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An exploratory study of dignity therapy for older people in care homes

Submission date 20/01/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/01/2009	**Overall study status** Completed	
Last Edited 19/12/2012	**Condition category** Other	

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 older people in care homes

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 older people in care homes. 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 older people in care homes
3. Determine whether Dignity Therapy is acceptable to residents and their families
4. Pilot methods for a larger randomised controlled trial (e.g., recruitment, randomisation, follow-up, suitability of measures)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Joint South London and Maudsley and the Institute of Psychiatry Research Ethics Committee, approved on 24/11/2008 (ref: 08/H0807/75)

Study design
Phase II randomised controlled open-label trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Ageing: in need of care

Interventions
Dignity Therapy: This is a brief psychotherapy to foster a sense of dignity and reduce psychological and spiritual distress in people reaching the end of life. The therapy involves a therapist conducting an interview with the resident using a standard framework of questions. This is given to residents 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 residents' cues, helping then 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 resident) and finding a suitable ending for the document which is appropriate to the residents' overall message. Another session is arranged for the therapist to read the edited transcript to the participants, who are invited to make any editorial suggestions, including identifying errors of omission or commission. Once the resident 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 psychological care.

The control group will receive standard psychological care. None of the care homes provide dignity therapy. Information on the nature of standard care is being collected as part of the trial. In addition residents in the control group 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 the interviews.

Intervention Type
Other

Phase
Phase II

Primary outcome measure
Residents' sense of dignity, assessed using the Patient Dignity Inventory at baseline, 1 and 8 weeks 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, 1 and 8 weeks post-intervention, and the equivalent in the control group, by the following:
1.1. Geriatric 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

2. Feasibility, recruitment (residents and their family and friends), assessed at the end of the trial:
2.1. Exclusions, drop-out rates
2.2. Time taken to obtain informed consent and organise and conduct the dignity therapy sessions, transcribe and edit narratives and collect outcomes
2.3. Deviations from the therapy protocol and uncompleted interventions and the reasons for this
2.4. Therapist's perceptions of competence as a result of training

3. Acceptability, assessed by semi-structured interviews with residents to obtain their views on Dignity Therapy (intervention group only) and on taking part in the study (both groups). These qualitative interviews will be conducted before quantitative measures are collected, 1 and 8 weeks post-intervention, and the equivalent in the control group. The therapist records her experiences of delivering the therapy and observations of resident's responses. Case reports will be produced for any difficult cases and, with the consent of participants, a detailed qualitative analysis of the therapy transcripts will be carried out. The latter might provide insight into concerns which might impact on the effectiveness of the intervention.

Overall study start date
01/12/2008

Completion date
31/03/2010

Eligibility

Key inclusion criteria
Residents (males and females) aged 65 years old or over, living in one of six care homes for older people, are included. Not all residents have a "terminal" illness and they are not selected on the basis of receiving palliative care. However, all residents in nursing homes are frail and could be considered as reaching the end of life. Participants are not screened for spiritual or psychological distress, or loss of dignity, however, these are assessed at baseline, to explore the potential moderating effects of these variables on the impact of the intervention.

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
64

Key exclusion criteria
1. Residents who are considered by the care home managers to be too ill to be interviewed
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
01/12/2008

Date of final enrolment
31/03/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Palliative Care, Policy & Rehabilitation
London
United Kingdom
SE5 9RJ

Sponsor information

Organisation
King's College London (UK)

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Sponsor type
University/education

Website
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ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Charity

Funder Name
The Dunhill Medical Trust (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?
Results article	results	01/07/2012		Yes	No