

**“Effects of a “walk, eat & breathe” nursing intervention for patients with esophageal cancer: a randomized controlled trial”**

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Esophageal cancer is a devastating disease with poor prognosis. This is largely due to its rather insidious progression, so most patients were diagnosed with advanced cancer stage. Patients with advanced stage therefore have to be treated with neoadjuvant chemoradiotherapy (CCRT) to shrink the tumor and followed by a curative surgery (i.e., esophagectomy). Patients’ nutritional status, functional walking capacity, and emotional well-being are substantially deteriorated, which often increase the incidence of postoperative pulmonary complications, thus the risk of surgical death is greatly increased. To better support patients with esophageal cancer, during this critical treatment course (approximate 4 months in length), we develop a “Walk, Eat, & Breathe” nursing intervention consisting of nutritional advice, walking exercise, and inspiratory muscle training. The purpose of this stratified randomized controlled trial (RCT) is to test the effects of Walk, Eat, & Breathe on preserving patients’ nutritional status, functional walking capacity, pulmonary function, and emotional well-being during the CCRT and surgery course. Additionally, effects to reduce treatment-related complications and length of hospital stay for esophagectomy will be evaluated between experimental and control groups.

For this three-year stratified RCT, a total of 144 consecutive patients will be enrolled to ensure the power of study. Patients will be eligible for the study if they had histologically documented, locally advanced tumors of the esophagus, defined as American Joint Committee on Cancer (AJCC) stage IIB or higher, were scheduled for neoadjuvant chemoradiotherapy and subsequent curative surgery, and had no contraindication precluding walking. After obtaining the consent, participants will be first stratified by two important covariates [intake status (oral intake or tube feeding) and tumor location (upper third or middle & lower third of esophagus)] and then randomized separately into the experimental or control group, according to computer-generated randomization tables.

Participants in the experimental group will receive “Walk, Eat, & Breathe” at initiation of CCRT and ends before curative surgery. Participants in the control group received usual care. Participants will undergo measurements at four points in time: before CCRT, after CCRT, before surgery, and 1-month after surgery. Primary

endpoints include nutritional status (body weight, lean muscle mass), functional walking capacity (hand-grip strength, 6-min walking distance), pulmonary function (forced vital capacity, forced expiratory volume in 1 second, maximal inspiratory pressure), and emotional well-being (anxiety/depression, quality of life). Secondary endpoints include treatment-related complications and length of hospital stay for esophagectomy. The treatment-related complications will include chemoradiotherapy-related toxicity (i.e., neutropenia, esophagitis), rates of interruptions (i.e., discontinuation, reduction) in chemotherapy or radiotherapy, unplanned hospital admission, incidence of postoperative pulmonary complications, and length of mechanical ventilation for surgery.