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Helping head and neck cancer patients eat better during radiotherapy: testing a personalised nutrition support program

Submission date 01/11/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 12/11/2025	**Overall study status** Completed	
Last Edited 11/11/2025	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
Head and neck cancer includes cancers in areas like the mouth, throat, and voice box. These cancers are common worldwide and are often treated with radiotherapy (also called radiation therapy), which helps control the cancer and improve survival. However, radiotherapy can cause painful side effects like mouth ulcers, dry mouth, changes in taste, and difficulty swallowing. These problems make it hard for patients to eat properly, putting them at high risk of malnutrition. Malnutrition can lead to worse treatment outcomes and lower quality of life.
This study aims to test a new nutrition support program that is tailored to each patient's needs and readiness to change their eating habits. The program is based on a psychological model called the Transtheoretical Model, which helps people gradually adopt healthier behaviours. The goal is to see if this personalised approach can improve nutrition in patients receiving radiotherapy for head and neck cancer.

Who can participate?
Adults with head and neck cancer who are receiving radiotherapy at Kunshan First People's Hospital may be eligible to take part.

What does the study involve?
Participants are randomly placed into one of two groups. One group receives standard care, while the other group takes part in the personalised nutrition program. This program includes support at three stages during radiotherapy: early, middle, and late. Researchers will measure things like weight, muscle strength, and blood protein levels to assess nutritional health. Participants will also complete a nutrition questionnaire.

What are the possible benefits and risks of participating?
The main benefit is improved nutrition during treatment, which may help reduce side effects and improve recovery. There are no known risks from taking part in this study.

Where is the study run from?
The study is being conducted at the Department of Radiation Oncology, Kunshan First People's Hospital (China)

When is the study starting and how long is it expected to run for?
The study started in January 2023 and is expected to run until December 2024.

Who is funding the study?
Kunshan First People's Hospital (China)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
2023-04-143-K143

Study information

Scientific Title

The effect of a transtheoretical model-based nutritional management program on nutritional status in head and neck cancer patients undergoing radiotherapy: a randomized controlled trial

Study objectives
To evaluate the effectiveness of a nutrition management program based on a cross-theoretical model in improving the nutritional status of head and neck cancer patients undergoing radiotherapy.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 16/06/2023, Ethics Committee of Kunshan First People's Hospital (Kunshan First People's Hospital, No. 566, East Qianjin Road, Kunshan City, 215300, China; +86 51257027996; 18272746946@163.com), ref: 2023-04-143-K143

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Improvement of nutritional status in patients with head and neck cancer undergoing radiotherapy

Interventions
Subjects were recruited before radiotherapy, and those meeting the inclusion criteria were randomly divided into two groups (intervention group and control group) according to computer-generated random numbers. The intervention group received TTM-based nutritional intervention and routine nursing care throughout one radiotherapy cycle, while the control group only received routine nursing care. Data were collected at two time points: before intervention (T1, during the first radiotherapy outpatient visit before radiotherapy for baseline data collection) and after intervention (T2, during the first radiotherapy outpatient follow-up visit 3 months after the end of one radiotherapy cycle). Interventions were delivered through face-to-face assessments and health education, distribution of manuals, viewing of health education videos, and on-site centralized rehabilitation training.
Potential head and neck cancer patients eligible for radiotherapy who meet the inclusion and exclusion criteria are dynamically screened by ward nurses from medical records 1-3 days before the initiation of radiotherapy plans. For patients who initially meet the criteria, nurses distribute research invitation letters on the spot and briefly explain the study objectives and the arrangement for interventions to be conducted simultaneously with radiotherapy. Subsequently, the Principal Investigator (PI) verifies the patient information within 24 hours. After confirming that the patients meet the inclusion criteria, the PI explains the study details to the patients and their families in full. Written informed consent is obtained after the patients fully understand the study and voluntarily agree to participate.
A research assistant (RA) not involved in the recruitment process presets dynamic block randomization parameters using the SPSS random module. Specifically, the system automatically

balances the grouping ratio with blocks of 8 patients to ensure a 1:1 balance in the number of patients between the two groups even when patients are admitted sporadically. After patients complete informed consent and baseline assessment (1 day before radiotherapy initiation), the RA immediately logs into a randomized system with exclusive access, using the hospitalization number as the patient's unique identifier. The system generates the patient's randomization result in real-time, which is only visible to the RA. The system automatically records the randomization process, and each patient's grouping result is generated immediately after their baseline assessment is completed, ensuring that subsequent patients can independently complete randomization even after the previous patient is discharged.
Neither the patients themselves nor the data collectors are aware of the grouping assignments. The intervention group starts the nutritional management program on the first day of radiotherapy, while the control group receives routine care on the same day, ensuring that radiotherapy and intervention are immediately initiated after grouping. To avoid contamination, the intervention group is admitted to Ward 1 of Radiation Oncology, and the control group to Ward 2 of Radiation Oncology. Two registered nurses, trained by the PI, are responsible for implementing the interventions. Due to the nature of the intervention methods in this study, blinding of the nursing researchers conducting the interventions is not feasible; however, data collectors are blinded and are members of the research team who are not involved in interventions or randomization.

The intervention was implemented by a multidisciplinary team for nutritional management in oncological radiotherapy, consisting of 13 members: 1 head nurse, 2 oncology specialists, 2 radiotherapy doctors, 3 primary nurses, 1 radiotherapy nurse, 1 dietitian, 1 rehabilitation therapist, and 2 nursing postgraduate students. The head nurse served as the team leader, responsible for coordinating the program and ensuring quality control. Doctors, dietitians, and rehabilitation therapists were primarily in charge of formulating nutritional plans for patients at different stages and providing follow-up consultations. Primary nurses and radiotherapy nurses were the main implementers of the intervention program, including conducting nutritional assessments for patients and their families during radiotherapy, implementing the three-step nutritional therapy, providing guidance on nutrition and functional exercises, and conducting post-discharge follow-ups. Postgraduate students were responsible for developing the intervention program, including preliminary literature retrieval, current situation investigation, pre-experiments, data collection, sorting, and analysis. Before the formal implementation of the intervention, the team leader organized training for all members to ensure the homogeneity of program execution.

In this study, the intervention group received a nutritional management program based on the five stages of the Transtheoretical Model (TTM), while the control group received conventional radiotherapy care (only basic dietary education). The intervention period lasted from the initiation of radiotherapy to 3 months after the end of radiotherapy:

Precontemplation Stage: Conducted when patients visited the radiotherapy clinic, aiming to improve nutritional cognition and health awareness. This was achieved by radiotherapy nurses distributing Health Education Manual for Radiotherapy Patients, establishing trust relationships, educating patients on dietary principles and exercise guidance for head and neck cancer radiotherapy, addressing disease-related concerns, and encouraging patients to participate in self-nutritional management. The interveners were outpatient doctors and radiotherapy nurses, who completed nutritional risk screening and assessment including NRS2002, BMI, PG-SGA, serum ALB/PAB, grip strength, eating habits, and family support.

Contemplation Stage: Implemented before the initiation of radiotherapy, focusing on clarifying nutritional needs and formulating intervention plans. A team composed of primary nurses,

dietitians, and nursing postgraduates, together with professionals from medical oncology, radiation oncology, and rehabilitation (with nursing staff as coordinators), formed a multidisciplinary team. The multidisciplinary team worked with patients to develop a pre-radiotherapy nutritional plan and initiate early nutritional supplementation (aimed at increasing protein intake and maintaining weight for nutritional reserve).

Preparation Stage: Carried out within 1 week before the start of radiotherapy, focusing on improving support conditions and strengthening implementation readiness. This included evaluating the implementation of the pre-radiotherapy nutritional plan and making dynamic adjustments, providing nutritional supplements and suggestions for Jiangsu-specific recipes, opening a nutrition science popularization corner in the radiotherapy department (equipped with food models and materials for making nutritious meals), communicating with family members to ensure support, and teaching patients/family members methods for calculating daily intake and weight management. Meanwhile, rehabilitation therapists guided aerobic exercises (organizing Baduanjin exercises at a fixed time every day, with teaching videos played continuously in the nutrition activity room). The interveners were primary nurses, dietitians, and rehabilitation therapists.

Action Stage: Covering the entire course of radiotherapy, with the core of implementing nutritional plans and addressing radiotherapy-related obstacles. Differentiated nutritional interventions were implemented: strengthening nutritional intake in the early stage of radiotherapy when there was no obvious mucosal reaction; increasing protein and vitamins and providing traditional Chinese medicine such as Sterculia lychnophora (pangdahai) soaked in water during the middle stage when mucosal redness and congestion occurred; and offering cool, soft foods with small and frequent meals in the later stage when mucosal ulcers appeared. Nutritional status was assessed weekly, and the plan was adjusted according to the principles of five-step nutritional therapy (upgrading when the previous step reached < 60% of the target amount for 3-5 days). Additionally, patients were encouraged to keep diet diaries through psychological counseling and peer support. Rehabilitation therapists formulated prescriptions according to the FITT principle (moderate-intensity aerobic exercise from 15:00 to 15:30 daily, combined with resistance training, chewing and swallowing exercises, language pronunciation training, breathing exercises, and shoulder-neck stretching exercises). The interveners were primary nurses, dietitians, and rehabilitation therapists.

Maintenance Stage: Lasting until 3 months after the end of radiotherapy, aiming to consolidate healthy behaviors and maintain nutritional effects. Weekly follow-ups were conducted via telephone or nutrition clinics to assess the implementation of patients' dietary plans and their nutritional status. Based on the assessment results, dietary plans were dynamically adjusted, and patients' healthy eating behaviors were positively affirmed to strengthen their motivation for long-term adherence. The interveners were primary nurses, dietitians, and nursing postgraduates.

For the control group, radiotherapy nurses distributed the department-developed Health Education Manual for Radiotherapy Patients at the radiotherapy clinic for patients and their families to study. After admission to the radiation oncology department, primary nurses provided conventional education, including ward introduction, reasonable diet, regular exercise, radiotherapy procedures, and management of adverse reactions. A nutrition education room in the radiation oncology department was open for patients and their families to access nutrition science popularization and exercise activities. During radiotherapy, radiotherapy nurses regularly conducted nutritional assessments and dietary guidance for patients, mainly through verbal education, to guide them in making reasonable food choices. On the day before the end of radiotherapy, radiotherapy nurses provided discharge education to patients and their

families, including monitoring and management of common short-term and long-term complications of head and neck radiotherapy, diet and activities, and follow-up information. After the end of radiotherapy, follow-up nurses conducted weekly telephone follow-ups for three months.

Intervention Type
Behavioural

Primary outcome(s)
Patient-Generated Subjective Global Assessment (PG-SGA) . This scale consists of two parts: patient self-assessment and medical staff assessment at baseline(day1ofradiotherapy)and intervention completion (the first radiotherapy clinic follow up visit 3 months after the end of one radiotherapy cycle).

Key secondary outcome(s))
1. Plasma protein concentration is measured using blood biochemical analysis at baseline (day 1 of radiotherapy) and at intervention completion (first radiotherapy clinic follow-up visit, 3 months after the end of one radiotherapy cycle)
2. Serum albumin level is measured using enzyme-linked immunosorbent assay (ELISA) at baseline and intervention completion
3. Serum prealbumin level is measured using enzyme-linked immunosorbent assay (ELISA) at baseline and intervention completion
4. Body height is measured using a stadiometer at baseline and intervention completion
5. Body weight is measured using a calibrated digital scale at baseline and intervention completion
6. Body mass index (BMI) is calculated as weight (kg) divided by the square of height (m^2) at baseline and intervention completion
7. Hand-grip strength is measured using the CAMRY EH101 electronic hand dynamometer at baseline and intervention completion

Completion date
01/06/2025

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Meeting the diagnostic criteria for head and neck cancer specified in the NCCN Clinical Practice Guidelines in Oncology: Head and Neck Cancers (Version 1.2023)
3. Undergoing head and neck radiotherapy for the first time
4. Having a nutritional risk, as indicated by a score of ≥ 3 on the Nutritional Risk Screening 2002 (NRS-2002)
5. Expected survival period > 6 months
6. Providing informed consent and voluntarily participating in the study
7. Having normal cognitive and communication abilities

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
67

Key exclusion criteria
1. Patients with other severe physical diseases such as concurrent malignant tumors, including multiple distant metastases, multiple organ failure, and loss of independent activity ability
2. Patients for whom the disease condition needs to be concealed at the request of their family members

Exclusion criteria (for withdrawal):
1. Termination of radiotherapy due to severe radiotherapy-related complications
2. Transfer to another hospital for treatment due to personal reasons
3. Voluntary withdrawal from the study or inability to complete the study for other reasons

Date of first enrolment
01/05/2023

Date of final enrolment
01/12/2024

Locations

Countries of recruitment
China

Study participating centre
Kunshan First People's Hospital
No. 566, East Qianjin Road
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Sponsor information

Organisation
First People's Hospital of Kunshan

ROR
https://ror.org/01kzsq416

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
First People's Hospital of Kunshan

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication.

IPD sharing plan summary
Published as a supplement to the results publication