

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
Registration date 30/01/2009	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 19/12/2012	Condition category Other	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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)

Primary study design

Interventional

Study design

Phase II randomised controlled open-label trial

Study type(s)

Treatment

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 as 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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Senior

Sex

All

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**

United Kingdom

England

Study participating centre

Department of Palliative Care, Policy & Rehabilitation

London

United Kingdom

SE5 9RJ

Sponsor information**Organisation**

King's College London (UK)

ROR

Funder(s)

Funder type

Charity

Funder Name

The Dunhill Medical Trust (UK)

Results and Publications

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