Corresponding Author: Dr. Astrid Müller, M.D., Ph.D.

Corresponding Author's Institution: Medical School Hannover

First Author: Astrid Müller, M.D., Ph.D.

Order of Authors: Astrid Müller, M.D., Ph.D.; Dirk Smits; Stefanie Jasper; Lea Berg; Laurence Claes; Ramin Ipaktchi; Peter M Vogt; Martina de Zwaan

Dear Dr. Wolf,

Thank you for considering a revised version of our manuscript for publication in *Burns*. We also wish to thank the two reviewers for their very helpful and constructive comments and we have addressed all remarks and modified our manuscript, accordingly. All changes are highlighted.

We are looking forward to hearing from you,

On behalf of all authors,

Yours sincerely,

Astrid Müller

Conflict of interest statement

The authors declare no conflict of interest.

Reviewer #1

I appreciated the opportunity to read this important paper. The title, highlights, and abstract are all appropriate and reflect the content of the paper. You may want to consider adding the word German as a keyword.
**We added the word 'German' as a keyword.

This paper is extremely well written so my comments will appear to be rather picky but I believe they will enhance the paper.
**We wish to thank the reviewer for his/her constructive comments.

1.   On pg 3 it might read better to say However in place of Though on line 3. On line 4 of the second paragraph of pg 3 please consider saying "Subsequently" rather than Later on.
You appear to have a typographical error at the beginning of the last sentence of paragraph 2 in the second paragraph—it reads Tough—I recommend you use the word But.
**We made the changes.

2.   On page 4 you have a couple of sentences that begin with the word As when you really mean Because. It is OK to start a sentence in a scientific paper with the word Because
(see line 3 and the last line). Also see line 2 of the second paragraph on pg 7 regarding this issue
**We changed the wording.

3.   On pg 5 you really are not presenting hypotheses—you are presenting aims—so it would better to say (line4) Based on prior studies, the aims of our study were fourfold. We aimed to:
Because the word "to" is placed before the colon you can deleted this word at the beginning of each aim.
**We changed the wording.

4.   Please take out the extra space between Surgery and "of" on line 3 of the Participants and Procedure section. On line 8 of that same section the word patient's should be patients' based on the way the rest of the sentence is written
**We made the changes.

5.   It was impressive that you engaged the expertise of Dr. Willebrand! Well done.
**Again, we wish to thank Dr. Willebrand.

6.   A paragraph usually must contain 3 sentences so please pull up the one sentence in the middle of page 6 that begins as: Furthermore: the German….
**We made the changes.

7.   On pg 8, line 4. The word "also" should precede "be". Please see the 3rd paragraph on pg 8 and consider changing the word "on" to about so the first sentence would read: Information about percent of burned… Also remove the extra space in the next sentence.
**We made the changes.

8.   I realize that normally a power analysis is not part of a psychometric paper but you are also providing results in the form of your correlations among the variables. It would be helpful if you could provide at least the results of a post-hoc power analysis.

** For all correlations significantly different from zero, we checked the power of all tests in table 4, post hoc, with the significance level set at .01. The power equaled at least .97, for all correlations which are significantly different from zero.
Furthermore, for the comparison of patients with low and high ABSI scores (Table 5), we performed a post-hoc power analysis for each Mann Whitney's U test. The power was sufficient for most analyses (>.70 or .80), but not very high for the SF-8 Mental Component score (β= .441) and the HADS-Depression (β= .583) comparisons. We added the information in the Results section on pages 9and 10.

9.   On pg 10, I believe there is a typographical error on line 6 of the second paragraph—I believe you meant to say that those with low ABSI scores were on average younger than participants in the high ABSI group.
*This was indeed a typesetting error that we corrected. Thank you.

10.   See pg 11, line 4—again I believe hypothesis should be replaced with the word aim. Please remove the word "on" in the first sentence of paragraph 2 of this page and also change the word hypothesis to aim in that paragraph and again in the next paragraph. In the last sentence of paragraph 3 on pg 11 it might be better to say that HRQoL after burn injury is known to be inversely related to burn size etc. The words "health status" don't fully capture the meaning as well (in my opinion). Change the word hypothesis to aim in paragraph 4 please.
**We made the changes.

11.   I appreciate your discussion of limitations, which is why a post-hoc power analysis would be helpful. Also, any researcher doing this type of work faces the limitation of only being able to analyze data from patients who consent to be in the study or complete the survey so your limitation in this regard is not avoidable.
**Please see our response above (comment #8).

12.   Your conclusions are well done!
**Thank you.

13.   The figures and tables do support the paper. However, Table 1 was slightly confusing because the alpha was provided on the diagonal. I would prefer to see a small separate table with the alphas clearly noted. Regarding the correlations—although the Spearman rank order correlations were all significant at the p>.01 level, not all of them are clinically relevant to the same extent. For example if you square r in any of the correlations below .5 (which is moderate) then only 9-24% of the variance is accounted for with these correlations. You have other correlations that are indeed higher and are more clinically relevant—you may want to consider addressing this issue in the discussion section of your paper.
**We now report the Cronbach's alphas in a separate table (Table 2).
**We now discuss the clinical relevant correlations in the discussion section on pages 11 to 12.

14.   See Table 3 in some places you have periods at the preceding the number and in other places you have commas—in the U.S. we usually use periods.
**We replaced the commas by periods as appropriate.

The references consisted of the appropriate literature for this paper.

Reviewer #2:

Thank you to the authors for submitting a good paper. The manuscript needs major rework but all elements of a publishable paper are evident.
**We thank the reviewer for his/her helpful comments.

Abstract:
Please shorten to 250 words as per Burns requirements and provide a succinct summary of the study.
**We recounted the words. The abstract consisted of only 234 words. We now made some changes resulting in a final word count of 239.

Intro:
This section mixes Methods with Introduction. The bulk of the lit review and discussion regarding the comparative psychometric properties of the various versions of the BSHS should be in Methods, though could be shortened significantly with prudent referencing. With the widespread use of the BSHS-B, there is little reason to explain the history of the scale, please shorten and focus the text on the scale of interest only. Move the bulk of the second, third and fourth paragraphs to Methods. The sentence between the aim and hypotheses should also be moved to Methods.
**We shortened the literature review but kept some parts of the second, third and fourth paragraphs in the Introduction as we do not think that this information belongs to Methods.
**In accordance with the reviewer's comment we moved the sentences before the aims beginning with "We explored the factor structure …" to Methods.

Method:
The Participants and Procedure section is disordered also. The description of the patient sample and the outcome of recruitment are results and should be placed there.
**We moved the description of the sample to Results.

While this paper is largely a statistical exercise, the Methods should lay the foundation for the Data Analysis sub-section. A lot of the detail required is currently in the Data Analysis sub-section.
**We modified the article structure in accordance with the guide for authors and replaced the subdivision 'Data Analysis' by the subdivision 'Calculation'.

Methods lacks justification or explanation of the establishment of reliability before progressing the comparisons to examine validity.
**We mentioned in the manuscript on page 6 (lines 6/7) that internal consistency of all BSHS-B scales was determined first, as the scales were used as indicators for the subsequent second order factor analysis.

The Assessment section should provide more detail relating to the aim and justification of each proposed scale comparison. For example, exactly why was SF8 considered a reasonable comparison and was the desire to examine construct or criterion validity?
**We now provide the requested information in the Assessment section.
**Given that both the BSHS-B and the SF-8 sample the domain of HRQoL (the patients' point of view) we used the SF-8 to examine construct validity.

The HADS, while used frequently to measure burn patient mental health status, is not validated in the burn population to this reviewer's knowledge. Please note that as a limitation of the use of this scale and justify why it was chosen.

**We included this limitation in the discussion. The HADS does not include items referring to symptoms that may have been caused by a physical illness or injury and is therefore considered to be unbiased by medical illnesses. It was used to examine criterion validity (relationship between burn-specific HRQoL and symptoms of anxiety/depression). We now provide this information in the Methods section.

Was the ABSI comparison used to examine validity? Please explain.
**Yes, the ABSI comparison was indeed used to examine validity. In accordance with Hattie and Cooksey (1984), we used the known-groups method to determine construct validity. We now provide this information in the Methods section.
We are aware that most BSHS-B validation studies (published in *Burns*) used the TBSA burned to examine construct validity. Reviewing the manuscript our group discussed the question of whether the correlation between the BSHS-B and the TBSA burned measures construct or rather criterion validity. Because individuals with higher burn severity are at-risk for diminished HRQoL (e.g., Davydow et al., *International Review of Psychiatry* 2009; Falder et al., Burns 2009) and given that the TBSA burned is one of the five variables included in the ABSI we think that the TBSA burned can be used to examine construct validity.

Data Analysis:
What method of imputation was used and why?
**We opted for an imputation per scale as primarily the responses on the same scale can be assumed to be predictive for the missing value. As no monotonicity was present in the missing data patterns per scale, missing data were imputed using a MCMC approach, linear regression as implemented in SPSS 21 (i.e. fully conditional method). Imputed values were restricted to integers conform the response scale. Descriptive statistics for the item and the scale were compared with and without imputation. Differences were only minor.

How did the authors treat the data from those 15 missing TBSA information?
**Missing TBSA data were not imputed but used as missings. Therefore, we had included the comment "[a] data available from *n*=126" in the note under Table 3 (now Table 4).

Please include and reference 'acceptable' cut-off wrt Cronbach's <alpha>.
**We included the following reference: Cortina, J.M. (1993). What is coefficient alpha? An examination of theory and applications. Journal of Applied Psychology, 78 (1): 98-104.

Last sentence of paragraph 3 (Factor Structure) requires rework wrt grammar please.
**We made the changes.

Results:
Sample Description - were the data collated as if at time of burn or at time of survey? How do the authors know that marital status and education level have not changed significantly since the burn injury?
**The sociodemographic data were collected at time of survey. Unfortunately, we have no information with regard to changes in marital status, etc. We now mention this as a limitation in the Discussion on page 12.

Discussion:
The discussion is very bland and the authors should explore the influence of demographics or other social determinants, especially with respect to the unexpected results or the contrasting result wrt Interpersonal Relationships.

** We added information on the influence of demographic variables. The ABSI groups did not differ with regard to marital status. This could have contributed to the lacking difference on this subscale. We added this thought in the discussion on page 12 (lines 6-8).

Generalisability (utility) of results must be explained as the survey was applied a minimum of 1 year post-burn and more than 8 years post-burn and the maximum burn size was 40% TBSA. What are the implications for use of the new version prior to 1 year post-burn?
**We added a comment on this in the Discussion on page 13 (lines 4/5).

In addition, were the demographics and injury characteristics of those who did not respond different from those who did respond?
** We used data from patients' charts only if the patients gave written informed consent. Demographic data at time of survey were available from only those patients who participated in the survey. Therefore, we cannot provide information about possible differences.

Conclusion:
One or two sentences only. Clear, concise messages for readers to apply or compare to their own clinical practice or situation is all that is required. Please remove repetition and restating of results.
**We deleted the second sentence and moved the last sentence to the end of the paragraph above.

- We validated the German version of the Burn Specific Health Scale-Brief (BSHS-B)
- Methods: confirmatory factor analysis, correlation analyses, know-groups technique
- Three main components: 'Affect and Relationship', 'Function' and 'Skin Involvement'
- The results indicate good psychometric properties of the German BSHS-B

1   Short title: German BSHS-B

2

3

4   **Validation of the German version of the Burn Specific Health Scale-Brief (BSHS-B)**

5

6   Astrid Müller[a,*], Dirk Smits[b,c], Stefanie Jasper[a], Lea Berg[a], Laurence Claes[c], Ramin Ipaktchi[d],

7   Peter M. Vogt[d], Martina de Zwaan[a]

8

9

10   [a] Department of Psychosomatic Medicine and Psychotherapy, Hannover Medical School,

11   Hannover, Germany

12   [b] Odisee University College, Brussels, Belgium

13   [c] Faculty of Psychology and Educational Sciences, University of Leuven, Leuven, Belgium

14   [d] Department of Plastic, Hand and Reconstructive Surgery, Hannover Medical School,

15   Hannover, Germany

16

17

18

19   *Correspondence:

20   Astrid Müller

21   Department of Psychosomatic Medicine and Psychotherapy

22   Hannover Medical School

23   Carl-Neuberg-Str. 1

24   D-30625 Hannover

25   Germany

26   Email: mueller.astrid@mh-hannover.de

1 **ABSTRACT**

2

3 *Background:* The Burn Specific Health Scale-Brief (BSHS-B) is recognized as a valid self-

4 rating scale to evaluate quality of life after burn injury. *Aim:* To validate the translated

5 German version of the BSHS-B. *Method:* 141 burn survivors (65.2% men) with a mean age of

6 49.62 years (SD=15.16) and a mean duration after burn injury of 45.01 months (SD=26.18)

7 answered the BSHS-B. Factor structure was tested by using confirmatory factor analysis,

8 reliability (internal consistency) of the scales was determined by means of Cronbach's α.

9 Construct validity was explored through correlations between the BSHS-B and the Short-

10 Form 8 Health Survey (SF-8). In addition, the know-groups technique was used to determine

11 to which degree the BSHS-B discriminates between patients with low and high burn severity

12 based on the abbreviated burn severity index (ABSI). The Hospital Anxiety and Depression

13 Scale (HADS) was used to examine criterion validity. *Results:* The nine BSHS-B subscales

14 showed good internal consistency. A second-order confirmatory factor analysis revealed the

15 following main components: (1) Affect and Relationship, (2) Function and (3) Skin

16 Involvement. The second-order factors were positively correlated with the SF-8 and

17 negatively correlated with symptoms of anxiety and depression. Patients with low ABSI

18 scored higher on all three BSHS-B domains than those with high ABSI. *Conclusions:* The

19 results indicate good psychometric properties of the German BSHS-B. Further studies are

20 needed to investigate the utility of the questionnaire in clinical routine practice, evaluation of

21 burn management programs, and burn-specific research.

22

23 *Keywords:* German Burn Specific Health Scale-Brief, health related quality of life, Hospital

24 Anxiety and Depression Scale, reliability, validity

25

1 **Introduction**

2 Burn injuries lead to physical and psychosocial sequelae and affect health related quality of

3 life (HRQoL) [1]. Information on health status after burn injury is often obtained from generic

4 measures of HRQoL. However, it is well known that burn survivors exhibit impairment in

5 burn-specific aspects of HRQoL such as heat sensitivity, body function, body image

6 satisfaction, sexuality, social and working life, etc. [1,2]. Therefore, instruments measuring

7 post-burn specific health status may provide valuable additional information on physical and

8 mental impairment, recovery after burn injury, treatment outcome, and specific aftercare

9 needs.

10 The Burn Specific Health Scale (BSHS) is recognized as a valid self-rating scale to

11 evaluate quality of life after burn injury [3]. The original 114-item BSHS was developed by

12 Blades, Mellis and Munster [4]. Subsequently, the BSHS was validated and shortened [5,6].

13 To address the shortcomings of prior versions, Kildal et al. [7] created the Burn Specific

14 Health Scale-Brief (BSHS-B). The BSHS-B represents a clinically useful instrument with 40

15 items that are answered on a 5-point Likert scale ranging from 0 (=extremely) to 4 (=not at

16 all). It consists of nine subscales: Heat Sensitivity, Affect, Hand Function, Treatment

17 Regimens, Work, Sexuality, Interpersonal Relationships, Simple Abilities, and Body Image

18 [7]. Higher scores refer to better burn-specific HRQoL. Because the interpretation and clinical

19 value of the BSHS-B was expected to be improved by a simplified structure with clinically

20 meaningful broader components of burn-specific health, Willebrand and Kildal [8] conducted

21 a second-order factor analysis on BSHS-B scores in a sample of 334 burn patients resulting in

22 the following three separable health domains: (1) Affect and Relations (subscales

23 Interpersonal Relationships, Affect, and Sexuality), (2) Function (subscales Simple Abilities

24 and Hand Function), and (3) Skin Involvement (subscales Heat Sensitivity, Treatment

25 Regimens, and Body Image). Due to the cross loading of the subscale Work on the factors

26 Function and Skin Involvement, the subscale Work was excluded and considered to be an

3

1 outcome domain in itself [8]. The second order component structure was replicated in a

2 sample of 94 Swedish patients with burns [9].

3   By now, the BSHS-B is a widely used instrument that has been translated into Chinese

4 [10], Hebrew [11], Italian [12], Persian [13], Polish [14], and Turkish [15]. Van Loey et al.

5 [16] examined the factor structure of the BSHS-B in a mixed sample of 506 Swedish, Dutch

6 and Belgian patients after burn injury without taking into account the different countries.

7 Although the results of this confirmatory factor analysis supported the earlier findings with

8 regard to the 9 first-order factors [7] and the 3 second-order factors [8,9] of the BSHS-B, the

9 best model fit was obtained for an 8-factor solution in which the scales Hand Function and

10 Simple Abilities were merged. Similarly, these subscales entered into the same factor in the

11 adapted Chinese version of the BSHS-B [10].

12   To the best of our knowledge, no authorized validated German version of the BSHS-B

13 is available so far. Hence, the aim of the present study was to validate the translated German

14 version of the BSHS-B. Based on prior studies, we aimed to 1) replicate the three main

15 BSHS-B domains in a German sample of burn survivors, 2) find a positive correlation

16 between the BSHS-B and a generic measure of HRQoL, 3) reveal a negative relationship

17 between high BSHS-B scores and percent of injured body surface, anxiety, and depression,

18 and 4) confirm that the BSHS-B discriminates between patients with low and high burn

19 severity.

20

21 **Material and Methods**

22 *Procedure*

23 Data were collected between December 2013 and May 2014. The study included adult burn

24 survivors ($\geq$ 18 years) who were admitted to the burn unit of the Department of Plastic, Hand

25 and Reconstructive Surgery of the Hannover Medical School between 2006 and 2012.

26 Patients treated at the unit during the aforementioned time period were identified via

1   electronic chart files. Patient information, informed consent forms and questionnaires were

2   sent to the identified patients. If unopened questionnaire packages were returned by post mail

3   we made enquiries at the registration offices about the patients' whereabouts and whether they

4   were still alive in order to detect patients who moved or passed away since their last

5   admission to the burn unit. Participation in the study was completely voluntary. The protocol

6   was approved by the Institutional Ethics Committee of the Hannover Medical School.

7

8   *Assessment*

9   All patients were invited to provide information on age, gender, marital status, education,

10   work ability and duration since burn injury. They were then asked to complete the *BSHS-B*.

11   The authorized German translation and back-translation of the original English version of the

12   BSHS-B was performed by a licensed translator (Translaw, Oxford, GB). The backward

13   translation was verified for discrepancies against the original form by an author of the original

14   scale (M. Willebrand).

15   Generic health-related quality of life (HRQoL) was measured with the *Short-Form 8*

16   *Health Survey* (SF-8) [17,18] which is the short version of the SF-36 Health Survey (SF-36)

17   [19]. The two summary scales of Physical and Mental Health were used. Symptoms of

18   anxiety and depression were measured with the *Hospital Anxiety and Depression Scale*

19   (HADS) [20,21]. The HADS does not include items referring to symptoms that may have

20   been caused by a physical illness or injury and is therefore considered to be unbiased by

21   medical illnesses.

22   Information on *total body surface area* (TBSA) burned and the *abbreviated burn*

23   *severity index* (ABSI) [22] was retrieved from patients' charts. The ABSI score estimates the

24   risk of mortality after burn trauma. It is based on 5 variables: age, gender, presence of

25   inhalation injury, presence of full thickness burn, and percentage of TBSA burned. An ABSI

of 2-3 indicates very low, of 4-5 moderate, of 6-7 moderately severe, of 8-9 serious, of 10-11 severe, and of 12-13 or more maximum threat to life [22,23].

Calculation

To examine construct validity, a second order confirmatory factor analysis was conducted on the BSHS-B scale scores. Because the scales were used as indicators for the factor analysis, internal consistency of all BSHS-B scales was determined in a first step. Then the second order confirmatory factor analysis was conducted using a maximum likelihood estimation algorithm with robust standard errors (MLR option, MPLUS 7.2). In accordance with Willebrand and Kildal [8] the fit of two models was compared: a three-factor model with the scales Affect, Interpersonal Relationships and Sexuality loading to a 'Affect and Relationships factor'; Simple Abilities, Hand Function and Work loading on a 'Function factor'; and Heat Sensitivity, Treatment regimens and Body Image loading on a 'Skin Involvement factor', versus a model in which the Work Scale is removed. As reported by Willebrand and Kildal [8], the Work scale was not uniquely associated with one factor, but had serious cross-loadings on the Function and Skin Involvement factors in previous studies. Model fit was assessed by multiple criteria: Satorra Bentler scaled χ^2 for absolute fit, comparative fit index (CFI) for fit relative to a null model, complemented with the standardized root mean square residual for overall fit. The criterion for good model fit were defined according to Hu and Bentler [24] as CFI >.95 (.90 is acceptable), and SRMR >.05 (.09 is acceptable).

The BSHS-B and the SF-8 are both considered to assess HRQoL. Therefore, construct validity was determined assessing the relationship between BSHS-B domains and the SF-8. Given that patients with different burn severity were theoretically expected to be also different with regard to injury-specific HRQoL, variables assessing burn severity (TBSA, ABSI) were

used to measure construct validity. The sample was divided into a first group with low or moderate burn severity (ABSI $\leq$ 5) and a second group with at least moderately severe burn severity (ABSI $\geq$ 6). To determine the degree in which the BSHS-B discriminates between patients with low and high ABSI scores, the known-groups technique [25] was applied.

Since prior studies showed an association between diminished HRQoL and other mental health criteria among burn survivors [2,26,27], the relationship between the BSHS-B and the HADS was analysed to determine criterion validity. Finally, we examined the influence of age, gender, marital status and duration since injury on BSHS-B domains.

Statistical analyses were performed using Mplus 7.2 and IBM SPSS Statistics version 21, as appropriate. Post hoc power analyses were conducted using G*Power 3.1.2. With respect to the BSHS-B, a maximum of 10% missing data per person was allowed. The remaining missing responses were imputed based on a regression per scale. Missing ABSI and TBSA data were not imputed. Group differences on continuous variables were examined using independent sample t-tests or nonparametric tests when the variable was not normally distributed. Categorical variables were compared by using χ^2-tests. Relationships between variables were determined calculating two-tailed Spearman's rank-order correlations

Results

Description of the sample

Figure 1 demonstrates the patient flow. Between 2006 and 2012, 870 patients were treated at the burn unit. Of those, 62 patients were already deceased according to the files. One-hundred forty-six patients participated in the study. Five of the 146 individuals had more than 10% missing data in the BSHS-B resulting in a final sample size of 141 burn survivors with valid BSHS-B data. The group included 92 men (65.2%) and 49 women (34.8%), had a mean age

1 of 49.62 years (*SD*=15.16, *range* 18-84) and reported a mean duration after burn of 45.01

2 months (*SD*=26.18, range 12-99).

3

4 (Please insert Figure 1 about here)

5

6 The majority of the sample reported having a partnership (50.4% married, 13.5%

7 living with a partner); 9.2% were divorced, 4.3% were widowed, and 1.4% were separated. In

8 terms of highest school graduation, 60.3% had a certificate of secondary education and 32.6%

9 an advanced college qualification or university entrance diploma. Inability to work was

10 present in 23.6% of the sample.

11 Information about ABSI and TBSA burned was available from 127 patients. They had

12 sustained burns with an on average TBSA of 12.9% (*SD*=10.31, *range* 1-40). Based on the

13 ABSI [22], 11.8% exhibited low, 45.7% moderate, 30.7% moderately severe, and 11.8%

14 serious severity of burn injury.

15

16 *Factor structure*

17 The first confirmatory factor analysis with 3 factors did not fit the data well (χ^2

18 =77.47, *df*=24, CFI= .83, SRMR= .09). After removing the Work scale, an acceptable fit was

19 obtained (χ^2=34.51, *df*=17, CFI= .93, SRMR= .07), although the loading of Treatment

20 Regimens on the Skin Involvement factor was rather low. The factor loadings for the final

21 second-order factor solution without the Work scale are shown in Table 1. The Affect and

22 Relationship factor correlated with the Function factor (*r*= .59) and with the Skin Involvement

23 factor (*r*= .72). The correlation between the Function and the Skin Involvement factors

24 equaled *r*= .55.

25 (Please insert Table 1 about here)

26

1   For some scales up to 80% of the participants obtained the maximum score. As can be seen in

2   Table 2, for all scales internal consistency turned out satisfactory [28] with Cronbach's α

3   ranging from .75 to .93. Spearman rank correlations between the scales are shown in Table 3.

4

5   (Please insert Tables 2 and 3 about here)

6

7   *Validity*

8   Table 4 displays the associations between the BSHS-B domains and TBSA burned, levels of

9   generic HRQoL (SF-8) and anxiety and depression (HADS). All three BSHS-B domains were

10   positively related to the SF-8 and negatively correlated with the HADS. Moreover, we found

11   a significant inverse relationship between the Affect and Relationship factor, the Skin

12   Involvement factor and TBSA burned. We performed a post-hoc power analysis with the

13   significance level set at $p= .01$. The results indicated that the power for all correlations which

14   significantly differed from zero equaled at least .97.

15

16   (Please insert Table 4 about here)

17

18   To compare patients with low and high burn severity, the sample was divided into two

19   subgroups based on ABSI scores. The first group consisted of 73 patients with low or

20   moderate mortality risk (ABSI $\leq$ 5) and the second group included 54 patients with at least

21   moderately severe mortality risk (ABSI $\geq$ 6). The groups did not differ with regard to duration

22   since injury, gender or marital status but those with low ABSI scores were on average

23   younger than participants in the high ABSI group (M_{low}=44.92, SD_{low}=13.46 vs. M_{high}=55.31,

24   SD_{high}=13.64, t=4.28, $p< .001$).

25   As can be seen in Table 5, the low ABSI group exhibited a higher burn specific health

26   status as measured with the three second-order BSHS-B factors compared with the high ABSI

1   group. In addition, patients with low ABSI scores reported more generic HRQoL and less

2   anxiety than those with high ABSI scores (see Table 5). The results of a post-hoc power

3   analysis showed that the power for most analyses approached at least .70 or .80. Only for the

4   SF-8 Mental Component score (β= .441) and the HADS-Depression (β= .583) comparisons

5   the power was not sufficient.

6   The ABSI groups were also compared with respect to all nine BSHS-B subscales. As

7   shown in Figure 2, the group with low burn severity scored significantly higher on all BSHS-

8   B subscales (thus showing higher burn-specific health status) with the exception of the

9   Interpersonal Relationship subscale.

10

11   (Please insert Table 5 about here)

12   (Please insert Figure 2 about here)

13

14   *Influence of age, gender, marital status and duration after injury*

15   Women exhibited lower scores on the Skin Involvement factor than men (M_{female}=41.57,

16   SD_{female}=14.45 vs. M_{male}=46.23, SD_{male}=11.87, U=1790.00, p= .044) but not on the other

17   domains. The subsequent comparison of the three subscales that constitute the Skin

18   Involvement factor (Heat Sensitivity, Treatment Regimens, Body Image) showed that the

19   gender effect can be explained by lower scores on the Body Image subscale (M_{female}=11.61,

20   SD_{female}=4.54 vs. M_{male}=13.35, SD_{male}=3.43, U=1792.00, p= .041). The difference on the other

21   two subscales did not reach statistical significance.

22   Lower age was significantly but weakly related to higher scores on the BSHS-B

23   Function factor (r_s=-0.231, p<0.01). The comparison of patients living with a partner (N=90)

24   with those who were single, widowed, divorced or separated (N=51) yielded significant

25   differences on the BSHS-B Affect and Relationship Factor (M_{with}=52.61, SD_{with}=8.45 vs.

26   M_{no}=47.49, SD_{no}=11.84, U=1465.50, p< .001) and the Function Factor (M_{with}=30.82,

1   SD_{with}=3.51 vs. M_{no}=29.74, SD_{no}=4.75, U=1913.00, p= .031). No significant correlation was

2   found between duration after injury and BSHS-B domains.

3

4   **Discussion**

5   The main results of the present study were that the nine BSHS-B subscales showed good

6   internal consistency and that the original 3-component structure obtained in the second-order

7   factor analysis based on eight subscales [8] was replicated in a German sample of patients

8   after burn injury. The finding is in line with our first aim and in accordance with earlier

9   studies [8,10,16]. The similarity of the second-order structure in comparison to the original

10   BSHS-B provides the opportunity to compare cross-cultural results.

11   In terms of construct validity, previous studies already reported high correlations

12   between the BSHS-B and measures of generic HRQoL [11,12,14]. In line with prior findings

13   and consistent with our second aim, the three main BSHS-B domains were positively

14   correlated with the SF-8 as a generic HRQoL measure (see Table 4). The strongest link was

15   found between the BSHS-B domain Affect and Relationship and the Mental Component

16   Score of the SF-8 highlighting that this component refers to mental aspects of HRQoL.

17   As expected, higher rates of burned body surface were associated with lower BSHS-B

18   levels, particularly with respect to the Affect and Relationship factor and the Skin

19   Involvement factor but not the Function factor (see Table 4). This finding suggests that

20   perceived difficulties with hand function (e.g., unlocking a door, eating with utensils, tying

21   shoelaces) or with simple abilities (e.g., bathing independently, dressing, getting in and out of

22   a chair) are related to a lesser extent to TBSA burned.

23   Furthermore, we found negative correlations between the BSHS-B and symptoms of

24   anxiety and depression. This finding supports the criterion validity of the BSHS-B given that

25   HRQoL after burn injury is known to be inversely related to anxiety and depression [2]. Not

26   surprisingly, the highest correlation was found with the Affect and Relationship factor.

With respect to our fourth aim, the findings demonstrate the discriminative value of the BSHS-B (see Table 5). Patients with low burn severity scored significantly higher on all three main BSHS-B components indicating a higher burn-specific HRQoL in this group compared to patients with high burn severity. Accordingly, patients with low burn severity reported higher levels on the BSHS-B subscales with the exception of the Interpersonal relationships subscale. The two ABSI groups did not differ with regard to marital status that may have contributed to the lacking difference on the Interpersonal Relationship subscale. However, this assumption needs further clarification and must be taken as tentative. As expected, the BSHS-B domains differentiated better between patients with low and high ABSI than the non-burn-specific SF-8 Mental Component score and the HADS. This pattern of results illustrates the burn specificity of the questionnaire.

Our findings indicated a link between some of the demographic variables and burn-specific HRQoL. It appears that women perceived more difficulties with regard to body image after burn injury than men. Those patients who were married or living with a partner exhibited higher burn-specific HRQoL with respect to the Affect and Relationship factor and the Function factor. However, causality between marital status and HRQoL cannot be established due to the cross-sectional design. Unfortunately, information about possible changes in marital status since injury was not available. Younger age was only weakly related to the Function factor and duration after injury did not show an effect on burn-specific HRQoL.

The strengths of the present study include the use of a confirmatory factor analysis to test the factor structure and the comparison of patients with low and high burn severity based on the ABSI that can be seen as an external validity criterion. Nevertheless, there are some limitations that should be addressed. The most important shortcoming refers to the relatively small sample size. Even though we made an effort to include patients who moved away via registration offices the number of participants in the study was relatively low. However, the results of a post-hoc power analysis showed that for most analyses the power was sufficient.

Another concern pertains to the HADS. Although this instrument is widely used to measure symptoms of anxiety and depression in patients with medical conditions it is not validated in patients after burn injuries. It is also notably that most patients scored high on the BSHS-B (i.e., ceiling effect) leading to a rather small variation in the data and that the survey did not include patients prior to one year post-burn restricting the generalizability of the findings. Further studies should investigate the application of the German BSHS-B in clinical routine practice, evaluation of burn management programs, and burn-specific research.

Conclusions

The results suggest that the German version of the BSHS-B has good psychometric properties.

Conflict of interest statement

The authors declare no conflict of interest.

Acknowledgements

We kindly thank the patients who made this study possible and also Dr. Mimmie Willebrand from the Uppsala University, Sweden, for her support during the course of this project.
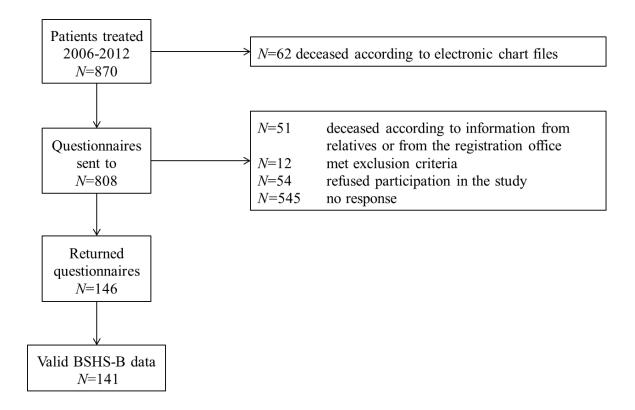
1   REFERENCES

2   [1]   Jasper S, Rennekampff HO, de Zwaan M. Psychiatric co-morbidity, body image

3   problems and psychotherapeutic interventions for burn survivors: a review. Psychother

4   Psychosom Med Psychol 2013;63(11):423-8.

5   [2]   Falder S, Browne A, Edgar D, Staples E, Fong J, Rea S, et al. Core outcomes for adult

6   burn survivors: a clinical overview. Burns 2009;35(59: 618-41.

7   [3]   Yoder LH, Nayback AM, Gaylord K. The evolution and utility of the burn specific

8   health scale: a systematic review. Burns 2010;36(8):1143-56.

9   [4]   Blades B, Mellis B, Munster AM. A burn specific health scale. J Trauma

10   1982;22(10):872-5.

11   [5]   Munster AM, Horowitz GL, Tudahl LA. The abbreviated burn specific health scale. J

12   Trauma 1987;27(4):425-8.

13   [6]   Blalock SJ, Bunker BJ, DeVellis RF. Measuring health status among survivors of burn

14   injury: revisions of the burn specific health scale. J Trauma 1994;36(4):508-5.

15   [7]   Kildal M, Andersson G, Fugl-Meyer AR, Lannerstam K, Gerdin B. Development of a

16   brief version of the burn specific health scale (BSHS-B). J Trauma 2001;51(4):740-6.

17   [8]   Willebrand M, Kildal M. A simplified domain structure of the Burn-Specific Health

18   Scale-Brief (BSHS-B): a tool to improve its value in routine clinical work. J Trauma

19   Injury Infect Clin Care 2008;64(6):1581-6.

20   [9]   Willebrand M, Kildal M. Burn specific health up to 24 months after the burn – a

21   prospective validation of the simplified model of the burn specific helath scale-brief. J

22   Trauma 2011;71(1):78-84.

23   [10]   Ling-Juan Z, Jie C, Xiao-Ying L, Ping F, Zhao-Fan X, Jian-Ling H, et al.

24   Development of quality of life scale in Chinese burn patients: cross-cultural adaptation

25   process of burn-specific health scale - brief. Burns 2012;38(8):1216-23.

1   [11]   Stavrou D, Haik J, Wiser I, Winkler E, Liran A, Holloway S, et al. Validation of the

2   Hebrew version of the burn specific health scale-brief questionnaire. Burns 2014; in

3   press.

4   [12]   Sideli l, Di Pasqale A, Prestifilippo A, Benigno A, Bartolotta A, Cirrincione CR, et al.

5   Validation of the Italian version of the burn specific health scale-brief. Burns 2014;

6   40(5):995-1000.

7   [13]   Pishnamazi Z, Rejeh N, Heravi-Karimooi M, Vaismoradi M. Validation of the Persian

8   version of the burn specific health scale-brief. Burns 2013;39(1):162-7.

9   [14]   Szczechowicz J, Lewandowski J, Sikorski J. Polish adaptation and validation of burn

10   specific health scale-brief. Burns 2014;40(5):1013-8.

11   [15]   Adam M, Leblebici B, Tarim MA, Yildirim S, Bagis S, Akman MN, et al. Validation

12   of a Turkish version of the burn-specific health scale. J Burn Care Res

13   2009;30(2):288-91.

14   [16]   Van Loey NE, Van de Dchoot R, Gerdin B, Faber AW, Sjöberg F, Willebrand M. The

15   burn specific health scale-brief: measurement invariant across European countries. J

16   Trauma Acute Care Surg 2013;74(5):1321-6.

17   [17]   Beierlein V, Morfeld M, Bergelt C, Bullinger M, Brähler E. Measuring health-related

18   quality of life with the SF-8: German norms from a representative self-administered

19   survey. Diagnostica 2012;58(3):145-53.

20   [18]   Ware JE, Kosinski M, Dewey JE, Gandek B. How to score and interpret single-item

21   health status measures: a manual for users of the SF-8TM health survey. Lincoln, RI:

22   Quality Metric Incorporated; 2001.

23   [19]   Ware J. SF-36 Health Survey: Manual and Interpretation Guide. New England

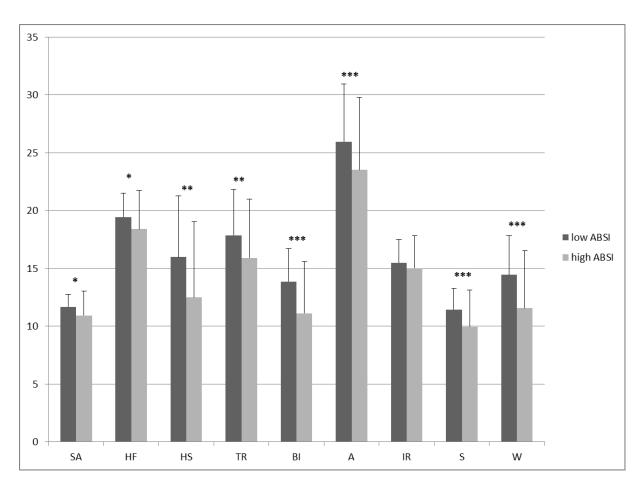24   Medical Center: The Health Institute; 1993.

1 [20] Herrmann C, Buss U, Snaith RP. Hospital Anxiety and Depression Scale – Deutsche

2   Version. Ein Fragebogen von Angst und Depressivität in der somatischen Medizin.

3   Bern, Schweiz: Hans Huber; 1995.

4 [21] Zigmond AS, Snaith RP. The hospital anxiety and depression scale. Acta Psychiatr

5   Scand 1983;67(6):361-70.

6 [22] Tobiasen J, Hiebert JM, Edlich RF. The abbreviated burn severity index. Ann Emerg

7   Med 1982;11:260-2.

8 [23] Forster NA, Zingg M, Haile SR, Künzi W, Giovanoli P, Guggenheim M. 30 years later

9   -- does the ABSI need revision? Burns 2011;37(6):958-63.

10 [24] Hu L, Bentler PM. Cutoff criteria for fit indexes in covariance structure analysis:

11   Conventional criteria versus new alternatives. Struct Equ Modeling 1999;6:1-55.

12 [25] Hattie J, Cooksey RW. Procedures for assessing the validities of tests using the

13   "known groups" method. Appl Psych Meas 1983;8(3):295-305.

14 [26] Palmu R, Suominen K, Vuola J, Isometsä E. Mental disorders among acute burn

15   patients. Burns 2010;36(7):1072-9.

16 [27] Davydow DS, Katon WJ, Zatzick DF. Psychiatric morbidity and functional

17   impairments in survivors of burns, traumatic injuries, and ICU stays for other critical

18   illnesses: a review of the literature. Int Rev Psychiatr 2009;21: 531-538.

19 [28] Cortina JM. What is coefficient alpha? An examination of theory and applications. J

20   Appl Psychol 1993;78: 98-104.

21

22

23

24

25

1   Figure 1: Patient flow

2   Figure 2: Comparison between patients with low and high abbreviated burn severity index

3   (ABSI) on the BSHS-B subscales

Figure

Figure 1

Patient flow

Figure 2

Comparison between patients with low and high abbreviated burn severity index (ABSI) on the BSHS-B subscales

Note. Low burn severity: ABSI $\leq$ 5, high burn severity: ABSI > 6; *p< .05, **p< .005, ***p< .001

       SA – Simple Abilities
       HF – Hand Function
       HS – Heat Sensitivity
       TR – Treatment Regimens
       BI – Body Image
       A – Affect
       IR – Interpersonal Relationships
       S – Sexuality
       W - Work

Table 1

Factor loadings of the BSHS-B subscales on the three BSHS-B domains

	Affect and Relationship factor	Function factor	Skin involvement factor
Affect	.89		
Interpersonal Relationships	.78		
Sexuality	.84		
Simple abilities		.91	
Hand function		.87	
Heat sensitivity			.77
Treatment Regimens			.25
Body Image			.95

Note. BSHS-B subscale Work is not included in the final model

Table 2

Internal consistency of the BSHS-B subscales

BSHS-B Subscales	Cronbach's α
Affect	.93
Interpersonal Relationships	.84
Sexuality	.84
Simple abilities	.75
Hand function	.89
Work	.92
Heat sensitivity	.93
Treatment Regimens	.92
Body Image	.86

Table 3

Spearman rank correlations between BSHS-B subscales

	IR	S	SA	HF	W	HS	TR	BI
Affect (A)	.56**	.65**	.35**	.35**	.57**	.50**	.53**	.60**
Interpersonal Relationships (IR)		.58**	.45**	.39**	.35**	.30**	.45**	.47**
Sexuality (S)			.50**	.44**	.49**	.34**	.44**	.47**
Simple abilities (SA)				.71**	.41**	.21**	.34**	.38**
Hand function (HF)					.53**	.29**	.39**	.39**
Work (W)						.61**	.63**	.61**
Heat sensitivity (HS)							.67**	.64**
Treatment Regimens (TR)								.69**
Body Image (BI)								-

Note: p < .01

Table 4

Relationships between the BSHS-B domains and percent of burned body surface area, levels of health-related quality of life and concurrent psychological symptoms

	Affect and Relationship factor	Function factor	Skin involvement factor
Percent of burned body surface area[a]	-.354**	-.115	-.340**
SF-8			
Physical Component Score	.454**	.419**	.422**
Mental Component Score	.671**	.393**	.537**
HADS			
Anxiety	-.709**	-.342**	-.565**
Depression	-.610**	-.414**	-.470**

Note. SF-8 = Short-Form 8 Health Survey, HADS = Hospital Anxiety and Depression Scale. **$p < 0.01$. [a] data available from $n=127$.

Table 5

Comparison between patients with low and high burn severity on BSHS-B domains,

levels of health-related quality of life and concurrent psychological symptoms

	Low burn severity ABSI $\leq$ 5	High burn severity ABSI > 6	Group comparison[a]	
	n=73	*n*=54		
BSHS-B domains	*M (SD)*	*M (SD)*		*p*
Affect and Relationship Factor	52.89 (8.27)	48.50 (10.71)	*U*=1208.00	< .001
Function Factor	31.12 (2.94)	29.35 (5.22)	*U*=1544.00	.006
Skin Involvement Factor	47.71 (10.61)	39.51 (14.75)	*U*=1263.50	.001
SF-8				
Physical Component Score	53.47 (7.73)	47.43 (9.56)	*U*=1172.50	< .001
Mental Component Score	52.95 (10.80)	49.78 (12.09)	*U*=1539.50	.035
HADS				
Anxiety	3.70 (3.83)	5.83 (5.52)	*U*=1570.00	.049
Depression	4.60 (2.98)	5.80 (3.96)	*U*=1729.50	.208

Note. ABSI = abbreviated burn severity index. SF-8 = Short-Form 8 Health Survey, HADS = Hospital Anxiety and Depression Scale. [a] Mann-Whitney's-U test was used because of non-normal distribution.