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Chapter 7

"Calendarium Vitae" for Hospice Patients and their Caregivers: A Pilot Study

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Additional information is available at the end of the chapter

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Abstract

Although palliative care is designed to provide holistic comfort care and support, several patients still experience loss of purpose in life, and suffer from distress, sadness, anxiety, or decreased quality of life (QoL). To address these unmet needs, novel interventions, focused on psychosocial sources of distress, in hospice patients are needed. One such intervention is dignity therapy (DT), defined as a brief, individualized psychotherapy, applied for the purpose of relieving psychological distress at the end of life. "Calendarium Vitae" (CV) as a form of DT represents a feasible, safe, and effective, patient-friendly approach, targeting end-of-life psychological issues. In particular, DT can alleviate suffering and distress, help preserve psychophysical integrity, and support caregivers, during the bereavement period. This pilot study is designed to collect preliminary data, prior to conducting a larger randomized controlled trial (RCT) that will investigate the correlations of DT intervention with QoL, and possible reduction of distress and suffering, in the Eastern and Central European hospice patients (and their caregivers). Since DT is unknown in this part of Europe, the proposed pilot study, followed by RCT, will be the first step on the way to explore the DT intervention in research, among the vulnerable hospice patient population.

Keywords: hospice, terminal disease, palliative care, distress, suffering, coping strategies

1. Introduction

1.1. Scientific aim of the project

Background: Despite enormous progress that has been made in reducing the morbidity and mortality from a variety of neoplastic diseases, a large number of cancer patients progress to

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advanced stages of malignancy. Such patients are usually referred for palliative care services, and if their prognosis is estimated to be less than 6 months, they are often admitted to the hospice setting [1]. In case of an incurable metastatic cancer, in addition to multiple disease-related physical symptoms, many of such patients painfully experience loss of purpose in life and severe distress [2]. Although palliative care is designed to provide holistic comfort care, spiritual and psychosocial support until the end of life (and also during bereavement, for family members), several hospice patients still suffer from psychological distress and decreased quality of life (QoL).

To fulfill these unmet needs, novel interventions, able to directly address psychosocial sources of distress, among the hospice patients are needed [3–5]. One such intervention is dignity therapy (DT), defined as a brief, individualized psychotherapy, applied for the purpose of relieving psychological distress at the end of life [6]. Based on scientific evidence from published research in this field, derived from international studies, DT has been shown to be a feasible and effective novel strategy that targets psychophysical suffering in terminally ill patients [7]. In particular, DT attempts to help such patients reflect upon issues that are most meaningful to them, and document them in form of the "final document" [8]. However, DT is unknown in Eastern and Central Europe, and thus should be explored among hospice patients in these countries.

1.2. The study hypothesis

The study hypothesis is that the proposed pilot study will gather necessary information to create a foundation for a further randomized controlled trial (RCT) that will explore the correlations (or impact) of dignity therapy (DT) intervention with quality of life (QoL), and possible reduction of distress and suffering, among the hospice patients in Eastern and Central Europe.

It is expected that the patients in the DT intervention group (study group, SG) might have improved QoL, compared to the control group (CG), receiving a standard palliative care only. In addition, the caregivers of patients in the DT intervention group (SG) may also have improved QoL and psychophysical health condition during bereavement, compared to the control group (CG).

2. Psychophysical and social importance of the study theme

2.1. State of the art relevant to knowledge on dignity therapy (DT) intervention in hospice setting

In many palliative care programs, a significant progress in pain management and symptomatic control has been accomplished among patients with terminal stages of metastatic cancer. However, despite these advances, dignity-related issues, including loss of personal autonomy and sense of purpose in life, or feeling a burden to family represent common causes of spiritual suffering, psychological distress (e.g., anxiety and depression), and decreased

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quality of life (QoL) among hospice patients. To respond to this challenge, innovative strategies are necessary. One such exemplary intervention is called dignity therapy (DT) [9]. DT is a psychotherapeutic intervention that was developed by Prof. Chochinov and colleagues, in 2012, in Canada. The main goal of DT is to decrease emotional and spiritual suffering, enhance quality of life, and increase a sense of meaning and purpose of life among terminally ill patients near death. In particular, DT attempts to help such patients reflect upon things that are most meaningful to them, and collect these memories in form of the "final document" [9].

Dignity therapy question protocol (DTQP) is a set of standard questions that a therapist asks during an interview (conveniently conducted at the bedside) with the patient [10]. Evidence from recent research studies (conducted in Canada, Australia, and the USA) has revealed significant reduction of sense of suffering, depressed mood, and improvement in sense of dignity among terminally ill patients [11]. In summary, DT was found to be satisfactory to the patients, helpful to their relatives during grief period, and acceptable to the hospice personnel (e.g., better relations with patients and increased job satisfaction were reported) [12, 13].

2.2. Justification of the study theme

The proposed novel pilot study is going to explore the correlations between the perceived distress (anxiety, sadness, and depression) and emotional suffering (related to terminal stages of cancer), and DT intervention (in form of the Calendarium Vitae, CV) in hospice patients.

An analysis of the data from this pilot study is going to answer the following research questions:

1. Is the DT intervention (used in the design of this study) feasible for the local hospice system?
2. In which way the study should be adapted to the local hospice setting?
3. Can this study estimate some effects in the area of psychological distress, and in quality of life (QoL) that are expected to happen in relation with the DT intervention?
4. Can this study assess the effects on psychophysical health of the caregivers (e.g., family members) of the hospice patients that are expected to happen with the DT intervention?

2.3. Justification of the innovative character of the study

Although many hospice patients suffer from psychological distress (anxiety and depression), they are usually not aware of potential benefits of the DT intervention. According to the scientific literature, implementation of DT, as one of the components of comprehensive palliative care, represents a manageable therapeutic approach to hospice population that might, to some extent, improve coping with end of life psychosocial distress, and alleviate mental and spiritual suffering. Therefore, DT—as an innovative, simple, safe, patient-friendly, and

cost-effective option to fulfill unmet needs among growing population of hospice patients—deserves an analysis in research. Moreover, it can be expected that in the future, depending on the preliminary study results, a possible implementation of DT, as a supportive care option, added to standard palliative care, could bring some beneficial effects for many suffering patients at the end-of-life stage in Eastern and Central European countries.

2.4. The importance of the study results for the development of scientific discipline and civilizational progress

The results of the proposed project (as evidenced in a recent, substantial body of scientific literature in this field) will have a significant impact on the development of several scientific disciplines, such as psycho-oncology, psychology, medicine, nursing, rehabilitation, pedagogy, humanistic, or social sciences, as well as general civilizational progress, civilizational progress oriented on universal human values.

In addition, research infrastructure, created in this study, will provide a unique opportunity for education and training of students and postgraduates in psycho-oncology and related disciplines. Moreover, the project will create a support network and educational center for caregivers ("care for the caregivers"), hospice personnel and volunteers, as well as students or postgraduates, working on their MS degrees in the above-mentioned medical, psychological, social, pedagogical, or other disciplines related to the health care. On the basis of the above facts, exploring DT intervention as a potential component of multidisciplinary palliative care is justified in the hospice setting and merits support. In conclusion, research studies (both pilot and RCT) investigating various aspects of DT (in form of the CV intervention) should have a chance of being conducted in hospice patients in Eastern and Central Europe.

3. The main concept and aims of the pilot study

3.1. Dignity therapy: a concept of the study

A concept of the study is dignity therapy (DT), which has international scientific recognition (as safe and effective supportive therapy), but is unknown in Eastern and Central Europe and should be explored in research (e.g., first in a pilot study and then in RCT) among hospice patients in Eastern and Central European countries.

The pilot study will collect preliminary data, prior to conducting a larger randomized controlled trial (RCT) that will investigate the correlations (impact) of dignity therapy (DT) intervention with quality of life (QoL), and possible reduction of distress and suffering in the Eastern and Central European hospice patients. Also, for caregivers of the study patients, the effects of DT intervention, in relation to their psychophysical health condition, during bereavement will be explored. Simultaneously, the caregivers will be asked to provide their opinions about the DT intervention.

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For the purpose of this study, a form of DT intervention, which is also called "Calendarium Vitae" (CV), involves both patients and (whenever possible) caregivers (participating as a team: patient and caregiver). The patients will be asked questions about their most important achievements, roles, and other important aspects of their life. In addition, CV intervention encourages patients to saying things to their loved ones that have remained unsaid. At the same time, CV invites the caregivers to contribute to the creation of the DT final document (CV album) that will be a "treasure" for the family and friends during bereavement.

3.2. The primary aims of this pilot study

The primary aims of this pilot study are as follows:

- Test feasibility of the dignity therapy (DT) before conducting a larger randomized clinical trial (RCT) among hospice patients in Eastern and Central European countries.
- Adapt the DT intervention to local health care circumstances (Eastern and Central European hospice patients).
- Learn the caregiver perspectives with regard to the benefits and possible concerns of DT intervention, when provided as a therapeutic procedure, added to palliative care.

3.3. The particular goals of RCT

The particular goals of RCT are as follows:

- To examine whether the addition of dignity therapy (DT) in form of the Calendarium Vitae (CV) to standard palliative care (PC) could reduce psychological distress (anxiety and depression) and augment quality of life among the hospice patients (Pts) in Eastern and Central European countries.
- To test whether the addition of the CV intervention (to standard PC for the patients) could influence their caregiver's psychophysical health.
- To conduct a follow-up assessment of the caregiver psychophysical health (post 6–12 months).

These findings will be compared to the results of the control group receiving standard PC.

3.4. A possible adaptation of the pilot study into Eastern and Central European hospice setting: initial plan of the study

It is estimated that in this study, a total of about 100 patients diagnosed with an advanced neoplastic disease and poor prognosis (life expectancy < 6 months), who receive palliative care in the hospice, will be randomly assigned to either DT (CV) or PC in a 1:1 ratio. Patients will be prescreened and included to the study, if they report increased psychological distress (anxiety or depression, based on the Hospital Anxiety and Depression Scale (HADS)).

The therapy will be guided by therapists (working in teams with postgraduate students). CV consists of three tape-recorded + one final sessions. The main goal of the CV intervention is to invite patients to reflect on their most important accomplishments, roles in their lives, or other things that they would most want to be remembered. Upon completion of the intervention, the recorded sessions will be transcribed and edited to provide a clear narrative CV document (album) that can be given to a person selected by the patient (e.g., family member, friend), or donated to hospice (as an option). The proposed CV intervention, in addition to the original DT model, introduces a patient-caregiver "team" approach in which both the patient and the caregiver (usually a close family member) actively participate in creation of the final DT document (CV album) (e.g., the patient is mostly involved with the 1st, "conceptual" part, and the caregiver is helping with the 2nd "executive" part, by "gathering evidence" (such as photos, for the CV album).

4. Study methodology

4.1. Methodology and implementation of the pilot study

Study design RCT: Interventional, experimental, prospective, randomized, controlled, parallel, with a follow-up (6–12 months).

Study group (SG): Hospice patients (with caregivers, women, and men, aged >18, with preserved cognitive skills, diagnosed with advanced cancer, with life expectancy <6 months), receiving palliative care at the stationary or home hospice setting, plus DT. Control group (CG) (similar in size to the SG), hospice patients (as in SG), receiving standard palliative care at the stationary or home hospice setting.

4.1.1. Study intervention

Calendarium Vitae (CV), as a form of DT, involves patients and caregivers (as teams) asking the patients questions about their most important achievements, roles, and other important aspects of life. Simultaneously, CV invites the caregivers to contributing to the creation of the DT final document (CV album).

4.1.2. Eligibility criteria

Inclusion criteria for patients (Pts):

- Signed informed consent form
- Diagnosis of advanced cancer, with life expectancy < 6 months
- Receiving palliative care at the hospice (stationary or home)
- ≥18 years of age
- Preserved cognitive skills

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Exclusion criteria for patients (Pts):

- Cognitive impairment (e.g., dementia, delirium)
- Deterioration of illness precluding further participation in the study

Inclusion criteria for caregivers:

- Signed informed consent form
- Taking care of a close relative admitted to hospice (stationary or home), with life expectancy < 6 months
- ≥18 years of age
- A desire to alleviate suffering and distress of the terminally ill relative, beyond standard care

Exclusion criteria for caregivers:

- Physical or mental illness precluding participation in the study

4.1.3. Study outcome measures (OM) and tools

Outcome measures for hospice patients (Pts):

1. Psychological distress: measured by the Hospital Anxiety and Depression Scale (HADS)
2. Health related quality of life: (HRQol)

(Time frame: Pre-postintervention (when the final study document = CV album is received by the patient, and again 2 weeks later)

Outcome measures for caregivers:

1. Psychophysical condition: measured by General Health Questionnaire (GHQ 12) and Patient Health Questionnaire (PHQ 9)
2. Brief survey presenting caregivers' opinions about the benefits and possible concerns relevant to the dignity therapy (in form of the CV), added to standard PC

(Time frame: 1, pre-postintervention, and again 2 weeks later; 2, with the last evaluation)

The main study procedures:

Orientation meeting for the study therapists, investigators, coordinators, hospice staff, and caregivers. CV intervention includes four sessions:

1. introduction (60');
2. intake session (60');
3. editing session (60');
4. final session (60')

(each session could be extended to 2 hours, depending on the patient's condition)

All sessions will be conducted by a team, including a therapist (e.g., a psychologist, or a physician) and a student (a graduate student preparing MS thesis, or a specially trained hospice volunteer (optional))

All therapy sessions will be tape-recorded, transcribed, edited by the team and returned to the patient and the caregiver.

Construction and editing of the CV album requires a brief training session for the team members (to assure quality of care and to avoid bias)

Total duration of pilot study: 2 weeks (intervention) + 3 months follow-up.

Total duration of RCT: 2 weeks (intervention) + 6, 12 months follow-up.

Statistical analysis: descriptive statistics.

Equipment: laptops, dictaphones, paper, pens, pencils, graphic, and printing services.

4.2. Detailed description of the study operationalization: logistics of the study

4.2.1. Setting

This study will be conducted in Eastern and Central European hospice setting. Therapists (such as psychologists or physicians in collaboration with MS students, forming teams) who are interested and eligible to participate in the study and who are professionally involved with palliative care (PC) hospice settings will be invited to participate. It is estimated that the number of therapist-investigators should be approximately 2–4.

4.2.2. Investigators

Before initiation of the program, each team will receive an individual training with regard to the study design, procedures, and methodology, as described in the study protocol. In addition, every therapist-investigator will be trained in DT, in order to conduct the DT intervention.

4.2.3. Participants

Adult patients with terminal stage of cancer (<6 months prognosis) who are referred by their attending physicians (oncologists or family physicians) for palliative care (PC) hospice service and who express their interest in participation in the study will be invited as candidates, shortly after admission to hospice within the study recruitment period. The participants will be recruited from adult oncology patients, discharged from the University Hospitals or Oncology Centers.

4.2.4. Recruitment

Information about the study, together with an invitation to participate in it, will be conveyed to potential candidates, during routine hospice visits via flyers, posters, and also through

advertisements in local newspapers, and via the Internet. Interested patients (and their caregivers) will receive detailed information regarding the DT course and will be screened (with the HADS). First-inclusion and exclusion criteria will be checked in a standardized interview, and then the patients (and the caregivers) will have a brief introduction conducted by the study investigator or coordinator.

It is estimated that the number of participants screened for the study should be approximately 100, in order to enroll into the study about 10–20 patients with terminal cancer, for the study group (SG), and about 10–20 patients, for the control group (CG). Eligible candidates will sign an ICF (after explanations about the study principles and voluntary participation in it) and will be enrolled into the study, which will be commenced in the year 2017.

4.2.5. Study groups

In 2017, about 100 adult patients, who suffer from terminal cancer (diagnosed at least 3 months prior to entering of the pilot study) will be randomized to a study group or control group.

The study group (SG) (N = 10–20) will be composed of women and men with terminal cancer, with <6 months prognosis, aged >18 years, treated with a standard palliative care will receive DT intervention.

The control group (CG) (similar in size, age, diagnosis, and prognosis to the SG) will be composed of hospice patients and will receive a standard palliative care (PC) only.

Duration of the study DT intervention equals to 2 weeks, and includes: 2-week DT process, with 4 bi-weekly sessions (the study intervention = Calendarium Vitae, CV).

The patients in the SG will be obligated to:

- participation in the DT sessions; and
- filling out research questionnaires.

The patients in the CG will be receiving PC only, and filling out research questionnaires.

The pilot study participants in both groups will continue their regular, standard PC.

4.2.6. Management of randomized controlled trial (RCT) examining DT intervention among hospice patients.

After completing of the pilot study, a subsequent step of recruitment of the volunteers-participants for the RCT (DT in hospice patients) will be conducted according to the same design, by therapists-investigators in the year 2017, and continued for the consecutive steps of the project.

As in the pilot study, during the above-mentioned recruitment periods, the therapists-investigators will invite to take part in this trial, a larger number of patients with terminal cancer admitted to hospice care facility. Adult men and women (>18 years of age) with

terminal cancer and <6 months prognosis, who are interested in participation in the trial will be given information about the study, upon admission to hospice, within the trial recruitment phase.

In the process of recruiting the hospice patients-volunteers to RCT (including distribution of the trial information and pre-screening via the standardized interview and HADS), the same methodology as in the pilot study will be used.

It is estimated that the number of participants screened for the RCT should be approximately 500, in order to enroll into the trial about 50–100 patients with terminal cancer for the study group (SG) and 50–100 patients with terminal cancer for the control group (CG).

Eligible candidates, who meet the Inclusion/exclusion criteria, will sign an ICF (after explanations about the trial principles, and voluntary participation in it), and will be enrolled into the trial, which will start in the year 2018. The trial will use the same procedures (including randomization), eligibility criteria, psychometric measurements, and outcome measures, as the pilot study. In 2019, a follow-up of this trial will be conducted using the same outcome measures as the ones used in the pilot study.

4.2.7. Inclusion/exclusion criteria: (pilot study and trial (RCT))

Eligibility criteria: Inclusion/exclusion for participants (as previously listed)

Based on:

- screening interview,
- meeting of the inclusion criteria (all the responses are Yes),
- meeting of the exclusion criteria (all the responses are No), and
- signing a voluntary informed consent form (ICF),

patients who meet qualification criteria will be enrolled into the pilot study/RCT.

The data derived from the study participants will be summarized and then utilized in statistical analyses. Pilot study parameters, which will be analyzed, according to the questionnaire, prepared for the purpose of this study, will contain the following variables:

1. The participant's identification number (for confidentiality purposes)
2. Date of birth (age)
3. Gender
4. Education (higher, medium, or elementary level)
5. Place of residence (country, town)
6. Type of the cancer
7. Duration of the oncological therapy—how many years?

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8. State of health prior to a diagnosis of cancer
9. Presence of serious/chronic diseases—what kind?

With regard to caregivers of the study patients, the analogical questionnaire (with modification of items 6–9) will be used as follows:

1. The caregiver's identification number (for confidentiality purposes)
2. Date of birth (age)
3. Gender
4. Education (higher, medium, or elementary level)
5. Place of residence (country, town)
6. Type of the cancer of the relative admitted to hospice care
7. Duration of to taking care of the relative with terminal cancer—how many years?
8. State of health prior to taking care of a relative with terminal cancer, admitted to hospice
9. Presence of preexisting serious/chronic diseases—what kind?

The electronic database will be created using software program, and analyses of variables will be performed, utilizing the statistical program. Decisions regarding exclusion of the records from the statistical analyses will be made in the case of:

1. lack of the complete answers in the questionnaire form;
2. illegible or ambiguous record in the questionnaire, precluding proper evaluation of variables in statistical analyses;
3. lack of written signature of the study/trial participant (informed consent form); and
4. documented information of the therapist-investigator regarding further participation in the study.

Psychometric measurements will be taken on the day of initial survey completion, and then post-DT intervention, and again, one 2 weeks after it. The study teams will collect the data using the study clinical report forms (CRF), based on the patients' questionnaires and psychometric measurements obtained during the study visits.

DT intervention (described in detail in another section) will be offered in one hospice center and will consists of a 1–2 hour sessions, 2 times per week (for 2 weeks), during which, the participants will complete the DT final document = CV album (including "life reflection interview" that will be transcribed and revised, before final edition of the CV album). The primary focus of the DT is to have a positive reflection on life, leading to decreased psychophysical distress and suffering that should translate into better QoL. Similarly, for the caregivers, the

main focus of the DT is to be able to better cope with stress and suffering, related to terminal disease of the relative.

4.2.8. Study timeline

Schedule of the research visits.

V# 1—Orientation/introduction (0 week),

V# 2—Intake/interview (1 week),

V# 3—Revision/edition (2 weeks),

V# 4—Final (3 weeks).

Abbreviations used in the schedule: V—visit.

From a practical point of view, the pilot study and RCT will analyze the measured psychological parameters, which characterize daily distress and health-related quality of life (QoL). Similarly, for the caregivers, the parameters that characterize psychophysical health will be analyzed. These measurements are easily available and can be promptly and safely conducted in the hospice setting. In addition, the caregivers will complete a survey related to the DT intervention benefits or possible concerns.

4.2.9. Statistical analysis

SG and CG will be compared using chi-square analysis for discrete data and independent *t*-tests for continuous data on demographics and baseline variables. For each outcome measure (except the caregivers' survey), the results of the DT intervention will be compared by analyses of covariance (ANCOVA) taking the postintervention measurement as dependent values. Respective baseline value of the outcome (V1) will served as a covariate. Within the statistical model, the group variable will serve as between-subject factor, and the postintervention measures as dependent factors. Statistical significance is set at the 0.05 level. The intention-to-treat principle will be used in this study. The CV transcript will be analyzed for content. All the statistical analyses will be conducted using the statistical program.

4.2.10. Reference therapy

Usual palliative care in patients with terminal cancer includes medically indicated nonpharmacological therapy, combined with pharmacological comfort care (e.g., pain control) and holistic care, focusing on management of psychophysical and spiritual needs and personal care (e.g., skin care). Despite that many hospice patients suffer on a daily basis from loss of personal autonomy, dignity, as well as mental distress, depression, and anxiety, in addition to physical discomfort.

Safety, potential risk of the study: No risk/adverse effects to participants have been documented with regard to the DT intervention.

Study discontinuation: The participants may withdraw from the study due to any reason, without any consequences, and they will continue palliative care.

Limitations of the study: The interpretation of the results might be limited due to a small sample size.

Conflict of interests: There is no conflict of interests.

5. Conclusion

In summary, dignity therapy (DT) (based on research evidence from international studies, published in scientific literature) represents a feasible, safe, and effective, patient-friendly approach, targeting end-of-life psychological problems. DT has a unique potential to help patients with terminal stages of cancer. In particular, DT can fulfill some unmet psychological and spiritual needs, help preserve psychophysical integrity, and distress, as well as support caregivers, during the bereavement period [3, 6, 11, 13]. Since DT is unknown in Eastern and Central Europe, the proposed pilot study, followed by RCT, will be the first step on the way to explore the DT intervention in research among hospice patients in this area.

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