

Effects of dignity therapy on psychological and behavioral outcomes in patients with end-stage renal disease undergoing hemodialysis: A randomized controlled trial

Yinhai Chen^{a,c}, Rong Huang^{b,c}, Tong Zhou^c, Chenxi Tang^b, Meng Qin^e, Lin Su^f, Xiong Ke^{a,d,*}

^a Key Laboratory of Digital-Intelligent Disease Surveillance and Health Governance, North Sichuan Medical College, Nanchong, China

^b Department of Nursing, Second Clinical Medical College of North Sichuan Medical College, Nanchong, China

^c School of Nursing, North Sichuan Medical College, Nanchong, China

^d Sichuan Primary Health Care Research Center, North Sichuan Medical College, Nanchong, China

^e Hemodialysis Center, Affiliated Hospital of North Sichuan Medical College, Nanchong, China

^f Nursing Department, Affiliated Hospital of North Sichuan Medical College, Nanchong, China

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ABSTRACT

Background: Dignity therapy has been shown to enhance well-being and preserve a sense of dignity in palliative care. Patients with end-stage renal disease receiving hemodialysis also experience persistent threats to dignity related to treatment dependence and disease burden. Evaluating dignity therapy within a chronic illness context may help clarify its potential applicability beyond terminal care settings.

Objective: To evaluate whether dignity therapy improves dignity-related distress, treatment adherence, hope, depressive symptoms, and quality of life among patients with end-stage renal disease undergoing maintenance hemodialysis.

Design: A randomized, two-arm, parallel-group controlled trial.

Setting and participants: Ninety-two patients were recruited between June and July 2025 from two tertiary hemodialysis centers in China and were randomly assigned to the intervention group (n = 46) or the control group (n = 46).

Methods: The intervention group received routine psychological care plus a contextually and culturally adapted dignity therapy for maintenance hemodialysis; the control group received routine psychological care alone. Outcomes were assessed at baseline and at 2, 4, and 8 weeks post-intervention and measured using the Patient Dignity Inventory, End-Stage Renal Disease Adherence Questionnaire, Herth Hope Index, Patient Health Questionnaire-9, 12-item Short Form Health Survey, and 24-item Kidney Disease Quality of Life instrument. Generalized estimating equations were used for analysis, and a per-protocol analysis was conducted to assess the robustness of the findings.

Results: Dignity therapy significantly reduced overall dignity-related distress ($\beta = -5.59$, $p = 0.030$), with the greatest improvements observed in the dependency ($\beta = -2.46$, $p = 0.002$) and symptom distress ($\beta = -1.37$, $p = 0.047$) domains. At 2 weeks post-intervention, participants receiving dignity therapy also demonstrated higher treatment adherence ($\beta = 6.50$, $p < 0.001$), greater hope ($\beta = 2.28$, $p = 0.005$), and fewer depressive symptoms ($\beta = -2.00$, $p = 0.011$) than controls. However, these improvements diminished by week 8. No significant changes were detected in kidney disease-specific quality-of-life measures. Sensitivity analyses supported the robustness of the primary results.

Conclusions: Dignity therapy may provide short-term psychological and behavioral benefits for patients with end-stage renal disease receiving hemodialysis. Integrating dignity therapy within a chronic illness adaptation framework could enhance its theoretical coherence and long-term sustainability for non-palliative populations. Further multicenter studies with longer follow-up periods are warranted.

Trial registration: Chinese Clinical Trial Registry (ChiCTR2500104449).

* Corresponding author at: 234 Fujiang Road, Shunqing District, Nanchong City, Sichuan Province, China.

E-mail address: kexiong@126.com (X. Ke).

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What is already known

- Dignity therapy has been shown to improve psychological well-being and a sense of dignity in palliative care settings, particularly for terminally ill patients.
- Previous studies mainly focused on dignity therapy's effectiveness in Western healthcare systems and end-of-life care, with limited exploration in chronic, life-limiting conditions.
- The effectiveness of dignity therapy in non-Western populations, particularly in end-stage renal disease patients undergoing hemodialysis, has not been well studied.

What this paper adds

- Dignity therapy significantly reduced dignity-related distress and improved treatment adherence, hope, and depressive symptoms in the short term.
- The intervention effects diminished by 8 weeks, and no significant changes were observed in kidney disease-specific quality of life.

1. Background

End-stage renal disease represents the terminal stage of chronic kidney disease, characterized by irreversible loss of renal function and dependence on renal replacement therapy for survival (Xie et al., 2023). According to the Global Burden of Disease Study, chronic kidney disease affects nearly 690 million individuals worldwide, with over 10 million progressing to end-stage renal disease each year (Bikbov et al., 2020). Among available treatments, maintenance hemodialysis remains the most common life-sustaining intervention aside from kidney transplantation (Bansal et al., 2023). Although hemodialysis improves survival, many patients continue to experience compromised quality of life and profound psychosocial distress resulting from the chronic, debilitating nature of the disease and its demanding treatment regimen (Qawaqzeh et al., 2023; Wachterman et al., 2017).

Psychological comorbidities such as anxiety and depression are highly prevalent among hemodialysis patients, affecting approximately 40–50% of this population (Al Naamani et al., 2021). Evidence from China indicates a similar or even greater psychosocial burden. For instance, a study from northern China reported prevalence rates of 55.1% for depressive symptoms and 25.9% for anxiety among patients receiving maintenance hemodialysis (Meng et al., 2022). In addition to emotional symptoms, psychosocial stressors, such as stigma, are also prevalent. Chinese studies have shown that many dialysis patients experience at least a moderate level of perceived stigma (Jiang et al., 2025; Li et al., 2023). Furthermore, functional decline and dependence on family members or healthcare providers may cause patients to perceive themselves as burdensome, which contributes to a loss of dignity and existential suffering (Chochinov et al., 2016). These dignity-related concerns not only diminish psychological well-being but can also undermine treatment adherence and overall health outcomes (Khodarahimi et al., 2021). Addressing such complex psychosocial needs has therefore become a key priority in contemporary nephrology and nursing practice.

Dignity therapy is a brief, structured psychotherapeutic intervention originally developed by Chochinov (2002) for patients nearing the end of life (Chochinov, 2002). It is grounded in the Dignity Model, which conceptualizes dignity as encompassing three interrelated domains: (1) illness-related concerns (e.g., symptom burden, physical discomfort), (2) dignity-conserving perspectives (e.g., identity, meaning, purpose), and (3) social dignity inventory (e.g., relationships, perceived social support) (Chochinov et al., 2005). Through a semi-structured interview, dignity therapy invites patients to reflect on life accomplishments, core values, and meaningful experiences, generating a “generativity

document” that can be shared with loved ones to affirm self-worth and preserve dignity (Wulandari and Rochmawati, 2024).

Originally validated in terminal cancer populations, dignity therapy has demonstrated significant benefits in reducing emotional distress and enhancing spiritual well-being (Gonzalez-Ling et al., 2022; Zhang et al., 2022). For example, a randomized controlled trial by Weru et al. (2020) involving 144 terminally ill cancer patients reported significant reductions in anxiety following dignity therapy. Similarly, Vincenzo et al. found that dignity therapy helped maintain inner peace and mitigate psychological suffering in a cohort of 67 patients receiving palliative care (De Vincenzo et al., 2024). Further evidence from studies conducted in Portugal (Julião et al., 2015), the United States (Emanuel et al., 2023), Australia (Vuksanovic et al., 2017), and Iran (Zaki-Nejad et al., 2020) supports the effectiveness of dignity therapy in improving psychological outcomes, perceived dignity, and quality of life among patients receiving end-of-life care. In addition, systematic reviews and meta-analyses provide higher-level evidence supporting the overall benefits of dignity therapy in cancer populations, including improvements in hope and quality of life and reductions in anxiety and depressive symptoms (Li et al., 2020; Zhang et al., 2022), offering a broader theoretical and empirical foundation for considering the potential applicability of dignity therapy beyond single-study findings. More recently, dignity therapy has been extended to patients with chronic obstructive pulmonary disease, heart failure, and neurodegenerative disorders, where it has shown potential in enhancing resilience and promoting meaning-centered adaptation (Brožek et al., 2019; Yang et al., 2023; Jenewein et al., 2021).

In mainland China, cultural and family-oriented adaptations of dignity therapy have been explored mainly in oncology contexts, including a family-participatory feasibility program (Wang et al., 2020), a family-oriented randomized controlled trial in patients with lung cancer (Xiao et al., 2022), a quasi-experimental study of Chinese culture-adapted dignity therapy among advanced cancer patients receiving chemotherapy (Lin et al., 2023), and a recent randomized trial of remote dignity therapy for patients with hematologic neoplasms and their significant others (Xie et al., 2024). Nevertheless, existing empirical studies of dignity therapy in China have largely focused on cancer-related or end-of-life care settings, and its application beyond palliative care—particularly in chronic, non-malignant conditions—has been relatively limited.

The psychosocial experiences of patients with end-stage renal disease can be understood within the Chronic Illness Adaptation Framework, which integrates principles from stress-coping and self-regulation theories (Livneh, 2001). This framework emphasizes the ongoing processes of appraisal, coping, and meaning reconstruction in chronic disease adaptation (Roy, 1999). Conceptually consistent with this model, dignity therapy may function as a meaning-centered intervention that supports adaptive coping and sustains a sense of dignity and self-coherence in the face of chronic illness. A preliminary study of dignity therapy in hemodialysis patients reported short-term improvements in stress and depressive symptoms (Adeleh et al., 2015), but methodological weaknesses—such as small sample size, unclear inclusion criteria, and limited follow-up—restrict its generalizability.

Given the chronic and psychologically burdensome nature of end-stage renal disease and the need for scalable psychosocial support within routine dialysis services, patients undergoing maintenance hemodialysis represent a highly relevant yet underexplored population for dignity therapy. Accordingly, this randomized controlled trial aimed to evaluate the effects of dignity therapy—delivered with context-appropriate adjustments to enhance acceptability—on dignity-related distress, treatment adherence, hope, depressive symptoms, and quality of life among patients with end-stage renal disease receiving hemodialysis in China.

2. Methods

2.1. Study design

This was a two-arm, parallel-group randomized controlled trial conducted to evaluate the impact of dignity therapy on dignity-related distress, treatment adherence, hope, depressive symptoms, and quality of life among patients with end-stage renal disease receiving maintenance hemodialysis. Due to the nature of the intervention, blinding participants and interventionists was not feasible.

2.2. Sample size calculation

Sample size was calculated using the formula for comparing two independent means in a two-sided test: $n_1 = n_2 = [2\sigma^2 (Z_{1-\alpha/2} + Z_{1-\beta})^2] / \delta^2$, where n_1 and n_2 represent the required sample size for the intervention and control groups, respectively (assuming equal size), δ is the expected between-group mean difference, and σ is the common standard deviation. A two-sided significance level of $\alpha = 0.05$ and power of $1 - \beta = 0.80$ were set, corresponding to $Z_{1-\alpha/2} = 1.96$ and $Z_{1-\beta} = 0.84$. Sample size calculations were performed for each outcome (dignity, treatment adherence, hope, depressive symptoms, and quality of life), and the largest required sample size was observed for hope; therefore, hope was used as the basis for the final estimation. Hope was assessed using the Herth Hope Index (total score range 12–48) (Herth, 1992). The expected between-group mean difference for hope ($\delta = 2.55$ points) was derived from Hall et al.'s dignity therapy trial, which reported a between-group difference in adjusted mean Herth Hope Index scores of 2.55 at 1-week follow-up (Hall et al., 2011). Using the corresponding standard deviation reported in that study ($\sigma = 3.5$), the minimum required sample size was 30 participants per group. Allowing for 20% attrition, the final target sample size was 38 per group (76 participants in total).

2.3. Participants

Participants were recruited face-to-face from two tertiary hospitals in Sichuan Province, China, between June and July 2025. The first author conducted preliminary eligibility screening via electronic medical records and approached patients meeting initial criteria. Attending nephrologists confirmed eligibility based on clinical assessment. Verbal and written information was provided to eligible individuals, and written informed consent was obtained prior to enrollment. Inclusion criteria were: (1) end-stage renal disease (stage 5 chronic kidney disease) diagnosed by a licensed physician according to the Kidney Disease: Improving Global Outcomes guidelines (Stevens and Levin, 2013) and currently receiving maintenance hemodialysis at the participating centers; (2) life expectancy ≥ 3 months (as judged by attending nephrologists based on routine clinical assessment and electronic medical record information, including comorbidities, recent hospitalizations, and overall clinical stability); (3) age ≥ 18 years; (4) awareness of diagnosis and treatment status; (5) cognitive capacity to comprehend intervention and questionnaires; (6) willingness to participate and sign informed consent. Exclusion criteria included: (1) diagnosis of cognitive or psychiatric disorders (e.g., dementia, schizophrenia); (2) concurrent participation in similar psychological interventions; (3) severe auditory or speech impairments that could compromise participation.

2.4. Data collection

Data were collected at four time points: baseline (T0), and at 2 weeks (T1), 4 weeks (T2), and 8 weeks (T3) post-intervention. Time points were selected based on prior dignity therapy studies (Deng et al., 2025; Xiao et al., 2022; Zhang et al., 2022), and the psychological volatility commonly observed among end-stage renal disease patients during dialysis. Two trained assistants conducted face-to-face assessments: the second author (primary data collector) and the third author (assistant).

Each participant was assigned a unique identifier to maintain confidentiality. Demographic and clinical variables were extracted from the hospital electronic records, whereas all scale-based outcomes were collected using paper questionnaires. Data entry and verification followed a predefined quality-control procedure. The second and third authors first checked transcription accuracy by comparing the electronic dataset with the original paper questionnaires to identify and correct transcription errors only. The fourth author then performed an independent item-by-item verification against the source questionnaires and completed data-cleaning procedures, including range checks, internal consistency checks across related fields, verification of assessment time points, and rescoring of scale totals according to scoring rules (including reverse-coded items). When missing values or discrepancies were identified, the team rechecked the original questionnaires and, when necessary, contacted participants to confirm responses before the dataset was finalized.

2.5. Randomization

A stratified block randomization method was used, with stratification by study site and fixed block size (block size = 4). The randomization sequence was generated by the fifth author using a computer-based randomization tool. To maintain allocation concealment, this author was not involved in intervention delivery or data collection. A total of 92 participants were enrolled: 45 from the first site (intervention: $n = 23$; control: $n = 22$) and 47 from the second site (intervention: $n = 23$; control: $n = 24$), yielding equal group sizes ($n = 46$) and balanced distribution.

2.6. Study groups

To ensure comparability across study sites and groups, both hemodialysis centers used the same institutional nursing protocol for standard psychological care. Prior to enrollment, nursing leads from the two centers held a joint site initiation meeting to align routine care procedures and standardize patient-education materials and checklists. Attending nurses delivered standard psychological care to participants in both the intervention and control groups; the only planned between-group difference was the addition of dignity therapy in the intervention arm.

Dignity therapy was delivered by the first author at both centers using the same standardized intervention framework and procedures. Adherence and fidelity to the dignity therapy protocol were assessed through structured session documentation. For each participant, the interventionist completed a brief session checklist documenting completion of the core dignity therapy components, including the interview session(s), preparation of the generativity document, and the final reading session. These records were reviewed by the research team to ensure protocol-concordant delivery and consistency across participants and sites.

2.6.1. Control group

Participants in the control group received standard psychological care from their attending nurses, including:

- (1) Health education: One-on-one sessions conducted before or after dialysis, addressing dialysis rationale, dietary restrictions, fluid control, and medication adherence. Materials included printed brochures and posters;
- (2) Psychological support: Emotional well-being was regularly monitored, with referrals made to mental health professionals as needed;
- (3) Dietary and fluid guidance: Personalized plans were developed to manage potassium, phosphorus, and sodium intake, with fluid restrictions tailored to individual dialysis parameters.

2.6.2. Intervention group

In addition to standard care, participants in the intervention group received dignity therapy based on Chochinov's Dignity Model (Chochinov, 2002) and conceptually informed by the Chronic Illness Adaptation Framework (Roy, 1999). This integration conceptualizes dignity therapy as a meaning-centered intervention to support adaptation to chronic illness by facilitating illness appraisal, coping and role adjustment, and meaning reconstruction while preserving self-worth and dignity. Consistent with this framework, the interview guide was structured to elicit reflections on living with a long-term, treatment-dependent condition, rather than focusing on end-of-life experiences. Accordingly, prompts were contextualized to capture dialysis-related dignity threats and adaptation demands (e.g., treatment burden, symptom distress, dependence on care, and role disruption). For example, questions addressing meaningful life experiences and valued roles were revised to explicitly reference experiences "during illness or dialysis" and changes "after starting dialysis" (Questions 1 and 3), supporting adaptive appraisal and role redefinition. In addition, the generativity-oriented prompt was broadened to include advice for others living with chronic illness or difficult treatment (Question 7), aligning with meaning reconstruction beyond a terminal context. In parallel, culturally sensitive modifications were implemented to enhance acceptability in the Chinese context, including removing overt death-related prompts to avoid unnecessary distress and revising wording to avoid assumptions about marital or parental status.

A contextual and cultural adaptation process was completed and the final version was fixed prior to recruitment. The standard dignity therapy question framework was first reviewed by an expert panel comprising three nephrologists, three senior hemodialysis nurses (≥ 10 years of clinical experience), and an advanced psychological counselor to evaluate clinical relevance, cultural appropriateness, and potential distress triggers. A pilot test with five hemodialysis patients was then conducted to assess comprehensibility and acceptability. Feedback indicated that some standard prompts were not contextually suitable or could provoke distress; therefore, wording, ordering, and contextual examples were refined, dialysis- and chronic-illness-specific phrasing was incorporated, and end-of-life-related prompts were removed. The final interview guide (Supplementary Table S1) retained the core dignity model structure and therapeutic targets (e.g., continuity of self, role preservation, generativity, and social connectedness) while incorporating culturally and clinically appropriate modifications for maintenance hemodialysis.

All interventions were delivered by trained research staff who completed a one-month dignity therapy training program covering theoretical foundations, structured interview procedures, communication techniques, and transcription practices. Training materials were drawn from Chochinov's manual Dignity Therapy: Final Words for Final Days (2018) (Barnosky, 2012).

Dignity therapy sessions were conducted in a private and quiet setting within the dialysis ward either when patients were stable during dialysis or shortly after dialysis ended. Before each session, the facilitator explained the purpose, structure, and procedures of dignity therapy and reviewed the interview outline with the participant to ensure informed and voluntary participation. Semi-structured interviews were conducted using a flexible guide, allowing the interviewer to adjust the order of questions, omit uncomfortable topics, or probe further when appropriate. Patients were encouraged to share their life stories, personal values, family connections, and future expectations.

Each patient completed 2 to 3 interview sessions (30–45 min each) within one week, depending on the patient's physical condition and dialysis schedule. Interviews were paused if strong negative emotions arose, and clinical follow-up was arranged as necessary. With consent, all interviews were audio-recorded and transcribed for the creation of a generativity document.

The final phase, known as "Sharing and Affirmation," is a critical component of dignity therapy. Within one week of completing the interviews, the research team compiled the transcribed content into a personalized generativity document, which was reviewed and approved by the patient. The narrative faithfully captured the patient's own words and sentiments, preserving the authenticity of their voice and emotional expression.

The patient then attended a separate, final face-to-face reading session with the interviewer, which served as an opportunity for reflection and affirmation of their life narrative. This reading session was conducted within one week after the generativity document was finalized; when clinically feasible, it could take place on the same day the document was returned to the patient. Overall, the intervention spanned approximately three weeks from the first interview to the final reading session. During this session, participants were invited to share their thoughts and feelings about the document, enabling them to reframe their experiences in a meaningful and constructive way. This process was designed to foster a sense of being heard and understood, thereby helping patients reaffirm their self-worth, social roles, and legacy. With the participant's consent, a copy of the document could be shared with family members or significant others, thereby facilitating emotional connection and extending the patient's spiritual presence within their close relationships.

2.7. Measurement

This study's primary outcome was patients' level of dignity. Secondary outcomes included hope, depressive symptoms, treatment adherence, and health-related quality of life, assessed at baseline and at 2, 4, and 8 weeks of follow-up.

2.7.1. Sociodemographic and clinical characteristics

This section was developed by the research team based on an extensive review of relevant literature. It includes: (1) Sociodemographic variables: age, sex, marital status, educational level, household registration, employment status, and income level; (2) Clinical characteristics: dialysis duration (years), comorbidities (e.g., diabetes, hypertension), weekly dialysis frequency, disease duration, and blood pressure; (3) Social support variables: family support (assessed by a single self-reported item rating perceived family support as none, limited, moderate, or strong), availability of a regular caregiver, recent dialysis attendance rate, history of psychological interventions, and history of depression or anxiety (ascertained from documented prior diagnoses in the electronic medical record).

2.7.2. Patient Dignity Inventory

The Patient Dignity Inventory, developed by Chochinov et al. (2002), is a validated instrument designed to assess dignity-related distress in patients with terminal illness. It has been widely applied among patients with cancer and chronic diseases. The inventory comprises 25 items across five dimensions: symptom distress (e.g., experiencing physical discomfort such as pain, shortness of breath, nausea, or vomiting), existential distress (e.g., feeling that one's life has had no meaning or contribution), peace of mind (e.g., worrying about the future), dependency (e.g., not being able to manage daily self-care such as bathing or dressing), and social support (e.g., feeling that friends and family are not supportive). Each item is rated on a 5-point severity scale (*none*, *mild*, *moderate*, *severe*, and *very severe*). Total scores range from 25 to 125, with higher scores indicating more severe dignity-related distress. We used the Chinese version translated and validated by Ge et al. (2016). In the current study, Cronbach's alpha ranged from 0.890 to 0.923 for the total scale and from 0.822 to 0.917 across subscales. Detailed Cronbach's alpha coefficients by time point (T0–T3) and subscale are provided in Supplementary Table S2.

2.7.3. End-Stage Renal Disease Adherence Questionnaire

Treatment adherence was assessed using the End-Stage Renal Disease Adherence Questionnaire developed by Zhang and Huang (2013). The instrument comprises 23 items across four domains: dietary adherence (8 items; e.g., following a light diet with less oil, salt, and spicy foods), fluid intake adherence (6 items; e.g., restricting daily fluid intake and using body weight as a reference for fluid control), medication adherence (5 items; e.g., taking medications on time and without missed doses), and dialysis regimen adherence (4 items; e.g., attending hemodialysis sessions according to the prescribed frequency and schedule and not requesting early termination). Items are rated on a 5-point Likert scale from *never* to *always*. Domain score ranges are 8–40 (diet), 6–30 (fluid intake), 5–25 (medication), and 4–20 (dialysis regimen), with a total score range of 23–115; higher scores indicate better adherence. Prior work reported Cronbach's α of 0.877 and test-retest reliability of 0.943. In the current study, Cronbach's alpha ranged from 0.903 to 0.941 for the total scale and from 0.79 to 0.91 across domains.

2.7.4. Herth Hope Index

Hope was assessed using the Herth Hope Index developed by Herth (1992), a concise instrument designed to measure individuals' level of hope. It includes 12 items categorized into three dimensions: positive attitude (e.g., maintaining an optimistic outlook toward life), goal-oriented behavior (e.g., having short-, medium-, or long-term goals), and connectedness (e.g., giving and receiving care and support from others). Items are rated on a 4-point Likert scale ranging from strongly disagree to strongly agree. Total scores range from 12 to 48, with higher scores indicating greater levels of hope. Scores of 12–23, 24–35, and 36–48 represent low, moderate, and high hope, respectively. We used the Chinese version introduced by Zhao and Wang (1997), which reported Cronbach's alpha of 0.85 in the original validation study. In the current study, Cronbach's alpha ranged from 0.901 to 0.936 across assessment points.

2.7.5. Patient Health Questionnaire-9

Depressive symptoms were assessed using the Patient Health Questionnaire with nine items, originally developed by Kroenke and colleagues in 2001 (Kroenke et al., 2001). This instrument comprises nine items corresponding to the diagnostic criteria for major depressive disorder as defined in the fourth edition of the *Diagnostic and Statistical Manual of Mental Disorders*, and evaluates the severity of depressive symptoms experienced over the previous two weeks (for example, "feeling down, depressed, or hopeless"). Each item is scored on a four-point response scale, resulting in a total score ranging from 0 to 27. Symptom severity is categorized as none (0–4), mild (5–9), moderate (10–14), moderately severe (15–19), and severe (20 or above). The Chinese version reported a Cronbach's coefficient of 0.89 and criterion validity indicated by a Pearson correlation coefficient of 0.73 with the Hamilton Depression Rating Scale (Löwe et al., 2004). In the present study, Cronbach's coefficients ranged from 0.845 to 0.921 across assessment points.

2.7.6. Instruments for quality of life assessment

Health-related quality of life was evaluated using two validated instruments: the 12-item Short Form Health Survey, originally developed by Ware and colleagues (Ware et al., 1996), and the 24-item Kidney Disease Quality of Life instrument developed by the RAND Corporation (Hays et al., 1994). The Chinese version of the twelve-item Short Form Health Survey, translated and validated by Su and Wang (2019), was used in this study. Cronbach's coefficients were 0.81 for the physical health component and 0.83 for the mental health component. Responses were scored according to the standard scoring algorithm to generate summary scores for physical and mental health, with higher scores indicating better health-related quality of life. The survey comprises twelve items covering eight domains, including physical functioning,

role limitations due to physical health problems, bodily pain, general health perceptions, vitality, social functioning, role limitations due to emotional problems, and mental health. Representative items address limitations in everyday physical activities (e.g., difficulties performing moderate activities or climbing stairs), role limitations due to physical or emotional problems, bodily pain, and emotional well-being (e.g., feeling calm and peaceful versus feeling downhearted).

The Kidney Disease Quality of Life instrument extends the twelve-item Short Form Health Survey by incorporating 24 kidney disease-specific items assessing domains such as kidney disease burden (e.g., feeling that kidney disease is a burden on daily life), symptom/problems (e.g., being bothered by dialysis- or kidney disease-related symptoms), effects of kidney disease (e.g., restrictions on work, travel, or daily routines), and functioning-related areas including cognitive function and social interaction. The official Chinese version provided by the RAND Corporation was used in this study (https://www.rand.org/health-care/surveys_tools/kdqol.html). Items were scored according to RAND guidelines, with domain scores linearly transformed to a 0–100 scale; higher scores indicate better kidney disease-related quality of life.

In the present study, Cronbach's coefficients ranged from 0.835 to 0.881 across assessment time points.

2.8. Statistical analysis

All data analyses were conducted using SPSS version 29.0. Continuous variables were presented as means \pm standard deviations (Mean \pm SD), while categorical variables were summarized as frequencies (n) and percentages (%). To compare baseline sociodemographic and clinical characteristics between the intervention and control groups, independent sample *t*-tests were used for normally distributed continuous variables, while chi-square tests or Fisher's exact tests (for small samples or expected frequencies < 5) were applied to categorical variables.

Intervention effects were evaluated using generalized estimating equation to account for repeated measurements at baseline and at 2, 4, and 8 weeks post-intervention. Group (intervention vs. control), time, and the Group \times Time interaction were specified as fixed effects, and an exchangeable working correlation structure was assumed. The generalized estimating equation models used all available observations, and participants contributed data for any time points completed. Missing outcome data were handled using an available-case approach within the generalized estimating equation framework. Little's missing completely at random test was performed to explore whether the missing-data pattern was consistent with missing completely at random (Little, 1988).

To provide a simple and intuitive comparison aligned with the randomized design, we additionally performed between-group comparisons of change from baseline at each follow-up time point. For each outcome, individual change scores were calculated as $\Delta = \text{follow-up} - \text{baseline}$ (at 2, 4, and 8 weeks), and group differences in change scores were tested using two-sample Welch *t*-tests. Sensitivity analyses were conducted using a per-protocol approach including participants who completed all intervention sessions and follow-up assessments (Abraham and Montedori, 2010). All statistical tests were two-tailed, and *p*-values < 0.05 were considered statistically significant.

2.9. Ethical considerations

The study was conducted in accordance with the ethical principles of the Declaration of Helsinki. All participants were fully informed about the study objectives, procedures, potential risks, and their right to withdraw at any time without affecting their hemodialysis care, and written informed consent was obtained prior to participation. Measures were taken to minimize psychological distress, including pausing interviews when necessary and arranging appropriate clinical follow-up. Participant confidentiality was ensured through the use of study codes and secure, password-protected data storage. The study protocol was approved by the institutional ethics committee of the participating

center (approval number: 2025004), and the trial was registered in the Chinese Clinical Trial Registry (ChiCTR2500104449).

2.10. Deviations from trial registration

This trial was prospectively registered in the Chinese Clinical Trial Registry (ChiCTR2500104449). Minor deviations from the registry entry are noted here for transparency. First, the criterion of life expectancy ≥ 3 months, which was listed as an exclusion criterion in the registry, was operationalized as an inclusion criterion in the manuscript; this reflects an equivalent clinical requirement and did not alter participant eligibility. Second, health-related quality of life, assessed using the 12-item Short Form Health Survey and the 24-item Kidney Disease Quality of Life instrument, was included in the manuscript as an additional outcome. Measurement of quality of life was planned prior to participant recruitment to explore potential broader effects of dignity therapy in patients undergoing hemodialysis, although it was not explicitly listed as an outcome in the trial registry. All prespecified registered outcomes, including dignity-related distress, depressive symptoms, hope, and treatment adherence, were fully assessed and reported as planned.

Third, the registered sample size ($n = 76$) reflected the initial estimate; to accommodate anticipated attrition and given recruitment feasibility, enrollment was increased to 92 participants before outcome analyses.

3. Results

This trial was conducted from June to October 2025 across two tertiary hospital hemodialysis centers in China. A total of 421 patients receiving maintenance hemodialysis were screened for eligibility. Based on predefined inclusion and exclusion criteria, 92 participants provided written informed consent and were randomly assigned to either the intervention group ($n = 46$) or the control group ($n = 46$). In the intervention group, 6 participants were lost to follow-up, yielding an attrition rate of 13.0%. In the control group, 7 participants were lost to follow-up (15.2%). The overall attrition rate was 14.1%. The primary reasons for loss to follow-up, aggregated across both groups and all follow-up time points, included referral to other facilities ($n = 7$, 53.8%), withdrawal of informed consent ($n = 4$, 30.8%), and clinical deterioration ($n = 2$, 15.4%), as detailed by group and assessment time in Fig. 1. The comparison of baseline demographic and clinical

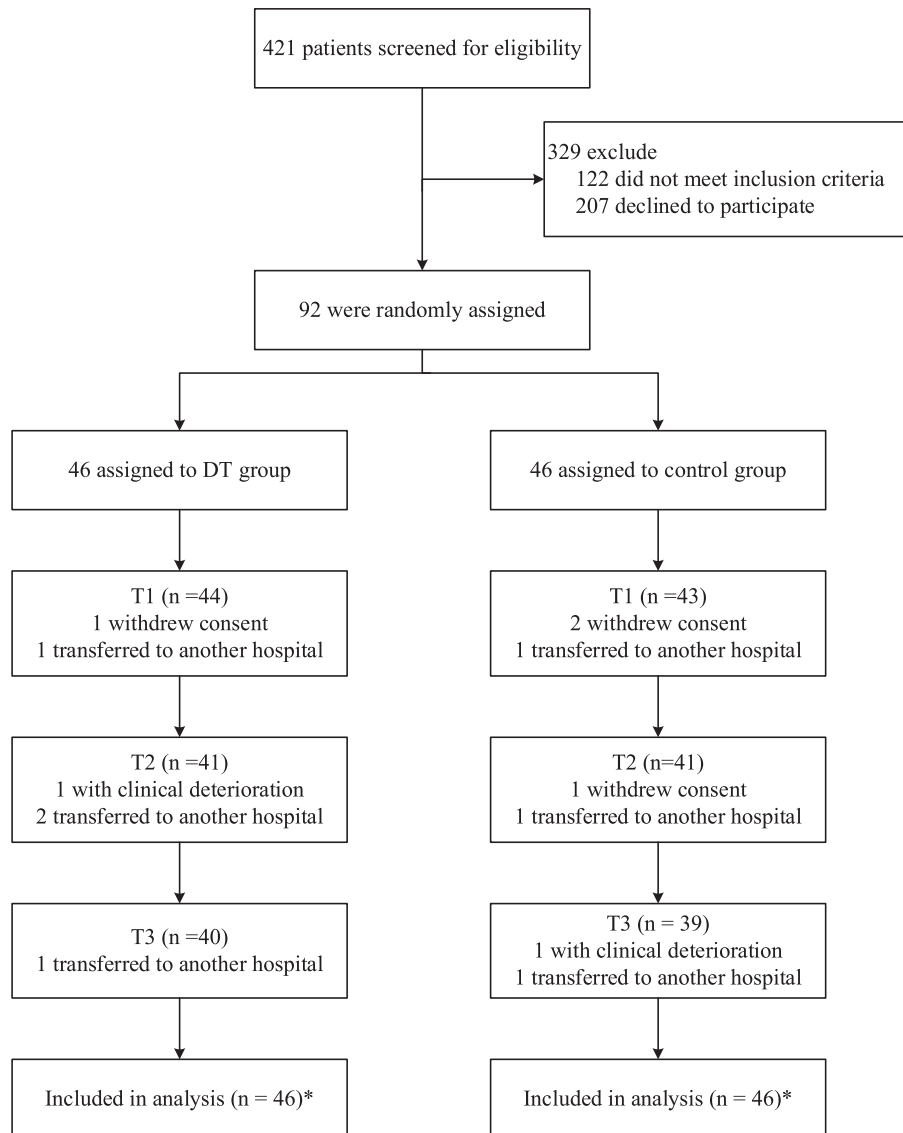


Fig. 1. Participant CONSORT flow chart.

Note: DT: dignity therapy; T0: baseline; T1: 2 weeks post-intervention; T2: 4 weeks post intervention; T3: 8 weeks post-intervention. *All randomized participants ($N = 92$) were included in the primary analyses according to their assigned groups.

characteristics between participants who completed the study and those lost to follow-up is summarized in Table S3. The results show no significant differences between the two groups, suggesting a low risk of attrition bias due to systematic differences in these measured baseline factors. All 92 randomized participants were included in the primary analyses, and all available outcome data were used.

3.1. Sociodemographic and clinical characteristics

Table 1 summarizes the baseline characteristics of the study population. The mean age was 62.54 ± 11.66 years in the intervention group

Table 1
Baseline characteristics of participants in the intervention and control groups.

Characteristic	Intervention group (N = 46) Mean (SD)/n (%)	Control group (N = 46) Mean (SD)/n (%)	χ^2/t	P value
Age (mean \pm SD)	62.54 \pm 11.66	60.46 \pm 11.89	-0.850	0.397 ^b
Sex			0.415	0.519 ^a
Male	27 (58.7)	30 (65.2)		
Female	19 (41.3)	16 (34.8)		
Residence			0.415	0.519 ^a
Urban	30 (65.2)	27 (58.7)		
Rural	16 (34.8)	19 (41.3)		
Marital status			1.476	0.761 ^c
Married	32 (69.6)	33 (71.7)		
Divorced	4 (8.7)	6 (13.0)		
Widowed	7 (15.2)	6 (13.0)		
Unmarried	3 (6.5)	1 (2.2)		
Number of children			0.600	1.000 ^c
0	3 (6.5)	2 (4.3)		
1	20 (43.5)	20 (43.5)		
2	16 (34.8)	17 (37.0)		
3	6 (13.0)	6 (13.0)		
4	1 (2.2)	1 (2.2)		
Education level			4.022	0.403 ^a
Illiterate	8 (17.4)	6 (13.0)		
Primary school	14 (30.4)	9 (19.6)		
Middle school	13 (28.3)	16 (34.8)		
High school	8 (17.4)	7 (15.2)		
College or above	3 (6.5)	8 (17.4)		
Medical insurance type			1.659	0.436 ^a
BMIUW	28 (60.9)	22 (47.8)		
BMIUR	12 (26.1)	17 (37.0)		
NRCMI	6 (13.0)	7 (15.2)		
Income level (RMB)			2.352	0.503 ^a
\leq 1000	4 (8.7)	7 (15.2)		
1001–3000	17 (37.0)	18 (39.1)		
3001–5000	14 (30.4)	15 (32.6)		
$>$ 5000	11 (23.9)	6 (13.0)		
Time since diagnosis (year)			3.333	0.355 ^a
$<$ 1	9 (19.6)	16 (34.8)		
1–3	11 (23.9)	9 (19.6)		
3–5	9 (19.6)	5 (10.9)		
$>$ 5	17 (37.0)	16 (34.8)		
Time since dialysis (year)			3.422	0.215 ^a
$<$ 1	19 (41.3)	26 (56.5)		
1–3	14 (30.4)	7 (15.2)		
$>$ 3	13 (28.3)	13 (28.3)		
Dialysis sessions per week (time)			0.090	0.765 ^a
2	7 (15.2)	6 (13.0)		
3	39 (84.8)	40 (87.0)		

Abbreviations: BMIUW = Basic Medical Insurance for Urban Workers; BMIUR = Basic Medical Insurance for Urban Residents; NRCMI = New Rural Cooperative Medical Insurance; RMB = Renminbi (Chinese Yuan).

Note:

^a Chi-square test.

^b Independent samples *t*-test.

^c Fisher's exact test.

and 60.46 ± 11.89 years in the control group ($t = -0.85$, $p = 0.397$). The distribution of sex, household registration type (urban/rural), marital status, number of children, educational attainment, and type of health insurance was comparable between groups. Additionally, no notable differences were observed in household income, duration since diagnosis, initiation time of dialysis, or weekly dialysis frequency, confirming baseline comparability between groups.

3.2. Baseline outcome measures

Table 2 displays the descriptive statistics for all outcome variables at baseline (T0), 2 weeks (T1), 4 weeks (T2), and 8 weeks (T3). At baseline, participants exhibited moderate levels of dignity-related distress (Patient Dignity Inventory total: 57.81 ± 18.27), with the highest burden reported in the symptom distress (13.74 ± 4.65) and dependency (16.73 ± 5.53) subdomains. Based on the End-Stage Renal Disease Adherence Questionnaire, overall treatment adherence was suboptimal (59.98 ± 12.03), with particularly low scores in fluid restriction (13.44 ± 4.12) and dialysis adherence (12.27 ± 3.23). Psychological assessment indicated elevated depressive symptoms (20.21 ± 5.89) and moderate levels of hope (31.58 ± 5.39). Health-related quality of life was at a moderate level, as indicated by scores derived from the twelve-item Short Form Health Survey (49.10 ± 9.92) and the Kidney Disease Quality of Life instrument (54.55 ± 11.95), and no floor or ceiling effects were observed.

3.3. Between-group comparisons of change from baseline

Table 3 presents between-group comparisons of change from baseline at each follow-up. At 2 weeks (T1), participants in the dignity therapy group demonstrated significantly greater improvements than those in the control group in total scores on the Patient Dignity Inventory, overall treatment adherence, levels of hope, depressive symptoms, and health-related quality of life as measured by the twelve-item Short Form Health Survey. No statistically significant between-group difference was observed for kidney disease-related quality of life at the two-week follow-up at T1. At 4 weeks (T2) and 8 weeks (T3), between-group differences in change from baseline were not statistically significant for any outcomes.

3.4. Effects of the intervention

Generalized estimating equation models was applied to assess group effects, time effects, and group \times time interaction effects following multiple imputation for missing data. The full results are provided in Table 4. Below is a summary of intervention effects across all outcome domains.

3.4.1. Dignity-related distress

The intervention significantly reduced overall dignity-related distress at T1 ($\beta = -5.587$, 95% CI: $-10.633, -0.541$; $P = 0.030$). Although scores continued to decline at T2 and T3, the changes did not reach statistical significance, suggesting that the primary benefit emerged early and was sustained over time without further improvement.

In subdomain analyses, symptom distress showed a significant reduction at T1 ($\beta = -1.370$, 95% CI: $-2.720, -0.020$; $P = 0.047$), with a non-significant downward trend at T2. Notably, the dependency domain demonstrated consistent and significant improvement at all three follow-up points—T1 ($\beta = -2.457$, 95% CI: $-3.983, -0.930$; $P = 0.002$), T2 ($\beta = -2.109$, 95% CI: $-3.828, -0.389$; $P = 0.016$), and T3 ($\beta = -2.065$, 95% CI: $-3.997, -0.133$; $P = 0.036$). Although reductions were observed in existential distress and social support subdomains, these did not reach statistical significance.

Table 2
Descriptive statistics and baseline comparison of outcome variables.

Outcome variables	Group	T0 (baseline) (N = 92)	T1 (two weeks) (N = 87)	T2 (four weeks) (N = 82)	T3 (eight weeks) (N = 79)	Comparison of groups at T0	
		Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	T	P
PDI	DT	56.96 ± 17.80	50.65 ± 8.65	53.65 ± 8.02	55.39 ± 7.83	0.445	0.657
	Control	58.65 ± 18.73	57.93 ± 17.60	59.02 ± 15.35	58.96 ± 13.37		
Symptom distress	DT	13.52 ± 4.70	12.04 ± 2.55	13.30 ± 2.47	13.89 ± 2.47	0.448	0.665
	Control	13.96 ± 4.60	13.85 ± 4.30	14.11 ± 3.69	13.93 ± 3.12		
Existential distress	DT	11.43 ± 4.02	10.26 ± 2.52	10.39 ± 2.35	10.78 ± 2.25	0.887	0.377
	Control	12.22 ± 4.43	11.91 ± 3.78	11.98 ± 3.56	12.02 ± 3.21		
Peace of mind	DT	8.98 ± 3.14	8.26 ± 2.20	8.85 ± 1.85	9.13 ± 1.88	0.688	0.493
	Control	9.43 ± 3.23	9.46 ± 3.17	9.70 ± 2.71	9.61 ± 2.15		
Dependency	DT	16.98 ± 5.86	14.24 ± 2.95	14.98 ± 2.65	15.11 ± 2.59	-0.433	0.666
	Control	16.48 ± 5.20	16.20 ± 5.04	16.59 ± 4.56	16.67 ± 4.11		
Social support	DT	6.04 ± 2.67	5.85 ± 2.08	6.15 ± 2.03	6.48 ± 2.13	0.831	0.408
	Control	6.57 ± 3.32	6.52 ± 3.24	6.65 ± 3.06	6.72 ± 2.80		
ESRD-AQ	DT	60.72 ± 12.55	67.41 ± 11.66	63.20 ± 8.66	59.91 ± 6.50	-0.589	0.558
	Control	59.24 ± 11.51	59.43 ± 9.82	59.20 ± 9.12	59.93 ± 7.96		
Dietary adherence	DT	19.72 ± 3.54	21.83 ± 3.87	20.59 ± 2.82	19.52 ± 3.14	-1.26	0.211
	Control	18.57 ± 5.09	18.87 ± 3.76	19.00 ± 3.35	19.70 ± 3.07		
Fluid adherence	DT	13.74 ± 3.75	16.00 ± 3.99	15.28 ± 3.55	15.02 ± 2.74	-0.587	0.279
	Control	13.15 ± 4.46	13.70 ± 3.92	13.24 ± 4.40	14.09 ± 3.36		
Medication adherence	DT	15.13 ± 4.74	16.24 ± 4.35	14.91 ± 3.63	13.65 ± 2.78	-0.120	0.905
	Control	15.02 ± 3.95	14.48 ± 3.79	14.17 ± 3.43	14.07 ± 3.12		
Dialysis adherence	DT	12.13 ± 3.44	13.35 ± 3.20	12.41 ± 3.18	11.72 ± 2.75	0.420	0.675
	Control	12.41 ± 3.00	12.39 ± 3.08	12.11 ± 2.78	12.09 ± 2.75		
HHI	DT	31.43 ± 5.18	33.85 ± 3.39	32.59 ± 3.22	31.61 ± 3.24	0.251	0.802
	Control	31.72 ± 5.60	31.85 ± 5.19	31.41 ± 4.47	30.13 ± 4.40		
PHQ-9	DT	19.85 ± 6.04	16.11 ± 4.29	16.48 ± 3.51	17.85 ± 3.37	0.584	0.561
	Control	20.57 ± 5.74	18.83 ± 4.71	18.09 ± 4.24	18.80 ± 3.47		
SF-12	DT	49.64 ± 10.35	55.19 ± 12.01	57.37 ± 12.67	54.41 ± 11.91	-0.526	0.600
	Control	48.55 ± 9.46	48.91 ± 9.70	52.05 ± 9.32	49.88 ± 9.41		
KDQOL	DT	56.44 ± 11.38	57.32 ± 12.08	56.49 ± 11.32	56.52 ± 10.56	-1.515	0.133
	Control	52.66 ± 12.50	52.89 ± 12.53	53.15 ± 12.05	55.03 ± 9.96		

Note: DT: dignity therapy; PDI: Patient Dignity Inventory (score range: 25–125); ESRD-AQ: End-Stage Renal Disease Adherence Questionnaire (score range: 23–115); HHI: Herth Hope Index (score range: 12–48); PHQ-9: Patient Health Questionnaire-9 (score range: 0–27); SF-12: 12-item Short Form Health Survey, standardized score (range: 0–100); KDQOL: Kidney Disease Quality of Life questionnaire, standardized score (range: 0–100). T0: baseline; T1: 2 weeks post-intervention; T2: 4 weeks post-intervention; T3: 8 weeks post-intervention. SD, standard deviation.

Table 3
Between-group comparisons of change from baseline in outcome measures at follow-up (T1–T3).

Outcome	Time point	DT (Δ Mean ± SD)	Control (Δ Mean ± SD)	T	P*
PDI	T1	-6.30 ± 17.17	-0.72 ± 4.11	2.15	0.017
	T2	-3.30 ± 17.68	0.37 ± 6.48	1.32	0.189
	T3	-1.57 ± 19.01	0.30 ± 8.49	0.61	0.544
ESRD-AQ	T1	6.70 ± 8.15	0.20 ± 5.24	-4.55	<0.001
	T2	2.48 ± 10.18	-0.04 ± 6.21	-1.43	0.155
	T3	-0.80 ± 11.25	0.70 ± 8.22	0.73	0.467
HHI	T1	2.41 ± 5.18	0.13 ± 2.16	-2.76	0.007
	T2	1.15 ± 5.59	-0.30 ± 3.29	-1.52	0.132
	T3	0.17 ± 5.59	-1.59 ± 3.82	-1.76	0.081
PHQ-9	T1	-3.74 ± 4.40	-1.74 ± 3.10	2.52	0.013
	T2	-3.37 ± 4.61	-2.48 ± 4.02	0.99	0.326
	T3	-2.00 ± 4.73	-1.76 ± 4.22	0.26	0.799
SF-12	T1	5.56 ± 14.36	0.36 ± 7.42	-2.18	0.032
	T2	7.73 ± 15.22	3.50 ± 8.14	-1.66	0.100
	T3	4.77 ± 15.01	1.33 ± 10.54	-1.27	0.206
KDQOL	T1	0.89 ± 6.94	0.23 ± 1.95	-0.62	0.537
	T2	0.06 ± 7.10	0.49 ± 3.66	0.36	0.716
	T3	0.09 ± 7.17	2.37 ± 6.46	1.61	0.111

Notes: Values are mean ± SD of change from baseline (Δ = follow-up – baseline); *Given multiple outcomes and follow-up time points, results in this table are provided for descriptive comparison only. Primary inference is based on analyses using generalized estimating equation models, as presented in Table 4; T1: 2 weeks post-intervention; T2: 4 weeks post-intervention; T3: 8 weeks post-intervention; DT: dignity therapy; PDI: Patient Dignity Inventory; ESRD-AQ: End-Stage Renal Disease Adherence Questionnaire; HHI: Herth Hope Index; PHQ-9: Patient Health Questionnaire-9; SF-12: 12-item Short Form Health Survey; KDQOL: Kidney Disease Quality of Life questionnaire; SD: standard deviation.

3.4.2. Treatment adherence

A significant group × time interaction was found for overall treatment adherence at T1 (β = 6.500, 95% CI: 3.729, 9.271; P < 0.001), indicating that the intervention markedly improved treatment adherence in the early phase. Although adherence levels remained elevated at T2 and T3, the differences between groups were no longer statistically significant.

Among the four adherence subdomains, significant improvements at T1 were observed in fluid adherence (β = 1.804, 95% CI: 0.766, 2.843; P < 0.001), medication adherence (β = 1.652, 95% CI: 0.473, 2.831; P = 0.006), and dietary adherence (β = 1.804, 95% CI: 0.417, 3.192; P = 0.011). However, these effects diminished over time and did not remain significant at later time points. Dialysis adherence showed no significant group × time interaction at any time point.

3.4.3. Hope

Hope levels significantly increased in the intervention group at T1 (β = 2.283, 95% CI: 0.679, 3.886; P = 0.005). Although further increases were observed at T2 (β = 1.457, 95% CI: -0.399, 3.312; P = 0.124) and T3 (β = 1.761, 95% CI: -0.018, 3.696; P = 0.075), these changes were not statistically significant, suggesting a potential trend toward a sustained benefit that warrants further investigation.

3.4.4. Depressive symptoms

For depressive symptoms, the intervention group exhibited a significant reduction at T1 (β = -2.000, 95% CI: -3.538, -0.462; P = 0.011), indicating a short-term alleviation of depressive symptoms. Although reductions persisted at T2 (β = -0.891, P = 0.318) and T3 (β = -0.239, P = 0.796), the differences were not statistically significant, suggesting that the main impact of the intervention occurred during the initial post-intervention period.

Table 4
Generalized estimating equation results for outcome variables.

Outcome variables	Regression coefficients													
	Group		T1		T2		T3		Group * T1		Group * T2		Group * T3	
	β (95% CI)	P	β (95% CI)	P	β (95% CI)	P	β (95% CI)	P	β (95% CI)	P	β (95% CI)	P	β (95% CI)	P
PDI	-1.696 (-9.081, 5.690)	0.653	-0.717 (-1.891, 0.457)	0.231	0.370 (-1.481, 2.220)	0.696	0.304 (-2.122, 2.731)	0.806	-5.587 (-10.633, -0.541)	0.030	-3.674 (-9.054, 1.706)	0.181	-1.870 (-7.820, 4.080)	0.538
Symptom distress	-0.435 (-2.315, 1.445)	0.650	-1.090 (-0.505, 0.287)	0.591	0.152 (-0.563, 0.868)	0.677	-0.220 (0-0.858, 0.814)	0.959	-1.370 (-2.720, -0.020)	0.047	-0.370 (-1.937, 1.198)	0.644	0.391 (-1.272, 2.054)	0.645
Existential distress	-0.783 (-2.493, 0.928)	0.370	-0.304 (-0.778, 0.170)	0.208	-0.239 (-0.775, 0.297)	0.382	-0.196 (-0.852, 0.461)	0.559	-0.870 (-2.227, 0.487)	0.209	-0.804 (-2.045, 0.437)	0.204	-0.457 (-1.813, 0.900)	0.510
Peace of mind	-0.457 (-1.743, 0.830)	0.487	0.022 (-0.258, 0.301)	0.879	0.261 (-0.188, 0.710)	0.254	0.174 (-0.366, 0.714)	0.528	-0.739 (-1.561, 0.083)	0.078	-0.391 (-1.385, 0.603)	0.440	-0.022 (-1.141, 1.098)	0.970
Dependency	0.500 (-1.738, 2.738)	0.616	-0.283 (-0.756, 0.191)	0.242	0.109 (-0.482, 0.700)	0.719	0.196 (-0.568, 0.959)	0.616	-2.457 (-3.983, -0.930)	0.002	-2.109 (-3.828, -0.389)	0.016	-2.065 (-3.997, -0.133)	0.036
Social support	-0.522 (-1.738, 0.695)	0.401	-0.043 (-0.191, 0.104)	0.562	0.087 (-0.153, 0.327)	0.477	0.152 (-0.214, 0.519)	0.416	-0.152 (-1.008, 0.703)	0.727	0.022 (-0.896, 0.940)	0.963	0.283 (-0.723, 1.288)	0.582
ESRD-AQ	1.478 (-3.390, 6.347)	0.522	0.196 (-1.303, 1.694)	0.798	-0.043 (-1.818, 1.731)	0.962	0.696 (-1.655, 3.046)	0.562	6.500 (3.729, 9.271)	<0.001	2.522 (-0.887, 5.930)	0.147	-1.500 (-5.483, 2.483)	0.460
Dietary adherence	1.152 (-0.620, 2.925)	0.203	0.304 (-0.601, 1.210)	0.510	0.435 (-0.500, 1.370)	0.362	1.130 (-0.127, 2.388)	0.078	1.804 (0.417, 3.192)	0.011	0.435 (-1.027, 1.896)	0.560	-1.326 (-3.085, 0.433)	0.140
Fluid adherence	0.500 (-1.152, 2.152)	0.553	0.457 (-0.085, 0.998)	0.098	0.674 (0.048, 1.300)	0.035	0.848 (0.055, 1.640)	0.036	1.804 (0.766, 2.843)	<0.001	0.870 (-0.295, 2.035)	0.143	0.435 (-0.868, 1.738)	0.513
Medication adherence	0.109 (-1.654, 1.872)	0.904	-0.543 (-1.349, 0.262)	0.186	-0.848 (-1.746, 0.050)	0.064	-0.957 (-1.884, -0.029)	0.043	1.652 (0.473, 2.831)	0.006	0.630 (-0.754, 2.015)	0.372	-0.522 (-1.960, 0.916)	0.477
Dialysis adherence	-0.283 (-1.586, 1.021)	0.671	-0.022 (-0.410, 0.366)	0.913	-0.304 (-0.930, 0.321)	0.341	-0.326 (-1.103, 0.450)	0.41	1.239 (0.600, 1.878)	<0.001	0.587 (-0.380, 1.554)	0.234	-0.087 (-1.222, 1.048)	0.881
HHI	-0.283 (-2.464, 1.899)	0.800	0.130 (-0.486, 0.747)	0.678	0.304 (-1.245, 0.637)	0.526	-1.587 (-2.679, -0.495)	0.004	2.283 (0.679, 3.886)	0.005	1.457 (-0.399, 3.312)	0.124	1.761 (-0.0175, 3.696)	0.075
PHQ-9	-0.717 (-3.098, 1.663)	0.555	-1.739 (-2.626, -0.853)	<0.001	-2.478 (-3.627, -1.329)	<0.001	-1.761 (-2.966, -0.555)	0.004	-2.000 (-3.538, -0.462)	0.011	-0.891 (-2.640, 0.857)	0.318	-0.239 (-2.050, 1.572)	0.796
SF-12	1.087 (-2.921, 5.095)	0.595	5.193 (-1.759, 2.484)	0.738	3.502 (1.174, 5.830)	0.003	1.329 (-1.683, 4.340)	0.387	5.193 (0.574, 9.812)	0.028	4.227 (-0.708, 9.162)	0.093	3.442 (-1.799, 8.683)	0.198
KDQOL	3.776 (-1.056, 8.607)	0.126	0.229 (-0.328, 0.786)	0.420	0.486 (-0.561, 1.533)	0.363	2.374 (0.527, 4.221)	0.012	0.658 (-1.403, 2.718)	0.531	-0.429 (-2.712, 1.854)	0.713	-2.288 (-5.046, 0.470)	0.104

Note: PDI: Patient Dignity Inventory; ESRD-AQ: End-Stage Renal Disease Adherence Questionnaire; HHI: Herth Hope Index; PHQ-9: Patient Health Questionnaire-9; SF-12: 12-item Short Form Health Survey, standardized score; KDQOL: Kidney Disease Quality of Life questionnaire, standardized score. T0: baseline; T1: 2 weeks post-intervention; T2: 4 weeks post-intervention; T3: 8 weeks post-intervention. SD, standard deviation; β, regression coefficient.

3.4.5. Quality of life

A statistically significant interaction between group and time was observed for scores on the twelve-item Short Form Health Survey at T1 (β = 5.193, 95% CI: 0.574, 9.812; P = 0.028) indicated early improvement in general health-related quality of life. This trend continued through T2 and T3 but was not statistically significant. In contrast, no statistically significant changes were detected in kidney disease-related quality of life at any follow-up assessment, suggesting that the intervention had limited effects on disease-specific aspects of quality of life.

3.5. Intervention tolerability

Temporary interruptions during dignity therapy sessions were documented. During dignity therapy sessions, interviews were paused in 4 participants in the intervention group (5 pauses in total), with 1 participant requiring 2 pauses. The reasons for pausing were perceived excessive session duration (1 participant), intense emotional distress (1 participant), and scheduling or procedural demands related to hemodialysis (2 participants). All paused interviews were subsequently resumed and completed the full interview procedures: 2 participants completed the sessions after a brief break, and 2 participants completed the sessions the following day. No serious adverse events were reported, and the interruptions did not result in long-term participant distress or impact intervention completion.

3.6. Sensitivity analysis

To evaluate the robustness of the primary findings, a sensitivity analysis was conducted using a per-protocol approach. In this analysis, only participants who completed the full intervention protocol and all

follow-up assessments at baseline and at 2, 4, and 8 weeks post-intervention were included. The per-protocol analysis examined whether intervention effects persisted under full adherence. As shown in Supplementary Table S4, the group-by-time interaction effects for key outcomes, including dignity-related distress, treatment adherence, hope, depressive symptoms, and quality of life, remained statistically significant and followed the same directional patterns as in the primary analysis. These results indicate that the main findings were robust to protocol deviations and incomplete follow-up and support the overall stability of the intervention effects.

4. Discussion

This randomized controlled trial is among the first to evaluate the effects of dignity therapy in patients with end-stage renal disease in China. The results demonstrate that dignity therapy had significant short-term benefits in improving patients' dignity, TA, hope, depressive symptoms, and general health-related quality of life. However, most outcomes did not maintain statistical significance at later time points (T2, T3), and the disease-specific quality of life did not show significant changes throughout the study. Moreover, the between-group comparisons of change from baseline presented in Table 3 showed patterns that were directionally consistent with the generalized estimating equation analyses presented in Table 4, indicating a similar profile of short-term improvement.

4.1. Effects of dignity therapy on dignity-related distress

Dignity therapy was originally designed to alleviate existential distress and enhance a sense of personal dignity in patients facing life-

limiting illness. Our findings provide preliminary support for its applicability in the context of end-stage renal disease. The overall score of dignity-related distress, as measured by the Patient Dignity Inventory, showed a statistically significant reduction at T1, indicating early effectiveness of the intervention. However, this effect did not sustain statistical significance at T2 and T3, suggesting a potential attenuation of benefit over time. A similar finding was reported by Xiao et al. (2022), who conducted a randomized controlled trial among lung cancer patients undergoing chemotherapy. Their study found a significant group-by-time interaction in dignity scores at T1, but no sustained effects were observed during subsequent follow-ups.

Among the five dimensions of dignity-related distress, the “dependency” subscale demonstrated the most robust response, with significant improvement observed at all post-intervention time points. This finding is aligned with prior dignity therapy studies in palliative oncology, where reductions in feelings of being a burden were a consistent outcome following narrative-based legacy interventions (Chochinov et al., 2005, 2011; Rodríguez-Prat et al., 2019). Given that end-stage renal disease patients frequently encounter progressive loss of physical autonomy and increasing reliance on caregivers, dignity therapy's emphasis on reaffirming personal agency may be especially impactful in mitigating dependency-related concerns. In many Chinese family-oriented contexts, shaped by Confucian values such as filial piety (Yeh and Bedford, 2003), individuals may experience heightened guilt and diminished self-worth when they perceive themselves as unable to contribute to their family, which may help explain why improvements in dependency-related distress were particularly salient in our sample. In addition, symptom distress also showed a statistically significant improvement at T1, though this benefit was not sustained at T2 or T3. This transient effect may be attributed to dignity therapy's immediate emotional and cognitive reappraisal effects, which may diminish over time without continued reinforcement or symptom-specific management. This observation is supported by the findings of Iani et al. (2020).

In contrast, the other subdomains—existential distress, peace of mind, and social support—did not demonstrate statistically significant intervention effects over time, and no consistent patterns of improvement were observed across follow-up assessments. Several explanations may account for this finding. First, existential aspects of dignity, such as meaning and inner peace, may require more sustained or repeated narrative engagement beyond a brief dignity therapy intervention. Second, domains such as perceived social support are often influenced by broader relational and structural factors that extend beyond the scope of a time-limited psychosocial intervention. Prior studies have similarly noted that existential and spiritual dimensions are among the most challenging outcomes to modify through brief interventions, often necessitating ongoing support or multidisciplinary approaches (Boston et al., 2011; Lee and Jeong, 2023).

4.2. Effects of dignity therapy on treatment adherence

Treatment Adherence is a critical determinant of prognosis in patients with end-stage renal disease, influencing not only biochemical outcomes but also hospitalization rates and quality of life (Arad et al., 2021). Although dignity therapy was originally developed as a psychological intervention to reduce existential and emotional distress, this study innovatively incorporated TREATMENT ADHERENCE as a secondary outcome to explore its potential behavioral implications. Surprisingly, our findings demonstrate that the intervention significantly improved overall treatment adherence at T1, particularly in the domains of fluid, medication, and dietary adherence. This result is consistent with prior evidence suggesting that psychological constructs—such as personal meaning, emotional resilience, and perceived self-efficacy—are closely associated with adherence behaviors in patients with end-stage renal disease (Khalil et al., 2013; Tsay et al., 2005). Although dignity therapy does not include explicit behavioral components, its structured

life reflection may enhance patients' internal motivation and sense of responsibility, thereby facilitating short-term adherence gains.

However, these improvements were not sustained at T2 or T3. This attenuation may reflect the transient nature of emotional uplift generated by dignity therapy, particularly in the absence of continuous psychological reinforcement or structural support. Previous studies on dignity therapy in chronic disease populations similarly reported that benefits in behavior-related outcomes often dissipate over time without booster sessions or integration with routine care (Hall et al., 2013; Ounalli et al., 2020). It is also plausible that as patients return to daily stressors, including rigid dialysis schedules and symptom burdens, initial motivational effects may be overridden by chronic fatigue or treatment-related distress.

Notably, dialysis adherence showed no statistically significant improvement at any time point. This may be due to the already high baseline adherence rates commonly observed in hemodialysis patients, driven by strict institutional scheduling and the potentially life-threatening consequences of missed sessions (Som et al., 2017). Unlike dietary or fluid restrictions, which rely heavily on personal initiative, dialysis attendance is largely externally regulated, thus less susceptible to change through psychosocial interventions alone. Moreover, in some clinical settings in China, dialysis adherence is often regarded as a non-negotiable medical requirement (Pan et al., 2025), reinforced by institutional scheduling and family expectations, rendering this component of adherence less amenable to change through psychosocial interventions alone.

In sum, dignity therapy appears to enhance modifiable domains of treatment adherence in the short term, but its effects may require reinforcement through sustained or multi-modal strategies to produce lasting behavioral change, particularly in less autonomous treatment behaviors such as dialysis attendance.

4.3. Effects of dignity therapy on hope and depressive symptoms

The dignity therapy group demonstrated a significant increase in hope and a reduction in depressive symptoms at T1, echoing findings from prior research in palliative care settings where dignity therapy has been shown to enhance existential well-being and alleviate psychological distress (Hall et al., 2012). These early effects may be attributed to the core mechanism of dignity therapy—facilitating reflection on meaningful life events and personal values—which is theorized to elicit emotional clarity and a renewed sense of self-worth (Martínez et al., 2017). In the Chinese cultural context, personal value is often closely tied to one's role within the family and to a sense of continuity across generations (Yeh and Bedford, 2003). The life review and legacy-focused elements of dignity therapy may therefore resonate with patients by highlighting past contributions and ongoing relational significance. This perspective may help explain the early improvements in hope and depressive symptoms observed after the intervention.

However, although upward trends in hope and downward trends in depressive symptoms persisted through T2 and T3, these changes did not reach statistical significance. Several factors may underlie this attenuation. First, the absence of reinforcement sessions likely limited the durability of therapeutic gains. Prior studies have indicated that without continued engagement, the emotional benefits of dignity therapy tend to wane over time (Li et al., 2024). Second, the clinical burden associated with maintenance dialysis—such as frequent hospital visits, fluctuating somatic symptoms, and limited autonomy—may counteract sustained psychological improvement, especially in the absence of ongoing psychosocial support (Bernier-Jean et al., 2022). Finally, it is possible that the emotional impact of a single dignity therapy session is more immediate than enduring, suggesting that booster sessions or integration with broader psychosocial care models may be necessary to consolidate and extend its effects.

4.4. Effects of dignity therapy on general and disease-specific quality of life

A modest but statistically significant improvement in scores on the twelve-item Short Form Health Survey at T1 suggests that dignity therapy may exert short-term benefits on general health perceptions and psychosocial functioning, aligning with previous findings in palliative and chronic care settings where dignity therapy was shown to enhance emotional and role-related well-being (Guo and Jacelon, 2014). However, this effect diminished at later follow-ups, indicating a possible time-limited impact in the absence of sustained engagement or reinforcement. This temporal pattern is consistent with prior studies demonstrating that the psychosocial gains from dignity therapy may attenuate without booster sessions or continued psychological support (Xiao et al., 2022).

In contrast, no statistically significant changes were observed over time in kidney disease-related quality of life, as assessed by the disease-specific instrument. This discrepancy may be explained by the differing conceptual emphases of the two measures. The twelve-item Short Form Health Survey primarily reflects broad domains of physical and mental health, whereas the kidney disease-specific quality of life instrument focuses on challenges directly related to kidney disease, including symptom burden, treatment-related side effects, and lifestyle restrictions associated with long-term dialysis. Dignity therapy, as a meaning-centered intervention, is not designed to directly address these physiological or functional aspects. Previous studies have similarly reported limited effects of dignity therapy on somatic domains or disease-specific functioning (Zhang et al., 2022), underscoring the need for integrated interventions that combine existential support with medical or behavioral strategies to produce measurable change in disease-focused outcomes.

4.5. Implementation challenges and practical implications

Implementing dignity therapy in end-stage renal disease care presents several practical and contextual challenges that differ from its original use in palliative oncology. First, unlike terminal cancer patients who often receive intensive psychological support, end-stage renal disease patients are typically embedded in a maintenance treatment framework that prioritizes physiological stability over existential concerns (Mai et al., 2018). This clinical orientation may result in limited institutional support or therapist availability for conducting reflective, narrative-based interventions like dignity therapy. This highlights the importance of increasing institutional awareness and integrating existential care into routine dialysis services, particularly through multidisciplinary team involvement (Kurella Tamura et al., 2022).

Second, the fluctuating physical condition and frequent treatment burden of dialysis patients—such as fatigue, cognitive fog, and session scheduling conflicts—can impede the continuity and depth of dignity therapy sessions (Mehrotra et al., 2023). In our trial, interviews were paused in 4 participants (5 pauses in total) due to session length, intense emotional distress, or hemodialysis-related scheduling demands. Although all paused interviews were subsequently resumed and completed, such interruptions could affect intervention completeness and emotional processing. Future studies may benefit from shorter or segmented sessions, flexible scheduling aligned with dialysis workflows, and a prespecified pause-and-resume procedure to reduce participant burden while preserving therapeutic fidelity.

Third, cultural norms surrounding expression of emotion, death, and personal legacy may shape patients' willingness to engage with dignity therapy content in full depth, especially in non-Western settings like China (Chiang et al., 2021; Tu et al., 2022). In Chinese cultural settings, open discussion of personal mortality is often avoided (Pun et al., 2020), which may limit patients' willingness to engage fully with reflective components of dignity therapy. This tendency may influence how individuals approach life review and legacy-related discussions. In

addition, family-centered care practices and indirect communication styles may shape how patients participate in and respond to the intervention. Consistent with these considerations, we implemented context-appropriate modifications in this trial. Further research is warranted to develop and systematically evaluate tailored delivery models, including flexible session formats and brief pre-session assessments of cognitive and emotional readiness. In addition, maintaining therapeutic momentum over time proved difficult. Our results showed that although early benefits were evident, most outcomes attenuated by T2 or T3. This may indicate a need for reinforcement strategies—such as booster sessions or integration into broader psychoeducational programs—to sustain psychological gains (Zhang et al., 2024).

From a theoretical perspective, these findings can be understood within the Chronic Illness Adaptation Framework (Roy, 1999), which posits that individuals living with long-term conditions continuously adjust to evolving stressors through processes of appraisal, coping, and meaning reconstruction (Chochinov et al., 2005). Within this framework, dignity therapy may serve as a meaning-centered adaptation intervention, facilitating short-term coping and restoration of dignity by helping patients reappraise their illness and reaffirm personal identity. However, as chronic illness adaptation is inherently dynamic, the initial benefits of dignity therapy may diminish without sustained opportunities for meaning-making or psychosocial reinforcement. This interpretation underscores the importance of integrating dignity therapy into ongoing care models that support continuous psychological adjustment rather than viewing it as a one-time intervention.

Future studies could build on the context-appropriate modifications used in the present trial and further evaluate scalable implementation approaches, including embedding dignity therapy within multidisciplinary care models, aligning session timing with patient energy levels, and refining culturally informed content adaptations. Furthermore, investing in trained facilitators and evaluating patient readiness prior to initiation may enhance engagement and outcome consistency. These strategies could maximize dignity therapy's feasibility and efficacy in nephrology contexts, paving the way for broader implementation beyond palliative oncology.

4.6. Limitations

This study has several limitations that warrant consideration. First, the intervention was conducted at only two tertiary hospitals, which may limit the generalizability of the findings to broader end-stage renal disease populations. Future studies should involve larger, more diverse samples across multiple centers to enhance external validity. Second, the implementation of dignity therapy requires contextual adaptation. Cultural variations in attitudes toward death, emotional expression, and personal legacy may influence both patient receptivity and the therapeutic process. Thus, the observed effects in this study, conducted within a Chinese cultural context, may not be directly transferable to other regions without cultural tailoring. Third, data collection relied primarily on self-reported measures. Although all instruments employed demonstrated strong psychometric properties, the use of subjective scales may still introduce response biases or inaccuracies due to social desirability or recall effects. Future studies may incorporate routinely collected dialysis-related laboratory and clinical indicators (e.g., blood urea nitrogen, serum creatinine, electrolytes, and dialysis adequacy measures) to provide complementary objective information on patients' clinical status and to triangulate self-reported outcomes. Lastly, while the study focused on short- to medium-term outcomes, the relatively limited follow-up period may not have fully captured the sustainability of dignity therapy effects. Further research with longer follow-up is warranted to characterize the durability and trajectory of dignity therapy effects in end-stage renal disease, including whether early benefits persist, attenuate, or can be sustained with reinforcement strategies.

5. Conclusions

This randomized controlled trial provides preliminary evidence for the feasibility and short-term efficacy of dignity therapy among Chinese patients with end-stage renal disease receiving maintenance hemodialysis. Dignity therapy produced significant early improvements in dignity-related distress, treatment adherence, hope, depressive symptoms, and general health-related quality of life, with particularly sustained benefits in the domain of dependency. These findings suggest that dignity therapy may serve as a meaning-centered intervention that supports psychological adaptation and preserves a sense of autonomy in chronically ill populations. However, the attenuation of effects over time highlights the need for reinforcement or integration within ongoing psychosocial care to consolidate therapeutic gains. Building on the refinements used in this trial, future research could further develop and systematically evaluate scalable implementation approaches, including multidisciplinary integration and culturally informed delivery procedures, to strengthen longer-term psychosocial outcomes and kidney disease-specific quality of life.

CRedit authorship contribution statement

Yinhai Chen: Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Software, Resources, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Rong Huang:** Writing – review & editing, Software, Resources, Methodology, Investigation, Data curation. **Tong Zhou:** Writing – original draft, Supervision, Investigation, Formal analysis, Conceptualization. **Chenxi Tang:** Writing – original draft, Resources, Funding acquisition, Conceptualization. **Meng Qin:** Writing – review & editing, Resources, Methodology, Investigation, Data curation, Conceptualization. **Lin Su:** Writing – review & editing, Resources, Project administration, Investigation, Formal analysis, Conceptualization. **Xiong Ke:** Writing – review & editing, Writing – original draft, Supervision, Resources, Project administration, Investigation, Data curation, Conceptualization.

Clinical trial number

The trial was registered in the Chinese Clinical Trial Registry (ChiCTR2500104449).

Consent for publication

All participants provided written informed consent for publication of their data.

Statement of ethics

The trial was approved by the Ethics Committee of North Sichuan Medical College (Approval ID: 2025004).

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Declaration of competing interest

The authors declare that they have no conflicts of interest.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ijnurstu.2026.105397>.

Data availability

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

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