

PEER REVIEW HISTORY

BMJ Paediatrics Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Development and Testing of a Videogame Intervention for Symptom Management among 8-18-Year- Old Children with Cancer: A Study Protocol
AUTHORS	Sajjad, Sehrish; Gul, Raisa; Sayani, Saleem; Fadoo, Zehra; Abbasi, Ahmed; Barolia, Rubina

VERSION 1 - REVIEW

REVIEWER NAME	<i>Luis Rajmil</i>
REVIEWER AFFILIATION	None disclosed
REVIEWER CONFLICT OF INTEREST	
DATE REVIEW RETURNED	22-Jun-2024

GENERAL COMMENTS	<p>The Ms is a protocol for the evaluation of an intervention based on the use of a videogame in pediatric cancer patients in Pakistan. It is about the development and evaluation of the intervention with a videogame. The authors describe the lack of these types of instruments in LMIC countries.</p> <p>The protocol is generally well planned and the development and results of 2 of the 3 phases proposed by the authors are explained. To try to improve the work, the following aspects could be considered:</p> <ol style="list-style-type: none">1) The Peds-QL is a widely known and used instrument. However, if an Urdu version did not exist, it would be advisable for the authors to follow the methodology traditionally recommended for adapting a new version (see for example Wild et al. Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcomes (PRO) Measures: Report of the ISPOR Task Force for Translation and Cultural Value Health 8(2): 94-104.) In this sense, the forward and back translation and adaptation process and a minimum evaluation of comparative reliability and validity between the original version and the Urdu version would facilitate assessing the equivalence between the versions.2) The sample selection criteria seem clear but perhaps it should be clarified which types of cancer are included, since the study deals primarily mainly with the impact and intervention on symptoms of anticancer therapies. For this reason, perhaps if it were possible, the inclusion criteria should delve into: the comparison between ages, types of cancer and stage at the time of inclusion in the study?3) Children in a critical stage will be excluded as a selection criterion, but what will happen if during the study they develop serious complications or die, how will the results be evaluated in those cases?4) Inclusion/exclusion criteria and analysis of results: As this is a study justified by the lack of evaluation in LMIC, how many are expected to be excluded due to lack of access to the internet/video
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	<p>games. Additionally, will the socioeconomic level and/or family educational level be taken into account in both groups?</p> <p>5) Minor changes: Perhaps in the title you could add that it is aimed at children aged 8-18.</p> <p>Page 2 line 8 and 9, please correct: "the feasibility will be assessed quantitatively and qualitatively"</p>
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VERSION 1 – AUTHOR RESPONSE

Comment 1: The Peds-QL is a widely known and used instrument. However, if an Urdu version did not exist, it would be advisable for the authors to follow the methodology traditionally recommended for adapting a new version (see for example Wild et al. Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcomes (PRO) Measures: Report of the ISPOR Task Force for Translation and Cultural Value Health 8(2): 94-104.) In this sense, the forward and back translation and adaptation process and a minimum evaluation of comparative reliability and validity between the original version and the Urdu version would facilitate assessing the equivalence between the versions.

Response: Thank you for the comment. The PedsQL 4.0 (generic core scale), already available in Urdu, is provided by the MAPI Research Trust. Our research team conducted the Urdu translation of PedsQL 3.0 (cancer module) following MAPI Research Trust guidelines, and it has been approved for use in this study. The Content Validity Index (CVI) for PedsQL 3.0 is 0.70 for reliability and 0.74 for clarity. The approved Urdu versions of both tools will be used in the study. This information can be found in the manuscript on page 13, lines 15-19.

Comment 2: The sample selection criteria seem clear but perhaps it should be clarified which types of cancer are included, since the study deals primarily mainly with the impact and intervention on symptoms of anticancer therapies. For this reason, perhaps if it were possible, the inclusion criteria should delve into: the comparison between ages, types of cancer and stage at the time of inclusion in the study?

Response:

1) This study uses a pilot randomized controlled trial (RCT) design in the third phase. We will enroll children with aged 8-18 years with any type and stage of cancer to assess the efficacy of the videogame intervention in the pediatric oncology population. This criterion was selected based on existing literature indicating poor health-related quality of life (HRQOL) in children across all age groups and cancer types and stages (Birnie et al., 2018; Dupuis et al., 2019; Tomlinson et al., 2019). Additionally, as this is an educational videogame, it will be provided to all children over 8 years old experiencing cancer symptoms to educate them about symptom management. Narrowing the inclusion criteria could limit the generalizability of the study's findings. Randomization will address the distribution of demographic and clinical variables in both groups. This information is added in the manuscript on page 11, lines 18-24. The reference list is also revised accordingly.

2) A subgroup analysis will also be performed to compare these variables and their impact on children's HRQOL. This information is added in the manuscript on page 16, lines 12-14.

Comment 3: Children in a critical stage will be excluded as a selection criterion, but what will happen if during the study they develop serious complications or die, how will the results be evaluated in those cases?

Response:

1) Our research team has two pediatric clinical oncologists who will help identify children at risk in critical stages and manage them as necessary. This information is written on page 17 last line and page 18 first line.

2) We will utilize an intention-to-treat (ITT) analysis to preserve the benefits of randomization. Analysis conducted through ITT will also reflect effectiveness of the intervention in praxis. This information is provided on page 16 lines 5-7.

Comment 4: Inclusion/exclusion criteria and analysis of results: As this is a study justified by the lack of evaluation in LMIC, how many are expected to be excluded due to lack of access to the internet/video games. Additionally, will the socioeconomic level and/or family educational level be taken into account in both groups?

Response: Thank you for the comment. We anticipate that 5-8% of children visiting our study setting from Karachi city and surrounding areas may be excluded due to lack of access to smartphones and the internet. Our preliminary assessment suggests that children from Karachi usually have access to smartphones and internet at home, either for themselves or their parents, which will allow them to play the videogame. For children visiting from outside Karachi, most of them stay with their relatives or family acquaintances in Karachi who have access to smartphones and the internet during their treatment period, enabling them to use the game. Additionally, the video game is designed to be played offline, so children without internet access at home can still benefit from it.

Comment 5: Perhaps in the title you could add that it is aimed at children aged 8-18.

Response: Thank you for your suggestion! We have revised the title as 'Development and Testing of a Videogame Intervention for Symptom Management among 8-18-year- old Children with Cancer: A Study Protocol'. It is mentioned on page 1, line 1.

Comment 6: Page 2 line 8 and 9, please correct: "the feasibility will be assessed quantitatively and qualitatively"

Response: Thank you for identifying the error. The changes are made on page 2 line 4.

VERSION 2 – REVIEW

REVIEWER NAME	<i>Luis Rajmil</i>
REVIEWER AFFILIATION	None disclosed

REVIEWER CONFLICT OF INTEREST	
DATE REVIEW RETURNED	08-Jul-2024

GENERAL COMMENTS	I think the authors have adequately answered my questions.
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