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Prophylactic swallowing exercise program in head and neck cancer patients

Submission date
08/11/2018

Recruitment status
No longer recruiting

Registration date
21/12/2018

Overall study status
Completed

Last Edited
09/08/2023

Condition category
Cancer

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Swallowing problems (dysphagia) are a common and serious complication after (chemo) radiotherapy for head-and-neck cancer patients, preventative swallowing exercises have been studied widely and have shown a significant positive effect on post-treatment swallowing function. Unfortunately, low adherence rates are a key issue in undermining the positive effects of the exercises. This study aims to compare 3 types of swallowing exercise therapies to improve adherence.

Who can participate?
Adult patients with head-and-neck cancer treated with radiotherapy or chemoradiotherapy

What does the study involve?
Patients will be randomly allocated to one of three groups.
Patients allocated to Group 1 perform the exercises at home without supervision of a speech language therapist but with a counselling session of 10 minutes every week. Group 2 will practice the exercises at home and receive continuous counselling and instructions video via an app. Group 3 will receive face-to-face therapy and will be counselled by a speech language therapist five times a week. All patients will complete 20 sessions of exercises.

What are the possible benefits and risks of participating?
The possible benefit of participating is that recent research shows the positive effect of these swallowing exercises on swallowing function. There are no known risks to participants taking part in this study.

Where is the study run from?
Antwerp University Hospital and 4 hospitals in Belgium and 1 in the Netherlands

When is the study starting and how long is it expected to run for?
September 2017 to June 2022

Who is funding the study?
Kom Op Tegen Kanker (Belgium)

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

Protocol serial number
B300201835273 - protocol version 2

Study information

Scientific Title
Towards a patient supported, well tolerated and evidence based prophylactic swallowing exercise program to improve quality of life and swallowing function in head and neck cancer patients treated with chemoradiotherapy: a multicentre randomized controlled trial

Acronym
PRESTO-trial

Study objectives
As patients' adherence is a key issue regarding prophylactic swallowing exercises in head and neck cancer patients, this multicentric, randomized controlled trial aims to compare 3 therapy modes differing from each other in degree and type of adherence improving measures. Patients referred to group 1 or 2 will practice at home following an instruction session. Adherence is enhanced by means of weekly follow-up sessions (group 1 and 2) and by means of an app – developed for this particular purpose (group 2). The third group receives speech therapist supervised therapy. The degree of compliance, muscle strength, swallowing function and quality of life are the main outcome variables. The study design also allows to gain further insight in factors influencing compliance and to perform a cost-effectiveness study.
The study hypotheses are therefore as follows:
1. Adherence will be larger in groups 2 and 3 compared to 1
2. A significant decrease of muscle strength, swallowing function and swallowing related quality of life is expected in every group
3. The higher the overall degree of adherence, the smaller the negative impact on muscle strength, swallowing function and swallowing related quality of life
4. The degree of adherence depends upon personality, intrinsic motivation, fatigue and pain in the oral cavity
5. The cost-effectiveness of group 2 is significantly higher compared to group 1 and 3

Ethics approval required
Old ethics approval format

Ethics approval(s)
Antwerp University Hospital Belgium, 12/03/2018, B300201835273

Study design
Interventional multi-centre three-armed randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Head and neck cancer treated with radiotherapy or concomitant chemoradiotherapy

Interventions
Participants will be randomly allocated to one of three groups using the Qminim program. All participants will complete prophylactic swallowing exercises during the first 4 weeks of treatment.
Group 1 will complete the exercises at home and have a weekly follow-up session.
Group 2 will complete the exercises at home and have support from an app, along with a weekly follow-up session.
Group 3 will practice the exercises under the continuous supervision of a speech language pathologist.
The exercises include tongue strengthening exercises, chin tucks against resistance and effortful swallows. Exercises will be perfomed 5 times per week, once per day, alternating tongue strength and chin tuck (chin tuck includes effortful swallows). Tongue strength exercises will involve 120 repetitions per day and chin tuck/effortful swallows will involve 150 reps per day.

The total duration for all groups is 4 weeks.
All participants will be followed weekly by a speech language therapist. After the radiotherapy treatment, all participants will be followed for 3 months - immediately after radiotherapy, after 1 month and after 3 months.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measure as of 15/02/2019:
Swallowing function assessed , using the Mann Assessment of Swallowing Ability – Cancer (MASA-C) at baseline, during the first 4 weeks of treatment, at the end of treatment, and 1 and 3 months after treatment

Previous primary outcome measure:
Degree of compliance, assessed weekly during the first 4 weeks of treatment, assessed using:
1. The total performed number of exercises per week, assessed by:
1.1. Daily patient (group 1 and group 2) and therapist (group 3) log book of performed exercises
1.2. IOPI device (group 2 and group 3) for tongue strengthening exercises
2. Time spent on the app per day (for group 2 only), automatically registered

Key secondary outcome(s))
Current secondary outcome measures as of 15/02/2019:
1. Degree of compliance: assessed weekly during the first 4 weeks of treatment, using:
1.1. The total performed number of exercises per week, assessed by:
1.1.1. Daily patient (group 1 and group 2) and therapist (group 3) log book of performed exercises
1.1.2. IOPI device (group 2 and group 3) for tongue strengthening exercises
1.2. Time spent on the app per day (for group 2 only), automatically registered
2. Swallowing function: assessed at baseline, during the first 4 weeks of treatment, at the end of treatment, and 1 and 3 months after treatment, using:
2.1. Eating Assessment Tool (EAT-10)
2.2. Self-perception of swallowing ability, assessed using a visual analogue scale ranging from 0 ("I can’t swallow at all") to 100 ("I can swallow perfectly")
2.3. Functional Oral Intake Scale 50 (FOIS)
3. Tongue strength, assessed using the Iowa Oral Performance Instrument (IOPI) to measure the maximum isometric tongue pressure at baseline, during the first 4 weeks of treatment, at the end of treatment, and 1 and 3 months after treatment
4. Maximum muscle strength during Chin Tuck Against Resistance (CTAR), assessed using a dynamometer at baseline, during the first 4 weeks of treatment, at the end of treatment, and 1 and 3 months after treatment
5. Quality of life: assessed at the baseline, at the end of treatment, and 1 and 3 months after treatment using:
5.1. Swallowing Quality of Life Questionnaire (SWAL-QoL)
5.2. Dysphagia Handicap Index (DHI)
6. Cost-effectiveness analysis regarding adherence to prophylactic swallowing exercises, assessed using the EQ-5D-5L at baseline, during the first 4 weeks of treatment, at the end of treatment, and 1 and 3 months after treatment

Previous secondary outcome measures:
1. Swallowing function, assessed at the baseline, after 6 weeks, at the end of treatment, and 1

and 3 months after treatment using:
1.1. Mann Assessment of Swallowing Ability--Cancer score (MASA-C)
1.2. Eating Assessment Tool (EAT-10)
1.3. Self-perception of swallowing ability, assessed using a visual anlogue scale ranging from 0 ("I can’t swallow at all") to 100 ("I can swallow perfectly")
1.4. Functional Oral Intake Scale 50 (FOIS)
2. Tongue strength, assessed at the baseline, after 6 weeks, at the end of treatment, and 1 and 3 months after treatment using the Iowa Oral Performance Instrument (IOPI) to measure the maximum isometric tongue pressure
3. Maximum muscle strength during Chin Tuck Against Resistance (CTAR), assessed at the baseline, after 6 weeks, at the end of treatment, and 1 and 3 months after treatment using a dynamometer
4. Quality of life, assessed at the baseline, after 4 and 5 weeks, at the end of treatment, and 1 and 3 months after treatment using:
4.1. Swallowing Quality of Life Questionnaire (SWAL-QoL)
4.2. Dysphagia Handicap Index (DHI)
5. Cost-effectiveness analysis regarding adherence to prophylactic swallowing exercises, assessed at the baseline, after 6 weeks, at the end of treatment, and 1 and 3 months after treatment using the EQ-5D-5L

Completion date
30/06/2022

Eligibility

Key inclusion criteria
1. Newly diagnosed squamous cell carcinoma of the oropharynx
2. Stage III or IV cancer (according to TNM-7 classification)
3. Treatment with radiotherapy or concomitant chemoradiotherapy with/without induction chemotherapy
4. Demonstrating sufficient cognitive and language abilities

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
150

Key exclusion criteria

1. Recurrent carcinoma or metastasis from a non-HNC (head and neck cancer) carcinoma
2. Previous radiotherapy and/or chemoradiotherapy ,or surgery in head-neck region with possible impact on swallowing function

Date of first enrolment
01/06/2018

Date of final enrolment
21/01/2022

Locations

Countries of recruitment
Belgium

Netherlands

Study participating centre
Antwerp University hopsital
Belgium
2650

Study participating centre
University of Ghent
Belgium
9000

Study participating centre
University Hospital Ghent
Belgium
9000

Study participating centre
University Hospital Leuven
Belgium
3000

Study participating centre

Az Sint Jan Brugge
Belgium
8000

Study participating centre
Antoni Van Leeuwenhoek Ziekenhuis - Netherlands Cancer Institute
Netherlands
1066CX

Sponsor information

Organisation
Antwerp University Hopsital

ROR
https://ror.org/01hwamj44

Funder(s)

Funder type
Charity

Funder Name
Kom Op Tegen Kanker

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository. All data will be stored in REDCap, a secure web application for building and managing online surveys and databases. (https://www.project-redcap.org/). Patient information (no identifying information), surveys and measurements will be shared. The data will be available for all participating study investigators until the end of the study. All data will be anonymised and patient's details will be encoded.

IPD sharing plan summary
Stored in repository

Study outputs

	Date	Date	Peer	Patient-

Output type	Details	created	added	reviewed?	facing?
Results article		19/09/2022	20/09/2022	Yes	No
Results article	Effect of service-delivery mode and overall adherence level	08/08/2023	09/08/2023	Yes	No
Protocol article	protocol	02/03/2020	04/03/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes