

PEER REVIEW HISTORY

BMJ 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)	Effectiveness of Acceptance Commitment Therapy for Head and Neck Cancer Patients with Body Image Distress in China: A Study Protocol for Randomized Controlled Trial
AUTHORS	Xu, Wenjie; Wan, Hongwei; Xiang, Lina; Wang, Shuman; Zhu, Yu; Zheng, Mimi

VERSION 1 - REVIEW

REVIEWER NAME	Bouatay, Rachida
REVIEWER AFFILIATION	University of Monastir
REVIEWER CONFLICT OF INTEREST	None
DATE REVIEW RETURNED	17-Mar-2024

GENERAL COMMENTS	<p>a very interesting subject to study and raise since the psychological side of these patients is often underestimated</p> <p>a very clear methodology</p> <p>the subject of the study deserves to include more patients</p> <p>the introduction is too long</p> <p>I did not understand the difference between these 2 parameters to evaluate "Head and neck cancer-related BID" and "cancer-related BID"</p> <p>another limitation of the study that must be raised is the subjectivity of the results</p>
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REVIEWER NAME	Perréard, Marion
REVIEWER AFFILIATION	Department of Otolaryngology-Head and Neck Surgery, CHU de Caen
REVIEWER CONFLICT OF INTEREST	No competing interests
DATE REVIEW RETURNED	05-May-2024

GENERAL COMMENTS	<p>The article is well written, the procedure of the trial is clearly explicated and seems simple and realistic to conduct</p> <p>I have a few remarks</p> <p>Abstract :</p> <p>I would add the dimension of breathing to "eating and speechin" to the main functional dimension of head and neck altered by the treatments</p> <p>"1 month after conclusion" : the follow up is short and should be discussed</p> <p>Introduction :</p>
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	<p>I would rather say "The head and neck area contain vital organs for..."</p> <p>"The resultant psychological distress" -> 'the resultant is psychological distress"</p> <p>"BID occurred..." : it would be relevant to know the delay of occurrence of BID and the duration</p> <p>"There are 3 interventions programm..." : it would be clearer to mention here at which group ACT belongs</p> <p>"However...a structured intervention programm and it is more difficult..."</p> <p>"Was 6.6 higher than that..." should be rephrased</p> <p>"Small sample size" : you don't mention the size of the different trial you cite</p> <p>MandM</p> <p>Recruitment : recruitment is not prospective and seems to be highly dependent on patient motivation to include the study which could lead to a big bias of recruitment</p> <p>Participations :</p> <p>"With no evidence of disease" : not clear. Other disease maybe ?</p> <p>Other disease in acute phase ?</p> <p>About exclusions criteria (a) and (b) : it's not explained who and especially how those criteria will be evaluated</p> <p>Intervention :</p> <p>I found that the definition of ACT would be more relevant in the introduction than in this part</p> <p>Discussion</p> <p>No comments</p>
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VERSION 1 – AUTHOR RESPONSE

Point-by-point respond to reviewers' comments :

Reviewer #1:

(1) a very interesting subject to study and raise since the psychological side of these patients is often underestimated. a very clear methodology.

Response: Thank you for your positive feedback; we're glad to know our focus on the psychological aspects of cancer patients and our methodology resonate with you.

(2) the subject of the study deserves to include more patients.

Response: We appreciated the suggestion. We focused on patients with head and neck cancer who have its unique body image distress, starting with a pilot RCT. If it goes well, we will include more patients.

(3) the introduction is too long.

Response: Thank you for your advice. We have made appropriate cuts to the introduction.

(4) I did not understand the difference between these 2 parameters to evaluate "Head and neck cancer-related BID" and "cancer-related BID".

Response: Thank you for your question. The evaluative dimensions differed between the Head and neck cancer-related BID and the cancer-related BID, mainly in that patients with HNC have a different focus on body image than other cancers. Indeed, our study focuses more on the former. However, for HNC-related BID, we have just completed the Chinese translation of the measurement tool, which is not widely used at present. While BIS is the most widely used measure of BID among HNC patients, and had a known cutoff score indicating clinically significant BID. So we hope to further confirm the effect of the intervention by combining the two.

(5) another limitation of the study that must be raised is the subjectivity of the results.

Response: Thank you for your suggestion. We have added the subjectivity of the results to the limitations. (Page 3)

Reviewer #2:

(1) The article is well written, the procedure of the trial is clearly explicated and seems simple and realistic to conduct.

Response: Thank you for your encouraging words; we're pleased to hear that.

(2) Abstract: I would add the dimension of breathing to "eating and speaking" to the main functional dimension of head and neck altered by the treatments.

Response: Thank you for your advice. We have modified this. (Page 2)

(3) "1 month after conclusion" : the follow up is short and should be discussed.

Response: Thank you for your suggestion. Indeed, we previously considered this issue. After team discussion, the rationale for adopting a follow-up time of 1 month is as follows: 1. A large number of studies have confirmed the significant effect of one month after ACT-based intervention. 2. For this pilot study, we would like to evaluate its effect initially. If there is an improvement in the short term, we will extend the follow-up period in subsequent studies. 3. The reintegration needs of the participants included in this research unit are high, so the short-term follow-up is more representative and economical.

(4) Introduction : I would rather say "The head and neck area contain vital organs for..."

Response: Thank you. We made the change. (Page 4)

(5) "The resultant psychological distress" -> 'the resultant is psychological distress"

Response: Thank you. We made the change. (Page 4)

(6) "BID occurred..." : it would be relevant to know the delay of occurrence of BID and the duration.

Response: Thanks to your suggestion, we've added a detailed elaboration of the correlation between BID and time. (Page 4)

(7) "There are 3 interventions programmed..." : it would be clearer to mention here at which group ACT belongs.

Response: Thanks to your suggestion, we've added this section to make it clearer. (Page 5)

(8) "However...a structured intervention program and it is more difficult..."

Response: Thank you for your detailed suggestions, we made the changes. (Page 5)

(9) "Was 6.6 higher than that..." should be rephrased.

Response: Thanks to your suggestion. We made the change. (Page 5)

(10) "Small sample size" : you don't mention the size of the different trial you cite.

Response: Thanks to your suggestion, we've added this section, "with 44 patients" , to make it clearer. (Page 5)

(11) Recruitment : recruitment is not prospective and seems to be highly dependent on patient motivation to include the study which could lead to a big bias of recruitment.

Response: Thank you for your feedback. Such recruitment is common, but it may indeed lead to some selection bias, and we have added a corresponding statement on the limitations of the study.

(12) Participations : "With no evidence of disease" : not clear. Other disease maybe ? Other disease in acute phase ?

Response: Thank you for bringing this to our attention. We have expressed this more clearly. (Page 7)

(13) About exclusions criteria (a) and (b) : it's not explained who and especially how those criteria will be evaluated

Response: Thanks for the heads up. We have made changes to this. (Page 7)

(14) Intervention: I found that the definition of ACT would be more relevant in the introduction than in this part

Response: Thank you for your advice. We couldn't agree more and have made changes to it. (Page 5)