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Humor and Laughing: The Benefit of Hospital Clowns in Pediatrics for Hospitalized Children and their Families: A Review

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Abstract

Introduction: Laughter and humor have been reported as an effective way to achieve physiological and psychological health-related benefits to reduce pain and increase stress tolerance during medical evaluation and painful procedures.

Objective: This literature review examines the effect of clown intervention in reducing anxiety, pain for pediatric patients before preoperative or during invasive medical procedures and evaluate methodological points used to assess the impact of clown intervention.

Methods: The search via PubMed was conducted on publications from 2005 to 2016. All studies published in English, in French and in Spanish were included, focusing on clown therapy intervention visits for children less than 18 years present on the pediatrics services. We analyzed for each publication: population targeted, medical service categories, medical procedure, measurement tools for anxiety, pain and other clinical outcomes, data focused on methodological points including design and analysis of clinical trial, population size, sample size calculation and statistical analysis.

Results: We selected 54 studies based on title relevance. After reading their abstracts we selected 28 publications, most were randomized prospective and controlled studies (n=18, 64%). The total studies sample was distributed considering the following children age groups: from 2 to 12-year-old (n=12, 43%), from 5 to 18 year-old (n=9, 32%) and from 0 to 18 year-old (n=7, 25%). The main result showed that the impact of clown intervention had a positive effect in clown group compared with control group. 10 studies showed the positive impact on reducing children's anxiety and 7 studies on reducing parent's anxiety before surgery. 5 studies described reduced pain perception during medical invasive procedure and/or postoperative period. This review provided some empirical evidences of the effect of clown interventions on anxiety and/or pain reduction in pediatric hospitals, and demonstrated that more evidence-based studies are needed in the future.

Keywords: Clown doctors; Medical clowning; Hospital clown; Clown therapy; Therapeutic clowning; Clown intervention

Abbreviations

Scale (m-YPAS): Modified Yale Preoperative Anxiety; Scale (STAIC): State and Trait Anxiety Inventory for Children; Scale (STAI): State and Trait Anxiety Inventory; Scale(CAPS-Anxiety): Children Anxiety and Pain Scales; CSWQ: Child Surgery Worries Questionnaire; Scale (SAM): Self-assessment Mannequin Scale; EAS: Child's Temperament; Scale (FAS): Facial Affective Scale; PBH: Post-hospital Behavior Questionnaire; CCPH: Cuestionario de Conducta Post-hospitalaria; Scale FLACC: Face, Legs, Activity, Cry and Consolability; Scale (CHEOPS): Children's Hospital of Eastern Ontario Pain Scale; Score(VAS): Visual Analog; PB: Blood Pressure; EMLA: Local Anesthetic Cream (EMLA®, Astrazeneca, London, UK); CL: Child Life

Introduction

Pediatric patients are stressed by separations from their parents, strange environments, fears of painful treatments and also treatment outcome insurances [1,2]. There are several ways to reduce anxiety and pain other than premedication. Among them, laughter and humor were reported as an effective way to reduce pain, increase stress tolerance during medical evaluation and painful procedures [3,4] and were developed by several methods as clown intervention distraction. Hospital clowns use distraction methods such as magic, music and storytelling to enable children to deal with emotions (such as fear, anxiety, and boredom) they may experience while there are in the hospital.

Hospital clowns (or clown doctors) were reported to be beneficial for the pediatric patients with these stressors and to circumvent the accompanying feelings of fear, helplessness and sadness, thus supporting the healing process; they help to make a difficult situation easier, more bearable or simply offer a welcome distraction from the ward routine [4,5]. Hospital clowning was developed in 1986 in the United States by Michael Christensen from the New York-based Big

Apple Circus, and spread quickly from there throughout Europe. In 2011 the European federation of hospital clowns was founded [6].

Previous reviews reported the effects of clown hospital on anxiety and pain but there was no comprehensive review of studies methodical design which assessed benefits of hospital clowning interventions [3,7,8]. The aim of this literature review is to analyze design of the studies, relating to the benefit of hospital clown interventions for hospitalized children.

Materials and Methods

A structured literature search was conducted via PubMed, National Library of Medicine. We have included all publications focusing on clowning hospital interventions for children under 18 years in the pediatrics services that were published in English, in French, and in Spanish from 2005 to 2016. The literature search involved a combination of key words including *clowning OR clown OR clown intervention OR therapeutic clowning OR clown AND children OR clown doctors OR hospital clowning OR clown OR medical clowns OR medical clowning OR clown therapy OR clown anxiety.*

We scanned titles and abstracts and retrieved the full text of potentially relevant articles, scanned the reference lists. Disagreements were resolved by consensus discussion. The articles were then independently reviewed by 2 of the authors. For each publication included, we analyzed: population targeted, medical specialties, medical procedure, anxiety and pain measurement instruments, other clinical outcomes and data focused on methodological points: clinical trial design, definition of target population, randomization, single-blind assessment, sample size calculation and statistical analysis. We have also reported the benefit of clown intervention on anxiety and/or pain or other clinical outcomes medical procedure. Any discrepancies were resolved by consensus with a third reviewer.

Results

The search via PubMed in February 2016 produced a total of 188 potential publications. We selected 54 of them on the basis of the relevance of the title. After reading their abstracts we selected 28 publications (Figure 1) [4,5,9-34]. The majority of studies (23 studies) were published between 2010 and 2016. These studies were published in different countries (Table 1).

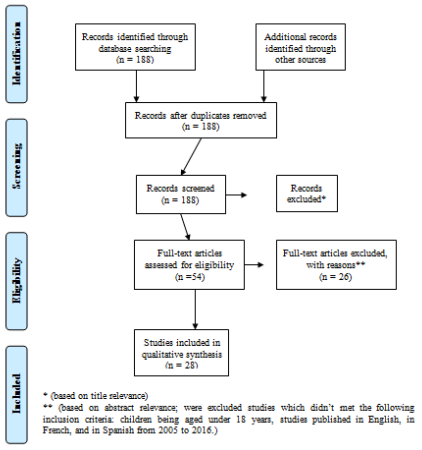

Figure 1: PRISMA 2009 flow diagram of review process and study selection.

Article	Study	Population of study	Number of group	Medical procedure	Clown Intervention	Outcome evaluation and tool	Criteria used to sample size calculation	Statistical analyses	Reduction After clown intervention	P-Value
Agostini et al. [9]	Randomized, prospective, controlled	Parents	n=50, clown group(n=25), control group (n= 25)	Anesthesia surgery	1 clown, 15 minutes Magic tricks, music, jokes, games	Anxiety (Parents) (STAI)	Anxiety 80% power, α<0.05 NSN=23×2	Multivariate mixed ANOVAs	↓level of perceived stress (Clown group) After separation: ↓Anxiety (clown group)	<0.0001; <0.0001
Bertini et al. [29]	Randomized, prospective, controlled	Children (clown group mean age = 7.71 ± 2.47 years; control group mean age = 7.54 ± 2.06 years)	n=44 (minus 1 patient for data loss); clown group (n=21); control group (n=22)	Hospitalization (pathology respiratory)	Clown: 3 hours; Magic tricks; gags, puppets, soap bubbles, games; word games	Children's clinical evolution (fever duration, hospitalization duration, time needed for healing); (Systolic BP) / (Behavioral), Pain; (Wong-Backer Scale, NRS, Cheops)	-	Univariate (ANOVA)	Clinical evolution: ↓Hospitalization duration; ↓Fever duration; ↓Time needed for healing; ↓Pain; ↓Wong-Backer Scale; ↓ NRS;↓Cheops	ns; ns; 0.03; <0.00001; 0.0001; 0.00001; 0.00001
Canto et al. [22]	Randomized,	Children (6-10 years-old)	n=60; clown group (n=30); control group (n=30)	Anesthesia surgery	Clown intervention	Children's anxiety;		Univariate	↔ Children's anxiety	ns

	prospective, controlled					(STAIC); Face scale; (CCPH)				
Dionigi et al. [12]	Randomized, prospective, controlled	Children (2-12 years-old), Parents	Children/Parents (n=77/119), clown group (n=52/89), control group (n=25/30)	Anesthesia surgery (Otolaryngology surgery)	2 clowns; 30minutes; Gags; soap bubbles; magic tricks; puppets	Children's anxiety; (m-YPAS); Parents' anxiety (STAI)	Anxiety (n =24×2), control group (n=24); clown group (n=48)	Univariate (ANOVA Spearman test)	↓preoperative children's anxiety (m-YPAS)-Parents' anxiety (STAI) ↑Mothers anxiety (control group)	0.004; ns
Felluga et al. [16]	Randomized, prospective, controlled	Children (4-11 years-old), Health professionals	n=40; clown group (n=20), control group (n=20)	Invasive medical procedure (Venous blood sampling, intravenous cannulation)	2 clowns, 20 minutes, pantomime techniques, prestidigitation, juggling and improvisation (puppets, music)	Anxiety (CAPS) (auto-evaluated); Pain (Pain Wong-Becker Scales/NRS)	Anxiety 90% power, α<.05 (≠50%) n=20×2	Univariate (Mann–Whitney U-test)	↓Anxiety (CAPS) during the medical care (clown group); ↔Pain (2 groups) Satisfaction+++	0.013; ns
Fernendes and Arriaga [10]	Randomized, prospective, controlled	Children (5-12 years-old), Parents, Health professionals	n=70, clown group (n=35), control group (n=35)	Anesthesia surgery	2 clowns, 15 minutes; Magic tricks, music, jokes, games and humor	Children: Worries/ Emotionality, (CSWQ/SAM), Temperament (EAS), Parents: Anxiety (STAI), Satisfaction of health professionals		Multivariate-MANOVA-Multiple linear regression (MLR)	↓Worries/Emotionality (CSWQ/SAM); ↔ Temperament (EAS) (2 groups); ↓ Anxiety (STAI) Satisfaction+++	<0.05; >0.05; <0.001
Ford et al. [26]	Qualitative	Children (5-14 years-old), families	n=14	Hospitalization	Clown Interviews 10-20 minutes	Children's anxiety Interviews		Qualitative	↓Children's anxiety (effect immediately)	NA
Golan et al. [18]	Randomized, prospective, controlled	Children (3-8 years-old), Parents	n=65, clown group (n=21), premedication group (n=22), control group (n=22)	Anesthesia surgery	2 clowns, 20-30 minutes, Magic tricks, gags, music, games, puppets, word games, soap bubbles	Children's anxiety (m-YPAS), Parent's anxiety (STAI), operating room-mask application, blinded evaluated		Multivariate MANOVA	-Operating room Children's anxiety (m-YPAS); -Parents' anxiety (STAI); -Mask Application Children's Anxiety; (m-YPAS)	<0.05; ns; ns
Goldberg et al. [28]	Randomized, prospective, controlled	Children (2-17 years-old); Parents	n=91; clown group (n=45); control group (n=46)	Invasive medical procedure test (SPT)	Clown intervention	Children: Anxiety (STAIC, m-YPAS); Pain (FLACC, VAS); Parents: Anxiety (STAI)		Univariate (ANOVA)	-Children: ↓Anxiety (m-YPAS; all children); ↓Anxiety (m-YPAS, 2-7 years); ↓Anxiety (m-YPAS, 8-17 years); ↓Anxiety (state-STAIC after test, 8-17 years); ↓Pain (FLACC, 2-7 years); ↔ Pain (VAS, 8-17 years); -Parents: ↓Anxiety (state-STAI, about all children)	0.001; 0.001; 0.009; 0.002; 0.001; ns; 0.004
Hansen et al. [30]	Randomized, prospective, controlled	Children (0-15 years-old)	n=60; clown group; (n=30), control group (n=30)	Invasive medical procedure (neurology -botulinum toxin) injections	1 Clown, 15 minutes, big skirt, painted face and big red nose	Crying duration (minutes)	Crying duration n=2 × 50, 80% power, α<0.05	Multivariate (Linear Mixed model)	↓ Crying duration (minutes); ↔ Pain (Children treated for the first time)	ns; ns

Heilbrun n et al. [19]	Randomized, prospective, controlled	Children (5-12 years-old)	n=120, clown group (n=45), Child Life group (CL) (n=45); control group; (n=30)	No Invasive medical procedure	Child Life, 5-10 minutes, clown: bubbles, joke-telling, balloons or music	Children's anxiety (m-YPAS)	Anxiety α<0.05, 80% power, (≠ 20%) clown group (n=45), CL (n=45), control group (n=30)	Univariate (ANOVA, Kappa coefficient)	Children's anxiety (m-YPAS)	ns
Kingsnorth S. [27]	mixed-method, (single-subject ABAB study design)	Children (n=7) nurses of participating children (n=13)	Clown group, Conditions-television exposure group	Rehabilitative and complex continuing care	Clown intervention	Children's physical, cognitive and/or developmental; congenital or acquired disabilities		Multivariate	↓ Children's anxiety	ns
Koller and Gryski [4]	Qualitative	Health professionals, Parents	Evaluation clown programed and impact	Hospitalization	Clown intervention	Health satisfaction, interviews		Qualitative	Satisfaction+++	NA
Lima et al. [33]	Qualitative	Children (6-12 years-old), families	n=8	Oncology (Cancer diagnosed)	Clown marionettes play puppets	Children's well-being Interviews		Qualitative	↑ well-being	NA
Linge et al. [31]	Qualitative	Children (10-14 years-old), families	n=10 Families	Orthopedic, oncology, medicine	Clown Magic, music, play	Children's well-being Interviews Families		Qualitative	↑ Psychological well-being	NA
Meiri et al. [15]	Randomized, prospective, controlled	Children (2-10 years-old), Parents	n=90, clown group (n=30), EMLA group (n=30), control group (n=30)	Invasive Medical procedure (Venous blood sampling, intravenous cannulation)	Clown, 10 minutes Music, magic tricks, stories	Children's Crying duration (minutes), Pain (VAS 10faces), Pain /Anxiety (VAS 10cm) (Parents/ Children)	Anxiety n=90, 80% power, α<0.05, (≠10%)	Univariate (ANOVA)	↓ Children's crying duration (minutes); Children's pain; ↓Pain/ Anxiety Parents on Children's	<0.05; ns; <0.05
Meisel et al. [21]	Randomized, prospective, controlled	Children (3-12 years-old)	n=61; clown group (n=28); control group (n=33)	Anesthesia minor surgery	Clown intervention	Children's anxiety (Facial affective scale, FAS), Post-hospital behavior questionnaire (PBH)/(CCPH)		Univariate	↔ Children's anxiety	ns
Ofir et al. [24]	Qualitative	Children (1-17 years-old), families	n=9	Medical forensic examiner (allegedly abused children)	Medical clowning intervention Theatrical and clowning tools	Children's anxiety Interviews		Qualitative (Hematic analysis methodology assisted Atlas-ti software program)	↓ Children's anxiety	NA
Pinquart et al. [34]	Randomized, prospective, controlled	Children (6-14 years old), Parents	n=100; clown group (n=50); control group (n=50)	Hospitalization	2 clowns; 8 minutes; Gags, music	Children's and parents well-being		Mutivariate	KINDL-R ↑ Psychological well-being at posttest; ↔Psychological well-	<0.05; ns; ns

									being at follow up; ↔ Physical well-being (posttest and follow up)	
Tener et al. [25]	Qualitative	Children,families	n=9	Medical forensic examiner (allegedly abused children)	Clown intervention	Children's anxiety, fear, Interviews		Qualitative	↓ Children's anxiety	NA
Tener et al. [5]	Qualitative	Children (1-17 years-old) families	n=3	Medical forensic examiner (allegedly abused children)	Clown intervention	Children's anxiety, fear, Interviews		Qualitative	↓Children's anxiety (calm atmosphere)	NA
Vagnoli et al. [14]	Randomized, prospective, controlled	Children (5-12 years-old), Parents	n=75, clown group (n=25), premedication group (n=25), control group (n=25)	Anesthesia surgery	2 clowns, 15 minutes, Magic tricks, gags, music, games,puppets, word games, soap bubbles	Children's anxiety (m-YPAS), Parents' anxiety (STAI)	Anxiety	Univariate (ANOVA ,post-hoc Schiff test, Pearson's correlation coefficient (r))	↓ Children's anxiety (m-YPAS) (clown group, induction room); ↔ Parents' anxiety (STAI)	0.0001; ns
Vagnoli et al. [13]	Randomized, prospective, controlled	Children (5-12 years-old), Parents, Health professionals	n=40, clown group (n=20), control group (n=20)	Anesthesia surgery	2 clowns, 15 minutes; Magic tricks, gags, music, games, puppets, word games, soap bubbles	Children's anxiety (m-YPAS), Parent's anxiety (STAI), satisfaction of health professionals		Univariate (ANOVA Pearson's correlation coefficient (r))	↓Children's anxiety (m-YPAS); ↔ Parents' anxiety (STAI) Satisfaction+++	0.001; ns
Viggiano et al. [17]	Randomized, prospective, controlled	Children (4-11 years-old)	n=40, clown group (n=15), animal group (n=12), musician group (n=13), control group (n=65)	IRM	2 Clowns telling; jokes or funny stories, animal, musician; 10 minutes	Children's anxiety,Fear; (Likert scale)		Multivariate (Logistic regression; P≤0.05)	↓ Children's anxiety; ↓Fear	0.01; 0.001
Weintraub et al. [20]	Cross sectional	Children (5-18 years-old)	n=32	Rheumatology service (intra-articular corticosteroid injection)	Clown intervention	Children's pain (VAS), stress (Heart rate ≥ 15%), also reported by parents, physician, clown and nurse		Univariate (Mann-Whitney U-test)	↓stress; ↓Pain ; ↑stress and ↑pain for 5patients (comparison for ↑pain to other children of the sample ; observed for children's report only)	NA; NA; <0.05 (for pain)
Wolyniez et al. [23]	Randomized, prospective, controlled, pilot	Children (3-16 years-old), Parents	n=47; clown group (n=21); control group (n=26)	Invasive medical procedure	1Clown, 15 minutes, magic tricks, gags, puppets, and telling jokes	Children:Anxiety, Pain (VAS, Faces Pain Scale–Revised, FPSR), Parents: Anxiety (STAI)		Univariate (Fisher's exact test, T-test, Wilcoxon-test)	↓ Pain (FPSR); ↔ Pain (VAS); ↓ Anxiety State STAI	ns; ns; ns
Yun et al. [11]	Randomized, prospective, controlled	Children (3-6 years-old), Parents	n=50, clown group (n=23), control group (n=27)	Anesthesia surgery strabismus	Clown–Nurse, 1 hour, pediatric distraction	Children: Pain (FPS-R), Anxiety (m-YPAS)	Anxiety 23×2; ≠50%; (30×2)	Univariate (Mann–Whitney	Pre-operative; Postoperative; - Children: ↓Systolic BP; ↓Behavioral	ns; 0.024;

						(Systolic BP) (Behavioral), Parents: Anxiety (STAI), (Systolic BP) (Behavioral), by nursing, head nurses		U-test, T-test)	anxiety; (m-YPAS); ↓Pain; -Parents: ↓Systolic BP; ↓Behavioral anxiety; ↓State-trait anxiety	<0.001; <0.001; 0.010; <0.001; 0.001
NA : Not Applicable										

Table 1: Characteristic of studies included.

General characteristics of studies

The main characteristics of the 28 studies are presented in Table 2. The majority of studies (n=18, 64%) are randomized prospective and controlled studies [5,10-26]. One third of the studies targeted specifically the benefits of the intervention of hospital clown for children [17,19-22,27,29,30]. Over half of the studies reported intervention benefits of hospital clown for children and their parents [5,11-12,14-15,18,23-26,28,31-34]. Four other studies have evaluated in addition the opinions of health professionals [4,10,13,16]. One study targeted only mother's anxiety [9].

Variables	Number of studies	Percentage (%)	References**
Studies design	28		[4,5,9-34]
Cross sectional studies	2	7.1	[20,27]
Qualitative studies	8	28.5	[4,5,24-26,31-33]
Randomized prospective controlled studies	18	64.2	[9-19,21-23,28-30,34]
Randomization			
Parallels groups (clown/ control)	14	77.7	[9-13,16,17,21-23,28-30,34]
Three groups	4	22.2	[14,15,18,19]
Clown/control/ EMLA	1	25	[15]
Clown/control/midazolam	2	50	[14,18]
Clown/control/Child Life (CL)	1	25	[19]
Sample size	18	64.2	
<30 subjects per group	9	50	[9,11,13,14,16,18,21,23,29]
30 subjects per group	4	22.2	[15,19,22,30]
>30 subjects per group	5	27.7	[10,12,17,28,34]
Sample size calculation primary endpoint	8	44.4	[9,11,12,14-16,19,30]
Child's anxiety	6	75	[11,12,14-16,19]
Parent's anxiety	1	12.5	[9]
Crying	1	12.5	[30]
Blinded evaluators	2	11.1	[18,19]
Target population	28		
Children only	9	32.1	[15,17,19-22,27,29,30]
Parents only	1	3.5	[9]
Children and parents	14	50	[5,11,12,14,18,23-26,28,31-34]
Children, parents and/or hospital staff	4	14.2	[4,10,13,16]
Age target	28		
2-12years-old	12	42.8	[9-19,21]
5-18years-old	9	32.1	[4,20,22,26,27,29,32-34]
0-18years-old	7	25	[5,23-25,28,30,31]
Medical service evaluation			
Surgery	9	32.1	[9-14,18,21,22]
Emergency department	4	14.2	[15,16,19,23]
Medicine Service	4	14.2	[4,26,29,31]
Medico-legal Service	3	10.7	[5,24,25]
Oncology department	3	10.7	[32-34]
Orthopedics	1	3.5	[32]
Rheumatology	1	3.5	[20]
Radiology department	1	3.5	[17]
Dermatology Service	1	3.5	[28]
Neurology Service	1	3.5	[30]
Rehabilitation department	1	3.5	[27]
Medical procedure	28		
Anesthesia before Surgery	9	32.1	[9-14,18,21,22]
Invasive medical procedure	10	35.7	[5,15-17,20,23-25,28,30]
Venous blood sampling and other	3	30	[15,16,23]

Examine Medico-legal	3	30	[5,24,25]
Allergy prick skin tests	1	10	[28]
Botulinum toxin injections	1	10	[30]
Intra-articular corticosteroid injection	1	10	[20]
Magnetic resonance imaging	1	10	[17]
No invasive procedures	9	32.1	[4,19,26,27,29,31-34]
Cough and Rhinorrhea	1	11.1	[19]
Hospitalization period	7	77.7	[4,26,29,31-34]
Rehabilitation	1	11.1	[27]
Outcome evaluation			
Anxiety (children and their parents)	15	53.5	[5,9,10,12-14,17-19,21,22,24-27]
Anxiety and pain	5	17.8	[11,16,20,23,28]
Crying duration	1	3.5	[30]
Crying duration, Anxiety, Pain	1	3.5	[15]
Well-being	4	14.2	[31-34]
Satisfaction of health professional	4	14.2	[4,10,13,16]
Clinical assessment measures and Pain	1	3.5	[29]
Statistical analyses	28		
Univariate analysis	13	46.4	[11-16,19-23,28,29]
Multivariate analysis	7	25	[9,10,14,18,27,30,34]
Regression analysis	4	57.1	[10,14,27,30]
Qualitative	8	29	[4,5,24-26,31-33]
*venous blood sampling and other: venous blood sampling, intravenous catheter, burn, wound dressing, immobilization of injured limbs and wound suture or blood			

Table 2: General analyses of studies (studies design, population targeted, medical service evaluation, medical procedure, outcome evaluation, statistical analysis).

The target population studies varied from a study to another. The age group most highly represented was 2 to 12 year-old (43%) [9-19,21]. The other inclusion criteria of studies were children in good health (children without a history of chronic illness, non-premature birth, non-developmental delay and non-significant hearing or visual impairments), children who had no experience of previous anesthetic and/or first attempt examination with or without sedation and the need to undergo painful procedures.

Thirty two percent of studies were focused on anesthesia before surgery as minor surgery, strabismus surgery, otolaryngology surgery [9-14,18,21-22]. Thirty six percent of studies were focused on invasive medical procedures including venous blood sampling, intravenous catheter, burn, wound dressing, immobilization of injured limbs, wound suture and blood tests [15-16,23], medical forensic examiner (allegedly abused children) [5,24-25], allergy prick skin tests 28, botulinum toxin injections 30, intra-articular corticosteroid injection 20, magnetic resonance imaging 17. Thirty two percent of studies targeted non-invasive procedures [4,19,26,27,29,31-34].

General conditions for the performances of hospital clowns

The main characteristics of the performances of hospital clowns are presented in Table 3. The clown intervention started at the waiting or medical Preoperative room and/or Emergency department. Working methods of clowns may vary across studies, as their professional training. Over half of studies of clown intervention lasted less than 15 minutes [3,4,12,15,16,21,22,25,27-34]. For seventy one percent of the studies the intervention is realized by one clown at one visit [4,5,9,11,15,16,19,21,23-33] and in twenty nine percent of the studies the clowns intervention is realized by two clown at one visit [10,12-14,17,18,22,34].

Variable	Number of studies	Percentage (%)	References
Methods distraction of clown intervention			
Magic tricks	16	57.1	[4,9,10,12-16,18,22,23,27,29,31,32,34]
Music	14	50	[4,9,10,13-19,27,31,32,34]
Funny stories, funny songs, telling jokes	12	42.8	[4,9-11,15,17,19,22,23,27,28,34]
Puppets	9	32.1	[12-14,16,18,22,23,29,33]
Gags	6	21.4	[12-14,18,23,29]
Games, word games	7	25	[9,10,13,14,18,29,33]
Theater of clowns, prestidigitation	5	17.8	[5,16,24,25,33]
Play	5	17.8	[26,31-34]
Humor, humorous noises of animals	2	7.1	[10,30]
Juggling	1	3.5	[16]
Pantomime	1	3.5	[16]
Make-up	1	3.5	[11]
Time of intervention:	28		
<15 mn	16	57.1	[4,5,15,17,19-21,24-28,31-34]
≥ 15 mn	8	28.5	[9,10,13,14,16,22,23,30]
≥ 30	4	14.2	[11,12,18,29]
Number of clown by visit			
1 clown by one visit	20	71.4	[4,5,9,11,15,16,19-21,23-33]
2 clowns by one visit	8	28.5	[10,12-14,17,18,22,34]

Table 3: General conditions for the performances of hospital clowns (methods distraction, time of intervention, number of clown).

Methods Evaluation

Studies design

Among the 28 included studies, 18 are randomized prospective and controlled studies and 14 of them have parallels groups design (clown-group/control-group) [9-13,16,17,21-23,28-30,34]. Half of the studies have a sample size of less than 30 patients per group [9,11,13,14,16,18,21,23,29]. In 2 of 28 studies, the evaluators were blinded to both, the study's design, hypothesis [18] and patients or parents group assignment [19].

Variables of outcomes and instruments

The main tools of efficacy measure are presented in Table 4. Most of the studies measured the impact of the clown intervention on anxiety and/or pain. In most of the cases, anxiety and pain were measured with standardized and validated self-report or observer-rated questionnaires, specifically developed for children according to the age group [6,10-13,16-26], or by visual analog scales [15,20,23,28] or crying duration [15,30]. Other clinical outcomes medical procedure were the length of time spent in hospital 29 or the systolic blood pressure [11,20,29]. In most of the cases, the well-being was evaluated by interview [31-33].

Tools	Age target (year)	Modality for evaluation	Number of studies	References*
Anxiety mensuration			21	[5,9-28]
Modified Yale preoperative anxiety (Scale m-YPAS)	2 to 7	Hetero-rated	7	[11-14,18,19,28]
Blinded evaluators			2	[18,19]
State and trait anxiety inventory for children (STAIC) scale	2 to 12	Self-rated	2	[22,28]
State and trait anxiety inventory (STAI)	adults	Self-rated	9	[9-14,18,23,28]
Likert scale		Self-rated	1	[17]
Children anxiety and pain scales (CAPS-Anxiety)	4 to 10	Self-rated	1	[16]
Child surgery worries questionnaire (CSWQ)	11 to 14	Self-rated	1	[10]
Self-assessment mannequin (SAM) scale	4 to 12	Self-rated	1	[10]
Child's temperament (EAS)	4 to 12	Hetero-rated	1	[10]
Facial affective scale (FAS)	3 to 4	Hetero-rated	1	[21]
Post-hospital behavior questionnaire (PBH)/ (CCPH)	3 to 12	Hetero-rated	2	[22]
Pain mensuration			7	[11,15,16,20,23,28,29]
Pain Wong- Becker Scales/	under 8	Self-rated		[16,29]
pain self-evaluation numeric scale (NRS-11)	4 to 12		2	
FLACC scale (face, legs, activity, cry and consolability)	2 to 7	Hetero-rated	1	[28]
Faces pain scale-revised	3 to 7	Self-rated	1	[29]
Children's hospital of eastern Ontario pain scale (CHEOPS)	1 to 7	Hetero-rated	1	[29]
visual analog score (VAS)	>7	Self-rated	4	[15,20,23,28]
Crying duration		Hetero-rated	2	[15,30]
Clinical assessment			1	[29]
Number of hospital day		Hetero-rated	1	[29]
Systolic PB		Hetero-rated	3	[11,20,29]
Well-being		Self-rated	4	[31-34]
KINDLR questionnaire pre-test	6 to 14	Self-rated	1	[34]

Table 4: Tools of efficacy mensuration (anxiety, pain mensuration, crying duration, clinical assessment, and well-being).

Statistical analyses methods

Only 8 studies presented the sample size calculation [9,11,12,14-16,19,30]. To determine the sample size the child's and/or parent's anxiety as primary endpoint was mainly used [9,11,12,14-16,19]. Only one study used the crying duration as primary endpoint 30. For comparison of anxiety, pain perception and/or well-being between the experimental group and control group, 12 of the 18 randomized prospective studies used univariate analysis [11-16,19,21-23,28-29], 6 studies used multivariate analysis [14,15,18,21,23-24] and only one cross sectional study without parallel groups used multivariate analysis 27 (Table 2).

Efficacy of clown intervention

Figure 2 describes efficacy of clown intervention for the 28 studies according to their different characteristics in design, using reduction in anxiety or pain as primary end point.

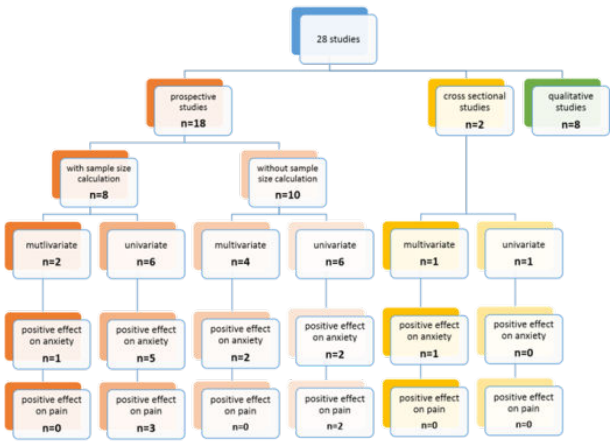

Figure 2: Diagram describing efficacy of clown's intervention for the 28 studies.

Anxiety (fear, stress, worries) level reduction

Twenty-one studies evaluated clown hospital intervention on the anxiety of children and/or parent, including one study on parent's anxiety, 8 studies on children's anxiety and 12 studies on both parent's and children's anxiety. We observed that 10 of 20 studies reported a positive impact on reducing children's anxiety [10-17,27,28] and 7 of 13 studies reported a positive impact on reducing parent's anxiety [10-12,19,23,24,26]. Hence, 50% of the total reviewed studies (n=28) presented a positive reduction of parent's or children's anxiety or pain, regardless of their study design.

Pain level reduction

Among 28 studies, there are 7 randomized prospective and controlled studies that evaluated impact effects of clown intervention on the children's pain perception during invasive medical procedure and/or post-operative period [11,15,16,20,23,28,29]; 5 of 7 studies showed a positive impact with significantly lower level of pain perception in the clown group compared with the control group [11,15,16,28,29]. However, none of them have calculated the sample size with the pain as the primary endpoint. None of the studies used multivariate analysis; hence no contingent confounding factor was taken into account.

Clinical assessment

Only one randomized prospective and controlled study has evaluated the impact of the presence of clown intervention on clinical outcome 29, but did not reveal any impact on the length of hospitalization, duration of the fever period and time taken to achieve clinical recovery. However, this study did not report any sample size calculation, which could argue for a non-significant result consequent to power analysis lacking.

Mental well-being and magical attachment

We identified 4 studies which examined the impact of clown interventions on well-being [31-34] of children and/or their parents. Three of them were qualitative studies without parallel groups and quantitative measures [31-33] and one of them was randomized prospective and controlled study. In this last study, authors used a multivariate analysis and reported that clown intervention had no impact on the well-being of children and their parents [34].

Opinion of health professionals regarding the presence of clowns in the preoperative or medical procedure room

The opinion of the health professionals is shown in Table 5. We identified 4 studies that evaluated the opinion of health professionals regarding the presence of clowns [4,10,13,16]. The validated opinions of health professionals are different from a study to another. This review showed that 44% to 93% of health professionals were satisfied with clown interventions and believed that the clown program was beneficial to the hospital and children's health care management [4,10,13,16]. Two studies showed that the majority (70% to 92%) of the health professionals opposed to continue the clown intervention, because of perceived interference with procedures in the preoperative or medical room (64%) [13,16]. However, one study showed that 96% of health professionals agreed with the presence of clowns continuing in the preoperative room, mainly because they considered that clowns were not disturbing agents (71.43%) [10]. These review show that health professionals considered clown interventions useful for the children (75% to 96.43%), for the parents (40% to 89.29%) and for themselves (35% to 64.29%) [4,10,13,16].

Studies	Vagnoli et al. [17]	Fernendes et al. [10]	Felluga et al. [16]	Koller and Gryski [4]
	(n=20)	(n=28)	(n=20)	(n=143)
Satisfied (%)	44	89.29	75	93
Less satisfied (%)	56		25	
This activity is useful				
For the child (%)	78	96.43	75	88
For the parent (%)	40	89.29	75	51
For the staff (%)	52	64.29	35	47
Clowns are a disturbance (%)	20		35	

Clowns are not disturbance (%)	16	71.43	35	
Sometimes clowns are a disturbance (%)	64			
Clown continuing in the waiting room (%)			95	
Clown continuing in the preoperative or medical room (%)	28	96.43	10	
No Clown continuing in the Preoperative or Medical room (%)	72		90	

Table 5: Assessment report on the medical staff of the interaction of the clowns.

Discussion

This literature review brings a comprehensive, systematic review of methodical design of studies which assess benefits of interventions of clowning hospital, and shows the variety of methods used to assess the impact of intervention of hospital clowns.

The results of our research reveals that only half of the studies concluded in favor of the intervention of the hospital's clowns, meanwhile the second half was against the intervention. This literature review was not able to show us the conclusions on the benefit of the clown intervention.

Among 28 studies analyzed, if the majority of studies (n=18) are randomized prospective and controlled studies, few of them have high level of evidence: only 8 of the 18 prospective studies complied the calculation of the sample size to compare the groups with and without intervention and reported the use of a primary endpoint [9,11,12,14-16,19,30], among them 2 studies had single-blind assessments. Only 7 of the studies used multivariate analysis [14,15,18,21,23,24,28], 6 of them were randomized prospective and controlled studies and took into account contingent confounding factors and the last one was cross-sectional.

Also, this literature review shows the variety of measurement tools, which makes it difficult to compare these studies. Most of the authors used tools that do not allow single-blind assessments. As it is an observer-rated questionnaire, only the m-YAS permitted to assess anxiety with blinded evaluators to group type.

Among 28 studies shown, clown interventions are heterogeneous in a study to another. The majority of studies used the same methods of distraction, such as magic tricks, music, funny stories, funny songs, telling jokes and puppets. Over half of study reported that the clown's intervention took less than 15 minutes in one intervention [3,4,8,12,15,16,21,22,25,27-33]. Again, it is of the utmost importance to get more homogeneity in the type of intervention and duration to improve the knowledge and the efficacy of the clown's intervention.

These results underlie the need for a better methodological assessment in future studies with stronger evidence-based approaches to strengthen positive effects of clowning interventions. Weaknesses in design methods and multiple assessment tools utilizations highlight the heterogeneity in measures. This may contribute to the methodological issues that future studies should consider to produce more robust, comparable and accurate estimates.

None of the studies are taking into account medico-economic evaluation of clown intervention. The clown intervention is very expensive with the documentation of the hourly wage (with an average rate of € 43.00 per hour) but previously non-existent transparency has been achieved 6. Moreover, clown intervention may also increase the total length of care and also the total cost, thus leading to question about its advantages in terms of cost-benefit. These points urge for future studies to develop more medico-economic evaluation (such as cost minimization studies, cost-effectiveness, cost-utility and cost-benefit analyses), and indicate the methodological problems commonly encountered in this field.

Conclusion

This review provided some empirical evidences of the effect of clown interventions, using laughing and humor, on anxiety and/or pain reduction in pediatric hospitals. Indeed, for some studies assessed, hospital clowns contributed to minimize children's and parent's anxiety levels, decrease children's surgery-invasive medical procedure-related pain and showed positive effects of psychological well-being in children's hospitals. However, the findings of the present study also suggested that conditions of the clown interventions should be defined better and diversity of the studied samples and measurement tools should be addressed, hence demonstrating that more evidence-based studies are needed in the future in the field of hospital clowns interventions.

Conflict of Interest

The authors declare that they have no competing interests.

Author's Contributions

SP: 1st author, involved in data collection, in drafting the manuscript; ST: 2nd author, involved in revising the manuscript; MA: 3rd author, involved in revising the manuscript; SG: last author and corresponding author involved in revising the manuscript, approved the final version to be published. All authors read and approved the final manuscript for this submission.

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