A feasibility study of dignity therapy in patients with stage IV colorectal cancer actively receiving second-line chemotherapy

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Background Randomized controlled trials support the use of dignity therapy (DT) in palliative care patients late in the course of their disease, but little is known about the feasibility of DT earlier in the course in patients with incurable malignant disease who are still receiving chemotherapy.

Objectives To assess the feasibility of DT relatively early in the disease trajectory (primary end point) and the effect on death acceptance, distress, symptoms, quality of life, peacefulness, and advanced care planning (secondary outcome end point).

Methods Stage IV colorectal cancer patients who progressed on first-line chemotherapy were enrolled. Patients received DT over 2 visits and had outcome measures assessed pre-DT, immediately post-DT and 1 month post-DT.

Results 15 of 17 patients (88%) who were approached enrolled in the study. Most of the patients who completed DT reported being satisfied and felt it was helpful, that it increased their sense of meaning, that it would be helpful to their family, and that it increased their sense of dignity, their sense of purpose, and their will to live.

Limitations This is a small study that lacks power for statistical significance of findings. There is no control group for comparison.

Conclusions DT is a highly feasible, satisfying, and meaningful intervention for advanced colorectal cancer patients who are receiving chemotherapy earlier in the course of their disease and may result in an understanding of disease and goals of care at the end-of-life. Larger feasibility and exploratory studies are warranted in advanced cancer patients.

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Although dignity has been variously defined, it has a high importance for all persons dealing with serious illness. Loss of dignity has a strong association with anxiety, depression, requests for a hastened death, hopelessness, feelings of being a burden, and an overall poor quality of life (QoL). 1-8 Dignity therapy (DT) is a structured psychotherapeutic interview that allows people to create a permanent document that focuses on life review, meaningful relationships, and words of comfort to loved ones. In terminal patients who are no longer receiving chemotherapy, this intervention improved most patients' sense of dignity, purpose, and meaning, and also reduced depression and self-reported suffering. 9 A large randomized controlled trial in a similar terminal population that received DT found improvements in QoL, a lessening of sadness or depression, improved spiritual wellbeing, and self-reported dignity. In addition, it was also helpful to family members and changed the way the person was seen and appreciated by the family. 10 DT is now seen as a viable and widely used psychotherapeutic intervention in the palliative care population. Little is known about the feasibility or impact of DT earlier in the course of patients with advanced incurable malignant disease, such as metastatic colorectal cancer, who are still receiving active second-line chemotherapy. An earlier focus on DT may allow for improved quality of care and outcomes for patients and families earlier in the illness trajectory.

In addition to assessing feasibility as our primary outcome, we hypothesized that engaging patients in DT may also better prepare them for their eventual deaths and thereby improve their acceptance of that event possibly changing their end-of-life goals of care. It is clear that having death acceptance, or terminal illness acknowledgement (TIA), leads to less anxiety and depression at the end of one's life. 11-12
and also to less aggressive choices for end-of-life care.\textsuperscript{13}\textsuperscript{17} Yet, more than one-third of cancer patients do not have this death acceptance, even in their last month of life.\textsuperscript{11} DT is a gentle and caring exercise that brings to light the terminal nature of the patient’s disease. In this respect, it can be considered a type of end-of-life conversation. A prospective, longitudinal, cohort study of advanced cancer patients, including 15\% with metastatic colorectal cancer, found that previous end-of-life conversations with patients was associated with an increase in TIA (52.9\% vs 28.7\%; $P \leq 0.001$), an increase in do-not-resuscitate orders (63\% vs 28.5\%; $P \leq 0.001$), an increase in preference for comfort care over life-extending therapy (85.4\% vs 70\%; $P \leq 0.001$), longer hospice enrollment and subsequent improved patient reported QoL, and decreased caregiver major depressive disorder during the bereavement period.\textsuperscript{16} Therefore, we investigated the effect of DT on death acceptance, distress, symptoms, quality of life, peacefulness, and scenario-based treatment choices in this population.

Materials and methods

Eligibility criteria

The participating patients had to have metastatic stage IV colorectal cancer. They had to have been receiving chemotherapy within 2 months after progression on first-line therapy at the Robert H Lurie Comprehensive Cancer Center in Chicago, Illinois. They must have been either cognitively intact as judged by the primary oncologist, have an Eastern Cooperative Oncology Group Performance Status of 2 or less, and be aged 18 years or older. This study was approved by the institutional review board (IRB). All of the patients had to give signed, informed consent to be registered in the study.

Outcomes

The primary endpoint of this study was to determine the feasibility of DT in patients who were undergoing active palliative chemotherapy. The secondary endpoints included assessing changes in death acceptance, distress, symptoms, QoL, peacefulness, and scenario-based end-of-life goals of care, and treatment choices before and after DT treatment for each patient.

Measures

Feasibility was assessed by the success rate of enrollment as well as with a satisfaction survey at the end of the intervention. Satisfaction was assessed as previously reported with DT, using a 0–7 Likert scale for responses to the following: [level of] Satisfaction; [level of] Helpfulness; I have an increased sense of dignity due to the therapy; I have an increased sense of purpose due to the therapy; I have an increased sense of meaning due to the therapy; I have an increased will to live due to the therapy; and I believe this has or will help my family.\textsuperscript{9}

Death acceptance was assessed using the TIA, which asks patients, How would you describe your current health status? with the following responses: 1 = Relatively healthy; 2 = Seriously but not terminally ill; 3 = Seriously and terminally ill. Positive acknowledgment was considered with an answer of 3.\textsuperscript{13} Distress was assessed using the Distress Thermometer on a 0–10 Likert scale that has been validated in cancer populations.\textsuperscript{17} Symptoms were assessed using the Edmonton Symptom Assessment System,\textsuperscript{18} and QoL was assessed using a 2-item QoL scale.\textsuperscript{19}

Peacefulness was assessed by asking patients, To what extent do you feel deep inner peace or harmony?, with answers on a 6-point Likert scale ranging from 1 = Never or almost never to 6 = Many times a day.\textsuperscript{20} Positive peacefulness was defined for answers of 3 or higher. In addition, peaceful awareness was defined by patients who answered 3 for TIA and 3 or higher for peacefulness.\textsuperscript{21}

A standardized and validated Hypothetical Advanced Care Planning Scenario (H-CAP-S) was used to assess scenario-based goals of care and treatment preferences. The patients were asked to complete the following sentence: If I have a terminal illness with weeks to live, and my mind is not working well enough to make decisions for myself, but I am sometimes awake and seem to have feelings, then my goals and specific wishes – if medically reasonable – for this and any additional illness would be … .\textsuperscript{22} Goals of care were elicited by having the patient choose from the following options: Prolong life, Treat everything; Attempt care, but reevaluate often; Limit to less invasive and less burdensome interventions; or Provide comfort care only. Patients who answered Prolong life, Treat everything; or Attempt care, but reevaluate often, were labeled as having life-prolonging goals of care, whereas patients who answered Limit to less invasive and less burdensome interventions or Provide comfort care only, were labeled as having non-life-prolonging goals of care.

Treatment preferences were elicited by having the patient choose either I want; I want treatment tried. If no clear improvement, stop (only for mechanical ventilation); I am undecided; or I do not want in regard to cardiopulmonary resuscitation (CPR), mechanical ventilation (MV), and antibiotics. Patients were considered as making life-prolonging treatment choices if they selected I want or I want treatment tried. If no clear improvement, stop (only for mechanical ventilation) for either CPR or MV. Patients were considered as making non-life-prolonging treatment choices if they selected I do not want to both CPR and MV. Patients who selected I am undecided to either CPR or MV were categorized as Undecided. Given that intensive care at the end of life is an emerging quality measure in oncology care, we based this designation only on preferences for CPR or MV and not antibiotic choice. In this H-ACP-S,
TABLE 1 Dignity Psychotherapy Question Protocol

<table>
<thead>
<tr>
<th>Question</th>
<th>#1 Consent Demographics Baseline measures</th>
<th>#2 Dignity therapy (Interview)</th>
<th>#3 Dignity therapy [Read back] Satisfaction Survey Repeat Measures</th>
<th>#4 Repeat measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>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?</td>
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<td>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?</td>
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<td>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?</td>
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<tr>
<td>What are your most important accomplishments, and what do you feel most proud of?</td>
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<tr>
<td>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?</td>
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</tr>
<tr>
<td>What have you learned about life that you would like to pass along to others? What advice or words of guidance would you wish to pass along to your [son, daughter, husband, wife, parents, other[[]]?</td>
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</tr>
<tr>
<td>Are there words or perhaps even instructions that you would like to offer your family to help prepare them for the future?</td>
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</tr>
<tr>
<td>In creating this permanent record, are there other things you would like included?</td>
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<td></td>
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</tbody>
</table>

goals of care preferences have a good predictive value for specific treatment options, especially the extremes of treat all and comfort.23

Protocol for enrolled patients

Figure 1 shows the study schema. After the patients were enrolled, information was collected including: age, sex, race/ethnicity, years of education, marital status, religion (Catholic, Protestant, Baptist, Jewish, Muslim, Pentecostal, Other, None), living situation (home, independent living facility, nursing home), primary caregiver (spouse, partner, children, sibling, parent, friend, none, other), and reported discussions with their oncologist about advanced-care planning, prognosis, curability, and goals of chemotherapy treatment. In addition, they completed questionnaires to provide baseline measures. These included: TIA, Distress Thermometer, ESAS, 2-item QOL, Peacefulness, and the H-CAP-S.

At the conclusion of their first visit, the patients were given the Dignity Psychotherapy Question Protocol (Table 1) to review before their first dignity therapy session. The DT intervention followed the DT manual supplied at the dignity therapist training. Within 2-3 weeks of enrollment, depending on patient scheduling and preferences, the patient met for the first session of dignity therapy with a trained dignity therapist. This consisted of an open-ended conversation covering the questions in Table 1 and audio recording the entirety of the conversation. After completion of the questions, the recorded session was transcribed and edited by the dignity therapist, with the following plan for developing a written record of the session: basic clarifications (eliminating colloquialisms, nonstarters, and portions of the transcript not related to generativity material [eg, needing to change a colostomy bag, interruptions that occurred during the course of the session such as visitors, care providers, and so on]), chronological corrections (it was common for patients to say things out of sequence or present their thoughts in an illogical order), tagging and editing any content that might inflict significant harm or suffering on the transcript’s recipient or recipients (these edits were always discussed and reviewed with the patient), and finding a statement or passage within the transcript that provided an appropriate ending (given that this was a generativity, legacy-making exercise, the ending needed to be appropriate to the patient’s overall message [eg, Life has been good, I wish my family all God’s blessings, I wouldn’t have changed a thing]). This transcribing and editing process would yield manuscripts that patients would feel captured their intent and achieved the appropriate final tone.

Within 2-3 weeks of the first session (although possibly up to 6 weeks, depending on patient preferences and scheduling), a second session was held with the dignity therapist during which the written transcript was read to the patient to ensure the document’s accuracy and give the patient the chance to make stylistic changes or add or remove details. Directly after the second session, patients completed questionnaires, including the Satisfaction Survey, TIA, Distress Thermometer, ESAS, 2-item QOL, Peacefulness, and the H-CAP-S.

The final written transcript that included all of the patient’s edited points was returned to the patient after the document was finalized. About 1 month after the final dignity therapy session, the patient would repeat the questionnaires relating to TIA, Distress Thermometer, ESAS, 2-item QOL, Peacefulness, and the H-CAP-S.
Analysis
Descriptive statistics were used for the primary and secondary outcomes in this study because of the small number of patients who participated. Physical symptoms (pain, tiredness, nausea, drowsiness, appetite, dyspnea) and emotional symptoms (anxiety, depression, sense of wellbeing, QoL rating, satisfaction with QoL, distress) were assessed by comparing changes in the symptoms from baseline to immediately post-DT and 1 month post-DT for each patient and were categorized as either Worse, Better, or No change. Clinical outcomes (death acceptance and H-CAP-S separated into preferences for goals of care and preferences for treatment options) were assessed by calculating the percentage of patients at each time point by their category.

Results
Between September 1, 2010 and November 7, 2011, 17 patients were approached about participating in the study, and 15 (88%) enrolled in the study. Six patients were removed from the study, and 9 completed it (see Figure 2). No patients withdrew their consent during the study or follow-up. They were a median age of 56 years and 75% were women. Most of the patients were white (75%; 13% African American, 12% Other), single (50%; 25% married, 25% divorced), Catholic (38%; 25% Baptist, 25% Other, 12% None), and all lived at home (100%), and most had no primary caregiver (57%). Of note, 88% of the patients reported discussing prognosis with their oncologist, but only 50% reported they had incurable cancer and were receiving chemotherapy for palliation rather than for cure. In addition, only 25% had discussed advanced care planning before participating in this study.

Primary outcome
In terms of the feasibility of this intervention (Table 2), 100% of the participating patients (N = 9) reported that they were satisfied or very satisfied with DT. In all, 88% of patients reported that DT was helpful or very helpful and agreed or strongly agreed that DT increased their sense of meaning and would be helpful to their family; 78% agreed or strongly agreed that DT increased their sense of dignity and sense of purpose; and 67% reported that DT increased their will to live.

Secondary outcomes
A summary of all secondary outcomes can be seen in Figures 3, 4, 5. In terms of physical symptoms (pain, tiredness, nausea, drowsiness, appetite, dyspnea), most of the symptoms were not changed by DT but appetite did seem to improve when assessed after DT. For emotional symptoms (anxiety, depression, sense of well-being, QoL rating, satisfaction with QoL, distress), there did not seem to be any negative impact of DT and most of the patients had no change in these symptoms.

Peacefulness was not assessed because almost every patient had this on enrollment. For clinical outcomes (death acceptance and H-CAP-S, separated into preferences for goals of care and preferences for treatment options), there seemed to be an increase in death acceptance over time (11% at baseline; 57% at 1 month post-DT), raising the possible-

![TABLE 2 Results of satisfaction survey after completion of dignity therapy](image)

<table>
<thead>
<tr>
<th>Response</th>
<th>% of patients</th>
<th>Level of satisfaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Satisfaction</td>
<td>100</td>
<td>Satisfied or Very Satisfied</td>
</tr>
<tr>
<td>Helpfulness</td>
<td>88</td>
<td>Helpful to Very Helpful</td>
</tr>
<tr>
<td>Increased sense of dignity</td>
<td>78</td>
<td>Agree to Strongly Agree</td>
</tr>
<tr>
<td>Increased sense of purpose</td>
<td>78</td>
<td>Agree to Strongly Agree</td>
</tr>
<tr>
<td>Increased sense of meaning</td>
<td>88</td>
<td>Agree to Strongly Agree</td>
</tr>
<tr>
<td>Increased will to live</td>
<td>67</td>
<td>Agree to Strongly Agree</td>
</tr>
<tr>
<td>Helpful to family</td>
<td>88</td>
<td>Agree to Strongly Agree</td>
</tr>
</tbody>
</table>

![FIGURE 2 Study flow chart](image)
ity of a delayed effect, which is consistent with Chochinov and colleagues’ secondary measures that occurred a week after DT.  

We also found a change in non-life-prolonging goals of care and treatment choices over time. Of note, in the preferences for treatment choices, there seemed to be a shift from undecided to non-life-prolonging since the life-prolonging percentage remained stable from baseline at 1 month post-DT.

**Discussion**

DT has become a standard psychotherapeutic intervention supported by a phase 3 randomized controlled trial in patients receiving best supportive care. It improves patients’ quality of life, spiritual well-being, depression, dignity, and has an impact on how they are viewed by their loved ones. Similar outcomes are needed in cancer patients receiving active antineoplastic therapy. Loss of dignity is common with 46% of oncology patients with a life expectancy of less than 6 months reporting some degree of loss. Dignity therapy in this population therefore offers the possibility of improved outcomes in aspects of care that are often times overlooked.

There are 2 publications from the same randomized phase 2 trial on patients with advanced cancer who received DT compared with patients who received standard care. The first publication showed improvement in hope and self-reported measures, but no change in anxiety, depression, distress, or quality of life. The follow-up qualitative analysis of this intervention revealed that DT helped with patient generativity, which was not evident in the control arm. Generativity was described as an “opportunity to leave behind something lasting or identify accomplishments, contributions, and connections to life that can be passed onto others after death.” Of note, these patients were enrolled after a palliative care consult was requested, suggesting that this intervention may have been later in the cancer course then our current study. In addition, death acceptance and alterations in care preferences at the end-of-life were not evaluated.

In the current study, we show that DT is well accepted by this upstream population of patients as evidenced by the high accrual rate and satisfaction with the intervention. Most of the patients reported that they felt that DT was satisfying, helpful to them and their families, and improved their dignity, purpose, meaning, and will to live. Despite the concern that such an intervention would distress individuals by addressing end-of-life issues “too early,” the high enrollment (only 1 out of 17 patients refused to participate because of concern about it being emotionally bur-
densome [Figure 2]), the lack of drop out or withdrawal of consent during the study and lack of changes in emotional outcomes support the concept that, at the very least, this is risk neutral.

Of interest for future studies is that most of this population had never had an advanced-care planning discussion with their oncologist, half still felt they were curable, and only 1 in 10 had death acceptance. Despite this, they enrolled in the study, completed the dignity therapy, and were satisfied with the intervention. This may speak to a wider acceptability of DT in cancer patients other than the incurable patients. Many patients perceive cancer as a death sentence, regardless of its curability. Of particular interest is the apparent trend toward more death acceptance paired with choosing less life-prolonging goals of care and treatment options in a hypothetical end-of-life scenario. Similar associations were found in metastatic lung cancer patients who were receiving palliative care early in their disease course in a randomized controlled study. In fact, it is becoming clear that having death acceptance (or TIA) leads to less anxiety and depression at the end of one's life and also to less aggressive choices for end-of-life care. End-of-life medical decision making and outcomes are tightly wed to a patient’s perception of their health, but not all people who are dying from their cancer view themselves in this way (22% of patients see themselves as terminally ill more than 6 months from death vs 65% 1 month before death). This is far more complicated than giving patients realistic prognoses, and focuses more on how a person is able to safely incorporate this knowledge. The “dying role” is likely the best description of this inner state of being. This role is multifaceted and includes practical tasks (ie, caring for dependants, last good-byes), relational tasks (ie, teaching the dying role, passing the mantle, placing a legacy capstone), and personal tasks (ie, adjustment to loss, reaching closure, and existential tasks). We feel that DT helps facilitate the dying role by encouraging these selected tasks and may thereby have an impact on death acceptance and ultimately, goals of care and treatment choices at the end of life. Table 3 summarizes some of the topics relating to the dying role that were raised by the participating patients during this study. At times, the beginning of that transition from “sick” to “dying” was visible during the DT interview, and one could observe the patient experiencing the world from a very different perspective.

There are limitations to this study. First, this feasibility study has limited power to measure statistically significant differences in physical symptoms, emotional symptoms, patient understanding of the disease, goals of care preferences, and end-of-life treatment choices. Second, in regard to the increased death acceptance and change to non-life-prolonging end-of-life care, these shifts happen naturally over time so without a control group we are not able to link these changes to DT. Despite this, it is interesting that the numbers for baseline death acceptance (11%) and post-DT death acceptance (57%) were relatively similar to those previously reported in a more diverse advanced cancer population in which investigators compared death acceptance in patients who did not report an end-of-life discussion (29%) and those who reported a discussion (53%) with their oncologist. Third, the data may not be generalizable because the study was performed only in colorectal cancer patients at a single institution. However, we would argue...
that despite differences in disease trajectory, this process of coming to death acceptance may be a common experience shared by patients with a life-limiting cancer. Fourth, it is possible there was a bias with the oncologists referring only those patients whom they felt were in a strong emotional place to do this work. This was somewhat minimized by recruiting through a weekly research meeting at which all active patients were screened and approached if they met inclusion criteria.

**Conclusions**

Dignity therapy is a feasible, highly satisfying, and meaningful intervention for advanced colorectal cancer patients receiving chemotherapy. Likely through its impact on death acceptance, it may alter end-of-life goals of care and treatment choices and allow for health system delivery with improved quality and cost efficiency. Larger feasibility and controlled studies are needed in a more heterogeneous population of patients with incurable malignancies to confirm the tolerability of this intervention upstream in the disease trajectory and to help establish the impact of DT on death acceptance and other end-of-life quality clinical outcomes in the advanced cancer population.

**Acknowledgments**

The authors thank Jennifer Yu and Jamie Metcalfe for their substantial efforts of enrolling subjects, collecting data, and help with analysis preparation, and Jamie von Roenn for her mentorship in general study design and focus.

<table>
<thead>
<tr>
<th>Dying role task</th>
<th>Quote</th>
</tr>
</thead>
<tbody>
<tr>
<td>Practical</td>
<td></td>
</tr>
<tr>
<td>Caring for dependents</td>
<td>They are good people, so I believe my family will be helping my kids. I am teaching them every day. That’s why I am praying I can last; I will be OK.</td>
</tr>
<tr>
<td>Saying last goodbyes</td>
<td>If I had to write him a letter thinking I’m going to die soon, I’d just thank him for all of the wonderful ways of being a father and a husband … and a clown. He loves to play jokes and goof around, you know. And that’s good. I’ve never thought about that, but that’s a good thought.</td>
</tr>
<tr>
<td>Relational</td>
<td></td>
</tr>
<tr>
<td>Teaching the dying role</td>
<td>We all tend to do that. We worry about tomorrow and socking it away. We are waiting for our retirement to come, and then things happen. It takes it away from you. Maybe you should enjoy it a little more along the way, you know.</td>
</tr>
<tr>
<td>Passing the mantle</td>
<td>I think the most important thing would be that they all stay connected – all five – and stay close. That would be so important to me. I just want them to be there for each other. If somebody gets thrown a curve ball in life, the other four have to step up.</td>
</tr>
<tr>
<td>Giving permission</td>
<td>This is an issue that I’m sure my kids are going to have a hard time with, but I don’t want [my husband] to spend the rest of his life alone. He really needs to be with somebody.</td>
</tr>
<tr>
<td>Placing a legacy capstone</td>
<td>They’re good memories and that’s really what is important. I think to a great extent, telling jokes and telling stories and being able to impart these kinds of experiences are some of the ways my kids know me. I’m a storyteller.</td>
</tr>
<tr>
<td>Personal</td>
<td></td>
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<tr>
<td>Adjustment to loss</td>
<td>Don’t be afraid of challenge. And always have challenges in life; different people, different forms; different timing. Mine happened to be health issues at a young age. But everybody has certain things, certain baggage in their life. And we just have to live beyond that. Just do your best and get the best out of any situation. Because from an outsider’s view, my life has been pretty rough. 35 years old, three cancers, dealing with stage IV cancer, could be dying any moment, and divorced and have no family. It seems really rough but I don’t think people know what I experience. I experience the extraordinary things beyond the material world as well. They don’t see the blessings through all my cancers. I do believe I’m very blessed. I’m very lucky just being able to be here today. And what else is important? Nothing. Nothing is that important. Material stuff, money. You get by with what you have.</td>
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<tr>
<td>Reaching closure</td>
<td>But the dying part – it’s really not a big deal. I hope that they could just remember that I really enjoyed myself and had a good time my whole life. After I left home, I had very little to make me unhappy so I would hope they would celebrate my life instead of crying over my death.</td>
</tr>
<tr>
<td>Existential tasks</td>
<td>I want it to be easy for my sister and brother. Don’t drag me around like a ball and chain, like sadness in your life. I don’t want to say I don’t want you to think of me, but not in sad ways. Think of me in happiness and I will be there. I will always be there.</td>
</tr>
</tbody>
</table>
References