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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

Type(s)
Scientific

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Study design
Multicenter longitudinal study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)

Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
03/08/2018

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
75

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
University Hospital of Ghent
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Sponsor type
Hospital/treatment centre

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ROR
https://ror.org/01hwamj44

Funder(s)

Funder type
Charity

Funder Name
Kom Op Tegen Kanker

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/12/2022

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