Clinimetric properties of measurements on neck and shoulder function, strength, exercise capacity, level of physical mobility and maximal opening of the mouth in head and neck cancer survivors

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The goal of this study is to be able to perform reliable measurements on AROM of neck and shoulders , exercise capacity, strength, MMO and functional mobility to evaluate the effectiveness rehabilitation programs in head and neck cancer survivors.

Ethical review	Approved WMO
Status	Pending
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Observational non invasive

Summary

ID

NL-OMON44631

Source
ToetsingOnline

Brief title
Functional tests in HNC survivors

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
head and neck cancer / malignancies

Research involving
Human

Sponsors and support

Primary sponsor: fysiotherapie centraal
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: head and neck cancer, measurement, psychometric properties, reliability

Outcome measures

Primary outcome

reliabilty measurements:

Shoulder function (Active Range of Motion, AROM)

Neck function (Active Range of Motion, AROM)

Muscle Strength (grip strength, shoulder elevantion strength with MRC scale,

30sec chair to stand test)

Exercise capacity (6 Minute Walking Test)

Level of physical mobility (Timed Up dan Go test)

Maximal opening of the mouth (mm)

Secondary outcome

shoulder pain and disability : The Shoulder Disability Questionnaire (SDQ), The

Shoulder Pain and Disability Index (SPADI)

Neck pain and function: The Neck Disability Index (NDI)

Quality of life : The EuroQol 5D (EQ-5D) , The EORTC QLQ C-30.

Study description

Background summary

Survivors of head and neck cancer commonly experience treatment-related morbidity that impairs exercise capacity, muscle strength, active range of motion (AROM) of neck and shoulder and maximal mouth opening (MMO). These problems limit daily activities and subsequently negatively influence Health related Quality of Life (HrQoL). Physical therapy, as part of the multidisciplinary team, focuses on these complaints. During treatment, 73% of all patients report the need for physical therapy, and 23% report such needs after 8-11 years. This could indicate that as well as during treatment, long term survivors of head and neck cancer could benefit from physical therapy. Physical therapy could include mobility exercises to improve maximal AROM of neck and shoulders and training to improve exercise capacity and general muscle strength. The evidence on physical therapy treatment modalities to improve MMO remains indecisive or absent (functional mobility). To evaluate physical therapy with treatment goals in AROM of neck and shoulders , exercise capacity, muscle strength, functional mobility and MMO and to ensure adequate training progression and intensity, repeated testing of these properties is necessary.

Study objective

The goal of this study is to be able to perform reliable measurements on AROM of neck and shoulders , exercise capacity, strength, MMO and functional mobility to evaluate the effectiveness rehabilitation programs in head and neck cancer survivors.

Study design

Clinimetric study with a test-retest design.

Study burden and risks

The research takes place at a regular meeting of the Dutch head and neck patient society. Possible participants are relatively old and possibly vulnerable. In this study we try to take this into account as much as possible and minimize possible risks. The research consists of two measurements during one day (1 in the morning, 1 in the afternoon) . The total amount of time necessary for the research is estimated between 60 and 80 minutes per participant in total. A measurement consist of active tests, questionnaires and the collection of demographic and patient characteristics. The physical tests consist of measurements that have been researched and performed safely in routine daily physiotherapy care in other vulnerable patient categories and patients with other oncological malignancies.
With the use of the PARQwe will identify patients at risk for cardiovascular or pulmonal problems . After completion of the research the patient gets a report describing his scores and intepretation of physical tests to compensate for time investment

Contacts

Public
Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Possible participants are head and neck cancer survivors and are all members of the Dutch patient organization for head and neck cancer survicors and 18 years or older.

Exclusion criteria

Patients undergoing medical treatment for head and neck cancer.
Patient receiving palliative treatment.
Patients that are not able to speak or understand Dutch. Patient that are walking aid dependent
Patients at risk when performing maximal exercise which will be assessed before inclusion using a modified Physical Activity Readiness Questionnaire (PARQ), leading to the exclusion of willing participants who answer yes to one or more questions.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2018
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO Date:	20-02-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	16-05-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL63632.091.17