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BMJ Open Effectiveness of a nurse-led coaching in self-care intervention for elderly undergoing total laryngectomy: a randomised controlled trial

Liyuan Zheng ,¹ Jian Chen,¹ Huifen Wang,² Danxia Peng,¹ Yuchen Lu,¹ Shu'e Liu,¹ Yan Liu,¹ Xue Li,¹ Sanxia Ye,¹ Zhidan Mei,¹ Lai Wei,³ Chun Xu¹

ABSTRACT

Wang H. et al. Effectiveness Objectives To evaluate the effectiveness of nurse-led coaching in self-care (SC) interventions for elderly patients undergoing total laryngectomy (TL) using multidimensional parameters. laryngectomy: a randomised **Design** This was a double-arm randomised, single-centre

trial that met the requirements of the CONSORT statement. Setting Head and neck department in a tertiary A-level hospital.

Intervention Elderly patients scheduled for TL were randomly allocated to either the control group (n=24) or the intervention group (n=23). Patients in the control group received routine nursing care during hospitalisation and, subsequently, at home after discharge, received conventional family care without the regular supervision of nurses. Patients in the intervention group received a series of SC interventions led by nurses during hospitalisation and discharge and implemented SC practice using the home SC manual (SC knowledge and SC diary), nurses regularly supervised and evaluated the SC effect. The primary outcome was the SC ability. Secondary outcomes were self- efficacy, quality of life (QoL) and nutritional status. Results The SC intervention improved the SC ability, self-efficacy, QoL and nutritional status scores of patients in the intervention group compared with that of patients in the control group (p<0.01). The outcomes showed that the intervention had a significant effect on SC ability, self-efficacy and QoL scores, with both the main effects of time and intervention, as well as their interaction being significant (p<0.05). Nutritional status, as assessed using the PG-SGA, was better in the intervention group than in the control group (p<0.001). No adverse events (AEs) were observed in either group.

Conclusion Nurse-led SC intervention for elderly patients with TL is an effective strategy that can bring multidimensional benefits, including higher self-efficacy. stronger SC ability to actively solve health problems, better QoL and nutritional status, as well as shorter hospital stays.

Trial registration number ChiCTR2100043731.

INTRODUCTION Background

Laryngeal squamous cell carcinoma (LSCC) is the second most common cancers of the head and neck, with internationally,

STRENGTHS AND LIMITATIONS OF THIS STUDY

- \Rightarrow Self-care intervention based on the transtheoretical model mobilises the self-efficacy of the elderly, focusing on promoting autonomous mastery of selfcare skills.
- \Rightarrow Self-care diaries effectively increase the compliance of older adults with total laryngectomy (TL) self-care, providing an effective way to improve self-rehabilitation for elderly with TL.
- \Rightarrow The role of nurses as supervisors and evaluators in the home-based rehabilitation should be considered.
- \Rightarrow Single-centre research has limitations in intervention project promotion.

approximately 1 700 000 cases each year, and almost 90000 deaths.^{1 2} Total laryngecõ tomy (TL) offers a curative approach for đ patients with locally advanced laryngeal cancer (T3 or T4 tumours), hypopharyngeal dry mouth, cough, invasion of the thyroid or cricoid cartilage and extra-laryngeal soft tissues, failed response to radiotherapy or chemoradiotherapy and extensive tumours of histologic entities.^{3 4} Given the complexity of the anatomical and physiological functions within the laryngeal area, the loss of articulation and swallowing function, large amounts of airway secretions, poor sleep after surgery and other complications result in poor quality of life (QoL),⁵⁶ even in patients with improved long-term survival.⁷ Physically, the **o** health problems of patients with TL include **g**. loss of swallowing and language, shortness of 🕏 breath and a reduced sense of smell due to permanent tracheostomy.⁸ ⁹ Psychologically, survivors face various emotional barriers such as self-closure, decreased self-esteem and stigmatisation caused by changes in neck shape.^{10–12} Owing to the long-term existence of these changes, the current situation of selfcare (SC) in patients with TL after discharge is still not optimistic, especially for the elderly.

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Barriers to accessing SC in elderly patients are considered to result from complex and multifaceted interactions between biological and social factors. For example, the ability of elderly patients with low educational levels to acquire health management knowledge is relatively poor. However, patients may experience poorer adherence to SC over time owing to a lack of continuous supervision or follow-up from nurses.

Previous research on early rehabilitation exercises based on networks or self-help for patients with TL has achieved positive results.^{13 14} However, such approaches have limited accessibility for the elderly, who often face functional impairments, comorbid conditions and communication barriers such as hearing loss and a lack of general medical knowledge. Therefore, overcoming the barriers to SC access for elderly patients with TL requires a multifaceted approach, including collaborative efforts from various stakeholders. This involves facilitating communication and nurse-led interventions among elderly patients, their family caregivers and healthcare providers, with a focus on the post-discharge period.

Theoretical framework and hypotheses

The transtheoretical model (TTM)¹⁵ is based on social psychology and proposes five stages of behavioural changes and self-efficacy transformation mechanisms, which aims to promote human health management behaviours and healthy lifestyles. It is a widely used model that is effective for behavioural change in various fields, including SC.¹⁶⁻¹⁸ In this study, the SC ability refers to a type of self-derived health management behaviour, the core of which is to mobilise the

BMJ Open: first published as 10.1136/bmjopen-2023-078948 on 20 December 2024. Downloaded from http://bmjopen.bmj.com/ on June 11, 2025 at Agence Bibliographique de Enseignement Superieur (ABES) . Protected by copyright, including for uses related to text and data mining, Al training, and similar technologies.

subjective initiative of patients through effective external intervention, reduce their sense of uselessness and inferiority and improve their bodily function and health status by promoting their own physical condition assessment, care and monitoring. This study conducted corresponding interventions in five separate stages to mobilise patients' self-efficacy, increase their SC ability and strengthen their awareness and compliance with SC.

To attain this objective, the researchers constructed a theoretical framework for the SC intervention programme based on TTM (the theoretical framework is detailed in figure 1). Through preoperative SC awareness cultivation, SC knowledge training and postoperative one-on-one rehabilitation guidance by nurses, we explored whether this SC intervention programme could improve the postoperative SC ability of elderly people who underwent TL, promote the persistence of healthy SC behaviour and improve their QoL and functional outcomes.

Hypotheses of this study

H1: The SC ability/self-efficacy and QoL scores of the elderly in the intervention groups will be higher than those in the control group.

H2: Elderly people in the intervention group will experience less malnutrition than those in the control group.

H3: Elderly in the intervention group will have a shorter length and lower cost of hospitalisation compared with those in the control group.



Figure 1 Study theoretical framework diagram.

METHODS Study design

This randomised controlled study used parallel trial design guided by the Consolidated Standards of Reporting Trial checklist (online supplemental file 1). The study was conducted from 1 March 2021 to 30 September 2022 in the Department of Head and Neck Surgery of a tertiary A-level cancer hospital. The first admission doctor was responsible for recruiting participants after obtaining the informed consent from the patients. The trial flow chart is shown in figure 2.

Randomisation

Participants who met the eligibility criteria were randomly assigned to either the control group or the intervention group using a random number table according to the



Figure 2 Flow chart.

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time of patients' hospital admission. The randomisation numbers were sealed in sequentially numbered opaque envelopes and stored in the head nurse's office. The head nurse was directly responsible for assigning patients to the intervention or control group.

Participants

Sample size

To verify the effect of SC intervention on the OoL of patients after TL, we designed a random control test with α =0.05, β =0.20 (a power of 80%), according to the calculation formula of sample size $N = \frac{(Z\alpha + Z\beta)^2 * 2\sigma^2}{\delta^2}$, 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 the hospital with a laryngeal malignancy diagnosis, and TL was planned; (2) the survival time was expected to be more than half a year; (3) were older than 65 years without obvious disability; (4) had certain reading, writing and communication skills. After obtaining informed consent, the patients were asked to complete the questionnaires.

Exclusion criteria

The exclusion criteria were as follows: (1) concurrent cancer; (2) severe heart, liver, kidney and other organic diseases and coagulation dysfunction; and (3) suffering from other psychological or mental diseases at the treatment stage.

Implementation intervention Intervention scheme

Participants in both groups underwent similar treatment and nursing; however, the intervention group received additional SC skills intervention from nurses to try SC during hospitalisation and implement it at home after discharge, under the continuing guidance of nurses.

The detailed intervention protocol is published on the website : https://bmjopen.bmj.com/content/12/8/ e061238

Blinding

During the entire intervention stage, the blinded doctors provided the same medical services to the two groups of patients. Only the nurses directly responsible for the intervention were aware of the patients assigned to their care and were not informed of the patients in the other groups. The data collector remained blinded to patient grouping to ensure the integrity of the study results.

Measurement

As outcome variables, we assessed the SC ability, selfefficacy, nutritional status and QoL at baseline, at 7 days, 1month, 3months and 6 months post-TL. These measurements are freely available in the Chinese public domain. In addition, we counted the unplanned readmission rates. All outcomes were assessed by a data collector who was unaware of the patient group allocation.

Exercise of self-care agency scale

This scale consists of four dimensions (43 items): SC skills, SC 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. The sum of the scores for each dimension is the total score. The higher the score, the higher the SC ability.¹⁹

General self-efficacy scale

The scale was derived from the German psychologist Ralf Schwarzer, its Cronbach's α is 0.87, the test-retest reliability is 0.83, the half reliability is 0.82 and the Chinese version GESE of Cronbach's α is 0.75–0.91. There are 10 items on the scale, which are scored on a four-point g Likert grade 4. The higher the score, the stronger the copyright, general self-efficacy.²⁰

Nutritional Risk Screening 2002 (NRS-2002)

This tool was recommended as a nutritional risk screening tool with good predictive and content validity by ESPEN.³

Patient-Generated Subjective Global Assessment (PG SGA)

This was first proposed by Ottery in 1994, is a nutritional **o** status assessment method especially designed for cancer uses related to patients, and its reliability and validity are higher than 0.7 in the Chinese cancer population.²²

Quality of life instruments for cancer patients with head and neck cancer

tex The scale includes five dimensions: physical function, psychological function, social function, common symptoms and side effects and specific symptoms, which comprise 7, 12, 6, 7 and 14 items, respectively, for a total of 46 items. The Cronbach's a of all dimensions was above 0.7 in Chinese. Higher scores indicate better OoL.²³

Data collection

≥ Once the patient's informed consent is signed, a fixed trair data collection nurse, who does not know the grouping of patients, is responsible for data collection during the entire process to avoid the bias resulting from heterogeneity evaluation. Patients' contact information and addresses were confirmed before discharge. The fixed nurse independently collected data throughout the process, such as baseline data, clinical observation data and three follow-ups at months 1, 3 and 6 after the TL technologies questionnaire data (QoL/self-efficacy/SC agency/NRS-2002/PGSGA). All study data were saved in Excel 2015 (v16.0.3601.1023) by a data-collection nurse.

Data analysis

The data transmitted by the data collection nurse were saved and analysed by the data analyst. All analyses were performed using SPSS statistical software (IBM version 22.0). The Shapiro-Wilk test was used to analyse the sample distribution. The Mean±SD and frequency were used to describe demographic and clinical characterisation data. Data that conformed to a normal distribution were analysed by generalised repeated measures analysis of variance, which was used to demonstrate the effect of intervention and time-intervention interaction. The comparisons of time evaluated the primary impact of time on the dependent variable by comparing the mean values at different time points. The comparisons between groups were determined by comparing the overall average scores of the dependent variable between the intervention and control groups at the corresponding time points to determine whether there were significant differences between the two groups at each time point. The time-group interaction evaluated whether the impact of time on the dependent variable varied between groups, indicating that the impact of intervention measures would change over time. For all measured variables, the estimated sphericity was verified using Mauchly's W test, and the Greenhouse-Geisser correction was used when p<0.05. If significant differences were found in the interaction effects, Bonferroni post-hoc testing was used to determine the specific time points or groups where these differences occurred. A value of p<0.05 threshold was maintained to determine the statistical significance. Given the nature of repeated measures, the p value was adjusted using Bonferroni correction. The data with skewed distribution adopts a generalised estimation equation (GEE). Independent sample t-test was used to compare days in the hospital and the medical expenses data of the two groups.

Ethics

The study procedures and informed consent forms were approved by the Ethics Committee of the Hubei Cancer Hospital in Hubei Province, China (reference number KYLLBA2020006). The Ethics Committee will periodically evaluate the progress of this trial and track information on any adverse events (AEs) until the patient reaches a stable state. The doctors communicated with the patients to ensure that the participants' information was anonymous and informed them to sign the informed consent form.

Patient and public involvement

The patients and/or the public were not involved in the design, conduct, reporting or dissemination plans of this study.

RESULTS

Based on the eligibility criteria, 49 patients were enrolled in this study. Owing to the persistence of the novel coronavirus diseases, the hospital had experienced several intermittent control measures, resulting in a number of patients not meeting expectations. One patient with laryngeal cancer and heart failure was excluded, while one patient experienced severe psychological pain and refused to participate.

A total of 47 patients with TL met the inclusion criteria and were randomly assigned to either the control group (n=24) or the intervention group (n=23). One dropout occurred in the control group because of self-closure

Table 1 Demographic and clinical characterisation data of two groups of patients

Item		Control group (n=23)	Intervention group (n=22)
Age (years)		69.96±3.444	69.64±2.920
Sex	Male	19	20
	Female	4	2
Residence	City/town	16	10
	Countryside	7	12
Living style	Live with family	21	19
	Live alone	2	3
Education	Primary education or low	15	15
	Middle	5	3
	High	3	4
Tumour stage	0	0	1
	I	2	1
	II	0	2
	Ш	8	7
	IV	13	11

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Demographic and clinical characteristics

Demographic data and clinical characterisation data of two groups of patients are presented in table 1.

Age conforms to a normal distribution, expressed as Mean and SD; categorical variables for sex, residence, living style, education and tumour stage are expressed as frequency.

Outcome evaluation

Primary outcome: SC ability

data mining, AI training, Table 2 presents the comparisons in SC ability scales from baseline to 6months post-TL in both groups. The data for each dimension data are presented in online supplemental table 1. There was a significant timegroup interaction (p<0.001) after the intervention. The comparisons between groups showed that 1 month post-TL, the SC ability of the intervention group was significantly higher than that of the control group (p<0.05), indicating that the intervention effectively improved the $\boldsymbol{\hat{G}}$ patient's SC ability in the short term. By 3 months post-TL, the SC ability of patients in the intervention group had further improved, while the control group showed only a slight improvement (p<0.05), indicating that the intervention effect remained significant during the maintenance period. By 6months post-TL, the SC ability of both groups had stabilised, but the intervention group's level was still significantly higher than that of the control group (p<0.05), suggesting that the intervention had a lasting effect. The comparisons of time showed that in

Table 2 Comparison of self-care ability and self-efficacy between two groups of patients and within group comparison (Mean \pm SD/Median (P_{as}, P_{az}), scores)

T1 Baseline	T2 7d post-TL	T3 1m post-TL	T4 3m post-TL	T5 6m post-TL	Group-Time F value (P value)	Group F value (P value)	Time F value (P value)
93.30±3.611	87.30±4.269*	94.13±5.918†	105.17±4.458*†	107.39±5.450*†	10.754 (<0.001)	37.259 (<0.001)	243.873 (<0.001)
92.95±3.047	88.91±3.571*	101.45±5.189*†	110.05±4.359*†	117.55±5.755*†			
22.30±2.344	17.48±2.254*†	19.52±2.333*†‡	22.65±1.898†‡§	22.57±1.472†‡§	15.088 (<0.001)	39.191 (<0.001)	106.836 (<0.001)
22.09±2.543	19.41±2.130*†	23.45±1.896†‡	26.95±2.459*†‡§	26.86±2.054*†‡§			
61.15±2.252	39.86±4.774*†	54.47±4.550*†‡	56.45±5.548†‡	59.48±5.503†‡	6.238 (<0.001)	51.357 (<0.001)	149.811 (<0.001)
61.14±2.217	46.89±3.214*†	60.64±5.321†‡	63.04±5.437†‡	67.84±6.308*†‡§¶			
2.43 (2,3)	3.30 (3,4)*	4.35 (4,5)*†‡	5.04 (5,5)*†‡§	5.65 (5,6)*†‡§¶	18.512 (0.001)	20.957 (<0.001)	360.210 (<0.001)
2.41 (2,3)	3.23 (3,4)*	3.55 (3,4)*†	4.18 (4,5)*†‡§	4.59 (4,5)*†‡§¶			
	T1 Baseline 93.30±3.611 92.95±3.047 92.95±3.047 92.95±3.047 22.30±2.344 92.95±2.543 61.15±2.252 61.115±2.252 61.14±2.217 92.43 (2,3) 2.43 (2,3) 92.41 (2,3)	T1 Baseline T2 7d post-TL 93.30±3.611 87.30±4.269* 92.95±3.047 88.91±3.571* 22.30±2.344 17.48±2.254*† 22.09±2.543 19.41±2.130*† 61.15±2.252 39.86±4.774*† 61.14±2.217 46.89±3.214*† 2.43 (2,3) 3.30 (3,4)* 2.41 (2,3) 3.23 (3,4)*	T1 BaselineT2 7d post-TLT3 Im post-TL93.30 \pm 3.61187.30 \pm 4.269*94.13 \pm 5.918†92.95 \pm 3.04788.91 \pm 3.571*101.45 \pm 5.189*†92.30 \pm 2.304788.91 \pm 3.571*101.45 \pm 5.189*†22.30 \pm 2.34417.48 \pm 2.254*†19.52 \pm 2.333*†‡22.09 \pm 2.54319.41 \pm 2.130*†23.45 \pm 1.896†‡61.15 \pm 2.25239.86 \pm 4.774*†54.47 \pm 4.550*†‡61.14 \pm 2.21746.89 \pm 3.214*†60.64 \pm 5.321†‡2.43 (2,3)3.30 (3,4)*4.35 (4,5)*†‡2.41 (2,3)3.23 (3,4)*3.55 (3,4)*†	T1 BaselineT2 7d post-TLT3 im post-TLT4 3m post-TL93.30 \pm 3.61187.30 \pm 4.269*94.13 \pm 5.918†105.17 \pm 4.458*†92.95 \pm 3.04788.91 \pm 3.571*101.45 \pm 5.189*†110.05 \pm 4.359*†22.30 \pm 2.34417.48 \pm 2.254*†19.52 \pm 2.333*† \pm 22.65 \pm 1.898† \pm \$22.09 \pm 2.54319.41 \pm 2.130*†23.45 \pm 1.896† \pm 26.95 \pm 2.459*† \pm \$61.15 \pm 2.25239.86 \pm 4.774*†54.47 \pm 4.550*† \pm 56.45 \pm 5.548† \pm 61.14 \pm 2.21746.89 \pm 3.214*†60.64 \pm 5.321† \pm 63.04 \pm 5.437† \pm 2.43 (2,3)3.30 (3,4)*4.35 (4,5)*† \pm \$5.04 (5,5)*† \pm \$2.41 (2,3)3.23 (3,4)*3.55 (3,4)*†4.18 (4,5)*† \pm \$	T1 BaselineT2 7d post-TLT3 1m post-TLT4 3m post-TLT5 6m post-TL93.30±3.611 $87.30\pm4.269^{\circ}$ $94.13\pm5.918^{\dagger}$ $105.17\pm4.458^{\circ}^{\dagger}$ $107.39\pm5.450^{\circ}^{\dagger}$ 92.95±3.047 $88.91\pm3.571^{\circ}$ $101.45\pm5.189^{\circ}^{\dagger}$ $110.05\pm4.359^{\circ}^{\dagger}$ $117.55\pm5.755^{\circ}^{\dagger}$ 22.30±2.344 $17.48\pm2.254^{\circ}^{\dagger}$ $19.52\pm2.333^{\circ}^{\dagger}^{\ddagger}$ $22.65\pm1.898^{\dagger}^{\ddagger}$ $22.57\pm1.472^{\dagger}^{\ddagger}$ 22.09±2.543 $19.41\pm2.130^{\circ}^{\dagger}$ $23.45\pm1.896^{\dagger}^{\ddagger}$ $26.95\pm2.459^{\circ}^{\dagger}^{\ddagger}$ $26.86\pm2.054^{\circ}^{\dagger}^{\dagger}^{\ddagger}$ 61.15±2.252 $39.86\pm4.774^{\circ}^{\dagger}$ $54.47\pm4.550^{\circ}^{\dagger}^{\ddagger}$ $63.04\pm5.437^{\dagger}^{\ddagger}$ $67.84\pm6.308^{\circ}^{\dagger}^{\ddagger}^{\$}$ 61.14±2.217 $46.89\pm3.214^{\circ}^{\dagger}$ $60.64\pm5.321^{\dagger}^{\dagger}$ $63.04\pm5.437^{\dagger}^{\ddagger}$ $67.84\pm6.308^{\circ}^{\dagger}^{\ddagger}^{\$}$ 2.43 (2.3) 3.30 (3.4) [*] 4.35 (4.5) [*] $^{\dagger}^{\ddagger}$ 5.04 (5.5) [*] $^{\ddagger}^{\$}$ 5.65 (5.6) [*] $^{\dagger}^{\ddagger}^{\$}$ 2.41 (2.3) 3.23 (3.4) [*] 3.55 (3.4) [*] † 4.18 (4.5) [*] $^{\ddagger}^{\$}$ 4.59 (4.5) [*] $^{\dagger}^{\ddagger}^{\$}$	$\begin{array}{c c c c c c c } \hline T2 & T3 & T4 & T5 & Group-Time \\ \hline F value \\$	$\begin{array}{c c c c c c c c c c c c c c c c c c c $

*Bonferroni's post hoc with p<0.005 compared to baseline

†Comparisons between groups with p<0.05.

Bonferroni's post hoc with p<0.005 compared to 7d post-TL.

§Bonferroni's post hoc with p<0.005 compared to 1m post-TL. ¶Bonferroni's post hoc with p<0.005 compared to 3m post-TL

PC-SGA, patient-generated subjective global assessment; post-TL, post total laryngectomy; QoL, quality of life; SC, self-care.

the control group, SC ability decreased at 7 days post-TL, returned to the preoperative level at 1 month post-TL, continued to rise to a significant level at 3 months post-TL, and stabilised at 6 months post-TL. In the intervention group, SC ability also decreased at 7 days post-TL but then consistently increased to a significant level at 1, 3 and 6 months post-TL (all of p<0.005).

Secondary outcome Self-efficacy

Table 2 presents the comparisons in self-efficacy scales from baseline to 6 month post-TL of SC training in both groups. There was a significant effect of time-group interaction (p<0.001) on self-efficacy. The comparisons between groups showed that both groups experienced a significant decrease in self-efficacy at 7 day post-TL (p<0.05). However, by 1 month post-TL, the intervention group had already returned to preoperative levels, whereas the control group remained below baseline (p<0.05), and at the 3months post-TL, the self-efficacy of the control group returned to preoperative levels (p<0.05), whereas the intervention group showed a significant improvement above the preoperative level (p<0.05). At 6 months post-TL, the intervention group maintained a significantly higher level of self-efficacy than the control group (p<0.05). The comparisons of time showed that self-efficacy in the control group continued to increase from 1 month to 3 months post-TL and returned to

preoperative levels at 3 months post-TL (p<0.005). In **contrast**, the intervention group not only returned to baseline by 1 month post-TL but also showed a significant improvement above the preoperative level by 3 months post-TL (p<0.005). From 3 to 6 months post-TL, self-efficacy in the intervention group remained stable at a higher level, while that in the control group also stabilised at a lower level (p<0.05). This indicates that the SC training provided to the intervention group led to a more rapid recovery and sustained enhancement in self-efficacy over time.

QoL scores

Table 2 presents the comparisons in QoL from baseline **Table 2** presents the comparisons in QoL from baseline to 6 month post-TL of the SC intervention in both groups. The data for each dimension are presented in online supplemental table 2. There was a significant effect of time-group interaction (p<0.001). The comparisons between groups showed that the QoL in the intervention group was significantly higher than that in the control group at all time points (all p<0.05). The comparisons of time showed that both groups had a sharp decrease in QoL from baseline to 7 days post-TL (p<0.005). After 1 month, the intervention group had already returned to preoperative levels, while the control group remained below baseline (p<0.005). By 3 months post-TL, QoL in the intervention group had further improved and exceeded preoperative levels (p<0.005). At 6 months

post-TL, the intervention group maintained a significantly higher QoL than the baseline and control group (p<0.005), while the control group only returned to its preoperative level.

Nutritional status

According to the Shapiro-Wilk test, the PG-SGA scores of both groups were compared using GEE and did not conform to a normal distribution (table 2).

Table 2 presents the comparisons in the PG-SGA scores from baseline to 6 months post-TL of the SC intervention in both groups. A significant effect of time-group interaction (p<0.001) was noted. The comparisons between the groups showed that the PG-SGA scores of the intervention group were consistently lower than those of the control group at all time points (p<0.05). The comparisons of time showed that both groups exhibited persistent deterioration in the nutritional status at all time points (all p<0.005). The intervention group showed a slower rate of deterioration, with PG-SGA scores increasing less sharply than those in the control group. These results indicate that, while both groups experienced a decline in nutritional status over time, the intervention was effective in slowing the rate of malnutrition progression in the intervention group compared with the control group.

Hospitalisation days and expenses

A statistically significant difference was found between the groups according to the duration of hospitalisation (p<0.05) (table 3). Although there was no statistically significant decrease in expenses (p=0.594), it suggested that the low-cost SC manual intervention did not increase the expenses of patients.

AEs

No AEs were reported in either patient group because of the interventions.

DISCUSSION

With the diversification of treatments, the survival rate of patients with laryngeal malignancy patients is increasing. Although the medical staff try their best to carry out the diagnosis, treatment and nursing in the hospital, the home rehabilitation of patients after discharge is insufficient owing to limited medical human resources. After TL, patients' long-term SC involves several aspects, such as tracheostomy nursing, food traits and swallowing management, diet structure and nutritional management. One study reported that elderly patients face a range of unmet supportive care issues after surgery.²⁴ Due to the

long-standing existence of these problems, it is necessary to take some measures to improve patients' SC ability and alleviate unmet nursing needs.

The TTM emphasises that the public can drive internal self-efficacy and make behavioural changes, resulting in a healthy lifestyle. This intervention based on TTM encouraged patients to of TL postoperative nursing preoper-enabled them to try SC gradually through the training on nursing skills. After discharge, the addition of a nursing diary was conducive to maintaining patients' SC compli-ance and improving the QoL. aged patients to have a comprehensive understanding

the health outcomes of elderly patients with TL

copy At baseline, in elderly patients with TL SC ability, the selfefficacy of both groups was similar. The survey showed that the self-efficacy, SC skills and self-concept of the two groups of patients reached a low point at 7 days postoperatively and then continued to recover. The SC knowledge of the control group reached its lowest point 1 month postoperatively, while the intervention group showed almost no decline postoperatively and a phased upward trend postoperatively. The overall level of SC responsibility showed a stable increase, and the improvement in the intervention group was better than that in the control group (p<0.05). Therefore, TTM-based interventions may effectively assist patients in improving their self-efficacy, 5 SC skills and SC knowledge levels. As previous studies e have shown, patient self-efficacy is affected by the TTM theory.¹⁸²⁵ This study conducted a 6months follow-up survey and found that home nursing diaries benefited from improving patient compliance. Future research could focus on the TTM theory and explore its effectiveness in promoting patient health knowledge levels.

In this study, there was a significant difference in QoL scores between the two groups (p<0.05), indicating that the intervention was effective. The trajectories of physical and mental functions of the two groups were almost the ğ same, and the intervention group showed a higher level of mental function. The social functioning of the intervention group was better than that of the control group. S In the intervention group, a cluster of common symptoms, side effects and specific symptoms were concentrated from 7 days to 1 month postoperatively. Perry²⁶ showed that the survivors have a lower QoL due to stigma-tisation of the airway fistula, significant changes in voice and destruction of self-image. A study²⁷ conducted in the Greek population 6 months after being affected by TL showed that patients had more problems with their voice,

Table 3 Comparison of days in hospital/ medical expenses between two groups of patients							
Outcomes	Control group (n=23)	Intervention group (n=22)	Т	Р			
Hospitalisation days	25.83±4.802	22.18±4.239	2.694	0.010			
Patient medical expense (CNY, ¥)	61233±12988	59163±12834	0.537	0.594			

senses and dyspnea, whereas the functional status of physical, social and emotional function was satisfactory. This coincides with our research findings, which indicated that the patient's physical, psychological and social functions recovered to preoperative levels 6 months after TL. Patients in the intervention group achieved better QoL, especially in terms of social function and specific symptoms, which may be due to better SC skills that, to some extent, alleviated specific symptoms.

This study showed that the nutritional status of the patients in both groups was inevitably deteriorated. It depends significantly on the energy expenditure associated with TL as well as the dietary pattern and food types that are limited. The slight advantage of the intervention group over the control group may be due to the supervision of dietary energy in the nursing diary of the intervention programme. Relying solely on nursing methods for the nutritional problems in elderly patients after TL is not sufficient. Recent systematic reviews²⁸²⁹ have indicated that diet-based nutritional interventions have a positive impact on body function; however, limited research has focused on this important issue. In the future, nutritionist participation is needed to develop more effective preoperative and postoperative nutritional management for elderly patients. This study also found that the average hospitalisation time of patients in the intervention group was 3 days shorter than that in the control group (p=0.010), although there was no statistical difference in the hospitalisation expenses.

Applicability of self-care manual in elderly patients with TL

Cnossen's¹³ team developed a set of SC application to investigate the feasibility and satisfaction of online SC education for the early postoperative rehabilitation of 55 patients with TL. The results showed that this application was feasible, and the user experience satisfaction of follow-up patients was high, although it was accompanied by a high loss of follow-up. Several other outcome variables are worth exploring. In contrast to Cnossen's study, the proportions of middle-aged people and those with a middle level of education were relatively low in this study. Our study focused on the phenomenon of restricted use of electronic devices, which is inevitable in elderly patients undergoing TL due to their poor biological function, low educational level and low social interaction. The SC manual and diary were more convenient for the elderly to read and understand, as well as to improve their self-efficacy and increase their SC compliance.

Limitations

This study had several limitations. First, it was conducted at a single, tertiary A-level cancer hospital with limited sociodemographic diversity, which limits the generalisability of our findings to other care settings. Second, the intervention group nurses had an average of 5 hours more service time per patient than the control group nurses during the complete intervention cycle. One intervention nurse reported that one patient could not tolerate the postoperative symptoms and stopped cooperating with the questionnaire. None of the nurses experienced an obvious psychological burden during the intervention. Third, an additional limitation was that we did not reach the a priori defined sample size of 60 patients. Owing to the constraints imposed by the time-limited lockdown policies, a reduction in the sample size may decrease the statistical power, increase the risk of false-negative results and compromise the robustness of the findings. Additionally, the smaller sample size limited the generalisability and external validity of the research outcomes. Future studies should address these issues by expanding the sample size to reduce potential bias, enhance the robustness of the results and validate the effectiveness of the y intervention.

CONCLUSION

This study compared the effects of a TTM-based SC intervention with routine care over 6 months. We assessed the participants' SC ability, self-efficacy, QoL and nutritional status. Research findings that improve the health outcomes of patients with TL provide evidence for highquality continuing nursing. Owing to the intervention plan of increasing nurses' working hours, future research could attempt to optimise the nursing work mode, such as selecting specialised rehabilitation nurses to be responsible for guidance and follow-up supervision throughout the process. Future studies should focus on strategies to improve the nutritional status of elderly people undergoing TL with the goal of establishing a high-quality and efficient nursing service system. Recognising the limitations of this study, which included a small sample size and the fact that it was conducted at a single centre, it is essential to validate the effectiveness of the intervention through multicentre studies for broader applicability and robustness.

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data mining, AI training, and similar technologies

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number KYLLBA2020006). Participants gave informed consent to participate in the study before taking part.

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