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:

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Juliana Belo Diniz, Ph.D., MD

Editor-in-Chief

Pilot and Feasibility Studies
Dear Dr. Juliana Belo Diniz,

Thank you for reviewing our manuscript entitled, "A mixed-methods study conducted with parents and healthcare professionals to improve the concept and tools of a psychosocial intervention program for parents in pediatric oncology", which was submitted in consideration for publication in Pilot and Feasibility Studies (PAFS-D-18-00117). We would like to extend our thanks 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.

Very sincerely,

David Ogez, Ph.D.

Reviewer #1:

Thank you for the opportunity to review the manuscript entitled 'A mixed-methods study conducted with parents and healthcare professionals to improve the concept and tools of a psychosocial intervention program for parents in pediatric oncology'. The authors describe the process of refining an intervention designed to reduce distress among pediatric oncology parents using the ORBIT Model. One of the advantages of a journal like Pilot and Feasibility Studies is the venue for publishing this phase of research, but the challenge for authors is to provide enough information to make sense of what work has been done previously and where it will lead. My comments are largely centered on that discord within this manuscript.

1) Abstract:

a) The first two sentences are slightly in disagreement with each other; if manualized programs are effective, then why do you need to do anything more? This is a nuanced argument that should be discussed in the background (see comments below) but is perhaps misleading in the abstract. Instead, I wonder if the abstract should make the case for the importance of parental distress and say something about how interventions are not currently effective.
Response: We modified the Background section of the abstract in line with changes made in the text of the manuscript. The section describing the intervention was transferred from the Methods to the Background section of the abstract.

Line 34: “Background: Studies have shown that supporting parents in pediatric oncology reduces family distress following a cancer diagnosis. Manualized programs for parents have therefore been developed to reduce family distress. However, these programs have limitations that need to be improved, such as better defining programs’ procedures, developing interventions focusing on the parents’ conjugal relationship, conducting rigorous evaluations of implementation, and proposing adaptations to various cultural dimensions. According to the ORBIT model for the development of behavior intervention, we improved these limitations and developed TAKING BACK CONTROL TOGETHER, a 6-session in-person intervention to support parents of children with cancer by taking the active components of two programs: Bright IDEAS and SCCIP. Referring to the redesign phase of the ORBIT model, the aim of this study is to refine the definition of the design of this program by interviewing parents and healthcare professionals. Methods: In order to refine the program, we used a sequential mixed-methods study…”

b) Line 37: Shouldn't the name of the intervention be capitalized?
Response: As recommended, we wrote the name of the program in capital letters in the abstract and in the manuscript.

2) Background: Overall, this section needs to be reorganized and expanded to demonstrate the problem, describe current intervention efforts, explain why they are not sufficient, and describe how these authors are going to use a rigorous process to make an improved intervention. In short, the need for this work needs to be more clearly articulated.

a) Paragraph on problem: Currently paragraph #1 (lines 57-66) does not adequately justify the couples’ component of the intervention. There is one sentence on marital functioning but given that two sessions of the intervention are couples focused, there needs to be some more justification here for why that is important.
Response: We provided additional rationale for the couple component in the Background section.

Line 74: “In addition to each parent’s distress, studies have also highlighted the specificities of conjugal distress in pediatric oncology [9, 10]. Parents’ intimacy, sexuality, time, and activities were negatively influenced by the child’s cancer. Importantly, it has been shown that spousal support on the current emotional and conjugal adjustment of each spouse improves the couples’
functioning in both the short and long term [11]. These observations are in line with the observation of a reduction of psychological distress and of conjugal conflict, and by a greater satisfaction of married life observed among both fathers and mothers who perceived receiving more support from their spouse [12].”

b) Paragraph about current interventions; currently paragraph 2 (lines 67-73): I can appreciate that the identification of 11 interventions and the review of those interventions was done elsewhere. However, the author needs to provide a brief summary here so that the reader can come to the same conclusion that this intervention is solving a need. The argument must be made that these programs are not sufficient and the need to apply the ORBIT Model. The authors could even say something to the effect of 'The results of this review are presented elsewhere, but briefly…'

Response: As recommended, we presented the results of this systematic review to make it easier for the reader to better understand the development of a new program.

Line 85: “We identified 11 manualized intervention programs aiming at supporting parents following their child’s cancer diagnosis. These programs followed various models of change including cognitive behavioral therapy (CBT), psychoeducation, and systemic therapy. An in-depth analysis of existing intervention programs, their structure and tools, and their hypotheses of change have highlighted a number of limitations in their definition of design that needs improvement [13]. On the one hand, a number of programs did not consider extant components with documented implementation and effects. Other programs did not always accurately document how targets and models of change were selected. On the other hand, a number of programs lacked a refinement of the design, pre-test and test phases that would have improved their acceptability, feasibility, and effectiveness. Finally, the programs were mostly defined for a population and were therefore not applicable to individuals from different cultures. The results of this review is available [13].”

c) Related, it would seem that lines 74-76 are the concluding remarks for paragraph #2.

Response: These lines was reframed according to your recommendations. The sentence was replaced by “Based on this review, we retained two programs with best evidence to date: Bright IDEAS and SCCIP [14, 15].” (Line 97). We included a paragraph on the two programs on which our program is based. In lines 97 to 117, we now discuss the advantages and the limits of these two programs, which allows to develop the definition of our program.
d) Line 70: I suggest clarifying that the support for parents is surrounding their child's cancer diagnosis.

Response: We modified the sentence as follows:

Line 85: “We identified 11 manualized intervention programs aiming to support parents following their child’s cancer diagnosis.”

e) Lines 76 - 87: This paragraph is focused on the ORBIT model, but as is does not clearly describe the advantage of the ORBIT model. The phases should likely be described in more detail and the work described herein should be placed within those phases. In particular, I think the authors need to define how they arrived at the 'best components'. As the authors are likely aware, there are other frameworks for optimizing interventions, such as the Multiphase Optimization Strategy (MOST) developed by Linda Collins. MOST would call for an empirical examination of the components of an intervention before arriving at the most effective, efficient, economical, and scalable intervention. It is probably worthwhile for the authors to put their approach in context of other strategies for making this intervention more effective.

Response: In line with your comment, we justified the choice of ORBIT and described this model in more details. We also explained how we chose the procedures for the new program and why our approach is in accord with the ORBIT Phase I.

Line 118: “Based on these observations, we addressed these programs’ limitations by combining their procedures, and thus their strengths, and by translating them into a program better suited for a French-language population in pediatric oncology [20]. The resulting program was therefore a new integrative intervention offering an active approach to meet parental needs. Several frameworks have been formalized for optimizing interventions [21-23]. Among these, ORBIT is a complete model of evaluation of intervention programs which explicitly describes the preliminary stages of program development [24]. This model consists of four phases: I- program definition phase, II- preliminary tests, III- efficacy studies and, IV-effectiveness studies. Phase I, in which the program is defined, consists of 2 stages: Ia- the definition and Ib- the refinement of the design. With regards to the definition of the new program, TAKING BACK CONTROL TOGETHER, we followed the ORBIT phase I recommendations: 1- definition of the target population, 2- selection of primary and secondary intervention targets of the program, 3- justification of the choice of models of change and their translation into interventional procedures, and 4- development of a coherent program comprising these procedures [25]. In order to standardize the administration of this intervention, we also created a manual for practitioners and parents, consistent with standard practice in behavioral sciences [26].”
f) Line 88: I am struggling with the idea of an 'integrative program'. It is not clear what this means and if it has been integrated in prior work, then the intervention described herein is now its own intervention, no longer integrated right?

Response: The idea of “integrative program” is related to a program that integrates several therapeutic procedures. In order to avoid confusing the reader, we removed this construct from the objectives of the study. We also specified the objectives of this manuscript as requested by Reviewer # 2.

Line 173: “The study’s main objective was to refine TAKING BACK CONTROL TOGETHER following interviews with end-users: pediatric oncology health professionals and parents of children with cancer. Specifically, this study aimed to (1) evaluate and (2) provide suggestions to improve the relevance and acceptability, material, practical implementation and techniques procedures of the program [29].”

3) Methods: This section also should be reorganized. The description of the intervention should be moved to the background section so that the method section focuses on what was done in this phase of the research. With so much detail on the procedures of the intervention, the
reader is led to believe that the paper is going to be about the implementation/delivery of the program when in reality the information about the program and its delivery was only provided to the participants. I suggest that instead the section of the methods

Response: We agree with your comment. The study focuses on the redesign of the program. For this reason, we moved the description of the intervention in the introduction (line 134 - see below).

a) In the description of the intervention, which again I feel strongly should be moved to the background section, there is likely a need for some reorganization. The aim of the program (Line 103) should be in the first sentence. The description should tell the reader what the focus of the intervention is, describe theoretical underpinnings, and then describe how it is implemented briefly. The authors might decide to include some detail of implementation on Figure 1 (which should go in the background section).

Response: We moved the definition of the TAKING BACK CONTROL TOGETHER program to the Background section and followed your recommendations to describe it. We first defined its objective, explained its theoretical aspects, and described its implementation.

Line 134: “TAKING BACK CONTROL TOGETHER aims to strengthen the sense of control and PSST of parents (heterosexual and homosexual couples) and focusing on dyadic coping to prevent distress. It is based on cognitive behavioral and systemic theories. It includes six sessions: four individual sessions, offered to each parent, and two couple sessions (See figure 1). The individual sessions focus on PSST from CBT, as well as acquiring, developing, and maintaining simple problem-solving skills to meet the needs of families facing childhood cancer. PSST includes six stages: 1) problem selection, 2) problem definition and operationalization, 3) generation of possible solutions, 4) decision-making, 5) solution implementation, and 6) effectiveness evaluation [27]. These sessions take place at the hospital during the child's treatment. They can also be offered to single-parent families. The two couple sessions are based on CBT and systemic therapy. They aim to enhance parents' communication and resilience by improving their ability to manage together real difficulties associated with childhood cancer [9, 28]. Couples sessions are provided either at the hospital or at the parents' residence according to the parents’ preference. In blended families, each parent can participate in the program with their new partner. A manual for health professionals (provider manual) provides specific instructions for each intervention to be used in all program sessions. Furthermore, the provider manual offers numerous examples of transcripts to convey the information to parents adequately and in a standardized manner. A manual for parents includes PSST toolkits for individual and couples’ sessions, as well as strategies related to communication and dyadic coping. Three illustrations are also available: 1) a video about a canoe trip disturbed by bad weather to illustrate the steps of problem solving, 2) a written clinical vignette illustrating an example of how a problem related
to a child's cancer is solved by the child's parents, and 3) a video in which parents of children with cancer discuss the challenges they face in their conjugal relationship. A complete description of the definition of the design of this intervention is available [20].”

b) When did the manualization occur - was that in the prior publication or was that between the identification of components and what is presented in this manuscript?

Response: Before this redesign study, a first manualization of the program was made during the definition of the program. Following this study, the manual has been improved. These two phases have been specified in the revised manuscript: in the Background section (line 131) and the Methods sections (line 228).

Line 131: “In order to standardize the administration of this intervention, we also created a manual for practitioners and parents, consistent with standard practice in behavioral sciences [26].”

Line 228: “Finally, after data analysis was completed, the intervention program’s manuals and tools were improved following the participants’ suggestions.”

c) Line 97: The transition is off here, probably an easy fix with punctuation.

Response: This problem has been fixed in the manuscript

d) Line 102: The authors use the word refining here, but I strongly suggest they reserve this word to describe the process they are presenting in this paper not the goal of the couples component.

Response: We replaced the word “refining” with “improving”

Line 144: “They aim to enhance parents' communication and resilience by improving their ability to manage together real difficulties associated with childhood cancer [9, 28].”

e) The illustrations (Line 111) are confusing; these are scenarios? Vignettes? It is unclear how they relate to the intervention.

Response: We added more specifications in the manuscript as recommended.
f) Line 120: As is, the first sentence does not explain how participants were recruited. I recommend moving Line 130 to line 120.

Response: We added this information in the manuscript as suggested (line 182).

g) Line 124: The fact that the parents in this sample are of children who are in remission likely warrants some discussion of this approach in the introduction. Again, I think that if the authors explain the ORBIT model and its process in more detail, this may become clearer to the reader, but the idea is that these are the ultimate end-users, parents who have made it through their child's cancer and they can offer some perspective of parents going through it. I could see a reader wondering why the authors did not have parents of children not in remission in the sample.

Response: As you mentioned, we wanted to interview parents who had a perspective on their child's cancer. In terms of feasibility, it is difficult to ask parents to give time at the difficult time of treatment, without benefit, while parents of patients in remission are often volunteers to help research and improve programs in pediatric oncology. Based on their experience, we wish to evaluate if the program would have met their expectations. The following stages of development will call for the perspective of parents currently experiencing cancer. We will conduct acceptability and feasibility studies with pilot tests involving such parents (phase II of ORBIT). We hope this is now clearer in the manuscript.

Line 192: “The decision to gather experiences from parents whose children are in remission is associated with the desire to evaluate the components of the program with participants who are somewhat at some distance of their experience with the pediatric cancer. Having more perspective on the disease, they are able to share the experience they have lived at different times, from diagnosis to remission.”

h) Line 128 - Line 130: I suggest this is moved to the end of the background to set the stage for what was done in this study.

Response: We specified the futures stages of the study in the background as suggested.
Line 170: “Following these preliminary tests, efficacy (ORBIT Phase III) and effectiveness (ORBIT Phase IV) studies could be conducted.”

i) Line 134: The authors say the participants had received documentation of the program 'beforehand'; I'd like to see a little more detail about how long the participants had the information before the interview.

Response: We specified that the interview was conducted one week after the initial contact, giving the authors time to read the documents.

Line 223: “Thirdly, one week after the initial contact and the description of the program, encounters with parents were …”

j) Line 142: Curious why the authors focused on the providers at first. I'd like to see some justification of why the process began with providers and not parents.

Response: This decision is clinically-based and justified by the criterion of methodological coherence. Since this is a support intervention, we first wished to collect the opinion of clinicians to avoid any inconsistency in what was going to be presented to parents, by making adjustments beforehand if needed. Additional information supporting this decision has been provided in the manuscript.

Line 203: “Meeting healthcare professionals first and parents second is a decision supported by the criterion of methodological coherence and by clinical evidence. We wanted to have the opinion of clinicians to avoid any inconsistency in the care of parents.”

k) Line 143: Is it a potential limitation that the parents were not interviewed in a group setting? If not, why is this called out? If the initial design was to do a focus group, it seems like this would be an important limitation.

Response: This limitation was added to the manuscript.

Line 640: “We were also faced with the impossibility of assembling all parents in one focus group as originally planned in our study. However, we conducted individual interviews that led to a diversity of pertinent experiences.”

l) Line 148: In what form were the evaluation questionnaires completed?
Response: Health professionals completed paper questionnaires whereas parents completed questionnaires in a PDF format on their computer or tablet. We added this information in the manuscript (lines 211 and 222).

m) Line 154: Were providers not compensated?
Response: Compensation was described in the manuscript.

Line 231: “Healthcare professionals did not want to receive financial compensation for their participation. Therefore, a donation of 30 $ was made to an association of their choice.”

n) Line 161-167: I would encourage the authors to offer some sample items for these measures. I might also suggest a table with mean scores for parents and providers. I think this would help with interpreting the qualitative results as a whole.
Response: As suggested, we added sample items (lines 243-258). Quantitative data were analyzed using descriptive statistics (frequencies) in order to identify and prioritize the critical elements to be discussed in the interviews. This information is in the manuscript:

Line 260: “The quantitative data were analyzed using descriptive statistics (frequencies) in order to identify and prioritize the critical elements to be discussed in the interviews.”

o) Line 175: Were kappas calculated for agreement in coding?
Response: Sample size and number of themes did not justify the use of Cohen’s Kappa in this case as there were very few discrepancies at the initial coding stage since the answers to open but direct questions were short and simple and the analytical approach was strictly descriptive. Moreover, inter-coder reliability was verified through discussions between analysts so as to reach consensus in the codes’ definitions.

Line 266: “3- completion of two meetings to discuss and evaluate the interrater agreement and the selections of themes between the authors by consensus (DO CJB RR).”

4) Results: The results of this approach are rich and deserve as much space as the authors have allocated to present. However, I think they are difficult to follow in this format. As mentioned above, I suggest that the quantitative results be presented in a table format. I think then the quantitative results should be presented in context with the qualitative results. This way it is almost as if the participants can explain their quantitative scores. I also recommend
that the results be consistent in the order in which they are presented; that is, for every theme, the provider feedback comes first then the parent. In the discussion the differences should be highlighted.

Response: Thank you for this proposal which improves the presentation of our results. We made changes accordingly to your suggestion. The quantitative results are now presented in a new table (table 1) and in their context with the qualitative results. The qualitative results are also presented in a coherent way. We were consistent in the titles of the results section using the same titles as in the tables 1 and 2. Wherever possible, we presented the results from the healthcare professionals and then the results of parents. Changes are in track change (from line 321). We also added information on this way of presenting our quantitative results in the analysis section.

Line 274: “The quantitative results (average scores on the main topics evaluated by the questionnaires) are summarized in a table and presented in context with the qualitative results.”

a) Line 213 Responses to questionnaires: The method section describes the quantitative measures on a 6-point scale. The results are presented in percentiles. It may be more effective to translate the findings to that 6-point scale and present the mean and standard deviation.

Response: As suggested, we reported the raw scores in a table and in the qualitative results section. Quantitative data were used to highlight the weaknesses of the programs, not to measure parents’ and providers’ mean scores. Therefore, we decided to simplify the presentation of these results by not adding the SD. We followed Reviewer # 2’s suggestions (comment #2). Information on the use of this data was added in the Analyses section of the manuscript.

Line 260: “The quantitative data were analyzed using descriptive statistics (frequencies) in order to identify and prioritize the critical elements to be discussed in the interviews.”

b) Line 235: "The participants began by talking about the parents' experience." Was this all participants? Providers? Parents?

Response: We specify this information in the manuscript

Line 321: “Both healthcare professionals and parents began by talking about the parents' experience.”

c) Line 243: The authors are using the word couple, but there are 2 parents who are not a couple. I have a problem with this conceptualization throughout the paper, and with the intervention. Is it only for heterosexual married couples? What about single parents who rely
on an extended family member for support - it seems like what is discussed may not be relevant for them.

Response: In the “Results” section, when mentioning couples, we put in brackets the codes of the two parents who make up the couple. An example is available in line 332: One couple (P3, P4) expected benefits even following the illness and return to work as well as the possibility of "later generalizing their newly acquired skills."

To facilitate readers’ understanding, we specified the corresponding codes in the Participants section (lines 286-292). This program is defined for both heterosexual and homosexual couples. The individual session can also be delivered to a single-parent or blended family. These details have been added to the manuscript (see lines 135, 143 and 147).

d) Line 356: Unclear who the term 'caregiver' refers to in this sentence.

Response: We specified “Healthcare professional(s)” in the manuscript. Examples are available in lines 284, 400. In line with this comment, we also changed "caregiver” and used the program provider’s attitude (from line 489 and in tables).

5) Discussion:

a) At the end of the discussion section, the authors use the word acceptability. I wonder if this shouldn't be used earlier in the manuscript? In particular, I was looking for the word acceptability around line 490.

Response: Acceptability is now mentioned much earlier, including in the objectives of the current study (see line170).

b) Line 563: The authors might consider clarifying that the feasibility testing would be conducted with parents who recently received a diagnosis.

Response: We specified this information in the manuscript.

Line 650: “The future pilot will be focus on evaluating treatment fidelity and overall feasibility in a pre-post study conducted with parents whose child recently received a pediatric cancer diagnosis. It will also measure the change associated with the intervention.”

c) Table 1: Is it important to note who the comments came from that led to the modification?
Response: This is not an important aspect as we looked at the result as whole in which themes are central, not individuals. It should be noted that in this type of configuration that involves critical judgment from the analysts, one comment made by only one participant could be considered very relevant and crucial and lead to modification.

d) Figure 1: I would like to see more information about implementation in this figure. I think this would streamline the introduction (where I am suggesting the description of the intervention goes now) and be a reference for the comments in the results section as well.

Response: We decided not to follow this suggestion as the present study is not an implementation study but the refining of an intervention program. The figure provides the reader with the initial design of the program: its content, format and tools.

Reviewer #2:

The manuscript entitled "A mixed-methods study conducted with parents and healthcare professionals to improve the concept and tools of a psychosocial intervention program for parents in pediatric oncology" describes the results of the initial assessment of a new treatment manual that improved and integrated previously available manualized intervention programs for parents of children with a cancer diagnosis. Some modifications might be helpful to clarify the study purposes and rationale. A critical point of this study is that the authors failed to explain what is the novelty and advantage of the protocol tested here when compared with already available options. In addition, the small number of observations makes it very hard to draw any conclusions in the quantitative standpoint. Unless extensively reformulated, I do not advise for the publication of this study in its current format.

1) First, I was a little bit confused about the phase in the intervention development that this study referred to. I guess this manuscript describes the feasibility phase for a new manualized protocol. If so, I suggest authors make it clear in the title and abstract.

Response: Our study focuses on the phase Ib of the ORBIT framework: the program’s redesign. The feasibility phase of this program (Phase II) will be conducted later. To avoid confusion, we restructured the Background of the manuscript according to the reviewer #1 recommendations. In this background, we added a paragraph clarifying the ORBIT model and specified the phases Ia and Ib of this model (line 122). We also mentioned that we would be focusing on the redesign phase in the objectives of the current study (line 173) and in the abstract (line 43). The title of
this article has been amended accordingly: 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.

Line 173: “The study’s main objective was to refine TAKING BACK CONTROL TOGETHER following interviews with end-users: pediatric oncology health professionals and parents of children with cancer. Specifically, this study aimed to (1) evaluate and (2) provide suggestions to improve the relevance and acceptability, material, practical implementation and techniques procedures of the program [29].”

2) In the Background section, the rationale for developing a new manualized protocol given that many were already available is not clear. Why did the authors consider the protocols available to that point required improvement and integration with a new manual?

Response: In order to justify the development of a new program, we specified in the Background the limits of existing programs resulting from a systematic review previously conducted. We developed this new program based on Bright IDEAS and SCCIP. We justified the modifications made to these programs in the Background in a paragraph discussing the advantages and limits of these two programs.

Line 97: “Based on this review, we retained two best programs with best evidence to date: Bright IDEAS and SCCIP [14, 15]. Bright IDEAS is an intervention program based on Problem Solving Skills techniques (PSST). Although Bright IDEAS has excellent US National Cancer Institute (NCI) scores on dissemination (5/5) and research integrity (4.4/5), this program still bears limitations. First, because it is only offered to mothers and administered individually, it received a limited impact score (2/5). Second, because it is relatively burdensome and somewhat repetitive (eight in-person sessions), the dropout rate was high (42%) [16]. SCCIP is based on the principles of CBT and systemic therapy. SCCIP consists of family interventions that focus on improving intrafamily communication and relies on different activities. For instance, it relies on the multiple family discussion group which suggests conducting a group discussion to clarify parental functions. A strength of this activity is its family-oriented approach which helps families cope with cancer [17, 18]. SCCIP has received fair NCI scores on research integrity (3.6/5) and dissemination (4/5), but a lower score on impact (1.3/5) [19]. The manual remains largely general with regards to the complexity required for communicational interventions in the family and lacks important details about the specific interventions to be carried out. Thus, it is difficult for professionals to use the interventions prescribed by the program in a systematic way. Of note, Bright IDEAS was developed in two languages (English and Spanish), whereas SCCIP was only developed in English. Like the vast majority (8/11) of available interventions, these programs were developed for a North American population which raises questions about these programs’
transferability to individuals who are from different cultural backgrounds or who do not speak English and/or Spanish [13].

Based on these observations, we addressed these programs’ limitations by combining their procedures, and thus their strengths, and by translating them into a program better suited for a French-language population in pediatric oncology [20]. ……”

3) The paragraph on the ORBIT model is confusing. Does this study concerns the phase II of the ORBIT model? If so, which aspects preconceived in this model were followed in the current study? What advantages this model has in comparison with feasibility trials?

Response: The advantage is that ORBIT specifically integrates a definition phase of the intervention program. Since this study focuses on development, we chose to refer to Phase I of ORBIT. In line with a commentary made by Reviewer #1, we improved the presentation of the ORBIT model (line 122). We also specify which stage of ORBIT is our study (161).

Line 122: “Among these, ORBIT is a complete model of evaluation of intervention programs which explicitly describes the preliminary stages of program development [24]. This model consists of four phases: I- program definition phase, II- preliminary tests, III- efficacy studies and, IV-effectiveness studies. Phase I, in which the program is defined, consists of 2 stages: Ia- the definition and Ib- the refinement of the design. With regards to the definition of the new program, TAKING BACK CONTROL TOGETHER, we followed the ORBIT phase I recommendations: …”

Line 161: “Following the definition of the intervention, design refinement is an essential step in program development that is also necessary to document. The design refinement of the intervention (ORBIT Phase Ib) aims to identify essential treatment components, determine aspects related to the administration of the intervention (such as its frequency and duration for example), and improve the strength and efficiency of the intervention [24].”

4) The paragraph concerning the study's objective (transcribed bellow) is too generic. How do the authors intend to refine their program? Which information will be extracted from the current study and how is it going to be used to refine the existing protocol?

Response: As recommended we specified the objectives of this study.

Line 173: “The study’s main objective was to refine TAKING BACK CONTROL TOGETHER following interviews with end-users: pediatric oncology health professionals and parents of children with cancer. Specifically, this study aimed to (1) evaluate and (2) provide suggestions to
improve the relevance and acceptability, material, practical implementation and techniques procedures of the program [29].”

5) If possible, please update situation of references 11 and 13 that at the time of this submission had been submitted for other journals but had not been yet accepted for publication.

Response: Reference 13 (now 20) has been updated. Reference 11 (now 13) is currently at the end of the revision stage. The reference will be available shortly.

6) When describing the intervention, the authors describe their protocol is based on the Problem-Solving Skills Training (PSST). Indeed, according to figure 1, PSST comprises most of their treatment program. Given that PSST is already a manualized treatment for the same target population what is the novelty in the current study intervention? Does it even make sense to name the protocol differently than PSST?

Response: As discussed previously, we actually use the PSST in the new program. However, Bright IDEAS, which offers eight problem-solving sessions, has limitations that affect adherence to the program. Therefore, we modified the Bright IDEAS protocol to solve this problem. This is now mentioned in the Background section.

Line 99: “Although Bright IDEAS has excellent US National Cancer Institute (NCI) scores on dissemination (5/5) and research integrity (4.4/5), this program still bears limitations. First, because it is only offered to mothers and administered individually, it received a limited impact score (2/5). Second, because it is relatively burdensome and somewhat repetitive (eight in-person sessions), the dropout rate was high (42%) [16].”

7) When describing the participants, please provide the rationale for including parents of children who were in remission for at least six months. In addition, please describe how the information of disease status was obtained.

Response: In agreement with your comment, we specified in the manuscript (line 192) why we have included the parents of children in remission for at least six months. In the invitation to participate in the study, we indicated this inclusion criterion (6 months of remission). During telephone contacts, the inclusion criteria were also checked with the parents. We added this information in the manuscript (see line183 and line 218).

Line 192: “The decision to gather experiences from parents whose children are in remission is associated with the desire to evaluate the components of the program with participants who are somewhat at some distance of their experience with pediatric cancer. Having more perspective
on the disease, they are able to share the experience they have lived at different times, from diagnosis to remission. Information power was reached through pertinence of selected participants and not by the importance of their number [31].”

Line 183: “A post was published on the Leucan Facebook page, a community support organization for children with cancer. The post invited parents to participate in the study and outlined the study’s inclusion criteria. Such recruitment procedure is frequent with population who are difficult to reach and allow participants to be included in the study on a voluntary basis.”

Line 218: “The procedure of these meetings was as follows. Firstly, participating parents were contacted by phone to present the intervention and check the inclusion criteria.”

8) The choice of invited parents through social media is curious. Please justify.
Response: We recruited parents through the Facebook page of community support organization to ensure they would participate in our study on a voluntary basis. We explained the inclusion criteria for parents in the manuscript (line 185). Such recruitment procedure is frequent with population who are difficult to reach: Kayrouz R, Dear BF, Karin E, Titov N. Facebook as an effective recruitment strategy for mental health research of hard to reach populations. Internet Interv. 2016;4:1-10.

9) Please provide rationale for the low number of invitations. Please justify the small number of individuals included in the study and why the authors believe such a small number of observations is sufficient for this phase of the study.
Response: In this project, a large N was not necessary. We opted for an in-depth interview of parents and health professionals who tested the material. These participants had time to reflect and gave us an explicit feedback. The relevance of the selection of participants and the rigor of procedures in this type of research sufficiently justify the power of information for qualitative analysis. This is now specified in the manuscript by and supported by a reference:

Line 196: “Information power was reached through pertinence of selected participants and not by the importance of their number [31].”


10) Given the small number of observations (6 professionals and 4 family units), the use of percentages±SD to illustrate the results seems highly inadequate. In a universe of 10
observations, absolute numbers are sufficiently illustrative. In addition, given the small number of observations any comparison between groups seems completely out of the scope for this study.

Response: Following your recommendation, we now report the raw scores on the scales. The quantitative results were also summarized in a new table (table 1) and presented in context with the qualitative results as suggested by reviewer # 1. In our study, we actually focused on qualitative evaluation of the new program, testimonials, and suggestions from participants. The quantitative data were analyzed using descriptive statistics (frequencies) in order to identify and prioritize the critical elements to be discussed in the interviews. This information is noted in the Analysis section of the manuscript.

Line 262: “The quantitative data were analyzed using descriptive statistics (frequencies) in order to identify and prioritize the critical elements to be discussed in the interviews.”