

ORIGINAL ARTICLE

The effectiveness of pre-operative clown intervention on psychological distress: A systematic review and meta-analysis

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Aim: This study aims to provide an overview of the current knowledge available on the effectiveness of pre-operative clown intervention on psychological distress in children and parents.

Methods: PubMed, MEDLINE, Embase and PsycINFO databases were searched to identify relevant studies. Systematic review procedures were followed including a quality assessment. Meta-analysis of suitable studies was conducted.

Results: Eight studies were included; six reported that clown intervention reduced children's pre-operative anxiety, while one found that children's pre-operative distress levels were unchanged. Two studies suggested that clown therapy decreased parents' state anxiety, while three others found inconsistent results. No differences were found on parents' trait anxiety score. Meta-analysis of the available data confirmed that clown intervention has a *great effect* to reduce children's pre-operative distress (six articles, 341 children, Hedges' $g = 0.867$, 95% confidence intervals: 0.374–1.360, $P = 0.001$), and also had a small-to-medium effect on reducing parents' state anxiety (five articles, 329 parents, Hedges' $g = 0.338$, 95% confidence intervals: 0.112–0.564, $P = 0.003$).

Conclusions: While significant variability existed between studies, the meta-analysis confirmed the effectiveness of pre-operative clown therapy on reducing psychological distress in children and parents. Larger randomised controlled trials and cross-cultural studies should be conducted to investigate the effectiveness of clown therapy in greater detail.

Key words: anxiety; clown intervention; distress; meta-analysis; pre-operative; systematic review.

What is already known on this topic

- 1 Using non-pharmacological techniques to alleviate children's and parent's pre-operative distress is increasing in popularity and appeal.
- 2 Studies on the effectiveness of pre-operative clown intervention has yielded inconsistent results.
- 3 Systematic review and meta-analysis of the effect of clown intervention have not been conducted.

What this paper adds

- 1 Meta-analysis confirms that clown intervention *has a great effect* on reducing children's pre-operative anxiety.
- 2 Meta-analysis confirms that clown intervention has a small-to-medium effect on reducing parents' pre-operative state anxiety.
- 3 Larger randomised controlled trials with more diverse populations should be conducted in order to investigate the effectiveness of clown therapy in greater detail.

Up to 75% of children experience severe anxiety or distress prior to undergoing surgery.¹ Studies report that children are particularly threatened by the anticipation of pain, parental separation, loss of control, surgical instruments and masked strangers.^{1,2} Several interventions have been proposed to reduce pre-operative anxiety,³ such as parental presence,^{4,5} music therapy,⁶ video game distraction,^{7,8} hypnosis⁹ and sedative premedication.^{10,11} However, due to the side effects and possibility of affecting

children's post-operative functioning, the use of pharmaceutical sedation was discouraged by several researchers.^{12,13} Consequently, non-pharmacological techniques, such as clown intervention, have begun to receive more attention.¹⁴

Manyande *et al.*¹⁵ conducted a review to assess the effect of several non-pharmacological interventions on reducing children and parent's pre-operative anxiety, and found that parental presence, hypnosis and music therapy did not significantly reduce children's anxiety. Contrarily, hand-held video games, computer packages and clown doctors were found beneficial to children. However, only three clown intervention studies with a total of 133 children were included in meta-analysis in this review. While the Cochrane systematic review undeniably provides us with broad knowledge about non-pharmacological interventions, it does not investigate pre-operative clown intervention in depth.

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Research findings on the impact of clown therapy are varied. Several studies report significant reduction in the anxiety, pain and fear experienced by children,^{5,16–18} and higher co-operation during medical procedures,¹⁹ while other researchers found opposite results.²⁰ Similarly, some studies^{16,21} found that clowns have a significant impact on lowering state anxiety of parents, whereas other studies^{5,18,19} found non-significant change. These inconsistencies demonstrate the need for the current study, which serves to determine the aggregate findings of the existing literature on clown intervention efficacy.

Methods

Literature search

The study was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines for systematic review and meta-analysis.²² Four databases were utilised: PubMed, Ovid MEDLINE (1946 to present), Embase (1974 to present) and PsycINFO (1806 to present). The search was performed by two independent reviewers (YZ and YY) using the OR and AND function. The reference lists of identified review articles and all included studies were also screened manually for additional relevant studies. No restrictions were placed on publication date. A description of the search strategy is outlined in Appendix I.

Inclusion criteria

To be included in the review, references had to (i) be published in a peer-reviewed journal; (ii) be written in English or Spanish; (iii) test the effect of pre-operative clown intervention; (iv) be compared with a control group and (v) be quantitative studies that reported psychological distress results.

Data extraction

For each retained study, the following information was recorded: the first author's name, year of publication, study design and basic demographic information, such as the country where the study was conducted, mean age of participants, sex distribution and sample size. Measurement of psychological distress and main findings were also noted. For two studies^{5,17} that compared multiple groups (clown, premedication and no clown group), only data from clown group and no clown group were extracted.

Quality assessment

The quality of each included study was assessed using the quality critical appraisal tool for randomised controlled trials from the Cochrane Handbook for Systematic Reviews of Interventions 5.1.0.²³ Each study was evaluated on six domains: selection bias, performance bias, detection bias, attrition bias, reporting and other bias. Each domain was classified as having 'low', 'unclear' or 'high' risk.

Statistical analysis

Upon completion of the systematic review, a quantitative meta-analytic approach was applied. The programme Comprehensive

Meta-analysis was employed.²⁴ The effect size was calculated by a standardised mean difference (Hedges' *g*) with accompanying 95% confidence intervals (CI) because several of the included articles had small sample sizes.²⁴ Effect size was interpreted according to Cohen's guidelines,²⁵ whereby 0.8 represents a large effect, 0.5 a moderate effect and 0.2 a small effect. The authors of articles with incomplete data were contacted by email to obtain the required data unavailable in the published article. Studies for which the corresponding authors could not be reached were subsequently excluded from the meta-analysis.

Statistical heterogeneity among the articles was reported by *Q* statistics, where a *P*-value of less than 0.10 or an *I*² value of greater than 50% was considered to be indicative of substantial heterogeneity. If substantial heterogeneity was observed, the Hedges' *g* was calculated according to a random-effects model, otherwise, the results were calculated based on a fixed-effects model. Rosenthal's 'fail safe *N*' procedure was adopted to

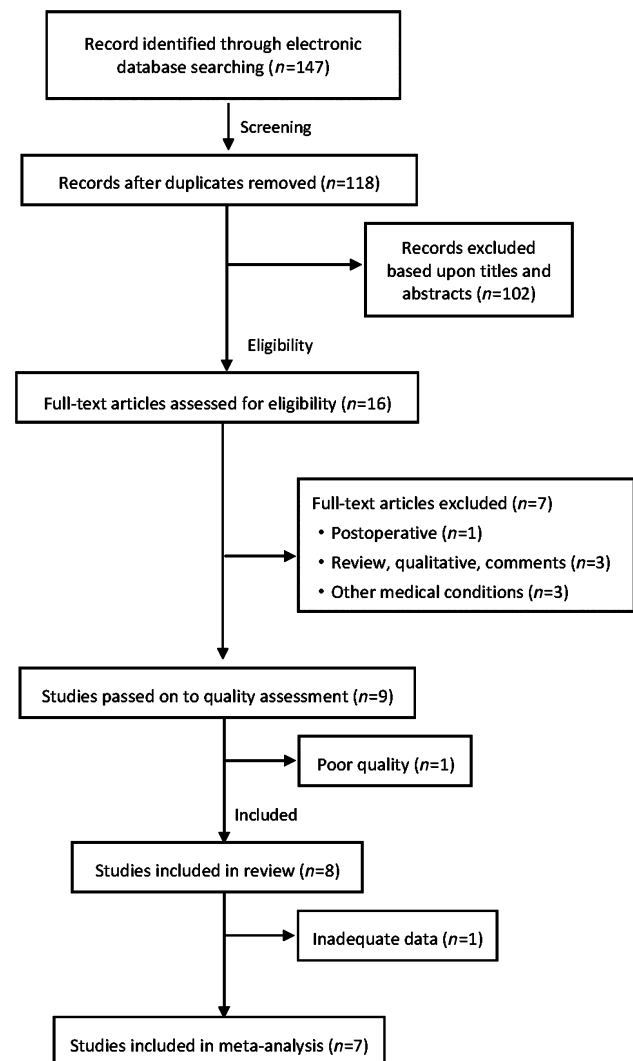


Fig. 1 Flowchart of the results of the literature search.

Table 1 Quality assessment of included studies

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Performance bias	Detection bias	Attrition bias	Reporting bias	Other bias (baseline imbalance, early stopping, source of funding, etc.)
Agostini 2014	+	+	+	+	+	+	+
Dionigi 2014	+	+	+	-	+	+	+
Vagnoli 2010	+	?	+	-	+	+	+
Fernandes 2010	-	+	+	+	+	-	+
Golan 2009	+	-	-	-	+	+	+
Meisel 2009	-	+	+	+	+	+	+
Canto 2008†	-	+	+	+	?	+	+
Vagnoli 2005	+	?	-	+	+	+	+
Smerling 1999‡	-	?	?	?	-	+	?

†Article excluded from meta-analysis due to insufficient data. ‡Article excluded due to poor quality. +, low risk of bias; -, moderate or high risk of bias; ?, uncertain risk.

estimate the number of negative studies that would be required to overturn the total aggregated result. A Funnel plot and Egger’s regression intercept test were also performed to assess the publication bias.

Results

An outline of the search process is presented in Figure 1. The literature search identified 147 references. After removing duplicates, 118 articles remained. Based on irrelevance of titles and abstracts, 102 studies were excluded. After further assessment of full texts, nine studies were passed on to quality assessment. Following evaluation using the quality critical appraisal tool for randomised controlled trials,²³ eight articles remained, one of which was excluded on the basis of insufficient data, thereby leaving a final count of seven articles for meta-analysis.

Quality assessment

The risk of bias of the included studies is presented in Table 1. Attrition or reporting bias was rarely reported, while selection and detection bias were more frequently identified. Five studies reported adequate random sequence generation, while the remaining were classified as having high risk bias. Five studies adequately carried out allocation concealment, while three others had insufficient information for assessment of this factor. Detection bias was found in three studies, uncertain in one study, and absent in the remaining articles. Eight out of nine studies were considered to be free from risk of other forms of bias. In all, the majority (8/9) of the articles presented a low risk of bias for all seven categories. Only one article²⁶ was excluded following quality assessment due to a general poor quality of work (six out of seven categories were classified as high or uncertain risk of bias). Thus, eight articles were included in the present review.

Characteristics of included studies

Half of the studies were conducted in Italy,^{5,18,19,21} two in Spain,^{20,27} one in the United States¹⁷ and one in Portugal.¹⁶ The cumulative sample size was 802 (354 parents and 448 children), with 211 children and 194 parents in clown groups, and 190 children and 135 parents in control groups. The age of children participating in the studies ranged from 3 to 12 years. The main characteristics and findings of the included publications are presented in Table 2. Detailed results are shown in Appendix II.

The effect of clown intervention on children

Six articles^{5,16-19,27} showed that – compared with those in control groups – children who were accompanied by clowns either with or without their parent reported significantly less anxiety, or showed less increase in anxiety scores in the waiting room and during the induction of anaesthesia. Additionally, one longitudinal study²⁷ reported that the relief provided by clown intervention persisted 7 days after operation. However, in contrast to these studies, another longitudinal study²⁰ found that the presence of clowns did not have any effect on reducing children’s pre-operative distress, and instead found that the intervention helped to reduce children’s post-operative maladaptive behaviours, even though the effect was non-significant.

An overall Hedges’ *g* was calculated to describe the combined effects of the six included studies (see Fig. 2). The heterogeneity test yielded a *Q*-value of 23.533, a *P*-value of 0.000, and an *I*² of 78.753, hence, a random-effect model was utilised. The estimate of the overall Hedges’ *g* was 0.867 (95% CI: 0.374–1.360, *Z* = 3.448, *P* = 0.001). The results confirmed that clown intervention had a strong effect on reducing children’s pre-operative anxiety. Additionally, the fail-safe-*N*-value was found to be 79.

Table 2 Characteristics of included studies

First author year, country	Study design	Participants	n	Age	Sex	Intervention		Outcome measure	Main findings
						Clown	Control		
Agostini 2014, Italy	RCT	Parents	50	36.45 ± 5.71 [†] 35.95 ± 3.99 [‡]	0/100	Presence of clowns and a nurse/mother	accompanied by a nurse/mother	The STAI The Rapid Stress Assessment Scale (VRS)	In the clown group, maternal state anxiety (STAI Y-1) significantly decrease; older children's (>6 years) mothers stress level also significantly reduced
Dionigi 2014, Italy	RCT	Children Parents	77 119	5.7 (2.1–12.5) [§] 6.0 (2.6–10.7) [¶]	60/40 [§] 40/60 [¶]	Presence of clowns and parents	Parental presence	m-YPAS The STAI	The clown intervention significantly reduced the children's anxiety; significant difference was found in anxiety between the children in CG and CoG; however, there was no significant difference in anxiety between the parents in the CG and CoG
Vagnoli 2010, Italy	RCT	Children Parents	75 75	7.04 ± 2.23 [§] 7.36 ± 2.61 [¶]	72/28 [§] 64/36 [¶]	Presence of clowns and a parent	Parental presence	m-YPAS The STAI	The clown group was significantly less anxious during the induction of anaesthesia compared with control group and premedication group, there was no significant difference between control and premedication group; also no differences were found in anxiety between parents in different groups
Fernandes 2010, Portugal	RCT	Children Parents	70 70	7.93 ± 2.36	76/24	Presence of clowns and a parent	Parental presence	The CSWQ The STAI	Children in the clown group reported significantly less worries than control group; reduction of pre-operative state anxiety and emotional responses were also showed in their parents
Golan 2009, USA	RCT	Children	65	4.5 (range 3–8)	—	Presence of clowns	No midazolam or clown presence	m-YPAS	The use of pre-operative clowns can significantly alleviate anxiety and the clown group had a significantly lower anxiety score in the pre-operative room compared to control and midazolam group, but do not have any effect once the anaesthesia mask is introduced
Meisel 2009, Spain	RCT + longitudinal	Children	61	6 ± 2.55 (range 3–12)	87/13	Presence of clowns	No clown	FAS PHBQ	The presence of clowns did not reduce the child's distress; children's post-operative maladaptive behaviours in the clown group were reduced but it was not statistically significant
Canto 2008, Spain	RCT + longitudinal	Children	60	Range 6–10	—	Presence of clowns	No clown	STAI-C Faces Scale	Both experiment and control group showed a tendency to increase anxiety but the children of the clown group showed less increase at the anxiety's score, and the results are maintained seven days after the operation
Vagnoli 2005, Italy	RCT	Children Parents	40 40	6.85 ± 2.21 [§] 7.30 ± 2.72 [¶]	70/30 [§] 75/25 [¶]	Presence of clowns and a parent	Parental presence	m-YPAS The STAI	Children in the clown group showed less anxious compared with the control group; anxiety was not significantly different in the clown group in 2 locations; also, no significant difference were found in parent's STAI Y-1/Y-2 average scores; staff was opposed to continuing clown intervention because of perceived 'interference'

[†]Parent's age/sex percentage in clown group. [‡]Parent's age/sex percentage in control group. [§]Child's age/sex percentage in clown group. [¶]Child's age/sex percentage in control group. CG, clown group; CoG, control group; CSWQ, Child Surgery Worries Questionnaire; FAS, Facial Affective Scale; m-YPAS, Modified Yale Pre-operative Anxiety Scale; PHBQ, Post-Hospital Behaviour Questionnaire; RCT, randomised controlled trial; SD, standard deviation; STAI, State and Trait Anxiety Inventory; STAI-C, State-Trait Anxiety Inventory; STAI-C Faces Scale; STAI Y-1, state anxiety of the parent; STAI Y-2, trait anxiety of the parent; VRS, The Rapid Stress Assessment Scale.

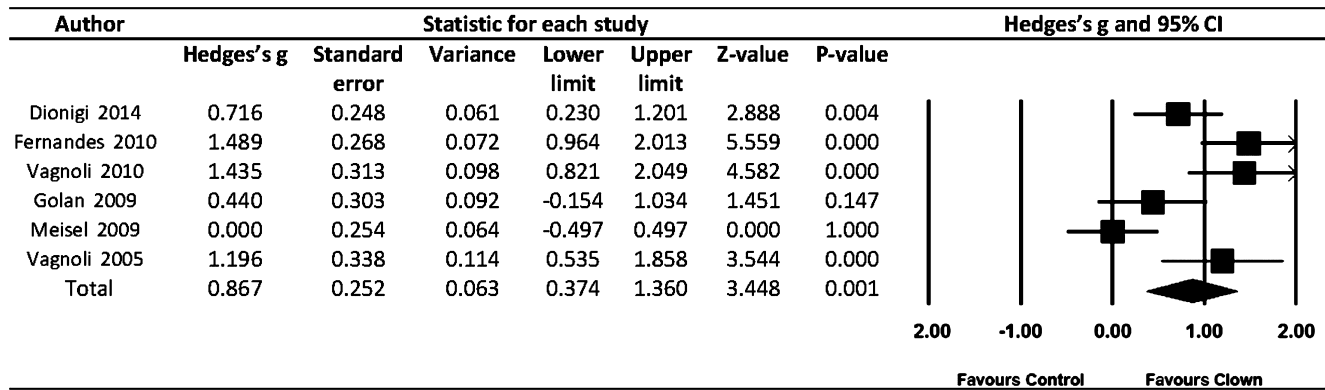


Fig. 2 Meta-analysis of clown intervention in children. Heterogeneity of totals: $Q = 23.533$, $P = 0.000$, $I^2 = 78.753$. The size of the squares indicates the weight of the study. The diamond indicates the summary correlation. CI, confidence interval.

Through examination of the funnel plot, studies were noticeably symmetrical in distribution (see Appendix III). Egger's regression intercept test of the studies was not statistically significant (intercept = 7.62; SE = 7.93; $T = 0.96$, and $P = 0.39$), thus no apparent publication bias was found.

The effect of clown intervention on parents

Five articles^{5,16,18,19,21} studied the effect of clown intervention on pre-operative worries in parents and produced inconsistent results. Three studies^{5,18,19} found no significant difference in state anxiety (STAI Y-1) between parents in clown groups and those in control groups, while the remaining two studies^{16,21} contrarily found a significant reduction in parents' STAI Y-1 scores. No significant differences were found in trait anxiety scores (STAI Y-2) in all studies. In addition, two articles reported an association between a child's age and the corresponding parent's anxiety and stress levels. Agostini *et al.*²¹ found that in the clown group,

compared with younger children's mothers, older children's (>6 years old) mothers reported a significant decrease in their stress level, while Vagnoli *et al.*⁵ found a significant negative correlation between the state anxiety of parents and the age of their child ($r = -0.24$, $P < 0.05$).

Meta-analysis of the five studies revealed that pre-operative clown therapy has a small-to-medium alleviating effect on parents' state anxiety (Hedges' g : 0.338, 95% CI: 0.112–0.564, $P = 0.003$, see Fig. 3). Heterogeneity test showed that there is no significant variation in the effect size ($Q = 5.831$, $P = 0.323$, $I^2 = 14.244$), thus, fixed-effect model was used. The funnel plot was symmetrical (see Appendix IV), and the corresponding Egger's regression test revealed that there is no significant bias ($P = 0.060$). However, the fail-safe- N -value was found to be 6. This value does not exceed Rosenthal's recommended tolerance value of $5n + 10$ (where n is the number of effect sizes),²⁴ which suggests that our data are not resistant to potential publication bias.

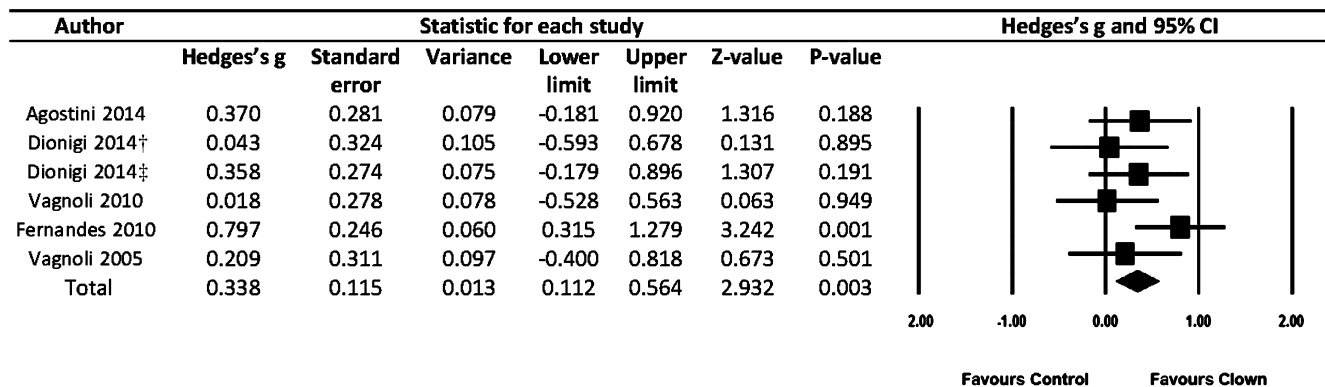


Fig. 3 Meta-analysis of clown intervention in parents (STAI Y-1). Heterogeneity of totals: $Q = 5.831$, $P = 0.323$, $I^2 = 14.244$. †Data from female participants. ‡Data from male participants. The size of the squares indicates the weight of the study. The diamond indicates the summary correlation. CI, confidence interval.

Discussion

Clown intervention first started in hospitals in New York City in 1986, under a programme named the Big Apple Circus Clown.¹⁹ It has been implemented all over the world,^{14,28,29} especially in paediatric wards.³⁰ The idea is that laughter or humour can relieve anxiety or worry within children without perpetuating post-operative distress or maladaptive behaviour.^{16,30,31} However, a meta-analysis of the possible beneficial effects of pre-operative clown intervention in children and parents has yet to be conducted, thereby providing the motive for the current study.

Six of the seven included studies and the overall meta-analysis have confirmed strong positive effects of clown therapy in children during the pre-operative period. Due to the fact that coping strategies and psychological resilience only develop in later years, young children tend to report high levels of anxiety and distress when confronting foreign situations such as induction of anaesthesia.²¹ However, hospital clowns, who aim to bring joy, laughter and imagination, help to develop a safe and supportive environment where children can relax and feel settled.³² Hospital clowns distract young patients and their families, even if only for a few minutes, from the unpleasant medical situations that they face. The work of clowns is based on the positive link between humour and health,³³ and humour has been considered the main reason for the beneficial impact of hospital clowns on patients.³⁴ Patients may use humour to alleviate stress, anger and frustration, cope with anxiety, and ease pain.³⁰ Studies found that the presence of clowns not only increases the communication among the child, parents and medical staff, but also helps children to achieve a sense of control.³¹ However, in contrast to these evidences, one longitudinal study reported that the presence of medical clowns has no influence on children's distress. One possible explanation for the inconsistency is that some children dislike and perhaps even fear clowns. Theoretically, a fear of clowns could have a negative effect on this method of anxiety alleviation.¹⁷

In clown intervention studies, a parent's anxiety is often separated into state anxiety (STAI Y-1) and trait anxiety (STAI Y-2).³⁵ Theoretically, state anxiety fluctuates over time and can change in intensity, whereas trait anxiety remains stable.^{19,35} Our meta-analysis revealed that clown therapy alleviates parents' STAI Y-1, but the effect is small. A potential explanation for this is that the clowns are focused on the children, hence, the intervention has greater effects on children than on their parents. Another possible reason is that children's anxiety is mainly due to unfamiliar medical staff and intimidating medical settings, while parents' anxiety is chiefly caused by the illness of their child. Therefore, clowns – who concentrate on alleviating foreignness and disorientation – are helpful for children, but not parents.

There are limitations of this study that should be considered. With 802, predominantly White, European participants, the main limitation of the study is the homogeneity and small size of the sample. Only eight eligible studies were identified, and only seven of which were involved in meta-analysis. Such research circumstances preclude generalisations to more diverse populations, therefore also deeming it premature to draw inferences for

clinical practice. Another limitation of this study is that we do not investigate deeply into the correlations between children and parents. Some studies^{3,36} had found that the parent's anxiety was a predictor of the child's anxiety during the pre-operative period, while other studies^{5,18} showed opposite results. However, due to the lack of sufficient data, the correlation was not analysed in this review.

Conclusion

In conclusion, the pre-operative presence of clowns is an effective way to manage anxiety experienced by children and parents. However, only a small number of studies exist, and research on the effectiveness of clown intervention is still in its infancy. More comprehensive evaluation of the effect of clown intervention on children and parent anxiety can be attained with utilisation of larger sample sizes and more diverse patient populations in future studies. If the results of this study are confirmed on wider samples, the use of pre-operative clown intervention to support children and their parents should be encouraged.

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APPENDIX I

Search strategy used for Medline

Database	#	Search strategy
Medline via Ovid	#1	clown.mp.
	#2	clowning.tw.
	#3	clown therapy.tw.
	#4	clown intervention.tw.
	#5	Laughter Therapy/ or "Wit and Humor as Topic"/
	#6	1 or 2 or 3 or 4 or 5
	#7	preoperative.mp.
	#8	Preoperative Period/ or Preoperative Care/
	#9	anaesthesia induction.tw.
	#10	induction of anaesthesia.tw.
	#11	Anaesthesia/ or Anaesthesia/
	#12	surgery.tw.
	#13	7 or 8 or 9 or 10 or 11 or 12
	#14	anxiety/
	#15	fear.tw. or Fear/
	#16	worry.tw.
	#17	stress.tw.
	#18	14 or 15 or 16 or 17
	#19	6 and 13 and 18

APPENDIX II

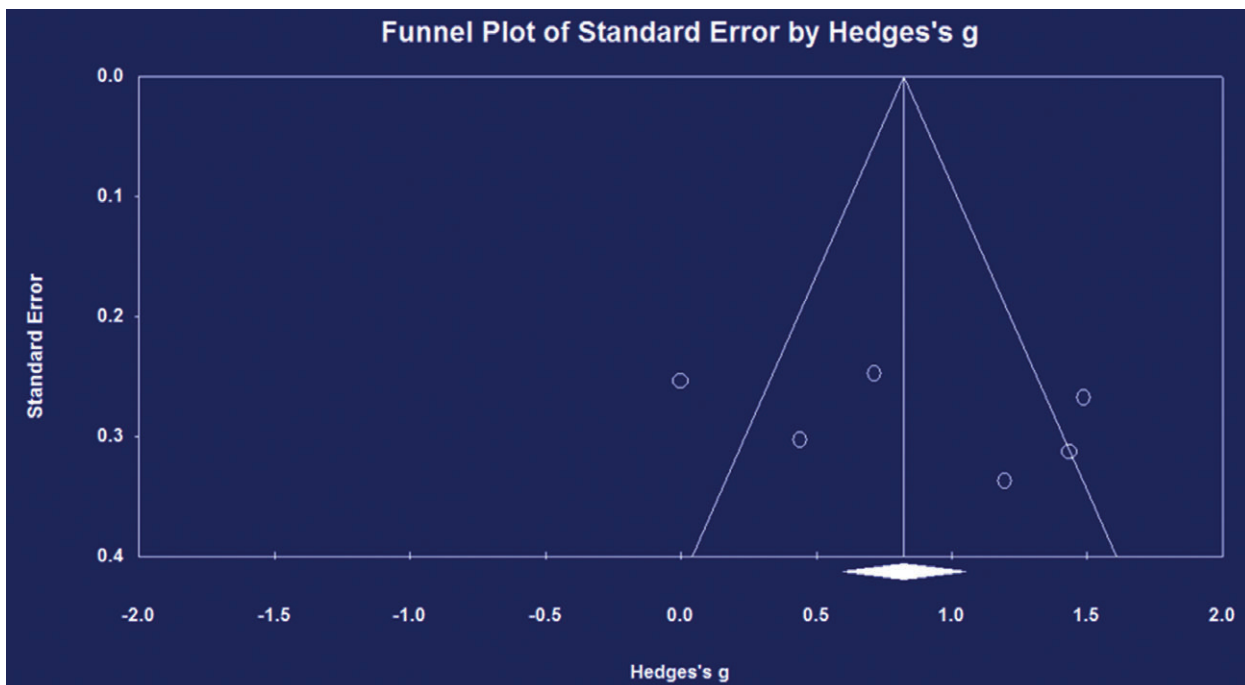
Results of included studies

First author and year	Participants	Outcome	Experiment group (clown)		Control group (no. of clown)		Values
			Pre- <i>n_E</i> mean ± SD	Post- mean ± SD	Pre- <i>n_C</i> mean ± SD	Post- mean ± SD	
Agostini, 2014	Mothers	STAI Y-1	25 43.76 ± 11.45	35.36 ± 8.96	25 46.04 ± 11.67	38.44 ± 7.37	Pre-post = 0.0001; group = 0.34
		STAI Y-2	35.84 ± 8.38	34.8 ± 9.68	38.68 ± 7.89	38.04 ± 8.55	Pre-post = 0.14; group = 0.35
Dionigi, 2014	Children	Anxiety†	52 50 (23– 97)	33 (23– 83)	25 33 (23– 97)	43 (23– 100)	Pre-post = 0.002**; group = 0.004‡
	Mothers	STAI Y-1	49 50 (25– 79)	49 (24– 79)	18 42 (33– 58)	55 (30– 65)	Pre-post = 0.035*; group = 0.193
		STAI Y-2	38 (25– 56)	38 (16– 58)	37.5 (29– 48)	37 (6– 48)	Pre-post = 0.001***; group = 0.261
	Fathers	STAI Y-1	40 36.5 (26– 72)	43 (25– 68)	12 36 (29– 56)	40.5 (29– 62)	Pre-post = 0.005***; group = 0.896
Vagnoli, 2010	Children	Anxiety†	25 29.48 ± 10.47	33.16 ± 18.82	25 34.96 ± 14.39	65.40 ± 24.97	Pre-group = 0.088; post-group = 0.000
	Parents	STAI Y-1	25 —	58.52 ± 12.73	25 —	58.32 ± 9.32	Group = 0.615
		STAI Y-2	—	45.48 ± 7.92	—	50.32 ± 10.41	Group = 0.187
	Children	Worries	35 —	0.95 ± 0.73	35 —	2.20 ± 0.92	$F = 39.54; \eta_p^2 = 0.37; P < 0.001$
Fernandes, 2010	Parents	STAI Y-1	35 —	1.80 ± 0.38	35 —	2.14 ± 0.46	$T(70) = -3.37; P < 0.001$
	Children	Anxiety†	21 28.3 ± 4.6	62.7 ± 14.6	22 38.4 ± 12.7	54.4 ± 21.6	Pre-group = 0.01; post-group > 0.05
Meisel, 2009	Children	Distress	28 0.33 ± 0.30	0.38 ± 0.32	33 0.34 ± 0.33	0.38 ± 0.29	Pre $T = -0.21$; post $T = -0.01$
Vagnoli, 2005	Children	Anxiety†	20 30.95 ± 11.34	37.50 ± 21.48	20 35.95 ± 15.64	68.25 ± 28.42	Pre-group = 0.254; post-group = 0.000
	Parents	STAI Y-1	20 —	73.10 ± 24.96	20 —	77.85 ± 19.19	Group = 0.504
		STAI Y-2	—	41.45 ± 22.11	—	53.25 ± 24.39	Group = 0.117

n_C, number of control group; *n_E*, number of experiment group; STAI Y-1, state anxiety of the parent; STAI Y-2, trait anxiety of the parent.

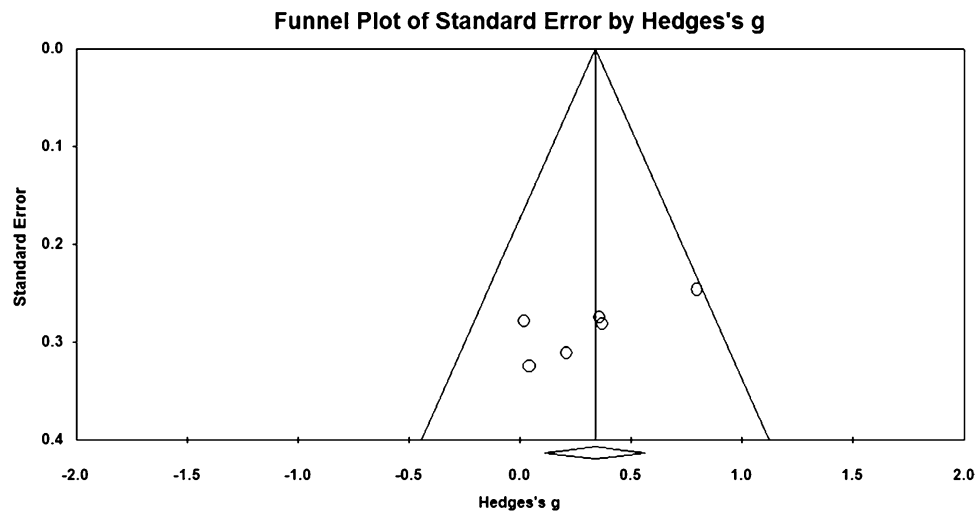
APPENDIX III

Funnel plot of clown intervention in children



APPENDIX IV

Funnel plot of clown intervention in parents (STAI Y-1)



Happy face by Manvi Rastogi (9), from Operation Art 2014.