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Effect of photobiomodulation on the severity of oral mucositis and molecular changes in head and neck cancer patients undergoing radiotherapy: a study protocol for a cost-effectiveness randomized clinical trial

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Abstract

Background: Oral mucositis (OM) is the most frequent and debilitating acute side effect associated with head and neck cancer (HNC) treatment. When present, severe OM negatively impacts the quality of life of patients undergoing HNC treatment. Photobiomodulation is a well-consolidated and effective therapy for the treatment and prevention of severe OM, and is associated with a cost reduction of the cancer treatment. Although an increase in the quality of life and a reduction in the severity of OM are well described, there is no study on cost-effectiveness for this approach considering the quality of life as a primary outcome. In addition, little is known about the photobiomodulation effects on salivary inflammatory mediators. Thus, this study aimed to assess the cost-effectiveness of the photobiomodulation therapy for the prevention and control of severe OM and its influence on the salivary inflammatory mediators.

Methods/design: This randomized, double-blind clinical trial will include 50 HNC patients undergoing radiotherapy or chemoradiotherapy. The participants will be randomized into two groups: intervention group (photobiomodulation) and control group (preventive oral care protocol). OM (clinical assessment), saliva (assessment of collected samples) and quality of life (Oral Health Impact Profile-14 and Patient-Reported Oral Mucositis Symptoms questionnaires) will be assessed at the 1st, 7th, 14th, 21st and 30th radiotherapy sessions. Oxidative stress and inflammatory cytokine levels will be measured in the saliva samples of all participants. The costs are identified, measured and evaluated considering the radiotherapy time interval. The incremental cost-effectiveness ratio will be estimated. The study will be conducted according to the Brazilian public health system perspective.

Discussion: Photobiomodulation is an effective therapy that reduces the cost associated with OM treatment. However, little is known about its cost-effectiveness, mainly when quality of life is the effectiveness measure. Additionally, this therapy is not supported by the Brazilian public health system. Therefore, this study widens the knowledge about the safety of and strengthens evidence for the use of photobiomodulation therapy, providing information for public policy-makers and also for dental care professionals. This study is strongly encouraged due to its clinical relevance and the possibility of incorporating new technology into public health systems.

Trial registration: Brazilian Registry of Clinical Trials-ReBEC, RBR-5h4y4n . Registered on 13 June 2017.

Keywords: Cost-effectiveness; Head and neck cancer; Inflammatory mediators; Oral mucositis; Oxidative stress.

Figures

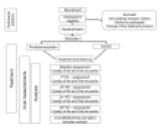

Fig. 1 Flowchart of the study. RT...

Fig. 2 Timeline of the study. *The...

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