

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/11/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 14/02/2019	Condition category Cancer	<input type="checkbox"/> 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
shuching@gw.cgust.edu.tw

Contact information

Type(s)
Scientific

Contact name
Prof Shu-Ching Chen

ORCID ID
<https://orcid.org/0000-0002-7921-1964>

Contact details
61, Wen-Hua 1st Road
Kweishan
Taoyuan
Taoyuan
Taiwan
33303
+886 (0)3 2118999 ext. 3436
shuching@gw.cgust.edu.tw

Additional identifiers

Protocol serial number
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

Study type(s)

Quality of life

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(s)

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

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

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