

# Oral Care Protocol for Chemotherapy- and Radiation Therapy-Induced Oral Complications in Cancer Patients: Study Protocol

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## ABSTRACT

**Objective:** The purpose of this study is to describe a randomized control trial protocol that assesses the effectiveness of an oral care protocol on chemotherapy- and radiation therapy-induced oral complications in cancer patients. **Methods:** This study is a randomized, outcome assessor blinded study. For Phase I training phase, one group pretest-posttest design will be implemented for training the staff nurses on oral care in cancer patients and for Phase II Intervention Phase, randomized clinical trial will be used to determine the effectiveness of oral care protocol. Twenty-five staff nurses working in radiation oncology areas hospital will be trained about oral care in cancer patients. Seventy newly diagnosed patients with head and neck cancer admitted to the oncology wards of a tertiary care hospital in South India will be enrolled. Patients will be randomly allotted

to a control and intervention group. The primary outcome variables are oral complications and oral health assessment. **Results:** The results of the preliminary survey conducted among 158 staff nurses showed that 81 (51.3%) of the staff nurses had poor knowledge regarding oral care of cancer patients and majority 128 (81.0%) of them suggested for training in the specific area of oral care of cancer patients. A pilot study conducted by the principal investigator to determine the feasibility of the study among 9 participants (4 experimental and 5 control) revealed that there was slight difference found in the incidence of oral complications among the group in relation to weeks of assessment. **Conclusions:** The present study may give data regarding the occurrence of oral complications in head and neck cancer patients, and even, it can enlighten on the effectiveness

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of oral care protocol on oral complications. If this protocol is found effective, then this protocol can be made part of daily nursing care to improve the patient outcome.

**Key words:** Cancer patients, chemotherapy, oral care protocol, oral complications, radiation therapy

## Introduction

The oral cavity is a host to a vast array of microorganisms. Oral mucositis leads to a disruption in oral mucosa in patients who are immunocompromised. Oral mucositis raises the risk of infection and sepsis. The local bacterial flora having an epithelial barrier in the mouth freely enters the bloodstream leading to a possible systemic infection.<sup>[1,2]</sup>

Approximately all (90%–97%) patients getting irradiation to the head and neck area develop a certain grade of mucositis. Over 40% of head and neck cancer patients develop severe mucositis (grades 3–4). Of the patients treated with chemotherapy/radiotherapy, 34%–43% develop severe mucositis.<sup>[2-4]</sup>

Patients receiving standard-dose chemotherapy or head and neck radiotherapy may experience incidence of 15%–40% of oral mucositis. The described occurrence of mucositis with standard-dose chemotherapy varies greatly. Mucositis incidence of less than 10%–20% rates and as high as 40%–70% (all grades) have been reported for various mucotoxic chemotherapy regimens.<sup>[5-7]</sup> Most patients suffered mucositis which ranged between second and third grades (22.9% and 47.5%, respectively).<sup>[8,9]</sup> Severity of oral mucositis increases in patients with primary tumors in the oral cavity, oropharynx, or nasopharynx, treated with concomitant chemotherapy, receiving a total dose over 5000 Centigray and treated with altered fractionation radiation schedules.<sup>[10,11]</sup>

Oral problems, as well as the occurrence of mucositis, can cause many severe and disturbing events in oncology areas. These oral problems may include severe pain and distress leading to difficulty in eating, drinking, swallowing, or speaking. The changes in the oral mucosa can even lead to the risk of getting local and systemic infections.<sup>[12]</sup> These complications increase morbidity, sometimes requiring more number of hospital visits, a requirement to alter the dosage, interruption, or stop of essential cancer treatment. Altogether, these events can lead to increased physical, emotional, and financial costs and in some cases can result in mortality.<sup>[13]</sup>

Nurses are primary caregivers and the first line of contact for patients. Hence, nurses can assume a significant role to screen for the oral problems and implement evidence-based oral care interventions to resolve the oral problems.<sup>[14]</sup> Oral health during cancer treatment necessitates requirement for multidisciplinary team collaboration for the development of oral care protocol.<sup>[15,16]</sup> Nurses reported interest in updating

the knowledge in the oral care of cancer patients.<sup>[11]</sup> Patient navigation by nurses is reported as an effective strategy to assist the patients to undergo treatment smoothly leading to improved quality of life.<sup>[17]</sup>

### Research gaps identified

- Oral care is one of the most neglected areas in nursing<sup>[11]</sup>
- Nurses' skill with oral care needs improvement<sup>[11,13]</sup>
- Very few clinical trials have evaluated the effectiveness of various interventions developed for the prophylaxis and treatment of oral complications of cancer treatment<sup>[12,13,15]</sup>
- Some of the adverse effects of oral mucositis include the change in treatment plans, increased risk for infection, pain, and increased health-care costs.<sup>[2,4,18]</sup>

### Importance of proposed research

- Patients undergoing chemotherapy and head and neck radiation therapy have reported oral problems as the most disturbing symptom
- Oral complications can cause increased health-care cost, supportive care, and length of hospital stay
- Implementing this oral care protocol can lead to dose reductions in chemotherapy and radiation possibly leading to good therapeutic response.

## Methods

This study monitors the present practice and knowledge of oral care among staff nurses and improves the patient outcome by implementing and evaluating an oral care protocol for prevention or reduction of oral problems of hospitalized patients undergoing head and neck radiation/chemoradiation.

### Objective

- To determine the prevailing knowledge and practice of the staff nurses regarding oral care of cancer
- To develop oral care protocol and to train the staff nurses in implementing the oral care protocol
- To evaluate the clinical impact of oral care protocol implementation using oral health assessment chart, documentation audit checklist, oral complication incidence checklist, and cost analysis checklist.

### Research hypothesis

- There will be a significant difference in pretest and posttest knowledge and practice scores of staff nurses regarding oral care in cancer patients

- There will be a significant difference in the oral health status of the control group and the experimental group treated with oral care protocol
- There will be a significant association between patients in the experimental and control group and their demographic variables.

### Research design

This study is a randomized, outcome assessor blind, parallel clinical trial aimed at determining the effectiveness of structured oral care protocol on oral complications in cancer patients receiving head and neck radiation therapy.

### Participants

Participants will be recruited from patients admitted in radiation oncology and special wards of a tertiary care hospital in India. Patient inclusion criteria are as follows:

#### Patient inclusion criteria

- Patients planned for the radiation to the head and neck region, patients who are in any stage of cancer receiving chemoradiation, only radiation or postoperative radiation
- Patients in 18–75 years age group
- At least 75% of both parotids are within the radiation field.

#### Patient exclusion criteria

- Patients with cancers other than those affecting the oropharyngeal region
- Radiation agent: Linac (linear accelerator)
- Radiation dose: An average of 60–70 Grays.

### Sample size calculation

#### Staff nurses

For training of the staff nurses in radiation oncology and special wards, 25 staff nurses will be taken using enumerative sampling technique.

#### Patient selection

The sample size is calculated using the formula:

$$n = \frac{2(Z\alpha + Z\beta) \sigma^2}{d^2}$$

Pilot study findings using the difference in oral health assessment scores from the beginning of the radiation therapy course till the completion of the radiation therapy were included in two arms of the study. Experimental group mean  $\pm$  standard deviation (SD) was (10.0  $\pm$  1.8) and control group mean  $\pm$  SD was (11.5  $\pm$  1.7). Using 90% power and 95% confidence level, a minimum of 29 subjects will be required in each group. Considering 20% attrition rate, additional 6 members will be taken.

This study will be carried out among cancer treatment groups (radiation therapy/chemoradiation). Hence, the total sample size required in both experimental and control arm will be 70.

### Randomization, sequence generation, allocation concealment, and blinding process

Participants will be allocated into experimental and control according to a computer-generated randomization list. Randomization sequence will be created and stratified with a 1:1 allocation using random block sizes of 10. The experimental group will be receiving study oral care protocol along with oral care kit and patient education materials, which is prepacked in a ziplock sachet and numbered according to the randomization plan for each patient [Figure 1].

The allocation sequence will be based on random sampling numbers. The principal investigator will identify and recruit the patients based on eligibility criteria. The nurse coordinator will assign the participants to the intervention or control group. Patients will be aware regarding allocation into the study group. A single-blind approach will be used where the outcome assessor (subject experts) will be kept blinded to the allocation as well as will be blinded for assessment of outcomes.

### Intervention

#### Oral care protocol intervention

In this study, the intervention group will receive the oral care protocol intervention. Nurses working in the oncology wards will be trained regarding oral care of cancer patients, with special emphasis on oral complications of head and neck radiation and chemotherapy. Information booklets will be handed over to staff nurses. The principal investigator will be giving oral care kit and education materials and educating the patients; trained staff nurses in the ward will be implementing the oral care protocol and documenting the oral care [Table 1].

#### Routine oral care

The control group will take the routine oral care as per the standard of care of the hospital. Both groups will accept regular care delivered by the physicians, nurses, and follow-up care services [Table 2].

### Outcome measures

The primary outcome measure of this study is the incidence of oral complications and oral health assessment. The incidence of oral complications will be collected from patient records. Oral health assessment tool includes both functional and activities of the mouth, namely mucous membrane, tongue, teeth, saliva, lips,

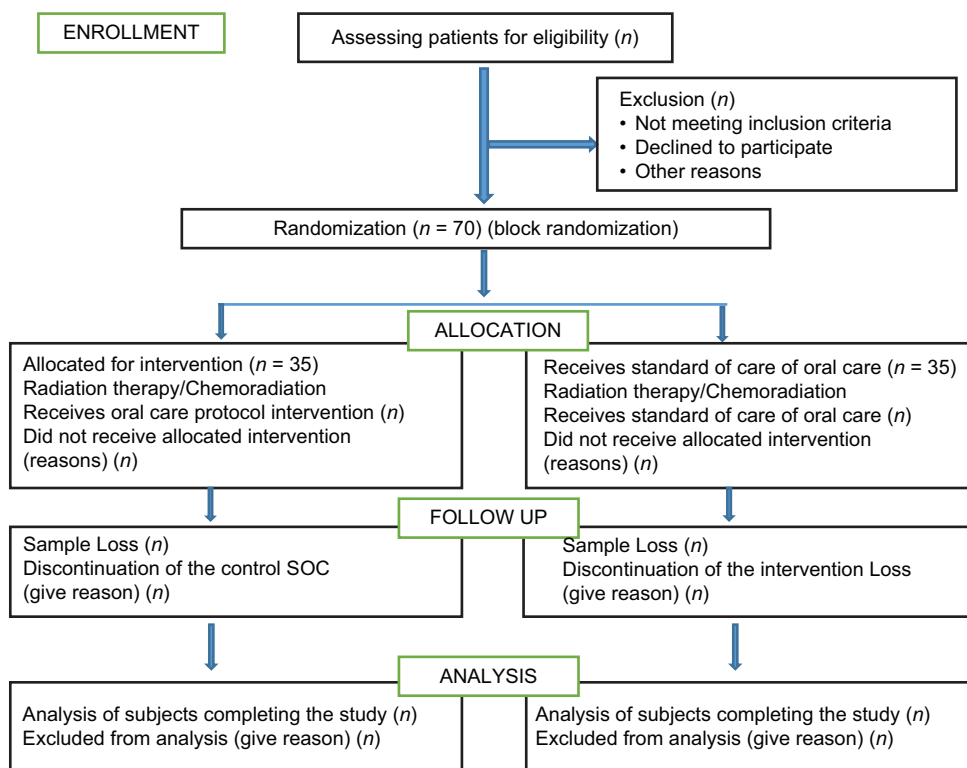


Figure 1: Study map constructed on Consolidated Standards of Reporting Trials (CONSORT) guidelines. © 2016 John Wiley and Sons Ltd

pain, taste, and infection. Activities include swallowing, chewing, speaking, and self-oral care. Each component has a score based on the appearance. The total score is 30. A score of 10 means good oral health, 11–20 indicates moderate risk for oral complications, and 21–30 indicates a high risk for oral complication. Oral mucositis is measured by WHO mucositis grading scale. This tool is classified as Grade 1 = soreness and erythema; Grade 2 = erythema, ulcers, patients can swallow solid diet; Grade 3 = ulcers, extensive erythema, patients cannot swallow solid diet; and Grade 4 = mucositis to the extent that alimentation is not possible. These tools will be assessed once every week.

Cost analysis, documentation audit, knowledge, and practice of staff nurses are secondary outcome measures. The cost analysis will be done by computing the loss of productive days for a patient/relative, extra consultation costs due to complications, extra costs such as food, transportation, and length of stay. Documentation audit will be carried out by checking the records for oral care documentation by nurses once a week during patient assessment. As there is staff nurse turnover or new nurse joining the department, oral care training will be conducted for all of them which will be monitored by a knowledge assessment questionnaire and practice assessment checklist. Demographic pro forma will be used to collect the details of staff nurses and patients.

Table 1: Description regarding the Experimental and Control arm

Arms	Description
Experimental arm: (Intervention) Oral Care Protocol	Procedure: Patient in this arm receive oral care according to protocol which includes nursing assessment with oral health assessment tool and oral care kit which contains ultrasoft bristle toothbrush, fluoridated toothpaste, oral rinses (salt, baking soda), chewy tubes, mirror, pen torch, denture brush and denture container, ice cube box, water bottle, patient educational material (Oral care during treatment and after discharge, Menu plan during the treatment). Patient receives intervention from day 1 of admission, till he/she completes the treatment and there after upto 1 year following completion of cancer chemotherapy/radiation therapy.
Control: (Comparator Agent) Standard of care (SOC) of oral care	Procedure: Patients in this control arm receive oral care according to SOC of oral care as per the hospital practices. It includes Nursing assessment which comprises of - Inspecting mouth (mucous membranes, lips, tongue, and gingiva) for oral changes like mucositis, ulcer, white patches. Documenting findings in the nursing care sheet, assisting patient with oral care as required.

### Data collection process

#### Phase I: Training phase

In this phase, a training module will be developed on oral care in cancer patients, which consists of importance of oral health, aims of the protocol, brief description of anatomy and physiology of oral cavity, oral complications of chemotherapy and radiation therapy, oral assessment tools, preventive measures to be implemented before,

during, and after chemotherapy and radiation therapy to reduce oral complications and nutritional considerations. Staff nurses working in oncology units will be trained on implementation of the oral care protocol.

Patient education material will be prepared in the form of the pamphlet which includes care of mouth, oral hygiene, food preference, dos and don'ts, tips, and menu plan during and after the cancer treatment. Oral care protocol will be prepared by reviewing the literature, comparing the oral protocols developed by other health centers, evidence-based interventions, and recommendations from the recognized councils. For this, a team consisting of medical oncologist, radiation oncologist, dentist from oral medicine, and radiology and oncology nurse will discuss and finalize a suitable oral care protocol for hospital practice. The study procedure is summarized and outlined in Table 2.

**Phase II: Intervention phase**

After validating the module and oral care protocol, an intervention was initiated in two steps. Initially, staff nurses were trained and oral care protocol intervention was done using oral care kit. Here, patient received the oral care based on the study intervention, which included brushing with ultra-soft bristled toothbrush using fluoridated toothpaste, rinsing mouth with soda bicarbonate, chewing the chewy tube before eating, denture care, and patient education on self-oral assessment. This oral care intervention will be performed four times a day. Along with these interventions, a structured menu plan will be given to the patient which

includes the type of foods to be consumed and the foods to be avoided during the treatment and advice of drinking 2–3 liters of water per day. This intervention phase will have a 1 year of follow-up period for the patients once they complete their chemoradiation or radiation therapy [Table 3].

**Statistical analysis**

After coding the data sheets, it will be analyzed using SPSS version 16 (SPSS Inc. Released 2007. SPSS for Windows, Version 16.0. Chicago, SPSS Inc.). To analyze the sample characteristics, descriptive statistic will be used. To determine if the data follows the normal distribution, normality tests will be used. Primary analysis method will be the intention to treat analysis (ITT). The baseline characteristics of the two groups will be compared by repeated measures ANOVA. The effectiveness of the staff nurses training will be determined by one group pretest posttest design.

**Ethical approval**

The institutional ethics committee accepted the study proposal in October 2014 (Approval No. IEC KMC MLR 08-14/162). A patient information sheet containing a brief explanation of the study will be handed over to participants by the principal investigator which gives a short report of the study including aims, techniques, and the role of participants, possible threat, and welfares involving the study. After taking written consent, it will be conveyed that

**Table 2: Schematic illustration of data collection procedure**

	Pretest measurements	Intervention	Posttest measurements	Follow up
Group	At admission for radiation therapy		Once in week till completion of treatment	Once in 2 month upto 1 year after treatment
Experimental group	O1 Oral health assessment WHO oral Mucositis grading scale	Oral care protocol intervention	O2 Oral health assessment WHO oral Mucositis grading scale	O3 Patient self-oral assessment
Control group	O1 Oral health assessment WHO oral Mucositis grading scale	Routine oral care	O2 Oral health assessment WHO oral Mucositis grading scale	O3 Patient self-oral assessment

O=Observations

**Table 3: Oral care protocol intervention procedure**

Phase	Intervention	Duration	Contents/Details of intervention	Researcher action
I Training of staff nurses	Training of staff nurses	1 h	Powerpoint presentation. Distribution of information booklet to nurses.	Teaching with powerpoint. Discussion. Pre and post test
II Intervention phase	Session with patient	30 min	Session with patient - collection of patient demographic proforma. Oral health assessment. Introduction of oral protocol intervention and oral care kit to patient. Patient and family education	Demonstration of oral care and oral care kit. Pamphlet distribution. Discussion
	Weekly oral assessment (once in every week till completion of radiation therapy)	15 min	Oral health assessment including activities such as speaking, swallowing, pain, self oral care etc. Monitoring oral complications Monitoring oral mucositis grades Identification of delay/stop/modification of treatment. Cost analysis of treatment of oral complications	Assessment of oral cavity. Patient education Documentation audit
III Follow up	Telephonic follow up (once in 2 months upto 1 year after head and neck radiation)	10 min	Oral complications and oral health	Discussion

their participation is voluntary and can withdraw consensus at any time and their choice will not disturb the upcoming management. Privacy and concealment will be guaranteed all over the study. The access to the data will be restricted to the investigators only. Investigator will discuss the data obtained from the intervention in relevant seminars/workshops or publish the preliminary findings in suitable indexed journals.

### Validity and reliability

The research pro formas used for the study were validated, and reliability was computed through an early pilot study finding. Confounding variables will be managed using a block randomization. Randomization integrity will be preserved after subjecting it to the ITT. The complete information collected will be examined for any errors and if any matters recognized will be rectified by the investigator.

For dealing the missing data during ITT analysis, the “Last Value Carried Forward” method is adopted. To guarantee intervention reliability, the study will be conducted by firmly adhering to the standard operating procedures and appropriate documentation. Overall, a study procedure assessment will be done among the patients to appraise the efficiency and the fulfillment of the intervention. The research advisory committee will have regular interaction to determine the study progress.

## Results

### Preliminary study findings

The results of the preliminary survey conducted among 158 staff nurses showed that 81 (51.3%) of the staff nurses had poor knowledge regarding oral care of cancer patients, and majority, i.e., 128 (81.0%) of them suggested for training in the specific area of oral care of cancer patients.<sup>[19]</sup> More than half of respondents [54 (34.2%)] did not perform oral care as a part of routine duties. Maintenance of various records, lack of manpower, and lack of standard operating procedures were major barriers in providing oral care.<sup>[20]</sup> A pilot study conducted by the principal investigator to determine the feasibility of the study among 9 participants (4 experimental and 5 control) revealed that there was slight difference found in the incidence of oral complications among the group in relation to weeks of assessment. Taste alteration, xerostomia, and bleeding gums appeared early in the experimental group in comparison with the control group, whereas swallowing difficulty, oral mucositis, infection, and the nutritional compromise were delayed in the experimental group.

The present study is planned for completion in March 2019. If this study finds to be effective, this protocol can become an integral part of oral care in cancer wards.

### Limitations

1. Different chemotherapy drugs will differ in its severity in causing oral problems
2. Patients receiving cytotoxic chemotherapy and radiation therapy will be having different types of cancers and will be in different stages of cancer, which can affect the prognosis
3. Individual response to the cancer treatment differs.

## Conclusion

Radiation therapy and chemotherapy lead to the increased incidence of mucositis and associated complications. Literature do not emphasize mainly on overall management of oral complications in cancer patients. Nurses are the professionals who are in contact with the patients all the time; there is a requirement to develop a standard protocol in the area of oral care of cancer patients. The protocol developed in this study assures uniform practice of oral care across the hospital. If the oral protocol intervention is found to be effective, this approach could be incorporated into the clinical setting to promote evidence-based practice and to maximize patient outcomes.

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Nil.

### Conflicts of interest

There are no conflicts of interest.

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