 Furthermore, psychosocial difficulty is not predicted by the size, location, or depth of a burn
67 [25] and many patients encounter new challenges as they progress through their treatment
68 and recovery [5]. It is, therefore, important to assess the needs of all patients rather than
69 focussing on those with more physically serious or visible injuries, and not to focus solely on
70 the acute recovery period.

71 However, psychosocial health professionals working in UK NHS (National Health Service)
72 Burn Services, often lack time and resources to assess all patients, or rely on information
73 from staff who do not have specialist training when deciding who would benefit from
74 psychosocial support [5]. Patient Reported Outcome Measures (PROMs) offer a potential
75 solution to issues of assessment in burn services. PROMs, which are standardised, rigorously
76 tested health-related questionnaires, enable health professionals to identify the needs of
77 their patients, and assess their therapeutic progress throughout the treatment pathway
78 [26]. Furthermore, communicating the status of one's own health can be an empowering
79 experience for patients; putting them at the centre of their own care [27]. Although the use
80 of PROMs within the UK was recommended by The NHS Next Stage Review [28], the
81 National Burn Care Review concluded that PROMs are not consistently used within UK Burn
82 Services and identified a lack of PROMs designed to assess the needs of burn patients being
83 treated within this system [29]. For this reason, the need to develop burn-specific UK

84 PROMs and the importance of rigorous outcome measurement within UK burn care have
85 been highlighted [1, 27].

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

94

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

108

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

113

114 **Methods**

115 All necessary University and NHS ethics approvals were obtained.

116 The CARE Burn Scale - Adult Form was developed following an established development and
117 validation process, identified as the gold standard for developing and evaluating PROMs [38,
118 39]. This involved item generation (developing a conceptual framework using a literature
119 review, qualitative interviews with patients and expert opinion), item reduction (using
120 psychometric criteria such as Rasch analysis) and psychometric evaluation (using
121 psychometric criteria).

122 **Stage 1.1: Conceptual framework development**

123 The conceptual framework of a PROM outlines the concepts/domains that it measures and
124 the scale items are then developed based on this framework [38]. Historically, 'top down'
125 methods have often been used in which the conceptual framework and related items are
126 developed based on reviews of the literature or existing measures or conceptual
127 frameworks [40]. Developing injury-specific measures (such as burn-specific PROMs) using
128 these 'top down' methods alone and not involving the patient population that the PROM is
129 intended for, increases the likelihood that key experiences related to the impact of the

130 injury on health outcomes will be missed [41]. This in turn can reduce the content validity
131 and the potential responsiveness of the PROM if it fails to measure key health domains that
132 are important to the patient population [40].

133 More recently, a number of PROM development guidelines recommend using qualitative
134 interviews or focus groups with patients to inform the conceptual framework and related
135 items to increase the content validity of the PROM being developed [38, 42, 43]. The
136 Cochrane Handbook of Systematic Reviews [42] in particular recommends that the
137 conceptual framework (i.e. the outline of the domains that a PROM measures) should be
138 elicited from qualitative interviews with patients from the target population (in this case
139 adult burn patients) and patients should be involved in generating the items that each
140 domain measures to ensure that all relevant aspects of the domain are measured. The
141 involvement of patients at the conceptual framework and item development stage is
142 deemed essential to the content validity of the measure [42].

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

147 Semi-structured interviews were conducted with adult burn patients and burns-specialist
148 health professionals to explore, in-depth, patients' experiences of living with a burn injury
149 and its impact on quality of life. Recruitment aimed to include patients with different types
150 of burn and from different age groups. Interviews took place face-to-face and over the
151 telephone between April 2013 – October 2013. They were tape recorded, transcribed
152 verbatim and subjected to a thematic analysis [46]. These findings informed a conceptual

153 framework to outline the key aspects of well-being that are influenced when living with a
154 burn injury, and the domains that the CARE Burn Scale would measure.

155 **Stage 1.2: Item generation, initial scale formation and pre-testing**

156 An extensive list of potential items was created for each domain in the conceptual
157 framework, based on the patient interview data. When possible, patients' own words or
158 phrases were incorporated to increase the content validity of the items. A systematic review
159 of patient reported outcome measures used in adult burn care research was also conducted
160 [30] and from this review relevant quality of life scales were obtained and reviewed. Any
161 new items identified in these scales that were not discussed in the interviews were added to
162 the relevant CARE Burn Scale domain. Lastly, psychologists, counsellors and nurses from
163 NHS Burn Services across the UK reviewed the draft measure and provided feedback to
164 ensure it was as comprehensive as possible, acceptable to its potential users and suggested
165 new items that were thought missing.

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

171 **Stage 2: Item reduction**

172 Field-test versions of the CARE Burn Scale were handed out in burn clinics and posted to
173 adult burn patients from 11 NHS Burn Services throughout the UK. Eligible participants were

174 adults aged 18 and over who had sustained a burn injury, had received treatment from an
175 NHS Burn Service, and were able to read English in order to complete the questionnaire.

176 *Rasch Measurement Model and Analyses*

177 For the purpose of the Rasch Analyses, the raw scores were transformed into logits and then
178 translated into a linear scoring system, using summated scales as described in Appendix B.
179 The Rasch measurement model [48-50] and analyses [51-53] were used for item reduction
180 using RUMM2030 [54]. The data collected for each domain of the conceptual framework
181 was analysed against the Rasch measurement criteria described below during the item
182 reduction phase.

183 *Item fit statistics*

184 Rasch analysis involves assessing whether the observed data is consistent with the
185 responses predicted by the Rasch mathematical model. Two indicators were examined: 1)
186 item-trait interaction where a non-significant chi-square value ($p > 0.05$) indicates negligible
187 deviation between observed data and expectations of the model); 2) the standardised
188 residual, for each item in the range -2.5 to +2.5 indicates good fit, and should also have non-
189 significant chi-square values (Bonferroni adjusted significance level of 0.01).

190 *Person separation index (PSI)*

191 The PSI measures whether the measurement of patients in this sample are reliably
192 separated. Higher scores reflect stronger reliability. The value of 0.7 indicated the possibility
193 to distinguish at least two groups of patients. The PSI is similar to Cronbach's alpha which is
194 commonly used to measure reliability [55, 56].

195 *Local dependency*

196 For each pair of items within a scale, a residual correlation >0.3 above the mean residual
197 correlation (of all item pairs for that scale) [57] indicates a problem with fit, suggesting the
198 existence of extraordinary association within the set of items.

199 *Unidimensionality*

200 Unidimensionality assumption was checked by application of Smith's procedure [58] based
201 on paired t-tests to see if the person estimates derived from most diverse subsets of items
202 are significantly different. Unidimensionality is supported if the percentage, or the lower
203 bound of the 95% binomial confidence interval, of significant t-tests ($p < 0.05$) is less than
204 5%.

205 *Differential Item Functioning*

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

217 *Targeting and item locations*

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

221 *Item thresholds*

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

226

227 *Traditional psychometric analysis (Classical test theory)*

228 Traditional psychometric analysis via classical test theory (CTT) were also conducted on the
229 data to show how the scale operates based on the CTT criteria: Cronbach's alphas (for each
230 scale domain) and item-total correlations. Analyses were undertaken using IBM SPSS
231 Statistics 23 [60] .

232 **Stage 3: Further psychometric evaluation**

233 The final version of the CARE Burn Scale was then tested in comparison to other validated
234 quality of life questionnaires in a different sample of adult burn patients to ascertain
235 evidence of concurrent and discriminant validity, following recommended PROM
236 development guidelines and criteria [61]. Questionnaires were handed out in burn clinics
237 and posted out to adult burn patients recruited from 11 NHS Burn Services throughout the
238 UK. Eligible participants were adults aged 18 and over who had sustained a burn injury and

239 received treatment from an NHS Burn Service. Patients needed to be able to read English
240 fluently in order to complete the questionnaire.

241 All statistical analyses were performed in Stata v.15.1 [62]. In addition to tests of data
242 quality and scaling assumptions, the following properties relating to validity and reliability
243 were examined:

244 1. Concurrent and discriminant validity: The final version of the CARE Burn Scale –
245 Adult Form was compared with existing health PROMs which measure similar
246 constructs (the Burn Specific Health Scale Abbreviated (BSHS-A) [63], EQ5ED [64],
247 PTSD CheckList – Civilian Version (PCL) [65] and the Post-traumatic Growth Inventory
248 [66]. It was hypothesised that the CARE Burn Scale – Adult Form subscales would
249 have moderate/high significant correlations with related constructs and low/no
250 significant correlations with dissimilar constructs. Criteria were used as guides in
251 terms of the magnitude of correlations, as opposed to pass/fail benchmarks (high
252 correlation, $r > 0.70$; and moderate correlation, $r = 0.30$ to 0.70).

253 Specifically, regarding the various subscales of the CARE Burn Scale – Adult Form
254 (described in the results section, below), it was hypothesised that:

- 255 • *Wound/Scar Discomfort* and *Physical Well-being* would moderately correlate
256 with the BSHS Physical Health scales.
- 257 • *Social Situations* would moderately correlated with the BSHS Social Health
258 total score.
- 259 • *Friend Support* would moderately correlate with the BSHS Social Friends
260 subscale.

- 261 • *Work Life and Family Support* would moderately correlate with the BSHS
262 Social Health total score.
- 263 • *Wound/Scar Dissatisfaction* would moderately correlate with the BSHS Body
264 Image subscale.
- 265 • *Trauma Symptoms, Negative Mood and Self-worth* would moderately
266 correlate with the BSHS Mental Health total score and BSHS Mental Affect
267 subscale.
- 268 • *Intimacy* would moderately correlate with the BSHS Social Sexual subscale.
- 269 • The Post Traumatic Growth Inventory would moderately correlate with
270 *Positive Growth* and have low/no correlations with the other CARE Burn
271 Scales since they are dissimilar constructs.
- 272 • *Trauma Symptoms* would moderately correlate with the PTSD CheckList –
273 Civilian Version (PCL).
- 274 • The EQ-5D-5L would have low/moderate correlations with the individual
275 CARE Burn Scale sub-scales since it is a general quality of life measure.

276

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

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

284 Results

285 Stage 1.1. Conceptual framework formation

286 Eleven adult burn patients (4 female, 7 male, aged 27 to 78 (M=51.90, SD: 18.68) (Table 1)
287 and ten of their family members (7 partners, 2 mothers and 1 daughter, 7 female, 3 male,
288 aged 42 to 78, M: 57.00, SD: 13.09) were interviewed. Four clinical psychologists who
289 worked with adults with a burn were also interviewed (in depth analysis of the health
290 professionals' interviews is reported in Guest et al, 2018 [5] and patient interview analysis is
291 reported in Griffiths [67]). Thematic analysis identified a range of themes which reflected
292 patients' experiences of living with a burn injury and its impact on quality of life. Informed
293 by these interviews, expert opinions and the systematic review [30]; 14 key domains formed
294 the conceptual framework of adult burn patients' experiences of living with a burn (see
295 Figure 1):

- 296 1. *Wound/Scar Discomfort*: the extent to which patients feel discomfort or pain in
297 relation to their burn wound/scar.
- 298 2. *Physical Well-being*: patients' physical health and their physical abilities.
- 299 3. *Wound/Scar Treatment*: the extent to which patients feel bothered by a range of
300 different wound/scar treatments such as dressing/bandage changes, washing and
301 dressing and physiotherapy exercises.
- 302 4. *Social Situations*: patient confidence in challenging social situations in which other
303 people may look, touch or ask questions about their burn wounds/scarring.
- 304 5. *Avoidance Behaviours*: the extent to which patients avoid looking at their burn or
305 avoid activities or situations because of how their burn wounds/scars look.
- 306 6. *Self-worth*: the extent to which a patient has positive feelings about themselves.

- 307 7. *Negative Mood*: the extent to which a patient reports low/negative mood.
- 308 8. *Wound/Scar Dissatisfaction*: how bothered patients feel about the look of their burn
309 wound/scarring.
- 310 9. *Work Life*: patients' perceptions of the quality of their work life.
- 311
- 312 10. *Family Support*: patients' perceptions of the quality of their family relationships.
- 313 11. *Friend Support*: patient perceptions of the quality of their friendships.
- 314 12. *Intimacy*: the extent to which patients' feel attractive to others and confident about
315 showing their burn wounds/scars in intimate situations.
- 316 13. *Trauma Symptoms*: negative psychological and behavioural symptoms related to the
317 patient's burn injury, such as flashbacks, bad dreams and anxiety.
- 318 14. *Positive Growth*: the extent to which patients report positive outcomes/personal
319 development after living with a burn injury.

320 *INSERT TABLE 1 AND FIGURE 1

321 **Stage 1.2: Item generation, initial scale formation and pre-testing**

322 Initial items (n = 110) were generated, covering all 14 domains of the conceptual
323 framework. Cognitive debriefing interviews were then conducted with 3 adult burn patients
324 and 1 family member, and feedback was also obtained from 7 health professionals (4 clinical
325 psychologists, 1 counsellor, 1 psychotherapist, 1 physiotherapist) and 1 international PROM
326 development expert. This resulted in minor changes to items (changes to wording, providing
327 more burn-specific examples, more simple language) and a further 99 items being added to
328 the existing domains, resulting in 209 items in the scale that was field tested.

329 The domains in which increasingly higher scores reflect increasingly poorer outcomes are:
330 *Burn Wound/Scar Discomfort, Wound/Scar Treatments, Wound/Scar Dissatisfaction,*
331 *Avoidance Behaviours, Trauma Symptoms, Negative Mood.* The domains in which
332 increasingly higher scores reflect increasingly better outcomes are: *Physical Well-being,*
333 *Confidence in Social Situations, Friendships, Family Life, Work Life, Intimacy, Self-Worth,*
334 *Positive Growth.*

335 **Stage 2: Item reduction phase**

336 **Sample**

337 A total of 304 participants completed the CARE Burn Scale – Adult Form. Participant
338 characteristics are shown in Table 2. The largely supported rule of thumb is that in order to
339 perform an accurate and precise Rasch analysis to >99% confidence and with item
340 calibrations within ± 0.5 logits, the advised sample size is 250[68] .

341 **Item reduction**

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

344 Of the 14 scales tested, a Rasch solution was found for 12 (Table 3). This was not the case
345 for the *Discomfort with Burn Wound/Scar Treatment* and *Avoidance Behaviours*, which are
346 reported as checklists. For *Discomfort with Burn Wound/Scar Treatment*, the items occupied
347 mostly the same space on the Rasch continuum, meaning that there is no requirement for
348 multiple items and thus a scale cannot be formed. For *Avoidance Behaviours*, multiple items
349 had multiple issues with combinations of model fit, local independence and differential item

350 functioning on gender and scar visibility. Despite all various attempts to find a solution,
351 none could be found to satisfy the criteria of the Rasch measurement model.

352 Overall, using the Rasch Measurement Model and Analyses (previously described in the
353 method section), the initial 194 items across the 12 scales were reduced to 45 items (see
354 Table 3). Scale reliability was generally supported by high PSI, with only *Low Mood* and
355 *Positive Growth* exhibiting PSI<0.70 (0.62 - 0.69 respectively). Fit to the Rasch model was
356 good, with all item-trait interactions non-significant and no items with fit residuals out of
357 range or presenting significant X^2 values. All final scale solutions contain no items with
358 reversed thresholds. However, all but *Positive Growth* required response thresholds to be
359 collapsed for this to be the case. For *Wound/Scar Discomfort*, *Wound/Scar Dissatisfaction*,
360 *Trauma Symptoms* and *Low Mood*, the second and third categories were collapsed. For
361 *Physical Well-being*, *Social Situations*, *Friend Support*, *Work Life*, *Family Support*, *Self-worth*
362 and *Intimacy*, the third and fourth categories were collapsed. All pairs of items within each
363 scale had a residual correlation less than 0.3 above the mean residual correlation (of all item
364 pairs for that scale), supporting local independence amongst items. The vast majority of
365 items did not exhibit DIF, suggesting that items remain invariant across different groups of
366 patients. Unidimensionality was confirmed via Smith's procedure [58] for all 12 scale
367 solutions.

368 Despite finding 12 solutions, all had gaps in the person location and item threshold
369 distributions, meaning that it is not possible to wholly reflect the range of the continuum
370 (Appendix A). *Physical Well-being*, *Social Situations*, *Friendship*, *Work Life*, *Family Life*, *Burn*
371 *Wound/Scar Dissatisfaction* and *Trauma Symptoms* had ceiling effects in their person
372 distributions. Also *Social Situations*, *Self-worth* and *Low Mood* had items with DIF issues.

373 However the evidence for these DIF issues is weak (p-value just less than the $\alpha = 0.05$
374 Bonferroni-corrected level) but are reported for full disclosure.

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

376 **Traditional psychometric analyses (Classical test theory)**

377 All scales with Rasch solutions passed criteria for acceptability, reliability and validity (Table
378 3): Cronbach's $\alpha > 0.80$ and all item-total correlation coefficients > 0.70 .

379 **Checklists**

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

384

385 *INSERT TABLES 2, 3 AND 4 HERE

386

387 **Stage 3: Further psychometric evaluation**

388 **Sample**

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

395

396 *INSERT TABLE 5 HERE

397 **Traditional Psychometric Analyses**

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

406 Scale validity was supported by the correlations between the CARE Burn Scale sub-scales
407 and the other validated quality of life/health psychometric measures (Table 8). Hypotheses
408 relating to correlations between CARE Burn Scale subscales, the Burn Specific Health Scales
409 [63], the EQ-5D-5L [64], PTSD CheckList – Civilian Version (PCL) [65] and the Post Traumatic
410 Growth Inventory [66] were widely supported through moderate correlations with related
411 constructs and low/no correlations with dissimilar constructs.

412 As predicted, the CARE Burn Scales correlated moderately/highly with many of the Burns
413 Specific Health Scales. In particular, *Wound/ Scar Discomfort* and *Physical Well-being*
414 moderately correlated with the all of the BSHS Physical Health subscales, *Social Situations*
415 moderately correlated with the BSHS Social Health total score, *Friend Support* was highly
416 correlated with the BSHS Social Health total score and the BSHS Social Friends subscale,
417 *Work Life* and *Family Support* were moderately correlated with the BSHS Social Health Total
418 Score. *Wound/Scar Dissatisfaction* was highly correlated with the BSHS Body Image

419 subscale, *Trauma Symptoms* moderately correlated with the BSHS Mental Health total score
420 and the BSHS Mental Affect subscale, *Negative Mood* was highly correlated with the BSHS
421 Mental Health total score and the BSHS Mental Affective subscale. However, *Self-worth* did
422 not significantly correlate with any of the BSHS Mental Health or Affect subscales and
423 *Intimacy* did not correlate with the BSHS Sexual subscale which was not consistent with the
424 predicted hypotheses.

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

430

431 ***INSERT TABLES 6, 7, 8 AND 9 HERE

432

433 Regression analysis identified significant relationships between 6 of the individual CARE
434 Burn Scale sub-scales and sociodemographic variables (i.e. age, time since burn, gender,
435 ethnicity, marital status and cause of injury) (Table 9). There was a significant effect of cause
436 of burn, with non-liquid injuries being significantly associated with greater wound/scar
437 discomfort compared to liquid injuries. Time since burn was significantly associated with
438 greater work well-being. Women and those sustaining non-liquid burn injuries were more
439 likely to report greater wound/scar dissatisfaction. Non-liquid injuries were also significantly
440 associated with more negative mood and time since injury was associated with greater

441 positive growth. However, since the majority of regression coefficients (66/72) were non-
442 significant, this provides evidence of discriminant validity.

443

444 ***INSERT TABLE 9 HERE

445

446 **Discussion**

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

458 The 12 scales with Rasch solutions showed good scale reliability was generally supported by
459 high PSI values, and fit to the Rasch model was good. Evidence of reliability and validity
460 based on traditional psychometric analyses was identified, as was concurrent and
461 discriminate validity with other measures and sociodemographic factors. Overall, these

462 findings indicate that the CARE Burn Scale – Adult Form is a valid and reliable scale to
463 measure quality of life for adults living with a burn injury.

464 The item reduction stage was led by Rasch analysis which permits individual patient and
465 subsample level measurement and produces interval level data that allows measurement
466 invariance to be tested and valid total scores to be created. These increase the potential for
467 the PROM to identify clinical change which will be of benefit to clinicians and researchers
468 alike [69]. Burns research is increasingly using Rasch analysis in PROM
469 development/validation papers, such as the Patient and Observer Scale (POSAS) and Lower
470 Limb Index [70] [71]. Researchers developing new PROMs for use in adult burn care should
471 consider using Rasch to ensure that the PROMS they develop are suitable for measuring the
472 health of both individual patients and subgroups.

473 *Comparing the CARE Burn Scale- Adult form with existing burn-specific PROMs*

474 The CARE Burn Scale – Adult Form does cover domains that some existing burn-
475 specific PROMs also measure such as *Wound/Scar Discomfort* [34, 35], *Physical Abilities* [32-
476 35], *Confidence in Social Situations* [34, 35, 37], *Friendships* [32-35, 37], *Family* [32-35, 37],
477 *Work* [33-35, 37], *Wound/Scar Dissatisfaction* [32-35], *Intimacy* [32-35, 37] and *Negative*
478 *Mood* [32-35].

479 However, the CARE Burn Scale – Adult Form has the advantage of including unique
480 domains which are not measured by existing PROMs (such as the Abbreviated Burn Specific
481 Health Scale (BSHS-A) [32], the Burn Specific Health Scale – Brief (BSHS-B) [33], Young Adult
482 Burn Outcome Questionnaire (YABOQ) [35], the Adult Burn Outcome Questionnaire
483 (YABOQ) Short Form [34], the Coping with Burns Questionnaire [72] and the Life
484 Impact Burn Recovery Evaluation (LIBRE) [37]). These unique domains are: *Trauma*
485 *Symptoms* (i.e. feeling upset, short tempered, experiencing bad dreams or flashbacks/vivid

486 memories), *Avoidance Behaviours* (i.e. avoiding looking at or touching burn wounds/scars,
487 covering up wounds/scars or avoiding certain social activities because of their
488 wounds/scars), *Self-Worth* (i.e. feeling confident, happy), *Wound/Scar Treatments* (i.e.
489 whether treatments such as dressing changes, creaming/massage and physiotherapy
490 exercises bother patients) and *Positive Growth* (i.e. life being more meaningful or feeling a
491 better person after a burn injury). Using in-depth interviews with patients and health
492 professionals to inform the conceptual framework and PROM items, rather than relying on
493 existing PROMs or conceptual frameworks, led to these additional new domains which other
494 scales do not cover. This further highlights the benefit of in-depth interviews when
495 developing new PROMs to ensure that the scale measures the breadth of health outcomes
496 that are most important to patients themselves [42].

497

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

502

503 **Limitations**

504 Men typically outnumber women in the prevalence of burn injuries [2]. Yet there was a
505 fairly even gender split in the Stage 2: Item reduction study. This might be explained by the
506 fact that the data collection was part of a research project rather than routine clinical audit;
507 women are significantly more likely to take part in research than men [73]. In the current
508 study patients were simply invited to take part and were responsible for returning their
509 questionnaire in the mail, or completed it online. Staff were not responsible for

510 motivating/encouraging participants to take part or for collecting questionnaires, which is a
511 different process to data collection in clinical audit which burn prevalence statistics are
512 based on. The common gender differences in research participation may therefore have
513 influenced the gender spilt in this study. Furthermore, the regression analysis showed that
514 gender did not have a significant effect on any domains of the CARE Burn Scale, apart from
515 *Wound/Scar Dissatisfaction* which showed women were more likely to be dissatisfied with
516 their scarring compared to men. This is a typical finding in burns research [74]. Therefore,
517 the less typical gender spilt in the sample did not have a significant effect on the overall
518 findings of the study.

519 The burn aetiology in this study was comparable to other studies with adult burn patients in
520 the UK; the current had 20.6% flame injuries compared to 21.12% reported by Stylianou et
521 al (using the UK IBID database for adult injuries that occurred from 2003- 2011) [2]. The
522 percentage of scald/liquid injuries was higher in the current study (44.8%) compared with
523 33.29% reported by Styliou et al, but since women are more likely to experience scalds
524 compared to flame injuries, the higher rates of scald injuries in our sample could be related
525 to our more even gender spilt compared to the male bias typical in burn injuries more
526 generally [2].

527 Another limitation of this study is the level of missing data identified in phase 3. Missing
528 data is very common in questionnaire design studies and when collecting data in healthcare
529 services, where less than 10% missing data is not thought to bias results [75, 76]. In the
530 current study, the majority of items had less than 10% missing data, but for 15 out of 44
531 items this was 12-42% (mostly 10% - 15%). However two domains (*Work Life* and *Intimacy*)
532 showed higher levels of missing data. This is not surprising since many adults delay returning

533 to work after a burn and some might not feel comfortable answering questions about their
534 intimate lives. A comparison of the Cronbach's alphas for each individual CARE Burn Scale
535 using datasets with and without missing data indicated a negligible impact of missing data
536 on the reliability of the scales and the dataset with missing data was therefore retained. In
537 phase 3, participants completed a number of other PROMs at the same time as the CARE
538 Burn Scale, therefore missing data might reflect patient burden or fatigue from the longer
539 survey length. Future research will test the final version of the CARE Burn Scale – Adult Form
540 without the inclusion of other quality of life scales to gain a more accurate record of the
541 level of missing data expected when completing it in routine clinical practice or research.
542 As with all psychometric scale development research, further ongoing validation work is
543 needed. Test-retest reliability and responsiveness data are required to further validate the
544 findings and explore the reliability of the CARE Burn Scale – Adult Form and its ability to
545 detect clinical changes over time. This is necessary in order that suitably robust measures
546 are available for longitudinal cohort studies within burns.

547 The CARE Burn Scale reported in this paper is only valid for adult burn patients. However
548 this scale is part of a suite of PROMs being developed by the authors, including measures for
549 use in burn care with children under 8 years of age (parental report), young people aged 8-
550 17 years and parents [77-79]. Additionally, the CARE Burn Scale – Adult Form, has been
551 tested with a UK population. Additional validation studies are warranted if they are to be
552 used elsewhere, translation studies are needed if they are to be used with non-English
553 speaking patients, and their value as a tool that can assess patient reported outcomes in
554 different cultures needs to be explored [80].

555 **Conclusions**

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

563 **Acknowledgements**

564 We would like to thank all the patients and family members who contributed to the studies
565 in this paper and the health professionals who recruited participants to the studies and/or
566 gave feedback on the initial measure. This work is part of a program of research that has
567 been funded by Restore Burn and Wound Research, the Scar Free Foundation, and Dan’s
568 Fund for Burns. The views expressed are those of the authors, and not necessarily those of
569 the funding bodies.

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