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

Submission date
16/12/2016

Recruitment status
No longer recruiting

Registration date
05/01/2017

Overall study status
Completed

Last Edited
18/04/2019

Condition category
Cancer

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

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
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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
-

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