Postoperative telerehabilitation to improve functional recovery in patients after esophagectomy: a feasibility-study

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Primary Objective: To investigate the feasibility of a 12 -week postoperative Telerehabilitation program for patients with esophageal cancer treated with esophagectomy and suffering from postoperative complicationsSecondary Objective: To investigate...

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

Summary

ID

NL-OMON43105

Source
ToetsingOnline

Brief title
Postoperative physiotherapy with telerehabilitation

Condition

- Gastrointestinal neoplasms malignant and unspecified
- Gastrointestinal therapeutic procedures

Synonym
Esophageal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Revalidatie
Source(s) of monetary or material Support: NWO promotiebeurs voor leraren

Intervention

Keyword: Esophageal cancer, Functional Status, Physiotherapy, Telerehabilitation

Outcome measures

Primary outcome

Feasibility outcomes include willingness to participate in the study, refusal rate, adherence to the Telerehabilitation intervention operationalized in amount of sessions attended, performance rate of exercises, amount and duration of email-, phone-, and/ or video calls conducted by patients and physiotherapists, duration of treatment per session and adverse events (defined as an unexpected negative effect directly related to the prescribed exercises) and patient satisfaction

The Telerehabiliation intervention is considered as feasible if at least 80 percent adherence rate will be achieved, no adverse events will take place and patient satisfaction will be scored positively.

Secondary outcome

Outcome data on effectiveness will be measurements of musculoskeletal- and cardiovascular functions and activities as well as participation according to the domains of the International Classification of Functioning, Disability and Health (ICF)9.

These outcome data include hand grip strength as a predictor of overall muscle strength 19, inspiratory and expiratory muscle strength, proximal muscle strength of the lower extremity, maximal short exercise capacity, walking

capacity, self reported activities and quality of life.

Study description

Background summary

Improvement of functional status with physiotherapy is an important goal for patients suffering from POC after esopahgectomy both during and after hospital stay. Patients with esophageal cancer and suffering from POC are usually referred to outpatient physiotherapy to further improve functional status. However, these patients often deal with a temporary loss of mobility directly postoperatively and they are at the same time confronted with integrated care from multiple health providers. Therefore these patients might benefit from a relief in burden of care and increased efficiency, by providing them with telerehabilitation in their home situation instead of conventional *face-to-face* rehabilitation.

Telerehabilitation is considered as a way of providing rehabilitation, with the main difference that care is moved from the inpatient setting to a patient*s home situation aimed at reducing hospitalization time and costs.
The aim of telerehabilitation is to be tailor-made, patient-centered care that improves health care quality and better manages the care, subsequently leading to higher patient satisfaction and adherence to improve clinical benefit.
Moreover, telerehabilitation has shown to be a valuable tool in managing postoperative outcomes and functional progress in surgical patients. It can serve as liaison between specialized treatment in the hospital and interventions in primary care to promote transition of complex patients.
There is some evidence that shows positive effects on clinical outcomes in cancer patients, cardiac patients, patients with musculoskeletal disorders and depression, but information on this highly complex surgical population is lacking.

Study objective

Primary Objective:
To investigate the feasibility of a 12 -week postoperative Telerehabilitation program for patients with esophageal cancer treated with esophagectomy and suffering from postoperative complications

Secondary Objective:
To investigate the preliminary effectiveness of Telerehabilitation on functional recovery compared to usual care

Study design

A prospective feasibility study with historical controls will be performed.

Participants undergoing the investigational treatment will be matched to baseline and clinical characteristics of 60 esophagectomy patients who suffered from POC between March 2012-October 2014 receiving usual care, to assess preliminary effectiveness.

The study will take place in a large tertiary referral center (the Academic Medical Center in Amsterdam) and will take 12 weeks after inclusion.

Intervention

Participants will receive a 12-week Telerehabilitation intervention after discharge from the hospital in their home situation. Before discharge from the hospital, a physiotherapist will instruct the patient on the Telerehabilitation intervention.
The Telerehabilitation intervention will be provided with Physitrack® (Physitrack Limited, Brighton, UK). Physitrack® is an eHealth platform for healthcare providers to design high-quality home exercise programs and track patient adherence. With Physitrack, progress in home exercise programs can be accurately monitored and adapted if necessary. In addition, built-in PROM surveys and questionnaires allow for detailed outcome measurement analysis to assess treatment effectiveness and optimize treatment plans for improved outcomes and efficiencies (Physitrack, 2015). Physitrack® runs on the browser and is available for iOS and Android as well.

The postoperative physiotherapeutic intervention with Telerehabilitation will be aimed at improvement of functional status. The intervention will take 12 weeks of two sessions per week (24 sessions in total). The exercises are tailor made to the patients* specific condition and needs. Patients* condition and needs are determined 1 day prior to discharge from the hospital. To determine the specific physiotherapy goals, the Patient Specific Complaint List will be used 22. Intensity and frequency of the functional exercises provided with Telerehabilitation will be determined according to the guidelines of the American College of Sports Medicine (ACSM). During training with Telerehabilitation, the BORG_RPE score will be used to monitor the Rate of Perceived Exertion.
Each treatment session will take approximately 1 hour including time spent on self-assessment, and regular communication with an experienced physiotherapist. Trained physiotherapists will weekly monitor and adjust Telerehabilitation treatments. The intervention is evidence based and broadly implemented in other post surgical populations. No additional risks are to be expected with study participation compared to usual post surgical physiotherapy treatment or at

least equal to the normal risks of treatment complications.

Study burden and risks

No additional risks are to be expected with study participation compared to usual post surgical physiotherapy treatment or at least equal to the normal risks of treatment complications.

Contacts

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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

Participants will be included if:
- they are aged 18 years or older,

- the primary reason of hospital stay is status after esophagectomy,
- suffering from a postoperative complication grade 3a or worse according to the Clavien-Dindo Classification,
- a postoperative length of hospital stay of more than 14 days,
- indicated for outpatient physiotherapy according to clinical expertise of hospital physiotherapist,
- having internet access at home and
- signed for informed consent.

Exclusion criteria

- unable to complete self-reported questionnaires,
- insufficiently able to read or speak the Dutch language,
- having cognitive disorders,
- or any other severe medical conditions that prevents the patient from doing exercises at home.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-01-2017
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	22-09-2016

Application type:	First submission
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	ID
CCMO	NL58388.018.16