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Positive outcomes in cancer care: emphasizing quality of life and legacy

Submission date
01/04/2015

Recruitment status
No longer recruiting

Registration date
06/08/2015

Overall study status
Completed

Last Edited
24/09/2015

Condition category
Cancer

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
End-of-life cancer care has two main goals: relieving pain and suffering while enhancing the quality of life for patients and their families. These goals are achieved by not only focusing on physical treatment, but by addressing the essential psychological, spiritual, and social needs of the dying. This is a study measuring the psychological aspects of end-of-life care, with an emphasis on how a psychological intervention (treatment) may positively enhance patients' experiences and their final legacy. This study will evaluate the impact of a brief psychotherapy where patients complete a written "legacy" document. The therapy provides a unique opportunity for dying patients to be audio recorded as they reminisce about their most cherished memories, the times they felt most alive, the lessons they learned in life, and any hopes, dreams, or final wishes they have for their loved ones. The audio recordings are then transcribed so that a polished written document is produced, one that is leather-bound and given directly to the patient as a gift. Per the patient's request, copies of this written document can then be given to family, friends, and loved ones, or simply kept for future generations as a cherished keepsake. This study will test whether completing these legacy documents can increase patients' positive emotions and provide a significant sense of closure and contentment. Previous studies have measured whether this intervention lowers distress, namely by measuring changes in depression and anxiety, but these studies produced mixed results. Perhaps these conflicting results are because, as patients who have already completed the process around the world suggest, creating a legacy document can bolster a sense of meaning in life, provide solace for themselves and their loved ones, and even significantly "change the way their family sees or appreciates them." It may be that by previously centering on pathological indicators, the positive impact provided by this therapy has been missed. Such positive outcomes would be systematically evaluated in this study through an innovative mixed-methods technique which blends the rigor of a randomized controlled trial with the personal touch of individualized patient interviews. In other words, once patients complete the study, we will purposely ask them about the nature of the treatment's impact on their lives, and listen to their perspectives regarding the relevance and importance of measuring positive outcomes in cancer research. This allows patients to offer specific suggestions, and their feedback can spotlight the need for future research to broaden from a focus on distress or pathology to one of striving for an improved quality of life for cancer patients.

Who can participate?
Adults (aged at least 18), enrolled as a patient at San Diego Hospice and The Institute for Palliative Medicine and has a life expectancy of no more than 6 months.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in group 1 are allocated to the digital therapy group (the intervention). This therapy typically takes four sessions over a two week period. In the first session (day 1 of intervention) each participant is asked about their motivations for having the treatment and what specific goals they have for creating the legacy document. The second session (in day 3) involves completing a 60 minute life review with each participant. The interview is recorded and the transcribed. At the third session (day 7), the typewritten document of the interview is then read to each participant. The participant can make edits to this document. A summary is then created for the document and also a title. The final session (day 14) , a leather bound hard-copy of the “legacy” document is given to each participant which can then be given to loved ones and family as a keepsake. Those patients in group 2 (the supportive attention control group) will have 4 sessions with a counselor to provide attention and care. The time spent with this counselor mirrors the time spent with the patients in group 1.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
San Diego Hospice and The Institute for Palliative Medicine (USA)

When is the study starting and how long is it expected to run for?
July 2013 to June 2018

Who is funding the study?
American Cancer Society

Who is the main contact?
Professor Lori Montross Thomas

Contact information

Type(s)
Public

Contact name
Dr Lori Montross Thomas

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MRSG-13-233-01-PCSM

Study information

Scientific Title
Randomized controlled trial of positive outcomes with dignity therapy

Study objectives
HYPOTHESIS 1: The dignity therapy group will score significantly higher on the positive affect scale than on the negative affect scale as measured by the 20-item positive and negative affect scale (PANAS) than patients in the supportive attention control group.
HYPOTHESIS 2: The dignity therapy group will score significantly higher on the contentment scale than on the contention scale as measured by the 20-item life closure scale (LCS) than patients in the supportive attention control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of California San Diego Institutional Review Board (IRB), 06/24/2013, ref: 130797

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Cancer care

Interventions
1. Dignity Therapy:
Dignity therapy is a brief, empirically-supported, individualized psychotherapy designed for adults at the end of life. The therapy is typically performed in four sessions over the course of two weeks. The first session (Day 1) involves a 60-minute consultation to evaluate the patient's motivation for treatment and to determine any specific goals they have for creating the legacy document. The second session (Day 3) involves the completion of a 60 minute life review at the patient at bedside, and is based upon the published 12-question interview protocol (e.g., "When did you feel most alive?", "What are your hopes and dreams for your loved ones", "What do you feel most proud of?"). The interview is digitally recorded and transcribed (the transcription usually requires 2-4 business days to complete). In the third session (Day 7), the typewritten document is then read to the patient in its entirety. This 60-minute session fosters autonomy by allowing the patient to provide personal edits as necessary, and ensures accuracy of content. Additional therapeutic value is gained since the reading provides an emotional reminder of the patient's cherished memories and verifies that his/her history has been witnessed and recorded according to his/her wishes. This session further involves the creation of an overall summary for the document, as well as a title. The final session (Day 14) is then conducted after all of the patient's edits have been completed and formatted into a polished leather binder (usually takes 5 business days). In this 30 minute session a hard-copy version of the "legacy" document is given to the patient, and can then be disseminated to desired loved ones and family members as a keepsake.

2. Supportive Attention:
Patients assigned to the supportive attention control group will be paired with a trained San Diego Hospice (Master's level) counselor. This therapist will spend approximately one hour visiting with the patient to provide attention and care, but will not be focused on providing legacy therapy. The time spent by the counselor will mirror the time spent with dignity therapy patients (on average, 4 sessions over the course of 14 days).

Intervention Type
Behavioural

Primary outcome measure
Positive affect and contentment, measured using the Positive and Negative Affect Scale (PANAS), at baseline, and then at day 1, 3, 7 and 14.

Secondary outcome measures
1. Hope, measured using Hearth Hope Index (HHI), at baseline and at day 14
2. Satisfaction with life using Satisfaction with Life (BPFSS) scale at baseline and day 14
3. Gratitude, measured using the Gratitude Questionnaire (GQ-6) and baseline and day 14
4. Resilience, measured using the Connor-Davidson Resilience Scale (CD-RISC) at baseline and day 14

Overall study start date
01/07/2013

Completion date
30/06/2018

Eligibility

Key inclusion criteria
1. Primary Hospice Diagnosis of Cancer
2. Age > 18
3. Enrolled in Hospice Care at San Diego Hospice and The Institute for Palliative Medicine (inpatient or homecare setting) with life expectancy of 6 months or less as reflected by hospice admission
4. Willing and able to give informed consent to participate
5. Speaks and understands English
6. Able to sustain attention and effort for approximately one hour of interaction

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
90

Key exclusion criteria
1. Current diagnosis of severe dementia, delirium, or other cognitive impairment
2. Unable to speak and understand English

Date of first enrolment
01/07/2013

Date of final enrolment
30/06/2018

Locations

Countries of recruitment
United States of America

Study participating centre
University of California, San Diego
9500 Gilman Drive #0664
La Jolla
United States of America
CA 92093

Sponsor information

Organisation
American Cancer Society

Sponsor details
250 Williams Street
Atlanta
United States of America
30303-1002

Sponsor type
Charity

ROR
https://ror.org/02e463172

Funder(s)

Funder type
Charity

Funder Name
American Cancer Society

Alternative Name(s)
American Cancer Society, Inc., Sociedad Americana Contra El Cáncer, ACS

Funding Body Type
Government organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United States of America

Results and Publications

Publication and dissemination plan

We plan to publish the results of the randomized controlled trial in late 2018-early 2019. Given the size of the data and the mixed-methods nature of the study, it will most likely involve both one quantitative research manuscript and one qualitative research manuscript. We will additionally be presenting our results at national conferences, most likely at AAHPM, NHPCO and /or APOS.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	21/09/2015		Yes	No