Creation of a Tool to Evaluate Supportive Care: Experiences from Socioesthetics

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Research Article

Keywords: Supportive care, socioesthetics, PRO

Posted Date: December 8th, 2021

DOI: https://doi.org/10.21203/rs.3.rs-1034649/v1

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Abstract

The absence of a specific tool to evaluate the impact of Supportive care in general and socioesthetics in particular as a rendered medical service is undoubtedly at the origin of the lack of published research based on scientific standards.

In this context, we developed one supportive-care patient-reported outcome [PRO] using the multistep methods following COSMIN recommendations.

Its construction followed all recommended steps: elaboration of the questionnaire, measurement properties of the questionnaire, internal and external validation, test-retest validation and translation, cross-cultural adaptation and cognitive debriefing.

In total, our questionnaire includes 11 items. It is scored by adding each VAS, making it range from 0 to 110, with a higher benefit when the score is higher. The Cronbach's $\alpha$ coefficient is 0.88 for the entire questionnaire.

The questionnaire thus constructed is a reflection of the patient's feelings, and it is quite natural that the name The “patient centricity questionnaire” (PCQ) was retained and validated by the Scientific Committee.

The PCQ correlated negatively and moderately with the PSS, positively and moderately with the mental dimension of the and poorly with the WB12, the physical dimension of the SF-12 and the satisfaction EVA.

Constructed according to the recommendations, the PCQ meets the prerequisite for this type of questionnaire. Its short format (11 questions) and simplicity of use allow it to be used by a large number of people and provides an pragmatic answer by making available to research teams a simple, reliable, easy-to-use and validated tool. It makes possible randomized studies to prove the impact on quality of life of the Supportive care in general and socioesthetics" in particular.

Rationale

Supportive care is defined as "all the care and support required by patients throughout their illness in conjunction with oncological or oncohematological treatments" and aims to ensure the best possible quality of life for patients on a physical, psychological and social level, taking into account the diversity of their needs and those of their family and friends, regardless of their place of care. [1]

A recent international study [Prevalence of radiotherapy, chemotherapy, and access to supportive care in cancer in France, Brazil, Russia, the United States and China, G Buiret] involving more than 11,000 individuals in five countries (France, China, Russia, the United States and Brazil) assessed the use of supportive cancer care (SCC). 63% of French respondents, 73% of American respondents, 84% of
Brazilian respondents, 64% of Russian respondents and 86% of Chinese respondents who had received chemotherapy or radiotherapy acknowledged that they had used supportive care [2].

Various SCC treatments, such as corrective makeup, massages, facial care, body care, and clothing advice, which are also called "socioesthetics" (SE), beauty treatments, "beauty care" or "beauty therapy" in some countries, were reported by numerous patients (Russia: 24%, China or Brazil: 60%, USA: 47% and France: 37%). It can be defined as "a professional practice of aesthetic care for populations suffering and weakened by an attack on their physical or psychological integrity or in social distress". Several surveys and qualitative studies have shown a positive clinical impact in patients receiving such beauty care, in terms of improved self-image and self-esteem, reduced anxiety, and improved sex life and treatment tolerance.

Thus, SE (also called "onco-aesthetics" in oncology) has largely found its place in supportive care, as it helps to address throughout the treatment process the undesirable effects of treatments on the skin and skin appendages, situations of stress and anxiety, and disturbances in body image. Recently, even antalgic effects for male and female cancer patients were proven for the first time [4].

Although patients and medical and nursing teams who refer their patients agree on the benefits of this practice, scientific proof of the improvements has not yet been demonstrated.

For instance, its benefits on the quality of life of cancer survivors have not been assessed thus far. Randomized controlled trials dedicated to beauty care (BC) patients' body image are needed to develop practice guidelines as well as define necessary resources and standardized procedures, adequate timing, and duration of supportive measures to bring meaningful early improvements to patients’ quality of life and sustain long-term impact. [3]

The absence of a specific tool to evaluate the impact of SE as a rendered medical service is undoubtedly at the origin of the lack of studies based on scientific standards.

**Methodology**

We developed this supportive-care patient-reported outcome using multistep methods following COSMIN recommendations. [5]

This project obtained a favorable opinion on September 11, 2019 from the Ethics Committee of the CHU La Pitié Salpêtrière, Paris [CCP Ile de France 6- 2019-A00204-53] and was conducted according to the Declaration of Helsinki. According to French regulations for this type of research [Reference Methodology 003], no written informed consent had to be obtained from participating patients, and an information and nonobjection note was given to them.

A standard methodology for the creation of a patient-reported outcome (PRO) was used, and a multidisciplinary working group of experts (professionals, such as physicians, public health experts, sociologists, supportive care experts, and socioestheticians) was created.
The questionnaire followed the recommendations proposed by Seidenberg et al. and Leidy et al. for the development of a self-report questionnaire. [6]

The same group of experts reached a consensus on how to respond. The choice was made to use a numerical visual scale ranging from 0 for "No, not at all" to 10 for "Yes, always".

To avoid missing data as much as possible, respondents had the option of not expressing themselves if they were not concerned by placing the cursor on zero.

To avoid any confusion regarding timing, all questions began with "currently".

The diversity of the recruiting centers ensured broad recruitment and a consistent diversity of patients in terms of pathologies, geographical location, age and sociological status. The participating subjects, aged at least 18 years, had to have received supportive care, SE in this case.

The construction of this questionnaire followed several steps: elaboration of the questionnaire, measurement properties of the questionnaire, internal and external validation, test-retest validation and translation, cross-cultural adaptation and cognitive debriefing.

**Step 1: Elaboration of the questionnaire**

We conducted a literature search on PubMed to identify published questionnaires or scoring systems related to SE. We used the algorithm developed by the COSMIN initiative and combined it with the terms “socioesthetic" and the medical subject subheading “aesthetics” as a major topic.

We then conducted a series of 23 individual interviews to elicit expectations and needs of patients in terms of management of physical appearance, self-esteem and relaxation as well as the role of SA in patient support. Using a triangulation approach, we interviewed 10 patients (who were using or used SA) [7] as well as 6 SE practitioners, five medical professionals advising SE and 2 members of the SE association. The verbatim data were analyzed using an itinerary method. [8,9,10,11] Such methods aim at contextualizing and understanding the entire process related to an intervention (when was it proposed, why, what it did, why was it stopped). The result of this analysis was then translated to a series of patients, trying to stay as close as possible to the patients’ words verbatim.

Finally, a multidisciplinary working group involving researchers, methodologists, clinicians (medical, paramedical, sociologist, supportive care expert and SE practitioner) and patients designed a preliminary questionnaire from the qualitative analysis. Each item of the questionnaire was evaluated with a numerical visual scale ranging from 0 for "No, not at all" to 10 for "Yes, always". To avoid missing data as much as possible, the respondents had the option of not expressing themselves if they were not concerned by placing the cursor on zero.

**Step 2: Measurement properties of the questionnaire**

The measurement properties of the questionnaire were assessed in six steps:
a. reduction of the number of items,
b. subscale repartition of items and assessment of factorial validity,
c. assessment of construct validity,
d. assessment of reliability,
e. evaluation of the minimal clinically important difference (MCID) and
f. transcultural validation in US English.

Reduction of the number of items. We reduced the number of items based on redundancy, which was suspected when the interitem correlation evaluated by the Spearman correlation coefficient was above 0.8 [12]. We wanted our questionnaire to be useful in all contexts of SE interventions. These items can differ greatly, as do benefits for patients. Therefore, we decided to exclude only items presenting a major ceiling or floor effect and did not exclude items because of low interitem correlation.

Subscale repartition of items and assessment of factorial validity. Suitability for factorial analysis was assessed by a Kaiser-Meyer-Olkin (KMO) value above 0.8 for all items [13]. A scree plot with parallel analysis was performed to determine the number of subscales. To allocate each item to a subscale, exploratory factor analysis (EFA) with a cluster rotation was performed. Items presenting a factor loading lower than 0.5 or a cross factor loading higher than 0.2 were excluded from the questionnaire [14]. We assessed internal consistency with Cronbach's alpha [15] and McDonald's omega coefficients, aiming to have both >0.7 for the entire questionnaire and each subscale. [16] Readability of the final questionnaire was assessed with a SMOG index corrected for French. [17,18]

Factorial validity was assessed using a higher-order factor confirmatory analysis. This analysis confirmed that the subscales could be combined into a single score. The model's suitability was assessed using three criteria: comparative fit index (CFI) above 0.9, Tucker-Lewis index (TLI) above 0.9 and root mean square error of approximation (RMSEA) under 0.08.

Construct validity. We hypothesized several relationships between the SE score and other constructs. Specifically, there was a moderate negative correlation with the stress evaluated through the Perceived Stress Scale (PSS),[19] a moderate positive correlation with the mental dimension of the SF12 [20] (r = 0.5-0.7) and a low correlation (r=0-0.3) with the physical dimension of the SF12, the satisfaction Visual Analog Scale [VAS] for SE intervention and well-being evaluated by the well-being questionnaire (WBQ12). [21]

Reliability. Fifty participants who did not previously answer the questionnaire were asked to complete it once and then again three weeks later. Reliability was measured by the intraclass correlation coefficient (ICC) for agreement and presented on a Bland and Altman plot. [22,23]

Evaluation of the minimal clinically important difference (MCID [24]). The MCID represents the smallest modification detectable in a clinical setting. It was determined using the standard deviation method and
the standard of mean method. Using two methods made our results more robust.

An American English version of the questionnaire was developed by translation and transcultural validation according to the ISPOR task force recommendation. [25]

All data were analyzed using R software version 3.613 for Windows. The significance level was set at p < 0.05.

Results

The literature review did not involve the retrieval of specifically developed and validated tools to evaluate SE intervention benefits.

The elaboration of the questionnaire led to the identification of 62 themes that were transformed into questions by the expert group.

From October 2019 to February 2020, 271 patients were involved in the assessment of the measurement properties of the questionnaire. Their mean age was 56 years (± 14.1); 233 were women (86%). Table 1

Reduction of the number of items. First, 90% or more of respondents answered that they were either not concerned or on one of the extremes of the VAS (0 or 10). This led to the elimination of 23 items. Among the 39 questions, 20 were formulated in a positive way, and 19 were formulated in a negative way. For simplicity of scoring purposes, the scientific committee decided to eliminate negative questions. All questions included in the subsequent analysis are presented in Table 2.

The interitem correlation matrix is presented in Figure 1. High interitem correlation was presented by Q3 (Currently, I feel like I'm in good spirits) and Q4 (Currently, I have the feeling that things are going well psychologically (or mentally)), which presented a correlation of 87.7% CI95% [84.6, 90.11]. Additionally, high interitem correlation was found for Q5 (Currently, I feel at peace with myself.) and Q6 (Currently, I feel at peace with myself), which presented a correlation of 82.2% CI95% [77.9%, 85.7%]. Therefore, Q3 and Q4 were eliminated because they were judged as less direct and more difficult to understand.

Subscale repartition of items and assessment of factorial validity. All KMO scores were above 0.85, which confirmed the compatibility of the items for factorial analysis. The scree plot determined three pertinent dimensions (Figure 2).

The EFA determined the repartition of items in the three subscales. These were related to “Serenity” (3 items), “Resilience” (4 items) and “Autonomy” (4 items). Seven items were eliminated due to a low factor loading (Q1, Q7, Q8, Q13, Q14, Q18, Q20), of which four also had high cross factor loading (Q1, Q13, Q14, Q18) (Table 1). Our shortened questionnaire, therefore, included 11 items. It is scored by adding each VAS, making it range from 0 to 110, with a higher benefit when the score is higher. In our population, the score ranged from 12.50 to 110.00, with a mean of 66.7 (22.3 sd).
The Cronbach’s α coefficient [10] was 0.88 CI95% [0.86, 0.9] for the entire questionnaire, 0.9 CI95% [0.88, 0.92] for the serenity subscale, 0.9 CI95% [0.88, 0.92] for the resilience subscale and 0.9 CI95% [0.88, 0.92] for the autonomy subscale. McDonald’s Omega coefficient was 0.87 CI95% [0.82, 0.9] for the entire questionnaire, 0.9 CI95% [0.88, 0.92] for the serenity subscale, 0.9 CI95% [0.88, 0.92] for the resilience subscale and 0.73 CI95% [0.66, 0.79] for the autonomy subscale. This confirmed the high coherence of our score.

The readability of the questionnaire was considered excellent (SMOG = 4.73).

The CFA diagram is presented in Figure 3. The TLI was 0.908 and CFI was 0.931, but the RMSEA was slightly above 0.08 (0.099). The poorer fit indicated by the RMSEA might have been due to the low number of items, as the RMSEA tends to be poorer in this situation. [26]

Construct validity. The 11-item questionnaire correlated negatively and moderately with the PSS -0.561 CI95% [-0.637, -0.473], positively and moderately with the mental dimension of the SF-12 CI95% 0.551 [0.459, 0.631] and poorly with the WB12 0.249 CI95% [0.133, 0.358], the physical dimension of the SF-12 0.372 CI95% [0.261, 0.473] and the satisfaction EVA 0.163 CI95% [0.044, 0.277].

The MCID according to the standard deviation method was 11.1 and according to the SEM method.

Reliability. Thirty-nine individuals participated in the test-retest analysis, of whom 23 did not present any event between the two testings. The ICC was 0.985 IC95% [0.453, 0.997], indicating good reliability. The Bland and Altman diagram (Figure 4) showed that the difference between the two answers did not depend on the mean.

The final cross-culturally adapted questionnaire is presented in Table 2.

Name of the tool

The questionnaire thus constructed is a reflection of the patient's feelings, and it is quite natural that the name The “patient centricity questionnaire” (PCQ) was retained and validated by the Scientific Committee.

Discussion

We developed an instrument with good internal and external validity to measure the impact of SE on quality of life.

Interest in instruments for measuring patient feelings through so-called quality of life questionnaires in clinical trials has developed rapidly in the context of the consideration of PROs [4, 24, 27,28].

At the end of the 2000s, both the US (Food and Drug Administration, 2009) and European (EMA, 2006) drug regulatory agencies published recommendations for the development of PRO measures in trials.
We know that nonspecific questionnaires (SF12 [21] or EQ5D [29] among the most used) exist, but if they are of major interest to allow comparison between two exposed populations, they are often not sensitive enough to assess particular domains.

Many specific questionnaires have been created to have tools that are more sensitive to change.

This is the case in cancerology, where specific questionnaires for oncology have been created in the first place. In a second phase, specific questionnaires for certain cancers were created to better understand the impact of a treatment on patients.

This is also the case in dermatology, where generic questionnaires, such as the DLQI [30] or SkinIndex [31], are widely used to compare skin diseases between them, but specific tools recently published in frequent dermatoses, such as acne or psoriasis, [32,33] or less frequent ones, such as vitiligo, ichthyosis or hemangioma [34,35,36]

Mahasti Saghatchian pointed out [3] that no study had formally demonstrated the improvement in quality of life by SA, recognizing that studies on this approach are difficult to implement according to scientific standards, as there are no specific tools to measure the impact of SA.

It was, therefore, important to create a specific tool to objectively and reproducibly evaluate supportive care in general and ADT in particular.

The patient centricity questionnaire (PCQ) is a short questionnaire that has been constructed according to the recommendations and meets the prerequisite for this type of questionnaire.

Its short format (11 questions) and simplicity of use allow it to be used by a large number of people.

This questionnaire provides an answer by making available to research teams a simple, reliable, easy-to-use and validated tool. It makes possible “randomized studies (…) to prove the impact of SE on quality of life.”[4]

Due to the lack of references in the literature, SE had been recently classified in wellness care, not in supportive care, by the French National Cancer Institute (INCa). This new tool should help reconsider this classification.

This questionnaire has been validated in the context of SE, but its construction allows us to speculate that it could be a tool for evaluating various support care services offered to patients as part of their treatment.

The PCQ is currently available for free in French, US English, Brazilian Portuguese and Italian.

Terms of use are available from the Fondation L'Oréal [sylviane.balustre@loreal.com] or from the corresponding author.
Declarations

Funding:

This project was funded through financial support from the L'Oreal Foundation, which did not otherwise intervene in the project. The promoter of the project was the company EMMA.

Conflicts of Interest/Competing Interests:

There are no conflicts of interest to declare.

Availability of data and materials:

All data are available upon request.

Code Availability:

Not applicable.

Author Contributions:

Charles Taieb wrote the protocol and its appendices, performed the statistical analysis, and wrote the publication.

Damien Giacchero, Guillaume Buiret, Cecile Grosjean, Mahasti Saghatchian, Ivan Krakowski validated the protocol, recruited the patients, and co-authored the publication.

Ethical approval:

This project obtained a favorable opinion on September 11, 2019 from the Ethics Committee of the CHU La Pitié Salpêtrière, Paris [CCP Ile de France 6- 2019-A00204-53] and was conducted according to the Declaration of Helsinki. According to French regulations for this type of research [Reference Methodology 003],

Consent to participate:

An information note respecting the French legislation was proposed. This note has been validated by the ethics committee.

Consent to publication:

Not applicable.

References

2. Buiret G, Delvigne V, Le Dantec G, Guyonnet-Debersac P, Taieb Prevalence of radiotherapy, chemotherapy and access to supportive care in cancer in France, Brazil, Russia, The USA & China; EADV, Vienne 2021


18. Cronbach LJ. Coefficient alpha and the internal structure of tests. Psychometrika. 1


28. A PRO is a measurement of an aspect of a patient’s health status that comes directly from the patient (i.e., without the interpretation of the patient’s responses by a physician or anyone else).


Tables

Table 1 Population description
<table>
<thead>
<tr>
<th>Gender</th>
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</thead>
<tbody>
<tr>
<td>Men</td>
<td>38</td>
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<td>Women</td>
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<table>
<thead>
<tr>
<th>Age mean ±SD</th>
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<td>56.01 ±14.1</td>
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<table>
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<tr>
<th>Concerning the treatment pathway</th>
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<tbody>
<tr>
<td>In treatment</td>
<td>177</td>
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</tr>
<tr>
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<td>Do not know</td>
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<tbody>
<tr>
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<td>7.75%</td>
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<tr>
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<td>21</td>
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<tr>
<td>Retired</td>
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<td>36.16%</td>
</tr>
<tr>
<td>On leave from work</td>
<td>119</td>
<td>43.91%</td>
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Table 2: Table presenting the questionnaire and exploratory factor analysis
Questions in red were eliminated because of redundancy for questions 5 and 6 and because of factor loading for other questions. Factor loadings for each dimension are colored according to the factor where the item has been attributed. The questionnaire is presented in its final transcultural validated form for questions kept in its final form, and other questions were translated from French by the authors.

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<th>Autonomy</th>
<th>Serenity</th>
<th>Resilience</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1  Currently, I feel like I have time for myself.</td>
<td>0.15</td>
<td>0.34</td>
<td>0.11</td>
</tr>
<tr>
<td>Q2  Currently, I feel like I’m happy again.</td>
<td>0.15</td>
<td>0.8</td>
<td>-0.14</td>
</tr>
<tr>
<td>Q3  Currently, I feel like I have a positive outlook.</td>
<td>0.03</td>
<td>0.89</td>
<td>-0.07</td>
</tr>
<tr>
<td>Q4  Currently, I have the feeling that things are going well psychologically (or mentally).</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q5  Currently, I have the feeling that I have regained my calm.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q6  Currently, I feel at peace.</td>
<td>-0.02</td>
<td>0.76</td>
<td>0.11</td>
</tr>
<tr>
<td>Q7  Currently, I feel pleasure watching a movie.</td>
<td>0.11</td>
<td>0.37</td>
<td>0.11</td>
</tr>
<tr>
<td>Q8  Currently, I have the feeling that I have regained my dignity.</td>
<td>0.49</td>
<td>0.21</td>
<td>0.01</td>
</tr>
<tr>
<td>Q9  Currently, I am enjoying taking care of myself.</td>
<td>0.87</td>
<td>-0.09</td>
<td>0.01</td>
</tr>
<tr>
<td>Q10 Currently, I feel in tune with myself.</td>
<td>0.6</td>
<td>0.32</td>
<td>0</td>
</tr>
<tr>
<td>Q11 Currently, I know how to reflect my best self.</td>
<td>0.77</td>
<td>0.14</td>
<td>-0.08</td>
</tr>
<tr>
<td>Q12 Currently, I feel like I’m taking better care of myself.</td>
<td>0.96</td>
<td>-0.22</td>
<td>0.05</td>
</tr>
<tr>
<td>Q13 Currently, I feel that I can talk more easily about my problems.</td>
<td>0.16</td>
<td>0.12</td>
<td>0.32</td>
</tr>
<tr>
<td>Q14 Currently, I feel reassured.</td>
<td>0</td>
<td>0.3</td>
<td>0.48</td>
</tr>
<tr>
<td>Q15 Currently, I feel listened to.</td>
<td>-0.13</td>
<td>0.16</td>
<td>0.66</td>
</tr>
<tr>
<td>Q16 Currently, I feel like I am actively involved in the management of my care.</td>
<td>-0.1</td>
<td>0.06</td>
<td>0.67</td>
</tr>
<tr>
<td>Q17 Currently, I feel like I’ve learned to take better care of myself.</td>
<td>0.17</td>
<td>-0.19</td>
<td>0.64</td>
</tr>
<tr>
<td>Q18 Currently, I feel like I can do the things I want.</td>
<td>0.13</td>
<td>0.41</td>
<td>0.25</td>
</tr>
<tr>
<td>Q19 Currently, I feel like I am motivated to fight against my illness.</td>
<td>-0.08</td>
<td>0.02</td>
<td>0.59</td>
</tr>
<tr>
<td>Q20 Currently, I feel capable of taking on the efforts of daily life.</td>
<td>0.45</td>
<td>0.19</td>
<td>0.02</td>
</tr>
</tbody>
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**Figures**
Figure 1

Interitem correlation matrix
Figure 2

Screen plot The number of factors is determined by comparing resampled data and actual data, keeping dimensions where actual data are greater than resampled data.

Figure 3
CFA diagram: The diagram presents factor loading on each subscale, F1 presents autonomy, F2 presents serenity and F3 presents resilience.

**Supplementary Files**

This is a list of supplementary files associated with this preprint. Click to download.

- AdditionalDataUSversionFrenchversion.docx