PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Effectiveness of a nurse-led coaching of self care agency intervention for elderly patients with total laryngectomy: Study protocol for a randomized controlled trial
AUTHORS	Zheng, Liyuan; Luo, Zhen; Wang, Huifen; Liu, Shu'e; Li, Xue; Peng, Danxia; Liu, Yan; Ye, Sanxia; Lu, Yuchen; Chen, Jian; Mei, Zhidan; Wei, Lai; Qian, Yu; Lin, Xi; Xu, Chun

VERSION 1 – REVIEW

REVIEWER	Swai, Joel University of Alberta Faculty of Medicine & Dentistry, Department of Medicine
REVIEW RETURNED	01-Mar-2022

GENERAL COMMENTS	Thank you for the invitation to review the manuscript entitled, " Effectiveness of a nurse-led coaching of self care agency intervention for elderly patients with total laryngectomy: Study protocol for a randomized controlled trial." The authors prepared a protocol of a randomized trial to explore whether the nurse led selfcare intervention is effective in improving various outcomes among elderly patients undergone total laryngectomy. The protocol is well-written, with a technically correct methodology. I suggest revisions below. Comment 1: Page 4, Line 14: The protocol has the registration number ChiCTR2100043731 on the Chinese Clinical Trial Registry. However, there are significant deviations between the information on the present protocol versus one displayed on the Chinese Clinical Trial Registry (https://www.chictr.org.cn/showprojen.aspx?proj=121921). For example, the current protocol included the elderly population (i.e., >65 years), while the one displayed on the Chinese Clinical Trial Registry includes 18-70 years only. There are more deviations. Did the study's funder review the present protocol and approve these deviations?

	Comment 2: Page 9 Line 38: Authors report that participants will be randomly assigned… Authors might want to specify the randomization technique. Comment 3: Page 15 Line 12: Measurements: Authors might want to report the Cronbach's alpha values for the validated instrument in the targeted population. Comment 4: Page 15 Line 12: Measurements: Authors might want to report whether the permission/license to use the measurement instruments was obtained from their respective authors, or the instruments are freely available to use without formal permission/license (i.e., public domain).

REVIEWER	Ishii, Ryo Tohoku University, Department of Otolaryngology-Head and Neck Surgery
REVIEW RETURNED	16-Mar-2022

GENERAL COMMENTS	Thank you for the opportunity to review this manuscript. This protocol of trial is appropriate to address the clinical needs, in which we explore whether this systematic self care intervention program can improve the postoperative self-care ability of elderly patients who received TL. In these points this manuscript is worth considering for publication, but there are some revisions needed to more logically support the methods of the trial. Major items: 1. In this trial, how the intervention team members were trained is very important. Please describe more detail about the intervention scheme and the home SC manual. If possible please attach to appendix these scheme or a part of the manual. 2. How many data collectors are going to assess the outcomes? If there are multiple collectors, please clarify whether you evaluate the inter-rater reliability. 3. Describe the potential for contamination between the intervention and control groups and what to do about it. 4. Figure 2 shows some overlap with the content already shown in Table 1, so please change the chart to make it easier to see. Minor items: 5. Please add the references to the sentence "At present, some scholars have conducted research on early rehabilitation exercise based on network or self-help for TL patients and achieved positive results." 6. Please add abbreviation: RCT in Study design section 7. "the" intervention group and the control group in Study design section 8. Unify the notation QoL and QOL 9. Please add a description about who is going to save data to Data collection section. 10. Please change "Excel 2015" to a formal expression including the version and vender name. 11. typo: the last observation-carried "forward" method in Statistical analysis section

	12. This sentence does not make sense: This study focused on the use of application, but the SC ability and QoL score of patients after use were not reported. 13. I feel that this expression is a leap from the context of this manuscript, so please reconsider: If the research proves that SC intervention can effectively improve the self-efficiency and SC ability of TL patients, so that they can care themselves independently, and no longer need to worry that the smell and secretion of tracheostomy will bring bad experience to the surrounding people.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Comment 1: Page 4, Line 14: The protocol has the registration number on the Chinese Clinical Trial Registry. However, there are significant deviations between the information on the present protocol versus one displayed on the Chinese Clinical Trial Registry (https://www.chictr.org.cn/showprojen.aspx?proj=121921). For example, the current protocol included the elderly population (i.e., >65 years), while the one displayed on the Chinese Clinical Trial Registry includes 18-70 years only. There are more deviations. Did the study's funder review the present protocol and approve these deviations?

Response:

We strongly agree with your comments that the content of the document needs to be consistent. However, what we need to explain is that, in terms of enrollment conditions, we limited the elderly patients, a smaller subgroup, to make the study more targeted. In fact, the range of 18-70 years is only a symbolic expression, because it is basically difficult to see laryngeal cancer patients younger than 40 years old. Secondly, regarding the supplements for outcome indicator, it is because we found that 2 endpoints are also important in our pilot research. Therefore, after discussion by our team, we thought that, without affecting the main framework of the study design, supplementation should result into more comprehensively assess the effects of our intervention.

All the details are as follows (Chinese Clinical Trial Registry):

(1) Participants: at first, we included participants aged 18-70. With the enrollment of patients, all patients were more than 50 years old, which was not expected when the study was originally designed. In addition, we found that the Chinese elderly have the characteristics of low health literacy and poor ability to accept health knowledge, and then more than 65 years old participants within the scope of the original study were selected for separate analysis, which has been convenient to verify whether the self care intervention is effective for the elderly. Therefore, we adjusted for elderly patients with laryngeal cancer over 65 years old.

(2) Observation outcome: The plan registered on our platform showed that quality of life is the main outcome indicator; Self efficacy and self-care agency were secondary outcome indicators, which did not change, but added additional observation of nutritional status and unplanned admission rate. With the deepening of study, we believe that patients' nutritional status and unplanned admission rate are also indicators worthy of attention. After obtaining the right to modify, we will also complete this content.

After obtaining the right to modify, we will immediately upload a novel version, although, we have to face the challenge of a time delay, due to the interference of the COVID-19 in China now.

Comment 2: Page 9 Line 38: Authors report that will be randomly assigned…

Authors might want to specify the randomization technique.

Response: Thank you for your comments. The description of the original manuscript is unclear. We choose the random number table because it is fast, simple and easy for clinical implementation, and suitable for small sample research, despite there are many ways of randomization. I have made a new description on page 7, line 19 of the manuscript. Participants meeting the eligibility criteria will be randomly assigned to control group or intervention group with a 1:1 ratio using random number table according to the time patients admitted to hospital.

Comment 3: Page 15 Line 12: Measurements: Authors might want to report the Cronbach's alpha values for the validated instrument in the targeted population.

Response: I agree with you that the supplement of Cronbach's alpha values increases the rigorism of the manuscript. The reason why I didn't show the Cronbach's alpha values is that the validated instrument had been widely certified in the population of cancer patients. It is undeniable that the increase the description of validated instrument is more rigorous, so I supplemented the Cronbach's alpha values of each instrument in Measurement section of the manuscript on page 15-16.

Comment 4: Page 15 Line 12: Measurements: Authors might want to report whether the permission/license to use the measurement instruments was obtained from their respective authors, or the instruments are freely available to use without formal permission/license (i.e., public domain).

Response: Thank you for your prompt. These measurements are freely available in the public domain in China. In China, these measurements have been published in journals and their authors have authorized journals. When using publicly published measurements, they are required to be indexed in the text and references, because it does not involve the interests of intellectual property rights. In addition, these measurements have been published for decades, and even if there are patents, they have exceeded the time limit, so they can be directly cited. I have made a statement in "Measurement" of the manuscript on page 15, line 9.

Reviewer: 2

Major items:

Comment 1: In this trial, how the intervention team members were trained is very important. Please describe more detail about the intervention scheme and the home SC manual. If possible please attach to appendix these scheme or a part of the manual.

Response: I credibly agree with your views how to train the intervention team members is important for the implementation of the project. We added a table to show the selection qualification, training content and work responsibilities team members, increased the details of this protocol. The four types of training audiences by face-to-face meetings were doctors, nurses for the intervention group, nurses for the control group and the data collector, which lasted for two weeks. The qualifications, training contents and work responsibilities of team members are shown in Table 1 of the manuscript on page 11.

The outline of the home care manual has been attached to the Supplemental Material.

Table 1 **Team member training**

Work roles	Selection qualification	Training content	Work responsibilities
Doctor	Full-time engaged in head and neck cancer medical work for more than 10 years, voluntary participation in this study.	Patient admission standards, treatment of complications and adverse events, ensure that the treatment of the enrolled patients was similar; answer of disease related knowledge, evaluation of rehabilitation effect, emphasize the follow-up of patients.	Screening of patients, diagnosis and treatment of patients' diseases, the answer of disease related knowledge and evaluation of rehabilitation effect
nurses in the control group	Nurse practitioner and above, full-time engaged in head and neck cancer care for more than 5 years, voluntary participation in this study.	Work flow, work responsibilities, standardization of routine nursing process during perioperative period, home nursing education before discharge (respiratory, swallowing and neck function training, trachestomy annular tube care, and home nutrition management)	Perioperative nursing and home nursing education before discharge
nurses in the intervention group	Nurse practitioner and above, full-time engaged in head and neck cancer care for more than 5 years, voluntary participation in this study.	Workflow, work responsibilities, SC intervention plan (help patients establish self-care awareness, the same home nursing content as the control group, additional consisting of SC feedback and supervision)	SC intervention plan, home care education before discharge, supervision of patients' home self-care
Data collector	Master degree or above, with clinical trial experience	Measurements, standardized terminology of questionnaire and post-discharge follow-up	Data collection at each time node

Comment 2: How many data collectors are going to assess the outcomes? If there are multiple collectors, please clarify whether you evaluate reliability.
Response: Indeed, it is a shortcoming of our article, if details about the data collector were not shown, even though we have performed well in practice. I am sorry for our negligence, without details about the data collector. In this project, a fixed nurse is responsible for data collection, who does not know the grouping of patients, during the whole process to avoid the bias resulted from heterogeneity evaluation. The nurse has a master's degree, experienced the training of clinical trials, and is familiar with the data collection principles and work norms of scientific research projects. These are shown on page 16, line 19 of the manuscript.

Comment 3: Describe the potential for contamination between the intervention and control groups and what to do about it.
Response: We do appreciate your reminder based on your considerable professional knowledges and we thought that the concern on crosstalk between groups is understandable. During the actual operation, I also considered this problem and adopted some strategies to avoid it.

First, when the patients signed the informed consent form, we have informed the patients of the intervention contents during the study period (from enrollment to the end of six-month follow-up), regardless of whether they entered the intervention group or the control group to avoid communicating with other patients. These contents are shown in the informed consent form.

Secondly, our ward is very large. The target number of cases collected is 60, and the duration of the study is 18 months. The number of beds in our ward is 50, and these patients have a very low probability of living in the same ward at the same time. Even if the patients may live together, the rehabilitation intervention and guidance of the two groups are separated.

Moreover, patients with laryngeal cancer cannot communicate through language within six months after operation, so the problem of contamination between groups can be almost avoided.

Comment 4. Figure 2 shows some overlap with the content already shown in Table 1, so please change the chart to make it easier to see.
Response: Thank you very much for your comments. The expressions of Table 1 and table 2 are cumbersome. In addition, we added the content table of team members training. Considering the impact of typesetting, so we deleted original Table 2 and modified the language description in the Data collection section of the manuscript, on page 17, line 2.

Minor items:
Comment 5. Please add the references to the sentence "At present, some scholars have conducted research on early rehabilitation exercise based on network or self-help for TL patients and achieved

positive results."

Response: References have been attached to the manuscript and reordered on page 5, line 12 of the manuscript.

10. Cnossen IC, van Uden-Kraan CF, Eerenstein SE, et al. An online self-care education program to support patients after total laryngectomy: feasibility and satisfaction. Support Care Cancer. 2016 Mar;24(3):1261-8. doi: 10.1007/s00520-015-2896-1. Epub 2015 Aug 26. PMID: 26306518; PMCID: PMC4729815.

12. Jansen F, Eerenstein S, Cnossen I C, et al. Effectiveness of a guided self-help exercise program tailored to patients treated with total laryngectomy: Results of a multi-center randomized controlled trial. Oral Oncology, 103. doi: 10.1016/j.oraloncology.2020.104586. Epub 2020 Feb 8. PMID: 32045734.

Comment 6. Please add abbreviation: RCT in Study design section

Response: Thank you for your comments. Changes have been made in Study design section on page 7, line 9 of the manuscript.

Comment 7. "the" intervention group and the control group in Study design section

Response: Thank you for your comments. Changes have been made in Study design section on page 7, line 10 of the manuscript.

Comment 8. Unify the notation QoL and QOL

Response: We apologize for any confusion caused. QoL has been uniformly described in the manuscript on page 8, line 6.

Comment 9. Please add a description about who is going to save data to Data collection section.

Response: Thank you for your thoughtful comment. All study data will be saved in an Excel 2015 (v16.0.3601.1023) by the data collection nurse. Both the data collector and the data analyst keep a copy of data, which can avoid accidental loss of data. The description of the person who saved the data has been supplemented in Data collection section on page 17, line 5.

Comment 10. Please change "Excel 2015" to a formal expression including the version and vender name.

Response: I appreciate your serious and rigorous attitude. I have added the version number of Excel 2015 (v16.0.3601.1023) on page 17, line 5.

Comment 11. typo: the last observation-carried "forward" method in Statistical analysis section **Response:** I'm sorry there was a typing error. It has been corrected in Statistical analysis section of the manuscript on page 17, line 19.

Comment 12. This sentence does not make sense: This study focused on the use of application, but the SC ability and QoL score of patients after use were not reported. **Response:** Thank you for your comments. This sentence is not easy to understand here. In fact, what I want to express is that this study focuses on the satisfaction of APP application and does not report the patient's health-related outcomes. However, there many other outcome variables worth exploring. This sentence has been deleted from the manuscript. I have re-described the above on page 20, line 5 of the manuscript.

Comment 13. I feel that this expression is a leap from the context of this manuscript, so please reconsider: If the research proves that SC intervention can effectively improve the self-efficiency and SC ability of TL patients, so that they can care themselves independently, and no longer need to worry that the smell and secretion of tracheostomy will bring bad experience to the surrounding people.

Response: Thank you for your thoughtful comment and valuable suggestions. After repeated reading, the language description is reorganized and modified on page 20, line 13.

We hope that all TL patients will have the opportunity to benefit from the SC program. For this purpose, we designed SC intervention scheme. Our aim was to evaluate the impact of SC intervention on SC agency and QoL of patients with TL, especially self management of tracheostomy and nutritional problems management. If the research proves that SC intervention can effectively improve the self-efficacy and SC agency of patients with TL, may provide reference for health providers to develop rehabilitation nursing program for patients with TL. Results from the protocol may provide the evidence of high-quality continuous nursing of oncology nurses, to optimally rearrange the continuous nursing responsibilities of oncology nurses and consequently improve the health outcomes of patients with TL.

VERSION 2 – REVIEW

REVIEWER	Swai, Joel University of Alberta Faculty of Medicine & Dentistry, Department of Medicine
REVIEW RETURNED	06-Jun-2022

GENERAL COMMENTS	Thank you, authors, for a revision. I have no further comments.

REVIEWER	Ishii, Ryo Tohoku University, Department of Otolaryngology-Head and Neck Surgery
REVIEW RETURNED	20-Jun-2022

GENERAL COMMENTS	The manuscript has been revised well at the points I indicated. I think this manuscript will be acceptable after some corrections have been done. *Please spell out SC in Table1 and 2.