# The feasibility of caregiver-delivered massage program for cancer patients undergoing palliative care

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
16/12/2016		Protocol		
Registration date	Overall study status	Statistical analysis plan		
05/01/2017	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
18/04/2019	Cancer			

## Plain English summary of protocol

Background and study aims

Cancer is often associated with severe physical and psychological suffering, especially during the terminal phase of the disease. Further, with the deterioration of the cancer patient, family members who provide care to these patients may suffer from increased anxiety, leading to a decline in their ability to provide effective care. It is therefore important to develop strategies to relieve the suffering of patients and caregivers alike. Previous studies have suggested that massage relieves many symptoms experienced by cancer patients, including pain, fatigue and anxiety. Further, massage was also shown to promote a sense of connectedness and reduce unnecessary emotional distancing between family caregivers and patients. All these suggest that massage may improve the effectiveness of care provision for cancer patients by family caregivers. A massage program would therefore be appropriate as one strategy of palliative care for patients with terminal cancer. This study aims to investigate whether a caregiver-delivered massage program would be feasible and acceptable to patients with terminal cancer in a home care setting. It also aims to find out whether this program reduces the level of distress and enhances the quality of life of both caregivers and patients.

## Who can participate?

Patients with terminal cancer who are taken care of by family caregivers in their own homes. Both the patients and the caregivers must be above the age of 18

## What does the study involve?

Participants are randomly allocated into two groups (Group A and Group B). In Group A, the caregivers receive training from an experienced palliative care nurse on gentle massage techniques at the caregivers' homes, using almond oil as the massage oil. During the training, detailed instructions are provided, and a video clip is shown to the caregivers for them to gain mastery of the massage techniques. The caregivers then provide sessions of gentle massage to the upper limbs of their cancer patients three times a week for 15-20 minutes per session. Both before and after the massage program, the cancer patients are required to complete a questionnaire and undertake certain tests in order to assess the severity of their symptoms, quality of life, level of distress and sleep quality. Likewise, the caregivers need to complete the

questionnaire and tests for the assessment of their quality of life, level of distress, sleep quality, as well as their perceived preparedness and competence to provide care to the cancer patients. For Group B, for the first four weeks after joining the study, the family caregivers deliver their normal care to the cancer patients. They are required to complete the questionnaire and undertake the tests as described above both one and four weeks after joining the study. Participants in Group B then receive the massage program as described above after Group A have completed the study.

What are the possible benefits and risks of participating?

The massage is expected to relieve the symptoms experienced by cancer patients, reducing their stress and anxiety levels and improving their quality of life. In addition, this massage program may also help relieve the level of distress experienced by family caregivers when providing care to the cancer patients. This in turn may enhance the preparedness and competence of these family caregivers in the provision of care, resulting in better quality of care received by the cancer patients. Side effects are not expected to occur.

Where is the study run from? Caritas Medical Centre (Hong Kong)

When is the study starting and how long is it expected to run for? November 2016 to October 2017

Who is funding the study? Chinese University of Hong Kong (Hong Kong)

Who is the main contact? Prof. Winnie K.W. So

# **Contact information**

# Type(s)

Scientific

#### Contact name

**Prof Winnie So** 

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# Additional identifiers

#### **EudraCT/CTIS** number

#### IRAS number

## ClinicalTrials.gov number

## Secondary identifying numbers

Protocol version 2

# Study information

#### Scientific Title

A feasibility study of caregiver-delivered massage program for cancer palliative care patients

#### **Study objectives**

- 1. The caregiver-delivered massage program is feasible and acceptable to Chinese patients with terminal cancer
- 2. This program helps reduce the level of distress and symptom burden, while improving sleep quality and quality of life of these patients
- 3. The program increases the perceived preparedness and competence of the family caregivers of these cancer patients in care delivery, improves their sleep quality and quality of life, and reduces their distress level

#### Ethics approval required

Old ethics approval format

# Ethics approval(s)

Joint Chinese University of Hong Kong - New Territories East Cluster Clinical Research Ethics Committee, 14/09/2016, ref: 2016.453

# Study design

Single-centre randomized controlled trial

# Primary study design

Interventional

# Secondary study design

Randomised controlled trial

# Study setting(s)

Home

# Study type(s)

Quality of life

# Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

# Health condition(s) or problem(s) studied

#### Terminal cancer

#### **Interventions**

Before the intervention, dyads (pairs of caregivers and cancer patients) will be randomized into intervention or wait-list control group. Each group will have 20 dyads. Double-blind randomization will be carried out for the purpose of subject allocation. A computer-generated randomization scheme with block sizes of 4 will be carried out by a research staff independent of the research team. Group allocation will be concealed by using consecutively numbered opaque sealed envelopes which will be opened after consents are obtained from the dyads.

The intervention involved in this study is a caregiver-delivered massage program, which is going to last for three weeks. During the intervention, family caregivers will be asked to follow the intervention protocol and provide the gentle massage to upper extremities of their corresponding patients 3 times per week for approximately 15-20 minutes per session.

Participants allocated to the wait-list control group will only receive the massage intervention after the participants in the intervention group have completed the massage intervention.

#### Intervention Type

Other

#### Primary outcome measure

- 1. Distress levels of patients and family caregivers will be measured using the distress thermometer, a visual analogue scale used to evaluate psychological distress at baseline and 3 weeks
- 2. Symptom burden will be measured using the Edmonton Symptom Assessment System at baseline and 3 weeks
- 3. Sleep quality of both patients and caregivers will be evaluated by the use of a wrist-worn sleep tracking device which will monitor the various sleep parameters of the participants, including total sleep time, sleep latency, sleep efficiency, immobility time, mean activity score, and number of awakening at baseline and 3 weeks
- 4. Quality of life of patients will be measured using the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 15-Palliative Care (EORTC QLQ-C15-PAL). Quality of life of family caregivers will be measured using the Short Form 12 Health Survey Questionnaire (SF12v2) at baseline and 3 weeks
- 5. Perceived preparedness of family caregivers will be measured using the Preparedness for caregiving scale, while their perceived competence will be measured using the Caregiving Competence Scale at baseline and 3 weeks

## Secondary outcome measures

- 1. Recruitment rate
- 2. Retention rate
- 3. Participant compliance to the intervention
- 4. Participant satisfaction

# Overall study start date

01/11/2016

# Completion date

31/10/2017

# Eligibility

#### Key inclusion criteria

#### Patients:

- 1. Aged 18 or above
- 2. Diagnosed with cancer
- 3. Able to communicate in Chinese
- 4. Staying at home
- 5. Willing to comply with the proposed intervention

#### Family caregivers:

- 1. Aged 18 or above
- 2. Able to communicate in Chinese
- 3. Willing to comply with the proposed intervention

#### Participant type(s)

Mixed

#### Age group

Adult

#### Lower age limit

18 Years

#### Sex

Both

# Target number of participants

40 pairs of patients and their caregivers (dyads)

#### Total final enrolment

49

#### Key exclusion criteria

- 1. Patients with deep vein thrombosis, devices and obvious skin problem/fracture/metastasis of the upper limb(s)
- 2. Patients and caregivers with any cognitive impairment that interferes with the completion of the study
- 3. Allergic to almond oil

#### Date of first enrolment

01/02/2016

#### Date of final enrolment

30/04/2017

# Locations

#### Countries of recruitment

China

#### Hong Kong

# Study participating centre Caritas Medical Centre

Wai Yee Block 111 Wing Hong St Sham Shui Po Hong Kong China

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# Sponsor information

# Organisation

Chinese University of Hong Kong

#### Sponsor details

The Nethersole School of Nursing Shatin The New Territories Hong Kong Hong Kong

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#### Sponsor type

University/education

#### **ROR**

https://ror.org/00t33hh48

# Funder(s)

# Funder type

University/education

#### **Funder Name**

Chinese University of Hong Kong

#### Alternative Name(s)

The Chinese University of Hong Kong, , CUHK

# **Funding Body Type**

#### Government organisation

# Funding Body Subtype

Universities (academic only)

#### Location

Hong Kong

# **Results and Publications**

# Publication and dissemination plan

To be confirmed at a later date

# Intention to publish date

31/10/2018

# Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Winnie K.W. So

#### IPD sharing plan summary

Available on request

# **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		18/04/2019	18/04/2019	No	No