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Effects of dignity therapy on dignity and spiritual well-being in people with advanced cancer: study protocol for a randomized controlled trial

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Abstract

Background Dignity Therapy is a person-centered psychotherapeutic intervention designed for people approaching the end of life, fostering reflection on meaningful aspects of life and creating a testimonial legacy. Since 2011, randomized trials have demonstrated its value in addressing psychospiritual needs and preserving dignity in palliative care. However, no controlled studies have been conducted in Latin America to assess its effectiveness within local cultural contexts.

Methods This is a protocol for an exploratory, randomized, parallel-group clinical trial (1:1 allocation) with an open-label design. A total of 96 hospitalized individuals with advanced cancer will participate, all receiving care from the Palliative Care Service of a university hospital in Fortaleza, Brazil. The control group will receive usual palliative care, while the intervention group will receive the same care along with Dignity Therapy, delivered in three structured sessions. Assessments will be conducted at baseline (T1), at the end of the intervention (T2), and short-term follow-up (T3). The primary outcome will be the perceived dignity impact of the intervention, measured by the Dignity Impact Scale. Secondary outcomes will include spiritual well-being, hope, anxiety, depression, and distress. Perceptions of the intervention experience will also be collected from individuals in the intervention group. The primary analysis will be performed using linear mixed models.

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Discussion This trial will provide evidence on the feasibility and potential benefits of Dignity Therapy in supporting dignity and spiritual well-being among individuals with advanced cancer, while also examining how the intervention performs within distinct cultural contexts that may shape perceptions of dignity and end-of-life care.

Trial registration Registro Brasileiro de Ensaios Clínicos (ReBEC), RBR-8r3vzw5. Registered on 13 October 2025.

Keywords Palliative care, Dignity, Cancer, Person-Centered approach, Psychotherapy

Introduction

Palliative care aims to improve the quality of life of individuals facing life-threatening illnesses by preventing and alleviating suffering across physical, emotional, social, and spiritual dimensions [1]. Although more than 56.8 million people require palliative care annually, the majority do not have access to effective and comprehensive services [1–3]. Despite international commitments to integrate palliative care into universal health coverage—as outlined in World Health Assembly Resolution 67.19 [4]—only 14% of those in need actually receive it [1, 5]. This gap, exacerbated by population aging and the growing burden of chronic multi-morbid diseases, highlights the need to develop palliative care models that are viable, sustainable, and culturally sensitive. Such models must address not only clinical aspects but also the priorities expressed by individuals living with serious illness [6].

In palliative care, *dignity* has emerged as a central focus, particularly in addressing the existential suffering often experienced by individuals with advanced illness. Although its definition varies across cultures and contexts, there is broad consensus that the perception of lost dignity can significantly affect emotional, spiritual, and relational well-being, influencing how individuals find meaning and transcendence at the end of life [7–11]. In response, conceptual frameworks have been developed to understand how dignity is constructed and preserved in such moments. One of the most influential is the dignity-conserving care model, proposed by Chochinov [12], which gave rise to clinical interventions aimed at mitigating psychospiritual suffering, such as Dignity Therapy.

Dignity Therapy is a brief, individualized psychotherapeutic intervention designed to facilitate reflection on meaningful aspects of life and the creation of a testimonial legacy, in alignment with each person's values and preferences. Through a reflective dialogue guided by a structured yet flexible protocol, participants' responses are recorded, transcribed, and compiled into a document that can be shared with significant others. This intervention has shown beneficial effects in reducing psychospiritual suffering, reducing dignity related distress, promoting spiritual well-being, and strengthening the sense of dignity in individuals with advanced illness [12, 13].

Available evidence highlights the clinical relevance of Dignity Therapy, given its simplicity, low cost, and therapeutic potential [14–21]. However, quantitative findings have been inconsistent regarding outcomes such as emotional discomfort, depressive symptoms, and quality of life, likely due to methodological, contextual, or population-specific variations [22–29]. Even so, in many of these studies, qualitative evaluations provided by the individuals who received the intervention consistently describe it as a deeply meaningful experience, one that facilitates the expression of legacy, strengthens emotional and relational bonds, and redefines the experience of illness. This divergence between measurable outcomes and subjective perceptions underscores the need to further explore its effectiveness and meaning across diverse clinical and cultural contexts.

Although Dignity Therapy has been adapted to various clinical and cultural contexts [22, 30–35], it has yet to be evaluated through controlled clinical trials in Latin America. A recent scoping review [36] identified that only Brazil and Mexico have made efforts to explore its implementation through case studies, empirical approaches, or a quasi-experimental study. To the authors' knowledge, no other Latin American countries have published research evaluating this intervention. This lack of evidence from controlled methodological designs not only limits the development of culturally relevant clinical recommendations but also prevents examining how Dignity Therapy is expressed and gains meaning in diverse sociocultural settings, as well as the potential tensions that may arise in its application.

In this context, the present clinical trial aims to generate evidence on the effectiveness of Dignity Therapy and contribute to the advancement of controlled research supporting its integration into health systems across diverse settings. The study focuses on a context where access to palliative care remains limited and structural barriers hinder the provision of comprehensive, person-centered care. This need becomes even more urgent in light of persistent gaps in palliative care, particularly in oncology, and the structural inequalities that restrict access to care that honors what is meaningful to each individual, including their sense of dignity and spiritual well-being [37–40]. The findings of this study are intended to provide relevant input for the context-sensitive incorporation of this intervention, especially in low- and middle-income countries, where these dimensions remain critical and still insufficiently addressed.

Objectives and hypotheses

Primary objective

1. To evaluate whether Dignity Therapy, in addition to usual palliative care, improves dignity compared with usual palliative care alone among hospitalized individuals with advanced cancer.

Primary hypothesis

H1: Individuals who receive Dignity Therapy in addition to usual palliative care will show greater improvements in dignity over the follow-up period compared with those who receive only usual palliative care.

Secondary objectives

2. To examine whether Dignity Therapy is associated with higher levels of spiritual well-being and hope, and lower levels of anxiety, depression, and distress compared to the control group.
3. To explore the temporal evolution of these outcomes within each group over the follow-up period.

Secondary hypotheses

H2: Individuals who receive Dignity Therapy will exhibit higher levels of spiritual well-being and hope, as well as lower levels of anxiety, depression, and distress at the end of follow-up, compared to the control group.

H3: Scores for dignity, spiritual well-being, anxiety, depression, and distress will change significantly over time, regardless of group assignment.

Methods

This study is a randomized, exploratory, parallel-group clinical trial with a 1:1 allocation ratio and an open-label design. The methodology is based on the recommendations of the European Medicines Agency [41] and the criteria of the RoB 2 tool for assessing the risk of bias in randomized controlled trials [42]. Although RoB 2 was not designed to guide trial design, its integration will support the identification and mitigation of potential sources of bias, including those related to the randomization process, deviations from intended interventions, handling of missing data, outcome measurement, and selection of reported results.

This protocol was developed in accordance with the SPIRIT-PRO Extension guidelines [43, 44] *(Supplementary material 1)*, which provide recommendations for the inclusion of patient-reported outcomes (PROs) in clinical trials. The final report will follow the CONSORT PRO Extension recommendations [44] to ensure a clear, full, and transparent presentation of the PRO-related findings.

Study period and setting

The study will be conducted between January 2026 and March 2027 at the Palliative Care Service (PCS) of Walter Cantídio University Hospital (HUWC), a tertiary teaching hospital affiliated with the Federal University of Ceará in Fortaleza, Brazil. The hospital offers medical and multidisciplinary residency programs and provides specialized care, particularly in oncology and advanced chronic diseases.

The PCS, established in 2016, is staffed by an interdisciplinary team composed of four physicians, two nurses, one psychologist, and one social worker, all of whom engage in both clinical care and teaching. Additionally, the service serves as a permanent site for clinical training, hosting residents from multiple disciplines such as nursing, pharmacy, psychology, social work, nutrition, and physical therapy, as well as medical residents specializing in palliative care, geriatrics, intensive care, and neurology. It also regularly welcomes medical and psychology students for supervised clinical rotations.

Care is organized into two main modalities. On the one hand, interdisciplinary outpatient care is provided through regular consultations for individuals with life-threatening illnesses. These consultations allow for clinical follow-up, symptom management, care planning, family support, and coordination with other professionals or services as needed. When hospitalization is deemed necessary, the team can arrange the individual's admission to available units within the hospital.

On the other hand, inpatient consultations are conducted at the request of treating teams, providing palliative care to individuals admitted to different hospital units. This modality includes interdisciplinary assessments focused on symptom control, prognostic evaluation, and the joint support of people living with serious illness and their families. Care is tailored to the specific needs of each case and integrates clinical, psychological, and social dimensions, in keeping with the service's comprehensive approach.

Eligibility criteria

Participant selection will be based on predefined inclusion, exclusion, and discontinuation criteria to ensure the intervention's clinical and cognitive suitability. These criteria are detailed in Table 1.

Sample size

The sample size was calculated using R software (version 4.1.1), with the primary outcome *dignity* as the reference. A standardized effect size (Cohen's d) of 0.30 was assumed, which is considered small to moderate in magnitude. This estimate was based on a meta-analysis [45] and on a previous randomized clinical trial of Dignity Therapy [25], both of which specifically evaluated sense

Table 1 Participant eligibility criteria

Inclusion criteria	Exclusion criteria	Discontinuation criteria
1. Age ≥ 18 years. 2. Diagnosis of advanced cancer, deemed incurable, including solid tumors or hematologic malignancies. 3. Life expectancy ≤ 6 months, as defined by an ECOG score of 3 (detailed in the instruments section) or according to the clinical judgment of the treating team. 4. Enrolled in Palliative Care. 5. Willingness to participate in three or four sessions over a period of up to 12 days. 6. Functional ability to communicate in Portuguese.	1. Severe cognitive impairment (dementia or delirium) that compromises participation in the intervention, whether clinically evident or identified through clinical evaluation. 2. Clinical diagnosis of severe mental illness. 3. Severe language disorders that interfere with comprehension or communication. 4. Evidence of collusion of silence.	1. Voluntary withdrawal by the participant after initiating the intervention. 2. Emergence of clinical complications during the study that significantly interfere with the communication or understanding required to continue the sessions. 3. Death during the follow-up period.

of dignity as an outcome. The meta-analysis reported an overall effect of − 0.38, while the clinical trial found a group × time interaction with a partial $\eta^2 = 0.10$, equivalent to $f \approx 0.33$ and $d \approx 0.30–0.35$. Based on these results, an intermediate value was selected, deemed appropriate for the exploratory purposes of this study.

The calculation was based on a linear mixed model for longitudinal data with three repeated measurements, assuming an intra-individual correlation of 0.5 under an autoregressive covariance structure of the first order (AR [1]). A standardized standard deviation of 1 was assumed, consistent with the use of standardized mean differences and given the absence of a robust empirical estimate for this parameter in the target population. This choice allows for greater comparability across studies and measurement instruments, which is appropriate in the exploratory context of the study.

A significance level of 0.05 and a statistical power of 80% were set. Based on these parameters, the required sample size was estimated at 33 participants per group. Considering an anticipated attrition rate of 30% [36], the adjusted sample size was 48 participants per group, for a total of 96 individuals in the study.

Recruitment and enrollment

Recruitment will take place at the PCS previously described, where the principal investigator has maintained ongoing participation for over a year as part of academic training. This ongoing presence has facilitated their integration into the team's routines, including outpatient consultations and interdisciplinary discussions. Throughout this process, a relationship of trust has been established with the service professionals, who are also members of the research team.

Participants will be identified through consultation requests submitted by the treating teams. Once an individual with a diagnosis of advanced cancer is referred for follow-up by the palliative care team, their medical record will be reviewed to verify compliance with the predefined eligibility criteria.

If the individual is deemed potentially eligible, the principal investigator, together with a member of the palliative care team and, when possible, a member of the treating team with an established prior relationship, will present the study as research comparing different forms of palliative care. It will be explained that some individuals will continue with usual care, while others will receive an additional intervention, without providing specific details that could create expectations or influence preferences.

If the individual expresses interest, an initial assessment of functional status will be conducted using the Eastern Cooperative Oncology Group (ECOG) Performance Status Scale to verify eligibility according to the clinical inclusion criteria. This will be followed by a reflective conversation aimed at assessing the individual's overall willingness to participate, taking into account their understanding, motivation, and capacity for active involvement. This process is intended to ensure that the decision is fully informed, voluntary, and appropriate to the individual's situation. Once eligibility is confirmed, the informed consent form will be signed and random assignment to the study group will take place. Whenever possible, baseline assessment will be conducted during the same encounter.

Given the sensitive nature of the clinical context, each individual will be offered a minimum period of 24 h to consider participation, if they so wish. During this time, they may ask questions or request clarifications, ensuring an informed decision that respects their autonomy.

As an additional strategy, the study protocol will be shared with other hospital services that care for individuals with advanced cancer, with the aim of expanding the reach of recruitment and facilitating the timely identification of potential participants. Figure 1.

Allocation

Eligible participants will be randomly assigned to the intervention or control group in a 1:1 ratio, using block randomization with variable block sizes (blocks of 4, 6, or 8 participants). This strategy helps maintain balance between groups throughout the recruitment process while minimizing the risk of allocation prediction, thereby strengthening allocation concealment and the methodological integrity of the study.

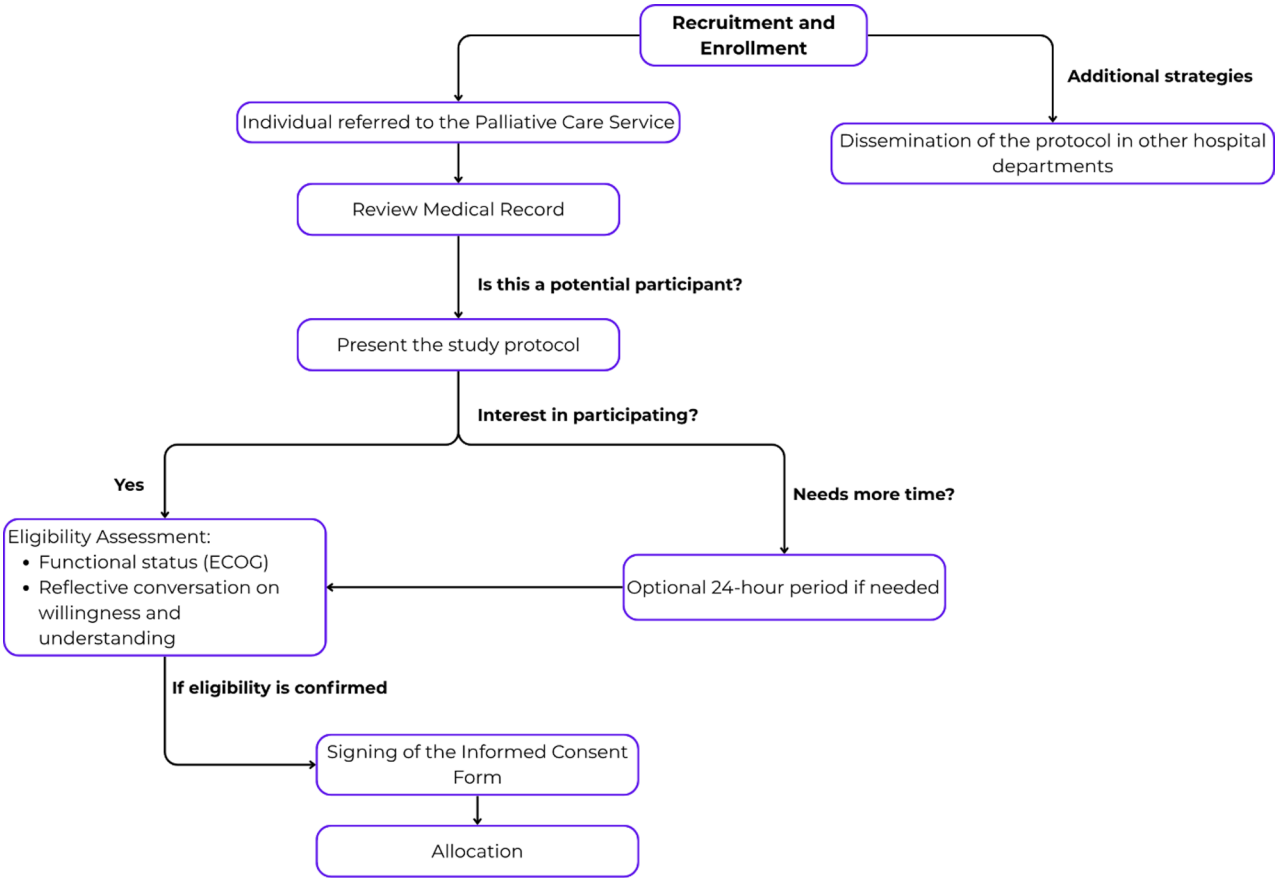

Fig. 1 Flow diagram of recruitment and enrollment procedures

The allocation sequence will be generated in Python (version ≥ 3.8) using random permutations of the possible combinations. This task will be carried out by the study statistician, who will have no contact with participants and no involvement in the recruitment process.

Individual assignment will be carried out using opaque, sealed, and sequentially numbered envelopes, prepared according to the order generated by the randomization sequence. Each envelope will be opened only after the individual's eligibility has been confirmed and informed consent has been obtained.

Interventions

Usual palliative care

Participants in the control group will receive only the usual palliative care provided by the service's interdisciplinary team. This integral care includes the management of physical symptoms (such as pain, dyspnea, or fatigue), emotional support, spiritual care in accordance with the individual's beliefs, and social interventions aimed at strengthening support networks and planning care.

Dignity therapy

Participants assigned to the intervention group will receive the usual palliative care provided by the service, as previously described, in addition to Dignity Therapy. This intervention will be delivered by the principal investigator, who completed an 18-hour training course covering theoretical foundations, ethical considerations, and practical activities focused on communication and therapeutic skills, and who also participated in a series of supervisory meetings with senior faculty experienced in Dignity Therapy, palliative care, and the design and conduct of clinical trials of Dignity Therapy.

The intervention will follow the original model developed by Chochinov et al., using the *Dignity Therapy Question Protocol* as a reflective guide for the interview. This instrument was previously translated and culturally adapted into Brazilian Portuguese, with content validation yielding an index of 1 for all equivalence items [46].

Sessions will be conducted in a carefully prepared setting, considering both the conditions of the hospital's environment and the individual's preferences, with the goal of ensuring privacy, confidentiality, and comfort. Before each session, the therapist will confirm with the participant whether the environment feels appropriate

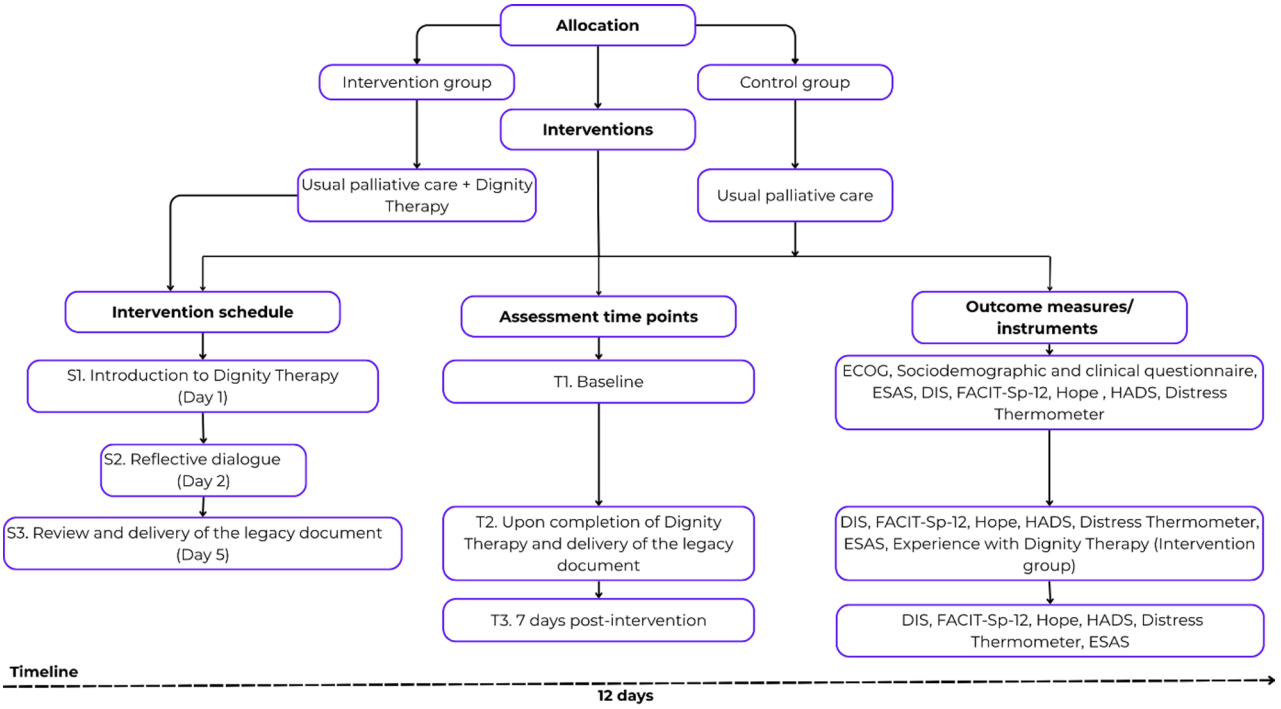

Fig. 2 Flow diagram of study design, interventions, and assessment time points

and whether they are in condition to take part. This check will include factors such as physical comfort, the likelihood of interruptions, and the sense of privacy. If any needs or concerns arise, necessary adjustments will be made before beginning.

The intervention will be carried out over three consecutive sessions:

Session 1 (S1): Introduction to the therapeutic process. The therapist will explain the purpose of the intervention and provide the participant with the printed question protocol, inviting them to reflect calmly on the topics they consider most relevant to address in the next session. This introductory conversation will last approximately 30 min.

Session 2 (S2): Reflective dialogue. Using the selected questions as a starting point, the therapist will facilitate a conversational space aimed at promoting dignity, allowing the individual to express themselves freely and meaningfully. The reflective life interview will be audio-recorded for transcription purposes and will last approximately 60 min, with adjustments made according to the person's clinical condition and preferences.

At the end of the interview, the reflection will be transcribed into text format using *TurboScribe*, an AI-assisted transcription tool. A member of the research team will then review the transcript to ensure its fidelity to the original content. The therapist will subsequently make aesthetic and readability adjustments to produce a prose-format text, referred to as the *legacy document*, presented in a personalized format for all participants.

Session 3 (S3): Review and delivery of the legacy document. The document will be provided to the individual in printed form (or read aloud, if preferred) and reviewed together. Any necessary corrections will be identified and the content adjusted accordingly. Finally, the individual will be invited to decide whether they wish to share the document with a significant other or with their family. Figure 2.

Outcomes

Outcomes reported by the individuals will be collected at three time points: baseline (T1), upon completion of Dignity Therapy (T2), and one week later (T3). Fig. 2.

Primary outcome

The primary outcome will be dignity impact, assessed using the *Dignity Impact Scale (DIS)* [47].

Secondary outcomes

Secondary outcomes will include the impact of the intervention on levels of spiritual well-being, hope, anxiety, depression, and distress. Spiritual well-being will be assessed using the *Functional Assessment of Chronic Illness Therapy – Spiritual Well-Being 12 Item Scale (FACIT-Sp-12)* [48]. Hope will be measured using the *Herth Hope Index (HHI)* [49]. Anxiety and depression will be assessed with the *Hospital Anxiety and Depression*

Scale (HADS) [50], and distress will be measured using the *Distress Thermometer* [51].

The selection of these PROs was based on a prior scoping review [36] conducted by the research team, which identified the main measures used in clinical trials evaluating Dignity Therapy. This was followed by an internal discussion to define the most relevant outcomes, taking into account both their clinical relevance and the availability of instruments validated in Brazilian Portuguese. In this context, we prioritized the *Dignity Impact Scale* over the *Patient Dignity Inventory*—although the latter is the most widely used measure—for assessing the primary outcome, given its conceptual alignment with the expected effects of Dignity Therapy, its simplicity and lower respondent burden, and the evidence of sensitivity to the intervention demonstrated in previous studies [47, 52].

Data collection methods and instruments

Data collection will be carried out by members of the research team. Prior to the start of the study, the team will undergo training that will include a detailed review of the protocol, guidance on the use of the instruments, and practical exercises designed to promote consistency in their application. During the data collection phase, regular meetings will be held to monitor progress, address questions, and ensure adherence to the established procedures.

The instruments will be administered in printed form and, preferably, self-completed by participants. In cases where health status or individual preferences pose difficulties, assisted structured interviews will be used. In either modality, the research team will be available to provide support if needed, whether to clarify items or to help complete responses. This approach is intended to facilitate comprehension of the instruments, reduce cognitive and emotional burden, and promote active, autonomous, and respectful participation in the evaluation process.

Measurements will be conducted at the three previously defined time points (T1, T2, and T3), using the following instruments:

ECOG performance status scale

This instrument is a widely used tool in clinical settings and palliative care research. Its purpose is to estimate the degree of autonomy in performing daily activities among individuals with advanced oncologic disease. The scale ranges from 0 (fully active) to 5 (deceased). Although it has not undergone formal psychometric validation for Brazilian Portuguese, it is widely used in national clinical practice and recognized by leading institutions in oncology and palliative care [53].

Sociodemographic and clinical data questionnaire

Sociodemographic and clinical data will be collected using a questionnaire adapted from previous studies [54, 55]. It will include information on sex, gender identity, age, race/ethnicity, marital status, educational level, religion, support networks, household income composition, and access to social benefits.

With respect to clinical data, information will be collected on cancer type and time since diagnosis, the presence of relevant comorbidities, current use of psychotropic medications, and ongoing palliative oncologic treatments. In addition, recent participation in structured psychosocial or spiritual interventions other than Dignity Therapy will be recorded, excluding routine religious practices not specifically organized as a form of support in the context of illness.

Edmonton symptom assessment system (ESAS)

This instrument is used to monitor the intensity of common physical and emotional symptoms in palliative care. It includes 10 items rated on a scale from 0 to 10, with higher scores indicating greater symptom intensity. The Brazilian Portuguese version was validated by Paiva et al. (2015) [56], demonstrating satisfactory internal consistency ($\alpha = 0.861$) and good test-retest reliability. In this study, ESAS will not be considered a formal secondary outcome, as Dignity Therapy is not directly aimed at managing physical symptoms. However, it will be administered at all three assessment points (T1, T2, and T3) with the goal of characterizing participants' clinical status, controlling for potential confounding variables, and exploring associations between symptom burden and response to the intervention.

Dignity impact scale

The DIS assesses the perceived impact of Dignity Therapy in individuals with advanced illness, addressing dimensions such as meaning, purpose, preparation for death, and benefits for the family. It consists of seven items rated on a 5-point Likert scale, with the mean score reflecting the overall level of impact; higher values indicate greater dignity-related benefit. The scale has demonstrated adequate internal consistency ($\alpha = 0.80–0.85$) and sensitivity to intervention in multicenter clinical trials [47, 52]. In this study, the Brazilian Portuguese version of the DIS—currently undergoing translation and cross-cultural adaptation—will be used. The data obtained will also contribute to the psychometric validation of this version in the Brazilian context.

Spiritual well-being

Spiritual well-being will be assessed using the FACIT-Sp-12, version 4 [48]. The instrument consists of 12 items organized into three subscales: meaning, peace,

and faith, each rated on a 5-point Likert scale, with some items reverse-coded. The Brazilian Portuguese version was obtained under license from the FACIT group, which granted formal authorization for its use in this study, ensuring the validity and reliability of the adapted version.

Herth hope index

This tool assesses the level of hope in individuals with chronic illnesses through 12 Likert-type items, with scores ranging from 12 to 48, where higher values indicate greater hope. Two items (3 and 6) are reverse-scored. The Brazilian Portuguese version was validated by Sartore and Grossi [49] in a sample composed of people receiving oncology care, individuals living with type 2 diabetes, and caregivers. It demonstrated adequate internal consistency (α = 0.834), good test-retest reliability, and both convergent and divergent validity with self-esteem and depression scales.

Hospital anxiety and depression scale

The HADS assesses emotional symptoms in individuals with physical illnesses and is widely used as a screening tool for anxiety and depression in hospital settings. It consists of 14 items divided into two subscales—anxiety and depression—with 7 items each, scored independently. Each item is rated on a scale from 0 to 3, with total scores ranging from 0 to 21 for each subscale, where higher scores indicate greater emotional discomfort. The Brazilian Portuguese version was adapted in 2007 [50] and has demonstrated adequate internal consistency: α = 0.76 for anxiety and α = 0.81 for depression.

Distress thermometer

The Distress Thermometer, developed by the National Comprehensive Cancer Network (NCCN), is a brief screening tool used to assess the level of distress perceived by an individual over the past week. It consists of a visual scale ranging from 0 (no distress) to 10 (extreme distress), with scores of 4 or higher typically considered indicative of clinically relevant distress. The Brazilian Portuguese version is officially available in the NCCN guidelines, supporting its validity and use in this study [51].

Experience with dignity therapy

The experience of individuals with Dignity Therapy will be assessed through an open-ended question inviting them to express, in their own words, what participating in the intervention meant to them. This question will be asked and audio-recorded by the researcher, after the delivery of the legacy document (T2), and only to participants in the intervention group. Participation will be voluntary and carried out with respect for each individual's emotional readiness. Figure 2.

Blinding

This study will not be blinded for participants or the therapist, as the nature of the intervention makes it impossible to conceal group allocation. To mitigate potential biases, the instruments will preferably be self-administered by the participants, with support from the research team provided only when necessary. Statistical analysis will be conducted by a professional external to the clinical team and blinded to group allocation, in order to preserve objectivity in the interpretation of the results.

Pilot study

Given the nature of the phenomenon under investigation and the characteristics of the intervention, a pilot study will be conducted to assess the feasibility of the proposed procedures, the acceptability of the intervention, and the overall operability of the study protocol. The pilot study will follow the same methodological guidelines as the main trial, except for the sample size.

The sample size for the pilot study was calculated based on the probability of identifying at least one event that could interfere with follow-up, with death being one of the most frequent outcomes in studies involving individuals at an advanced stage of illness. Following the approach proposed by Viechtbauer et al. [57] and assuming an estimated event rate of 30%, a sample of 9 participants would be sufficient to observe at least one such case with 95% confidence. For operational purposes, this number was rounded to 10 participants to facilitate study implementation.

Statistical analysis

Data will be entered into the REDCap platform and analyzed using the Python programming language (version ≥ 3.8), with core libraries including *pandas*, *numpy*, *statsmodels*, and *matplotlib*. Continuous variables will be described using measures of central tendency (mean and median) and dispersion (standard deviation), while categorical variables will be presented as absolute and relative frequencies, along with their respective confidence intervals.

The primary analysis will be conducted using a linear mixed model, which will include fixed effects for group (intervention vs. control), time (T1, T2, T3), and the group × time interaction, as well as random effects at the participant level to account for intra-individual variability. An autoregressive covariance structure of the first order (AR [1]) will be assumed, as it is appropriate for repeated measurements over short time intervals.

Model assumptions will be evaluated, including the normality of residuals, homogeneity of variances, and the

adequacy of the covariance structure. In case of violations, alternative structures (such as compound symmetry or unstructured) or robust estimation methods will be considered, with the most appropriate model selected based on fit indices such as AIC or BIC.

The primary effect of interest will be the group × time interaction, which will allow for the evaluation of whether changes in dignity differ between groups over the course of follow-up. Analogous models will be used for the secondary outcomes (spiritual well-being, anxiety, depression, and distress). When clinically appropriate, or if relevant imbalances are identified at baseline, the models will be adjusted for potentially confounding sociodemographic and clinical variables.

All analyses will follow the intention-to-treat (ITT) principle, preserving the participants' original group assignments. Additionally, a per-protocol (PP) analysis will be conducted to explore the effects among those who complete the intervention as planned. Missing data will be handled using multiple imputation via Markov Chain Monte Carlo (MCMC), with sensitivity analyses conducted to verify the robustness of the results.

Given the exploratory approach of the study and the inclusion of multiple outcomes, a stricter threshold for statistical significance ($p < 0.01$) will be adopted to reduce the risk of Type I errors.

To ensure the rigor and transparency of the statistical procedures, a detailed Statistical Analysis Plan was preregistered in the Open Science Framework, specifying all analytic steps, procedures for handling missing data, and planned sensitivity analyses (https://doi.org/10.17605/OSF.IO/3NRVY).

Monitoring

Study monitoring will be carried out by the principal investigator and an external member who is not part of the research team. Together, they will coordinate monthly meetings with the team to follow the progress of the trial, review protocol adherence, and assess the quality of the collected data. These meetings will be collaborative, aiming to identify opportunities for improvement, resolve methodological questions, and ensure that procedures remain aligned with the study objectives. Special attention will be given to adherence in the collection and recording of PROs. Any difficulties that arise may be addressed directly with the principal investigator, allowing for timely and context-sensitive responses.

Throughout each study visit, participants will be closely supported in order to identify any difficulties related to their participation. When needed, the intervention of the service's psychologist may be requested to address emotional events that arise during or after the delivery of Dignity Therapy, thereby ensuring a timely and appropriate clinical response. To minimize the burden associated with assessments, these will be scheduled at times compatible with each participant's availability and clinical condition. Mechanisms will be implemented to detect missing data early, and, if necessary, participants will be contacted to complete the information, always with a respectful approach centered on their well-being. Should any ethically relevant situations arise during the study, they will be reported and discussed with the hospital's ethics committee, ensuring that all decisions made uphold the participants' rights, dignity, and autonomy.

Ethics and dissemination

This study was approved by the Research Ethics Committees of the Federal University of Ceará and the Walter Cantídio University Hospital, and was registered in the Brazilian Clinical Trials Registry. All procedures will adhere to the ethical principles outlined in the Belmont Report and comply with current Brazilian regulations (Resolution No. 466/2012).

Participation will require the signing of the Free and Informed Consent Form by the participant or their legal representative, in accordance with established ethical guidelines. Comprehension of the document and the voluntary nature of participation will be ensured. Data protection will be carried out in accordance with the Brazilian General Data Protection Law (Law No. 13.709/2018).

Recordings of the Dignity Therapy sessions will be made exclusively on hospital premises and transferred to a secure server immediately afterward. Each participant will be identified by an alphanumeric code, with no names or personal information directly linked to the collected data. Only authorized members of the research team will have access to this information.

Although individual data will not be publicly available, they may be shared with other researchers through justified and approved requests, in accordance with national regulations on research collaboration and data sharing. Throughout the entire process of data collection, analysis, and dissemination of results, participant confidentiality and anonymity will be strictly maintained.

The study results will be disseminated through publications in peer-reviewed scientific journals and presentations at national and international scientific events, promoting access to the knowledge generated while upholding ethical principles in the communication of findings.

Discussion

This study proposes a randomized clinical trial to evaluate the effects of Dignity Therapy on dignity and spiritual well-being among hospitalized individuals with advanced cancer, within the context of palliative care in Brazil. It is the first controlled study in the country and in Latin America to examine the effectiveness of this intervention.

Among the strengths of this protocol are its controlled methodological approach, developed in collaboration with multidisciplinary professionals experienced in palliative care and Dignity Therapy, whose perspectives have enriched the methodological decisions. Notable features also include the use of appropriate statistical models for longitudinal data analysis and the inclusion of PROs, in alignment with international SPIRIT-PRO and CONSORT-PRO recommendations. Additionally, including a measure of experience will help capture the subjective perceptions of participants receiving the intervention, providing a complementary perspective to the quantitative data.

The study acknowledges methodological limitations inherent to its design and implementation context. Although the sample size was estimated using statistical procedures appropriate to the primary objective, its exploratory and single-center nature may limit the generalizability of the findings to other clinical or population settings. Regarding blinding, it is clarified that Dignity Therapy, due to its relational and personalized nature, does not allow for, nor aim at, therapist blinding, as its therapeutic meaning is constructed jointly with the individual. Nevertheless, to mitigate potential bias in outcome assessment, the protocol includes measures such as blinding of the statistical analysis and the preferred use of self-administered instruments.

The findings of this study may provide relevant empirical evidence on the effects of Dignity Therapy in individuals with advanced cancer within the Brazilian context. By integrating clinically meaningful outcomes and the subjective experiences of the participants themselves, the study will contribute to a more comprehensive understanding of the intervention's impact and how it gains meaning in different sociocultural settings. In addition to informing clinical practice in palliative care, the results may guide future research in other Latin American countries, support the development of multicenter studies, and inform public policies that promote culturally contextualized psychosocial interventions centered on what individuals value at the end of life.

Abbreviations

CONSORT-PRO	Consolidated Standards of Reporting Trials – Patient-Reported Outcomes
DIS	Dignity Impact Scale
ECOG	Eastern Cooperative Oncology Group
ESAS	Edmonton Symptom Assessment System
FACIT-Sp-12	Functional Assessment of Chronic Illness Therapy – Spiritual Well-Being 12 Item Scale
HADS	Hospital Anxiety and Depression Scale
HHI	Herth Hope Index
HUWC	Walter Cantídio University Hospital
ITT	Intention-to-treat Analysis
MCMC	Markov Chain Monte Carlo
PCS	Palliative Care Service
PP	Per-protocol Analysis
PROs	Patient-Reported Outcomes
ReBEC	Registro Brasileiro de Ensaios Clínicos
SPIRIT-PRO	Standard Protocol Items: Recommendations for Interventional Trials – Patient-Reported Outcomes

Supplementary Information

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Supplementary Material 1.

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Declaration of generative AI in the writing process

During the preparation of this work, the author(s) used ChatGPT (licensed subscription) to assist in improving the readability and linguistic accuracy of the manuscript. After using this tool, the author(s) reviewed and edited the content as needed and take(s) full responsibility for the content of the published article.

Authors' contributions

The study concept and design were developed by RJVY, JS, BSRP, BJ, and CL. Statistical planning and analysis were carried out by DT. AFCF, MVTBS, RCA, CFSNA, MEBG, LLFM, MTC, ACFB, RCMBC, MBNG, and NCAM contributed to discussions regarding the logistical aspects of implementation within the Palliative Care Service. The first draft of the manuscript was written by RJVY, and all authors contributed to revisions and approved the final version of the protocol for submission.

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Data availability

No datasets were generated or analyzed for this study protocol. All materials related to the trial procedures are available from the corresponding author upon reasonable request.

Declarations

Ethics approval and consent to participate

The study protocol was approved by the Research Ethics Committee of the Universidade Federal do Ceará – PROPESQ/UFC (CAAE 82778724.0.0000.5054; approval no. 7.423.769, version 2) and by the Research Ethics Committee of the Hospital Universitário Walter Cantídio (CAAE 82778724.0.3001.5045; approval no. 7.694.038, version 1). All participants will provide written informed consent before enrollment, and all procedures will comply with the ethical standards.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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