

# Effect of a survivorship care plan on resilience in a multi-cultural population of female primary caregivers of patients with advanced oral cavity cancer: trajectory, intervention model and longitudinal effects

<b>Submission date</b> 15/10/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 17/10/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/11/2023	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

The aim of this study is to examine the effects of a 6-month Survivorship Care Plan (SCP) on the physical status, caregiver burden, emotional distress, social support, quality of life, and resilience of primary caregivers of patients with advanced oral cavity (mouth) cancer during the first 6 months of the survival period. The study also compares the gender differences of the effects of SCP.

### Who can participate?

Primary caregivers of patients with oral cavity cancer

### What does the study involve?

Participants are randomly allocated to either the control group or the experimental group. The control group receive routine hospital care. The experimental group receive the 6-month SCP. Physical status, caregiver burden, emotional distress, social support, quality of life and resilience are assessed at the start of the study and at 1, 3, and 6 months after first receiving the SCP.

### What are the possible benefits and risks of participating?

If the SCP is useful and effective, a scientific program will be developed, based on the SCP intervention, to improve caregiver burden and enhance the resilience of primary caregivers of patients with advanced oral cavity cancer in Taiwan.

### 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 2015 to December 2018

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-Hua 1st Road  
Kweishan  
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**  
N/A

## Study information

**Scientific Title**  
Effect of a survivorship care plan on resilience in a multi-cultural population of female primary caregivers of patients with advanced oral cavity cancer

**Acronym**  
SCP

**Study objectives**  
SCP significantly helps caregivers cope with adverse events, lower feelings of distress, and increase resilience.

**Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Chang Gung Institutional Review Board, Taiwan, 03/12/2015, ref: 103-7644B

### **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**

Primary caregivers of oral cavity cancer

### **Interventions**

Eligible participants will be recruited from the time patients first complete treatment for six months and randomized into a control group (patients receive routine hospital care) and an experimental group (patients receive the 6-month SCP). Subjective and objective measures will be collected at four timepoints: at baseline (before the SCP, T0) and at 1, 3, and 6 months after first receiving the SCP (T1, T2, and T3, respectively). The GEE will be used to analyze the data. The plan is to recruit 40 patient-caregiver dyads for each group.

### **Intervention Type**

Behavioural

### **Primary outcome measure**

Resilience, measured using the Resilience Scale (RS) at baseline (before the SCP, T0) and at 1, 3, and 6 months after first receiving the SCP (T1, T2, and T3, respectively)

### **Secondary outcome measures**

1. Physical status, measured using Karnofsky's Performance Status Index (KPS)
2. Caregiving burden measured using the Caregiver Reaction Assessment (CRA)
3. Distress, measured using the Distress Thermometer (DT)
4. Social support, measured using by Medical Outcomes Study Social Support Survey-modified (MOS SS-m)
5. Health-related quality of life, measured using by the Medical Outcomes Study Short Form SF-12 (MOS SF-12)

Measured at baseline (before the SCP, T0) and at 1, 3, and 6 months after first receiving the SCP (T1, T2, and T3, respectively)

**Overall study start date**

01/08/2015

**Completion date**

31/07/2019

## **Eligibility**

**Key inclusion criteria**

Primary caregivers:

1. Pathologic confirmation that the patient has oral cavity squamous cell carcinoma (OSCC)
2. New diagnosis of oral cavity cancer with cancer stage on III and IV; receipt of surgery and RT or CCRT; and completion of treatment within the previous 6 months
3. Disease free survivor (i.e., patient shows no apparent signs of cancer)
4. Female (male) primary caregivers aged 20-70 years
5. Female (male) primary caregiver provides uncompensated care or assistance to a patient and is identified by the patient as the primary family caregiver
6. RS score <145 and DT score >4
7. Agreement to participate in the study after explanation of its purposes and procedures

**Participant type(s)**

Carer

**Age group**

Adult

**Sex**

Female

**Target number of participants**

80

**Total final enrolment**

100

**Key exclusion criteria**

1. Oral cavity cancer patient with any prior surgery, RT, or chemotherapy;
2. Female primary caregiver with any unstable systemic disease (heart disease, hypertension, active infection, or other underlying disease)
3. Female primary caregiver with any condition likely to cause discomfort during the research interview

**Date of first enrolment**

01/08/2016

**Date of final enrolment**

31/12/2018

# Locations

## Countries of recruitment

Taiwan

## Study participating centre

Linkou Chang Gung Hospital, Taiwan

#5, Fu-Hsing St. Kweshain

Taoyuan

Taiwan

333

# Sponsor information

## Organisation

Ministry of Science and Technology, Taiwan

## Sponsor details

#106, Ho-Ping Eastern Road

Taipei

Taiwan

106

+886 (0)2 27377992

llchen@most.gov.tw

## Sponsor type

Government

## Website

<http://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**

The results will be published in a cancer journal.

**Intention to publish date**

01/08/2021

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Shu-Ching Chen (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?
<a href="#">Results article</a>		11/04/2023	21/11/2023	Yes	No