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Short version life review intervention for palliative patients

Submission date	Recruitment status	[ ] Prospectively registered
01/04/2018	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
03/05/2018	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/11/2019	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol
Background and Aims:

Psychological and spiritual distresses compounded with physical sufferings are common in palliative care patients. If the spiritual distress of the patients at the end of life are left unattended, the psychosocial wellbeing and quality of life of the patients can be threatened. Studies found that life review based on Erikson's developmental theory, is an effective intervention to enhance spiritual wellbeing and lower anxiety and depression in palliative care patients. Unfortunately, conventional life review interventions are too lengthy beyond the life expectancy and physical tolerance of these patients. A short version life review intervention was identified through literature search, which we are testing for effectiveness and applicability. Therefore, this study aimed at evaluating the effectiveness of the short term life review intervention in enhancing spiritual well-being, and lowering anxiety and depression in Chinese palliative care patients.

What does the study involve?

Palliative care patients meeting the inclusion criteria are recruited and randomly assigned to intervention group or control group. The intervention group received the short version life review intervention. The control group receive usual care. Both the patients and the outcome assessors were blinded to group assignment.

The intervention is evaluated by measuring improvement in spiritual wellbeing, anxiety and depression using two set of questionnaires, the McGill Quality of Life Questionnaire - Hong Kong version (MQOL-HK) and the Hospital Anxiety and Depression Scale (HADS) Chinese version.

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CREC Ref. no. 2015.273-T

Study information

Scientific Title
A randomized controlled trial study to evaluate the effectiveness of a short version life review intervention in enhancing the spiritual wellbeing and lowering anxiety and depression in Chinese palliative care patients

Study objectives
Palliative care patients who received the short version life review intervention would have enhanced spiritual well-being and lowered anxiety and depression as compared to those without such intervention

Ethics approval required
Old ethics approval format

Ethics approval(s)
Joint Chinese University of Hong Kong -New Territories East Cluster - Clinical Research Ethics Committee, 25/09/2015, 2015.273-T

Study design
Multicenter double-blind randomized controlled 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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Spiritual wellbeing in palliative care patients

Interventions
The intervention: The short version life review intervention consisted of two communication sessions with the participants. Each session lasted for approximately 45 min. An interval of one week between the first and second sessions was provided to the intervention group. In the first session, patients were asked the eight life review guiding questions to explore their life stories. Answers to each question were written down. The intervener edited the content into a personalized life review booklet with relevant pictures and photographs inserted to enrich the presentation. A week later in the second session, the intervener and the patient viewed the personal life review booklet and went through the contents together. The personal life review booklet was then presented to the participant for retention. The eight life review questions were adopted from the Ando et.al. (2010) and the intervention protocol was obtained from Dr. Ando. The questions were translated from English to Chinese. Expert opinions and face validity were sought from five nurse consultants in palliative care, one nursing professor, who is an expert in palliative care, and one clinical psychologist serving the palliative care units. All questions yielded good face validity.
Data collection: Patients who availed of the palliative care service during the study period and met the inclusion criteria were invited by their primary doctors or nurses. The first assessor would introduce the research in detail, obtained consent and administered the psycho-spiritual questionnaires as baseline. Then, the assessor would allocate the patients to groups according to the sequentially numbered opaque sealed envelopes (SNOSE) containing assignment information. The intervener then administered Set A questions (STLR questions) to the intervention group while Set B questions (social conversations) were administered to the control group. The intervener was an experienced palliative care nurse consultant. She was the only intervener so as to preserve the integrity and uniformity of the process. After one week, the second assessor administered the same sets of questionnaires to both groups. The second assessor had no knowledge on which group the patients were allocated. She was solely responsible for collecting the post-intervention questionnaires.

Randomisation:
Random numbers for the intervention or control group were computer-generated in a block size of 6, and then placed in sealed envelopes. A patient was assigned to the treatment or control group according to the sequentially assigned envelope. Random assignment to either group occurred after the baseline psycho-spiritual measurements had been taken. SNOSE was used for patients recruited in an in-patient or home setting. Block randomization was adopted for patients recruited at Day Hospice. Assignment to the intervention or control group was based on the day of the week they attended the day care centers.

Intervention Type
Other

Primary outcome measure
1. Spiritual well-being was measured by the McQill Quality of Life Index—Hong Kong version (MQOL-HK) (Cohen et al., 1995, Lo et al., 2001). At baseline and on the 8th day. Questionnaires are administered pre-intervention and post-intervention.

Secondary outcome measures
1. Anxiety and depression is measured using the Hospital Anxiety and Depression Scale - Chinese at baseline and the 8th day. Questionnaires are administered pre-intervention and post-intervention.

Overall study start date
01/02/2016

Completion date
31/01/2017

Eligibility

Key inclusion criteria
1. Adult patients aged 18 years or above
2. Ability to communicate in Chinese
3. Life expectancy of not less than one month as estimated by a primary doctor.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
102

Key exclusion criteria
1.Patients who are cognitively impaired, such as those suffering from dementia or delirium.
2.Patients who are too ill to complete the intervention.

Date of first enrolment
01/02/2016

Date of final enrolment
31/01/2017

Locations

Countries of recruitment
Hong Kong

Study participating centre
Bradbury Hospice
17 A Kung Kok Shan Road, Shatin, New Territories
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Sponsor information

Organisation
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Sponsor type
Other

ROR
https://ror.org/00t33hh48

Funder(s)

Funder type

Not defined

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
The study has been presented at the Asia Pacific Hospice Conference in July, 2017, held in Singapore. The paper is being prepared for submission to an international journal.

Intention to publish date
01/07/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available