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Effects of an ritual training program in the head and neck cancer patients: a randomized controlled trial

Submission date
17/11/2017

Recruitment status
No longer recruiting

Registration date
21/11/2017

Overall study status
Completed

Last Edited
14/02/2019

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Head and neck cancer (HNC) is one of the most lethal cancers. It ranks as the fifth most common cancer worldwide and is the most common neoplasm in central Asia. Males are affected significantly more often than females. Radical excision (removal of tumors) and reconstruction is the primary treatment modality for patients with head and neck cancer. Surgical resection may involve anatomical destruction and lead to varying levels of physical and psychological disturbance, especially related to change in body image and facial disfigurement. The aim of this study is to evaluate if participants who undergo a ritual training program will have better body image, less disfigurement, better social interaction and higher self-esteem than those who do not undergo a ritual training program.

Who can participate?
Adults aged 20 to 70 years old who have completed treatment for first occurrence of male and female HNC

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive the ritual training program twice a week for eight weeks. This includes education and demonstrations. Those in the second group receive their routine care. Participants are followed up for their quality of life at 6 months.

What are the possible benefits and risks of participating?
Ritual training program has been demonstrated to be a safe strategy for managing change in body image and facial disfigurement. This study will not involve any invasive intervention and does not carry any risks.

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

When is the study starting and how long is it expected to run for?
January 2017 to December 2018

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

Who is the main contact?
Professor Shu-Ching Chen
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MOST 103-2629-B-255 -001

Study information

Scientific Title
Effects of an Ritual Training Program on body image, disfigurement, social interaction, depression, self-esteem

Acronym
RTP

Study objectives
Patients attend an Ritual Training Program will have better body image, disfigurement, social interaction, depression, self-esteem than those who not attend an Ritual Training Program.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Chang Gung Institutional Review Board in Taiwan, 2012/07/31, ref: 100-4206B

Study design
Interventional randomised controlled single-centre study

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

Health condition(s) or problem(s) studied
Head and neck cancer, survival, psychosocial dimension and quality of life

Interventions
Participants are randomly allocated to one of two groups.

Experimental: Ritual training program ritual training program for 8 weeks, biweekly. The ritual training program includes education and demonstration.

Placebo comparator group: Participants receive routine care following hospital care.

Participants are followed up at six months to assess their quality of life, body image, disfigurement, social interaction, depression and self-esteem.

Intervention Type
Behavioural

Primary outcome measure
Quality of Life is measured using the UW-QOL Scale from baseline quality of life at 6 months

Secondary outcome measures

1. Body Image is measured using Body Image Scale from baseline body image at 6 months
2. Disfigurement is measured using Observer-rated disfigurement scale from baseline body image at 6 months
3. Social Interaction is measured using Liebowitz Social Anxiety Scale from baseline social interaction at 6 months
4. Depression is measured using Hospital Anxiety and Depression Scale-Depression Subscale from baseline depression at 6 months
5. Self-esteem is measured using Rosenberg Self-Esteem Scale from baseline self-esteem at 6 months

Overall study start date
01/01/2017

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. 20 to 70 years
2. Newly diagnosed first occurrence of male and female HNC
3. Completion of treatment and more than 3 months post-treatment

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100

Key exclusion criteria
Patients with cancer recurrence during completion treatment

Date of first enrolment
01/12/2017

Date of final enrolment
30/06/2018

Locations

Countries of recruitment
Taiwan

Study participating centre
Chang Gung Memorial Hospital
Chang Gung Medical Foundation
#5, Fusing Street, Keiwshan
Taoyuan
Taiwan
33303

Sponsor information

Organisation
The Ministry of Science and Technology, Taiwan

Sponsor details
Ministry of Science and Technology
106
Sec. 2
Heping E. Road
Taipei
Taiwan
10622

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

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 high-impact peer reviewed journal.

Intention to publish date
01/08/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Principal investigator: Shu-Ching Chen, PhD, Professor Department of Nursing, Chang Gung University of Science and Technology at shuching@gw.cgust.edu.tw.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2019		Yes	No