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Assessing the Dutch-language version of a questionnaire designed to assess the impact of the side effects of radiotherapy in patients with head and neck cancer

Submission date
27/09/2021

Recruitment status
No longer recruiting

Registration date
20/11/2021

Overall study status
Completed

Last Edited
22/01/2024

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
The aim of this study is to assess the Dutch-language version of a questionnaire designed to assess the impact of the side effects of radiotherapy in patients with head and neck cancer. The questionnaire examines quality of life related to dysphagia (swallowing difficulties) and explores the patient's view of his/her swallowing problem and the resulting limitations in activities and participation. This questionnaire was originally developed in English and has already been translated and validated in Chinese. A Dutch equivalent does not exist to date.

Who can participate?
Patients aged 18 years and over with head and neck cancer who were treated with (chemo) radiotherapy and/or surgery at least 6 months ago

What does the study involve?
All patients are asked to fill out three questionnaires. At the same time, a speech-language pathologist will interview the patient to assess their performance status and their speech, diet and ability to eat in public. Patients are given a second copy of the questionnaire to take home and are asked to fill it in again after 1 week.

What are the possible benefits and risks of participating?
There are no additional risks or benefits of participating in this study.

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

When is the study starting and how long is it expected to run for?
January 2021 to December 2021

Who is funding the study?
Antwerp University Hospital (Belgium)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
B3002021000111

Study information

Scientific Title
Validation and assessment of the psychometric characteristics of the Head and Neck Cancer Survivors' Assessment of Mealtimes (D-HNSAM)

Acronym
D-HNSAM

Study objectives
It is hypothesized that the Dutch version of the Head and Neck Cancer Survivors' Assessment of Mealtimes (D-HNSAM), a patient-oriented questionnaire designed specifically for head and neck cancer (HNC) patients, is a valid, reliable and feasible instrument in patients treated with radiotherapy for HNC.
The questionnaire is based on the ICF (International Classification of Functioning, Disability and Health) model and focuses on the psychosocial problems experienced by HNC patients with dysphagia. It examines dysphagia-related quality of life (QoL) and explores the patient's own view of his/her swallowing problems and the resulting limitations in activities and participation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/07/2021, Ethical Committee of the University of Antwerp (Prinsstraat 13, 2000 Antwerpen, Belgium; +32 (0)38213897; ethisch.comite@uza.be), ref: 2021-0264 - Edge 001685

Study design
Multicenter longitudinal study

Primary study design
Observational

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Patients with head and neck cancer treated with radiotherapy, surgery, chemoradiotherapy or a combination of the before mentioned treatment modalities

Interventions
This is a multicenter, longitudinal study with the aim of validating the Dutch version of the Head and Neck Cancer Survivors' Assessment of Mealtimes (D-HNSAM). The D-HNSAM is first translated according to the cross-cultural adaptation process described in international guidelines.

The D-HNSAM is filled in together with the Dysphagia Handicap Index (DHI) and the Utrecht Scale for Evaluation of Rehabilitation Participation (USER-P). The speech-language pathologist

will complete the Performance Status Scale - Head and Neck Cancer (PSS-HN) and the Functional Oral Intake Scale (FOIS) based on a short interview with the patient.
All instruments are administered at baseline and after 1 week, patients are asked to fill out the D-HNSAM again for test-retest reliability evaluation.

This data is used to assess the validity and reliability of the D-HNSAM.

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. Dysphagia-related quality of life (QoL) and the patient's own view of his/her swallowing problems and the resulting limitations in activities and participation, assessed using the Dutch-Head and Neck Cancer Survivors' Assessment of Mealtimes (D-HNSAM) (patient questionnaire) at baseline and after 1 week
2. Swallowing-related quality of life assessed using the Dysphagia Handicap Index (DHI) (patient questionnaire) at baseline
3. Objective and subjective rehabilitation participation assessed using the Utrecht Scale for Evaluation of Rehabilitation Participation (USER-P) (patient questionnaire) at baseline
4. Normality of diet, eating in public, and speech intelligibility assessed using the Performance Status Scale - Head and Neck Cancer (PSS-HN) (clinician-based interview) at baseline
5. Oral intake capabilities assessed using the Functional Oral Intake Scale (FOIS) (clinician-based interview) at baseline

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

Completion date
20/12/2021

Eligibility

Key inclusion criteria
1. Patients with head and neck cancer treated with radiotherapy or chemoradiotherapy; tumor located in the oral cavity, oropharynx, nasopharynx, hypopharynx or larynx
2. Patients with head and neck cancer treated with surgery; tumor located in the oral cavity, oropharynx, nasopharynx, hypopharynx or larynx
3. The treatment was completed at least 6 months ago
4. Aged 18 years or older
5. Without any cognitive disorders

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 years

Sex
All

Total final enrolment
60

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
20/07/2021

Date of final enrolment
31/07/2021

Locations

Countries of recruitment
Belgium

Study participating centre
Univeristy Hospital of Antwerp
Wilrijkstraat 10
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Belgium
2650

Study participating centre
University Hospital of Ghent
Corneel Heymanslaan 10
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Sponsor information

Organisation
Antwerp University Hospital

ROR
https://ror.org/01hwamj44

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Universitair Ziekenhuis Antwerpen

Alternative Name(s)
Antwerp University Hospital, University Hospital Antwerp, UZA

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Belgium

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 non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		23/10/2022	22/01/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes