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A cancer rehabilitation and lymphedema care program for patients with resected advanced head and neck cancer

Submission date
17/10/2017

Recruitment status
No longer recruiting

Registration date
18/10/2017

Overall study status
Completed

Last Edited
15/06/2021

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Swelling of the face or neck (lymphoedema) can occur after treatment for head and neck cancer. The aim of this study is to examine the effects of a 6-month Cancer Rehabilitation and Lymphedema Care Program (CRLCP) on lymphoedema-related symptoms, body image and functional outcomes.

Who can participate?
Patients aged 20 to 70 with head and neck cancer-related lymphoedema (HNCRL)

What does the study involve?
Participants are recruited three months after the completion of treatment and randomly allocated into either the control group (who receive routine hospital care) or the experimental group (who receive the 6-month CRLCP). Symptoms, body image and functional outcomes are assessed before the CRLCP and 1, 3, and 6 months after first participating in the CRLCP.

What are the possible benefits and risks of participating?
If the CRLCP is effective, a scientific program will be developed based on the CRLCP intervention to improve HNCRL-related symptoms, body image and functional outcomes among Taiwanese patients with head and neck cancer. This study does not involve any invasive intervention. Cancer rehabilitation with lymphoedema care has been demonstrated to be a safe means of managing lymphedema. Before beginning the program, patients undergo an evaluation of their skin integrity. If any participant develops skin defects or a skin infection, they are referred to their attending physician for treatment.

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?
January 2016 to December 2019

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

Who is the main contact?
Prof. Shu-Ching Chen
shuching@gw.cgust.edu.tw

Contact information

Type(s)
Scientific

Contact name
Prof Shu-Ching Chen

Contact details
261, Wen-Hwu 1st Road, Kweshian
Taoyuan
Taiwan
33303
+886 (0)3 2118999 Ext. 3436
shuching@gw.cgust.edu.tw

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MOST105-2628-B-255-001-MY3

Study information

Scientific Title
A cancer rehabilitation and lymphedema care program for patients with resected advanced head and neck cancer: the prevalence and risk factors for head and neck cancer-related lymphedema and development and testing of an intervention and longitudinal measures of its functional outcomes

Acronym
CRLCP

Study objectives
The prevalence of HNCRL and the risk factors for HNCRL in head and neck cancer patients post-treatment have not yet been examined. A Cancer Rehabilitation and Lymphedema Care Program can prevent the progression of adverse effects, decrease functional impairment, and maximize functional ability in these patients. According to official reports on cancer rehabilitation and

lymphedema care, and a previous study, a Cancer Rehabilitation and Lymphedema Care Program (CRLCP) significantly helps patients cope with HNCRL-related symptoms, improved body image, and increase HNCRL-related functional outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Institutional Review Board of Chang Gung Memorial Hospital, Taiwan, 19/01/2016, ref: 104-8655B

Study design
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 to request a patient information sheet

Health condition(s) or problem(s) studied
Head and neck cancer

Interventions
Eligible participants will be recruited three months after the completion of treatment and randomized by casting lots for odd or even numbers (even-control, odd-experimental) into a control group (who will receive routine hospital care) and an experimental group (who will receive the 6-month Cancer Rehabilitation and Lymphedema Care Program (CRLCP)).

Subjective and objective data will be collected at four time points: baseline (before the CRLCP) (T0) and 1, 3, and 6 months after first participating in the CRLCP (T1, T2, and T3, respectively). Mixed-model analysis will be used to assess the effectiveness of the intervention program on patients' HNCRL-related symptoms, body image, and HNCRL-related functional outcomes.

Intervention Type
Behavioural

Primary outcome measure

Functional outcomes measured by the Brief International Classification of Functioning, Disability and Health (ICF) Core Set for Head and Neck Cancer (BCSQ-H&N) at four time points: baseline (before the CRLCP) (T0) and 1, 3, and 6 months after first participating in the CRLCP (T1, T2, and T3, respectively)

Secondary outcome measures
Measured at four time points: baseline (before the CRLCP) (T0) and 1, 3, and 6 months after first participating in the CRLCP (T1, T2, and T3, respectively):
1. Symptom distress measured by the Symptom Distress Scale–Modified for Head and Neck Cancer (SDS-mhnc)
2. Body image measured by the Body Image Scale–Modified (BIS-m)
3. Stage of lymphedema measured by the MD Anderson Head and Neck Lymphedema Rating Scale (MDAHNLRS)
4. Shoulder motion measured by the UCLA Shoulder Rating Scale (UCLA SRS)
5. Physical performance measured by the Karnofsky Performance Status Index (KPS)

Overall study start date
08/01/2016

Completion date
31/12/2019

Eligibility

Key inclusion criteria
1. Pathologic confirmation of advanced HNSCC (stage III or IV) and patient awareness of the diagnosis
2. Receipt of radical surgery and RT or CCRT
3. Completion of radical surgery and RT or CCRT from 3 months to 5 years in the past
4. Have HNCRL based on physical examination (Foldi's Scale score > stage I)
5. Currently free of evidence of cancer
6. Age greater than 20 years and less than 70 years
7. Karnofsky's Performance Status Index (KPS) score of 60 or greater
8. 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. Unresected head and neck cancer
2. Actively undergoing chemotherapy or RT
3. Having metastatic cancer or any other active cancer
4. Any unstable systemic disease (heart disease, active infection, or other underlying disease)
5. KPS score of 60 or less
6. Any condition likely to cause discomfort during the research interview

Date of first enrolment
01/08/2017

Date of final enrolment
31/07/2019

Locations

Countries of recruitment
Taiwan

Study participating centre
Linkou Chang Gung Hospital
5, Fu Hsing Street, Kweshian
Taoyuan
Taiwan
333

Sponsor information

Organisation
Ministry of Science and Technology, Taiwan

Sponsor details
106, Sec. 2
Heping E. Rd.
Taipei
Taiwan
106
+886 (0)2 27377541
chiough@nsc.gov.tw

Sponsor type
Government

Website
https://www.most.gov.tw/

ROR
https://ror.org/02kv4zf79

Funder(s)

Funder type
Government

Funder Name
Ministry of Science and Technology, Taiwan (MOST105-2628-B-255-001-MY3)

Alternative Name(s)
Ministry of Science and Technology, R.O.C. (Taiwan), Ministry of Science and Technology of Taiwan, MOST

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Taiwan

Results and Publications

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

Intention to publish date
31/12/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available.

IPD sharing plan summary
Not expected to be made available