ISCTE IUL
REPOSITÓRIO
INSTITUTO UNIVERSITÁRIO DE LISBOA

Repositório ISCTE-IUL

Deposited in *Repositório ISCTE-IUL*:
2020-05-21

Deposited version:
Post-print

Peer-review status of attached file:
Peer-reviewed

Citation for published item:
Arriaga, P., Melo, A. & Caires, S. (2019). The effects of hospital clowning on physical and emotional states of pediatric patients during chemotherapy treatment. Child and Youth Care Forum. N/A

Further information on publisher's website:
10.1007/s10566-019-09532-6

Publisher's copyright statement:
This is the peer reviewed version of the following article: Arriaga, P., Melo, A. & Caires, S. (2019). The effects of hospital clowning on physical and emotional states of pediatric patients during chemotherapy treatment. Child and Youth Care Forum. N/A, which has been published in final form at https://dx.doi.org/10.1007/s10566-019-09532-6. This article may be used for non-commercial purposes in accordance with the Publisher's Terms and Conditions for self-archiving.

Use policy

Creative Commons CC BY 4.0
The full-text may be used and/or reproduced, and given to third parties in any format or medium, without prior permission or charge, for personal research or study, educational, or not-for-profit purposes provided that:

- a full bibliographic reference is made to the original source
- a link is made to the metadata record in the Repository
- the full-text is not changed in any way

The full-text must not be sold in any format or medium without the formal permission of the copyright holders.

Serviços de Informação e Documentação, Instituto Universitário de Lisboa (ISCTE-IUL)
Av. das Forças Armadas, Edifício II, 1649-026 Lisboa Portugal
Phone: +(351) 217 903 024 | e-mail: administrador.repositorio@iscte-iul.pt
https://repositorio.iscte-iul.pt

Child & Youth Care Forum
https://doi.org/10.1007/s10566-019-09532-6

ORIGINAL PAPER

The Effects of Hospital Clowning on Physical and Emotional States of Pediatric Patients During Chemotherapy Treatment

Patrícia Arriaga[1] · **Ana Sofia Melo**[2,3] · **Susana Caires**[2]

© Springer Science+Business Media, LLC, part of Springer Nature 2019

Abstract

Background Pediatric cancer treatments interfere with the patient's life on physical, psychological, and social levels. Hospital Clowns (HCs) use nonpharmacological techniques to reduce the distress that hospital treatments can cause and increase children's wellbeing, but few studies have analyzed their effects.

Objective This study examined the HC effects on the physical and emotional responses of pediatric patients during ambulatory chemotherapy. Given the variability in patients' adjustments to cancer treatment, the role of a child's age and temperament, and caregiver anxiety was considered in explaining the responses over and beyond the HC effects on patient outcomes.

Method Following a quasi-experimental design, 82 pediatric patients were assigned to one of two conditions: HC intervention versus control group (CG) in two separate trials. Pediatric patients self-reported of physical symptoms (pain, nausea, and fatigue) and emotional states (distress, happiness, and calm) were measured at baseline and post-chemotherapy in both trials. Caregivers provided information on children's temperament and reported their own anxiety. Marginal Multilevel Modeling was used to examine the effects of the HC interventions on the outcomes by controlling caregiver anxiety, and child age and emotionality.

Results Compared to the CG, patients receiving the HC visit during chemotherapy reported higher levels of calm and happiness, and less fatigue, pain, and distress. HCs did not affect nausea.

Conclusions This study showed the importance of HCs as agents of supportive pediatric care, whose short-term effects during ambulatory chemotherapy seem to contribute to increasing the well-being of pediatric patients.

Keywords Pediatric · Chemotherapy · Distress · Hospital Clowns

✉ Patrícia Arriaga
patricia.arriaga@iscte-iul.pt

Extended author information available on the last page of the article

Published online: 01 November 2019

Background

Cancer is a cause of death in pediatric patients, although survival rates have improved substantially, mainly due to more effective treatments like chemotherapy (Noone et al. 2018). However, these advances have their own costs, interfering in patients' life at physical, psychological, and social levels, affecting the recovery process and long-term functioning (Miller et al. 2011). Although most patients adapt well to the disease, patients and relatives face difficult challenges, and can develop social and emotional problems (Van Schoors et al. 2017; Von Essen et al. 2000). Physical symptoms such as nausea, pain, and fatigue are commonly related to chemotherapy which have implications for therapeutic adherence and recovery (Miller et al. 2011). Major predictors of psychological functioning include factors associated with the disease and treatment, but also related to individual differences (e.g. age, temperament) (Howard Sharp et al. 2015) and to the interpersonal and emotional support they receive from health care professionals, friends and family (Zebrack et al. 2010).

Holistic approaches, based on biopsychosocial models, are being sought to facilitate patient adaptation to cancer management by considering the interactions between biological and sociopsychological factors (Hildenbrand et al. 2011). The ideal approach is effective while being minimally invasive for the patient, which usually requires multidisciplinary pharmacological and nonpharmacological interventions and techniques. For example, to reduce physical nausea symptoms many patients are often prescribed antiemetic treatment. Analgesia can be used to reduce pain, although it can also have negative side effects such as fatigue and nausea, and therefore it is prescribed only in extreme cases (McCulloch et al. 2014). Regarding the complemented nonpharmacological techniques, several have been tested (Landier and Tse 2010). For example, play seems to facilitate children's engagement in medical care (Stenman et al. 2019), distraction, imagery, and the use of music all seem also to be useful complementary techniques to help children cope with more intrusive and painful cancer treatments (Landier and Tse 2010; Thrane 2013). Several of these techniques are used in combination by Hospital Clowns (HCs), whose main goal is to increase the well-being of all individuals with whom they interact at the hospital. Thus, in the present study, our aim was to examine their effects on pediatric patients undergoing outpatient chemotherapy.

HCs are professional artistic performers that try to develop warm interpersonal relations with patients, caregivers, and medical staff, and create a positive atmosphere at the Hospital, through play and laughter (Spitzer 2006). Most common techniques they use to facilitate the interaction and capture patient's attention are humor and improvisation, which also aims to distract them from the negative impact of stressors and enhance positive emotions (Auerbach 2017; Martin 2006; Spitzer 2006; Sridharan and Sivaramakrishnan 2016). Several theories have been developed to explain the role of humor and laughter in helping individuals cope with stress, including earlier arousal theories (e.g. Energy-Release, Tension-Relief), and more recently Humor-Reversal theory which consider humor as a playful activity and, as such, can be used to challenge negative circumstances instead of regarding them as serious threats. In addition, humor may reframe the stressors by diminishing their initial negative impact (for a review see Martin 2006).

HC's intervention targets a broader age range of patients, from infants to the elderly (Kontos et al. 2017), a variety of health services and units, and different domains of intervention. The impact of HCs during surgery and intensive care has been most frequently studied in pediatric samples. Studies in these conditions have shown promising findings,

such as a decrease in the negative impact of hospitalization and surgery experience, mostly in the anxiety of pediatric patients but also on caregiver's anxiety (e.g. Agostini et al. 2014; Arriaga and Pacheco 2016; Dionigi et al. 2014; Fernandes and Arriaga 2010; Vagnoli et al. 2005). These findings have also been highlighted in three meta-analyses based on randomized controlled trials (Könsgen et al. 2019; Sridharan and Sivaramakrishnan 2016; Zhang et al. 2017). Other empirical studies have evaluated the HC impact during the administration of invasive medical procedures and potentially anxiety-provoking procedures, such as skin allergy tests (Goldberg et al. 2014), venipuncture (e.g. Kristensen et al. 2019a), intravenous catheter insertion (Wolyniez et al. 2013), injections of botulinum toxin (e.g. Ben-Pazi et al. 2017; Hansen et al. 2011), or other recurrent hospitalizations requiring repeated painful procedures (Kristensen et al. 2019b). Overall, these studies also suggest that HC interventions are valuable in relieving the pain and emotional distress in children undergoing painful and stressful procedures. A more recent meta-analysis focusing on the broader effects of HC undergoing potentially anxiety-inducing procedures has also reported their effectiveness on children's anxiety during medical procedures (Könsgen et al. 2019).

Despite the favorable results of HC's intervention with pediatric populations, less research has been conducted with other procedures such as cancer treatment. To our knowledge, there are only three studies in this area: two reported in conference proceedings (Petrangeli et al. 2012; Gorfinkle et al. 1998) and one pilot study (Lopes-Júnior et al. 2018). Petrangeli et al. (2012) indicated that HCs reduced fatigue in patients aged 7–18 years undergoing chemotherapy, whereas Gorfinkle et al. (1998) found no effects from HC presence on distress among 3–18 years old patients. Finally, Lopes-Júnior et al. (2018) study included only six inpatients aged 6–15 years old and found no changes in cortisol, psychological stress or fatigue levels following HC interventions.

To overcome the limitations of the above studies, our study examined the effects of HCs on the physical and emotional states of pediatric patients undergoing outpatient chemotherapy in a larger sample. Moreover, to also evaluate the consistency of HC interventions, we implemented a Balaam's design (Balaam 1968). This design is an extension of a crossover design in which data from different group treatments are recruited with two phases, providing information about the within-patient variability and increasing precision in the group comparison. In our study, the HC group was compared to a Control Group (CG), and data were collected in two separate trials (T1 and T2). Using this design, pediatric participants were assigned to one of four groups sequences: HC(T1)–HC(T2), CG(T1)–CG(T2), HC(T1)–CG(T2), and CG(T1)–HC (T2).

Given that initial emotional and physical states can predispose patients to respond differently to chemotherapy and to the HCs, pre-posttest assessments were also collected at both trials. Based on evidence showing the positive effects of HCs, we expected that patients exposed to the HC intervention during the outpatient chemotherapy session would report less physical symptoms, less distress, happier and calmer states than patients who did not receive the HC visit in both trials (control group).

Taking into account the high variability in patients' adjustments to cancer (Miller et al. 2009), we considered the role of individual factors (child age and temperament) and caregiver anxiety in explaining the responses over and beyond the HC effects on patient outcomes. A systematic review has reported that pediatric age was one major variable considered in studies on oncology treatment adherence (Goh et al. 2017), but concluded that more research is required to understand its role on adherence to treatment. Although children tend to more readily show their emotional discomfort (Mavrides and Pao 2014), adolescents tend to suppress their emotions and may exhibit more behavioral control (Lebaron

et al. 1988), especially in the presence of peers or strangers (Kestler and LoBiondo-Wood 2012). Temperament has been linked to anxiety and depression in children with cancer (Miller et al. 2009), although few studies have tested the role of temperament on other physical and emotional states of patients with cancer. Because dispositional emotionality, in particular, has been related to worries about treatment (Fernandes et al. 2014), this variable was included. Finally, studies have consistently found a positive relationship between caregivers' anxiety and the level of distress and worry that children experience with different procedures and medical interventions (e.g., Brown et al. 2018; Fernandes and Arriaga 2010). Longitudinal studies have also found moderate-to-strong agreement between the caregiver's and the child's own evaluations of emotional functioning during cancer treatment (Parsons et al. 2012). Thus, we also accounted for caregiver anxiety because we expected a positive link between caregiver anxiety and the child's rating of emotional distress and arousal.

Method

Participants, Recruitment, and Procedures

Conforming to the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments, the Ethical committees of the three hospitals involved in this study approved the study: Lisbon IPO Francisco Gentil [UIC/781, No.164/13], Oporto IPO [CES-IPO:203/013], and Oporto S. João Hospital Center [CES-HSJ:26/09/2012].

Inclusion criteria included children 8–15 years old undergoing outpatient chemotherapy. These inclusion criteria were based on the typical socio-cognitive development of participants within this age range. School-age children with more than 7 years of age are already capable of evaluating and reporting their symptoms and emotions (e.g. Fernandes et al. 2014). In addition, we included adolescents but restricted their age to 15 years in order to gather a more homogeneous sample.

Exclusion criteria were patients scheduled for their first or last chemotherapy session; receiving chemotherapy orally or via lumbar puncture; and presenting with any cognitive or language impairment that would prevent their understanding of the assessment.

To estimate sample size, we considered the effect sizes reported by a meta-analysis of emotional expression (Morgan and Case 2013) with similar psychological well-being outcomes (Cohen's $d = 0.66$, $f = .33$) and made a priori estimations using GPower 3.1. Firstly, by selecting analyses of covariance with three between-factors and four covariates, setting statistical power = .80, $\alpha = .05$, and $f = .33$, we obtained a recommendation of 92 participants. Secondly, we considered the same parameters for repeated measures, and added two trials with moderate estimates of correlations between trials (.40) since the outcomes in our study reflect temporary states. The sample estimate for this analysis with the repeated trials was 66 participants. Based on these two estimates, we selected the maximum number of pediatric patients within this size range, during a period of 2 years, and collected a total of 82 eligible participants.

The health professionals present on the days of data collection selected the patients and later provided the clinical information. After selection, caregivers provided written informed consent and pediatric patients gave verbal assent. Adherence was 100%. Participants were told that they were going to participate in an evaluation of how pediatric patients were feeling before and after the chemotherapy treatment.

The procedures involved two trials with an interval of at least 1 week. A quasi-experimental methodology was employed because the inclusion of patients in the HC group was depended on the coincidence of the chemotherapy treatment with the day and time of previously scheduled HC visits. In each trial, participants were assigned to one of two conditions: HC intervention during the chemotherapy or just chemotherapy (Control Group, CG). The procedures were the same in all the Hospitals involved. In each Hospital, the chemotherapy treatment was applied in a pediatric room. The data collection (pre and post-test) was conducted similarly in each hospital in one of the available rooms that provided the privacy required, either in a doctoral room or in a private space of a pediatric waiting room. The caregivers provided sociodemographic data, patient temperament, and caregiver anxiety. Pediatric patients provided their physical and emotions responses at baseline and after the chemotherapy session. A total of 82 eligible participants were enrolled in T1, and 73 in T2. The retention rate was strong (89%), with only nine patients not enrolled in T2 due to changes in the days of treatment or in clinical conditions. The interval between the two trials was on average 21.45 days and the time between the scales administration in each trial was on average 219.65 min.

Intervention

According to the number of times patients received the HC intervention, three groups were formed: (1) no HC visit (CG) ($n=28$); (2) one HC visit, either in T1 or T2 (HC1 group) ($n=33$); and (3) HC visit in both trials (HC2 group) ($n=20$).

The HCs who collaborated are professionals with specialized training to work with children in hospitals. They worked in pairs, dressed in simple and colorful costumes. Although HCs prepare sketches in advance, their interventions were largely dependent on the dynamic interaction with all individuals present at the time of the intervention.

Measures

Sociodemographic data included caregiver and child gender, age, level of education, nationality, previous contacts with HCs. *Clinical information* included diagnosis (disease, year of onset, relapse), chemotherapeutic treatment (type and administration method) and procedures (antiemetic and/or analgesic).

Patient temperament was assessed by the caregivers using the Emotionality, Activity and Sociability Temperament Survey for Children: Parental Ratings (EAS-P) (Buss and Plomin 1984). The EAS-P is a 20 items survey that was originally developed to filled out by parents to evaluate children's temperaments ranging in age from 1 to 9 years (Buss and Plomin 1984). Other studies have expanded this age range to evaluate adolescent's temperament until 16 years old (e.g. Mazzone et al. 2006). The EAS-P has four subscales with five items each: emotionality (disposition to become easily distressed), activity (disposition to have high levels of energy), sociability (disposition to developing social interactions), and Shyness (disposition to being inhibited). Responses can vary from 1 ("not characteristic or typical") to 5 ("very characteristic or typical"). The EAS-P has been used in Portuguese hospital settings, including in a study investigating the effects of HCs on preoperative responses in children between 5 and 12 years of age, showing low but acceptable reliability estimates for emotionality ($\alpha=.78$), activity ($\alpha=0.64$), sociability ($\alpha=0.71$), and shyness ($\alpha=0.67$) (Fernandes and Arriaga 2010). Temperament was only evaluated in T1 since it is considered relatively stable. Scores for each dimension were averaged.

Caregiver Anxiety was measured with the Portuguese version of the 20-item state-anxiety subscale of the State-Trait Anxiety Inventory, Form Y (STAI -Y) (Santos and Silva 1997; Spielberger 1983). Caregivers reported how they were feeling at the time of application (pre-chemotherapy) at both trials on a 4-point scale ranging from 1 (not at all) to 4 (very much). Total scores could range from 20 to 80, with higher scores indicating a high anxiety state. Studies have demonstrated the reliability and validity of the STAI-Y in hospital settings (Fernandes et al. 2014; Fernandes and Arriaga 2010).

To evaluate the emotional and physical outcomes from the perspective of patients, we selected the response format scales with schematic faces to make it easily understood by children and adolescents. All these measures were applied in both trials, before and following chemotherapy.

Patient *nausea* was measured using the Baxter Retching Faces Scale (BARF) (Baxter et al. 2011), which presents six faces ranging from 0 (neutral face/no nausea) to 10 (face vomiting/high nausea). BARF has strong psychometric qualities (Baxter et al. 2011).

To evaluate *pain*, the Wong-Baker Faces Scale (FACES) was administrated (Wong and Baker 1988). Studies have shown strong psychometric qualities (Stinson et al. 2006), including in Portugal (Oliveira et al. 2014). The scale has six faces representing pain intensity ranging from 0 (smiling face/not hurting) to 5 (crying face/hurts the worst). To assess patients' acute *fatigue* and *emotional distress* we used the Present Functioning Visual Analogue Scales (PedsQL™ VAS) (Sherman et al. 2006). The instrument includes 6 items (fear, sadness, anger, worry, fatigue, discomfort), each with visual analog scales of 0–100 mm (0 = not feeling the target emotion; 100 = feeling the emotion very strongly). Some guidelines for adaptation were followed (Sousa and Rojjanasrirat 2011), involved two independent bilingual translators, including a health professional, and then a back-translation by a bilingual person. The PedsQL™ VAS was then evaluated by a convenience sample of 15 non-clinical Portuguese participants, between 7 and 18 years old. All these participants showed and explicitly stated having a clear understanding of the instructions, the items, and the response scale format.

To compute emotional distress, we average of responses to the fear, sadness, anger, and worry items (Sherman et al. 2006). Finally, *positive affect* and *arousal* were assessed using the Self-Assessment Mannequin (SAM) scales (Bradley and Lang 1994). Each scale has five pictorial images: valence ranges from 1 (happy/smiling) to 5 (sad/frowning figure) and arousal ranges from 1 (calm) to 5 (very nervous). Items were reverse scored so that higher scores correspond to high positive affect and calmer states, respectively. In contrast with the PedScale, which has only items ranked negatively, these scales have positive emotional extremes, allowing the assessment of two components of well-being, i.e. how happy and calm the patient was feeling (Bech et al. 2003). This instrument has been used in Portugal with pediatric patients (Fernandes and Arriaga 2010).

Statistical Analysis

IBM SPSS V24 software was used in all analyses. We computed the coefficient alpha for estimating the internal consistency of the measures with several items, and Person correlation coefficients to evaluate test–retest reliability. Chi-square test, *t*-tests, and multivariate analysis of variance compared the groups at baseline (T1). Pre-treatment scores of the outcomes were collected in both trials to control for individual differences at the baseline, reduce the error variance, and increase the precision of the measures (Dimitrov and Rumrill 2003). In addition, Marginal Multilevel Models using Maximum Likelihood estimation

examined the HC effects on patient outcomes, allowing the inclusion of all eligible participants. To select the covariate structure with a better fit, the likelihood ratio test analyzed the differences in deviance. For each outcome, three models were estimated. The first was the unconditional model (no predictors), used to select the covariate structure. Then, two conditional models were tested: Model 1 compared the groups on the outcomes, using the pretest scores as a covariate (Dimitrov and Rumrill 2003); Model 2 added three covariates: child age and emotionality plus caregiver anxiety. We used the Satterthwaite correction for calculating the degrees of freedom, $\alpha < .05$ (2-sided), and Cohen's d to estimate the effect sizes, relying on Cohen's suggestions (Cohen 1988) that $d \geq 0.8$ are "large", 0.5–0.8 are "moderate", and $d \leq 0.5$ are "small" effect sizes.

Results

Descriptive Data

The flow diagram of participants is presented in Fig. 1 and Table 1 presents the sample description.

At baseline (T1), the patients' ages ranged from 8 to 15 years ($M = 11.48 \pm 2.38$ *SD*), with 45 boys and 37 girls. Almost all (97.6%) had previous contacts with HCs. Based on the International Classification of Childhood Cancer (ICC-3) (Steliarova-Foucher et al.

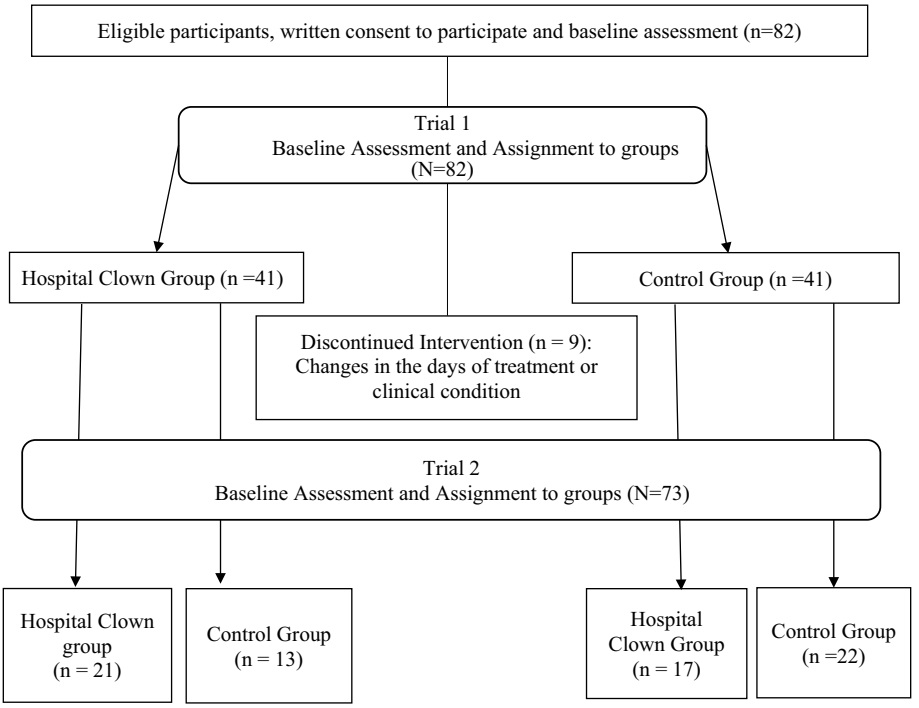

Fig. 1 Flow diagram of participants through each stage (based on the flowchart offered by the CONSORT Group)

Table 1 Sociodemographic and clinical data at baseline (trial 1)

	Total ($n=82$)		Hospital Clown ($n=41$)		Control ($n=41$)		$\chi 2$
	N	%	*N*	%	*N*	%	
Pediatric patients							
Gender							1.23
Male	45	54.9	20	24.4	25	30.5	
Female	37	45.1	21	25.6	16	19.5	
Nacionality							2.63
Portuguese	71	86.6	33	40.2	38	46.3	
Other	11	13.4	8	9.8	3	3.7	
HC prior contact	80	97.6	41	50.0	39	47.6	2.05
Diagnosis							1.64
Leukemias, myeloproliferative and myelodysplastic	32	39	17	20	15	18.3	
CNS and miscellaneous neoplasms	21	25.6	8	7	13	15.9	
Lymphomas and reticuloendothelial neoplasms	16	19.5	9	9.8	7	8.5	
Other tumors	13	15.9	7	8.5	6	7.3	
Relapses	13	15.9	6	7.3	7	8.5	.091
Chemotheraphy							
Curative	80	97.6	40	48.8	40	48.8	
Palliative	2	2.4	1	1.2	1	1.2	
Chemotherapy administration							2.50
Intravenous	74	60.2	39	47.6	35	42.7	
Intramuscular	7	8.5	2	2.4	5	6.1	
Both	1	1.2	0	0.0	1	1.2	
Antiemetic therapy	58	70.7	32	39.0	26	31.7	2.12
Caregiver relationship							7.63*
Mother	69	84.1	30	36.6	39	47.6	
Father	11	13.4	9	11.0	2	2.4	
Sibling	2	2.4	2	2.4	0	0	
	M	*DP*	*M*	*DP*	*M*	*DP*	*t*
Age	11.48	2.38	11.56	2.29	11.39	2.50	0.32
Education	4.94	2.24	4.98	2.20	4.90	2.30	0.15
Age at diagnosis	9.77	3.41	9.68	3.51	9.85	3.34	0.23
Chemo cycles received	8.17	8.72	7.37	6.89	8.98	10.26	0.83
Temperament							1.66
Emotionality	2.66	0.92	2.72	1.01	2.61	0.82	
Activity	3.33	0.87	3.13	0.88	3.53	0.82	
Sociability	3.69	0.78	3.54	0.81	3.84	0.73	
Shyness	2.28	0.77	2.47	0.70	2.09	0.80	
Pain	0.48	0.77	0.39	0.74	0.56	0.81	1.00
Nausea	0.41	0.98	0.49	0.98	0.34	0.99	−0.67
Fatigue	16.07	24.13	14.73	21.05	17.41	27.05	0.50
Distress	15.76	13.24	15.55	11.90	15.98	14.61	0.15
Happy	2.06	0.85	1.90	0.80	2.22	0.88	1.71
Calm	2.26	0.81	2.12	0.71	2.39	0.89	1.50
Caregiver anxiety	47.29	13.95	47.71	15.18	46.88	12.77	0.27

*$p < .05$

2005), 39% were diagnosed with leukemia, myeloproliferative or myelodysplastic diseases, and 25.6% had tumors of the central nervous system (CNS) or miscellaneous neoplasms. Patient age at the time of diagnosis was an average of 10 years ($SD = 3.41$). The majority had not had relapses (84.1%), were performing curative chemotherapy (97.6%) by intravenous administration (60.2%), received antiemetic therapy (70.7%), and no patient underwent analgesia. All caregivers were family members, with the majority being the mother (84.1%). Although the groups were not fully randomized, the participants assigned to the HCs and the CGs were similar in most of their sociodemographic and clinical data ($ps > .05$), except that more mothers were in the CG than in the HC group.

Psychometric proprieties of the measures

In our study, all measures showed acceptable reliability scores. For internal consistency, the Cronbach's alpha values was very strong for the STAI-Y ($\alpha = .95$ in both trials), ranged from .70 (sociability) to .82 (emotionality) for the EAS-P, and presented low but still acceptable estimates for the emotional distress scores of the PedsQL™ VAS in both T1 ($\alpha_{baseline} = .66$; $\alpha_{post\text{-}chemotherapy} = .69$) and T2 ($\alpha_{baseline} = .69$; $\alpha_{post\text{-}chemotherapy} = .67$). The retest reliability of the STAI-Y was very high, $r(73) = .96$, $p < .001$. Retest reliability between both baseline trials were also high for the BARF scale (.71), the happy (.62) and arousal scales of the SAM (.70), the emotional distress (.62) and the fatigue scales (.60) of the PedsQL™ VAS, and moderate for the FACES scale (.43), $ps < .001$.

Effects of the Intervention

Overall, the outcomes were relatively skewed, suggesting that pediatric patients were not feeling strongly negative physical symptoms or negative emotions.

Before testing our hypothesis, we first compared different covariance structures (unstructured, autoregressive, compound symmetry) using the unconditional model (with no predictors) to analyze model fit. These three different structures were selected for comparison because we expected a moderate association between both trials for each outcome. Our results indicated that the compound symmetry structure provided a better fit. This covariance structure has also a simple structure and requires a few degrees of freedom; therefore, it was considered adequate to test our hypothesis. Then, we proceed by testing whether the conditional models, which had the HC group as the main predictor and the pretest scores as a covariate, provided a better fit than the unconditional model. The results indicated that both conditional models fitted the data better than the unconditional, using the deviance difference tests ($ps < .001$). Finally, we compared the two conditional models: Model 1 only included the HC group as a fixed effect and the pretest scores as a covariate; Model 2 also added the child's age and emotionality and the caregiver's anxiety as covariates. Table 2 displays the results for the group comparisons on each outcome for each Model. Table 3 shows the means and the effect sizes for the pairwise comparisons at the posttest.

Overall, a comparison between models 1 and 2 have only shown improvements in Model 2 when the outcomes were pain, $\chi^2(3) = 13.46$, $p = .004$, and distress, $\chi^2(3) = 8.69$, $p = .034$. As can be seen in Table 2, the groups receiving the HC visit reported low levels of pain, fatigue, and distress, after adjusting for the covariates in both conditional

Table 2 Results of physical and emotional responses comparing the hospital clowns interventions with the control group, adjusting for pretest in Model 1, and adjusting for pretest, child's age and emotionality, and caregiver anxiety, in Model 2

	Model 1		Model 2		Model 1		Model 2		Model 1		Model 2	
	Nausea				Pain				Fatigue			
Fixed effects	*F*	*B*	*F*	*B*	*F*	*B*	*F*	*B*	*F*	*B*	*F*	*B*
Intercept	4.38***	0.33***	0.17	−0.01	25.71***	0.53***	6.51*	−0.43	26.57***	13.83***	0.04	5.06
Groups	1.79		1.75		9.79***		12.32***		7.18**		7.66***	
[HC2 vs. CG]		−0.30 (0.17)		−0.29 (0.17)		−0.47*** (0.11)		−0.49*** (0.10)		−10.80*** (3.11)		−10.96*** (3.10)
[HC1 vs. CG]		−0.24 (0.16)		−0.23 (0.16)		−0.33** (0.10)		−0.32*** (0.09)		−8.66** (2.81)		−9.12** (2.83)
Pretest	42.01***	0.44***	42.00***	0.44***	39.94***	0.39***	44.74***	0.39***	183.21***	0.76***	163.52***	0.74***
Age			0.16	0.01			4.13*	0.04*			1.73	0.71
Emotionality			2.12	0.11			9.42**	0.14**			0.73	1.17
Caregiver anxiety			0.13	−0.002			1.53	0.004			0.21	−0.04
	Model 1		Model 2		Model 1		Model 2		Model 1		Model 2	
	Distress				Happy				Calm			
Fixed effects	*F*	*B*	*F*	*B*	*F*	*B*	*F*	*B*	*F*	*B*	*F*	*B*
Intercept	0.32	2.78*	6.63*	−7.47	163.62***	0.94***	30.09***	1.39***	223.24***	1.55***	38.51***	2.08***
Groups	4.25*		5.63**		26.75***		28.93***		16.70***		18.05***	
[HC2 vs. CG]		−4.43** (1.52)		−4.81** (1.45)		0.74*** (0.10)		0.76*** (0.32)		0.64*** (0.12)		0.64*** (0.11)

Table 2 (continued)

	Model 1		Model 2		Model 1		Model 2		Model 1		Model 2	
	Distress				Happy				Calm			
Fixed effects	*F*	*B*	*F*	*B*	*F*	*B*	*F*	*B*	*F*	*B*	*F*	*B*
[HC1 vs. CG]		−2.30 (1.38)		−2.76* (1.31)		0.42*** (0.09)		0.44*** (0.10)		0.49*** (0.11)		0.51*** (0.11)
Pretest	193.65***	0.65***	157.79***	0.60***	139.92**	0.58**	122.83***	0.56***	16.70***	0.34***	29.02***	0.34***
Age			8.38**	0.73*			3.11	−0.03			4.31*	−0.04*
Emotionality			0.92	0.61			0.01	.004			1.09	−0.06
Caregiver's anxiety			0.40	0.03			0.34	−0.02			0.23	0.002

Groups (categorial variable with 3 levels): HC2, group with the Hospital Clown visit in two Trials; HC1, group with the Hospital Clown visit in only one trial; CG, control group, the reference group in the analyses with no Hospital Clown visit; In both models Groups was the predictor. Model 1 covariates, pretest scores; Model 2 covariates, pretest scores, child's age and emotionality, and caregiver anxiety

*$p < .05$; **$p < .01$; ***$p < .001$

Table 3 Means (standard errors) and effect sizes for the outcomes after the chemotherapy (posttest), adjusting for pretest, child age and emotionality, and caregiver anxiety (Model 2)

	HC2 (n = 21) *M* (*SE*)	HC1 (n = 33) *M* (*SE*)	CG (n = 28) *M* (*SE*)	Comparison	*p*	*d*
Nausea	0.22 (0.13)	0.28 (0.11)	0.52 (0.12)	HC2 versus CG	.09	0.50
				HC1 versus CG	.14	0.39
Pain	0.21 (0.08)	0.39 (0.06)	0.70 (0.07)	HC2 versus CG	< .001	1.36
				HC1 versus CG	< .001	0.88
Fatigue	13.45 (2.28)	15.29 (1.87)	24.41 (2.09)	HC2 versus CG	< .001	1.04
				HC1 versus CG	.002	0.85
Distress	8.37 (1.07)	10.42 (0.87)	13.18 (0.97)	HC2 versus CG	.001	0.98
				HC1 versus CG	.039	0.55
Happy	2.83 (0.07)	2.51 (0.06)	2.07 (0.07)	HC2 versus CG	< .001	2.22
				HC1 versus CG	< .001	1.25
				HC2 versus HC1	.002	0.97
Calm	2.92 (0.09)	2.79 (0.07)	2.28 (0.08)	HC2 versus CG	< .001	1.56
				HC1 versus CG	< .001	1.26

HC2, group with the Hospital Clown visit in two trials; HC1, group with the Hospital Clown visit in only one trial; CG, control group

models. Additionally, the patients in the HC group reported higher levels of happy and calm feelings compared to the CG (*ps* < .05), with higher effect sizes for patients in HC2 than in HC1. The happy affect was also higher in HC2 than HC1, $p = .002$. For nausea, the HC interventions had no effect. Regarding the covariates, besides the positive association between pre-posttest scores on all the outcomes (*ps* < .001), the following predictors remained significant after adjusting for the Groups and the other covariates in Model 2: Higher emotionality [$B = 0.14$, $SE = 0.05$, $p = .003$] and increased age [$B = 0.04$, $SE = 0.02$, $p = .046$] were associated with high reports of pain; increased child age predicted more distress [$B = 0.73$, $SE = 0.25$, $p = .005$] and calmer states [$B = -0.04$, $SE = 0.02$, $p = .041$]. For the other variables, the covariates in Model 2 were not statistically significant.

Discussion and Conclusions

This study examined the effects of HC interventions on physical and emotional states of pediatric patients submitted to outpatient chemotherapy with data being collected in two separate trials, including pre-post assessment. The inclusion of these measures was based on the principles of the biopsychosocial model which highlight the need to consider the interaction of biological, psychological and social factors to approach illness.

Overall, pediatric patients submitted to outpatient chemotherapy reported low levels of negative physical symptoms and negative emotions, a result in line with studies indicating that most patients adjust well to the disease and treatment (Van Schoors et al. 2017; Von Essen et al. 2000). Nevertheless, except for nausea, we found positive effects of the HC interventions from at least one session on physical (lower pain and fatigue) and emotional states (lower stress, more calm and happy feelings) of pediatric patients. Moreover, these positive effects of the HCs were higher in patients receiving an HC visit during both

sessions, indicating that their intervention may extend beyond the short-term effect of a single session. These results agree with studies that have examined HC effects with other samples of pediatric patients in different clinical conditions (e.g., Könsgen et al. 2019; Sridharan and Sivaramakrishnan 2016; Zhang et al. 2017).

Data also showed that older patients reported more pain, more emotional distress and less calm, over and above the HC effect. Although this result contrasts with studies showing that children may exhibit more distress during cancer treatment than adolescents (Mavrides and Pao 2014), it has been highlighted that adolescents may suppress emotions and suffer in silence (Lebaron et al. 1988). Therefore, self-report measures have the advantage of allowing older participants to express emotions and symptoms in a more concealed way. Additionally, emotionality was a predictor of reports of more pain, indicating the importance of temperament to understand patient symptoms, but the caregiver's anxiety was not a predictor of our outcome variables, after adjusting for the other factors that were included in the model.

Some limitations should be also discussed. The first is the use of a convenience sample, although most patients were from the main reference hospitals for the treatment of pediatric cancer. Nevertheless, increase data from different hospitals will be important for future studies. Secondly, the inclusion criteria allowed for a wide age range, different clinical data (e.g. diagnosis) and treatment processes (e.g. duration). Different socio-cognitive skills of children and adolescents may also have implications for their understanding of the disease and treatment, and their ability to verbalize their experiences (Kestler and LoBiondo-Wood 2012). Also, adolescents might have a more distant and skeptical attitude towards HCs than children (Linge 2012). These differences could have affected their responses to the chemotherapy treatment and to the HCs. Future studies should examine the effects of HCs among patients more homogeneous concerning sociodemographic, diagnosis, and treatment protocols. Third, the measurements were exclusively subjective. In the future, complimenting survey responses with biophysiological markers should allow for better differentiation of the constructs. Fourth, a full randomization of the HCs was not feasible, which limits causal inferences. However, the quasi-experimental design has the advantage of including intact groups, not disrupting the hospital routines or the regular HC intervention at the hospitals, therefore improving the external validity of the study (Dimitrov and Rumrill 2003). Fifth, this study cannot provide insight into the specific role of how the variation of the HC techniques could affect the outcomes. Was it the humor, the distraction, the social bond created, or the combination of all these techniques that contributed to better outcomes? Future studies could include comparison groups to evaluate different HC techniques. For example, Liguori et al. (2016) developed a 6-minute video with two HCs making jokes in a playful way while providing information about the situations and objects that children will encounter in an operating room. This video was incorporated in an application (app) for tablets and mobile devices to be used by children undergoing elective surgical procedures. The effects of this app were compared to a standard informative session about surgical procedures. Although the authors have not compared the app to the real physical presence of HCs, their results indicated that the HC humor displayed in an app combined with preoperative information was more effective in reducing preoperative anxiety than a standard informative session. These results are relevant given that HCs are not always present in the Hospital. This type of material could also be developed and tested in different hospital settings with children with distinct clinical conditions, such as in an ambulatory chemotherapy setting.

Cancer-related physical symptoms and negative emotions in pediatric patients remain a serious concern in clinical practice, causing difficulties in adaptation to the disease, reducing patient's therapeutic adherence and recovery (Madi and Clinton 2018; Miller et al. 2011). Because pharmacological interventions do not seem to eliminate fully these problems,

complementary nonpharmacological approaches have been proposed. Our study suggested that HC visits promote pediatric patient well-being by reducing their experience of fatigue, pain, distress, and increasing positive emotions and calmer states. The HCs collaborating in this study already worked at the hospitals in which our sample was selected, and most patients already were familiar with their work. They are professionals working for several hospitals in different pediatric units with pediatric patients with distinct clinical conditions. Although this study has not assessed the cost-effectiveness of the HC practice, their intervention may reduce the costs often associated with cancer treatment, by lowering the patient's negative emotions and physical symptoms and increasing their well-being while they undertake the chemotherapy treatment prescribed for their condition. Nevertheless, because the research with HCs is still scarce (Lopes-Júnior et al. 2018; Petrangeli et al. 2012; Gorfinkle et al. 1998), the benefits associated with their work merits further investigation.

Acknowledgements The authors would like to express their gratitude to all participants, Nurses, to the Hospital Clowns and to Operação Nariz Vermelho who made this research possible.

Author Contributions All the authors take responsibility for the integrity of the data. The first author drafted the manuscript, performed the data analysis and takes responsibility for the accuracy of the data analysis; the second author collected the data; all authors contributed to the design of the study and to the interpretation of data.

Funding The Portuguese National Foundation for Science and Technology (FCT) funded this study through the Grants SFRH/BD/80378/2011, UID/PSI/03125/2019, and UID/CED/01661/2019.

Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical Approval All procedures were in accordance with the ethical standards of the institutional and national research committee of the three Hospitals in which the study was conducted (Lisbon IPO Francisco Gentil, UIC/781, No.164/13; Oporto IPO, CES-IPO:203/013, and Oporto S. João Hospital Center, CES-HSJ:26/09/2012) and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent Informed consent was obtained from all individual participants included in the study. Caregivers provided written informed consent and pediatric patients gave verbal assent.

References

Agostini, F., Monti, F., Neri, E., Dellabartola, S., de Pascalis, L., & Bozicevic, L. (2014). Parental anxiety and stress before pediatric anesthesia: A pilot study on the effectiveness of preoperative clown intervention. *Journal of Health Psychology, 19*(5), 587–601. https://doi.org/10.1177/1359105313475900.

Arriaga, P., & Pacheco, C. (2016). Effects of clown doctors on child and caregiver anxiety at the entrance to the surgery care unit and separation from caregivers. *International Journal of Emotional Education, 8*(1), 19–34.

Auerbach, S. (2017). Are clowns good for everyone? The influence of trait cheerfulness on emotional reactions to a hospital clown intervention. *Frontiers in Psychology, 8,* 1973. https://doi.org/10.3389/fpsyg.2017.01973.

Balaam, L. N. (1968). A two-period design with t2 experimental units. *Biometries, 24*(1), 61–73.

Baxter, A. L., Watcha, M. F., Baxter, W. V., Leong, T., & Wyatt, M. M. (2011). Development and validation of a pictorial nausea rating scale for children. *Pediatrics, 127*(6), E1542–E1549. https://doi.org/10.1542/peds.2010-1410.

Bech, P., Olsen, L. R., Kjoller, M., & Rasmussen, N. K. (2003). Measuring well-being rather than the absence of distress symptoms: A comparison of the SF-36 mental health subscale and the

WHO-Five well-being scale. *International Journal of Methods in Psychiatric Research, 12*(2), 85–91. https://doi.org/10.1002/Mpr.145.

Ben-Pazi, H., Cohen, A., Kroyzer, N., Lotem-Ophir, R., Shvili, Y., Winter, G., et al. (2017). Clown-care reduces pain in children with cerebral palsy undergoing recurrent botulinum toxin injections—A quasi-randomized controlled crossover study. *PLoS ONE, 12*(4), e0175028. https://doi.org/10.1371/journal.pone.0175028.

Bradley, M. M., & Lang, P. J. (1994). Measuring emotion: The self-assessment mannequin and the semantic differential. *Journal of Behavior Therapy and Experimental Psychiatry, 25*(1), 49–59. https://doi.org/10.1016/0005-7916(94)90063-9.

Brown, E. A., De Young, A., Kimble, R., & Kenardy, J. (2018). Review of a parent's influence on pediatric procedural distress and recovery. *Clinical Child and Family Psychology Review, 21*(2), 224–245. https://doi.org/10.1007/s1056.

Buss, A. H., & Plomin, R. (1984). *Temperament: Early developing personality traits*. Hillsdale, NJ: Lawrence Erlbaum.

Cohen, J. (1988). *Statistical power analysis for the behavioral sciences* (2nd ed.). Hillsdale, NJ: Lawrence Earlbaum Associates.

Dimitrov, D. M., & Rumrill, P. D., Jr. (2003). Pretest-posttest designs and measurement of change. *Work, 20*(2), 159–165.

Dionigi, A., Sangiorgi, D., & Flangini, R. (2014). Clown intervention to reduce preoperative anxiety in children and parents: A randomized controlled trial. *Journal of Health Psychology, 19*(3), 369–380. https://doi.org/10.1177/1359105312471567.

Fernandes, S., Arriaga, P., & Esteves, F. (2014). Providing preoperative information for children undergoing surgery: A randomized study testing different types of educational material to reduce children's preoperative worries. *Health Education Research, 29*(6), 1058–1076. https://doi.org/10.1093/her/cyu066.

Fernandes, S. C., & Arriaga, P. (2010). The effects of clown intervention on worries and emotional responses in children undergoing surgery. *Journal of Health Psychology, 15*(3), 405–415. https://doi.org/10.1177/1359105309350231.

Goh, X. T. W., Tan, Y. B., Thirumoorthy, T., & Kwan, Y. H. (2017). A systematic review of factors that influence treatment adherence in paediatric oncology patients. *Journal of Clinical Pharmacy and Therapeutics, 42*(1), 1–7. https://doi.org/10.1111/jcpt.12441.

Goldberg, A., Stauber, T., Peleg, O., Hanuka, P., Eshayek, L., & Confino-Cohen, R. (2014). Medical clowns ease anxiety and pain perceived by children undergoing allergy prick skin tests. *Allergy*, *69*(10), 1372–1379. https://doi.org/10.1111/all.12463.

Gorfinkle, K. S., Slater, J. A., Bagiella, E., Tager, F. A., & Labinsky, E. B. (1998). Child behavioral distress during invasive oncologic procedures and cardiac catheterization with the Big Apple Circus Clown Care Unit • 55. *Pediatric Research, 43*(S4), 12. https://doi.org/10.1203/00006450-199804001-00076.

Hansen, L. K., Kibaek, M., Martinussen, T., Kragh, L., & Hejl, M. (2011). Effect of a clown's presence at botulinum toxin injections in children: A randomized prospective study. *Journal of Pain Research, 4*(1), 297–300. https://doi.org/10.2147/JPR.S23199.

Hildenbrand, A. K., Clawson, K. J., Alderfer, M. A., & Marsac, M. L. (2011). Coping with pediatric cancer: Strategies employed by children and their parents to manage cancer-related stressors during treatment. *Journal of Pediatric Oncology Nursing, 28*(6), 344–354. https://doi.org/10.1177/1043454211430823.

Howard Sharp, K. M., Rowe, A. E., Russell, K., Long, A., & Phipps, S. (2015). Predictors of psychological functioning in children with cancer: Disposition and cumulative life stressors. *Psycho-Oncology, 24*(7), 779–786. https://doi.org/10.1002/pon.3643.

Kestler, S. A., & LoBiondo-Wood, G. (2012). Review of symptom experiences in children and adolescents with cancer. *Cancer Nursing, 35*(2), E31–E49. https://doi.org/10.1097/NCC.0b013e3182207a2a.

Könsgen, N., Polus, S., Rombey, T., & Pieper, D. (2019). Clowning in children undergoing potentially anxiety-provoking procedures: A systematic review and meta-analysis. *Systematic Reviews, 8*(178), 1–12. https://doi.org/10.1186/s13643-019-1095-4.

Kontos, P., Miller, K. L., Mitchell, G. J., & Stirling-Twist, J. (2017). Presence redefined: The reciprocal nature of engagement between elder-clowns and persons with dementia. *Dementia-International Journal of Social Research and Practice, 16*(1), 46–66. https://doi.org/10.1177/1471301215580895.

Kristensen, H. N., Sørensen, E. E., Stinson, J., & Haslund-Thomsen, H. (2019a). "WE do it together!" An ethnographic study of the alliance between child and hospital clown during venipunctures. *Journal of Pediatric Nursing, 46,* e77–e85. https://doi.org/10.1016/j.pedn.2019.03.013.

Kristensen, H. N., Sørensen, E. E., Stinson, J., & Haslund-Thomsen, H. (2019b). *An ongoing WE: A focused ethnographic study of the relationship between child and hospital clown during recurrent pain-related*

procedures and conditions. Paediatric and Neonatal Pain: Advance Online publication. https://doi.org/10.1002/pne2.12005.

Landier, W., & Tse, A. M. (2010). Use of complementary and alternative medical interventions for the management of procedure-related pain, anxiety, and distress in pediatric oncology: An integrative review. *Journal of Pediatric Nursing, 25*(6), 566–579. https://doi.org/10.1016/j.pedn.2010.01.009.

Lebaron, S., Zeltzer, L. K., Lebaron, C., Scott, S. E., & Zeltzer, P. M. (1988). Chemotherapy side-effects in pediatric oncology patients: Drugs, age, and sex as risk-factors. *Medical and Pediatric Oncology, 16*(4), 263–268. https://doi.org/10.1002/mpo.2950160408.

Liguori, S., Stacchini, M., Ciofi, D., Olivini, N., Bisogni, S., & Festini, F. (2016). Effectiveness of an app for reducing preoperative anxiety in children: A randomized clinical trial. *JAMA Pediatrics, 170*(8), e160533. https://doi.org/10.1001/jamapediatrics.2016.0533.

Linge, L. (2012). Magical attachment: Children in magical relations with hospital clowns. *International Journal of Qualitative Studies on Health and Well-Being, 7,* 11862. https://doi.org/10.3402/qhw.v7i0.11862.

Lopes-Júnior, L. C., Pereira-da-Silva, G., Silveira, D. S., Veronez, L. C., Santos, J. C., Alonso, J. B., et al. (2018). The effect of clown intervention on self-report and biomarker measures of stress and fatigue in pediatric osteosarcoma inpatients: A pilot study. *Integrative Cancer Therapies, 17*(3), 928–940. https://doi.org/10.1177/1534735418781725.

Madi, D., & Clinton, M. (2018). Pain and its impact on the functional ability in children treated at the Children's Cancer Center of Lebanon. *The Journal of Pediatric Nursing, 39,* e11–e20. https://doi.org/10.1016/j.pedn.2017.12.004.

Martin, R. A. (2006). *Psychology of humor: An integrative approach*. New York: Academic Press.

Mavrides, N., & Pao, M. (2014). Updates in paediatric psycho-oncology. *International Review of Psychiatry, 26*(1), 63–73. https://doi.org/10.3109/09540261.2013.870537.

Mazzone, L., Vitiello, B., Incorpora, G., & Mazzone, D. (2006). Behavioural and temperamental characteristics of children and adolescents suffering from primary headache. *Cephalalgia, 26*(2), 194–201. https://doi.org/10.1111/j.1468-2982.2005.01015.x.

McCulloch, R., Hemsley, J., & Kelly, P. (2014). Symptom management during chemotherapy. *Paediatrics and Child Health, 24*(4), 166–171. https://doi.org/10.1016/j.paed.2013.10.007.

Miller, E., Jacob, E., & Hockenberry, M. J. (2011). Nausea, pain, fatigue, and multiple symptoms in hospitalized children with cancer. *Oncology Nursing Forum, 38*(5), E382–E393. https://doi.org/10.1188/11.ONF.E382-E393.

Miller, K. S., Vannatta, K., Compas, B. E., Vasey, M., McGoron, K. D., Salley, C. G., et al. (2009). The role of coping and temperament in the adjustment of children with cancer. *Journal of Pediatric Psychology, 34*(10), 1135–1143. https://doi.org/10.1093/jpepsy/jsp037.

Morgan, T. M., & Case, L. D. (2013). Conservative sample size determination for repeated measures analysis of covariance. *Annals of Biometrics & Biostatistics, 1*(1), 1002.

Noone, A. M., Howlader, N., Krapcho, M., Miller, D., Brest, A., Yu, M., et al. (2018). *SEER Cancer Statistics Review, 1975–2015*. Bethesda, MD: National Cancer Institute.

Oliveira, A. M., Batalha, L. M. C., Fernandes, A. M., Gonçalves, J. C., & Viegas, R. G. (2014). Uma análise funcional da Wong-Baker Faces Pain Rating Scale: linearidade, discriminabilidade e amplitude [A functional analysis of the Wong-Baker Faces Pain Rating Scale: Linearity, discriminability and amplitude]. *Revista de Enfermagem Referência, IV*(3), 121–130. https://doi.org/10.12707/riv14018.

Parsons, S. K., Fairclough, D. L., Wang, J., & Hinds, P. S. (2012). Comparing longitudinal assessments of quality of life by patient and parent in newly diagnosed children with cancer: The value of both raters' perspectives. *Quality of Life Research, 21*(5), 915–923. https://doi.org/10.1007/s11136-011-9986-4.

Petrangeli, F., Sili, A., D'Agostino, F., Petrangeli, T., Cittadini, N., Antonacci, E., et al. (2012). The effects of clown intervention on fatigue in children with cancer undergoing chemotherapy. *Archives of Disease in Childhood, 97*(Suppl 2), A537. https://doi.org/10.1136/archdischild-2012-302724.1904.

Santos, D. S., & Silva, D. (1997). Adaptacão do State-Trait Anxiety Inventory (STAI)-Forma Y para a população Portuguesa [Adaptation of the State-Trait Anxiety Inventory (STAI)-Form Y for the Portuguese population]. *Revista Portuguesa de Psicologia, 32,* 85–98.

Sherman, S. A., Eisen, S., Burwinkle, T. M., & Varni, J. W. (2006). The PedsQL™ present functioning visual analogue scales: Preliminary reliability and validity. *Health and Quality of Life Outcomes, 4*(75), 1–10. https://doi.org/10.1186/1477-7525-4-75.

Sousa, V. D., & Rojjanasrirat, W. (2011). Translation, adaptation and validation of instruments or scales for use in cross-cultural health care research: a clear and user-friendly guideline. *Journal of Evaluation in Clinical Practice, 17*(2), 268–274. https://doi.org/10.1111/j.1365-2753.2010.01434.x.

Spielberger, C. (1983). *State-trait anxiety inventory: A comprehensive bibliography*. Palo Alto, CA: Consulting Psychologists Press.

Spitzer, P. (2006). Essay: Hospital clowns-modern-day court jesters at work. *The Lancet*, *368*, S34–S35. https://doi.org/10.1016/S0140-6736(06)69919-4.

Sridharan, K., & Sivaramakrishnan, G. (2016). Therapeutic clowns in pediatrics: A systematic review and meta-analysis of randomized controlled trials. *European Journal of Pediatrics, 175*(10), 1353–1360. https://doi.org/10.1007/s00431-016-2764-0.

Steliarova-Foucher, E., Stiller, C., Lacour, B., & Kaatsch, P. (2005). International classification of childhood cancer (3rd edition). *Cancer, 103*(7), 1457–1467. https://doi.org/10.1002/cncr.20910.

Stenman, K., Christofferson, J., Alderfer, M. A., Pierce, J., Kelly, C., Schifano, E., et al. (2019). Integrating play in trauma-informed care: Multidisciplinary pediatric healthcare provider perspectives. *Psychological Services, 16*(1), 7–15. https://doi.org/10.1037/ser0000294.

Stinson, J. N., Kavanagh, T., Yamada, J., Gill, N., & Stevens, B. (2006). Systematic review of the psychometric properties, interpretability and feasibility of self-report pain intensity measures for use in clinical trials in children and adolescents. *Pain, 125*(1–2), 143–157. https://doi.org/10.1016/j.pain.2006.05.006.

Thrane, S. (2013). Effectiveness of integrative modalities for pain and anxiety in children and adolescents with cancer: A systematic review. *Journal of Pediatric Oncology Nursing, 30*(6), 320–332. https://doi.org/10.1177/1043454213511538.

Vagnoli, L., Caprilli, S., Robiglio, A., & Messeri, A. (2005). Clown doctors as a treatment for preoperative anxiety in children: A randomized, prospective study. *Pediatrics, 116*(4), E563–E567. https://doi.org/10.1542/peds.2005-0466.

Van Schoors, M., Caes, L., Knoble, N. B., Goubert, L., Verhofstadt, L. L., & Alderfer, M. A. (2017). Systematic review: Associations between family functioning and child adjustment after pediatric cancer diagnosis: A meta-analysis. *Journal of Pediatric Psychology, 42*(1), 6–18. https://doi.org/10.1093/jpepsy/jsw070.

Von Essen, L., Enskar, K., Kreuger, A., Larsson, B., & Sjoden, P. O. (2000). Self-esteem, depression and anxiety among Swedish children and adolescents on and off cancer treatment. *Acta Paediatrica, 89*(2), 229–236. https://doi.org/10.1111/j.1651-2227.2000.tb01221.x.

Wolyniez, I., Rimon, A., Scolnik, D., Gruber, A., Tavor, O., Haviv, E., et al. (2013). The effect of a medical clown on pain during intravenous access in the pediatric emergency department: A randomized prospective pilot study. *Clinical Pediatrics, 52*(12), 1168–1172. https://doi.org/10.1177/0009922813502257.

Wong, D. L., & Baker, C. M. (1988). Pain in children: Comparison of assessment scales. *Pediatric Nursing, 14*(1), 9–17.

Zebrack, B., Chesler, M. A., & Kaplan, S. (2010). To foster healing among adolescents and young adults with cancer: What helps? What hurts? *Supportive Care in Cancer, 18*(1), 131–135. https://doi.org/10.1007/s00520-009-0719-y.

Zhang, Y., Yang, Y., Lau, W. Y., Garg, S., & Lao, J. (2017). Effectiveness of pre-operative clown intervention on psychological distress: A systematic review and meta-analysis. *Journal of Paediatrics and Child Health, 53*(3), 237–245. https://doi.org/10.1111/jpc.13369.

Publisher's Note Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.

Affiliations

Patrícia Arriaga[1] · Ana Sofia Melo[2,3] · Susana Caires[2]

Ana Sofia Melo
anasofiamelo@hotmail.com

Susana Caires
s.caires@sapo.pt

[1] ISCTE-Instituto Universitário de Lisboa, CIS-IUL, Avenida das Forças Armadas, 1649-026 Lisbon, Portugal

[2] Institute of Education, University of Minho, Campus de Gualtar, 4710-057 Braga, Portugal

[3] Agrupamento Escolas de Briteiros, Guimarães, Rua Manuel Pereira, n.º 9, 3D, 4710-188 Braga, Portugal