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Swallowing impairment in oral cavity cancer patients treated with radiation therapy - current status, its impacts and effects of a swallowing exercise education program

Submission date
17/10/2017

Recruitment status
No longer recruiting

Registration date
19/10/2017

Overall study status
Completed

Last Edited
10/01/2020

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Oral cavity cancer (OOC) includes malignancy of any tissues in the oral cavity (mouth area) such as the mucosa, muscles, nerves, teeth, bone, blood vessels, and salivary glands. Treating oral cavity cancer can cause swallowing impairment issues, which could need treatment. This study has two parts, the first part is to develop an exercise programme for patients with oral cavity cancer during the survival period based on previous studies and the second part of the study is to test this programme. The aim of this study is to examine if this excerise programme can improve swallowing ability in oral cavity cancer patients.

Who can participate?
Adults aged 20-70 who have completed treatment for oral cavity cancer and are around three months to three years post treatment.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive the Swallowing Exercise Education Program (SEP) for six months. They participate in the SEP three times each day for 6-months during the study period. Those in the second group receive routine hospital care. In order to consider patients' tolerance levels, the questionnaires are administered at four time points: baseline (before the SEP) and 1, 2, 3, and 6 months after first receiving the intervention.

What are the possible benefits and risks of participating?
Participants may benefit from enhancing positive swallowing ability and quality of life among Taiwanese survivors with oral cavity cancer. This study will not involve any invasive intervention. Swallowing exercise has been demonstrated to be a safe strategy for managing swallowing impairment. Patients could become choked or aspirate food, fluid and /or saliva when practicing the swallowing exercise. The SEP occurs under the guidance of trained research nurses. Signs and management of choking will be also taught to participants.

Where is the study run from?
Linkou Chang Gung Hospital (Taiwan)

When is the study starting and how long is it expected to run for?
August 2014 to December 2017

Who is funding the study?
Ministry of Science and Technology (Taiwan)

Who is the main contact?
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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MOST 103-2314-B-255 -004 and MOST 104-2314-B-255-002

Study information

Scientific Title
Swallowing Exercise Education Program (SEEP)

Acronym
SEEP

Study objectives

Hypotheses:
1. Oral cavity cancer patients with swallowing impairment who have attended a swallowing exercise education program will have a higher level of swallowing ability to patients who not attended with the intervention
2. Oral cavity cancer patients with swallowing impairment who have attended a swallowing exercise education program will have a lower level of swallowing dysfunction symptom to patients who not attended with the intervention
3. Oral cavity cancer patients with swallowing impairment who have attended a swallowing exercise education program will have a higher level of dysphagia-specific quality of life to patients who not attended with the intervention

Ethics approval required
Old ethics approval format

Ethics approval(s)
Chang Gung Hospital Human Subjects Ethics Committee, 26/12/2013, ref: 102-4368B

Study design
A prospective randomized controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Oral Cavity Cancer Patients

Interventions
This study has two parts. The first part of the study is to develop a Swallowing Exercise Program (SEP) to use in the care of patients with oral cavity cancer (in the first 6 months of the first year) and to examine the effects of a 6-months Swallowing Exercise Program (SEP) on depression, swallowing ability, swallowing dysfunction symptoms, and dysphagia-specific quality of life in patients with oral cavity cancer during the survival period over 6 months (longitudinal survey). Phase 2 of this study, covering the second half of the first year and the second year, will evaluate the effectiveness of the program.

Phase 1, covering the first half of the first year: The Swallowing Exercise Program (SEP) is developed for patients with oral cavity cancer during the survival period based on previous studies and the results of our previous study (the first stage of this research program).

Phase 2 will evaluate the SEP. Participants are recruited three months after they have completed treatment. Demographic information and disease and treatment characteristics were collected through chart review. Demographic information consisted of age, occupation, marital status, educational level, and religion. Disease and treatment characteristics included tumor site, cancer stage, medical treatment, and radiation dose.

Participants are randomly allocated to one of two groups:
Experimental group: Participants follow the Swallowing Exercise Education Program (SEP) for 6 months. The experimental group will participate in the SEP three times each day for 6-months during the study period.
Control group: Participants receive routine hospital care.

In order to consider patients' tolerance levels, the questionnaires are administered at four time points: baseline (before the SEP) and 1, 2, 3, and 6 months after first receiving the intervention.

Intervention Type
Behavioural

Primary outcome measure
Dysphagia-specific health-related QOL is measured using the MD Anderson Dysphagia Inventory (MDADI) at baseline, one, two, three and six months.

Secondary outcome measures
1. Swallowing ability is measured using Sydney Swallowing Questionnaire (SSQ) at baseline, one, two, three and six months
2. Depression is measured using Hospital Anxiety and Depression Scale (HADS)–Depression Subscale at baseline, one, two, three and six months
3. Functional level of oral intake of food and liquid measured using the Functional Oral Intake Scale (FOIS) at baseline, one, two, three and six months
4. Physical performance is measured using the Karnofsky's performance status index (KPS) at baseline, one, two, three and six months

Overall study start date
01/08/2014

Completion date
31/12/2017

Eligibility

Key inclusion criteria
1. Age greater than 20 years and less than 70 years
2. Pathologic confirmation of oral cavity squamous cell carcinoma (OSCC)
3. KPS score of 60 or greater
4. New diagnosis and recurrence of oral cavity cancer and patient awareness of the diagnosis
5. Completion of treatment and status of more than 3 months to 3 years post-treatment
6. Eating Assessment Tool-10 score of 3 or more (3-40 is indicative of swallowing problems)53 and Modified Water Swallowing Test (MWST) levels of I, II, and III;54
6. Disease-free survival, defined as no disease evident in the patient after treatment
7. Agreement to participate in the study after explanation of its purposes and procedures

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
80

Key exclusion criteria
1. Current therapy with surgery, RT, or CCRT in oral cavity cancer
2. Any unstable systemic disease (heart disease, hypertension, active infection, or other underlying disease)
3. KPS score of 60 or less
4. Any condition likely to cause discomfort during the research interview

Date of first enrolment
01/08/2015

Date of final enrolment
30/08/2017

Locations

Countries of recruitment
Taiwan

Study participating centre
Linkou Chang Gung Hospital
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Sponsor information

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Funder(s)

Funder type
Government

Funder Name
Ministry of Science and Technology, Taiwan

Results and Publications

Publication and dissemination plan
Planned publication in a cancer related academic journal.

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study is not expected to be made available due to this data only for reviewing, but not using for secondary data analysis.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2018		Yes	No