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Efficacy of dignity therapy in psychological and existential distress of terminally-ill patients

Submission date
06/09/2011

Recruitment status
No longer recruiting

Registration date
19/09/2011

Overall study status
Completed

Last Edited
09/02/2017

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Terminally-ill patients are confronted with different types of feelings. Psychological and existential suffering (for example, depression, anxiety, feeling of hopelessness and helplessness) are one of the most debilitating conditions in dying patients, although they tend to be under-recognised and they are difficult to take care of. They cause suffering in terminally-ill patients and their families, reducing quality of life, increasing pain and other symptoms. Dignity is one of the basic requirements that must be provided when caring for terminally-ill patients. The dignity model developed by Chochinov is a brief individualised intervention designed to address psychosocial and existential distress among terminally-ill patients. Some studies have taken place in Canada, USA and Australia. Europe is lacking the evidence to show that this model works well and there is no data in Portugal. In our trial we proposed to perform a long term follow-up (30 days) to study the possible maintenance of the psychotherapeutic effect on various measures of psychosocial and existential distress. The main aim of this study is to assess how well dignity therapy works for people with a life-threatening disease who have been referred to an in-patient palliative medicine unit. The study will include a long term follow-up (30 days). The expected usefulness of dignity therapy as part of regular palliative care programs will be measured in terms of health benefits (reduced psychological suffering and improved quality of life).

Who can participate?
Patients age ≥ 18 years old who are admitted to our palliative medicine unit with a life-threatening disease

What does the study involve?
By accepting to participate in this study, patients will randomly be allocated to one of two groups:. intervention group, consisting of dignity therapy and standard palliative care or control group, consisting only of standard palliative care
Both groups will receive medical treatment as usual (standard palliative care). Patients allocated to dignity therapy are asked to tape-record aspects of their lives they would most want their loved ones to remember. To decrease suffering, enhance quality of life, sense of meaning, purpose and dignity, patients are offered the opportunity to talk in a very flexible way about issues that matter the most to them, that they feel were the most important and meaningful

moments of their lives, to speak to things they would like to be remembered after their death or even dispense advice to their family and friends. The tape-recorded psychotherapy sessions generate an edited transcript (generativity document) that is returned to the patient for them to share with the individuals of their choosing. Standard palliative care consists of a multi-professional palliative medicine team assessment, including nurses, a psychologist, a psychosocial worker and clinical care delivered by the doctor. Clinical care consists of clinical interview, physical examination, symptom assessment and management, addressing patients and families questions, understanding of illness and treatment, existential and psychosocial support.

What are the possible benefits and risks of participating?
All participants, including controls, will receive state-of-the-art palliative care and will see improvements in their quality of life and comfort, as their physical and psychological symptoms are managed. There are no known risks to participants.

Where is the study run from?
The study takes place at a ten bed specialized palliative medicine in the surroundings of Lisbon, Portugal

When is the study starting and how long is it expected to run for?
May 2010 to May 2013

Who is funding the study?
This is an investigator funded study

Who is the main contact?
Dr Miguel Julião
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Efficacy of dignity therapy in psychological and existential distress of terminally-ill patients: randomized controlled trial

Study objectives
The aim of our study was to assess the long term efficacy of dignity therapy (DT) in reducing psychological and existential distress in people with a life-threatening disease who have been referred to an in-patient palliative care unit. We also performed a brief feasibility analysis of DT including a qualitative analysis of the content of the generativity documents.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Instituto das Irmãs Hospitaleiras do Sagrado Coração de Jesus Ethics Committee - Casa de Saúde da Idanha, 26/05/2010
2. Faculty of Medicine, University of Lisbon Ethics Committee, 07/05/2010

Study design
Phase II open-label 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 to request a patient information sheet

Health condition(s) or problem(s) studied
Psychological and existential distress of terminally-ill patients

Interventions

Standard palliative care:
Standard palliative care (SPC) consisted of a multi-professional palliative care team assessment, including nurses, a psychologist, a psychosocial worker and clinical care delivered by the main investigator. Clinical care (median=20 minutes; range 10-30) consisted of clinical interview, physical examination, symptom assessment and management, addressing patients and families questions as well as family and patients coping, illness and treatment understanding, existential and psychosocial support.

SPC during the RCT protocol was always performed by the main investigator and by neither of the other two doctors in the palliative care team.

Dignity therapy:
DT is a brief psychotherapeutic approach with the aim of bolstering the patient´s sense of meaning and purpose, reinforcing a continued sense of worth within a framework that is supportive, nurturing and accessible for those proximate to death. Therapeutic sessions, running between 30 and 60 minutes,were offered at patients' bedside. DT was tape-recorded after written informed consent was obtained. Every tape-recorded session was erased after the completion of the study protocol.

The standard framework of questions outlined in DT interview was based on the themes and sub-themes that arise from the dignity model 9. Once patients completed the baseline assessment (T1), they were provided with the standard framework of questions, thus giving them time to reflect and shape eventual responses.

The taped session of DT began with the question Tell me a little about your life history, particularly the parts that you either remember or think were most important?. After this introductory question, the question framework provided a flexible guide to the therapist to shape the interview, based on the level of explicit interest of each answer. The therapist followed the patients cues, helping them to structure and organizes their thoughts (local and time sequences, p.e.). The therapist main task was to connect the dots facilitating the disclosure of feelings, thoughts and memories. Another metaphor used to enrich patients ability to describe their life details was asking Imagine that you and I are looking at a picture book or album of your life. Tell me in as much detail as you can about some of the pictures we might see.

Once the taped session was complete, over the course of the next 2 to 3 days, the patients´ recorded dialogue was transcribed verbatim and then reshaped into a written narrative, after an editing process. This editing process included elimination of nonstarters and colloquialisms, chronological corrections, tagging and editing any harmful or conflictive statement for the generativity document recipient. Once this editing process was complete, another session was arranged in a short time period for the therapist to read the document to the patient, allowing editorial corrections, including identifying possible errors.

During this RCT, DT was performed as previously described only by the main Investigator who received formal training in DT with Harvey Chochinov. The RCT protocol was only performed during the main Investigator´s working hours in the palliative care unit (2 days a week). During these two week periods, the main Investigator would perform DT and SPC on the same day (to patients on intervention group and control group).

Intervention Type
Other

Phase

Phase II

Primary outcome measure
To determine the efficacy of DT in reducing depression symptoms

Secondary outcome measures
1. The efficacy of DT on the following psychosocial and existential aspects: anxiety symptoms; demoralization; desire for death; sense of dignity; patients satisfaction, helpfulness, sense of meaning and purpose after performing dignity therapy; and physical symptoms.
1.1. Depression and anxiety: Hospital and Anxiety Depression Scale (HADS)
1.2. Demoralization: Demoralization Criteria
1.3. Desire for Death: Desire for Death Rating Scale (DDRS)
1.4. Sense of Dignity: Patient Dignity Inventory (PDI)
1.5. Satisfaction with dignity therapy: Patient Dignity Questionnaire (PDQ)
1.6. Physical Symptoms: Edmonton Symptom Assessment Scale (ESAS)
2. The prevalence of depression, anxiety, demoralization and desire for death
3. Brief feasibility analysis of DT and a qualitative analysis of the content of all generativity documents

Day 1: collection of demographic and clinical data (T0)
Day 2: baseline assessment using all the scales mentioned above (with the exception of PDQ), before dignity therapy or standard palliative care (T1)
Day 7, 8 or 9: post-intervention assessment using all scales mentioned above (T2)
Day 15: assessment using HADS and ESAS (T3)
Day 30: assessment using HADS and ESAS (T4)

Overall study start date
01/05/2010

Completion date
01/05/2013

Eligibility

Key inclusion criteria
1. Age ≥ 18 years old
2. Patient with a life-threatening disease
3. Patient able to read and speak Portuguese
4. Patient able to provide written informed consent
5. Patient with no evidence or diagnosis of dementia or delirium, demonstrated by information on medical chart or by clinical consensus between the main investigator and another palliative care physician
6. Mini Mental State score ≥ 20
7. Availability to have 4 to 5 research encounters, over a period of one month

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100 (50+50)

Key exclusion criteria
Patients enrolled on other palliative care programs

Date of first enrolment
01/05/2010

Date of final enrolment
01/05/2013

Locations

Countries of recruitment
Portugal

Study participating centre
Rua Pedro Hispano
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Portugal
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Sponsor information

Organisation
University of Lisbon (Portugal)

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Sponsor type
University/education

Website
http://www.ul.pt/portal/page?_pageid=173,1&_dad=portal&_schema=PORTAL

ROR
https://ror.org/01c27hj86

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (Portugal)

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	01/12/2017		Yes	No