Development and Validation of the QUALI-PALLI-FAM Questionnaire for Assessing Relatives’ Perception of Quality of Inpatient Palliative Care: A Prospective Cross-Sectional Survey

Frédéric Guirimand, Carole Bouleuc, Marine Sahut d’Izarn, Patricia Martel-Samb, Christian Guy-Coichard, Stéphane Picard, Bernard Devalois, Véronique Ghadi, Philippe Aegerter

To cite this version:

HAL Id: hal-03230897
https://hal.science/hal-03230897
Submitted on 9 May 2023

HAL is a multi-disciplinary open access archive for the deposit and dissemination of scientific research documents, whether they are published or not. The documents may come from teaching and research institutions in France or abroad, or from public or private research centers.

L’archive ouverte pluridisciplinaire HAL, est destinée au dépôt et à la diffusion de documents scientifiques de niveau recherche, publiés ou non, émanant des établissements d’enseignement et de recherche français ou étrangers, des laboratoires publics ou privés.

Distributed under a Creative Commons Attribution - NonCommercial 4.0 International License
Development and validation of the QUALI-PALLI-FAM questionnaire for assessing relatives’ perception of quality of inpatient palliative care: A prospective cross-sectional survey

Frédéric Guirimand MD PhD, Carole Boulec MD, Marine Sahut d’Izarn MD, Patricia Martel-Samb MD, Christian Guy-Coichard MD, Stéphane Picard MD, Bernard Devalois MD, Véronique Ghadi and Philippe Aegerter MD, PhD on behalf of the QUALI-PALLI group*

1 - Pôle Recherche SPES ‘Soins Palliatifs en Société’ and Université Paris-Saclay, UVSQ
2 - Institut Curie, Département interdisciplinaire des Soins de Support, Paris, France
3 - AP-HP, Hôpital Ambroise Paré, Equipe Mobile de Soins Palliatifs, Boulogne, France
4 - AP-HP, Unité de Recherche Clinique URC HU PIFO, Hôpital Ambroise Paré, Boulogne, France
5 - AH-HP, Hôpital Saint Antoine, Equipe Mobile de Soins Palliatifs, Paris, France
6 - Groupe Hospitalier Diaconesses Croix Saint-Simon, Unité de Soins Palliatifs, Paris, France
7 - Centre de Recherche et d’Enseignement interprofessionnel Bientraitance et fin de vie and AGORA (EA7892) université CY Cergy Paris Université, France
8 - Haute Autorité de Santé, Saint Denis, France
9 – GIRCI-IDF, Cellule Méthodologie, Paris, France et Université Paris-Saclay, UVSQ, Inserm, Équipe d’Épidémiologie respiratoire intégrative, CESP - Centre de recherche en Epidémiologie et Santé des Populations U1018 INSERM UPS UVSQ, 94807, Villejuif, France

*QUALI-PALLI group: Anne Abel, Laure Copel, Louise Geoffroy, Laurence Gineston, Hélène Godard, Xavier Grenet, Karima Nfissi, Jean-François Richard, Sylvie Rostaing, Yael Tibi-Lévy, Isabelle Vedel, Kate Vincent.

CORRESPONDING AUTHOR:
Frédéric Guirimand
Pôle Recherche SPES ‘Soins Palliatifs en Société’
Maison Médicale Jeanne Garnier
106 Avenue Emile Zola
75015 Paris, France
Tel: 33 1 43 92 21 00
Fax: 33 1 43 92 21 11
Email: frederic@guirimand.fr

Number of tables: 5

© 2020 published by Elsevier. This manuscript is made available under the CC BY NC user license https://creativecommons.org/licenses/by-nc/4.0/
Number of figures: 1
Number of references 63
Word count: 3455
Number of addition files: 5
Abstract

Context
Relatives of patients receiving palliative care are at risk for psychological and physical distress, and their perception of quality of care can influence patients’ quality of life.

Objectives
The purpose of this study was to develop and validate the QUALI-PALLI-FAM questionnaire to measure families’ perception of and satisfaction with palliative care.

Methods
An exploratory factor analysis was conducted, and we evaluated the questionnaire’s internal consistency using Cronbach’s alpha, its stability across various strata, and the correlation between the QUALI-PALLI-FAM (factors, total score, and global satisfaction) and the total score of the FAMCARE questionnaire.

Results
This multicentric prospective cross-sectional survey was conducted in seven French hospitals, namely, three palliative care units and four standard medical units with a mobile palliative care team. The questionnaire was completed by 170 relatives of patients (over 90% of patients had advanced cancer). The final questionnaire included 14 items across three domains: organisation of care and availability of caregivers, medical information provision, and confidence and involvement of relatives. Internal consistency was good for all subscales (Cronbach’s α: 0.74–0.86). Our questionnaire was stable across various strata: age and gender (patients and relatives), Palliative Performance Scale scores, and care settings. The QUALI-PALLI-FAM total score was correlated with the total FAMCARE score.

Conclusion
The QUALI-PALLI-FAM appears to be a valid, reliable, and well-accepted tool to explore relatives’ perception of quality of inpatient palliative care and complements the QUALI-PALLI-PAT questionnaire. Further testing is required in various settings and countries.

Key words: palliative care, quality of health care, outcome measure, questionnaire, validation study, family

Running title:
Relatives’ perception of quality of care

Key message
The QUALI-PALLI-FAM questionnaire appears to be a valid and reliable tool to assess relatives’ perception of and satisfaction with the quality of palliative care. It explores three domains: organisation of care and availability of caregivers, medical information provision, and confidence and involvement of relatives. It complements the patient questionnaire QUALI-PALLI-PAT.
Introduction

The quality of life of patients confronting the end stage of their life may be severely compromised without the support of relatives. However, being a relative of a palliative care patient is challenging, and many relatives experience a wide range of problems, such as physical and psychological exhaustion.[1–4] Another cause of suffering for relatives is dissatisfaction with the medical information they receive and their involvement in care.[5] Unsolved problems or unmet caregiver needs may not only decrease their own quality of life but also affect patients’ health outcomes negatively,[6–9] as there is an interdependence between patients’ quality of life and relatives’ burden.[10] Moreover, negative perceptions of the quality of end-of-life care are significantly associated with complicated grief.[11]

Family support is an essential task in palliative care, which is often described as patient/family-centred care.[12] Teams should systematically address the concerns and needs of relatives to offer them tailored support. Randomised studies have demonstrated that early palliative care can improve relatives’ quality of life and satisfaction with care.[13,14] Relatives’ perception of quality of care is thus a major outcome.[15,16] Furthermore, identifying the opinions of patients is more difficult in the terminal phase, which adds value to relatives’ viewpoints.[17]

In a recent review, the priorities in end-of-life care identified by patients and their families were expert care, effective communication and shared decision-making, respectful and compassionate care, adequate environment for care, family involvement, and support with financial affairs.[18,19] Systematic reviews have identified instruments for evaluating the quality of palliative care and different concepts have been addressed, such as end-of-life care experience, satisfaction with care, and caregivers’ well-being.[20,21] Two Canadian psychometric questionnaires assessing family caregivers’ satisfaction with care have been extensively used, namely the CANHELP and FAMCARE-2 questionnaires.[22–31]

Our research program, the “QUALI-PALLI project” aims to obtain a comprehensive assessment of palliative care including (i) the patient’s point of view, (ii) relatives’ perspectives, (iii) file review for care assessment, and (iv) professional caregivers’ well-being.[15,32] To ensure coherency, we developed our own instruments and refrained from using existing questionnaires, regardless of their quality. The aim of the present study was to develop and validate the QUALI-PALLI-FAM questionnaire to assess relatives’ perception of and satisfaction with quality of care in various palliative care settings.

Methods

Development of the QUALI-PALLI-FAM questionnaire

The Quali-Pall project[32] was approved by a regional ethics committee including patient representatives (CPP IDF-XI, #12059, 2012-09-24).

A multidisciplinary steering committee of palliative-related professionals (physicians, nurses, psychologists, social workers, and volunteers) developed a 45-item questionnaire based on our initial qualitative study and relevant literature.[15,33] Four domains were included: quality of information about health status and care of relatives (3 items), relation with physicians and caregivers (11 items), well-being of relatives (10 items), and functioning of the unit (21 items; Table 1). Items were rated on a 4-point Likert-type scale (‘no, not at all’; ‘not really’; ‘almost’; ‘yes, exactly’) or as ‘Does not apply to
me or my relative’ (i.e. not applicable). A 46th item assessed global satisfaction with palliative care on a 4-point scale.

To assess the face validity of the questionnaire, twelve relatives from three different settings, participated in a pilot study where they completed the initial version of the questionnaire and rated items in terms of wording, understanding, relevance, and any offensive issues.[34]

**Clinical study**

A cross-sectional study was conducted in the Paris region of France in seven sites pertaining to two categories: three hospital-based palliative care units (PCUs) and four standard medical units with a mobile palliative team. Relatives were eligible if they were fluent in French and had a related adult patient hospitalised for palliative care for more than 72 hours with a life expectancy of under 3 months.

At each site, one trained research assistant asked the health care team (without involving patients) to indicate the relatives who were present at the patients’ bedside, among family members, friends, and neighbours. The research assistant met the relatives during a visit to either the PCU or standard medical unit, provided them with information, and invited them to participate in the study, reassuring them about confidentiality concerns and independence from the palliative care team and hospital. After providing verbal consent, the relatives completed the written version of QUALI-PALLI-FAM questionnaire and the FAMCARE scale (French version, 20 items), which has been used in different advanced cancer care settings to assess relatives’ satisfaction with care.[35,36]. Relatives completed both measures independently without a researcher present at all. The questionnaire was hand-delivered to the research assistant or delivered via mail using pre-paid postage without interaction between the relatives and the local team. The Palliative Performance Scale (PPS v2) was completed using data from the patient’s file to determine the patient’s palliative performance status.[37,38] We planned to recruit around 30 relatives per site and 5 respondents per item, for 210–220 respondents in total.[39–41]

**Statistical analyses**

Item responses were re-scaled to range between 1 (‘no, not at all’) and 4 (‘yes, exactly’), with eventual inversion so that higher scores indicated higher care quality. Not applicable (NA) responses and missing data (MD) were considered to be a non-response (NR). Acceptability was estimated based on the proportion of MD per item and overall.

**Item analysis**

Items were tagged for removal if they showed any of the following: high rate of NR (≥ 25%), floor or ceiling effects (≥ 90% of extreme-category responses), or redundancy between items (polychoric correlation R > 0.70). The choice of removal was moderated by the steering committee as a function of the clinical relevance or interest shown in the literature or in our qualitative study.[15] Due to the ‘all-structures all settings’ principle of our project, an item considered interesting for one care setting may have been retained despite poor overall performance.

We analysed the response distribution according to the age and gender of relatives and patients, relationship with the patient, PPS score, and type of setting.
Factorial structure

Subsequently, considering the remaining items, participants with more than one-third of the items considered NR, or more than nine-tenths of them showing ceiling effects, were henceforth withdrawn.

Exploratory factor analysis (EFA) was then used to reveal the underlying structure of the items. To jointly deal with MD and robustness issues, we considered the following proposals. When using multiple imputations prior to the EFA, the eigenvector may mutate from one imputation to another, so averaging the eigenvectors becomes meaningless. Thus, we estimated one correlation matrix from all the matrices issued from imputed datasets, using Rubin’s rule, then applied the EFA on this unique synthesis matrix. Missing responses were imputed from a model considering seven covariates, namely age and gender of relatives and patients, relative relationship, site, and PPS score, by using the ‘mice’ procedure from the mifa R package. A total of 200 imputations (10 iterations each) were performed. Global satisfaction and FAMCARE scores were not imputed.

The suitability of the imputed data for EFA was assessed using Bartlett’s sphericity test, completed for each item with the Kaiser–Meyer–Olkin (KMO) test and squared multiple correlations (SMC). Responses being ordinal, a polychoric correlation matrix was calculated, and the extraction of factors used the ‘minimum residuals’ method, free from distributional assumptions. Anticipating some inter-factor correlations, an oblique rotation (promax) of the solution was performed. Parallel analysis and minimum average partial (MAP) correlation were used to identify the number of factors to extract.

The retention of items involved predetermined criteria: KMO (> 0.5) and SMC (> 0.3), loading (≥ 0.35), separation (minimal difference between the two top loadings ≥ 0.1), uniqueness (< 0.75), complexity (< 2.5), and Cronbach’s alpha gain for the related factor when the item is dropped (< 0.05). Concurrent solutions were compared with the Bayesian information criterion (BIC). Within each subscale, a mean subscore was generated by summing all item scores divided by the number of items.

Subsequently, reliability was assessed, first with Cronbach’s α, globally and for any identified factor (subscale), then also with beta coefficients and Guttman’s G6, as alpha coefficients may be biased for ordinal data. We used the psych R package.

Consistency was also evaluated by calculating (i) the average inter-item correlations within subscales, (ii) the correlation of items in one subscale with the other subscales, and (iii) item-total correlations. The independence of dimensions was ascertained from the inter-subscale correlation matrix.

The stability of the solution was checked (i) by performing EFA using either Spearman correlations, the principal components extraction method, or oblimin rotation, (ii) by averaging statistics calculated on data at each imputation cycle instead of calculating statistics on unique ‘synthesis’ data, and (iii) by comparing scores across different strata of relatives, patients, care settings, and also a random split. Finally, the same EFA procedure was conducted independently on participants in the strata formed by each characteristic, then structural replicability was estimated from the proportion of items that were attributed to the same factors across the strata; for concordant pairs, the paired absolute difference indicated whether the loadings were close in magnitude.
For all tests, bilateral statistical significance was set at .05, without any adjustment for multiplicity.

**Content validity**

The steering committee interpreted the results of the EFA, focusing on the clinical sense of the subscales.

**Reproducibility**

Test-retest procedures should show the stability of the scores over time when no change has occurred. The delay between two tests must be long enough to prevent recall bias, but short enough to ensure absence of changes in care or patient status, which are infrequent at the end of life.[20]

**Criterion-related validity**

The relationships of QUALI-PALLI-FAM factors and global satisfaction with FAMCARE scores were assessed using Spearman correlations.

The QUALI-PALLI-FAM was not conceived in order to obtain a proxy measure of care quality from a relative instead of from a given patient, which is why we did not sample pairs of patients and their own relatives. By sampling patients (data taken from the QUALI-PALLI-PAT study [32]) and relatives separately, our goal was to obtain two parallel but independent measures of care provided at a site. Thus, comparisons of mean scores from the two questionnaires, the QUALI-PALLI-FAM and QUALI-PALLI-PAT (concerning unrelated patients), were performed at each site to investigate the congruence between patients’ and relatives’ perspectives.[32]

**Results**

**Description of study population**

From March 2012 to April 2014, 170 relatives of palliative inpatients (90% had advanced stage cancer) completed the 46-item questionnaire; however, one site withdrew, thus preventing us from reaching the target sample size (Table 2). Twenty-one participants were excluded because of MD or ceiling effects; their characteristics were similar to those of the remaining ones, except that the remaining participants were more likely to be a spouse/partner of the patient (33% vs. 58%, p = 0.06; data not reported).

**Face validity**

The 12 pilot testers easily completed the questionnaire, with all items being fully understood. Thus, the initial version was left unmodified. In the clinical study, 104 participants (61.2%) provided questionnaires without MD but with some NA responses. Globally, 14.5% of the responses were missing (1106/7650); 21 questionnaires had either too many NR items (n = 11) or items with ceiling effects (n = 10).

**Item selection**
MD per item ranged from 0% to 7.6%. A total of 19 items presented a high rate of NR (n = 12) or ceiling effects (n = 14). However, due to our initial qualitative study, items 15 (pain relief), 20–21 (help and dignity), 29–32 (volunteers), 34–36 (staying with patient), and 41–45 (social or psychological support) were included in the analysis. [15] When pairs of items were highly correlated (r ≥ 0.70; p < 0.0001; items 10–11; 29–30; 31–32; 41–42; 43–44), the steering committee favoured items showing necessary improvements (depending on the structure, notably) or focused on the relative instead of the patient; thus only 9 items were discarded, leaving 36 items (Table 1).

**Construct validity**

The KMO was 0.64, and Bartlett’s test was significant, indicating that the sample was adequate for EFA. After imputations, EFA on the resulting matrix of 36 items identified either a three- or four-factor solution, as indicated by parallel analysis and MAP. On each initial solution, descending procedures led to a final set of 14 items across three factors. With regard to our qualitative study, ‘Involvement with care’ (item 13) was maintained despite cross-factoring, as well as ‘philosophical or religious support of the patient’ despite an unfavourable response distribution (40% NA).

The three factors could be interpreted as (i) organisation of care and availability of caregivers (6 items); (ii) medical information provision (4 items); and (iii) rest, confidence, and involvement of the relatives (4 items). This solution accounted for 62% of the total variance, while the model fit was quite good (root mean square error of approximation = 0.079). Table 3 shows the item loadings by factor, with their quality criteria. Average communality was 0.52. All items except two had a strong loading on only one factor, and the average load by factor was over 0.6 (Table 4). Therefore, the final QUALI-PALLI-FAM questionnaire included 14 specific items plus the item on global satisfaction.

**Consistency**

The mean subscale scores indicated a high level of satisfaction (Table 4). Cronbach’s alpha was high overall (0.97) and good for all factors. Accordingly, reliability based on beta coefficients and Guttman G6 was good. The inter-item correlations indicated an adequate level of homogeneity (Table 4). Item-total correlations and item-scale correlations for the item’s own subscale indicated internal consistency (Supplementary File 1). Inter-subscale correlations evidenced independence of factors (Supplementary File 2).

**Stability**

We confirmed the stability of the questionnaire by obtaining similar combinations of items within factors using either a Spearman correlation matrix, a principal axis factorisation method, or an oblimin rotation, except for item 13, which was moved once from factor 2 to factor 3 (not presented).

Factorisations performed across strata of characteristics showed consistency: more than two-thirds of items belonged to similar factors, except for patient’s age, relative relationship, and of course random split (100% agreement; Supplementary File 3a). The mean subscale scores were similar regardless of the characteristics of relatives or patients (Supplementary File 3b), but scores were higher, as expected, when general satisfaction was high, and also PCUs. These setting-related differences ranged from 0.2 to 0.4, while the difference between moderate and high satisfaction was approximately 0.3. When these comparisons between strata were performed at each of the 200
Imputations and then summarised (data not shown), conclusions were roughly the same as those presented above, obtained on the final synthesis matrix.

**Reproducibility**

As the patients’ conditions were too unstable, only 10 relatives performed the retest procedure, preventing statistical analysis.

**External validation**

FAMCARE scores were high (mean = 4.19, SD = 0.64). Global satisfaction with care \((r = 0.56, p < 0.001)\), and subscale scores of the QUALI-PALLI-FAM were moderately correlated with FAMCARE scores, with the best correlation being with the QUALI-PALLI-FAM total score \((r = 0.71, p < 0.001;\) Table 5).

The average global satisfaction scores from the QUALI-PALLI-FAM and QUALI-PALLI-PAT ranked the sites in the same order, but patients systematically tended to give higher scores than relatives (Figure 1 and Supplementary File 4).

**Discussion**

Our study involved the development and validation of the QUALI-PALLI-FAM questionnaire for assessing the quality of palliative care from the perspective of patients’ relatives. This questionnaire contains 14 items exploring three domains: organisation of care and availability of caregivers; medical information provision; and confidence and involvement of relatives.

The QUALI-PALLI-FAM complements our patient multidimensional questionnaire, the QUALI-PALLI-PAT.[32] Each domain of the QUALI-PALLI-PAT except one (i.e. possibility for the patient to refuse care or volunteers) has one or more corresponding items on the QUALI-PALLI-FAM. This allows us to consider the concerns of patients and relatives regarding similar topics. Conversely, only two items were specific to the QUALI-PALLI-FAM: confidence in the team (item 39) and appreciation of patient’s well-being (item 22). The three domains explored by the QUALI-PALLI-FAM are in agreement with the results of previous qualitative studies.[16,55] Our results highlight that the availability of professional caregivers is an essential component of the quality of palliative care, and this aspect has been understated in previous questionnaires.[15,32,55] Medical communication and involvement in care were also reported as essential factors of quality care, although these aspects of care are not a priority for health care professionals.[56–58] Our study shows that the layout of the unit and rooms was a key point for the perception of quality of care, as was the atmosphere of the setting, which again distinguishes patients and relatives from professionals.[16]

Our study shows that relatives rated the quality of care as high globally and for each of the three subscales. This high level of satisfaction is frequently observed in clinical trials, and the ceiling effects limit the comparison of various palliative settings. However, we observed higher scores on the three subscales in PCUs. This might be because PCUs may be considered the gold standard, providing extensive support and having abundant resources and highly trained staff.[16,27,28,59]

The robust method used to develop and validate the QUALI-PALLI-FAM makes it a sound and valid instrument, which meets most of the criteria formalised in the COSMIN checklist.
The instrument was developed based on a conceptual model, with a target population and a delineated context of use. The content relied on a previous qualitative study, and concept elicitation was completed through a pilot test of comprehensibility. Construct validity was based on EFA, while the stability of the structure was checked against several factors. A satisfactory interpretation of the final subscales was achieved. The stability observed in the three domains regardless of the characteristics of patients and relatives allows the QUALI-PALLI-FAM to be used irrespective of the case-mix of patients. The stability across various settings was a key result allowing comparison between PCUs and standard medical wards with palliative care teams. Differences in satisfaction according to relatives’ gender or age were weak, thus not supporting Porter’s discrepancy theory.

Several limitations to this study should be mentioned. First, the health care team and research assistant discussed the choice of family members, which may have caused selection bias. An independent selection method needs to be used in the future. Second, relatives may have withheld their criticisms or complaints so as not to risk displeasing the health care team.[28] However, as the questionnaires were provided in a written format by a research assistant independent of the health care team, this risk may have been reduced. Third, the total sample size was smaller than expected, which prevented us from performing a sample split for a confirmatory factorial analysis on the second subsample. Our sample size nevertheless appeared sufficient both in view of the responder-to-item and mean item-to-factor ratios, and the high value of the loadings, averaging near 0.7 for each factor, while the structure appeared stable.[63] Fourth, the study found a relatively high proportion of items with ceiling effects and NA responses, which may reflect the top-notch palliative services provided by a team already committed to a high-quality approach. Finally, it was not possible to conduct test-retest validation, as patients’ length of stay was too short (median around 12 days). A period of 48 hours after admission was necessary before completing the questionnaire, and patients’ clinical conditions were too unstable. For the same reason, we could not assess inter-rater reliability.

Conclusion

The QUALI-PALLI-FAM questionnaire appears to be a valid, reliable, and well-accepted French-language tool that assesses the quality of and satisfaction with inpatient palliative care from the point of view of patients’ relatives, and can be used in combination with the patient questionnaire QUALI-PALLI-PAT (Supplementary File 5; French version). Tested in different types of palliative care wards, the QUALI-PALLI-FAM questionnaire is usable as a ‘one-size-fits-all’ questionnaire for inpatient palliative care. The shortness of the final form allows its periodic use to evaluate the quality of care through its three domains. A larger study involving a higher number of settings and participants is nevertheless mandatory to assess the promises of this tool.

The QUALI-PALLI-FAM and QUALI-PALI-PAT results highlight the importance of caregivers’ availability. Quality of care does not only depend on the effectiveness of technical care (i.e., time spent in quantifiable clinical interactions) but also on the creation of a caregiver–patient relationship. This relationship requires caregivers to be available for informal interactions, which are neither quantifiable nor predictable. Consequently, a purely accounting and technical management of caregivers’ working time would lead to a decline in the overall quality of palliative care.
Disclosures and Acknowledgements

Conflicts of interest: The authors declare that they have no competing interests

Acknowledgements: The investigators thank the members of the Quali-Palli Group: Anne Abel, Laure Copel, Louise Geoffroy, Laurence Gineston, Hélène Godard, Xavier Grenet, Karima Nfissi, Jean-François Richard, Sylvie Rostaing, Yael Tibi-Lévy, Isabelle Vedel, Kate Vincent, and the Clinical Research Unit team that worked on Quali-Palli (Layde Meaude, Sylvie Laot-Cabon, Sarah Gaston-Dreyfus, Audrey Angelard, Yasmine Saidji, Karima Mesbahi, and Wen Teng).

Authorship: FG and PA were responsible for the study concept and design, obtained funding, and supervising the study. PA and PMS carried out the statistical analysis. The QUALI-PALLI Group conducted the literature review and selected the first set of items. All authors analysed and interpreted the data. FG, PA, and CB drafted the manuscript. All authors critically revised the manuscript, read, and approved the final version of the manuscript.

Funding: This study was supported by a grant from the French Ministry of Health (PreQHos 2009–04) and sponsored by the Assistance Publique-Hôpitaux de Paris (NI10052).

Ethics and consent: This study was approved by a regional ethics committee (#12059, Comité de Protection des Personnes ‘CPP île de France XI’, Saint Germain-en-Laye, France) and was registered on clinicaltrials.gov (NCT02814682). All participants were duly informed and oral consent was obtained prior to the research. According to French health regulations, no written informed consent was required, as this was an observational study using registered data.

Data sharing: The datasets generated and/or analysed during the current study are not publicly available to protect confidentiality, but aggregated data are available from the corresponding author on reasonable request.
References


Table 1. Initial questionnaire tested by relatives
For each item, the percentages of uninformative (italicized if ≥ 25%) and ceiling responses (italicized if ≥ 90%) are reported. The 14 items retained in the final questionnaire are in bold type.

<table>
<thead>
<tr>
<th>Information about health and care of my relative</th>
<th>Uninformative response percentage</th>
<th>Ceiling response percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>I have received very clear information concerning:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q1 - the evolution of his/her state of health</td>
<td>4.7</td>
<td>78.4</td>
</tr>
<tr>
<td>Q2 - the objective of the treatments (medication, methods)</td>
<td>11.8</td>
<td>83.3</td>
</tr>
<tr>
<td>Q3 - possible adverse effects of treatments</td>
<td>16.5</td>
<td>64.8</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Relations with the doctors and caregivers</th>
<th>Uninformative response percentage</th>
<th>Ceiling response percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q4 I know the doctor who deals with my relative</td>
<td>1.8</td>
<td>77.2</td>
</tr>
<tr>
<td>Q5 It is difficult to meet the doctor who deals with my relative</td>
<td>5.9</td>
<td>9.4</td>
</tr>
<tr>
<td>Q6 The doctors answer all my questions</td>
<td>4.7</td>
<td>76.5</td>
</tr>
<tr>
<td>Q7 My interactions with the doctors take place in a quiet setting, confidentially</td>
<td>7.6</td>
<td>82.2</td>
</tr>
<tr>
<td>Q8 The doctor has been disturbed during our exchange</td>
<td>9.4</td>
<td>10.4</td>
</tr>
<tr>
<td>Q9 I get information easily from whomever I am talking</td>
<td>3.5</td>
<td>70.1</td>
</tr>
<tr>
<td>Q10 The carers are always available to answer to my questions</td>
<td>1.2</td>
<td>80.4</td>
</tr>
<tr>
<td>Q11 The carers are available to listen to me</td>
<td>2.9</td>
<td>86.7</td>
</tr>
<tr>
<td>Q12 I feel psychologically supported</td>
<td>15.9</td>
<td>67.8</td>
</tr>
<tr>
<td>Q13 I feel involved in the care and decisions concerning my relative</td>
<td>8.8</td>
<td>70.3</td>
</tr>
<tr>
<td>Q14 My relative gave his/her consent for me to be informed</td>
<td>15.9</td>
<td>95.1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Wellbeing of my relative</th>
<th>Uninformative response percentage</th>
<th>Ceiling response percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q15 The utmost is done to relieve my relative’s pain</td>
<td>3.5</td>
<td>92.1</td>
</tr>
<tr>
<td>Q16 My relative’s pain is quickly taken care of when it is reported</td>
<td>5.3</td>
<td>89.4</td>
</tr>
<tr>
<td>Q17 The utmost is done for my relative to be comfortable</td>
<td>0.6</td>
<td>89.3</td>
</tr>
<tr>
<td>Q18 Carers quickly respond to my relative’s requests</td>
<td>5.3</td>
<td>78.3</td>
</tr>
<tr>
<td>Q19 The utmost is done when my relative is anxious, worried, or sad</td>
<td>10.0</td>
<td>75.2</td>
</tr>
<tr>
<td>Q20 My relative receives appropriate help when he/she eats</td>
<td>29.4</td>
<td>64.2</td>
</tr>
<tr>
<td>Q21 A bedpan or toileting assistance is offered to him/her in a respectful way</td>
<td>31.8</td>
<td>91.4</td>
</tr>
<tr>
<td>Q22 I feel my relative is generally relaxed</td>
<td>5.3</td>
<td>44.7</td>
</tr>
<tr>
<td>Q23 The bedroom and the unit provide a calm and restful environment</td>
<td>1.2</td>
<td>81.5</td>
</tr>
</tbody>
</table>
Q24 My relative can rest as much as he/she wishes 2.9 87.3

Functioning of the unit
Q25 Caregivers are available 2.9 80.0
Q26 Doctors are available 7.1 69.6
Q27 There is excellent coordination in the unit 14.1 79.5
Q28 The atmosphere in the unit is very good 12.4 91.3
Q29 I can take advantage of the presence of volunteers if I wish to do so 39.4 96.1
Q30 My relative can take advantage of the presence of volunteers if he/she wishes to do so 37.1 95.3
Q31 My relative feels he/she can refuse the presence of volunteers 37.1 94.4
Q32 I feel I can refuse the presence of the volunteers 36.5 96.3
Q33 I always feel welcome in the unit 3.5 92.7
Q34 I can go to my relative whenever I want 1.8 98.8
Q35 I can stay with my relative for as long as I want 2.9 97.0
Q36 There are good accommodation and catering options available to me 34.7 80.2
Q37 There are places in the unit where I can rest outside the room 16.5 83.1
Q38 I know that even in my absence, my relative isn't alone 11.2 72.8
Q39 I am reassured when I leave the unit 2.9 74.5
Q40 I have confidence in the care of my relative even in my absence 1.2 91.7
Q41 I can see a psychologist when I need one 33.5 88.5
Q42 My relative can see a psychologist when he/she needs one 25.9 93.7
Q43 I can see a social worker when I need one 40.0 85.3
Q44 My relative can see a social worker when he or she needs it 40.0 89.2
Q45 My relative can talk to someone about philosophical or religious issues if he/she wishes 44.1 95.8

Global satisfaction
Q46 Overall, what is your level of satisfaction?
<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Relatives (n=170)</th>
<th>Patients (n=170)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (years)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean±SD</td>
<td>59.5±14.7</td>
<td>65.9±15.6</td>
</tr>
<tr>
<td>Min-Max</td>
<td>23–95</td>
<td>18–99</td>
</tr>
<tr>
<td>&lt;50</td>
<td>26%</td>
<td></td>
</tr>
<tr>
<td>50–59</td>
<td>26%</td>
<td></td>
</tr>
<tr>
<td>60–69</td>
<td>25%</td>
<td></td>
</tr>
<tr>
<td>≥70</td>
<td>23%</td>
<td></td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>65.4%</td>
<td>51.7%</td>
</tr>
<tr>
<td><strong>Setting</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No PCU</td>
<td>41%</td>
<td></td>
</tr>
<tr>
<td><strong>PPS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥60%</td>
<td>12%</td>
<td></td>
</tr>
<tr>
<td>40–50%</td>
<td>30%</td>
<td></td>
</tr>
<tr>
<td>≤30%</td>
<td>58%</td>
<td></td>
</tr>
<tr>
<td><strong>Relationship to patient</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Husband/wife/partner</td>
<td>55%</td>
<td></td>
</tr>
<tr>
<td>Child</td>
<td>21%</td>
<td></td>
</tr>
<tr>
<td>Parent</td>
<td>11%</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>13%</td>
<td></td>
</tr>
</tbody>
</table>

SD: standard deviation; PPS: Palliative Performance Scale (French version 2); PCU: palliative care unit.
Table 3. Exploratory factorial analysis (oblimin rotation): loadings and quality criteria

<table>
<thead>
<tr>
<th>Item</th>
<th>F1</th>
<th>F2</th>
<th>F3</th>
<th>Uniqueness</th>
<th>Complexity</th>
<th>KMO</th>
<th>SMC</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 I have received very clear information concerning the evolution of his/her state of health</td>
<td>0.00</td>
<td>0.73</td>
<td>0.02</td>
<td>0.45</td>
<td>1.0</td>
<td>0.76</td>
<td>0.55</td>
</tr>
<tr>
<td>3 I have received very clear information concerning the possible adverse effects of treatments</td>
<td>0.11</td>
<td>0.56</td>
<td>-0.17</td>
<td>0.68</td>
<td>1.3</td>
<td>0.72</td>
<td>0.40</td>
</tr>
<tr>
<td>5 It is difficult to meet the doctor who deals with my relative</td>
<td>0.11</td>
<td>0.57</td>
<td>0.06</td>
<td>0.57</td>
<td>1.1</td>
<td>0.80</td>
<td>0.51</td>
</tr>
<tr>
<td>6 The doctors answer all my question</td>
<td>-0.02</td>
<td>0.81</td>
<td>0.01</td>
<td>0.35</td>
<td>1.0</td>
<td>0.74</td>
<td>0.62</td>
</tr>
<tr>
<td>13 I feel involved in the care and decisions concerning my relative</td>
<td>-0.27</td>
<td>0.48</td>
<td>0.52</td>
<td>0.49</td>
<td>2.5</td>
<td>0.75</td>
<td>0.46</td>
</tr>
<tr>
<td>16 My relative’s pain is quickly taken care of when it is reported</td>
<td>0.74</td>
<td>0.06</td>
<td>-0.15</td>
<td>0.51</td>
<td>1.1</td>
<td>0.82</td>
<td>0.54</td>
</tr>
<tr>
<td>18 Carers quickly respond to my relative’s requests</td>
<td>0.69</td>
<td>0.13</td>
<td>0.11</td>
<td>0.33</td>
<td>1.1</td>
<td>0.86</td>
<td>0.65</td>
</tr>
<tr>
<td>22 I feel my relative is generally relaxed</td>
<td>0.44</td>
<td>-0.08</td>
<td>0.23</td>
<td>0.69</td>
<td>1.6</td>
<td>0.79</td>
<td>0.40</td>
</tr>
<tr>
<td>23 The bedroom and the unit provide a calm and restful environment</td>
<td>0.61</td>
<td>0.09</td>
<td>0.07</td>
<td>0.53</td>
<td>1.1</td>
<td>0.85</td>
<td>0.52</td>
</tr>
<tr>
<td>25 Caregivers are available</td>
<td>0.84</td>
<td>-0.10</td>
<td>-0.06</td>
<td>0.40</td>
<td>1.0</td>
<td>0.78</td>
<td>0.61</td>
</tr>
<tr>
<td>27 There’s excellent coordination in the unit</td>
<td>0.73</td>
<td>0.25</td>
<td>-0.01</td>
<td>0.27</td>
<td>1.2</td>
<td>0.87</td>
<td>0.70</td>
</tr>
<tr>
<td>37 There are places in the unit where I can rest outside the room</td>
<td>0.08</td>
<td>0.02</td>
<td>0.74</td>
<td>0.37</td>
<td>1.0</td>
<td>0.72</td>
<td>0.58</td>
</tr>
<tr>
<td>39 I am reassured when I leave the unit</td>
<td>0.39</td>
<td>-0.15</td>
<td>0.50</td>
<td>0.50</td>
<td>2.1</td>
<td>0.84</td>
<td>0.48</td>
</tr>
<tr>
<td>45 My relative can talk to someone about philosophical or religious issues if he/she wishes</td>
<td>-0.03</td>
<td>-0.06</td>
<td>0.68</td>
<td>0.58</td>
<td>1.0</td>
<td>0.62</td>
<td>0.47</td>
</tr>
</tbody>
</table>

KMO: Kaiser–Meyer–Olkin; SMC: squared multiple correlations; F1, F2, F3: factors.
<table>
<thead>
<tr>
<th>Factor</th>
<th>No. items</th>
<th>Loadings mean</th>
<th>Subscale score mean [median] (SD)</th>
<th>Cronbach’s α</th>
<th>Beta (minimum split-half reliability)</th>
<th>Guttman G6</th>
<th>Spearman inter-item correlation: mean [median] (min-max)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Factor 1</td>
<td>6</td>
<td>0.68</td>
<td>3.64 [3.83] (0.4)</td>
<td>0.86</td>
<td>0.81</td>
<td>0.88</td>
<td>0.45 [0.46] (0.33-0.53)</td>
</tr>
<tr>
<td>Factor 2</td>
<td>4</td>
<td>0.67</td>
<td>3.43 [3.50] (0.6)</td>
<td>0.77</td>
<td>0.68</td>
<td>0.80</td>
<td>0.45 [0.44] (0.38-0.56)</td>
</tr>
<tr>
<td>Factor 3</td>
<td>4</td>
<td>0.61</td>
<td>3.49 [3.75] (0.6)</td>
<td>0.74</td>
<td>0.70</td>
<td>0.78</td>
<td>0.44 [0.42] (0.36-0.54)</td>
</tr>
</tbody>
</table>
Table 5. External validation: correlations of QUALI-PALLI-FAM factors and global satisfaction with FAMCARE scores

<table>
<thead>
<tr>
<th></th>
<th>Factor 1</th>
<th>Factor 2</th>
<th>Factor 3</th>
<th>Total score</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FAMCARE</strong></td>
<td>0.53, p&lt;0.001</td>
<td>0.63, p&lt;0.001</td>
<td>0.5, p&lt;0.001</td>
<td>0.71, p&lt;0.001</td>
</tr>
<tr>
<td><strong>Global satisfaction</strong></td>
<td>0.41, p&lt;0.001</td>
<td>0.34, p&lt;0.001</td>
<td>0.27, p&lt;0.001</td>
<td>0.42, p&lt;0.001</td>
</tr>
</tbody>
</table>

Spearman correlation: rho, two-sided p-value.