

## DIGNITY THERAPY RESEARCH DESIGN AND METHODS

### **OVERVIEW OF STUDY DESIGN:**

This study will use a randomized, controlled, repeated measures design to investigate the impact of Dignity Therapy, compared to Client Centered Visits and standard care, on the sense of dignity, desire for death/will to live, suffering, sense of meaning, purpose, generativity and overall quality of life for patients who are terminally ill. Patients with advanced end stage cancer, who according to their treatment team have less than a 6-month life expectancy (but are expected to live at least the duration of the average Dignity Intervention protocol i.e. about 7-10 days), and are receiving end-of-life care at one of the designated research affiliated units in Winnipeg, Canada, New York, NY, or Perth, Australia, will be deemed eligible. Patients will be recruited from both inpatient units, as well as outpatient ambulatory care settings; while some will thus been seen in a hospital setting, others will be seen in their homes. Treatment staff in the affiliated centres will be informed of the nature of the research in order to facilitate referrals. Patients who either contact or are referred for the study will be screened for study inclusion and exclusion criteria. Those who are eligible (see below) will be informed about the study, its methods, the details regarding randomization, the relevant risks and benefits, and offered participation.

Patients will also be screened to rule out overt psychotic disorders, cognitive impairment (using the the Blessed Orientation-Memory-Concentration [BOMC]) (1), and marked functional impairment (using the Palliative Performance Scale [PPS]) (2). Following the provision of informed consent, patients will be assigned a subject number and randomized to one of three study arms; Dignity Therapy, Client Centered Visits, or standard care. All participants will then be administered the baseline assessment battery, which will include demographic (age, ethnicity, education, SES, etc) and clinical data (cancer diagnosis, stage of disease). The psychometric battery will try and balance thoroughness, with sensitively to patient protocol burden, and utilize both brief single item screening approaches that are suitable to highly vulnerable dying patients, as well as some slightly longer and well validated measures of psychosocial distress. These measures include the FACIT Spiritual Well-Being Scale (a measure of spiritual well-being with 2 subscales measuring Meaning/Peace and Faith), the Hospital Anxiety and Depression Scale (HADS). We will use a single item screening approach (a method we have helped to develop and validate) to measure Sense of Dignity(3), Desire for Death(4), depression(5), suicide(3); suffering and hopelessness(3), and quality of life(6). We will also measure symptom prevalence and severity, using the modified Edmonton Symptom Assessment Scale(7) and the Patient Dignity Inventory(8). These psychometrics will be re-administered upon completion of all three study arms, along with a specific intervention satisfaction questionnaire.

Family feedback regarding the impact of the intervention on the patient and themselves will also be sought. The Dignity Therapy manuscript is usually bequeathed to a family member/friend, and it is therefore important to examine the possible salutary effects of this intervention on the bereavement experience. Each study participant will be asked to name a family member, from whom feedback regarding the study will be solicited. Family member/friend demographic data will be collected at the time the patient is recruited into the study; baseline psychosocial distress of family member participants will be measured using the Beck Depression Inventory (BDI) (given the proximity of their loved one to death, the brevity of this measure is critical). Follow-up data from family members will be solicited six to nine months following the death of the patient. The initial measures of psychosocial distress will be reapplied at that time, along with the Family Care Satisfaction Questionnaire(9). We will also use the Inventory of Complicated Grief (10) and the Core Bereavement Items(11) to examine the surviving family members of patients in all study arms, thereby allowing us to explore the differential impact of Dignity Therapy on the bereavement experience. Family members will also fill out a post-study survey, eliciting their response to their designated intervention arm.

## DESCRIPTION OF RCT STUDY ARMS

### **Dignity Therapy**

First Dignity Therapy Contact: (This is a highly abbreviated version of the fully manualized therapist guide; the approach was developed, piloted, and revised on the basis of a Phase I trial of one hundred terminally ill patients). Those patients randomised to receive Dignity Therapy will be offered an explanation for how this procedure was developed and how it works. They will be told that it is based on studies of patients who are critically ill, and our understanding of how those patients understand the notion of dignity in those particular circumstances. Furthermore, they will be told that this therapy has been piloted in about one hundred patients prior to this trial, which will now be comparing its efficacy with other forms of support.

Patients will be reminded that Dignity Therapy consists of tape-recorded sessions, which will provide them the opportunity to speak to issues that they believe are most important, and which they would want preserved as part of a legacy making exercise. These sessions will be transcribed, edited, and given back to the patient, to be given or bequeathed to a family member/friend. The editing process (described in detail below) is a critical feature of this intervention, in that it gives patients licence to share their free form thoughts, knowing that there will be a process to reorganize and rework their transcript to the extent necessary, to produce a legacy generating document that they feel is aesthetically pleasing and accurate in content; in all, a document they can feel proud of as a final statement preceding their death.

In preparation for the actual taped session(s), patients will be provided with a copy of the questions the therapy will address (see below), in order to begin considering the nature of the material they might wish to include within the session(s). A follow up meeting, to record the first therapy session, will be scheduled as soon as the patient is able and willing to do so. Optimally, this will take place within the next 24 hours.

Second Dignity Therapy Contact: Within 24 hours - and certainly no more than 48 hours - the second contact within the Dignity Therapy protocol will take place. Patients expressing particular content preferences will be invited to begin their tape-recorded Dignity Therapy session by addressing those particular themes, thoughts or feelings that they would most want to broach within the initial recorded therapy session. In our experience, this will be the minority of patients, with most willing to take instruction or be guided through a series of questions around which they can construct the therapy(12). These questions will consist of the following:

1. Tell me a little about your life history; particularly the parts that you either remember most, or think are the most important? When did you feel most alive?
2. Are there specific things that you would want your family to know about you, and are there particular things you would want them to remember?
3. What are the most important roles you have played in life (family roles, vocational roles, community service roles, etc)? Why were they so important to you, and what do you think you accomplished in those roles?
4. What are your most important accomplishments, and what do you feel most proud of?
5. What are your hopes and dreams for your loved ones?
6. What have you learned about life that you would want to pass along to others?
7. What advice or words of guidance would you wish to pass along to your [son, daughter, husband, wife, parents, other(s)]?
8. Are there particular things that you feel still need to be said to your loved ones, or things that you would want to take the time to say once again?
9. Are their words or perhaps even instructions you would like to offer your family, in order to provide help prepare them for the future?
10. In creating this permanent record, are there other things that you would like included?

Not every patient will necessarily address each of these questions in detail, and for some, specific questions may hold more interest than do others. The critical feature of this session is that it be highly flexible, to accommodate the patient's particular needs and choices. Patients will be told that upon request, the taping can be stopped at any time. For most patients, this second session will take between 45 to 75 minutes.

While this may seem a considerable period of time given the vulnerability of this patient population, our experience tells us that this time is very well tolerated. In fact, patients in the pilot study expressed little if any in the way of protocol burden. In large measure, this was because they were invited to speak only to the issues that wished to address. If there were areas of questioning that they wished to omit, or conversely areas they wished to focus on exclusively, they were invited and in fact encouraged to do so.

At the conclusion of the initial taped session, the patient will be given time to reflect on their feelings towards the experience. The research nurse will take detailed field notes of these responses, which will be content analysed as a way of further refining the intervention and protocol. The debriefing with the patient will conclude with setting a time with the next two days (as soon as possible) for a follow up (third contact) session.

The Role of the Therapist: In the tradition of other psychotherapeutic approaches, Dignity Therapy will be conducted in the context of a supportive, therapeutic alliance. ‘Care Tenor’ as described in the Dignity model, or a tone of care denoting respect, empathy and support, is particularly important for patients who are highly vulnerable in the face of a rapidly deteriorating illness. For them, the undermining of dignity is highly influenced by the texture or tone of their care. Thus, a gentle, supportive, nonjudgmental therapeutic stance is of critical importance.

The therapist’s function is to structure the intervention for patients, who in most instances will not have the energy or organizational capacity to do it for themselves. There should be a high degree of collaboration between the therapist and the patient to ensure that the patient remains actively engaged, involved, encouraged, and nurtured. The protocol questions (see above) serve as a guide for the therapist, who has the latitude to expand or contrast the scope of questioning, depending on the interest and response elicited from individual patients. The role of the therapist in facilitating this process is therefore critical. The therapist must be able to engage and guide the patient in this meaning-enhancing therapeutic intervention. In order for patients to move easily through the intervention, the therapist needs to follow the patient’s leads and yet supply the necessary structure that allows patients to easily follow sequences, provide elaboration, or make logical connections. Open-ended questions provide an initial starting point, with the follow-up questions being more specific and targeted at eliciting further details.

In Dignity Therapy, the therapist needs to be prepared to take on an active role. An illustrative metaphor is the child’s game of ‘draw by numbers’. Numbered dots are connected in sequence, enabling even the least of skilled artist to make simple, or even complex, shapes. In a similar fashion, the role of the Dignity Psychotherapist is to supply patients with the necessary ‘dots’ so to speak, in order to help them draw their particular life manuscript. By skilfully supplying the appropriate ‘dots’, the Dignity Psychotherapist will be able to facilitate the completion of a meaningful life manuscript. This can be done by soliciting further detail when necessary, or gentle prompting when needed. One technique that has proven very effective in drawing patients out is the following: “Imagine that you and I are looking at a picture book of your life. Tell me, in as much detail as you can, about some of the pictures we might see”. Asking about the people, places or events documented in these pictures often has the effect of jogging the patient’s memory, and eliciting further meaningful material, thereby guiding the patient through the process of creating their life manuscript.

Transcription: The Dignity Therapy sessions must be transcribed immediately following their completion. This should be done within no more than a 24-hour time frame. These transcriptions should be a word for word documentation of the complete interview, and be provided back to the research team as both a hard copy as well as in electronic form. The latter is critical, in that this will serve as the mechanism to begin the careful process of transcript editing. For purposes of quality assurance, three final forms of the transcript should be maintained a) the unedited complete transcript, b) a ‘tracked’ version of the edited transcript, and c) the final edited version.

Editing: Participants in the Dignity Therapy arm will be told that all transcripts will be edited by the research team, prior to their being returned to the patient, at which time they too will have an opportunity to edit the manuscript in any way they see fit. The editing process is a critical component of the intervention, in that it allows patients to speak more freely during the course of the therapy,

knowing that it will be possible to address any changes, perceived imperfections, errors of omission or commission. There are various different aspects to editing, including the following:

Basic cleaning of the transcript: This involves eliminating colloquialisms, non-starters, and portions of the manuscript not targeted in any way to generativity related material (for example, based on actual pilot cases, needing to change ones colostomy bag, the patient's indicating the wish to withdraw a joke they made in poor taste, interruptions that may have occurred during the course of the session, such as visitors, care providers, etc).

Chronology Corrections: It was common in the pilot work for patients to pick up their train of thought along different points of the interview. Most often, this occurred in the form of things being said out of sequence, with strains of earlier historical material being presented in an illogical time sequence. Corrections such as these were easy to make, resulting in a much more readable, and accessible manuscript. Grouping chronological events, and subject matter issues together greatly improved the patient and family satisfaction with the final manuscript.

Dealing with 'Ugly Stories': In our experience, there are occasions when the patient might disclose details in their therapy, which have the potential to inflict pain or cause harm to the manuscript recipients - we refer to these as the 'ugly stories'. Our practice is to address these instances with the patient at the time they occur. In every instance within the pilot study, the patients chose to withdraw these disclosures from the manuscript (e.g. disclosure of sexual abuse by a relative; disclosing a strong negative feeling toward one's child). Such content is easily eliminated; patients will be encouraged to deal with these issues face to face with their families, should they feel the need to do so.

Finding an Ending: Every interview will have innumerable instances where the patient's words could serve as an appropriate 'ending'. Given that this is a generativity, legacy making exercise, it is important for the ending to ring true to the patients overall message (such as [actual examples]: 'life has been good'; 'I wish my family all Gods blessings'; 'I wouldn't have changed a thing'). Although this is highly orchestrated, it results in a manuscript that patients feel captures their intent and as important, strikes the required, appropriate final tone.

The Patient has the Final Say: It is critical that patients have the final say regarding the full and complete content of their transcript. As such, they are invited to give feedback regarding every aspect of the transcript, from the most minor (an elderly immigrant who stated upon reviewing his transcript, "Not Bavaria, but Bulgaria"), to very major changes (e.g. a middle aged dying woman who felt she needed to say more regarding one of her two children, about whom she had said very little).

Third Dignity Therapy Contact: The timing of this session will be as proximate to the second contact session as possible. In our pilot data, this was usually two to three days. This rapid turn around time establishes the necessary ethos of 'immediacy' and 'attentiveness' that is so needed in responding to patients who are experiencing end of life distress; it also reinforces the esteem with which the patients' words are received and the value they are ascribed (reinforcing many of the themes and sub-themes in the category, Dignity Conserving Outlooks). This third contact session consists of several tasks:

Manuscript delivery and editing: Patients will be presented with the edited transcription of their taped session, and invited to review it with the therapist. We have found that having the therapist read it out to the patient in its entirety usually works very well, and gives the patient the best sense of the overall manuscript (should patients be slightly more robust and wish to do so, they may read they manuscript themselves). Any wish for editorial changes - be they minor or major - will be elicited and made, or arrangements for them to be completed as quickly as possible (within no more than a 24 - 48 hours). The generativity document will be given to the patient, for them to give to a family or loved one, as they see fit. When the document raises issues that could be of value for the family prior to the patients death as opposed to afterwards (e.g. issues that might be worked through prior to the patients death), we do not hesitate to provide gentle advise in that direction. However, we defer to the expressed wishes of the patient participants.

Patient qualitative feedback: At the time of the transcript review, patients will be asked to reflect on their experience of the Dignity Therapy intervention, by way of a piloted Dignity Therapy satisfaction questionnaire (includes both qualitative and quantitative data).

Patient quantitative feedback: Patients will be asked to complete the initial battery of psychometric instruments, including a study arm satisfaction questionnaire.

Follow up sessions: Occasionally (about 10% of patients, based on pilot experience), some patients will request an additional taped session. For these patients, arrangements to do so will be made at the

third contact session. The content of these sessions usually follows the semi-structured interview guideline - often eliciting further details, anecdotes or additional life history, while always being responsive to the patient's lead.

In order to avoid any possible response bias, two nurses will attend the final patient meeting, irrespective of which arm the patient had been randomized to. This will allow the nurse with whom they have had no prior contact, to administer the psychometric instruments soliciting information regarding their experience as a study participant, thus eliminating the potential for bias.

#### **Client Centred Supportive Patient Visits**

This arm of the study will be critical to control for the time spent between the dying patient taking part in the Dignity Therapy intervention and the study nurse-therapist. As such, patients randomised to this arm of the study will receive three visits, the first being 30 minutes (the average length of the 'First Contact' for Dignity Therapy recipients), the second taking place the following day and being 45 - 75 minutes (depending on the wishes of the patient), and a final 30 minute visit taking place two days later. These sessions will be tape-recorded, transcribed, with a randomised selection of transcripts (1:4) being reviewed by the local study PI, to ensure adherence to the protocol, and lack of contamination with the Dignity Therapy intervention themes.

The basic position of the therapist in the client centred approach is to listen, understand, and reflect what he or she perceives the patient to feel(13,14). The aim of this approach is to create an interpersonal environment in which the patient can be placed at ease, and invited to reflect on their particular thoughts or concerns. In this approach, the therapist sets three conditions that foster relaxation and engagement in the therapy. The first is congruence or genuineness, which describes an ability to be present as a person, i.e. to be real in the relationship with the client; the second is unconditional positive regard, which conveys a sense of being accepted and not judged or evaluated; the third condition is empathic understanding, which is the ability to stand in the patients shoes, or see the world from that vantage point. With these conditions being met, the client is able to feel understood, and able to accept and integrate their worldview.

The client-centered approach was chosen in order to offer an intervention that in essence, controls for the time patients are directly exposed to an empathic therapist in the Dignity Therapy study arm. The client-centered intervention offers this ability, and provides a formatted approach that can be standardized across sites. Life review is only one aspect of Dignity Therapy; many patients have little or no need to review their life story, but instead choose to share ideas, wisdom, words of gratitude or regret, extend wishes or pass along specific information, advise or directions. None of these will be entirely avoidable in the Client Centered arm of the study. However, unlike Dignity Therapy, the therapist will not be instructed to facilitate the creation of a life narrative, or to use the facilitative approaches outlined in the intervention manual. Should patients within the client centered arm spontaneously speak about these dignity content issues, the therapists role will be to listen, and respond supportively but without questioning that would encourage further elaboration. The fallback content area in the client centered approach will be 'here/now' issues; reflecting on how they are doing now, day to day challenges, how comfortable they are, practical concerns pertaining to comfort care; how they are coping, what seems to be helping, how their family is coping, what they might want done differently, etc.

In contrast to Dignity Therapy, the client-centered intervention will not consist of having the patient addressing issues, nor come up with words, that are intended for the ears of a designated recipient (other than the therapist him or her self). This is a vital difference; the notion that ones words are being spoken or bequeathed to a particular audience with whom one is closely connected, changes the texture, content, and overall poignancy of the intervention. Finally, unlike Dignity Therapy, the Client Centered approach does not include the creation of a generativity document. This document is, in essence, the culmination of the Dignity Therapy intervention. Its absence from the other two study arms make those approaches fundamentally unlike Dignity Therapy.

First Client Centred Visit Contact:

The patient will be told that they are being seen as part of a study to explore various different kinds of support that might be of benefit to patients who are critically ill. This session will focus on making general introductions, and describing the 'here-now' focus of these sessions.

Second Client Centred Supportive Visit Contact:

Unlike Dignity Therapy, client centred therapists will not initiate questions that lead the patient through a life narrative (given how this approach begins to approximate the Dignity Therapy Intervention in terms of content), nor will it entail the creation of a generativity life manuscript. A focus on 'here now' will guide the interview. Questions will include enquiry into how they are doing, how comfortable they feel, the things they are most concerned about, how they are coping; what seems to be helping them, to what extent they believe their preferences are being solicited and adhered to; what is and is not helping, and with regard to the latter, how have they tried to address that; how is their family coping, is there anything that they would want done differently.

Third Client Centred Visit Contact:

This last session will complete any remaining conversations they may have begun in the first session. Given that it is only a 30-minute session, follow up on those previously raised issues will be relatively brief. The session will also solicit feedback on the patients' experience of the intervention. This will be accomplished by way of re-administering the baseline psychometric instruments, along with a patient satisfaction questionnaire soliciting qualitative and quantitative feedback.

**Standard Palliative Care**

Patients randomised to standard care will be eligible to receive the full range of psychosocial support, and palliative care services, offered within their care facility or affiliated with their outpatient care provider(s). At the initial point of contact they will be told that we are investigating various forms of support that patients receive while in care. They will be asked to fill out an initial battery of psychometric instruments (as per the other two arms of the RCT), thereby establishing their baseline responses.

Five to seven days later (the average time frame of the two other study conditions), the initial battery of psychometrics will be re-administered, along with a satisfaction questionnaire, which solicits qualitative and quantitative data pertaining to their satisfaction with the study arm experience.

Winnipeg: Patients registered with the Winnipeg Regional Health Authority Palliative Care Program have access to a compressive range of end of life care services and professionals. The physicians affiliated with this program come from a variety of backgrounds including Medical Oncology, Neurology, Psychiatry and Family Medicine (with a Specialty in Palliative Care under the auspices of the College of Family Physicians). Nursing staff have training in palliative care, either by way of the License Practical Nurse Program, or the Registered Nurse Program. The Palliative Care Regional Coordinators largely derive from nursing, and hold a Masters Degree, or more than seven years of palliative care nursing experience.

Patients have access to a variety of psychosocial support services, including social work, psychiatric consultation (on a referral basis), clinical psychology and pastoral care. None of these, however, include the provision of Dignity Therapy, nor the creation of a generativity document. While life review can sometimes take place on an ad hoc basis, none of these supportive services contain the formatted approached contained within the Dignity Therapy protocol.

Perth: The Silver Chain Hospice Care Service adopts a holistic approach to specialized health care and support for people with a life limiting illness, and for their families and carers. Providing care in the home, this service focuses is on easing pain, controlling symptoms and providing psychosocial and spiritual support to maximize quality of life. Interdisciplinary teams deliver expert professional care. Each care team is comprised of registered nurses, care aides, doctors, chaplains, counselors and trained volunteers. The Case Coordinator, a Registered Nurse who is experienced and skilled in palliative care, coordinates the team, ensuring that care is planned and appropriate. The team meets weekly to review the way they are providing care. Clinical Nurse Consultants and a Medical Consultant are available 24 hours a day, to support the teams. Referral to the service is made by a General Practitioner (GP), a specialist or hospital

through the Silver Chain Customer Centre. The family GP can choose to remain the principal care coordinator, working with the Hospice Care Service, or can hand over responsibility to the Hospice Care team and be kept fully informed of the client's progress.

The Cancer Foundation of Western Australia Centre for Palliative Care Cottage Hospice provides short-term acute palliative care for people with a progressive illness for which there is no known cure. Admission is based on individual needs, and may be for; palliation; control of unpleasant or distressing symptoms; to provide rest for carers; or provide comfort and care during the final weeks or days of life. Support is also offered to family and friends. Expert professional care is delivered by an interdisciplinary team, made up of nurses, doctors, occupational therapists, physiotherapists, social workers, and chaplains who work together with volunteers and other staff to meet the special needs of people at this time of their lives. Referral to the service can be made by a doctor or from the Silver Chain Hospice Care Service. In both Australian services, patients have access to a variety of psychosocial support services, including social work, counseling and pastoral care. However these services do not include the provision of Dignity Therapy, or the creation of a generativity document.

Given that none of the three participating sites offer Dignity Therapy, or something approximating this interventional approach, we do not anticipate slight regional variations in palliative care to have any particular impact on the study results.

New York: New York: Patients who are cared for by the MSKCC Pain and Palliative Care Service (P&PCS) have access to a wide range of comprehensive palliative and end of life care services and professionals. The physicians in the MSKCC P&PCS are all full time, academic clinician researchers with extensive expertise in pain and palliative care, many of whom have written or contributed to the major texts in the fields of cancer pain and palliative care. This service is a multidisciplinary program of palliative care physicians, nurses, social workers, physical therapists, psychiatrists and chaplaincy. There are 5 full-time palliative care physicians led by Dr Richard Payne, M.D. Chief, Pain and Palliative Care Service. The MSKCC P&PCS is one of the foremost academic and clinic research oriented palliative care programs in the world. The physicians include neuro-oncologists, internists; palliative care specialists, anesthesiologists, and psychiatrists. The vast majority of physicians are board certified in their subs-specialties and in pain management and palliative care. Nursing staff has extensive experience and training in palliative care, again being primarily academicians and clinicians who have written or contributed to the major texts in palliative care nursing. Patients have access to a variety of psychosocial support services, including a full time social worker and psychiatric consultation, by referral, as well as art therapy and chaplaincy services. None of these services include the provision of Dignity Therapy, nor the creation of a generativity document.

## **SUBJECTS**

This randomized control trial of Dignity Therapy will be run out of three sites, with Winnipeg, Canada serving as the coordinating centre. The other two sites will include Perth, Australia and New York, New York. The Canadian and Australian sites conducted the background work leading to the creation of the Dignity Model, as well as the development and refining of the Dignity Therapy protocol. A United States site has been added for the following reasons: 1) it is important to examine the application of this approach in an American site; 2) there is a long standing collaborative affiliation with Dr. Breitbart and the Psychiatry Service at Memorial Sloan Kettering; 3) Dr. Breitbart will bring a complementary set of skills and talents to this team and this work. The participation of these three centers will ensure that the sample size can be retrieved within a limited time frame, and will establish the efficacy and generalizability of the intervention across a broad range of end of life care facilities.

Winnipeg: In Winnipeg, Dr. Chochinov will serve as the overall study co-ordinator, and the local Principal Investigator. He and his research group developed and piloted the Dignity Therapy intervention over the course of the last three years. For the proposed study, Dr. Chochinov and his local research team will draw upon dying patients admitted to the Riverview Health Centre and the St. Boniface General Hospital Palliative Care Units in Winnipeg (serving approximately 500 patients per year). The average length of stay for these patients is 13 days. These inpatient facilities are largely but not exclusively comprised of patients with end stage cancer, and both units have participated in Dr. Chochinov's research for over 10 years.

Outpatients will be drawn from patients who are registered with the Winnipeg Regional Authority Palliative Care subprogram. This program registers about 1,100 new patients annually, with about 950 deaths per year.

Perth, Australia: Dr. Linda Kristjanson will serve as the local Principal Investigator in Perth, Australia. Over the past 18 months she has supervised three research nurses, in their administration of Dignity Therapy as part of the pilot study. Her team has recruited nearly 30 patients as part of this pilot work. Patients for the current RCT will be recruited in Perth from two settings. The first is a 20-bed inpatient, freestanding hospice, funded by the Cancer Foundation of Western Australia. Approximately 400 patients receive palliative care services for advanced cancer each year in this facility. The majority of these patients are admitted for terminal care, although some are admitted for respite or for symptom management with an expectation that they will return home. The average length of stay for those admitted for terminal care is approximately 6 days. Those admitted for respite or symptom management and subsequent discharge home have a mean length of stay of 11 days. The second site that will be involved for recruitment of patients will be the Silver Chain Home Hospice Service. Approximately 500 patients at any one time receive palliative care services in their own homes. The majority of these patients have an advanced cancer diagnosis. The average length of stay for patients receiving care through this service is 60 days. Both clinical settings have participated in numerous palliative care research projects headed by Dr. Kristjanson, and have demonstrated ability to recruit and administer the Dignity Therapy Intervention.

New York, New York: Dr. William Breitbart will serve as the local Principal Investigator in New York City, and will recruit inpatients and ambulatory care patients affiliated with the Pain and Palliative Care service located at Memorial Sloan Kettering Cancer Center. Memorial Sloan-Kettering Cancer Center was founded in 1884, and is the largest privately owned cancer center in the world. Memorial Hospital, the patient arm of Memorial Sloan-Kettering Cancer Center, provides cancer care to the entire metropolitan New York City area. In 1999, Memorial Hospital had 8464 new patients receiving care and more than 21,000 patients receiving care overall. In 1999, the hospital provided over 320,000 ambulatory care visits. Approximately 39% of the patients treated at Memorial Hospital have advanced cancer (stage III or IV disease). For the purposes of this study, recruitment will derive from inpatient and ambulatory care patients affiliated with the Pain and Palliative Care Service located at Memorial Sloan Kettering Cancer Center (see Recruitment).

### **Criteria for Patient/Subject Eligibility**

#### Patient/Subject Inclusion Criteria

- 1) The patient must be at least 18 years of age (because of the nature of Dignity Therapy, which presumes a relatively advanced level of social and psychological development, subjects under the age of 18 will be excluded from study participation). This intervention was developed for and piloted amongst adult patients. One cannot assume that the psychological and existential issues facing dying younger patients (and thus the therapeutic approach being tested) would be identical or even salient.
- 2) Have a terminal illness (a prognosis of less than 6 months, but expected to live at least 7 to 10 days i.e. the average length of the protocol);
- 3) Must be able to identify a family member who agrees to participate in the study (in the case of Dignity Therapy, this family member will receive the generativity document).
- 4) Be able to read and speak English (patients who are visually impaired will be offered assistance with the consent forms and surveys);
- 5) Have an end stage cancer that is being treated/managed either within one of the PIs' (HMC; LK, WB) research affiliated hospitals or the associated outpatients/ambulatory care programs.
- 6) Be able to provide valid, informed consent.

#### Patient/Subject Exclusion Criteria

- 1) Significant psychiatric disturbance sufficient to preclude participation in a psychotherapeutic intervention (e.g. acute, severe psychiatric symptoms which would require individual treatment and medication management rather than a psychotherapy intervention). Patients will be excluded from the study if they have an active psychotic mental disorder (e.g., schizophrenia, acute mania),



- or marked paranoid ideation. Patients who are on stable regimens of psychotropic medications (e.g. antidepressants for clinical depression) or who are in concurrent individual or group psychotherapy will not be excluded.
- 2) Presence of a cognitive disturbance (i.e. delirium or dementia i.e. >16 on the BOMC) sufficient to preclude obtaining meaningful informed consent, participation in psychotherapy, and/or data collection.
  - 3) Physical limitations or illness severity sufficient to preclude participation in psychotherapy.

### **SELECTION, TRAINING AND SUPERVISION OF STUDY PERSONNEL**

Winnipeg and Perth currently have highly trained staff who are well versed in administering the Dignity therapeutic intervention. Additional staff will be hired to carry out the client centred intervention, as described in the protocol. The local site PI will carry out any necessary hiring. Any additional new staff required to carry out the psychotherapy intervention will be trained by the Principal Investigator (HMC), and provided with a full treatment manual detailing the intervention. These individuals will either be highly experienced palliative care nurses, doctoral level clinical psychologists, social workers, or post-doctoral psychiatry or psychology fellows/graduate students. Ongoing supervision will be provided by way of initially direct observation, and ongoing review of the interview transcripts (by local PI, and HMC). There will also be ongoing telephone, AV conferencing, and e-mail feedback.

### **ADHERENCE TO INTERVENTION FORMAT**

The Dignity Therapy and Client Centred Supportive Visit arms will be audio taped and transcribed, with prior consent of the participants. Research staff will be provided with corrective feedback regarding any perceived violations of the prescribed format. Each of the Dignity Therapy interviews will be transcribed, and later edited; the original, tracked, and finally edited versions will each be reviewed by the site PI, and the Principal Investigator (HMC), thereby ensuring that the intervention is being carried out in accordance with the prescribed protocol. Regular feedback will be provided, to ensure adherence to the protocol and quality assurance. To standardize this evaluation process, we have devised a Dignity Therapy Adherence form (see appendices). Adherence will be determined on the basis of scoring at least 7 out of 10 on this form. Scores of less than 7 will precipitate a review with the nurse therapist, to ensure appropriate remedial action is taking. Transcripts scoring under 7 will be excluded from the data analysis. A random sample of the Client Centred Visit transcripts (1:4) will be reviewed by the Principal Investigators at each site, to ensure adherence to the prescribed intervention format, and lack of contamination with the Dignity Therapy intervention. The Dignity Therapy Adherence form will serve as a guide to monitor for contamination.

### **DIGNITY RCT STUDY MEASURES**

Following the provision of informed consent, patients will be assigned a subject number and randomized to one of three study arms; Dignity Therapy, Client Centered Visits, or standard care. All participants will then be administered the baseline assessment battery, utilizing both brief single item screening approaches that are suitable to and necessary for highly vulnerable dying patients, as well as some slightly longer and well validated measures of psychosocial distress for patients with advanced malignancies. The General Health Status, and measures of depression, dignity and meaning/purpose Questionnaires, will be re-administered following the completion of whichever study arm the patient has been assigned to, along with a previously piloted, post study intervention satisfaction survey.

Six to nine months following the death of the patient, family members will be re-contacted to provide further feedback. The individual who has been bequeathed the Dignity Therapy Document or, in the case of the other two study arms, an identified close family/friend contact (permission to do so having been obtained as part of the consent process), will be asked to respond to a previously piloted, post intervention study arm Family Feedback Survey, the BDI, the Inventory of Complicated Grief(10), the Core Bereavement Items(11) and the Palliative Care Family Survey(9).

1. Socio-demographic Questionnaire: Socio-demographic information will be obtained for all patients and families at the baseline assessment, consisting of questions concerning age, gender, ethnicity, education, employment history, marital status and household composition, and religious affiliation and practices.

2. General Health Status, Quality of Life and Social Support:

- a) The Modified Edmonton Symptom Assessment Scale (ESAS): This multi-dimensional instrument consists of a series of visual analogue scales, and measures symptom distress across a broad range of common sources of distress in highly vulnerable patients(7). We have extensive experience using this modified ESAS (which includes a 'Will to Live' visual analogue), and have published our findings broadly(15).
- b) The Quality of Life Scale: The Quality of Life Scale (QLS) is a 2-item scale formatted using a 10-point Likert-type scale: one question rating the quality of the patient's life and a second rating the patient's satisfaction with his/her current quality of life(6).
- c) Palliative Performance Scale(2). The Palliative Performance Scale (PPS) is a valid, reliable functional assessment tool developed by Victoria Hospice that is based on the Karnofsky Performance Scale. This tool provides a framework for measuring progressive decline in palliative patients.
- d) The Blessed Orientation-Memory-Concentration (BOMC) (1). Scores of >16 will be excluded from study participation(1). Subjects with less significant degrees of impairment will be included in the study, providing they can give valid informed consent, and are intact enough to participate in a brief psychotherapeutic intervention.

### 3. Measures of Well Being Depression, Dignity and Meaning/Purpose:

- a) The Dignity Single item screening instrument: This item, developed by Wilson et al and modelled on the format of the SADS interview, has been used extensively by our group in our prior research addressing the issue of dignity. We have administered it to hundreds of palliative care patients, and have found it to be easily tolerated by this patient population(16).
- b) The Desire for Death, Depression, and Suicide single item screening instruments: These items are based on the SADS interview; our group has reported extensively on their use and the co-morbidity between desire for death and other causes of symptom distress amongst the dying (17,4,5).
- c) The Suffering and Hopelessness single item screening instruments: These items, also developed by Wilson et al (2000), have been modelled on the SADS interview and shown to be easily administered to highly vulnerable patients with advanced malignancy, with excellent inter-rater reliability ( $r = 0.93-0.98$ ).
- d) FACIT Spiritual Well-Being Scale (SWBS): The FACIT Spiritual Well-Being Scale is a brief self-report measure designed to assess the nature and extent of individual's spiritual well-being(18, 19). This measure, which generates two sub-scales, one corresponding to Faith (the importance of faith/spirituality) and a second assessing Meaning /Peace (one's sense of meaning and purpose in life), has been demonstrated to have strong internal reliability for both the total score as well as each subscale (coefficient alpha = .87 for the total scale, .88 for the faith factor and .81 for the meaning factor).
- e) Hospital Anxiety and Depression Scale (HADS): This is a 14 item self-rated questionnaire, containing Depression and Anxiety Subscales of seven items each. It is considered particularly useful for patients with chronic disease because of the absence of somatic items that often confound the determination of psychiatric problems among the medically ill. Reported anxiety and depression cutoff scores on the HADS have varied from eight(20) to eleven(21). Total cutoff score for psychological distress has varied from 13 to detect adjustment disorders to 19 to detect major depressive disorders(22). Ibbotson and colleagues' (1994) study found that an overall cutoff score of 15 or greater resulted in 80% sensitivity, 76% specificity, and a positive predictive value of 41%. Strong test-retest reliability is reported in a large sample of elderly patients(23) and patients with AIDS(24).
- f) The Patient Dignity Inventory (see appendices) (8). The 25-items of the PDI derive from a model of dignity in the terminally ill. Cronbach's coefficient alpha for the PDI was 0.93; the test-retest reliability was  $r = 0.85$ . Factor analysis resulted in a five-factor solution; factor labels include Symptom Distress, Existential Distress, Dependency, Peace of Mind, and Social Support, accounting for 58% of the overall variance. Evidence for concurrent validity was reported by way of significant associations between PDI factors and concurrent measures of distress. The PDI is a valid and reliable new instrument, which could assist clinicians to routinely detect end-of-life dignity-related distress.

### 4. Post-study intervention satisfaction survey (see appendices).

## 5. Family Satisfaction/Bereavement Outcome Measures

- a) Dignity Therapy-Family Feedback Questionnaire: This questionnaire is a modification of a questionnaire used in our pilot study. It has been changed to obtain family member(s) feedback on the influence of this intervention, and includes questions about, i) mechanical issues such as where the manuscript is kept, who has read it, how often it has been read, how many copies have been made; ii) what influence family members feel it had on their loved one; iii) what influence family members feel it has had on their loved ones professional care provider(s); iv) what influence family members feel it has had on them personally. While this questionnaire solicits quantitative data, it also invites more open-ended qualitative feedback, which will be hand written and content analysed.
- b) Beck Depression Inventory(25,26): This self-report scale measures various symptoms, affects and thoughts characteristic of depression. It yields a score that corresponds to the patient's severity of depression at the time of assessment. Inter-item reliability coefficients range from .81 to .86. Concurrent validity has been demonstrated by significant correlations between psychiatric rating of depression and BDI scores ( $r=.60$  to  $.74$ ) (given to family members only)
- c) Inventory of Complicated Grief(10): Data for this scale were derived from 97 conjugally bereaved elders who completed the ICG, along with other self-report scales measuring grief, depression, and background characteristics. Exploratory factor analyses indicated high internal consistency and test-retest reliability. This scale has demonstrated internal consistency, and convergent and criterion validity, provides an easily administered assessment for symptoms of complicated grief. The ICG total score's association with severity of depressive symptoms and a general measure of grief suggested a valid, distinct, assessment of emotional distress. Respondents with ICG scores  $> 25$  are significantly more impaired in social, general, mental, and physical health functioning and in bodily pain than those with ICG scores  $\leq 25$ .
- d) Core Bereavement Items(CBI): As part of a longitudinal study of bereavement phenomena in three groups (bereaved spouses, bereaved adult children and bereaved parents) scale development was carried out using a pool of bereavement phenomenology questions administered prospectively. Factor analysis yielded three subscales, which formed the basis of a single measure, labeled the Core Bereavement Items (CBI) (11). This CBI has been shown to demonstrate high reliability and sound face and discriminant validity. In a cohort of 115 bereaved subjects (43 spouses, 39 adult children, and 33 parents) followed prospectively over 12 months following the acute bereavement period, the Core Bereavement Items, at each time point for each group, correlated significantly with scores on the Zung Depression Scale, state and trait anxiety, and neuroticism (27).
- e) Palliative Care Family Survey(9): The FAMCARE Scale was developed to measure family satisfaction with advanced cancer care. It is based upon qualitative research identifying the most salient indicators of family satisfaction. The FAMCARE scale has demonstrated internal consistency estimates of 0.93 at two testing times, a test-retest correlation of 0.91, and estimates of criterion validity using the McCusker Scale of 0.80 and 0.77. It appears to be psychometrically sound and useful for measurement of family satisfaction with advanced cancer care.

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## Dignity Therapy Adherence Form

1. Did the therapist ask questions as per the Dignity Therapy protocol?	Yes _____	No _____
2. Was the therapist flexible to include content areas as directed by the patient?	Yes _____	No _____
3. Was the therapist respectful to the patient's direction about content areas they wished not to have included in the generativity document?	Yes _____	No _____
4. Was the tone of the intervention respectful, and the therapist non-judgmental in attitude?	Yes _____	No _____
5. Did the therapist use elaborative techniques (as defined in the Dignity Therapy Manual) to elicit further detail when needed?	Yes _____	No _____
6. Was the sequence of contacts as per the Dignity Therapy protocol?	Yes _____	No _____
7. Was the participant prompted to designate at least one recipient of the Dignity Therapy generativity document?	Yes _____	No _____
8. Was the editing process carried out in accordance with the Dignity Therapy protocol?	Yes _____	No _____
9. Was the participant given ample opportunity to make changes to the generativity document?	Yes _____	No _____
10. Was the generativity document read to the patient in its entirety?	Yes _____	No _____
Total Score:	_____ out of 10	

## Patient Dignity Inventory

For each item, please indicate how much of a problem or concern these have been for you within the last few days.

	Not a problem	A slight problem	A problem	A major problem	An overwhelming problem
1. Not being able to carry out tasks associated with daily living (e.g. washing myself, getting dressed).	1	2	3	4	5
2. Not being able to attend to my bodily functions independently (eg. needing assistance with toileting-related activities).	1	2	3	4	5
3. Experiencing physically distressing symptoms (such as pain, shortness of breath, nausea).	1	2	3	4	5
4. Feeling that how I look to others has changed significantly.	1	2	3	4	5
5. Feeling depressed.	1	2	3	4	5
6. Feeling anxious.	1	2	3	4	5
7. Feeling uncertain about my health and health care.	1	2	3	4	5
8. Worrying about my future.	1	2	3	4	5
9. Not being able to think clearly.	1	2	3	4	5
10. Not being able to continue with my usual routines.	1	2	3	4	5
11. Feeling like I am no longer who I was.	1	2	3	4	5
12. Not feeling worthwhile or valued.	1	2	3	4	5
13. Not being able to carry out important roles (e.g. spouse, parent).	1	2	3	4	5
14. Feeling that life no longer has meaning or purpose.	1	2	3	4	5
15. Feeling that I have not made a meaningful and/or lasting contribution in my life.	1	2	3	4	5
16. Feeling that I have 'unfinished business' (e.g. things that I have yet to say or do, or that feel incomplete).	1	2	3	4	5
17. Concern that my spiritual life is not meaningful.	1	2	3	4	5
18. Feeling that I am a burden to others.	1	2	3	4	5
19. Feeling that I don't have control over my life.	1	2	3	4	5
20. Feeling that my health and care needs have reduced my privacy.	1	2	3	4	5
21. Not feeling supported by my community of friends and family.	1	2	3	4	5
22. Not feeling supported by my health care providers.	1	2	3	4	5
23. Feeling like I am no longer able to mentally cope with challenges to my health.	1	2	3	4	5
24. Not being able to accept the way things are.	1	2	3	4	5
25. Not being treated with respect or understanding by others.	1	2	3	4	5