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# Assessing Dutch-language versions of two questionnaires design to assess the impact of side effects of radiotherapy in patients with head and neck cancer

**Submission date**
25/09/2020

**Recruitment status**
No longer recruiting

**Registration date**
05/10/2020

**Overall study status**
Completed

**Last Edited**
12/02/2025

**Condition category**
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Radiotherapy uses radiation to kill cancer cells. Along with surgery, it is the most frequently used treatment for patients with head and neck cancer (HNC, cancer in the mouth, nose and throat). Unfortunately, radiotherapy in the head and neck area can also damage healthy tissues. This can reduce people's ability to carry out daily activities of life as they did before, which can then impact on their quality of life (QoL). The most common side effects during radiotherapy are radiation dermatitis (skin irritation and soreness), oral mucositis (mouth irritation and soreness), xerostomia (dry mouth), loss of taste, fatigue, dysphagia (swallowing problems) and dysphonia (problems with speaking).
Oral mucositis tends to be the problem that results in a reduction in radiotherapy dose or frequency. It results in pain, bleeding and infections, which can lead to problems with swallowing and reduction in food intake. Since this side effect has a significant impact on QoL, it is important to assess oral mucositis in patients with HNC during their treatment.
All of the radiation-associated side effects can severely affect patients and their social, family and work activities and relationships. They can even harm a person's self-esteem. This means it is also important to assess patients' abilities to perform daily life activities and their quality of life.
The aim of this study is to translate from English to Dutch two questionnaires that assess the impact of oral mucositis and the impact of HNC radiotherapy on the patient's ability to speak, diet and ability to eat in public and to assess their usefulness in measuring the impact on the patient.

Who can participate?
Adult HNC patients treated with radiotherapy with or without chemotherapy (drug treatment combined with radiotherapy)

What does the study involve?
All patients are asked to fill out three questionnaires before the start of radiotherapy and during weeks 3, 4 and 5 of radiotherapy. At the same times, a cancer radiotherapy specialist will assess

their side effects and a speech specialist will interview the patient to assess their speech, diet and ability to eat in public.

What are the possible benefits and risks of participating?
There are no additional risks or benefits of participating in this study, since the patients will receive their cancer treatment as normal.

Where is the study run from?
Antwerp University Hospital (Belgium)

When is the study starting and how long is it expected to run for?
August 2018 to May 2020

Who is funding the study?
Kom Op Tegen Kanker (Belgium)

Who is the main contact?
Prof. Dr. Gwen Van Nuffelen
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# Contact information

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Scientific

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# Additional identifiers

### Protocol serial number
B300201837097

# Study information

### Scientific Title
The validation and psychometric properties of the Dutch version of the Oral Mucositis Weekly Questionnaire-Head and Neck Cancer (D-OMWQ-HN) and the Performance Status Scale-Head and Neck Cancer (D-PSS-HN)

### Study objectives
We hypothesize that the Dutch version of the Oral Mucositis Weekly Questionnaire (D-OMWQ-HN), a questionnaire designed to assess the symptoms of oral mucositis and their impact on patient function and well-being) and the Dutch version of the Performance Status Scale for Head and Neck Cancer (D-PSS-HN), a questionnaire designed to assess function (including understandability of speech, normalcy of diet and eating in public), are valid, reliable and feasible instruments in patients treated with radiotherapy for head and neck cancer.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 14/08/2018, Ethical Committee of the University of Antwerp (Prinsstraat 13, 2000 Antwerpen, Belgium; +32 38213000; ethisch.comite@uza.be), ref: 18/05/056

### Primary study design
Interventional

### Study design
Multicenter longitudinal study

### Study type(s)
Quality of life

### Health condition(s) or problem(s) studied
Patients treated with (adjuvant) radiotherapy for head and neck cancer

### Interventions
This is a multicenter, longitudinal study with the aim of validating the Dutch version of the Oral Mucositis Weekly Questionnaire and the Performance Status Scale for Head and Neck Cancer patients.

The D-OMWQ-HN and D-PSS-HN are first translated according to the cross-cultural adaptation process described in international guidelines.

The D-OMWQ-HN is filled in together with the Functional Assessment of Cancer Therapy - Head & Neck cancer (FACT-HN) and the Dutch version of the dysphagia-related quality of life assessment tool D-SWAL-QOL. The RTOG/EORTC grading of radiation-inmduced morbidity is completed by the radiation oncologist. The Functional Oral Intake Scale (FOIS) and D-PSS-HN are completed by a speech and language pathologist based on a short interview with the patient. All instruments are administered at baseline and during week 3, 4 and 5 of radiotherapy treatment. This data is used to assess the validity and reliability of the D-OMWQ-HN and D-PSS-HN.

During week 4, the D-OMWQ-HN and D-PSS-HN are filled in twice within 24-48 h for test-retest reliability evaluation.

Data collected during week 5 is used to assess reliability and validity.

This is a multicentre trial: the University Hospital of Anwerp and the University Hospital of Ghent are participating in this trial.

## Intervention Type
Other

## Primary outcome(s)
1. D-OMWQ-HN (Dutch Oral Mucositis Weekly Questionnaire Head and Neck Cancer): mucositis-specific questionnaire assessing patient well-being and function
Method of measurement: patient questionnaire
Timepoint: baseline, week 3, 4 (twice within 24-48 hours) and 5 of radiotherapy.
2. D-PSS-HN (Dutch Performance Status Scale Head and Neck Cancer): clinician-rated instrument consisting of three subscales addressing areas of diet, speech and eating in public
Method of measurement: patient interview
Timepoint: baseline, week 3, 4 (twice within 24-48 hours) and 5 of radiotherapy.
3. FACT-HN (Functional Assessment of Cancer Therapy Head and Neck Cancer): multidimensional quality of life instrument developed specifically for the oncologic population
Method of measurement: patient questionnaire
Timepoint: baseline, week 3, 4 and 5 of radiotherapy.
Measure: used to assess the discriminant validity of the D-PSS-HN and the D-OMWQ-HN and the convergent validity of the D-OMWQ-HN
4. SWAL-QOL (Swallowing Quality of Life Questionnaire): is a dysphagia-specific patient questionnaire evaluating domains of dysphagia related to quality of life: general burden, eating duration, eating desire, food selection, communication, fear of eating, social functioning, mental health, sleep and fatigue
Method of measurement: patient questionnaire
Timepoint: baseline, week 3, 4 and 5 of radiotherapy.
Measure: used to assess the convergent validity of the D-PSS-HN and the discriminant validity of the D-OMWQ-HN
5. RTOG/EORTC (the Toxicity criteria of the Radiation Therapy Oncology Group (RTOG) /European Organization for Research and Treatment of Cancer (EORTC)): the radiation oncologist determines the grade of oral mucositis by means of a clinical examination
Method of measurement: clinical examination
Timepoint: baseline, week 3, 4 and 5 of radiotherapy
Measure: used to assess the convergent validity of the D-OMWQ-HN

6. FOIS (Functional Oral Intake Scale): is a clinican-rated scale, used to assess the current status and changes in oral intake
Method of measurement: patient interview
Timepoint: baseline, week 3, 4 and 5 of radiotherapy
Measure: used to assess the convergent validity of the D-PSS-HN

### Key secondary outcome(s)
There are no secondary outcome measures

### Completion date
25/05/2020

## Eligibility

### Key inclusion criteria
1. Patients with head and neck cancer treated with radiotherapy or chemoradiotherapy
2. Tumor located in the oral cavity, oropharynx, nasopharynx, hypopharynx or larynx
3. Aged 18 years or older

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 Years

### Sex
All

### Key exclusion criteria
1. Patients treated with experimental medication used for oral mucositis
2. Cognitive problems

### Date of first enrolment
11/12/2018

### Date of final enrolment
27/04/2020

## Locations

### Countries of recruitment
Belgium

**Study participating centre**
**Univeristy Hospital of Antwerp**
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**Study participating centre**
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# Sponsor information

**Organisation**
Antwerp University Hospital

**ROR**
https://ror.org/01hwamj44

# Funder(s)

**Funder type**
Charity

**Funder Name**
Kom Op Tegen Kanker

# Results and Publications

**Individual participant data (IPD) sharing plan**
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository.
All data will be stored in REDCap, a secure web application for building and managing online surveys and databases. (https://www.project-redcap.org/).
Patient information (no identifying information), surveys and measurements will be shared.
The data will be available for all participating study investigators until the end of the study.
All data will be anonymised, patient's details will be encoded.

## IPD sharing plan summary

Stored in repository

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | Results for D-OMWQ-HN | 01/10/2022 | 02/11/2022 | Yes | No |
| Results article | Results for D-PSS-HN | 15/05/2023 | 12/02/2025 | Yes | No |