

Efficacy of a guided self-help exercise program targeting speech, swallowing and shoulder problems in laryngectomized patients: a randomized controlled trial

Published: 21-01-2015

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To investigate the efficacy of the guided self-help exercise program of *in Tune without Cords* among laryngectomized patients.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON43884

Source

ToetsingOnline

Brief title

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

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

Synonym

head and neck cancer, laryngeal cancer

Research involving

Human

Sponsors and support

Primary sponsor: KNO/hoofd-halschirurgie

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

Intervention

Keyword: Exercises, Head and neck cancer, Laryngectomy, Selfmanagement and eHealth

Outcome measures

Primary outcome

Primary outcome measures are differences in swallowing quality (swallowing quality of life questionnaire), speech problems (speech handicap index) and shoulder disability (shoulder disability questionnaire) between the intervention and control group at follow-up measurements.

Secondary outcome

Secondary outcome measures are generic and head and neck cancer specific quality of life (EORTC quality of life core module and head and neck cancer module), the incremental cost effectiveness ratio (calculated using different cost questionnaires and the EuroQol-5 dimensions) and self-management (patients activation measure).

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.

Study objective

To investigate the efficacy of the guided self-help exercise program of *in Tune without Cords* among laryngectomized patients.

Study design

A prospective randomized controlled trial with two parallel groups (1:1) comparing a guided self-help exercise program targeting speech, swallowing and neck and shoulder problems to a control group with measures 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 provided by Internet or booklet plus DVD targeting speech, swallowing and shoulder problems. Patients are asked to exercise themselves at home using the Internet or booklet plus DVD containing written instructions, images and videos of prescribed exercises. Patients are asked to exercise three times a day (10-15 minutes a time) for 12 weeks.

Study burden and risks

Risks are negligible and burden is low. In case of positive results, participating patients will probably benefit immediately from the guided self-help exercise program.

Contacts

Public

Selecteer

de Boelelaan 1117 de Boelelaan 1117
Amsterdam 1081 HV
NL

Scientific

Selecteer

de Boelelaan 1117 de Boelelaan 1117
Amsterdam 1081 HV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Patients treated with total laryngectomy in the last 5 years

Exclusion criteria

Patients treated with total laryngectomy combined with a total glossectomy, patients treated with a partial laryngectomy, patients younger than 18 years, patients with cognitive impairments or who do not understand the Dutch language.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-06-2015
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO	
Date:	21-01-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	17-06-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	17-07-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	19-10-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	10-05-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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

CCMO

ID

NL51261.029.14