BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers’ comments and the authors’ responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (http://bmjopen.bmj.com).

If you have any questions on BMJ Open’s open peer review process please email info.bmjopen@bmj.com
Effectiveness of a nurse-led coaching of self care agency intervention for elderly patients with total laryngectomy: Study protocol for a randomized controlled trial

| Journal: | BMJ Open |
|----------|----------|
| Manuscript ID | bmjopen-2022-061238 |
| Article Type: | Protocol |
| Date Submitted by the Author: | 28-Jan-2022 |

Complete List of Authors:

Zheng, Liyuan; Hubei Cancer Hospital,
Luo, Zhen; Hubei cancer hospital, Department of Head and Neck Surgery
Wang, Huifen; Hubei cancer hospital, Department of Head and Neck Surgery
Liu, Shu'e; Hubei Cancer Hospital
Li, Xue; Hubei cancer hospital, Department of Head and Neck Surgery
Peng, Danxia; Hubei cancer hospital, Department of Head and Neck Surgery
Liu, Yan; Hubei cancer hospital, Department of Head and Neck Surgery
Ye, Sanxia; Hubei cancer hospital, Department of Head and Neck Surgery
Lu, Yuchen; Hubei cancer hospital, Department of Head and Neck Surgery
Chen, Jian; Hubei cancer hospital, Department of Head and Neck Surgery
Mei, Zhidan; Hubei cancer hospital, Department of Head and Neck Surgery
Wei, Lai; Hubei Cancer Hospital, Department of radiotherapy
Qian, Yu; Tongji Hospital of Tongji Medical College of Huazhong University of Science and Technology,
Lin, Xi; Hubei Cancer Hospital, Department of thoracic medicine
Xu, Chun; Hubei Cancer Hospital, Department of Head and Neck Surgery

Keywords:

Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Adult oncology < ONCOLOGY, Clinical trials < THERAPEUTICS
Effectiveness of a nurse-led coaching of self care agency intervention for elderly patients with total laryngectomy: Study protocol for a randomized controlled trial

Liyuan Zheng, M.S., Zhen Luo, M.S., Huifen Wang, M.S., Shu’e Liu, B.S., Xue Li, B.S., Danxia Peng, B.S., Yan Liu, B.S., Sanxia Ye, B.S., Yuchen Lu, B.S., Jian Chen, Ph.D., Zhidan Mei, Ph.D., Lai Wei, M.S., Yu Qian, M.D, Ph.D., Xi Lin, B.S., Chun Xu, M.S.,

1 Department of Head and Neck Surgery, Hubei Cancer Hospital, Wuhan 430079, People’s Republic of China.
2. Department of nursing, Hubei Cancer Hospital, Wuhan 430079, People’s Republic of China.
3. Department of radiotherapy, Hubei Cancer Hospital, Wuhan 430079, People’s Republic of China.
4. Department of thoracic medicine, Hubei Cancer Hospital, Wuhan 430079, People’s Republic of China.

Correspondence should be addressed to Chun Xu, Department of Head and Neck Surgery, Hubei Cancer Hospital, Wuhan 430079, People’s Republic of China. Email: 473560831@qq.com; Phone number: 13971498009.

Word count: 3946 words.
Effectiveness of a nurse-led coaching of self care agency intervention for elderly patients with total laryngectomy: Study protocol for a randomized controlled trial

Abstract

Introduction: Due to functional defects and structural destruction after total laryngectomy, patients experienced poor quality of life, especially for elderly. The barriers to accessing self-care in elderly patients were considered to result from complex and multifaceted interactions of biologic and social factors. Therefore, specific efforts to improve elderly patients’ quality of life are needed. The purpose of our study is to verify nurse-led coaching of elderly patient self-care approaches, which can reduce logistic burden of patients, and obtain the successful functional rehabilitation ultimately.

Methods and Analysis: Elderly patients (n=60) scheduled for total laryngectomy will be randomly divided into the intervention group and the control group. Patients in the control group received routinely nursing during hospitalization and thereby at home after discharge received conventional family care without regular supervision of nurses. Patients in the intervention group will receive a series of self care intervention based on the transtheoretical model during hospitalization. During home after discharge, nurses will additionally evaluate and supervise the self-care effect of patients. The two groups of patients’ self care agency, self-efficacy, quality of life and nutritional status will be recorded separately at different time points. Primary outcome is the improvement of patients’ self care agency, and secondary outcome is the improvements of patients’ self-efficacy, quality of life, nutritional states and three-month unplanned readmission rate.
Ethics and Dissemination

The Ethics Committee of Hubei Cancer Hospital has approved this protocol (KYLLBA2020006). The findings of the trial will be disseminated through peer-reviewed journals, national or international conferences.

Trial registration number: ChiCTR2100043731.

Keywords

elderly patients; total laryngectomy; self-care agency; quality of life; the transtheoretical model

Strengths and limitations of this study

- Self care is carried out by elderly TL patients independently in the family, and there are uncertainties factors in the implementation process. The close relationship between medical team and elderly patients ensures the safety and effective implementation of home self care scheme.

- We will use high reliability and validity, widely used scales to measure the patients’s outcome objectively, and additionally report length of stay and cost of hospitalization for elderly TL patients.

- This is a single center small sample trial. No matter whether the patient’s hospitalization expenses and length of stay will produce positive results, it will provide data for the study of cost-benefit analysis.
INTRODUCTION

This protocol followed published guidelines for clinical trials protocols, along with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT 2013 Checklist). This protocol is V.03, written on 20 May. 2021.

BACKGROUND AND SIGNIFICANCE

Head and neck squamous cell carcinoma (HNSCC) is the sixth most commonly diagnosed cancer, and its incidence continues to rise\(^1,2\). Laryngeal squamous cell carcinoma (LSCC) is the second location after oral cavity squamous cell carcinoma, with the age-adjustment standardized incidence rate was 3.6/100000 for men and 0.5/100000 for women, the age-adjustment mortality rate is 1.9/100000 for men and 0.3/100000 for women\(^3\). Total laryngectomy (TL) offers a curative approach for patients with advanced laryngeal cancer or hypopharynx with the invasion of thyroid or cricoid cartilage and extra laryngeal soft tissues, failed response to radiotherapy or chemoradiotherapy and extensive tumors of histologic entities not suitable for conservative treatment.\(^4,5\) It is well-known that patients often experience specific symptoms, such as swallowing and speech impairments, given the complex nature of everyday functions and the anatomical complexity within the larynx area, despite in who long-term survival was achieved. Indeed, with the increase in incidence and improved survival rates, more patients are confronted with numerous, profound physical and emotional disabilities owing to insufficient residual tissues and regional structural destruction\(^6\) following total laryngectomy treatment, which can also affect patients’ families. and are often present long-term.
The health problems of TL patients are reflected in all aspects of social life. Physiological changes of tracheotomy: permanent tracheostomy changes their respiratory tract, causing function loss of swallowing and language, dry mouth, cough, shortness of breath and a reduced sense of smell. Social pressure caused by the change of body image: the stigmatization of tracheostomy and the change of body image leads to patients’ self-closed, decreased self-esteem, and stigmatising, resulting in the limitation of work scope. It’s obvious that the physical and mental changes and social embarrassment brought by TL seriously affected patients’ quality of life (QoL). At present, some scholars have conducted research on early rehabilitation exercise based on network or self-help for TL patients and achieved positive results. It is suitable for patients with high educational level and could master electronic equipment freely. Elderly patients, who typically have more functional impairments or comorbid conditions and various obstacles in communication (such as deafness, and lack of medical general knowledges), the opportunity to participate in high-quality self-care is often limited. The barriers to accessing self-care in elderly patients were considered to result from complex and multifaceted interactions of biologic and social factors, often involving medical provider, patient and family caregivers, especially the lack of communication between patients and care providers after discharge. It goes without saying that their QoL and survival rate have not improved significantly. In view of this, this study attempts to develop a pictorial exercise manual and exercise diary to improve the understanding of elderly patients with laryngeal cancer and the compliance of home self-care (SC), reduce the disease burden of patients and family caregivers,
and promote the successful functional rehabilitation of elderly patients with TL.

The specific self-care education and exercise program targeted to elderly TL patients had been developed according to the transtheoretical model (TTM) which is firstly proposed by Prochaska\(^\text{13}\) (Fig. 1). This theory is based on social psychology and focuses on the process of individual needs and behavior changes, by psychological, personal, family, social and other aspects of guidance and intervention on unhealthy behavior, aims to promote health management behavior and the formation of healthy lifestyles of patients. SC ability refers to a kind of health management behavior derived from oneself, which core is to mobilize the subjective initiative of patients through effective external intervention, reduce their sense of uselessness and inferiority, to improve their body function and health status by promoting their own physical condition assessment, care and monitoring. Undoubtedly, effective SC is a dynamic process in which patients gradually change from passive behavior to active participation in rehabilitation promotion\(^\text{14,15}\), and it will have benefits for the rational use of nursing resources and the alleviation of logistic burdens, especially the elderly patients with weak economic income.

**OBJECTIVE**

In this study, through preoperative elderly patients’ self-care awareness cultivation, self-care knowledge training, postoperative one-on-one rehabilitation guidance by nurse-led based on the theoretical framework of TTM\(^\text{13}\), to explore whether this systematic SC intervention program developed by our research group can improve the postoperative self-care ability of TL elderly patients, promote the persistence of self-
care healthy behavior, improve QoL and functional outcomes.

METHODS AND ANALYSIS

Study design

It is a single-center RCT, with 60 patients will be randomly divided into two groups (intervention group and the control group) after admission to Department of head and neck surgery, Hubei cancer hospital (Wuhan, China) in March 2021, ending in September 2022. The first admission doctor is responsible for recruiting the participants after obtaining the informed consent of the patients in the study. The trial flow chart is shown in Fig.2.

Patient and public involvement

Neither patients nor the public were involved in the design, conduct, reporting, or dissemination plans of this research.

Randomization procedure

Participants meeting the eligibility criteria will be randomly assigned to control group or intervention group with a 1:1 ratio. Random group generated by random number table. The randomization list was sealed in the opaque envelopes numbered in sequence, which were put in the head nurse’s office. Data collection and randomization were performed by the same researcher who is not involved in recruitment.

Participants

Sample size

To verify that the effect of SC intervention on the QOL of patients after TL, we designed a random control test with $\alpha = 0.05$, $\beta = 0.20$ (a power of 80%). According to
the calculation formula of sample size \( n = \frac{(z_{1-\alpha} + z_{\beta})^2 \cdot 2\sigma^2}{\delta^2} \), considering a 20% loss of follow-up rate, no less than 60 participants.

**Eligibility criteria**

Patients eligible for study participation met the following inclusion criteria: 1) were admitted to hospital with laryngeal malignancy diagnosis, and TL was planned; 2) the survival time is expected to be more than half a year; 3) elderly over 65 years without obvious disability; 4) have certain reading and writing skills and communication skills.

After receiving informed consent, patients were asked to fill out some questionnaires.

We will exclude patients with obvious defects in SC ability, such as 1) concurrent cancer; 2) severe heart, liver, kidney and other organic diseases, coagulation dysfunction; 3) Suffering from other psychological or mental diseases in the treatment stage.

**Implementation intervention**

All eligible patients will be randomly assigned in a 1:1 allocation ratio to the control or intervention group. Participants in both groups will undergo similar treatment and nursing, but the intervention group patients will receive additional SC skills intervention from nurses to try SC during hospitalization, and continue to implement SC during home after discharge, under the continuing guidance of nurse-led health providers.

**Preparation before intervention**

(a) **Establish SC intervention team.** The intervention team consisted of qualified members in professional fields, including a project leader (head nurse of head
and neck surgery), 2 head and neck surgeons, 1 radiation therapist, and 8 nurses involved in rehabilitation, psychology and nutrition. The project leader is responsible for carrying out project training and project emergency plan to ensure that all team members implement it according to the project process. Doctors are responsible for disease diagnosis, patient admission control, formulate prescription, and handling complications and adverse events; nurses are responsible for the implementation of the plan, supervising and recording patient feedback.

(b) Determine the intervention scheme and form the home SC manual for TL patients. After two rounds of expert consultation, the intervention scheme was determined, and the home SC manual (including some videos of SC) for TL patients was established. The intervention scheme is detailed in the “Intervention process”. The home SC manual mainly includes SC knowledge and SC diary. The SC knowledge includes: trachestomy annular tube care, respiratory, swallowing and neck function training, and nutrition management after TL; the SC diary includes the records of trachestomy annular tube care, respiratory, swallowing and neck function training, and nutrition management.

(c) Intervention content training on team members. Team members were trained by the project leader for two weeks.

Doctors. The training content included the control of patient admission standards, treatment of complications and adverse events, and ensuring that the treatment plan of the enrolled patients was similar; the answer of disease related
knowledge and the evaluation of rehabilitation effect emphasize the follow-up of
patients.

**Nurses.** Nurses in intervention group and control group were trained separately. The training contents of nurses in the control group include the workflow, work responsibilities, standardization of perioperative routine nursing process and health education of home nursing before discharge (respiratory, swallowing and neck function training, tracheostomy annular tube care, and home nutrition management). The training contents of nurses in the intervention group include the workflow, work responsibilities, SC intervention scheme (help patients establish self-care awareness, health education of home care before discharge the same as the content of control group, additional structured follow-up consisting of SC feedback and supervision). During the study, the two groups of nurses are respectively responsible for the whole process management of their patients, and the implementation of the project could not be discussed.

**Data investigators.** The training contents include research instrument, the standardized terminology of questionnaires and follow-up survey after discharge.

**Intervention process**

Once the patient informed consent is signed, the whole process of nursing was carried out by a nurse from admission, perioperative nursing, discharge, 1st month follow-up, 3rd months follow-up to the end of 6th months follow-up. The details scheme of the two groups are shown in Table 1.
| Time                  | The details scheme and corresponding implementers                                                                 | Intervention group | Control group |
|----------------------|------------------------------------------------------------------------------------------------------------------------|--------------------|---------------|
|                      | Evaluate disease-related situation, and answer the patient’s disease-related questions                             | ✓                  | ✓             |
|                      | Inform patients the importance of SC, obtain patients’ support                                                      | -                  | ✓             |
|                      | Establish awareness of behavior change, understand the importance of SC and cultivate SC awareness                   | -                  | ✓             |
|                      | Help patients prepare for surgery                                                                                  | -                  | ✓             |
|                      | Through the manual, video instruct patients to learn postoperative nursing content (aerosol inhalation, effective cough and expectoration, tracheostomy care, nasal feeding and comfortable position management, etc.) | -                  | ✓             |
| 1-3 days before surgery | Postoperative nursing; routine propaganda and education of postoperative nursing                                   | -                  | ✓             |
|                      | Guide and educate the postoperative nursing again; encourage and help patients to participate in SC                 | ✓                  | -             |
|                      | Participate in postoperative SC; set SC goals                                                                       | -                  | ✓             |
|                      | Propaganda and education of home care ([aerosol inhalation, tracheostomy nursing, weight monitoring, swallowing function exercise, neck function exercise, nutrition management](http://bmjopen.bmj.com/site/about/guidelines.xhtml)) | -                  | ✓             |
|                      | Discharge preparation services for patients, propaganda and education of home SC (the purpose, significance and content of self-care) | -                  | ✓             |
|                      | Help patients set goals                                                                                             | -                  | ✓             |
|                      | Inform follow-up ([postoperative recovery, self-efficacy, SC agency, nutritional status, QoL, unplanned readmission, goal achievement](http://bmjopen.bmj.com/site/about/guidelines.xhtml)) | ✓                  | -             |
|                      | Inform follow-up ([postoperative recovery, self-efficacy, SC agency, nutritional status, QoL, unplanned readmission](http://bmjopen.bmj.com/site/about/guidelines.xhtml)) | -                  | ✓             |
| Before discharge | Monitor the postoperative recovery; follow-up management                                                                | ✓                  | ✓             |
|                      | Evaluate the achievement of goals and reward patients; help patients adjust goals and encourage them                | -                  | ✓             |
|                      | Adjust goals and adhere to the implementation                                                                           | -                  | ✓             |
| 1st, 6th month follow-up | Monitor the postoperative recovery; follow-up management                                                              | ✓                  | ✓             |
|                      | Evaluate and affirm the patient's training results and strengthen the realization of goals                            | -                  | ✓             |
| Adhere to SC | - | - | ✓ | - | - | - |
(1) Control group scheme

Doctors are mainly responsible for the assessment of the disease, the answer of disease-related knowledge, the evaluation of rehabilitation effect and other medical related questions. Nurses implement routinely nursing for TL patients, including admission education, preoperative preparations, postoperative tracheal tube nursing (online video), feeding diet guidance, medication nursing, psychological nursing, discharge health education (including rehabilitation training exercise) and regular follow-up, etc and thereby at home after discharge patients received conventional family care without regular supervision and guidance of nurses.

(2) Intervention group scheme

Doctors are mainly responsible for the assessment of the disease, the explicate of disease-related knowledge, the evaluation of rehabilitation effect and other health related questions. Nurses explain the concept of SC 1-3 days before operation, so that patients can understand the importance of self-care, establish self-care awareness, understand the content of postoperative SC; 3-7 days after operation, while nurses implement postoperative nursing, they guide patients to gradually master self-care methods and skills one-on-one; 2-3 days before discharge, nurses evaluate the patients’ subsequent care needs, guide patients to self-care management at home, adhere to rehabilitation exercise, and assist patients to set home rehabilitation goals; within 6 months after discharge, nurses follow up the patients’ SC management at home: evaluate patients’ postoperative recovery, nutrition, goal achievement of the previous stage, and individualized guide the goal setting of the next stage.
Blinding

In the whole intervention stage, the blinded doctors take the same medical service to the two groups of patients. The data collector is also unaware of the grouping of patients.

Measurement

As outcome variables, we assessed TL elderly patient self-care agency level, self efficacy, nutritional status and QoL at baseline, 7 days, 1 month, 3 months and 6 months after TL. In addition, we will count the unplanned readmission rate. All outcomes were assessed by a data collector who was unaware of the patients’ group allocation.

Patient self-care agency level will be assessed with exercise of self-care agency scale\textsuperscript{16} (ESCA), which consists of four dimensions: self-care skills, self-care responsibility, self-concept and health knowledge level. There are 43 items in total. The sum of the scores of each dimension is the total score. The higher the score, the higher the self-care ability.

Patient self efficacy will be assessed using general self efficacy scale (GSES)\textsuperscript{17}, which was sinicized by Schwarzer, was used to measure the self-efficacy. The scale was derived from the German psychologist Ralf Schwarzer\textsuperscript{18}, and had good reliability and validity. There are 10 items in the scale, which were scored by Likert grade 4, all of which were positive scores. The higher the score, the stronger the general self-efficacy.

NRS-2002\textsuperscript{19} is a nutritional risk screening method recommended by ESPEN, used for nutritional risk screening. PG-SGA\textsuperscript{20} was first proposed by Ottery in 1994, which is a nutritional status assessment method specially designed for cancer patients.
Patient QoL level will be assessed by quality of life instruments for cancer patients-head and neck cancer\textsuperscript{21} (QLICP-HN), which is a scale suitable for Chinese cultural background and clinical practice of cancer treatment. It is suitable to evaluate the QoL of patients with head and neck cancer in clinical work. The scale includes five dimensions: physical function (PHD), psychological function (PSD), social function (SOD), common symptoms and side effects (SSD) and specific symptoms (SPD), which are composed of 7, 12, 6, 7 and 14 items respectively, with a total of 46 items. The higher the score, the better the QoL.

**Data collection, management and analysis**

**Data collection**

Similarly, once the patient informed consent is signed, a researcher independently collected data throughout the whole process, such as baseline data, clinical observation data, Questionnaire data. All study data will be stored in an Excel 2015. The contact information and address of patients will be confirmed before hospital discharge. Three follow-up visits will be carried out in the outpatient clinic and collected by the same researcher. The detailed data collection is shown in Table 2.

**Table 2 Data items collection at each time points**

| Outcome measure            | Baseline | 7 days after surgery | 1st month follow-up | 3rd month follow-up | 6th month follow-up |
|----------------------------|----------|----------------------|----------------------|---------------------|---------------------|
| Quality of life            | ✓        | ✓                    | ✓                    | ✓                   | ✓                   |
| Self-efficacy              | ✓        | ✓                    | ✓                    | ✓                   | ✓                   |
| Self-care agency           | ✓        | ✓                    | ✓                    | ✓                   | ✓                   |
Statistical analysis

All the analyses were performed using SPSS statistical software (IBM version 22.0). We used descriptive statistics and constituent ratio to analyze the demographic data, self-efficacy, self-care agency, nutritional status, health outcomes and unplanned readmission of participants. Normally or non-normally distributed continuous data will be compared by independent samples t test or the Mann-Whitney U test, and the chi-square test will be used to compare categorical variables of the intervention and control groups. Generalised repeated measures analysis of variance (ANOVA) will be used to demonstrate the effect of intervention and the time-intervention interaction. A value of p < 0.05 will be considered significant (two-tailed). An intention-to-treat analysis was performed, and missing data were analyzed by the last observation-carried forward method.

Data statement

The data will be publicly approved by resman in six months after the end of the trial.

ETHICS AND DISSEMINATION

Ethics approval
The study procedures and informed consent form have been approved by the Ethics Committee of Hubei Cancer Hospital in Hubei province, China [reference number KYLLBA2020006]. The Ethics Committee is obliged to periodically evaluate the progress of this trial and track information on any adverse events (AEs) until the patient reaches a stable state. The doctors communicate with patients to ensure that participants’ information is anonymous and inform patients to sign the informed consent. Results will be disseminated in peer-reviewed journals and conferences, and sent to participating practices.

DISCUSSION

With the diversification of treatment, the survival rate of laryngeal malignancy patients is increasing. Although the medical staff try their best to carry out diagnosis, treatment and nursing in the hospital, the home rehabilitation of patients after discharge is not enough due to the limited medical human resources. After TL, patients complete lung ventilation through the tracheal stoma, which is located in front of neck, this special position determines the importance of postoperative SC. In order to achieve active rehabilitation and high QoL, it is still necessary to take measures to promote patients’ self rehabilitation management ability.

TTM theory was initially applied to the intervention of quitting smoking behavior in a wide range of people, and gradually developed to clinical management and group intervention, especially the management of patients with chronic diseases in recent 20 years. Relevant studies show that intervention based on TTM theory can effectively improve patients’ self-efficacy. In view of this, we propose a research
hypothesis: SC intervention based on TTM will have a positive impact on self-efficacy and self-care ability of patients undergoing TL. This study will evaluate patients’ self-efficacy, SC ability, QoL and nutritional status at 7 days, 1 month, 3 months and 6 months after operation. These time points are important time nodes for changes in patients’ SC ability, QoL and nutritional status. They are also consistent with the routine follow-up time of patients, ensuring a high follow-up rate.

For self-efficacy and QoL, Alison$^{26}$ evaluated the self-efficacy score and QoL of TL survivors. The result showed that the self-efficacy score of TL survivors is higher than the normal level, although the survivals have lower QoL due to stigmatization of airway fistula, significant changes in voice, destruction of self-image. However, this study has a limitation, that is, all the data are from long-term survivors, who have participated in the rehabilitation association, which may be an important factor affecting the level of self-efficacy. Moreover, this is data from a cross-sectional study. On the contrary, our study is a prospective assessment of QoL at important time points, and we hope this study can provide further evidence for the results.

Cnossens’s$^{27}$ team developed a set of SC application to investigate the feasibility and satisfaction of online SC education for early postoperative rehabilitation of 55 TL patients. The results showed that this scheme is basically feasible, and the use experience satisfaction of follow-up patients is high, although it is accompanied by high loss of follow-up. This study focused on the use of application, but the SC ability and QoL score of patients after use were not reported. Different from the above study, our study proposes to start early self-care ability intervention before operation by the
systematic SC manual based on the TTM, which is more convenient for the elderly to read. We expect that our results will exceed the effect of previous studies, because their research does not fully mobilize the enthusiasm of patients. Based on the improvement of patients’ self-efficacy and SC ability, we expect that their QoL and nutritional status will also be greatly improved half a year after surgery.

If the research proves that SC intervention can effectively improve the self-efficacy 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. In that case, our intervention program will become an important and beautiful rebirth measure for TL patients, and also provide reference for health providers to develop rehabilitation nursing program for TL patients. Results from the present protocol may provide the evidence of high-quality continuous nursing of oncology nurses, so as to optimally rearrange the continuous nursing responsibilities of oncology nurses and consequently improve the health outcomes of patients.

**Research ethics approval**

This study is approved by the Ethics Committee of Hubei Cancer Hospital (KYLLBA2020006).

**Author Contributions**

Chun Xu proposed and designed the research and participated in the guidance of this research. Huifen Wang, Jian Chen, Zhidan Mei, Lai Wei, Yu Qian and Xi Lin tested the feasibility of the study; Zhen Luo, Liyuan Zheng participated in the literature search;
Shu’e Liu, Danxia Peng, Xue Li, Yan Liu, Sanxia Ye and Yuchen Lu are the main nurses who will perform nursing measures in the intervention group; Liyuan Zheng formulated the intervention program design, the intervention files, SC diary for elderly patients after total laryngectomy and wrote the manuscript. All authors approved the final version of the manuscript.

**Funding statement**

This research was financed by the funds of Hubei Health Committee [WJ2021M191].

**Conflicts of Interests**

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

**Acknowledgements**

Thanks to Hubei Health Committee, Hubei Cancer Hospital, head and neck surgery colleagues for their support.

**Word count:** 3946 words.

**REFERENCES**

1. Ferlay, J. et al. Estimating the global cancer incidence and mortality in 2018: GLOBOCAN sources and methods. International Journal of Cancer. 2019, 144(8): 1941–1953.

2. Ferlay, J. et al. Global Cancer Observatory: Cancer Today. Lyon, France:
International Agency for Research on Cancer (accessed 18 September 2020).

3. Sung H, Ferlay J, Siegel R, et al. Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries. CA Cancer J Clin. 2021,71:209–249.

4. Bozec A, Boscagli M, Serris M, et al. Long-term functional and quality of life outcomes in laryngeomized patients after successful voice restoration using tracheoesophageal prostheses. Surg Oncol. 2021 Apr 14;38:101580. doi: 10.1016/j.suronc.2021.101580. Epub ahead of print. PMID: 33862577.

5. Bozec A, D Culić, Poissonnet G, et al. Current Role of Total Laryngectomy in the Era of Organ Preservation[J]. Cancers. 2020, 12(3):584-599.

6. Bickford J, Coveney J, Baker J, et al. Validating the Changes to Self-identity After Total Laryngectomy. Cancer Nurs. 2019 Jul/Aug;42(4):314-322. doi: 10.1097/NCC.0000000000000610. PMID: 29846191

7. Joseph Z, Tessa G, Glenn B, et al. State of the art: Rehabilitation of speech and swallowing after total laryngectomy. Oral Oncology. 2018; 86:38-47.

8. Longobardi Y, Savoia V, Bussu F, et al. Integrated rehabilitation after total laryngectomy: a pilot trial study. Support Care Cancer. 2019 Sep;27(9):3537-3544. doi: 10.1007/s00520-019-4647-1. Epub 2019 Jan 26. PMID: 30685792.

9. Cnossen IC, van Uden-Kraan CF, Eerenstein SE, et al. A Participatory Design Approach to Develop a Web-Based Self-Care Program Supporting Early Rehabilitation among Patients after Total Laryngectomy. Folia Phoniatri Logop. 2015;67(4):193-201. doi: 10.1159/000441251. Epub 2016 Jan 16. PMID: 26771305.
10. Cnossen IC, van Uden-Kraan CF, Eerenstein SE, et al. An online self-care education program to support patients after total larynectomy: 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.

11. Teruya N, Sunagawa Y, Toyosato T, Yokota T. Association between Daily Life Difficulties and Acceptance of Disability in Cancer Survivors after Total Laryngectomy: a Cross-Sectional Survey. Asia Pac J Oncol Nurs. 2019 Apr-Jun;6(2):170-176. doi: 10.4103/apjon.apjon_50_18. PMID: 30931362; PMCID: PMC6371676.

12. Gao F, Bai J, Zhang M. Influencing factors of long-term efficacy and quality of life in elderly patients with laryngeal cancer. Chinese Journal of Gerontology. 2020 (8):1615-1618.

13. Prochaska JO, Velicer WF. The transtheoretical model of health behavior change. American Journal of Health Promotion.1997;12:38-48.

14. Kim SH, Kim K, Mayer DK. Self-Management Intervention for Adult Cancer Survivors After Treatment: A Systematic Review and Meta-Analysis. Oncol Nurs Forum. 2017;44:719-28.

15. McCorkle R, Ercolano E, Lazenby M, et al. Self-management: Enabling and empowering patients living with cancer as a chronic illness. CA Cancer J Clin. 2011;61:50-62.

16. Kearny B, Fleisher B. Development of all instrument measure exercise of self-care agency. Research in Nursing and Health.1979;2:25-34.

17. Ralf Schwarzer, John Mueller, Esther Greenglass. Assessment of perceived general
self-efficacy on the internet: Data collection in cyberspace. Anxiety, Stress & Coping. 1999;12: 145-61.

18. Schwarzer, R. & Aristi B. Optimistic self-beliefs: Assessment of general perceived self-efficacy in Thirteen cultures. Word Psychology. 1997;3:177-90.

19. Kondrup J, Rasmussen HJ, Hamberg O, et al. Nutritional risk screening (NRS 2002): a new method based on an analysis of controlled clinical trials. Appendix Clin Nutr. 2003;22:321.

20. Ottery FD. Rethinking nutritional support of the cancer patient: the new field of nutritional oncology. Semin Oncol. 1994;21:770-8.

21. Jiahong Luo, Chonghua Wan, Qiong Meng, et al. Development and evaluation on Chinese quality of life instruments for cancer patients-Head and neck cancer. Modern Preventive Medicine. 2007;34:4023-5.

22. Winter SJ, Sheats JL, King AC. The Use of Behavior Change Techniques and Theory in Technologies for Cardiovascular Disease Prevention and Treatment in Adults: A Comprehensive Review. Prog Cardiovasc Dis. 2016;58(6):605-612.

23. Sardi L, Idri A, Carrillo de Gea JM, Toval Á, Fernández-Alemán JL. Applying trans-theoretical model for blood donation among Spanish adults: a cross-sectional study. BMC Public Health. 2019;19(1):1724.

24. Middelkamp J, Rooijen M V, Wolfhagen P. The Effects of a Self-Efficacy Intervention on Exercise Behavior of Fitness Club Members in 52 Weeks and Long-Term Relationships of Transtheoretical Model Constructs. Journal of sports science & medicine, 2017, 16(2):163-171.
25. Sha-Li Wen, Li J, An-Ni Wang, et al. Effects of transtheoretical model-based intervention on the self-management of patients with an ostomy: A randomised controlled trial. Journal of Clinical Nursing, 2019, 28(9-10).

26. Perry, A., Casey, E., & Cotton, S. Quality of life after total laryngectomy: functioning, psychological well-being and self-efficacy. International Journal of Language & Communication Disorders, 2015, 50(4): 467–475.

27. Cnossen IC, van UK CF. and Eerenstein SE. An online self-care education program to support patients after total laryngectomy: feasibility and satisfaction. Supportive Care in Cancer. 2016, 24:1261-8.

Figure legends

**Fig. 1** Study theoretical framework diagram.

**Fig.2** Flow chart.
Study theoretical framework diagram.

196x106mm (144 x 144 DPI)
Flow chart.

278x367mm (72 x 72 DPI)
Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

**Instructions to authors**

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin J, Dickersin K, Hróbjartsson A, Schulz KF, Parulekar WR, Krleža-Jerić K, Laupacis A, Moher D. SPIRIT 2013 Explanation and Elaboration: Guidance for protocols of clinical trials. BMJ. 2013;346:e7586

| Reporting Item | Page Number |
|----------------|-------------|
| **Administrative information** | |
| Title | #1 | Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym |
| Trial registration | #2a | Trial identifier and registry name. If not yet registered, |

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml
name of intended registry

Trial registration: #2b All items from the World Health Organization Trial data set Registration Data Set

Protocol version #3 Date and version identifier 4

Funding #4 Sources and types of financial, material, and other support 19

Roles and responsibilities: #5a Names, affiliations, and roles of protocol contributors 18-19 contributorship

Roles and responsibilities: #5b Name and contact information for the trial sponsor sponsor contact information

Roles and responsibilities: #5c Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities sponsor and funder

Roles and responsibilities: #5d Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committees committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)

Introduction
Background and rationale: Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention.

Background and rationale: choice of comparators: Explanation for choice of comparators.

Objectives: Specific objectives or hypotheses.

Trial design: Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory).

Methods: Participants, interventions, and outcomes:

Study setting: Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained.

Eligibility criteria: Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg,
surgeons, psychotherapists)

Interventions: #11a Interventions for each group with sufficient detail to allow replication, including how and when they will be administered

Interventions: #11b Criteria for discontinuing or modifying allocated modifications interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)

Interventions: #11c Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)

Interventions: #11d Relevant concomitant care and interventions that are permitted or prohibited during the trial

Outcomes #12 Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended

Participant timeline #13 Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)
Sample size  #14  Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations

Recruitment  #15  Strategies for achieving adequate participant enrolment to reach target sample size

Methods:
Assignment of interventions (for controlled trials)

Allocation:  #16a  Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions

Allocation  #16b  Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned

Allocation:  #16c  Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions
Blinding #17a Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how

Blinding #17b If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant’s allocated intervention during the trial

Methods: Data collection, management, and analysis

Data collection #18a Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol

Data collection #18b Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols

Data #19 Plans for data entry, coding, security, and storage,
management including any related processes to promote data quality (eg, double data entry; range checks for data values).

Reference to where details of data management procedures can be found, if not in the protocol

Statistics: #20a Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol

Statistics: #20b Methods for any additional analyses (eg, subgroup and adjusted analyses)

Statistics: #20c Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)

Methods:

Monitoring

Data monitoring: #21a Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed

Data monitoring: #21b Description of any interim analyses and stopping guidelines, including who will have access to these interim
results and make the final decision to terminate the trial

| Harms | #22 | Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct |
|-------|-----|----------------------------------------------------------------------------------------------------------------------|
| Auditing | #23 | Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor |

**Ethics and dissemination**

| Research ethics | #24 | Plans for seeking research ethics committee / institutional review board (REC / IRB) approval |
|-----------------|-----|--------------------------------------------------------------------------------------------|
| Protocol amendments | #25 | Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators) |
| Consent or assent | #26a | Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) |
| Consent or assent: ancillary studies | #26b | Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable |

Confidentiality | #27 | How personal information about potential and enrolled
participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial.

Declaration of interests #28 Financial and other competing interests for principal investigators for the overall trial and each study site.

Data access #29 Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators.

Ancillary and post trial care #30 Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation.

Dissemination policy: trial results #31a Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions.

Dissemination policy: authorship #31b Authorship eligibility guidelines and any intended use of professional writers.

Dissemination policy: reproducible research #31c Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code.

Appendices
| **Informed consent materials** | Model consent form and other related documentation given to participants and authorised surrogates |
|-------------------------------|--------------------------------------------------------------------------------------------------|
| **Biological specimens**     | Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable |

None The SPIRIT Explanation and Elaboration paper is distributed under the terms of the Creative Commons Attribution License CC-BY-NC. This checklist can be completed online using [https://www.goodreports.org/](https://www.goodreports.org/), a tool made by the EQUATOR Network in collaboration with Penelope.ai
Effectiveness of a nurse-led coaching of self-care agency intervention for elderly patients with total laryngectomy: Study protocol for a randomized controlled trial

| Journal: | BMJ Open |
| --- | --- |
| Manuscript ID: | bmjopen-2022-061238.R1 |
| Article Type: | Protocol |
| Date Submitted by the Author: | 02-Jun-2022 |

Complete List of Authors:
Zheng, Liyuan; Hubei Cancer Hospital, Luo, Zhen; Hubei cancer hospital, Department of Head and Neck Surgery Wang, Huifen; Hubei cancer hospital, Department of Head and Neck Surgery Liu, Shue'e; Hubei Cancer Hospital Li, Xue; Hubei cancer hospital, Department of Head and Neck Surgery Peng, Danxia; Hubei cancer hospital, Department of Head and Neck Surgery Liu, Yan; Hubei cancer hospital, Department of Head and Neck Surgery Ye, Sanxia; Hubei cancer hospital, Department of Head and Neck Surgery Lu, Yuchen; Hubei cancer hospital, Department of Head and Neck Surgery Chen, Jian; Hubei cancer hospital, Department of Head and Neck Surgery Mei, Zhidan; Hubei cancer hospital, Department of Head and Neck Surgery Wei, Lai; Hubei Cancer Hospital, Department of radiotherapy Qian, Yu; Tongji Hospital of Tongji Medical College of Huazhong University of Science and Technology, Lin, Xi; Hub"el Cancer Hospital, Department of thoracic medicine Xu, Chun; Hub"el Cancer Hospital, Department of Head and Neck Surgery

**Primary Subject Heading**: Oncology

**Secondary Subject Heading**: Ear, nose and throat/otolaryngology, Medical education and training, Nursing, Oncology, Rehabilitation medicine

**Keywords**: Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Adult oncology < ONCOLOGY, Clinical trials < THERAPEUTICS
Effectiveness of a nurse-led coaching of self care agency intervention for elderly patients with total laryngectomy: Study protocol for a randomized controlled trial

Liyuan Zheng, M.S.¹, Zhen Luo, M.S.¹, Huifen Wang, M.S.², Shu’e Liu, B.S.¹, Xue Li, B.S.¹, Danxia Peng, B.S.¹, Yan Liu, B.S.¹, Sanxia Ye, B.S.¹, Yuchen Lu, B.S.¹, Jian Chen, Ph.D.¹, Zhidan Mei, Ph.D.¹, Lai Wei, M.S.³, Yu Qian, M.D, Ph.D.⁴, Xi Lin, B.S.⁴, Chun Xu, M.S.¹

1. Department of Head and Neck Surgery, Hubei Cancer Hospital, Tongji Medical College, Huazhong University of Science and Technology, Wuhan 430079, People’s Republic of China.
2. Department of nursing, Hubei Cancer Hospital, Tongji Medical College, Huazhong University of Science and Technology, Wuhan 430079, People’s Republic of China.
3. Department of radiotherapy, Hubei Cancer Hospital, Tongji Medical College, Huazhong University of Science and Technology, Wuhan 430079, People’s Republic of China.
4. Department of thoracic medicine, Hubei Cancer Hospital, Tongji Medical College, Huazhong University of Science and Technology, Wuhan 430079, People’s Republic of China.

Correspondence should be addressed to Chun Xu, Department of Head and Neck Surgery, Hubei Cancer Hospital, Tongji Medical College, Huazhong University of Science and Technology, Wuhan 430079, People’s Republic of China.
Science and Technology, Wuhan 430079, People’s Republic of China. Email: 473560831@qq.com; Phone number: 13971498009.

Word count: 4264 words.
Effectiveness of a nurse-led coaching of self care agency intervention for elderly patients with total laryngectomy: Study protocol for a randomized controlled trial

Abstract

Introduction: Due to functional defects and structural destruction after total laryngectomy, patients experienced poor the quality of life, especially for elderly. The barriers to accessing self-care in elderly patients were considered to result from complex and multifaceted interactions of biologic and social factors. Therefore, specific efforts to improve elderly patients’ quality of life are needed. The purpose of our study is to verify nurse-led coaching of elderly patient self-care approaches, which can reduce logistic burden of patients, and obtain the successful functional rehabilitation ultimately.

Methods and Analysis: Elderly patients (n=60) scheduled for total laryngectomy will be randomly divided into the intervention group and the control group. Patients in the control group received routinely nursing during hospitalization and thereby at home after discharge received conventional family care without regular supervision of nurses. Patients in the intervention group will receive a series of self care intervention based on the transtheoretical model during hospitalization. During home after discharge, nurses will additionally evaluate and supervise the self-care effect of patients. The two groups of patients’ self care agency, self-efficacy, quality of life and nutritional status will be recorded separately at different time points. Primary outcome is the improvement of patients’ self care agency, and secondary outcome is the improvements
of patients’ self-efficacy, quality of life, nutritional states and three-month unplanned readmission rate.

**Ethics and Dissemination**

The Ethics Committee of Hubei Cancer Hospital has approved this protocol (KYLLBA2020006). The findings of the trial will be disseminated through peer-reviewed journals, national or international conferences.

**Trial registration number:** ChiCTR2100043731.

**Keywords**

elderly patients; total laryngectomy; self-care agency; quality of life; the transtheoretical model

**Strengths and limitations of this study**

- The protocol mobilizes the self-efficacy of patients before operation, focusing on patients’ autonomous mastery of self care skills.
- The close relationship between medical team and elderly patients ensures the safety and effective implementation of home self care scheme.
- The forms of promoting patients’ self care agency are not limited to theories and atlas, but also the home care diary.
- Close follow-up and supervise by nurses in the intervention group may take a lot of working time when patients are at home.
- Another limitation is that the trial is a single center small sample test, and its popularization may be limited.
INTRODUCTION

This protocol followed published guidelines for clinical trials protocols, along with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT 2013 Checklist). This protocol is V.03, written on 20 May. 2021.

BACKGROUND AND SIGNIFICANCE

Head and neck squamous cell carcinoma (HNSCC) is the sixth most commonly diagnosed cancer, and its incidence continues to rise\(^1\). Laryngeal squamous cell carcinoma (LSCC) is the second location after oral cavity squamous cell carcinoma, with the age-adjustment standardized incidence rate was 3.6/100000 for men and 0.5/100000 for women, the age-adjustment mortality rate is 1.9/100000 for men and 0.3/100000 for women\(^3\). Total laryngectomy (TL) offers a curative approach for patients with advanced laryngeal cancer or hypopharynx with the invasion of thyroid or cricoid cartilage and extra laryngeal soft tissues, failed response to radiotherapy or chemoradiotherapy and extensive tumors of histologic entities not suitable for conservative treatment. \(^4,5\) It is well-known that patients often experience specific symptoms, such as swallowing and speech impairments, given the complex nature of everyday functions and the anatomical complexity within the larynx area, despite in who long-term survival was achieved. Indeed, with the increase in incidence and improved survival rates, more patients are confronted with numerous, profound physical and emotional disabilities owing to insufficient residual tissues and regional
structural destruction following total laryngectomy treatment, which can also affect patients’ families and are often present long-term.

The health problems of patients with TL are reflected in all aspects of social life. Physiological changes of tracheotomy: permanent tracheostomy changes their respiratory tract, causing function loss of swallowing and language, dry mouth, cough, shortness of breath and a reduced sense of smell. Social pressure caused by the change of body image: the stigmatization of tracheostomy and the change of body image leads to patients’ self-closed, decreased self-esteem, and stigmatizing, resulting in the limitation of work scope. It’s obvious that the physical and mental changes and social embarrassment brought by TL seriously affected patients’ quality of life (QoL). At present, some scholars have conducted research on early rehabilitation exercise based on network or self-help for patients with TL and achieved positive results. It is suitable for patients with high educational level and could master electronic equipment freely. Elderly patients, who typically have more functional impairments or comorbid conditions and various obstacles in communication (such as deafness, and lack of medical general knowledges), the opportunity to participate in high-quality self-care is often limited. The barriers to accessing self-care in elderly patients were considered to result from complex and multifaceted interactions of biologic and social factors, often involving medical provider, patient and family caregivers, especially the lack of communication between patients and care providers after discharge. It goes without saying that their QoL and survival rate have not improved significantly. In view of
this, this study attempts to develop a pictorial exercise manual and exercise diary to improve the understanding of elderly patients with laryngeal cancer and the compliance of home self-care (SC), reduce the disease burden of patients and family caregivers, and promote the successful functional rehabilitation of elderly patients with TL.

The specific self-care education and exercise program targeted to elderly patients with TL had been developed according to the transtheoretical model (TTM) which is firstly proposed by Prochaska\textsuperscript{14}(Fig.1). This theory is based on social psychology and focuses on the process of individual needs and behavior changes, by psychological, personal, family, social and other aspects of guidance and intervention on unhealthy behavior, aims to promote health management behavior and the formation of healthy lifestyles of patients. SC ability refers to a kind of health management behavior derived from oneself, which core is to mobilize the subjective initiative of patients through effective external intervention, reduce their sense of uselessness and inferiority, to improve their body function and health status by promoting their own physical condition assessment, care and monitoring. Undoubtedly, effective SC is a dynamic process in which patients gradually change from passive behavior to active participation in rehabilitation promotion\textsuperscript{15,16}, and it will have benefits for the rational use of nursing resources and the alleviation of logistic burdens, especially the elderly patients with weak economic income.

**OBJECTIVE**
In this study, through preoperative elderly patients’ self-care awareness cultivation, self-care knowledge training, postoperative one-on-one rehabilitation guidance by nurse-led based on the theoretical framework of TTM\textsuperscript{14}, to explore whether this systematic SC intervention program developed by our research group can improve the postoperative self-care ability of TL elderly patients, promote the persistence of self-care healthy behavior, improve QoL and functional outcomes.

**METHODS AND ANALYSIS**

**Study design**

It is a single-center randomized controlled study (RCT), with 60 patients will be randomly divided into two groups (the intervention group and the control group) after admission to Department of head and neck surgery, Hubei cancer hospital (Wuhan, China) in March 1, 2021, ending in September 30, 2022. The first admission doctor is responsible for recruiting the participants after obtaining the informed consent of the patients in the study. The trial flow chart is shown in Fig.2.

**Patient and public involvement**

Neither patients nor the public were involved in the design, conduct, reporting, or dissemination plans of this research.

**Randomization procedure**

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. The randomization numbers were sealed in the opaque
envelopes numbered in sequence, which were put in the head nurse’s office. The head
nurse is directly responsible for assigning patients to nurses in the intervention or
control group.

Participants

Sample size

To verify that the effect of SC intervention on the QoL of patients after TL, we designed
a random control test with $\alpha = 0.05$, $\beta = 0.20$ (a power of 80%). According to the
calculation formula of sample size $n = \frac{(z_{1-\alpha} + z_{1-\beta})^2 \times \sigma^2}{\delta^2}$, considering a 20% loss of follow-up rate, no less than 60 participants.

Eligibility criteria

Patients eligible for study participation met the following inclusion criteria: 1) were
admitted to hospital with laryngeal malignancy diagnosis, and TL was planned; 2) the
survival time is expected to be more than half a year; 3) elderly over 65 years without
obvious disability; 4) have certain reading and writing skills and communication skills.

After receiving informed consent, patients were asked to fill out some questionnaires.

We will exclude patients with obvious defects in SC ability, such as 1) concurrent
cancer; 2) severe heart, liver, kidney and other organic diseases, coagulation
dysfunction; 3) Suffering from other psychological or mental diseases in the treatment
stage.

Implementation intervention
All eligible patients will be randomly assigned in a 1:1 allocation ratio to the control or intervention group. Participants in both groups will undergo similar treatment and nursing, but the intervention group patients will receive additional SC skills intervention from nurses to try SC during hospitalization, and continue to implement SC during home after discharge, under the continuing guidance of nurse-led health providers.

**Preparation before intervention**

(a) **Establish SC intervention team.** The intervention team consisted of qualified members in professional fields, including a project leader (head nurse of head and neck surgery), 2 head and neck surgeons, 1 radiation therapist, and 8 nurses involved in rehabilitation, psychology and nutrition. The project leader is responsible for carrying out project training and project emergency plan to ensure that all team members implement it according to the project process. Doctors are responsible for disease diagnosis, patient admission control, formulate prescription, and handling complications and adverse events; nurses are responsible for the implementation of the plan, supervising and recording patient feedback.

(b) **Determine the intervention scheme and form the home SC manual (see supplementary materials for details) for patients with TL.** After two rounds of expert consultation, the intervention scheme was determined, and the home SC manual (including some videos of SC) for patients with TL was
established. The intervention scheme is detailed in the “Intervention process”.

The home SC manual mainly includes SC knowledge and SC diary. The SC knowledge includes: trachestomy annular tube care, respiratory, swallowing and neck function training, and nutrition management after TL; the SC diary includes the records of trachestomy annular tube care, respiratory, swallowing and neck function training, and nutrition management.

(c) Intervention content training on team members. The training audiences of four face-to-face meetings were doctors, nurses in the intervention group, nurses in the control group and data collector, which lasted for two weeks. The qualifications, training contents and job responsibilities of team members are shown in Table 1.
### Table 1 Team numbers training

| Work roles                  | Selection qualification                                                                 | The content of training                                                                                           | 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. | Workflow, 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, self-care intervention plan (help patients establish self-care awareness, the same home nursing content as the control group, additional consisting of self-care feedback and supervision). | Self-care intervention plan, home care education before discharge, supervision of patients’ home self care. |
| Data collector              | Master degree with clinical trial experience.                                            | Measurements, standardized terminology of questionnaire and post-discharge follow-up.                            | Data collection at each time node.                                                      |
**Intervention process**

Once the patient informed consent is signed, the whole process of nursing was carried out by a nurse from admission, perioperative nursing, discharge, 1st month follow-up, 3rd months follow-up to the end of 6th months follow-up. The details scheme of the two groups are shown in Table 2.
### Table 2 Two groups of implementation scheme.

| Time                  | The details scheme and corresponding implementers                                                                 | Intervention group | Control group |
|-----------------------|--------------------------------------------------------------------------------------------------------------------|--------------------|---------------|
|                       |                                                                                                                    | Doctors | Nurses | Patients | Doctors | Nurses | Patients |
| 1-3 days before surgery| Evaluate disease-related situation, and answer the patient’s disease-related questions                          | ✓       | ✓       | -        | ✓       | ✓       | -        |
|                       | Inform patients the importance of self-care, obtain patients’ support                                           | -       | ✓       | -        | -       | -       | -        |
|                       | Establish awareness of behavior change, understand the importance of self-care and cultivate self-care awareness | -       | -       | ✓        | -       | -       | -        |
|                       | Help patients prepare for surgery                                                                               | -       | ✓       | -        | -       | -       | -        |
|                       | Through the manual, video instruct patients to learn postoperative nursing content (aerosol inhalation,        | -       | ✓       | ✓        | -       | ✓       | ✓        |
|                       | effective cough and expectoration, tracheostomy care, nasal feeding and comfortable position management,        |         |         |         |         |         |          |
|                       | etc.)                                                                                                             |         |         |         |         |         |          |
| 3-7 days after surgery | Postoperative nursing; routine propaganda and education of postoperative nursing                                  | -       | ✓       | -        | -       | ✓       | -        |
|                       | Guide and educate the postoperative nursing again; encourage and help patients to participate in self-care       | ✓       |         |          |         |         |          |
|                       | Participate in postoperative self-care; set self-care goals                                                    | -       | -       | ✓        | -       | -       | -        |
| Before discharge      | Propaganda and education of home care (aerosol inhalation, tracheostomy nursing, weight monitoring,              | -       | ✓       | -        | -       | ✓       | -        |
|                       | swallowing function exercise, neck function exercise, nutrition management)                                       |         |         |         |         |         |          |
|                       | Discharge preparation services for patients, propaganda and education of home self-care (the purpose, significance and content of self-care) | -       | ✓       | -        | -       | -       | -        |
|                       | Help patients set goals                                                                                          | -       | ✓       | ✓        | -       | -       | -        |
|                       | Inform follow-up (postoperative recovery, self-efficacy, self-care agency, nutritional status, QoL, unplanned readmission, goal achievement) | ✓       | ✓       | -        | -       | -       | -        |
|                       | Inform follow-up (postoperative recovery, self-efficacy, self-care agency, nutritional status, QoL, unplanned readmission) | -       | -       | -        | ✓       | ✓       | -        |
| 1st month follow-up   | Monitor the postoperative recovery; follow-up management                                                          | ✓       | ✓       | -        | ✓       | ✓       | -        |
|                       | Evaluate the achievement of goals and reward patients; help patients adjust goals and encourage them             | -       | ✓       | -        | -       | -       | -        |
|                       | Adjust goals and adhere to the implementation                                                                     | -       | -       | ✓        | -       | -       | -        |
| 3rd, 6th month follow-up | Monitor the postoperative recovery; follow-up management                                                          | ✓       | ✓       | -        | ✓       | ✓       | -        |
|                       | Evaluate and affirm the patient’s training results and strengthen the realization of goals                       | -       | ✓       | -        | -       | -       | -        |
|                       | Adhere to self-care                                                                                                | -       | -       | ✓        | -       | -       | -        |
(1) Control group scheme

Doctors are mainly responsible for the assessment of the disease, the answer of disease-related knowledge, the evaluation of rehabilitation effect and other medical related questions. Nurses implement routinely nursing for patients with TL, including admission education, preoperative preparations, postoperative tracheal tube nursing (online video), feeding diet guidance, medication nursing, psychological nursing, discharge health education (including rehabilitation training exercise) and regular follow-up, etc and thereby at home after discharge patients received conventional family care without regular supervision and guidance of nurses.

(2) Intervention group scheme

Doctors are mainly responsible for the assessment of the disease, the explicate of disease-related knowledge, the evaluation of rehabilitation effect and other health related questions. Nurses explain the concept of SC 1-3 days before operation, so that patients can understand the importance of self-care, establish self-care awareness, understand the content of postoperative SC; 3-7 days after operation, while nurses implement postoperative nursing, they guide patients to gradually master self-care methods and skills one-on-one; 2-3 days before discharge, nurses evaluate the patients’ subsequent care needs, guide patients to self-care management at home, adhere to rehabilitation exercise, and assist patients to set home rehabilitation goals; within 6 months after discharge, nurses follow up the patients’ SC management at home:
evaluate patients’ postoperative recovery, nutrition, goal achievement of the previous stage, and individualized guide the goal setting of the next stage.

**Blinding**

In the whole intervention stage, the blinded doctors take the same medical service to the two groups of patients. The data collector is also unaware of the grouping of patients.

**Measurement**

As outcome variables, we assessed TL elderly patient self-care agency level, self-efficacy, nutritional status and QoL at baseline, 7 days, 1 month, 3 months and 6 months after TL. These measurements are freely available in the public domain in China. In addition, we will count the unplanned readmission rate. All outcomes were assessed by a data collector who was unaware of the patients’ group allocation.

Patient self-care agency level will be assessed with exercise of self-care agency scale\(^{17}\) (ESCA), which consists of four dimensions: self-care skills, self-care responsibility, self-concept and health knowledge level. The half reliability of the scale was 0.77 and the test-retest reliability was 0.80 ~ 0.81. There are 43 items in total. The sum of the scores of each dimension is the total score. The higher the score, the higher the self-care ability.

Patient self efficacy will be assessed using general self efficacy scale (GSES)\(^{18}\), which was sinicized by Schwarzer, was used to measure the self-efficacy. The scale was derived from the German psychologist Ralf Schwarzer\(^{19}\), and its Cronbach’s α was 0.87, and the test-retest reliability was 0.83, the half reliability is 0.82, and the Chinese
version GESE of Cronbach’s $\alpha$ is 0.75 ~ 0.91. There are 10 items in the scale, which were scored by Likert grade 4, all of which were positive scores. The higher the score, the stronger the general self-efficacy.

NRS-2002\textsuperscript{20} was recommended as a nutritional risk screening tool with good predictive validity and content validity by ESPEN. PG-SGA\textsuperscript{21} was first proposed by Ottery in 1994, which is a nutritional status assessment method specially designed for cancer patients, the reliability and validity were higher than 0.7 in Chinese cancer population.

Patient QoL level will be assessed by quality of life instruments for cancer patients-head and neck cancer\textsuperscript{22} (QLICP-HN), which is a scale suitable for Chinese cultural background and clinical practice of cancer treatment, the Cronbach’s $\alpha$ of all dimensions were above 0.7. It is suitable to evaluate the QoL of patients with head and neck cancer in clinical work. The scale includes five dimensions: physical function (PHD), psychological function (PSD), social function (SOD), common symptoms and side effects (SSD) and specific symptoms (SPD), which are composed of 7, 12, 6, 7 and 14 items respectively, with a total of 46 items. The higher the score, the better the QoL.

**Data collection, management and analysis**

**Data collection**

Once the patient informed consent is signed, a fixed data collection 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 contact
information and address of patients will be confirmed before hospital discharge. The fixed nurse collect data throughout the whole process independently, such as baseline data, clinical observation data, and three follow-ups at 1, 3 and 6 months after operation questionnaire data (QoL/ Self-efficacy/ Self-care agency/ NRS-2002/ PG-SGA). All study data will be saved in an Excel 2015 (v16.0.3601.1023) by the data collection nurse.

**Statistical analysis**

The data transmitted by the data collection nurse is saved and analyzed by the data analyst. All the analyses were performed using SPSS statistical software (IBM version 22.0). We used descriptive statistics and constituent ratio to analyze the demographic data, self-efficacy, self-care agency, nutritional status, health outcomes and unplanned readmission of participants. Normally or non-normally distributed continuous data will be compared by independent samples t test or the Mann-Whitney U test, and the chi-square test will be used to compare categorical variables of the intervention and control groups. Generalized repeated measures analysis of variance (ANOVA) will be used to demonstrate the effect of intervention and the time-intervention interaction. A value of p < 0.05 will be considered significant (two-tailed). An intention-to-treat analysis was performed, and missing data were analyzed by the last observation-carried forward method.

**Data statement**
The data will be publicly approved by Resman in six months after the end of the trial.

ETHICS AND DISSEMINATION

Ethics approval

The study procedures and informed consent form have been approved by the Ethics Committee of Hubei Cancer Hospital in Hubei province, China [reference number KYLLBA2020006]. The Ethics Committee is obliged to periodically evaluate the progress of this trial and track information on any adverse events (AEs) until the patient reaches a stable state. The doctors communicate with patients to ensure that participants’ information is anonymous and inform patients to sign the informed consent. Results will be disseminated in peer-reviewed journals and conferences, and sent to participating practices.

DISCUSSION

With the diversification of treatment, the survival rate of laryngeal malignancy patients is increasing. Although the medical staff try their best to carry out diagnosis, treatment and nursing in the hospital, the home rehabilitation of patients after discharge is not enough due to the limited medical human resources. After TL, patients complete lung ventilation through the tracheal stoma, which is located in front of neck, this special position determines the importance of postoperative SC. In order to achieve active rehabilitation and high QoL, it is still necessary to take measures to promote patients’ self rehabilitation management ability.
TTM theory was initially applied to the intervention of quitting smoking behavior in a wide range of people, and gradually developed to clinical management and group intervention, especially the management of patients with chronic diseases in recent 20 years\textsuperscript{23,24}. Relevant studies\textsuperscript{25,26} show that intervention based on TTM theory can effectively improve patients’ self-efficacy. In view of this, we propose a research hypothesis: SC intervention based on TTM will have a positive impact on self-efficacy and self-care ability of patients undergoing TL. This study will evaluate patients’ self-efficacy, SC ability, QoL and nutritional status at 7 days, 1 month, 3 months and 6 months after operation. These time points are important time nodes for changes in patients’ SC ability, QoL and nutritional status. They are also consistent with the routine follow-up time of patients, ensuring a high follow-up rate.

For self-efficacy and QoL, Alison\textsuperscript{27} evaluated the self-efficacy score and QoL of TL survivors. The result showed that the self-efficacy score of TL survivors is higher than the normal level, although the survivals have lower QoL due to stigmatization of airway fistula, significant changes in voice, destruction of self-image. However, this study has a limitation, that is, all the data are from long-term survivors, who have participated in the rehabilitation association, which may be an important factor affecting the level of self-efficacy. Moreover, this is data from a cross-sectional study. On the contrary, our study is a prospective assessment of QoL at important time points, and we hope this study can provide further evidence for the results.
Cnossen’s team developed a set of SC application to investigate the feasibility and satisfaction of online SC education for early postoperative rehabilitation of 55 patients with TL. The results showed that this application is basically feasible, and the use experience satisfaction of follow-up patients is high, although it is accompanied by high loss of follow-up. However, there many other outcome variables worth exploring. Different from the above study, our study proposes to start early self-care ability intervention before operation by the systematic SC manual based on the TTM, which is more convenient for the elderly to read. We expect that our results will exceed the effect of previous studies, because their research does not fully mobilize the enthusiasm of patients. Based on the improvement of patients’ self-efficacy and SC ability, we expect that their QoL and nutritional status will also be greatly improved half a year after surgery.

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.

**Research ethics approval**

This study is approved by the Ethics Committee of Hubei Cancer Hospital (KYLLBA2020006).

**Author Contributions**

Chun Xu proposed and designed the research and participated in the guidance of this research. Huifen Wang, Jian Chen, Zhidan Mei, Lai Wei, Yu Qian and Xi Lin tested the feasibility of the study; Zhen Luo, Liyuan Zheng participated in the literature search; Shu’e Liu, Danxia Peng, Xue Li, Yan Liu, Sanxia Ye and Yuchen Lu are the main nurses who will perform nursing measures in the intervention group; Liyuan Zheng formulated the intervention program design, the intervention files, SC diary for elderly patients after total laryngectomy and wrote the manuscript. All authors approved the final version of the manuscript.

**Funding statement**

This research was financed by the funds of Hubei Province health and family planning scientific research project [WJ2021M191].

**Conflicts of Interests**

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

**Acknowledgements**
Thanks to Hubei Province health and family planning, Hubei Cancer Hospital, head and neck surgery colleagues for their support.

**Word count:** 4264 words.

**REFERENCES**

1. Ferlay, J. et al. Estimating the global cancer incidence and mortality in 2018: GLOBOCAN sources and methods. International Journal of Cancer. 2019, 144(8): 1941–1953.

2. Ferlay, J. et al. Global Cancer Observatory: Cancer Today. Lyon, France: International Agency for Research on Cancer (accessed 18 September 2020).

3. Sung H, Ferlay J, Siegel R, et al. Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries. CA Cancer J Clin. 2021, 71:209–249.

4. Bozec A, Boscagli M, Serris M, et al. Long-term functional and quality of life outcomes in laryngectomized patients after successful voice restoration using tracheoesophageal prostheses. Surg Oncol. 2021 Apr 14;38:101580. doi: 10.1016/j.suronc.2021.101580. Epub ahead of print. PMID: 33862577.

5. Bozec A, Culié, Poissonnet G, et al. Current Role of Total Laryngectomy in the Era of Organ Preservation[J]. Cancers. 2020, 12(3):584-599.
6. Bickford J, Coveney J, Baker J, et al. Validating the Changes to Self-identity After Total Laryngectomy. Cancer Nurs. 2019 Jul/Aug;42(4):314-322. doi: 10.1097/NCC.0000000000000610. PMID: 29846191

7. Joseph Z, Tessa G, Glenn B, et al. State of the art: Rehabilitation of speech and swallowing after total laryngectomy. Oral Oncology. 2018; 86:38-47.

8. Longobardi Y, Savoia V, Bussu F, et al. Integrated rehabilitation after total laryngectomy: a pilot trial study. Support Care Cancer. 2019 Sep;27(9):3537-3544. doi: 10.1007/s00520-019-4647-1. Epub 2019 Jan 26. PMID: 30685792.

9. Cnossen IC, van Uden-Kraan CF, Eerenstein SE, et al. A Participatory Design Approach to Develop a Web-Based Self-Care Program Supporting Early Rehabilitation among Patients after Total Laryngectomy. Folia Phoniatr Logop. 2015;67(4):193-201. doi: 10.1159/000441251. Epub 2016 Jan 16. PMID: 26771305.

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.

11. Teruya N, Sunagawa Y, Toyosato T, Yokota T. Association between Daily Life Difficulties and Acceptance of Disability in Cancer Survivors after Total Laryngectomy: a Cross-Sectional Survey. Asia Pac J Oncol Nurs. 2019 Apr-Jun;6(2):170-176. doi: 10.4103/apjpn.apjpn_50_18. PMID: 30931362; PMCID: PMC6371676.
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.

13. Gao F, Bai J, Zhang M. Influencing factors of long-term efficacy and quality of life in elderly patients with laryngeal cancer. Chinese Journal of Gerontology. 2020 (8): 1615-1618.

14. Prochaska JO, Velicer WF. The transtheoretical model of health behavior change. American Journal of Health Promotion.1997;12:38-48.

15. Kim SH, Kim K, Mayer DK. Self-Management Intervention for Adult Cancer Survivors After Treatment: A Systematic Review and Meta-Analysis. Oncol Nurs Forum. 2017;44:719-28.

16. McCorkle R, Ercolano E, Lazenby M, et al. Self-management: Enabling and empowering patients living with cancer as a chronic illness. CA Cancer J Clin. 2011;61:50-62.

17. Kearny B, Fleisher B. Development of all instrument measure exercise of self-care agency. Research in Nursing and Health.1979;2:25-34.

18. Ralf Schwarzer, John Mueller, Esther Greenglass. Assessment of perceived general self-efficacy on the internet: Data collection in cyberspace. Anxiety, Stress & Coping. 1999;12: 145-61.
19. Schwarzer, R. & Aristi B. Optimistic self-beliefs: Assessment of general perceived self-efficacy in Thirteen cultures. Word Psychology. 1997;3:177-90.

20. Kondrup J, Rasmussen HJ, Hamberg O, et al. Nutritional risk screening (NRS 2002): a new method based on an analysis of controlled clinical trials. Appendix Clin Nutr. 2003;22:321.

21. Ottery FD. Rethinking nutritional support of the cancer patient: the new field of nutritional oncology. Semin Oncol. 1994;21:770-8.

22. Jiahong Luo, Chonghua Wan, Qiong Meng, et al. Development and evaluation on Chinese quality of life instruments for cancer patients-Head and neck cancer. Modern Preventive Medicine. 2007;34:4023-5.

23. Winter SJ, Sheats JL, King AC. The Use of Behavior Change Techniques and Theory in Technologies for Cardiovascular Disease Prevention and Treatment in Adults: A Comprehensive Review. Prog Cardiovasc Dis. 2016;58(6):605-612.

24. Sardi L, Idri A, Carrillo de Gea JM, Toval Á, Fernández-Alemán JL. Applying trans-theoretical model for blood donation among Spanish adults: a cross-sectional study. BMC Public Health. 2019;19(1):1724.

25. Middelkamp J, Rooijen M V, Wolfhagen P. The Effects of a Self-Efficacy Intervention on Exercise Behavior of Fitness Club Members in 52 Weeks and Long-Term Relationships of Transtheoretical Model Constructs. Journal of sports science & medicine, 2017, 16(2):163-171.
26. Sha-Li Wen, Li J, An-Ni Wang, et al. Effects of transtheoretical model-based intervention on the self-management of patients with an ostomy: A randomised controlled trial. Journal of Clinical Nursing, 2019, 28(9-10).

27. Perry, A., Casey, E., & Cotton, S. Quality of life after total laryngectomy: functioning, psychological well-being and self-efficacy. International Journal of Language & Communication Disorders, 2015, 50(4): 467–475.

**Figure legends**

**Fig. 1** Study theoretical framework diagram.

**Fig. 2** Flow chart.
Study theoretical framework diagram.

196x106mm (144 x 144 DPI)
Patients who receive TL at Hubei Cancer Hospital.

Eligibility criteria
- Elderly over 65 years;
- Survival time have prediction beyond half a year;
- Writing skills and communication skills;
- Voluntary participation.

Informed consent signed by patients. Patients are randomized on completion of consent.

Allocate to control group

Baseline

Surgery

Patients received the same surgery, treatment

Postoperative nursing will be carried out by nurses

Postoperative nursing will be carried out by nurses

Nurses conduct health education propaganda of home care for patients and their home caregivers

Discharge

Follow-up

Follow-up postoperative recovery, self-efficacy, SC ability, nutritional status, QoL, unplanned readmission

Allocate to intervention group

Nurses guided patients to learn the SC manual and video of TL

7 days after surgery

Patients implemented SC after the patients recovered well;
Assess patient subsequent care needs and develop measures

Patients adhere to SC and set rehabilitation goals

Flow chart.

278x367mm (72 x 72 DPI)
A letter to the patients

Dear patients!

You are going to have total laryngectomy (TL). TL refers to the removal of the larynx with tumor invasion by surgery. Larynx is an important organ to maintain respiratory and vocal function. Permanent tracheostomy should be performed after TL to ensure airway patency. In this process, you may face difficulties such as dysphagia and aphasia, and you may feel helpless and confused. This self-care manual is designed to help you get rid of confusion and lead you to participate in self-care actions.

Self care refers to a kind of health management behavior from their own. In this process, you will gradually change from passive acceptance of disease treatment measures to active and spontaneous participation in the process of rehabilitation promotion, so that you can take the initiative to control your own quality of life from psychological and health behavior, and return to family and society as soon as possible.

I wish you a speedy recovery!

Department of head and neck surgery, Hubei Cancer Hospital
contents

Respiratory function exercise .................................................... 2
  Effective cough ................................................................. 2
    Purpose .................................................................................. 2
    Method .................................................................................. 2
    Reminder ................................................................................ 2
  Atomization inhalation ............................................................. 2
    Reminder ................................................................................ 2
  Respiratory function exercise ................................................... 3
    Purpose .................................................................................. 3
    Method .................................................................................. 3
    Reminder ................................................................................ 5
Airway management ................................................................. 6
  Tracheostomy ............................................................................ 6
    Purpose .................................................................................. 6
  Tracheal tube nursing ............................................................... 6
    Material preparation .................................................................. 6
    Remove annular tubes ............................................................ 6
    Clear annular tubes ............................................................... 6
    Disinfect annular tubes ........................................................... 6

Disinfection of stoma ...................................................................... 6
Wear annular tubes ....................................................................... 7
Reminder .................................................................................... 7
Common problems and Solutions ............................................... 7
Evaluation and training of swallowing function ............................ 9
  Swallowing function evaluation ............................................... 9
    Purpose .................................................................................. 10
    Method .................................................................................. 10
    Feeding training ...................................................................... 10
      Reminder ................................................................................ 11
  Neck function exercise ............................................................ 12
    Purpose .................................................................................. 12
    Method .................................................................................. 12
  Home nutrition management .................................................... 14
    Purpose .................................................................................. 14
    Principles of nutrition support ................................................. 14
    Nutrition support pathway ...................................................... 14
      Reminder ................................................................................ 14
    Identification and management of major complications of EN ....... 15

...
Self care diary of patients after TL

Patient information

Admission number: __________
Name: _____________________
Gender: _________________
Age: _________________
Operation date: ____________
Discharge date: ____________

Note:
Self care diary is a kind of tool for self-care after discharge. In the time after discharge, through standardized records, improve your attention to self-care, strengthen the rehabilitation effect, and help accelerate the recovery after surgery.
Take tracheal cannula nursing as an example

| Set goals                       | D1 | D2 | D3 | D4 | D5 | D6 | D7 |
|---------------------------------|----|----|----|----|----|----|----|
| **Exercise program**            |    |    |    |    |    |    |    |
| **Take tubes**                  |    |    |    |    |    |    |    |
| **Cleaning tubes**              |    |    |    |    |    |    |    |
| **Tubes disinfection**          |    |    |    |    |    |    |    |
| **Disinfection of tracheostomy**|    |    |    |    |    |    |    |
| **Wear tracheal cannula**       |    |    |    |    |    |    |    |

Exercise duration: __________

Problem: __________

......

Respiratory function training

| Set goals                       | D1 | D2 | D3 | D4 | D5 | D6 | D7 |
|---------------------------------|----|----|----|----|----|----|----|
| **Exercise program**            |    |    |    |    |    |    |    |
| **Effective cough**             |    |    |    |    |    |    |    |
| **Atomization inhalation**      |    |    |    |    |    |    |    |
| **Breathing exercises**         |    |    |    |    |    |    |    |

Exercise duration: __________

Problem: __________
## Neck function training

| First month             | First week | Set goals |
|-------------------------|------------|-----------|
| Exercise program        | D1         | D2        | D3 | D4 | D5 | D6 | D7 |
| Neck rotation left and right |             |           |    |    |    |    |    |
| Neck flexion and supination |           |           |    |    |    |    |    |
| Lateral flexion of neck |             |           |    |    |    |    |    |
| Shrugging               |             |           |    |    |    |    |    |
| Shoulder traction       |             |           |    |    |    |    |    |
| Shoulder lift           |             |           |    |    |    |    |    |

**Exercise duration:** __________

**Problem:** __________

......

## Feeding training

| First month | First week | Set goals |
|-------------|------------|-----------|
| Exercise program | D1 | D2 | D3 | D4 | D5 | D6 | D7 |
| Empty swallowing training | | | | | | | |
| Direct eating training | | | | | | | |
| Compensatory training | | | | | | | |

**Exercise duration:** __________

**Problem:** __________

......
Nutrition monitoring

| First month | D1 | D2 | D3 | D4 | D5 | D6 | D7 |
|-------------|----|----|----|----|----|----|----|
| First week  |    |    |    |    |    |    |    |
| Monitoring  |    |    |    |    |    |    |    |
| content     |    |    |    |    |    |    |    |
| Weight (kg) |    |    |    |    |    |    |    |
| Food intake |    |    |    |    |    |    |    |
| Factors     |    |    |    |    |    |    |    |
| affecting   |    |    |    |    |    |    |    |
| eating      |    |    |    |    |    |    |    |

Problem: __________

Note:
Food intake record: 0: normal, 1: decrease, 2: increase;
Records of factors affecting eating: 0: No, 1: poor appetite caused by taste, 2: swallowing related problems, 3: gastrointestinal problems, 4: problems caused by emotional disorders.

Prompt card for postoperative follow-up visit

| Follow up                        | Date | Next follow up date | Notes                  |
|----------------------------------|------|---------------------|------------------------|
| One month after total laryngectomy |      |                     |                        |
| Three months after total laryngectomy |      |                     |                        |
| Six months after total laryngectomy |      |                     |                        |

Warm tips: please take your ID card and other valid documents with you and go back to the head and neck surgery clinic of Hubei cancer hospital for follow-up. Since you are still recovering after operation, the follow-up after operation is very important. We suggest you insist on follow-up!
Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

**Instructions to authors**

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Götzsche PC, Altman DG, Mann H, Berlin J, Dickersin K, Hróbjartsson A, Schulz KF, Parulekar WR, Krleža-Jerić K, Laupacis A, Moher D. SPIRIT 2013 Explanation and Elaboration: Guidance for protocols of clinical trials. BMJ. 2013;346:e7586

---

**Administrative information**

| Reporting Item | Page Number |
|----------------|-------------|
| Title          | 1           |
| Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym |
| Trial registration | 3       |
| Trial identifier and registry name. If not yet registered, name of intended registry |
| Trial registration: data set | 4       |
| All items from the World Health Organization Trial Registration Data Set |
| Protocol version | 4       |
| Date and version identifier |
| Funding         | 21          |
| Sources and types of financial, material, and other support |
| Roles and responsibilities: contributorship | 21 |
| Names, affiliations, and roles of protocol contributors |
| Roles and | 21          |
| Name and contact information for the trial sponsor |

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml
Responsibilities:
Sponsor contact information

Roles and responsibilities: sponsor and funder

Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities

Roles and responsibilities: committees

Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)

Introduction

Background and rationale

Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention

Background and rationale: choice of comparators

Explanation for choice of comparators

Objectives

Specific objectives or hypotheses

Trial design

Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)

Methods:
Participants, interventions, and outcomes

Study setting

Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained

Eligibility criteria

Inclusion and exclusion criteria for participants. If applicable,
eligibility criteria for study centres and individuals who will
perform the interventions (eg, surgeons, psychotherapists)

Interventions: #11a Interventions for each group with sufficient detail to allow
description replication, including how and when they will be administered

Interventions: #11b Criteria for discontinuing or modifying allocated interventions
modifications for a given trial participant (eg, drug dose change in response to
harms, participant request, or improving / worsening disease)

Interventions: #11c Strategies to improve adherence to intervention protocols, and
adherance any procedures for monitoring adherence (eg, drug tablet return;
laboratory tests)

Interventions: #11d Relevant concomitant care and interventions that are permitted
concomitant care or prohibited during the trial

Outcomes #12 Primary, secondary, and other outcomes, including the specific
measurement variable (eg, systolic blood pressure), analysis
metric (eg, change from baseline, final value, time to event),
method of aggregation (eg, median, proportion), and time point
for each outcome. Explanation of the clinical relevance of
chosen efficacy and harm outcomes is strongly recommended

Participant timeline #13 Time schedule of enrolment, interventions (including any run-
ins and washouts), assessments, and visits for participants. A
schematic diagram is highly recommended (see Figure)

Sample size #14 Estimated number of participants needed to achieve study
objectives and how it was determined, including clinical and
statistical assumptions supporting any sample size calculations

Recruitment #15 Strategies for achieving adequate participant enrolment to reach
target sample size

Methods:
Assignment of interventions (for controlled trials)

Allocation: sequence #16a Method of generating the allocation sequence (eg, computer-
generation generated random numbers), and list of any factors for
stratification. To reduce predictability of a random sequence,
details of any planned restriction (eg, blocking) should be

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml
For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml
### Methods: 

#### Monitoring

| #   | Description |
|-----|-------------|
| #21a| Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed. |
| #21b| Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial. |

#### Harms

| #22 | Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct. |

#### Auditing

| #23 | Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor. |

#### Ethics and dissemination

| #24 | Plans for seeking research ethics committee / institutional review board (REC / IRB) approval. |
| #25 | Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators). |
| #26a| Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32). |

For peer review only: [http://bmjopen.bmj.com/site/about/guidelines.xhtml](http://bmjopen.bmj.com/site/about/guidelines.xhtml)
Consent or assent: #26b Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable

Confidentiality #27 How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial

Declaration of interests #28 Financial and other competing interests for principal investigators for the overall trial and each study site

Data access #29 Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators

Ancillary and post-trial care #30 Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation

Dissemination policy: trial results #31a Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (e.g., via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions

Dissemination policy: authorship #31b Authorship eligibility guidelines and any intended use of professional writers

Dissemination policy: reproducible research #31c Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code

Appendices

Informed consent materials #32 Model consent form and other related documentation given to participants and authorized surrogates

Biological specimens #33 Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable

None The SPIRIT Explanation and Elaboration paper is distributed under the terms of the Creative Commons Attribution License CC-BY-NC. This checklist can be completed online using https://www.goodreports.org/, a tool made by the EQUATOR Network in collaboration with Penelope.ai