Physical activity pattern and energy expenditure of head and neck cancer patients: an explorative study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON39298

Source
ToetsingOnline

Brief title
PAP study

Condition

- Other condition
- Appetite and general nutritional disorders

Synonym
loss of muscle mass and strength; malnutrition

Health condition

ondervoeding; hoofd-halskanker

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Energy expenditure, Head and neck cancer, Physical activity

Outcome measures

Primary outcome

- Daily step count

- Energy expenditure

Secondary outcome

Quantitative study:

Secondary outcome variables:

- Types of physical activity

- Muscle mass/fat-free mass (kg)

- Muscle strength (number of stand ups)

- Estimated energy expenditure (kcal)

Co-variables

- Age

- Gender

- Body weight

- Body Mass Index (BMI)

- Malnutrition (PG-SGA score C)

- Frailty

- Dietary intake (protein in gr/d; energy, in kcal/d)

- Self regulation

- Self efficacy

- Motivation

- Fatigue

- Smoking and drinking habits

- Performance status

- Tumor- or treatment-related symptoms

- Comorbidity

Qualitative study:

The qualitative research will give insight in physical activity and exercise

barriers and facilitators, and preferences by head and neck cancer patients.

Study description

Background summary

Head and neck cancer patients lose muscle mass and muscle strength during treatment with (postoperative) radiotherapy or chemoradiation. Patients lose about 5% of their fat-free mass, an indicator of muscle mass, and about 10% of their hand grip strength (Jager-Wittenaar et al., 2011a) in that period. Malnutrition, characterized by loss of muscle mass and muscle strength, affects quality of life (Ravasco et al., 2004; Jager-Wittenaar et al., 2011b), and increases morbidity and mortality. Malnourished patients seem to be prone to toxic effects of chemotherapy, resulting in dose reductions and treatment interruptions (Fearon et al., 2011). Furthermore, malnutrition results in a shorter survival and a prolonged hospital stay and higher health care costs (Correia & Waitzberg, 2003; Datema e.a., 2011).

Loss of muscle mass and strength during head and neck cancer treatment is multifactorial. Besides local factors, systemic factors are involved. Local

factors are tumor- and treatment-related oral symptoms, resulting in reduced food intake (Jager-Wittenaar et al., 2007; Jager-Wittenaar et al., 2011c). Depending on the type of tumor, patients are treated with either surgery, radiotherapy or chemoradiation, or combinations. Both surgery and (chemo)radiation induce problems with chewing and swallowing and especially the combination of both types of treatment hamper oral food intake. Therefore, head and neck cancer patients routinely receive dietary counselling by a dietitan, in order to meet nutritional requirements (e.g. energy and protein). Systemic factors are disease-related and radiation-induced inflammation activity (Ehrsson et al., 2009; Ki et al., 2009), which cause breakdown of muscle protein. Furthermore, the treatment is accompanied by fatigue. As a result, patients may reduce their daily physical activity (Rogers et al., 2008). Hence, muscle protein synthesis will decline, resulting in loss of muscle mass (*disuse atrophy*) (Guadagni & Biolo, 2009). The proportion of head and neck cancer patients not meeting the public health exercise guidelines increases from 69% pre-treatment to 91% post-treatment (Rogers et al., 2006). Given the decreased physical activity and malnutrition, head and neck cancer patients may have symptoms of frailty as well.

Dietary treatment including a protein and energy enriched diet cannot prevent loss of muscle mass and strength during and after head and neck cancer treatment (Jager-Wittenaar et al., 2011a). Furthermore, patients may not regain body weight lost during treatment, despite sufficient intake (Jager-Wittenaar et al., 2011b). As not only food intake is an anabolic stimulus (Rennie et al, 1982), but physical exercise is another anabolic stimulus (Chesley at al, 1992), we hypothesize that lack of physical activity may contribute to loss of muscle mass and strength in head and neck cancer patients.

Until now, little is known about physical activity, intensity and frequency, of head and neck cancer patients and its relationship with loss of muscle mass and strength. Insight in physical activity, intensity and frequency, is needed, to determine whether physical activity needs to be stimulated in these patients, in order to lower the risk of disuse atrophy contributing to the risk for malnutrition.

Moreover, to be able offer a tailored exercise intervention in the future, the interventions should meet specific demands of head and neck cancer patients. Therefore, insight is needed in which factors hinder and facilitate physical activity and exercise in head and neck cancer patients, as well as insight in physical activity and exercise preferences of these patients.

Moreover, measurement of physical activity also enables gain of knowledge on energy expenditure of head and neck cancer patients. In clinical practice, total energy expenditure is estimated. However, use of current formulae to predict energy expenditure results in prediction errors, resulting in over- or underfeeding. Insight in energy expenditure from physical activity and its relationship with physical performance status is needed, to reduce prediction

errors.

Study objective

This study primarily aims to explore changes in physical activity pattern and energy expenditure in head and neck cancer patients, during and after treatment with surgery with or without (chemo)radiation.
The secondary aim of this study is to gain insight in perceived exercise barriers and facilitators, and exercise preferences of head and neck cancer patients.

Study design

The quantitave part of the study has an explorative, longitudinal design.
The qualitative part of the study has a cross-sectional design.

Study burden and risks

Participation in this study is not expected to cause any additional physical harm to the subjects* health. Wearing the SenseWearPro armband poses no health risk (Bodymedia, 2010). The most frequently reported side effect, occurring in less than 1% of users, is a mild to severe skin irritation resulting from wearing the Armband. This issue is easily resolved by following proper wear and cleaning guidelines. Participants will receive instructions regarding wear and cleaning guidelines. Participants will also be instructed to discontinue use and consult a physician regarding skin irritations in case skin irritation occurs.

All measurements are considered non-invasive, as no blood samples will be collected en subjects will not be exposed to radiation.

All study measurements will be conducted three times: 1) one week before start of treatment, 2) six weeks after end of treatment, and 3) three months after end of treatment. All study measurements will be planned shortly before or after a regular control visit to the physician.
Participants will be asked to fast 4 hours before the study measurements.

At the three study measurements, the following non-invasive tests will be performed within the 90 minutes:
weight, length, mid upper arm circumference, triceps skinfold, calf circumference, hand grip strength, chair to stand test, bio-electrical impedance analysis, and indirect calorimetry.

Furthermore, the following questionnaires will be filled in: Patient-Generated Subjective Global Assessment (PG-SGA), Frailty Instrument for Primary Care of

the Survey of Health, Ageing and Retirement in Europe (SHARE-FI), MVI-20, Self-Regulation Questionnaire Exercise, Exercise Self Efficacy Scale, WHO performance score, and EORTC QLQ-HN35.

Moreover, the participants will wear a pedometer during one week, three times. In that week, the participant will also wear an accelerometer (SenseWearPro armband) and fill in a food diary during three days.

In addition to the measurements performed during the three study measurements, participants wil be asked to be interviewd once, six weeks post-treatment. The duration of this in-depth interview will be 60 minuts at maximum.

If indicated necessary based upon the results of this study, this study will be followed by an intervention study to evaluate effectiveness of one ore more interventions. Moreover, insight in energy expenditure will give practitioners tools to reduce risk of overfeeding and underfeeding.

As the study is not expected to cause any additional physical harm to the subjects* health, we consider the burden of participation in proportion to the potential value of the research.

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

- Newly diagnosed T1, T2, T3 or T3 malignancy in the oral cavity, larynx, oro- or hypopharynx, to be treated with surgery with or without (chemo)radiation
- Age: >=18 years
- Able to understand and speak the Dutch language

Exclusion criteria

- Second primary tumor, outside the head and neck region
- Fibula transplantation
- Wheel chair dependency
- Comorbidity with a contra-indication for physical exercise
- Severe cognitive disabilities
- Skin allergy or highly sensitive skin
- Palliative treatment

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2012
Enrollment:	23

Type:	Actual

Ethics review

Approved WMO Date:	18-06-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	10-04-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	27-11-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL39927.042.12