

# Clown Care In A Palliative Care Unit: A Useful Paradox? A Preliminary Pilot Study Involving Questionnaires And Text Analysis.

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## Research Article

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# Abstract

**Title:** The impact of Clown Therapy in a Palliative Care Unit (PCU); a pilot study

**Background:** Although several studies on clown therapy have demonstrated benefits for children and the elderly, few studies exist on its impact on quality of life in adult terminal patients.

We devised this monocentric, prospective, descriptive pilot study, covering both quantitative and qualitative aspects, to test the hypothesis that “clowning” in the PCU would help to improve the quality of life of patients, and benefit those accompanying them and their carers.

**Methods:** 30 terminal patients [age range 63-79, 19 women, 11 men] from the palliative care unit at Nîmes University Hospital were included in the study from 31/03/2016 to 08/11/2016. All had given written informed consent. 2 clowns visited the patients and their companions, inviting them to take part in 15 to 30-minute improvised role-plays to prepare them for the inevitable separation. Primary outcome measures for the impact of the clowns’ interventions were: The Edmonton Symptom Assessment System evaluating patients’ physical symptoms and the McGill Quality of Life Questionnaire assessing patients’ quality of life. The secondary outcome measure was Alceste textual data analysis software to analyse semi-structured interviews held with patients, their companions and carers.

**Results:** However long the clown’s intervention, the ESAS scores indicated a significant improvement in nausea ( $p=0.0248$ ) and dyspnea ( $p=0.0476$ ). Scores for depression ( $p=0.0160$ ) also showed an improvement. A slight difference in the scores for anxiety ( $p=0.0900$ ) and drowsiness ( $p=0.0812$ ) was also observed. 2 days after the clowns’ intervention, the Mc Gill scores revealed a significantly greater physical quality of life ( $p=0.0044$ ) and a very slight increase in the patients’ overall quality of life ( $p=0.0807$ ). Results of the lexical analysis with Alceste revealed benefits for all those involved and gave an indication for better patient management at the PCU.

**Conclusions:** This pilot study demonstrating the impact of “clowning” on various physical and mental symptoms in adult patients indicates the benefits of such interventions for patients, their companions and carers. Although the usefulness of clowns for children with life-threatening diseases is clear, the results obtained with our study clearly indicate the benefits of these interventions in adult, end-of-life patients. Further studies would be required to confirm these findings.

**Date of first registration :** 20/11/2015

**Trial registration:** ClinicalTrials.gov ID: NCT02610452

This research was registered under the following reference : IDRCB 2015-A00719-40 and approved by the local committee for the protection of persons, CPP Sud-Méditerranée III-Nîmes on November 6th, 2015 under the reference 2015.06.03.

## Background

Clown therapy in an end-of-life environment has long been a subject of study in clinical research and seems to have demonstrated its efficacy for improving the quality of life of patients [1][2][3].

According to research, Hippocrates (470 BC–350 BC) believed a person's mood could influence healing and is claimed to have used clowns and musicians to help the sick [4]. In mediaeval times, court jesters used their wit to break the ice when bad news was announced and difficult decisions were being discussed[5]. Indeed, since then clowns have always been around to help us deal with the darker side of life.

More recently, in 1971, the American physician, comedian and clown Hunter "Patch" Adams dared to bring clowning into the hospital environment. He founded the "Gesundheit! Institute", an original free hospital with treatment based on humor and, more especially, laughter [6].

The idea caught on at the same time in Canada with the first experiments benefitting children. In 1986, the children's specialist Karen Ridd, set up an experimental project at the Children's Hospital in Winnipeg, Canada [7][8].

Meanwhile, in 1986, the Big Apple Circus in New York developed a Clown Care program with over 80 professional clowns, trained extensively in hospital procedures, circus skills, and improvisation. These 'clown therapists' did the rounds at various pediatric hospitals in the U.S. visiting children in both inpatients' and outpatients' units, including intensive care, emergency physiotherapy, bone marrow transplant, pediatric AIDS, and hematology/oncology departments [9].

The Big Apple Circus was soon to become a training center for clowns all over the world and the idea quickly spread to Europe. In France, American-born Caroline Simonds became a forerunner in medical clowning and set up an association called « *Le Rire Médecin* » in Paris in 1991[10]. The approach soon spread to geriatric units [10] and a few experiments were conducted in pediatric palliative care [11].

More generally speaking, a great deal of research has been made into the healing power of humor [12] [13] [14] and its use for pain relief [15], relieving stress and anxiety [16] and even boosting the immune system [17].

Today, the benefits of clown therapy are clearly recognized and accepted in pediatric and geriatric hospitals and several articles dealing with the beneficial effects of clown care for children [18][19] and the elderly [20][21][22] have been published. However, apart from four particularly interesting randomized controlled studies evaluating "clown care" and its powers of reducing stress in children [23][24][25][26] there have been very few studies dealing with the effect of clown therapists' interventions on adult patients undergoing palliative care, and their impact on the quality of life of these patients.

In 2002, the World Health Organization's definition of palliative care reminded us that its main purpose is to preserve the quality of life of patients and those around them in the overall management of symptoms and their consequences at the onset of serious, life-threatening illnesses [27]. As far back as 1947 the World Health Organization defined Quality of Life as a "state of complete physical, mental and social

well-being, and not merely the absence of disease and infirmity” [28]. But how is this concept of quality of life (QOL) applied to palliative care patients? The normal course of action aims not only to relieve physical pain and other symptoms but also take into account the psychological, social and spiritual suffering. QOL is a measurable concept and we wanted to measure some of these aspects.

We began with the hypothesis that clown interventions for patients admitted to the palliative care unit would help to improve their quality of life and also have an impact on those accompanying them, and their carers.

For the palliative care patient, the announcement of imminent death comes as a shock. The sudden realization that something is going to stop, that all creativity will be suspended, leads to great suffering. The patient’s scope for self-expression is reduced and he/she is no longer an actor of his/her life. Clowns can play a role in this context of imminent death by accompanying the person from the position of being a non-actor to one in which he/she can play an active role again. We believed that clowning interventions in the palliative care unit would act as a catalyzer to help patients cross the line and completely change the way they saw their lives.

With very little reference material in the literature and, in the absence of subsequent, more significant studies, a randomized study was not considered for this work. This research was envisaged more as a preliminary pilot study.

This original prospective, descriptive study, covering both quantitative and qualitative aspects, focuses on an in-depth evaluation of the impact of clown care in a palliative care unit. The purpose of this research was therefore to clinically evaluate, not only the efficacy of the clown therapists’ intervention, but also to try and objectify its potentially positive impact on the quality of life of each of the protagonists in the care-help relationship: the patients, their family and friends and the healthcare team.

This paper is therefore an attempt to demonstrate the impact of clowning interventions on various symptoms, both physical and mental: pain, anxiety, drowsiness, fatigue, mood, etc... in adult palliative care patients. If this impact could be measured, we wanted to highlight the evolution or improvement in the quality of life of these patients undergoing palliative care and also the benefits of the approach for their companions and the healthcare team. We argued that the clown care interventions would stimulate the imagination, help these patients express themselves in a different way, reveal their true feelings as closely as possible and help them speak in metaphors about their vision of death. For this reason, we thought it would be interesting to analyze the language used by the patients, their companions and the nursing staff and deduce a framework for future interventions.

Furthermore, as the two clowns in our study were a fully qualified psychologist and a psycho-practitioner, their experience could be drawn upon to develop this practice depending on the profile of patients who might be eligible for clown care.

## Methods

This research was registered under the following reference : IDRCB 2015-A00719-40 and approved by the local committee for the protection of persons, CPP Sud-Méditerranée III-Nîmes on November 6th, 2015 under the reference 2015.06.03.

## **Study design and patients**

The study protocol was approved by the institutional human investigation committee (Comité de Protection des Personnes, CPP, Nîmes, France, *RCB: 2015-A00719-40*) and registered before starting on ClinicalTrials.gov (NCT02610452). The study population consisted of adult patients admitted for treatment in the Palliative Care Unit at Nîmes University Hospital, whatever their original pathology.

All patients in the study had given their free, informed consent.

## **Intervention and assessment**

Each session required approximately 3 ½ hours of the clowns' presence in the PCU and this time was divided as follows: Exchanges with the healthcare teams: 30 minutes, 1 hour for the clowns to get ready (make-up, bodily and vocal warm-ups) and 1 hour for their intervention. For any given patient, the session lasted 5 to 30 minutes maximum. The clowns worked in pairs and, each time they came to the PCU, two patients could benefit from the intervention. Once over, this was followed by an hour-long debriefing session with the clowns, once they had changed back into their normal clothes.

One hour after each session, the clown interventions were monitored using various tools; the Edmonton Symptom Assessment System (ESAS) [29] to evaluate the patient's physical symptoms (scores ranging from 0 to 10 points) and the McGill Quality of Life Questionnaire (MQOL) [30] a self-assessment tool based on a scale (scores ranging from 0 to 10 points).

In qualitative terms, in order to have a realistic appreciation of the experience, the protocol also involved gathering all the words spoken during interviews with each of the subjects who had agreed to take part in the study. Using a corpus of answers to questions recorded on tape or noted during the interviews, Alceste text statistics software (*developed by IMAGE and the CNRS in 1979 [www.image-zafar.com/Logiciel.html](http://www.image-zafar.com/Logiciel.html)*), allowed us to make an in-depth analysis and interpretation of the overall results obtained [31]. The analysis of these interviews could then be used in the same way as the results obtained with the validated questionnaires.

The reliability of the evaluation and the pertinence of the tools used seemed as close as possible to the reality of what was feasible for patients on palliative care treatment.

## **Aims**

The main purpose of this prospective pilot study was to evaluate the existence of an improvement in the Edmonton Symptom Assessment System (ESAS) self-evaluation score[29], one hour after the clown therapists' intervention (T+1).

Secondary aims included evaluating the evolution of these patients' quality of life, the appreciation of their family and friends, and that of the healthcare teams. For this part of the study we decided to use semi-structured interviews analyzed with text analysis software, the McGill Quality of Life Questionnaire (MQOL) [30] at T+1 and 48 hours later intervention (D2) and ESAS questionnaire at D2.

## **Statistical analysis**

All statistical analyses were performed using SAS® (SAS Institute, Cary, NC, USA) version 9.4. Continuous variables were expressed as mean and standard deviation or median with 25th and 75th percentiles. Qualitative variables were expressed as frequency with percentages.

Endpoints were tested using the Wilcoxon signed rank test.

All statistical tests were conducted as 0.05 two-sided tests.

Semi-structured interviews were analysed using Alceste (Analyse Lexicale par Contexte d'un Ensemble de Segments de Texte) textual statistics software was developed in 1979 by IMAGE in collaboration with the CNRS (Centre National de la Recherche Scientifique). The main purpose of Alceste is to analyze, classify and resume[31]. Alceste makes a detailed analysis of the vocabulary from the corpus and forms a dictionary of words together with their root and frequency. It then breaks the text down into homogeneous segments, each containing a sufficient number of words, and classifies these segments by picking out the strongest oppositions. By this means it is possible to extract classes of meanings made up of the most significant words and phrases. The classes thus obtained represent the most dominant ideas and themes of the corpus. Once all the results have been sorted according to their pertinence and depicted in graph form, the user can easily interpret and analyze them.

# **Results**

## **Population of the study and intervention**

Thirty patients from the palliative care unit at Nîmes University Hospital had been included in the study from 31/03/2016 to 08/11/2016.

These patients were 71 [63-79] years old and 19 (63%) of them were women; 23 of them (73%) had a WHO status of 3 or 4. The majority of these were cancer patients (89%), but 5% had neurological disorders, 1% had multiple pathologies afflicting the elderly, 1% had a cardiopathy and 4% had various other conditions.

Among the many reasons for their admission to the palliative care unit, 20 of the 30 patients (67%) reported intractable pain, 12/30 (40%) had persistent symptoms, 2/30 (7%) reported intense moral suffering, 9/30 (30%) were in a complex social situation, 12/30 (40%) were in a complex family situation, 11/30 (37%) had become too great a burden for other hospital departments and 9/30 (30%) were under evaluation for a return home.

During the study, 4 patients had an adverse event including 2 deaths. One patient interrupted his participation in the study before the evaluation at T-1 due to referral to another department (Fig.1).

The clown care intervention was therefore performed for the remaining 29 patients and lasted about 20 [15-20] minutes per patient.

The T-1 evaluation was performed about 6 [5-6] hours before the clowns went into the patient's room and the T+1 evaluation was performed about 2 [2-3] hours after the end of the clowns' intervention in the patient's room.

Semi-structured interviews were held between the patient's family, friends or carer on Day 0 (D0). For 15/27 (56%) patients there was no friend or relative available to interview.

These interviews were held with the healthcare team (2 to 3 members of the healthcare team performed the interview for 70% of them).

### **Primary outcome**

After the clown therapists' intervention, compared with the evaluation performed before it, the ESAS scores were reduced for depression (-0.40 [-1.95; 0.20],  $p=0.0257$ ), anxiety (-0.60 [-1.15; 0.15],  $p=0.0452$ ), loss of appetite (-0.20 [-1.30; 0.10],  $p=0.0452$ ) and dyspnea (-0.10 [-1.50; 0.00],  $p=0.0098$ ) (Table 1).

During the study, certain treatments for nausea, depression and anxiety symptoms had been modified. A complementary analysis performed for a sub-samples of patients whose treatment for the symptom under study had not been modified brought to light same results with moderate reduction for depression (-0.40 [-1.75; 0.20],  $p=0.0529$ ,  $n=27$ ) and anxiety (-0.60 [-1.05; 0.15],  $p=0.0576$ ,  $n=24$ ).

### **Secondary outcomes**

Two days after the clown therapists' intervention, compared with the evaluation performed before this intervention, the ESAS scores were reduced for nausea (-0.15 [-1.30; 0.00],  $p=0.0353$ ), depression (-0.60 [-1.45; 0.15],  $p=0.0216$ ) and dyspnea (-0.10 [-1.05; 0.00],  $p=0.0053$ ) (Table 1). The complementary analysis performed for the sub-samples of patients who had undergone no modification in the treatment of the symptom under study gave the same results.

Table 1: ESAS comparisons before (T-1) and after (T+1, D2) the clown therapists' intervention.

| ESAS dimension   | T-1                  | T+1                  | D2                   | T+1 – T-1 Difference   | T+1 – T-1 P value | D2 – T-1 Difference    | D2 – T-1 P value |
|------------------|----------------------|----------------------|----------------------|------------------------|-------------------|------------------------|------------------|
| Pain             | 1.85<br>[0.45; 5.90] | 2.00<br>[0.25; 4.85] | 2.45<br>[0.40; 6.30] | -0.45<br>[-1.45; 0.85] | 0.2776            | -0.10<br>[-1.05; 1.40] | 0.8246           |
| Tired            | 5.80<br>[1.05; 8.15] | 4.90<br>[1.00; 8.25] | 6.60<br>[1.30; 8.85] | 0.00<br>[-1.40; 1.25]  | 0.9116            | 0.10<br>[-0.85; 1.35]  | 0.4077           |
| Nausea           | 0.40<br>[0.10; 2.00] | 0.35<br>[0.00; 1.25] | 0.20<br>[0.00; 0.80] | -0.10<br>[-0.45; 0.05] | 0.1210            | -0.15<br>[-1.30; 0.00] | 0.0353           |
| Depression       | 2.10<br>[0.65; 4.30] | 0.90<br>[0.35; 3.60] | 0.80<br>[0.25; 2.35] | -0.40<br>[-1.95; 0.20] | 0.0257            | -0.60<br>[-1.45; 0.05] | 0.0216           |
| Anxiety          | 2.40<br>[1.00; 5.25] | 1.45<br>[0.20; 6.00] | 1.50<br>[0.35; 4.85] | -0.60<br>[-1.15; 0.15] | 0.0452            | -0.75<br>[-2.05; 0.45] | 0.1201           |
| Drowsiness       | 4.20<br>[0.50; 8.10] | 3.40<br>[0.40; 8.80] | 4.15<br>[1.40; 8.95] | 0.00<br>[-1.15; 1.05]  | 0.9118            | 0.00<br>[-1.45; 1.50]  | 0.5547           |
| Loss of appetite | 3.95<br>[0.30; 7.60] | 1.25<br>[0.15; 7.35] | 1.90<br>[0.45; 7.90] | -0.20<br>[-1.30; 0.10] | 0.0190            | 0.00<br>[-2.35; 0.40]  | 0.4353           |
| Ill-being        | 4.75<br>[0.80; 6.70] | 4.50<br>[0.65; 5.45] | 4.10<br>[1.85; 5.75] | -0.10<br>[-1.60; 0.55] | 0.4607            | 0.30<br>[-1.90; 1.10]  | 0.6978           |
| Dyspnea          | 0.45<br>[0.05; 6.15] | 0.35<br>[0.00; 2.50] | 0.30<br>[0.00; 2.15] | -0.10<br>[-1.50; 0.00] | 0.0098            | -0.10<br>[-1.05; 0.00] | 0.0053           |

Data are medians [25<sup>th</sup>-75<sup>th</sup>].

Two days after the clown therapists' intervention, during the evaluation via the MQOL, patients seemed to report greater physical quality of life (1.33 [0.00; 2.67], p=0.0044) (Table 2).

These results were independent of the duration of the clown's intervention.

Table 2: MQOL comparisons before (T-1) and after (D2) the clown therapists' intervention.

| MQOL               | T-1                   | D2                    | D2 – T-1 Difference   | D2 – T-1 P value |
|--------------------|-----------------------|-----------------------|-----------------------|------------------|
| Physical symptoms  | 6.67<br>[3.33; 10.00] | 8.00<br>[5.00; 10.00] | 1.33<br>[0.00; 2.67]  | 0.0044           |
| Physical Wellbeing | 6.00<br>[3.00; 7.00]  | 5.00<br>[2.00; 8.00]  | 0.00<br>[-1.00; 1.00] | 0.6333           |
| Psychological      | 6.25<br>[2.75; 7.25]  | 6.50<br>[3.75; 8.50]  | 0.00<br>[-0.25; 1.75] | 0.1147           |
| Existential        | 5.17<br>[3.50; 6.83]  | 5.33<br>[4.00; 6.50]  | 0.00<br>[0.00; 0.67]  | 0.2211           |
| Support            | 9.00<br>[7.50; 10.00] | 9.00<br>[7.50; 10.00] | 0.00<br>[-0.50; 0.00] | 1                |
| Total              | 6.83<br>[4.88; 7.25]  | 7.02<br>[5.40; 7.40]  | 0.25<br>[-0.45; 1.00] | 0.3115           |

### Semi-structured interviews:

The units classified at the time of qualitative processing are divided into 8 classes of significant statements.

Class 1 (Figure 2), the first to transpire from the classification tree, is the most specific. Its vocabulary is the most homogeneous representing 11% of the classified text units, and it appears to characterize the population of carers, justifying the clown intervention with terms such as *establish, strange, work, confident, absolutely, considerable\**.

Class 2 (Figure 2), representing 10% of the classified text units. This appears to represent friends and family. Its significant words are *breath, fresh air, experience, lovely, live, patient\**.

*“A lovely experience for the patient, a breath of fresh air”*

Class 3 (Figure 2), representing 8% of the text units, characterizes the population of carers. Its significant words are *loved-one, unexpected, discuss, intervention, thing, pleasant\**.

*“-yes, sometimes [...] a pleasant time for my loved-one, it’s still unexpected [...] yes, by talking or even during the intervention [...] it was especially for the patient, to experience something else.”*

Class 4 (Figure 2), representing 11% of the classified text units, is marked by the words *capture, public, concern, taken, intervene, good\**. The rules for this intervention appear to be rather vague, as if the intervention had been imposed.

Class 5 (Figure 2), represents 21% of classified text units. It characterizes the patient group and is marked by words such as *fatigue, time, adult, imaginary, considerable\**.

Class 6 (Figure 2), represents 18% of classified text units and is marked by the words *evaluate, instant, beneficial, opening, creation, symptom\**. It represents the group of carers, especially the auxiliary nurses.

*"-You have to dare to do it. I wouldn't do it. [...]What's going on in the room? And what about our presence? Us carers? [...] It's a space, at the present time, strictly reserved for the patients."*

Class 7 (Figure 2), represents 11% of classified text units, marked by the words *stranger, getting to know each other, functioning, respect, relationship, adapt\**. It is characterized by the group of carers, especially the nurses.

Class 8 (Figure 2), characterized by the patients and friends or family groups, represents 10% of classified text units. It is marked by the words *toilet, important, physiotherapist, say, organization, imagine\**.

The in-depth analysis of results highlights the guidelines for the corpus under analysis.

*\*NDT: Words translated from French to English according to context by a professional translator.*

## Discussion

Clown-therapists are very different from ordinary circus clowns in that their mission is not to put on a show for a group of people but to give individual attention to patients, one at a time. Clowns are present in the department for a given patient and his/her family or friends if they are there. Through this magical encounter, the clown aims to arouse emotions within the patient and his/her friends and family. Before beginning the session the clowns offer their services but never impose them. They require tacit or verbal agreement from the patient.

In order to achieve this, the clowns go in to meet the patient in a different way, full of active presence, inviting transformation and diversion. They allow their interlocutors to reconnect to that creative part of a person that stimulates self-renewal[32]. This meeting involves an improvised role-play game, a game of make-believe, choosing one's own reality, acting on it, inventing and pushing the limits of the unacceptable to be free of one's bodily restrictions.

The clown is an imaginary character, both in body and voice. Far removed from the circus clown stereotypes, the clown is a naïve, spontaneous character, always attentive to emotions and imagination and there are no limits to his/her field of intervention. He/she is cheerful, sometimes even joyful, with a great sense of humor, open to all patients and willing to listen, full of empathy.

This study has allowed us to consider, as clearly reported in the French and international literature[33][34],that the intervention by clown doctors in a palliative care unit leads to an improvement in the quality of patient life.

This experiment, with its in-depth analysis, goes even further by envisaging the clown therapists' intervention as a true catalyzer, leading to a significantly greater physical quality of patient life.

It also allows us to reflect upon the implementation of such a scheme, the practical arrangements for running it and integrating it into a coherent care project, driven by a multi-professional team.

A significant evolution in the experience, emotional aspects and positioning of the healthcare team has come to light. Although the team was initially rather on the defensive, even reluctant, due to the type of intervention at the palliative care unit at Nîmes University Hospital and the originality of this project, they soon adapted and integrated it in a rather positive way with a surprisingly constructive drive. The clown care interventions were described by the team as a "wonderful experience", a "breath of fresh air for everybody", a time when "everything seemed to stand still". Indeed, the clowns' visits soon became a time for imagination, albeit within the confines of the patient's room.

For the nurses at the palliative care unit, clown care interventions may be perceived as an added complication to their already demanding jobs [35]. For clown care to function correctly, the whole team must accept the project and develop inter-professional collaborative skills [36][37] integrating the clowns' visits into a coherent, organized program focused solely on the patient. Cooperation based on trust must be established and the task cannot simply be conceived as "*getting a stranger to go in*". It is a complex, difficult approach, in which all the protagonists must be attentive to one another and the patient's symptoms must be evaluated at all times in order to adapt to them. The essential stages for successfully carrying out such a project are: building up a relationship, getting to know each other and respecting the functioning of the department.

As observed by Auerbach et al in 2016 [38] and Wild et al in 2007 [39], the auxiliary nurses at our palliative care unit tend to favor the originality of this approach, which completes the healthcare package offered to patients. It is a creative approach which helps the patients relax [7]. Clown therapists are considered as third party outsiders bringing joy, an interlude, an aside from day-to-day life and a break from the daily care routine. The heavy-light contradiction embodied by the clowns helps to break the ice and preserve a form of gaiety, even in the most tragic of situations. Clowns are borderline characters walking the tightrope between laughter and tears. They are characters full of contradictions, capable of breaking the rules and changing people's way of seeing things [40]. They are good listeners when patients need to talk, can help the patients and their friends or family members express themselves and accompany the patient on the imaginary journey to "the other side"[41]. When the clowns enter the patient's room, the patient and his/her friends and family show a certain surprise and their visit is perceived as an unexpected bonus in the healthcare package provided.

# Conclusions

From our experience, however, these clown care interventions do have a real impact on the patient's clinical condition and we believe that the intervention time should be adapted to avoid tiring patients further. Collaboration among the healthcare team members is once again primordial and if we are to set up durable clown care interventions, a proper strategy must be defined.

According to the patients' wishes, the most appropriate setting for these clown care interventions would appear to be in the patient's room. A special time-slot should be set aside and a particular context created for this "imagination time", outside the normal care routine and volunteer visits, in order for the patient to be able to fully appreciate it. The targeted audience must be clearly identified and the staff needs to define the organization of clown care around the other forms of care in the department. Indeed, as the family and friends of the patients we questioned emphasized, with the constant need for the hierarchical grading of healthcare, in which the idea of such interventions has always remained in the background, how can we combine the need for specific care, especially major treatment, and the fundamental requirements of spontaneity that this type of intervention requires ? Further studies would be required to answer these questions.

Finally, both the qualitative and quantitative analyses of our study clearly indicate that clown care is perfectly suitable for adult patients[42]. This leads us to question the image of clown interventions hitherto set in the collective subconscious as being reserved merely for children [43] or geriatric patients[10][34][44].

# Declarations

## Acknowledgements

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## Author information: NA

## Competing interests

The authors declare that they have no competing interests in this study

## Authors' contributions

SB was responsible for the study design and final manuscript. LH designed the study, collected the data, wrote the manuscript and validated the final manuscript. SA performed the data analysis. TS and MG revised the manuscript. PF-P oversaw the study design and devised the methodology. All authors have read and approved the final manuscript.

## Other information

This research was recorded on Clinical Trials on July 27<sup>th</sup>, 2017 under the reference no. NCT02610452.

All data to support the findings of this study are available from the corresponding author, L.H., upon reasonable request.

**Ethics and Consent to Participate** : This research was registered under the following reference : IDRCB 2015-A00719-40 and approved by the local committee for the protection of persons, CPP Sud-Méditerranée III-Nîmes on November 6<sup>th</sup>, 2015 under the reference 2015.06.03.

### Consent to participate :

All authors declare ethical approval and consent to participate in this study

For this research involving human participants, informed consent to participate in the study was obtained from the participants.

All methods were performed in accordance with the relevant guidelines and regulations in accordance with the Declaration of Helsinki

**Consent for publication:** *'Not Applicable'*

### Availability of data and material:

The datasets used and/or analysed during the current study available from the corresponding author on reasonable request:

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## Figures

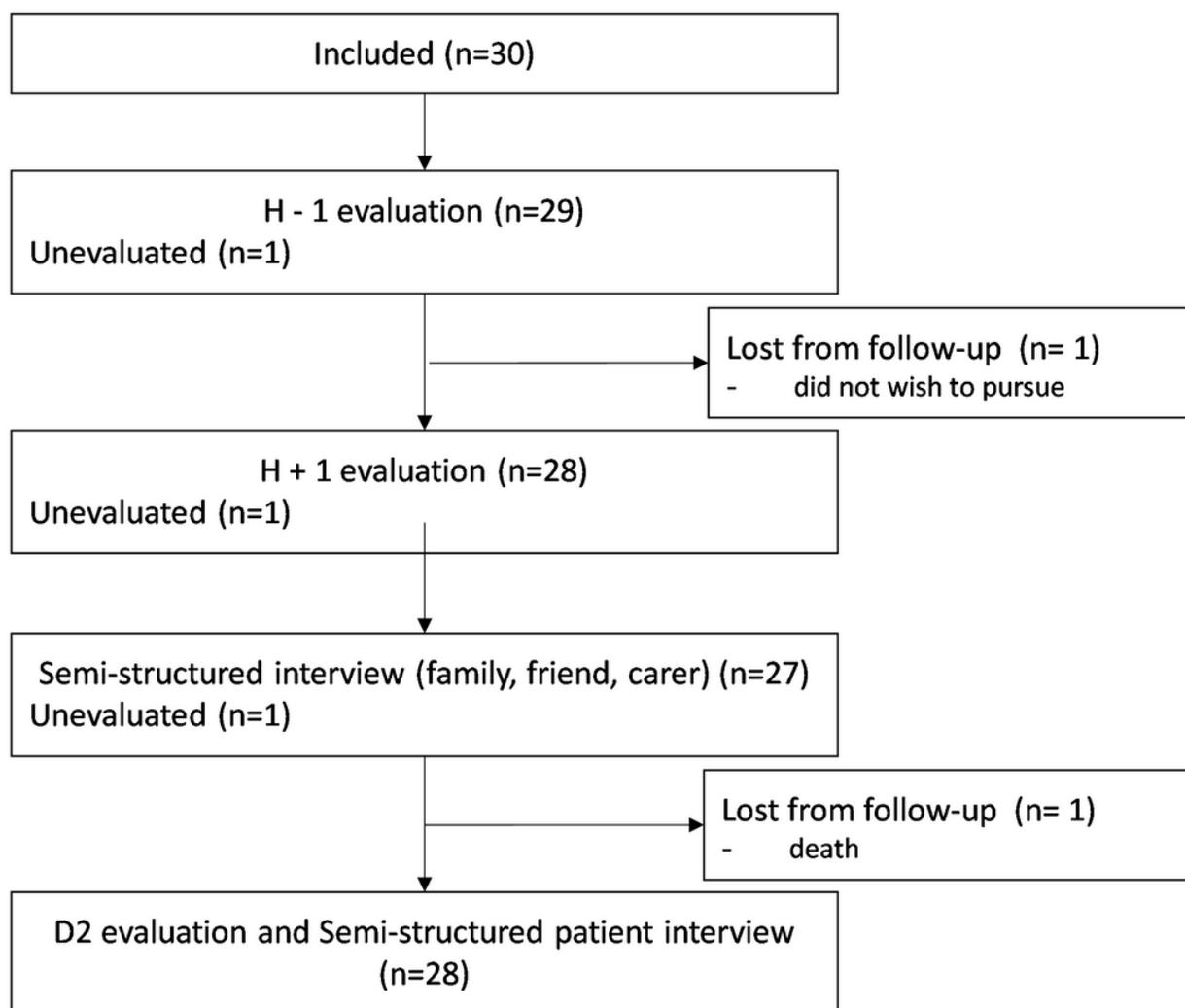


Figure 1

Flow Diagram

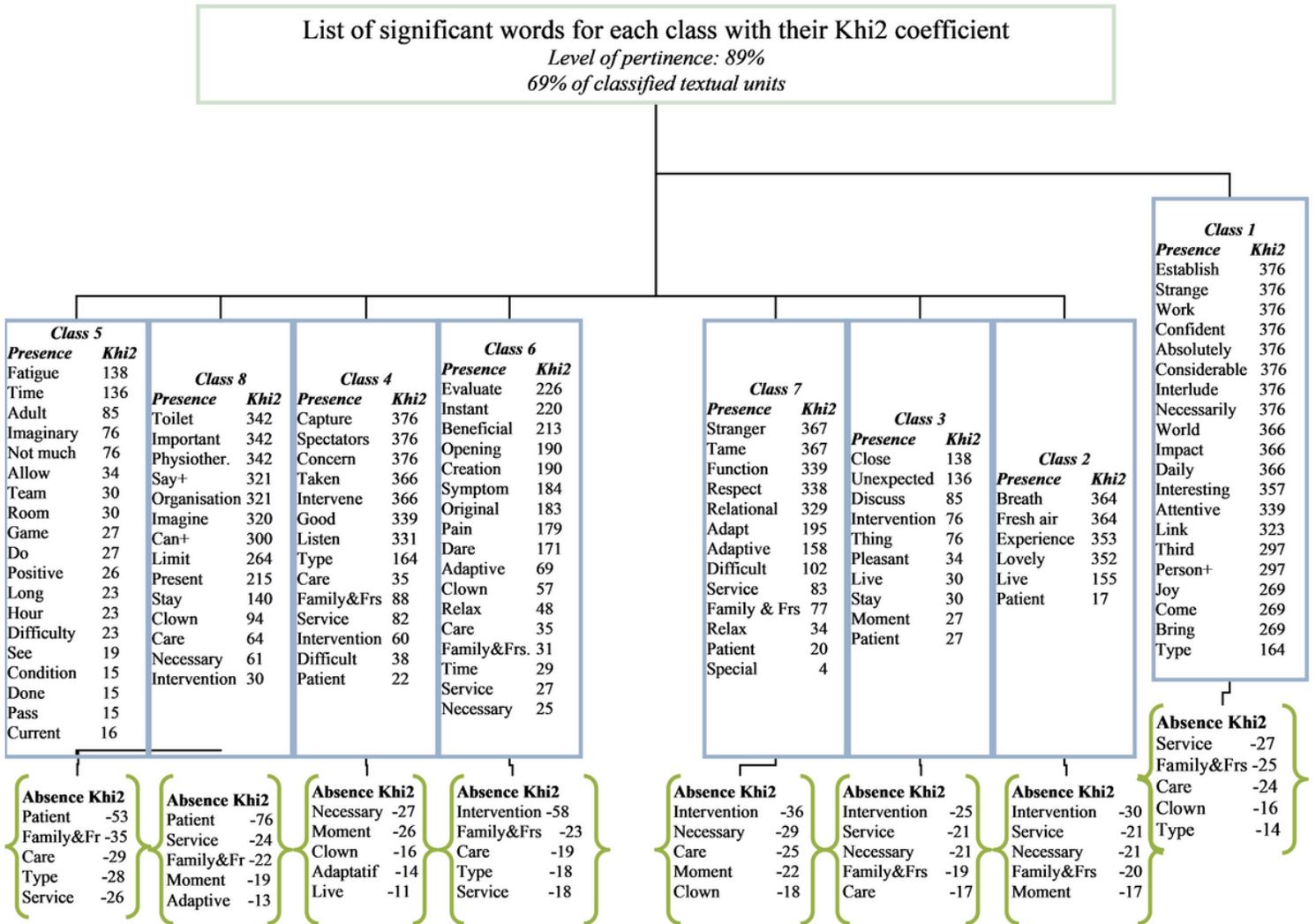


Figure 2

Alceste classification tree