Peer Review File

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External Peer-Review: Reviewer A

General Comments: This manuscript presents a valuable discussion of the feasibility and acceptability of an online app to support children with cancer and their familial caregivers. While this study focused primarily on the acceptability and feasibility of the app itself, preventing analysis of its impact for this group, it should be commended for the strong sample size obtained for a difficult group to recruit.

Response: We thank Reviewer A for the thoughtful review, suggestions provided, and favorable comments.

Comment A.1: While this manuscript is interesting, the focus on acceptability/feasibility rather than impact for caregivers is of concern. Recent systematic reviews in the area of connected health (which includes m-Health generally), have highlighted a high volume of studies which focus on acceptability/feasibility rather than impact, limiting our understanding of the actual impact of mHealth supports on actual outcomes for children and families. The researchers have collected data on impact, and this manuscript may be well served by amending the overall structure to focus more on impact than feasibility. Further, considering that the design and development of this app is available (though I could not find this information), what additional knowledge or benefit does this manuscript provide?

Response A.1: We are grateful that Reviewer A found this manuscript interesting, and we appreciate the very thoughtful comments**.** We agree with the need for understanding the impact of mHealth on outcomes for children and families. Our study protocol was designed *a priori* as a pilot intervention. The study's sample size was not powered to examine impact of the intervention on the survey outcomes. Accordingly, while we collected outcomes on health-related quality of life domains (e.g., mental, physical, social) and wearable sensors data, we reported these results as exploratory in nature. In taking a stepwise approach, our goal is to eventually design and execute a full-scale randomized controlled trial that will be appropriately powered to examine impact. As suggested by Reviewers A and C, we have substantially revised the Introduction (please see Reviewer C.1). We have amended the overall structure of the Introduction, which we believe still maintains consistency with our *a priori* study design of feasibility and acceptability yet highlights the preliminary findings on outcomes.

In sum, the Introduction has been significantly shortened and the Introduction flow is greatly improved, in accordance with Reviewer A.1's and C.3's recommendations. Additionally, we expanded on the conceptual framework, in accordance with Reviewer A.3's comments and suggestions.

Changes in the Text A.1: The entire Introduction section has been completely revised, reflected in lines 37–65 (marked in red).

We also included "*Roadmap's Preliminary Efficacy on HRQOL Outcomes"* in the header of Exploratory Analyses within the Results section (line 250) and similar discussion point in the Discussion (lines 333–334).

Comment A.2: A second key concern is the apparent absence of the patient/caregiver voice in the design of the ONC Roadmap. As the link included within the manuscript to how the app was developed appears incorrect (it sends you to a page for participants, with no information on development that I could find), the specific approach to development remains outstanding. Additional detail on how (and if) PPI or co-design strategies were used in development would be beneficial.

Response A.2: Thank you for this comment. While we frequently published our early stages of design/development of Roadmap (references 12, 13), we published less in the later stages of the mHealth app. Most of the methods used (e.g., qualitative, quantitative, mixed methods), including use of focus groups, user-centered design groups, surveys, were published in the early stages, but less so in more recent times. A list of some of our early studies are appended at the end of this Response.

Changes in the Text A.2: No modifications or edits were made based on Comment A.2. References 12 and 13 are new.

Comment A.3: A final comment pertains to the need for significant additional detail across the manuscript, particularly with regards a rationale for the study aims. While the introduction presented general information on the needs of caregivers, additional focus on the rationale for this specific study would have been of benefit. Additional detail is needed in the introduction on the specific aspects of positive psychology included in the intervention. Carbonneau's conceptual framework is mentioned, but there is no rationale for inclusion. Why was this specific approach selected? What is the rationale for including it? What impact has this, or similar approaches had on HRQOL in the past? Or on other caregiver outcomes? How did this framework impact the specific activities included in the app? Significantly more detail here is needed to allow the researcher to understand the hypothesized mechanisms of change.

Response A.3: Thank you for these excellent comments and suggestions. We have substantially revised the Introduction based on Reviewers A and C's suggestions. A conceptual framework guides research aims and outcomes and allows researchers to evaluate relationships among constructs of interest. In turn, research advances the science and may modify the constructs of the framework. Carbonneau's conceptual framework has been examined in caregiving for dementia patients; we applied this framework in guiding our work.

We postulated that enrichment events in caregiver daily life, such as positive activity exercises (e.g., Random Acts of Kindness, Savoring, Positive Piggy Bank), will *positively* affect the: **i)** quality of patient and caregiver relationship; **ii)** caregiver's feelings of accomplishment; **iii)** and meaning of caregiver's role in daily life. Ultimately, this will *positively* impact both the caregiver's and patient's well-being and health outcomes (Carbonneau H, Caron C, Desrosiers J. Development of a conceptual framework of positive aspects of caregiving in dementia. Dementia. 2010 Aug;9(3):327–53.). Recognizing the importance of prototyping, pilot testing, and iteratively refining content for usability throughout the design and development process of technology-based interventions, applying Carbonneau's conceptual framework guided the selection of enrichment events in daily life (i.e., the positive activity exercises) and selection of HRQOL measures.

Changes in the Text A.3: As noted in Response A.1, we have modified the Introduction substantially and included text about Carbonneau's conceptual framework along with its application to our study.

Comment A.4: Introduction, on line 93 the term 'exciting' is used – However as mHealth has been around for quite a while at this point, this may be a little overstated.

Response A.4: Thank you for bringing this to our attention.

Changes in the Text A.4: As suggested by Reviewer A.4, we have removed the word "exciting" from this sentence.

Comment A.5: Method, why were patients required to be over 5 years of age? A rationale is needed here

Response A.5: We appreciate Reviewer A's question. Developmental milestones (and the variability in achieving them) would require additional consideration that is beyond the scope of this study. Importantly, there is a longstanding lack of assessments prior to age 5 years due to the developmental milestones.

Changes in the Text A.5: The following text and new reference (16) have been added in Methods as rationale for this eligibility criterion.

The study team has other IRB-approved studies in this patient population (age ≥5 years) where technology and wearable sensors are being examined. Patients in this age group have been participants in similar studies (16).

Comment A.6: Method, what is the rationale for the 50% agree/strongly agree with the feasibility and acceptability of ONC Roadmap. This seems somewhat low. Surely feasibility/acceptability is demonstrated primarily through on-going use over the 120 days, particularly in the context of the research which shows a common 30-day cut-off point for most mHealth apps.

Response A.6: We appreciate Reviewer A's comments. Now, after seeing the responses from the 49 caregivers, we agree that the rationale for 50% *Agree/Strongly Agree* appears somewhat low. This was the first time that our research team used the Feasibility and Acceptability questionnaire as well as the Mobile App Rating Scale in our mHealth studies. There was limited literature in its application for mHealth studies related to families of patients with cancer. Our goal was that more than half of the participants would Agree or Strongly Agree with the feasibility and acceptability of ONC Roadmap over a ~4-

month study period (120 days). The findings herein will help guide new target ranges when using these scales in this patient population.

Changes in the Text A.6: No modifications or edits were made based on Comment A.6.

Comment A.7: Method, the rationale for inclusion of measures is needed (though this will likely be supported by adding a more detailed rationale to the introduction). It seems many different measures were included, but the reasons why are not clear. Specifically, what was the point of the Fitbit? To prompt sleep hygiene or exercise? Or simply to collect data.

Response A.7: Thank you for these questions. The rationale for the measures were guided by our conceptual framework and each of the HRQOL domains that the team was interested in evaluating based on the mHealth platform (see Figure 1) – physical, mental, and social HRQOL domains. The wearable sensor was integrated into the platform to obtain objective physiological measures over the study period.

Changes in the Text A.7: The entire Introduction section has been completely revised. More text has been provided regarding the conceptual framework that guided the selection of measures.

Comment A.8: Results, very low compliance for patients overall – Should be mentioned in the limitations.

Response A.8: We agree with Reviewer A; thank you for this recommendation.

Changes in the Text A.8: We added the following sentence within the Discussion section, reflected in lines 373–375 (marked in red).

"While caregivers were compliant with completing assessments, reporting mood scores, and wearing Fitbit®, patients were more variable in completing the study-related procedures."

Comment A.9: Results, some really interesting impacts on HRQOL are noted. Additional detail on these would be very useful as it shows actual impact.

Response A.9: We appreciate Reviewer A's comment and agree that there are interesting impacts on HRQOL despite the small sample size and the lack of statistical power.

Changes in the Text A.9: We added the following sentences in the Abstract (lines 26–30) near the beginning of the *Exploratory Analyses* (Results) section, reflected in lines 252–254 and lines 264–265 and Discussion lines 333–342:

Abstract: *"Improvements were seen across the majority of the mental HRQOL domains across all groups; even though underpowered, there were significant improvements in caregiver-specific aspects of HRQOL and anxiety and in depression and* *fatigue for children (ages 8–17 years), and a trend toward improvement in depression for children ages 8–17 years and in fatigue for adult patients.”*

Results: *“In general, although most analyses failed to meet conventional levels of statistical significance, there were improvements in all the different mental HRQOL domains across all of the groups over time….* lines 264–265: *No significant changes were observed by parent proxy in patients 5–7 years; however, the means were in the anticipated direction*.”

Discussion: *“While this study was not powered to assess the efficacy of the ONC Roadmap in HRQOL outcomes, exploratory analyses suggest preliminary efficacy on HRQOL outcomes. In general, we saw improvements in mental HRQOL over the 120-day study period for all groups, although this difference only met conventional levels of significance in a few instances, primarily for the caregiver group (where the intervention was intended for). Specifically, there were significant improvements in caregiver-specific strain, caregiver-specific anxiety, and general anxiety at day 120. Interestingly, higher baseline care-specific anxiety scores were associated with less app use; and higher baseline patient (8–17 years) depression scores were associated with less caregiver app use (data not shown). There was also evidence to suggest that patient fatigue improved with caregivers receiving the intervention.”*

Comment A.10: Results, physical health and positive affect were also lower – any rationale as to why?

Response A.10: This is a great question! We briefly touched upon this with the following, *“It is possible that caregivers experienced increased physical burden while caring for other family members at home during the pandemic. We also speculate that with the PROMIS positive affect’s measure of “In the past 7 days: I felt cheerful,” it may better reflect pleasurable engagement (e.g., ecstatic happiness), separate from general well-being, as assessed by the PROMIS global mental health.”*

In the present research, our study sample was small and not sufficiently powered to detect meaningful differences. Nonetheless, there are several possibilities that could explain these observations. We have added the following text and new reference (48) to discuss these possibilities, reflected in lines 352–361.

Changes in the Text A.10:

***“**Lyuobomirsky and Laous’ positive activity model (48) suggests that the dosage and variety of positive activities coupled with motivation and effort of the individual (i.e., person-activity fit) may influence the degree to which well-being is enhanced. Thus, this intersection between characteristics of the individual and the positive activities may be important considerations in how well those activities are able to enhance individual well-being. In the present research, we did not obtain information regarding psychological conditions/disorders or personality traits. These variables could have impacted the findings and will be considered in the design of our future studies. In our ongoing qualitative interviews, we are assessing these considerations in more detail.”*

Comment A.11: Discussion, it is noted that engagement was a particular weakness, specifically entertainment and interest. This should be stated in results. More detail needed here.

Response A.11: Thank you for bringing this to our attention and allowing us to clarify our findings. While Entertainment and Interest were the lowest ratings within the category of Engagement amongst other topics, such as Customization, Interactivity and Target Group, these scores remained higher compared with the Stoyanov review of 50 other published independent ratings. Thus, additional text was provided in the Discussion. Importantly, to address Reviewer A's comment, we state these findings in the Results, as suggested.

Changes in the Text A.11: We have reflected the requested changes in lines 225–226 (marked in red) and lines 290–293 (marked in red):

> ***"****The ONC Roadmap app quality total mean score was 3.59 (SD=0.78) and overall star rating was 3.38 (SD=0.86). The sub-scales, functionality and aesthetic, had the highest reported mean subscale scores of 4.01 (SD=0.66) and 3.88 (SD=0.74), respectively (****Table 4****), followed by information and engagement (mean subscale scores of 3.76 [SD=0.75] and 2.99 [SD=0.87], respectively)."*
>
> *"While overall a specific weakness was engagement, specific elements of entertainment and interest had mean scores higher than previously published studies on independent ratings of 50 mental health and well-being apps (20)".*

Comment A.12: Discussion, it is noted that semi-structured interviews with the dyads are ongoing. I do wonder if this paper would be much stronger had that information been added. Such qualitative data would provide much needed context on the factors impacting the acceptability of the mHealth tool, and barriers to its use. This rich data would really enhance the current manuscript and provide much greater value than the manuscript as it stands.

Response A.12: We appreciate Reviewer A's acknowledgement that the qualitative interviews will provide rich data. Indeed, we wholeheartedly agree. These data will serve as the basis for our next manuscript.

Changes in the Text A.12: No modifications or edits were made based on Comment A.12.

Comment A.13: Discussion, on p15 it is stated: 'Indeed, robust psychosocial support that is low-burden, cost-effective, and dyadic-focused are needed to integrate seamlessly with cancer care delivery'. However, I am not sure that the intervention included in this manuscript meets these criteria. As this intervention requires a smartphone and a fitbit, participants require sufficient finances to afford these technologies, alongside strong wifi signal, and sufficient power to charge the devices. Review of figure 3 notes that there were 3 individuals who did not participate as they didn't have a smartphone and 7 who did not want to use a Fitbit. Additionally, results indicate some challenges for participants particularly around using the Fitbit (linking to phone etc.) querying its ease of use. This statement may need to be amended slightly.

Response A.13: Thank you for bringing this to our attention.

Changes in the Text A.13: We removed the term “robust” and “cost-effective” from this sentence, reflected in lines 316–318.

“Indeed, psychosocial support that is low-burden and dyadic-focused are needed to integrate seamlessly with cancer care delivery.”

Comment A. 14: Thank you for the opportunity to review this very interesting paper. I feel that with greater focus on impact, detail on the underlying rationale and development process, and perhaps the qualitative data (if available), this manuscript may be of interest to those who support caregivers of children with illness.

Response A.14: We are grateful for Reviewer A’s time and efforts in providing a critical review of our manuscript. In addition to the critiques, we especially appreciate the suggested changes to make the manuscript more clear and reader-friendly. We are very pleased with the revised manuscript based on the excellent recommendations provided.

External Peer-Review: Reviewer B

General Comments: The current study reviews the feasibility and acceptability of an mHealth app that to improve caregiver psychosocial support. I appreciate the authors use of evidenced based evaluation frameworks to increase the comparability potential for the application. I had a few small comments that may strengthen the comprehension for readers unfamiliar with app use and psychosocial support measures.

Response: We thank Reviewer B for the thoughtful review, suggestions provided, and favorable comments.

Comment B.1: Introduction, Paragraph 3, you discuss the importance of education / psychoeducation interventions. As I read this, I found myself asking "what are education interventions". Additional context through the inclusion of 1-2 examples may clarify the breadth of these interventions, so that the reader can follow how these examples can be incorporated into mHealth applications, as you present in the next paragraph.

Response B.1: Thank you for this comment. Reviewer B's comment along with Reviewer A's and C's comments led us to substantially revise the Introduction altogether. In doing so, we removed the paragraph that included mention of the psychoeducation interventions. We hope that in doing so, this is much clearer and reader-friendly.

Changes in the Text B.1: The entire Introduction section has been completely revised, reflected in lines 37–65 (marked in red).

Comment B.2:
Methods: Recruitment, you say that both members of the dyad had to agree to participate. As you included children >5, was there assent for younger children? Typical age of assent is age >7-11, depending on complexity of study and individual IRB requirements. Were younger patients asked for assent as well? Would just add line to clarify procedure.

Response B.2: Thank you for this question. In accordance with our IRB, children (age 10–14 years) assented to participate in this study by signing the IRB-approved Assent Form document and adolescents (age 15–17 years) assented by signing the IRB-approved Consent Form document. This was in addition to parents/guardian signing their own IRB-approved Consent Form documents. Pediatric patients (age 5–9 years) did not sign assent/consent documents, in accordance with this IRB-approved study.

Changes in the Text B.2: The following text has been added to the Methods section, reflected in lines 97–100:

> *"Of note, children (age 10–14 years) signed the IRB-approved Assent Form document and adolescents (age 15–17 years) signed the IRB-approved Consent Form document; children (age 5–9 years) did not sign any Assent Form documents."*

Comment B.3: Figure 1: Perhaps I am confused by the numbers. You report 1,116 eligible patients, with 603 excluded for eligibility, then all remaining 513 were also excluded (442 + 54+17), so I am not clear where the additional 50 participants are in the chart.

Response B.3: Thank you for picking up this error. We have now corrected this mistake.

Changes in the Text B.3: Figure 1 TREND Diagram – the “Did not discuss/inquire about study at clinic visit” category should be N=392.

Comment B.4: Assessment: clarify if parents were asked to complete proxy assessments for all age groups, and which patients were eligible to complete self-assessment (i.e. ->8yo)

Response B.4: Thank you for this comment. We have clarified this within the Methods section.

Changes in the Text B.4: The following text has been added, reflected in lines 128–130: *“While patients (age ≥8 years) and family caregivers (age ≥18 years) completed self-assessments, parent proxy assessments were also completed by family caregivers for patients (age 5–17 years only).”*

Comment B.5: Results: 50 were enrolled, but only 49 included in the evaluation. Why was one dyad excluded? (Figure 1)

Response B.5: Thank you for this comment. We inadvertently left this out of Figure 1’s sidenote (orange box, righthand margin). We have now amended it to include the reason for which this dyad was not included in the exploratory analyses. The patient proceeded to hematopoietic cell transplant very shortly after enrolling in the study. While the family caregiver’s data were used to examine the primary outcome (feasibility), it was determined by the study team to not include the patient’s and caregiver’s exploratory analyses data.

Changes in the Text B.5: Figure 1 has been amended with the orange box in the righthand margin that describes the N=1 who proceeded to HCT.

Comment B.6: Line 262 – typo, should be 120-day study period.

Response B.6: Thank you for catching this. We have amended the manuscript to reflect this change, as reflected in line 235.

Changes in the Text B.6: *“In caregivers, the median wear time of sensors across the 120-day study period was:….”*

Comment B.7: Any differences in baseline HRQOL/ health measures and utilization of the app? i.e., – those who had higher baseline were more likely to be engaged, while those with more baseline depression scores or reported hardship/ stress were less likely to use it.

Response B.7: Thank you for this question. As suggested, we performed this analysis by doing a Spearman Correlation between baseline HRQOL scores and Month 1 App Use. As shown in Supplemental Table 2, baseline caregiver specific anxiety negatively correlated with App Use at Month 1.

Changes in the Text B.7: We added the following sentences, as reflected in lines 257–259 (results) and 338–342 (Discussion), to address this question:

"Interestingly, caregiver-specific anxiety at T0 was negatively correlated with app use at T1 (i.e., higher baseline anxiety scores were associated with less app use over the next 30 days)."

"Interestingly, higher baseline care-specific anxiety scores were associated with less app use; and higher baseline patient (8–17 years) depression scores were associated with less caregiver app use (data not shown). There was also evidence to suggest that patient fatigue improved with caregivers receiving the intervention."

Comment B.8: Discussion, how did the large drop in patient compliance with fitbit use potentially affect your results? Thoughts on why they only wore for an hour at the end? I think your discussion of engagement is good. But the lack of engaging interface would be a constant. Maybe waning effect of novelty.

Response B.8: Thank you for these important questions. We are very interested in how we can better engage our participants. The study's focus was primarily on the caregiver. Our future studies will incorporate the dyad and emphasize both individuals from initial stages of *Onboarding*. Nonetheless, we are currently examining such questions (related to engagement) in our qualitative interviews across ongoing studies involving diverse patient populations. We appreciate Reviewer B's insights and will include the limitation of waning effect of novelty.

Changes in the Text B.8: The following text has been added, reflected in lines 366–370, as suggested.

"In the present study, patient compliance waned over time. The patient was not emphasized as the primary member of the study. It is possible their involvement was no longer considered novel or important over time. In future studies, we hope to incorporate the dyad as its primary target rather than one member of the dyad alone (e.g., caregiver)."

Comment B.9: This may be something you are exploring in your post interviews. Although not powered to demonstrate feasibility, were there any reportable trends that use was correlated to higher HRQOL scores? Meaning among those who used higher times per week, they on average had higher scores at time T1/ T2?

Response B.9: Excellent question. Please see Response B.7.

Changes in the Text B.9: No modifications or edits were made based on Comment B.9.

External Peer-Review: Reviewer C

Overall Comments:
In this paper, Koblick et al evaluated outcomes associated with the use of an mHealth tool directed at caregivers of children with cancer. Overall, the content of this manuscript is highly relevant and contribute towards the medical literature in a meaningful way. The manuscript would benefit from improvements in flow and organization.

Response: We thank Reviewer A for the thoughtful review, suggestions provided, and favorable comments.

Comment C.1: The abstract appears to add in information collected in the study. For example, "unpaid family caregiver" seems to refer to information gathered about employment status that was not a pre-requisite for enrollment. Take a step back and focus on the why, the what, and then the who and how it turned out. The methods were lacking a clear understanding of what was measured.

Response C.1: We are grateful to Reviewer C for these comments; we revised our Abstract accordingly while remaining within the 350-word limit per the journal requirements.

Changes in the Text C.1: Major edits were made to the Abstract, as reflect in lines 4–16 (marked in red).

> ***"Methods:*** *Eligibility for study participation included: family caregivers age ≥18 years and self-reported as the primary caregiver of their pediatric patient with cancer; patients age ≥5 years and receiving cancer care at the University of Michigan. Feasibility was calculated as the percentage of caregivers who logged into ONC Roadmap and engaged with it at least twice weekly for at least 50% of the 120-day study duration. Feasibility and acceptability of the ONC Roadmap platform was also assessed through a Feasibility and Acceptability questionnaire and the Mobile App Rating Scale to specifically assess app-quality. Exploratory analyses were also conducted to assess HRQOL self- or parent proxy assessments and physiological data capture (e.g., heart rate, sleep, activity) in caregivers and patients. For descriptive statistics, continuous measures were described using means/medians (M) and standard deviation (SD)/interquartile range (IQR), while categorical measures were summarized using frequencies and proportions. These data were analyzed using R (version 4.1.1)."*

Comment C.2: I would suggest that the term "pediatric cancer patients" be avoided. They are children first and foremost, who have cancer. Therefore children with cancer or pediatric patients with cancer is more appropriate – this was a gem that Dr. Robert Arceci passed down to me early in my career.

Response C.2: Thank you for this excellent recommendation. We have modified the Title as well as any text that previously stated "pediatric cancer patients" and replaced with "pediatric patients with cancer."

Changes in the Text C.2: As suggested, these modifications have been made in the Title, Abstract (lines 5 and 32), Introduction (lines 57 and 60), Methods (line 87), Results (line 202), and Discussion (line 279)

Comment C.3: The introduction was longer than was needed and lacked a clear flow. Unlike adult oncology where caregiving becomes a role that an adult takes on when someone they love has cancer; parents and caregivers (i.e. legal guardian, grandparent, etc) are inherently caregiving (it's a legal obligation and one most people assume they will take when they parent a child). I would focus more on the basis of why you did this intervention – there seemed to be prior work on the app.
1- We created this app because…
2- Caregivers of children with cancer experience distress…
3- So we are using this app to intervene on this population
It seemed that your outcomes were more than what the title suggestion:
1. HRQoL
2. Biomarkers through the Fitbit
3. MARS to assess acceptability
4. App usage to assess feasibility
It almost feels like these could be two separate papers with the first 2 being separated from the second 2.

Response C.3: We are grateful to Reviewer C for this outstanding recommendation and for providing the suggested text to use. We have incorporated the suggestions.

Changes in the Text C.3: The Introduction has been substantially revised (lines 37–65). The amount of text is significantly shortened, and the flow of the Introduction is greatly improved. Of note, in accordance to Reviewer A Comment A.3, we expanded the text about the point about the conceptual framework, please see Response A.3.

Comment C.4:
The methods also need clarity. List the population with inclusion/exclusion, the intervention (aka details about the app – broad ones), then the entire set of outcomes you are measuring, and then how each measurement is going to be assessed. Most of this was there but out of order.

Response C.4: Thank you for this recommendation. We appreciate the guidance in the method chronology. The order has been modified accordingly.

Changes in the Text C.4: As suggested, the following order of the Methods has been revised and new text have been included, reflected in lines 67–159 (marked in red):

1. Ethical Statement (journal requirement per the "Submission Checklist for Authors": in the main text as well as footnote)
2. Study Site
3. Recruitment and Enrollment (Inclusion Criteria)
4. The Intervention: Study Procedures
    a. Self-Reported Assessments

    b. Roadmap and Fitbit Apps
    c. Wearable Sensor
5. Statistical Analyses

Comment C.5: These changes will then inform the flow of the results and discussion. Of note, it isn't always necessary to include percentages in the first paragraph of the discussion – it feels like you are just repeating the results. Rather, frame it so that whomever just reads that one paragraph understands the overall picture of how the study went (in this case – seemed like it was feasible and acceptable). What this means to the literature, and where this should go next.

Response C.5: We appreciate this recommendation. We hope the following order and revised text have improved the clarity of the Discussion:

- Paragraphs 1–3 of the Discussion focus on feasibility and acceptability.
- Paragraph 4 discusses reasons that may have impacted feasibility and acceptability (as well as the HRQOL outcomes), namely caregiver burden.
- Paragraph 5 discusses strategies to improve mHealth studies designs involving family caregivers, such as dyadic studies (incorporating the care partner and recipient as opposed to one member of dyad).
- Paragraph 6 discusses the exploratory analyses
- Paragraph 7 was added as new to address Reviewer A.10 (see Response A.10).
- Paragraph 8 wraps the Discussion up with Strengths and Limitations

Changes in the Text C.5: As suggested, we have revised the first paragraph of the Introduction with removal of the percentages such that the Results section is not repeated, reflected in lines 279–283 (marked in red):

"In this study, family caregivers of pediatric patients met our a priori defined measure for Feasibility for the study duration (120-days). The majority of family caregivers agreed that the ONC Roadmap app, Fitbit®, and study design were feasible and acceptable. They also indicated they were likely to engage in a similar future study lasting up to 6-months."

External Peer-Review: Reviewer D

General Comment: I found this to be an informative and interesting paper which provides good support for the feasibility and acceptability of apps in the support of caregivers.

Response: We thank Reviewer D for the thoughtful review, suggestions provided, and favorable comments.

Comment D.1: There is little explanation for the ~50% that occurs on line 238 and in other places in the paper. Why an approximation? How was that calculated?

Response D.1: Thank you for this question. Please also see Response A.7. We used an approximation based on our other current mHealth IRB protocols in the hematopoietic cell transplantation setting where at least 50% was used for at least twice weekly. There was no “science” per se to selecting that approximation, rather, it was based on our other mHealth studies and being consistent in our IRB application.

Changes in the Text D.1: No modifications or edits were made based on Comment D.1.

Comment D.2: Please provide more explanation re: the assessment of HRQOL outcomes. You say the study was not powered to assess it, yet you provide an exploratory analysis. Would it be better to present the completed work?

Response D.2: Thank you for this comment. We apologize if the use of “exploratory” was confusing. It was meant more in the terms of clinical trials/research, where the primary outcome of the study was feasibility and acceptability, and the other outcomes were preliminary in nature due to the lack of statistical power. We have presented the completed analyses for this pilot intervention. We hope that we have improved the clarity and readability of the manuscript by addressing the queries and comments/suggestions provided by all the reviewers.

Changes in the Text D.2: No modifications or edits were made based on Comment D.1.

Comment D.3: Your conclusion focuses on the above "suggestions" rather than the main study question (feasibility / acceptability)

Response D.3: Thank you for the comment. We hope that by addressing the collective Reviewers’ queries and comments, the clarity and readability of the manuscript have improved, in line with the studies focus on feasibility and acceptability.

- Paragraphs 1–3 of the Discussion focus on feasibility and acceptability.
- Paragraph 4 discusses reasons that may have impacted feasibility and acceptability (as well as the HRQOL outcomes), namely caregiver burden.
- Paragraph 5 discusses strategies to improve mHealth studies designs involving family caregivers, such as dyadic studies (incorporating the care partner and recipient as opposed to one member of dyad).
- Paragraph 6 discusses the exploratory analyses

- Paragraph 7 was added as new to address Reviewer A.10 (see Response A.10).
- Paragraph 8 wraps the Discussion up with Strengths and Limitations

Changes in the Text D.3: No modifications or edits were made based on Comment D.1.

Comment D.4: Looking forward to the feedback from users in the interviews.

Response D.4: Thank you, we are looking forward to the analyses. The data collection and analyses are ongoing and we be written as a separate manuscript. Indeed, the Reviewers' queries and comments provided herein will serve as the basis for additional items we will add to our Interview Guide for mHealth studies using the Roadmap platform in other patient populations.

Changes in the Text D.4: No modifications or edits were made based on Comment D.4.

References for Response to A.2:

1. Maher M, Hanauer DA, Kaziunas E, et al. A Novel Health Information Technology Communication System to Increase Caregiver Activation in the Context of Hospital-Based Pediatric Hematopoietic Cell Transplantation: A Pilot Study. JMIR Res Protoc 2015;4(4):e119.

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