Dying in Dignity. An evaluation of dignity therapy among terminal patients

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON35116

Source
ToetsingOnline

Brief title
Dying in dignity

Condition

- Other condition

Synonym
NVT

Health condition

terminale fase

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: (1) Stichting Pius (deel van de kosten) (zie protocol;pag. 38 voor toelichting)

Intervention

Keyword: dignity, dying, loneliness, suffering

Outcome measures

Primary outcome

Primary parameters are:

* The effect of dignity therapy on the perceived dignity of terminal patients

Secondary outcome

Secondary parameters are:

* The effect of dignity therapy on suffering, loneliness, quality of life and

meaning of life (patients)

* The effect of dignity therapy on feelings of depression and the bereavement

process (family/freinds)

* Feasibility and desirability to implement dignity therapy into the palliative

program of hospice/hospital?

Study description

Background summary

Recent research has noted that in the care for the terminally ill, there is a shortage of palliative care interventions in which there is attention for the psycho-social and spiritual needs of terminal patients. In order to meet to these objections, several kinds of terminal care have been developed. Dignity therapy is a Canadian care program that aims to strengthen feelings of dignity and meaning of life among (terminal) patients. The adoption of dignity therapy

may encourage (older) terminal patients to talk about dying, spirituality, and a good death, and it may lessen psychosocial and existential suffering. Results may lead to new insights and may add to notions about palliative care and theories on meaning and purpose-of-life, suffering, and dignity.

Study objective

The primary goal of the present study is to evaluate the effects of dignity therapy on terminal patients and their family/friends. In case of the patients, effects will be measured regarding their perceived dignity (primary outcome measures), suffering, loneliness, quality of life and meaning of life (secundary outcome measures). In case of family members/friends, effects will be assessed with respect to feelings of depression and the bereavement process.

Study design

The study will take place in hospices and hospitals. To be able to measure the effects of the dignity therapy, questionnaires will be administered before and following the intervention. Patients in the intervention group will have the dignity therapy; patients in the control group will not participate in the therapy; they will only receive the standard care. However, control-patients who wish to join the therapy, are allowed to do so directly after finishing the follow-up measurement, given that they have a sufficient physical condition and life expectancy. Apart from patients, their family/friends and care takers will be included in the study.

Intervention

The intervention consists of a semi-structured interview (Chochinov e.a., 2005) in which open ended questions are asked about:
(a) the life history of patients,
(b) the most important feelings, thoughts, and experiences, and
(c) the subjects that patients would like to discuss with their family and/or friends.
The interviews will be summarized in writing; the summary has to be seen and approved by the patient, and may be used as an aid in conversations with others about their terminal illness, life and death.

Study burden and risks

The intervention and questions may lead to new questions and elicit strong emotions among the patients and their family/friends. These reactions can be seen as enrichment, but may also be experienced as aggravating. Therefore, there will be special attention for:
* the recruitment and informed consent of patients and their family/friends
* the physical and mental capacity and needs of the patients will be monitored

throughout the interviews
* interviews can be divided into smaller parts
* monitoring and attention for possible care needs following the interviews, in close consultation with the coordinator
* participation to study can be interrupted or ended at any time

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

o 18 years of age and older
o able to give informed consent
o only patients who realise that they will be dying soon (e.g., patients in hospices; patients who leave the hospital to die)
o life expectancy of min. 3-4 weeks and max. 6 months (patients)

o informed consent

Exclusion criteria

o life expectancy shorter than 3-4 weeks (patients)
o who (will) are treated with palliative chemotherapy
o who participate in a fase I-trial

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2011
Enrollment:	174
Type:	Actual

Ethics review

Approved WMO

Date:	10-08-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL30034.029.09