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Design of a multicenter randomized controlled trial to assess the effects of exercise And Diet on quality of life in patients with Incurable Cancer of Esophagus and Stomach: the RADICES study

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Background

Patients with incurable gastroesophageal adenocarcinoma (GAC) experience an impaired health-related quality of life (HRQoL), which might further deteriorate over time. These patients are often confronted with significant life-impacting symptoms, such as fatigue and reduced physical functioning. Exercise combined with nutritional support may improve these outcomes. However, careful evaluation of such an intervention is needed to avoid burdening patients at this vulnerable stage. Therefore, this study aims to evaluate the effects of a combined exercise and nutritional intervention on HRQoL in patients with incurable GAC.

Methods

The RADICES study is a multicenter randomized controlled trial and planning to enroll 196 patients with incurable GAC. Participants are randomly assigned (1:1) to either a patient-tailored intervention or a control group. Patients in the intervention group will receive two supervised training sessions per week and two-weekly nutritional consultations, delivered by trained physiotherapists and dietitians over a 12-week period. The control group will continue to receive standard care, supplemented with general physical activity advice. All patients will receive a Fitbit. As of Dec 12th, 76 patients have been included.

The primary outcome is the between-group difference in HRQoL at 12 weeks, adjusted for baseline HRQoL, measured by the EORTC QLQ-C30 summary score. HRQoL is assessed at baseline, 6, 12 weeks, and every 3 months thereafter up to 1 year. Key secondary outcomes include patient-reported outcomes (including physical functioning, role functioning and fatigue), cardiorespiratory fitness, dietary intake, disease progression, overall survival and cost-effectiveness. Adherence and safety are monitored throughout the intervention period.

Discussion

This study will generate evidence on the effectiveness of a patient-tailored combined exercise and nutritional intervention in patients with incurable GAC. If the intervention shows improvement in HRQoL, it could be integrated into standard care for patients with incurable GAC.

Keywords

gastroesophageal cancer, exercise and nutrition intervention, quality of life, randomized controlled trial

Conflict of Interest & Ethical Approval

yes

Abstract submitters declaration

yes

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