

Efficacy of a guided self-help exercise program in laryngectomized patients

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21069

Source

NTR

Health condition

Patients treated with total laryngectomy, laryngeal cancer, speech problems, swallowing problems, shoulder problems

Sponsors and support

Primary sponsor: VU University Medical Center

Source(s) of monetary or material Support: Michel Keijzer Fund

Intervention

Outcome measures

Primary outcome

The primary outcome measure of this study is the swallowing quality of life questionnaire (SWAL-QoL).

Secondary outcome

Secondary outcome measures of this study are the speech handicap index (SHI), the shoulder disability questionnaire (SDQ), the EORTC generic and head and neck cancer specific quality

of life questionnaires (EORTC-QLQC30 and H&N35), the EuroQol-5 dimensions (EQ-5d), cost questionnaires and the Patient Activation Measure (PAM).

Study description

Background summary

Treatment of patients diagnosed with laryngeal cancer with total laryngectomy with or without (chemo)radiation often induces speech, swallowing and shoulder complaints. Speech, swallowing and shoulder exercises may prevent or diminish these complaints. The aim of this study is to investigate the efficacy and cost-effectiveness of the guided self-help exercise program build into the application “in Tune without Cords” to prevent or reduce speech, swallowing and neck and shoulder problems in patients treated with total laryngectomy.

Study objective

Treatment of patients diagnosed with laryngeal cancer with total laryngectomy with or without (chemo)radiation often induces speech, swallowing and shoulder complaints. Speech, swallowing and shoulder exercises may prevent or diminish these complaints. The aim of this study is to investigate the efficacy and cost-effectiveness of the guided self-help exercise program build into the application “in Tune without Cords” to prevent or reduce speech, swallowing and neck and shoulder problems in patients treated with total laryngectomy.

Study design

Patient reported outcome measures will be assessed at baseline, after the intervention or control period and three months after the intervention or control period.

Intervention

The intervention investigated in this study is a guided self-help exercise program targeting speech, swallowing and shoulder problems called “In Tune without Cords”. This guided self-help exercise program is provided by Internet or booklet plus DVD.

Contacts

Public

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a patient must meet all of the following criteria:

- 1) treated with total laryngectomy with or without (chemo)radiation up to five years ago in one of the participating head and neck cancer centers; and
- 2) provided written informed consent.

Exclusion criteria

A potential participant who meets any of the following criteria will be excluded from participation in this study:

- 1) treated with total laryngectomy combined with a total glossectomy;
- 2) treated with partial laryngectomy;
- 3) younger than 18 years;
- 4) having cognitive impairments; and/or
- 5) unable to understand the Dutch language.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-01-2015
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion	
Date:	17-06-2015
Application type:	First submission

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

NTR-new

NTR-old

Other

ID

NL5123

NTR5255

: METC VUmc 2014.514

Study results