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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

Submission date
15/10/2017

Recruitment status
No longer recruiting

Registration date
17/10/2017

Overall study status
Completed

Last Edited
21/11/2023

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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Contact information

Type(s)
Scientific

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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
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Sponsor information

Organisation
Ministry of Science and Technology, Taiwan

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Sponsor type
Government

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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?
Results article		11/04/2023	21/11/2023	Yes	No