Author’s response to reviews

Title: Definition and improvement of the concept and tools of a psychosocial intervention program for parents in pediatric oncology: A mixed-methods feasibility study conducted with parents and healthcare professionals

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Author’s response to reviews:

Montreal, 12th December 2018

Juliana Belo Diniz, Ph.D., MD
Editor-in-Chief
Pilot and Feasibility Studies
Dear Dr. Juliana Belo Diniz,

Thank you for reviewing the revised version of our manuscript entitled, "Definition and improvement of the concept and tools of a psychosocial intervention program for parents in pediatric oncology: A mixed-methods study conducted with parents and healthcare professionals", which was submitted in consideration for publication in Pilot and Feasibility Studies (PAFS-D-18-00117R1). We would like to extend our sincere gratitude to the two reviewers who examined our manuscript in depth. Each of the reviewers’ suggestions and comments has been taken into consideration and we modified the manuscript accordingly. We hope that you will find this revised manuscript suitable for publication in your journal. Thank you for your time and consideration.

Sincerely,

David Ogez, Ph.D.

Reviewer #1:

Thank you for the opportunity to review a revised version of the manuscript entitled "Definition and improvement of the concept and tools of a psychosocial intervention program for parents in pediatric oncology: A mixed-methods study conducted with parents and health care professionals". The authors were very responsive to my and the other reviewers comments. I have only a few minor suggestions moving forward, all of my other comments were adequately addressed:

1. Page 4: It is not clear why the authors sought to review these programs in the first place. There needs to be some context - what necessitates a review of the interventions designed to support parents of children with cancer?

Response: To learn more about psychosocial support offered to parents, we identified the evidenced based manualized programs, and studied their design and implementation in pediatric oncology. Initially, we did not specify this information as it is described in the review that we cite in our manuscript (reference 13). Following your comment, we note that it is useful to add this information to help the reader understand. Therefore, we added the following information in the manuscript:
In order to evaluate the psychosocial support offered to parents, we conducted a systematic review to identify the evidenced based manualized programs that had been developed, and how they were designed and implemented in pediatric oncology clinics [13].”

More precision on the analyzes performed in this systematic review is also specified in the manuscript (line 84).

2. Page 5:

a) Based on what criteria did the authors decide to 'retain' the two programs?

Response: Bright IDEAS and SCCIP were retained for the definition of our intervention program. These programs are more effective and are recommended by the National Cancer Institute (NCI). In agreement with your comment, we specified this information in the manuscript:

LINE 94: “Based on this review, we retained two programs, Bright IDEAS and SCCIP, which have the best effects on their primary outcomes and are the only ones recommended by the US National Cancer Institute (NCI) [14, 15] …”

b) It is also not clear for what the authors retained these programs.

Response: In order to develop “taking back control together”, we retained the two primary outcomes of these programs: Problem Solving Skills techniques (Bright IDEAS) and family interventions activities that aim to improve coping and marital/intrafamily communication (SCCIP). Accordingly, we specified this information in the manuscript (lines 94 and 102). We also provide this information when we describe the objectives of our intervention (line 134).

3. Page 5: Combining programs

a) How did you decide what to include?

Response: We decided to include these programs’ primary outcomes because they had shown more effects. A description of these components has been added to the manuscript, in line with your comment 2 (see lines 94 and 102).
b) How do you know what you selected produces an effect on the desired outcome? How do you know that what you picked does not have an iatrogenic effect when combined?

Response: The aim of this article is the definition and the refinement of a new manualized program (ORBIT Phase I). To evaluate the clinically significant positive effect of the program on targets, we need to perform a preliminary study (ORBIT phase II). We are currently carrying out this study with parents. If this pilot study shows conclusive results, we will be able to perform RCTs to evaluate the effectiveness of this intervention program (ORBIT Phases III and IV). In the manuscript, we specified the future stages of our program’s development (see line 161).

Line 161: “Following the definition of the intervention, design refinement is an essential step in program development that is necessary to document. The design refinement of the intervention program (ORBIT Phase Ib) aims to identify essential treatment components, determine aspects related to its administration (such as its frequency and duration), and improve its strength and efficiency [24]. The milestones necessary to achieve before progressing to the following step (preliminary testing of the ORBIT Phase II) are to have established the treatment package’s essential components, to ensure that it is safe and acceptable for the target population, and that it is likely to produce a clinically significant positive effect on the target. During these preliminary tests, we will conduct a pilot test which will assess the new program’s acceptability and feasibility. Following these preliminary tests, efficacy (ORBIT Phase III) and effectiveness (ORBIT Phase IV) studies could be conducted.”

4. Page 5: Did you have any buy-in/support from the original program developers?

Response: Following this systematic review, we studied the two programs in depth. Members of our team are also trained in Bright IDEAS and SCCIP. Following this training, we also had the opportunity to discuss aspects of development method with the authors of these programs. Their advice was relevant in the present work. In agreement with your comment, we added this information in the manuscript.

LINE 118: “In order to translate and correctly articulate these programs, members of our team were trained in both programs and met with the authors.”

5. Reference 22 is old and reflects older thinking regarding MOST. Strongly suggest the 2018 Collins book as a replacement for this reference.