Determinants and mediating mechanisms of quality of life and disease-specific symptoms among thyroid cancer patients: the WaTCh study

Published: 05-12-2018
Last updated: 12-04-2024

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Thyroid gland disorders
Study type	Observational invasive

Summary

ID

NL-OMON54712

Source
ToetsingOnline

Brief title
The WaTCh study

Condition

- Thyroid gland disorders
- Endocrine neoplasms malignant and unspecified

Synonym
Thyroid cancer, thyroid carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg
Source(s) of monetary or material Support: Ministerie van OC&W,NWO investeringsaanvraag groot

Intervention

Keyword: Patient-reported Outcomes, Thyroid cancer

Outcome measures

Primary outcome

QoL and disease-specific symptoms over time.

Secondary outcome

fatigue, sleep, physical activity, anxiety, depression, health care

utilisation, and employment.

Study description

Background summary

Whilst some studies have found that individuals with thyroid cancer (TC) generally have a quality of life (QoL) that it is comparable to those in the general population most recent studies reported statistically significant and clinically relevant lower levels of physical and psychosocial functioning, and significantly more symptoms (e.g. fatigue, dyspnea, insomnia, appetite problems) among TC patients compared to an age- and sex matched normative population. However, most studies on QoL among TC patients are limited by the cross-sectional study designs and lack of data about (mediating) mechanisms. More research is needed into the mechanisms leading to worse QoL outcomes among thyroid cancer patients.

Study objective

Our main objective is to assess QoL and disease-specific symptoms over time. Our secondary objectives are to identify demographic, environmental, biological, physiological and personality characteristics of TC patients who are at high risk for poor physical and psychosocial outcomes (general and disease-specific QoL, fatigue, sleep, physical activity, anxiety, depression,

health care utilisation, and employment).
Another objective is to analyse mediating mechanisms (e.g. inflammation levels, genetic markers, expression levels, bacterial flora, body composition, and heart rate) associated with poor outcomes in TC patients.

The main research questions that need to be answered are:
1) What is the level of QoL and disease-specific symptoms over time among TC patients?
2) What is the role of demographic (age, gender), environmental factors (food intake, body weight, body composition), clinical (tumour stage, treatment), biological (DNA and serum markers), physiological (heart rate) and personality (optimism, illness perception) characteristics on physical and psychosocial outcomes (general and disease-specific quality of life, fatigue, sleep, physical activity, anxiety, depression, health care utilisation, and employment) of TC patients? In other words, who is at risk?
3) What is the association of mediating mechanisms (e.g. inflammation levels including Dietary Inflammatory Index, genetic markers, expression levels, bacterial flora (microbiome), body composition, and heart rate) with poor outcomes in TC patients? In other words, why is a person at risk?

Study design

Longitudinal population-based study.

Study burden and risks

On an individual level, patients who participate are asked to complete questionnaires so there is no risk in participation. The collection of blood (which takes about 10 minutes) and stool samples (only at Radboud and UMCG) is minimally invasive. Optionally, patients can choose whether they are interested in filling out food diaries (3 days). Wearing the Fitbit for 14 consecutive days and having a weighing scale at the house is considered to be minimally invasive. Furthermore, patients can call a researcher (psychologist) or an independent doctor for more information about this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Thyroid cancer population
In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Diagnosed with thyroid cancer
- 18 years or older
- Able to fill out questionnaires in Dutch

Norm population
In order to be eligible for participation in this study, a participant must meet all of the following criteria:
- 18 years or older
- Able to fill out questionnaires in Dutch
- Live near one of the WaTCh-hospitals for blood draw

Exclusion criteria

TC patients:
A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Patients with cognitive impairment will not be included because of expected difficulties in completing these questionnaires without assistance.

- Patients who are not able to read or write Dutch will be excluded, as they are not able to complete a Dutch questionnaire.

Norm population:
A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Participants with cognitive impairment will not be included because of expected difficulties in completing the questionnaire without assistance (already not included in the LISS panel).
- Participants who are not able to read or write Dutch will be excluded, as they are not able to complete a Dutch questionnaire (already not included in the LISS panel).
- Participants with a (previous) diagnosis of a carcinoma, except for basal cell carcinoma of the skin.
- Participants who have a household member already included in this study, to ensure independence of answers.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-08-2020
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO

Date:	05-12-2018
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	17-04-2019
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	18-07-2019
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	08-04-2020
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	27-08-2020
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	14-12-2020
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	14-04-2021
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	18-10-2021
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	21-04-2023
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL65161.028.18