ISRCTN29868352 https://doi.org/10.1186/ISRCTN29868352

An exploratory study of Dignity Therapy for people with advanced cancer

Submission date 05/02/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 12/02/2009	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 02/03/2016	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A phase II randomised controlled trial assessing the feasibility, acceptability and potential effectiveness of Dignity Therapy for people with advanced cancer

Study objectives
The broad aims of this phase II randomised controlled trial (RCT) are to assess the feasibility, acceptability and potential effectiveness of Dignity Therapy to reduce psychological and spiritual distress in people with advanced cancer who have been referred to a hospital based palliative care team. The specific objectives are to:
1. Determine whether Dignity Therapy is likely to increase peoples sense of dignity and reduce psychological or spiritual distress
2. Determine whether it is feasible to provide Dignity Therapy to people with advanced cancer in this setting
3. Determine whether Dignity Therapy is acceptable to patients and their families
4. Pilot methods for a larger RCT (e.g. recruitment, randomisation, follow-up, suitability of measures)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Kings College Hospital Research Ethics Committee gave approval on the 10th November 2008 (ref: 08/H0808/155)

Study design
Phase II randomised controlled open-label trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Advanced cancer

Interventions
Dignity Therapy: this is a brief psychotherapy to foster a sense of dignity and reduce psychological and spiritual distress in people with advanced cancer. The therapy involves a therapist conducting an interview with the patient using a standard framework of questions. This is given to patients at least a day before the therapy session to give them the opportunity

to think about their responses beforehand. The question framework provides a flexible guide for the therapist to shape the interview, based on patients' level of interest and responses. The therapist follows the patients' cues, helping them to structure and organise their thoughts, for example, by asking questions about time sequences, how events are causally related to each other and facilitating the disclosure of thoughts, feelings and memories. These interviews are tape-recorded, quickly transcribed verbatim then shaped into a narrative using a formatted editing process. This includes clarifications (eliminating colloquialisms, non-starters and sections not related to the "generativity" material, such an interruptions), chronological corrections, tagging and editing any content that might inflict significant harm on recipients of the document (after discussion with the patient) and finding a suitable ending for the document which is appropriate to the patient's overall message. Another session is arranged for the therapist to read the edited transcript to the patient, who is invited to make any editorial suggestions, including identifying errors of omission or commission. Once the patient is satisfied with the document, they can give it, or bequeath it, to people of their choosing. Dignity Therapy is given in addition to standard palliative care (patients are assessed by a multi-professional palliative care team, including nurses, a psychosocial worker and doctors trained in providing psychosocial support). Patients in this group will also have at least three interviews with the research assistant to assess outcomes.

In addition to standard palliative care, the control group will have at least three interviews with the research assistant. Completing the measures and taking part in the interview gives them an opportunity to talk about their feelings. The extent to which they feel that this is therapeutic is explored in qualitative interviews.

The initial Dignity Therapy interview lasts for approximately one hour. This is followed approximately 3 - 4 days later with a review interview, also lasting about an hour. However, if patients become fatigued these can take longer, be split over more than one session, or be delayed.

Duration of follow-up: interviews last about 1 hour, however, if patients become fatigued these can take longer, or be split over more than one session.

Intervention Type
Other

Phase
Phase II

Primary outcome measure
Patients' sense of dignity, assessed using the Patient Dignity Inventory at baseline, as soon as possible after the intervention has been completed and 1 month post-intervention, and the equivalent in the control group. Themes covered by this questionnaire include physical, psychosocial, existential and spiritual domains of concern or distress.

Secondary outcome measures
1. Potential effectiveness, assessed at baseline, as soon as possible after the intervention has been completed and 1 month post-intervention, and the equivalent in the control group, by the following:
1.1. Hospital Anxiety and Depression Scale
1.2. Herth Hope Index
1.3. Euroqol EQ-5D

1.4. A two-item measure of quality of life specifically designed to assess the effectiveness of the Dignity Therapy
1.5. The Distress Thermometer
2. Acceptability of Dignity Therapy (intervention group only). Patients views on the intervention assessed as soon as possible after the intervention has been completed and 1 month post-intervention using semi-structured face-to-face qualitative interviews
3. Outcomes for family, friends and recipients of "generativity" documents; potential effectiveness, assessed at three months post- bereavement for patients who die during the study period using the following:
3.1. Hospital Anxiety and Depression Scale
3.2. Complicated Grief Assessment Scale
3.3. Palliative Care Outcome Scale
4. Acceptability of Dignity Therapy (intervention group only). Views of patients' family, friends and recipients of "generativity" documents on the intervention, assessed as soon as possible after the intervention has been completed and 3 months post- bereavement (for patients who die in the study period) using semi-structured qualitative telephone interviews
5. Feasibility of delivering Dignity Therapy in this setting will be assessed by recording:
5.1. Time taken to organise and conduct the Dignity Therapy sessions, transcribe and edit narratives
5.2. Deviations from the therapy protocol and the reasons for this
5.3. The therapists perceptions of competence as a result of training
6. Methods for a phase III trial; to assess the feasibility our methodology, the following will be recorded:
6.1. Exclusions
6.2. Recruitment rates (patients and their family, friends and recipients of the generativity documents)
6.3. Loss to follow-up
6.4. Time taken to obtain informed consent
6.5. Time taken to collect outcomes
6.6. Missing data and the reasons for this
7. Acceptability. To assess the acceptability of our methodology to patients and their family, friends and recipients of the generativity documents we will obtain their views on taking part in the study and completing the measures at each follow-up using semi-structured qualitative interviews.

Overall study start date
05/01/2009

Completion date
31/12/2009

Eligibility

Key inclusion criteria
Adults aged greater than or equal to 18 years, either sex, with advanced cancer who have been referred to a hospital-based palliative care team. In one hospital trust only patients being cared for in the community will be included. In the other hospital only in-patients and those visiting out-patient clinics will be included. Participants will not be screened for spiritual or psychological distress, or loss of dignity, however, they will be assessed at baseline, to explore the potential moderating effects of these on the impact of the intervention.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Patients who are considered by the palliative care team to be too ill to take part in a protocol lasting two weeks
2. Unable to provide informed consent either due to cognitive problems, or to the severity of their illness, or because they are unable to understand English

Date of first enrolment
05/01/2009

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Weston Education Centre
London
United Kingdom
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Sponsor information

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Sponsor type
University/education

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ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Charity

Funder Name
Dimbleby Cancer Care (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	16/05/2009		Yes	No
Results article	results	01/12/2011		Yes	No