

Short version life review intervention for palliative patients

Submission date 01/04/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 03/05/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 07/11/2019	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Hong Kong

Hong Kong

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Sponsor information**Organisation**

The Nethersole School of Nursing, Faculty of Medicine, The Chinese University of Hong Kong

Sponsor details

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NA

Hong Kong

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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