PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	A SYSTEMATIC REVIEW PROTOCOL EXAMINING THE EFFECTIVENESS OF HOSPITAL CLOWNS FOR SYMPTOM CLUSTER MANAGEMENT IN PEDIATRICS
AUTHORS	LOPES-JÚNIOR, LUÍS CARLOS; Lima, Regina Aparecida Garcia; Olson, Karin; Bomfim, Emiliana; Neves, Eliane Tatsch; Silveira, Denise Sayuri Calheiros da; Nunes, Michelle Darezzo Rodrigues; Nascimento, Lucila; Pereira-da-Silva, Gabriela

VERSION 1 – REVIEW

REVIEWER	Kannan Sridharan Arabian Gulf University
REVIEW RETURNED	21-Oct-2018

GENERAL COMMENTS	The protocol is close to perfection with few clarifications and suggestions as outlined below: 1. Language restriction is likely to reduce the yield of appropriate articles and also generalizability. Hence, the authors should consider including all irrespective of languages and indulge in translation. 2. If coulrophobia has been stated as an exclusion criterion, then all the studies should have mentioned this in their eligibility criteria. I doubt whether this would be the case and this again may reduce the number. Secondly, the studies would be using different criterion to assess this parameter if at all they have it as a criterion. This may lead to heterogeneity. 3. Various sub-group analysis are possible and this reviewer encourages the authors to include it in the protocol. 4. How are the authors going to grade the outcome estimates? 5. How will the heterogeneity be assessed?

REVIEWER	Alberto Dionigi Federazione Nazionale Clowndottori Italy
REVIEW RETURNED	26-Oct-2018

GENERAL COMMENTS	It was my pleasure to review this manuscript. This is a paper with a topic that is of great interest for the field of healthcare clowning. I have some suggestions and questions that I hope will help to strengthen the potential contribution of this topic in any revision the author(s) might undertake. Introduction Pag. 3 lines 23-25 I would say: "As clown intervention, a non-pharmacological approach, has been shown to have a generally positive effect in the outcomes of pediatric patients". Reviews conducted in on this theme (e.g., Sridharan & Sivaramakrishnan, 2016; Zhang, et al., 2017; Dionigi 2018), showed conflicting results.

	Pag. 4, line 48 Please cite also Dionigi 2018
	Pag. 5 line 15 Please also include "Medical Clown", as this term is used by Israeli researchers.
	Pag. 5 Study selection criteria: how do the authors will assess coulrophobia? This is a great limit of studies that must be considered when writing the review.

VERSION 1 – AUTHOR RESPONSE

- Reviewer: 1
Reviewer Name: Kannan Sridharan
Institution and Country: Arabian Gulf University
Please state any competing interests or state 'None declared': None declared.
Please leave your comments for the authors below:
The protocol is close to perfection with few clarifications and suggestions as outlined below:
Response: Thank you so much!
1. Language restriction is likely to reduce the yield of appropriate articles and also generalizability. Hence, the authors should consider including all irrespective of languages and indulge in translation.
Response: OK. We agree with you! Some editions were done in this sentence according to your recommendation. There will be no restriction regarding the language to avoid the reduce the yield of appropriate articles and also generalizability".

2. If coulrophobia has been stated as an exclusion criterion, then all the studies should have mentioned this in their eligibility criteria. I doubt whether this would be the case and this again may reduce the number. Secondly, the studies would be using different criterion to assess this parameter if at all they have it as a criterion. This may lead to heterogeneity.
Response: You are right! Thanks for this carefully consideration. In order to avoid the reduce the number of records in the search strategy we removed this particular exclusion criterion for minimizing the heterogeneity.

3. Various sub-group analysis are possible and this reviewer encourages the authors to include it in the protocol.
Response: OK! Done! Symptom clusters outcomes will be measured all three dimensions of symptom occurrence, severity, and distress according to Dong et al., 2014. Thanks for this suggestion!

4. How are the authors going to grade the outcome estimates?
Response: OK! Done! The key outcome will be measured considering the extent of symptom cluster felt by children during the hospitalization. The primary outcome measures will be the number of children with any symptom cluster during hospitalization, the extent of symptom cluster felt by children measured by any validated scale for the respective symptoms. The secondary outcome measures will be the number of children with acute conditions or chronic disorders, number of children satisfied with the care provided, number of parents satisfied with the care provided.
It is noteworthy that symptom cluster composition, consistency, and stability vary widely depending on a host of measurement factors, including the optimal assessment tool (long vs. short), the most clinically relevant symptom dimensions (prevalence vs. severity or distress caused), the optimal analytical method to derive the cluster, the optimal statistical "cutoff" points to define symptom cluster, and the optimal timing of assessment (Dong et al., 2014; Xiao, 2010).
Thus, we will consider in our analysis factors such as variation in measurement timing, the number of symptoms included in an analysis, in order to generalizability of symptom cluster over time (Kim et al., 2013; Aktas et al., 2012).

5. How will the heterogeneity be assessed?
Response: We I rewrote this paragraph. "All effect sizes will be transformed into a common metric, in order to make them comparable across studies – the bias-corrected standardised difference in means (Hedges' g) – classified as positive when in favour of the intervention and negative when in favour of the control. For continuous outcome measures, standardized mean diferences (SMD) and risk ratio (RR) for categorical outcomes will be considered for the final assessment from individual studies. SMD was chosen as a measure of pooled results considering the likely variability in the measuring scales for continuous outcomes (Sridharan; Sivaramakrishnan, 2016). The SMD will be categorized as small, medium, and large based on the thresholds 0.2, 0.5, and 0.8, respectively, as suggested by Cohen's (1998). The 95 % CI will be used to represent the deviation from the point estimate for both the individual studies and the pooled estimate. Heterogeneity between the studies will be assessed using forest plot visually, as well as I2 statistics (Egger et al., 1997). Random effect models will be used in case of moderate to severe heterogeneity otherwise fixed effect models will be generated. In addition, the presence of publication bias will be evaluated by use of a funnel plot and the Duval and Tweedie's trim and fill method (Duval; Tweedie, 2000)".

Reviewer: 2

Reviewer Name: Alberto Dionigi
Institution and Country: Federazione Nazionale Clowndottori, Italy
Please state any competing interests or state 'None declared': None declared

Please leave your comments for the authors below
It was my pleasure to review this manuscript. This is a paper with a topic that is of great interest for the field of healthcare clowning. I have some suggestions and questions that I hope will help to strengthen the potential contribution of this topic in any revision the author(s) might undertake.
Response: Thank you so much!

Introduction
Pag. 3 lines 23-25 I would say: "As clown intervention, a non-pharmacological approach, has been shown to have a generally positive effect in the outcomes of pediatric patients". Reviews conducted in on this theme (e.g., Sridharan & Sivaramakrishnan, 2016; Zhang, et al., 2017; Dionigi 2018), showed conflicting results.
Response: OK. Done. Thanks for this suggestion!

Pag. 4, line 48 Please cite also Dionigi 2018
Response: OK. Done. I have added a paragraph for this study. Thanks!

Pag. 5 line 15 Please also include "Medical Clown", as this term is used by Israeli researchers.
Response: OK. Done.

Pag. 5 Study selection criteria: how do the authors will assess coulrophobia? This is a great limit of studies that must be considered when writing the review.
Response: This point was addressed according to suggestion of reviewer 1. Thanks!

VERSION 2 – REVIEW

REVIEWER	Kannan Sridharan
	Arabian Gulf University
REVIEW RETURNED	21-Nov-2018

| GENERAL COMMENTS | The revisions are satisfactory. |

REVIEWER	Alberto Dionigi
	Federazione Nazionale Clowndottori - ITALY
REVIEW RETURNED	29-Nov-2018

| GENERAL COMMENTS | I have read the modified paper and in my opinion it suits the required criteria to be published. |