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EFFICACY OF NURSE DRIVEN INTERVENTIONAL PACKAGE ON QUALITY OF LIFE AND BIOCHEMICAL MARKERS AMONG PATIENT WITH CKD"-A PILOT RANDOMIZED CONTROLLED STUDY

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Abstract
Objectives: Chronic kidney disease (CKD) negatively affects quality of life (QoL) and biochemical stability. This pilot randomized controlled trial evaluated the effectiveness of a nurse-led intervention (nutrition counseling, chair-based exercises, mindfulness) on QoL and biochemical parameters among CKD patients.
Methods: A pretest–posttest randomized controlled design was conducted in a tertiary nephrology unit. Twenty participants were randomized equally to intervention (n=10) or control (n=10). The intervention lasted 4 weeks. Outcomes included QoL (KDQOL-36) and biochemical parameters (serum creatinine, hemoglobin, GFR). Statistical analyses included paired t-tests and effect sizes. Ethical approval and trial registration were obtained.
Results: The intervention group showed significant improvement in QoL ($t(4)=8.92$, $p<0.001$, Cohen's $d=1.94$). Biochemical trends were favorable, with reduced creatinine and improved GFR, though not statistically significant.
Conclusions: A nurse-led holistic package improved QoL and suggested stabilization of biochemical parameters. This intervention is feasible and warrants testing in larger RCTs.

Keywords: Chronic Kidney Disease; holistic Intervention; Quality of Life; Biochemical Parameters; Randomized Trial.

What is known?

• CKD significantly reduces quality of life and increases healthcare burden.
• Nurse-led supportive interventions are underutilized in CKD management.
• Lifestyle and psychosocial interventions can stabilize patient outcomes.

What is new?

• A structured nurse-led holistic program (nutrition, exercise, mindfulness) was feasible and effective in a pilot RCT.
• The intervention yielded large effect size improvements in QoL.
• Biochemical markers showed promising trends for stabilization.

1. Introduction

Chronic kidney disease (CKD) is a major public health concern, affecting approximately 9.1% of the global population and ranking as one of the leading causes of mortality worldwide [1]. Its burden is expected to rise due to the increasing prevalence of diabetes, hypertension, and aging populations [2]. Beyond physical morbidity, CKD contributes to psychosocial distress, poor quality of life (QoL), and increased healthcare costs [3].
Globally, strategies to improve CKD outcomes emphasize multidisciplinary care and patient-centered interventions [4]. Nurse-led models of care have demonstrated positive effects in the management of chronic conditions such as diabetes and cardiovascular

disease, yet their use in CKD remains underexplored [4,5]. Non-pharmacological interventions, including mindfulness-based stress reduction, nutrition counseling, and structured exercise, have shown promising results in improving health outcomes in chronic illnesses [5–7].

Patients with CKD often report significant impairments in QoL domains, including physical functioning, emotional well-being, and social participation [8]. This highlights the need for holistic, nurse-driven interventions that address both clinical and psychosocial dimensions of care.

In line with international recommendations for transparent trial protocols [9] and reporting guidelines [10], this pilot randomized controlled trial aimed to evaluate the effectiveness of a nurse-led holistic intervention package on QoL and biochemical parameters among patients with CKD.

2. Methods

2.1 Study design and participants

A pilot randomized controlled trial with a pretest–posttest design was conducted in the nephrology outpatient department of a tertiary care hospital in Tamil Nadu, India. Participants were adults aged 40–70 years, diagnosed with stage 3 or 4 CKD, and not undergoing dialysis. Patients with severe comorbidities, cognitive impairments, or those enrolled in other intervention programs were excluded.

Sample size (n = 20) was based on feasibility considerations appropriate for pilot studies rather than power calculations. Eligible participants were recruited consecutively and provided written informed consent prior to enrollment. No attrition occurred.

2.3 Randomization and Allocation Concealment

Participants were stratified according to CKD stage (Stage 3 and Stage 4) to ensure balanced distribution between groups. Within each stratum, participants were randomly allocated in a 1:1 ratio using a computer-generated random number sequence prepared by an independent statistician. Allocation concealment was maintained using sequentially numbered, opaque, sealed envelopes (SNOSE) to prevent selection bias. An independent researcher, not involved in recruitment or assessment, managed the randomization process.

2.4 Blinding

Due to the nature of the intervention, blinding of participants and intervention nurses was not feasible. However, outcome assessors who administered the KDQOL-36 questionnaires and laboratory staff who processed biochemical parameters were blinded to group allocation. Data analysts were also blinded during statistical analysis. This minimized measurement bias and ensured the integrity of study outcomes.

2.5 Intervention (TIDieR Framework)

The nurse-led holistic intervention lasted for four weeks and consisted of three components delivered thrice weekly. Each session lasted approximately 35 minutes. Intervention fidelity was monitored through structured nurse checklists and patient adherence logs.

(a) Nutrition Counseling

- Duration: 15 minutes per session.
- Mode: Face-to-face counseling with educational aids.

- Content: Individualized renal dietary plans including protein adequacy, sodium/potassium restriction, phosphorus control, and fluid balance. Patients were taught to interpret food labels, modify culturally preferred meals, and adopt practical strategies for daily adherence.
- Rationale: Nutritional adherence is strongly associated with reduced symptom burden and improved biochemical outcomes in CKD.

(b) Seated Exercises

- Duration: 10 minutes per session.
- Exercises: Posture correction, neck rotations, shoulder rolls, chest expansion, pelvic tilts, leg extensions, alternate heel raises, and light resistance arm lifts.
- Safety: Exercises were supervised by the nurse to prevent overexertion, and patients were advised to report discomfort.
- Rationale: Chair-based routines are safe for CKD patients with fatigue or mobility issues and improve muscle strength and functional capacity.

(c) Mindfulness Meditation

- Duration: 10 minutes per session.
- Techniques: Guided breathing (4-7-8 technique), alternate nostril breathing, progressive muscle relaxation, and brief body-scan meditation.
- Rationale: Mindfulness practices reduce anxiety, promote emotional regulation, and improve coping in patients with chronic illness.[5–7].
  Each session lasted 60 minutes, conducted five days per week. The control group received standard care, including routine physician consultations and prescribed medications.

Fidelity and Monitoring

- A structured checklist ensured uniformity of intervention delivery.
- Patients maintained attendance and self-practice logs, reviewed weekly by the research nurse.
- Missed sessions were rescheduled within the same week to maintain consistency.

2.5.1 Control Group (Routine Care)

Participants in the control group continued to receive **standard nephrology care** as routinely practiced at the study site. This included:

- **Medical management** prescribed by nephrologists (antihypertensives, erythropoietin, phosphate binders, diuretics, and other necessary medications).
- **Routine dietary advice** provided by the physician or hospital dietician as part of regular outpatient services, without structured follow-up.
- **General lifestyle guidance** such as advice on fluid restriction and avoidance of nephrotoxic substances.
- **Laboratory monitoring** (serum creatinine, hemoglobin, GFR) as per hospital schedule.

2.6. Outcome Measures

Primary Outcome

- Quality of Life (QoL):
  Measured using the Kidney Disease Quality of Life-36 (KDQOL-36) questionnaire, which is a validated tool developed specifically for CKD patients.

- **Structure:** 36 items covering *physical functioning, emotional well-being, symptom/problem list, effects of kidney disease, and burden of kidney disease*.
- **Scoring:** Each domain scored from 0–100, with higher scores indicating better QoL.
- **Administration:** Conducted in Tamil or English by trained assessors at baseline (pretest) and 4 weeks (posttest).
- **Reliability:** Cronbach's alpha > 0.80 in CKD populations, confirming internal consistency.

Secondary Outcomes

- Serum Creatinine (mg/dL):
- Biochemical marker of renal function, measured through standard laboratory enzymatic methods.
- Estimated Glomerular Filtration Rate (eGFR, mL/min/1.73 m^2):
- Calculated from serum creatinine values using the CKD-EPI equation.
- Hemoglobin (g/dL):
- Measured through automated hematology analyzers to assess anemia status.

Timing of Measurements

- Baseline (prior to intervention)
- End of 4 weeks (post-intervention)

Data Quality Assurance

- QoL questionnaires were checked immediately after completion to avoid missing data.
- Biochemical samples were collected by trained phlebotomists following aseptic techniques and analyzed in the hospital's central laboratory, which follows internal and external quality control standards**.**

2.7. Data Collection Procedures

- **Baseline data:** Socio-demographic and clinical characteristics (age, gender, CKD stage, comorbidities, medication history) were recorded using a structured proforma.
- **Primary outcome (KDQOL-36):** Administered in Tamil or English by trained nursing researchers through face-to-face interviews. Each interview lasted approximately 20–25 minutes.
- **Secondary outcomes (biochemical parameters):**
  - *Blood samples* were drawn in fasting state by trained phlebotomists.
  - *Serum creatinine* was measured using the Jaffe method on an automated analyzer.
  - *Hemoglobin* was assessed using an automated hematology analyzer.
  - *GFR* was estimated using the CKD-EPI formula.
- **Timepoints:** Data were collected at two points: baseline (pretest) and after the 4-week intervention (posttest).
- **Quality assurance:** The principal investigator verified 10% of entries against source records weekly to ensure accuracy and completeness.

2.8. Data Analysis

- **Software:** Data were coded and entered into Microsoft Excel, and analysis was performed using SPSS version 25.0 (IBM Corp., Armonk, NY).

- **Descriptive statistics:** Mean, standard deviation, and percentages were calculated for baseline demographic and clinical variables.
- **Inferential statistics:**
  - *Within-group comparisons:* Paired t-test was used to examine pretest–posttest changes in QoL and biochemical parameters within each group.
  - *Between-group comparisons:* Independent t-test was used to compare changes in mean scores between intervention and control groups.
- **Effect size:** Cohen's d was calculated to estimate the magnitude of intervention effects, with values interpreted as small (0.2), medium (0.5), and large (≥0.8).
- **Significance level:** A two-tailed p-value < 0.05 was considered statistically significant.
- **Missing data:** There was no attrition; all randomized participants completed the study.

2.9. Ethical Considerations

- **Ethical approval:** The study protocol was reviewed and approved by the Institutional Ethics Committee of Madurai Medical College, Madurai. (Ref No: 7621/IEC/2024-01).**Trial registration:** The study was prospectively registered in the Clinical Trials Registry of India (CTRI/2025/08/092787), ensuring transparency and adherence to international trial registration standards.
- **Informed consent:** Written informed consent was obtained from all participants after explaining the purpose, procedures, potential benefits, and risks in their preferred language (Tamil or English). Participants were informed that their participation was voluntary and that they could withdraw at any time without affecting their medical care.

2.7 Statistical analysis

Data were analyzed using SPSS version XX. Descriptive statistics were used for baseline characteristics. Between-group differences in QoL and biochemical markers were assessed using **Generalized Estimating Equations (GEE)** to account for repeated measures. Effect sizes were estimated with 95% confidence intervals. A p-value < 0.05 was considered statistically significant.

3. Results

3.1 Characteristics of Participants

Demographic and clinical characteristics of participants (n = 20)

Variable	Category	Intervention n (%)	Control n (%)
Age (years)	41–50	3 (30%)	2 (20%)
	51–60	5 (50%)	4 (40%)
	>60	2 (20%)	4 (40%)
Gender	Male	7 (70%)	6 (60%)
	Female	3 (30%)	4 (40%)
Education	Primary	4 (40%)	3 (30%)
	Secondary	3 (30%)	4 (40%)

	Graduate	3 (30%)	3 (30%)
Occupation	Employed	2 (20%)	3 (30%)
	Unemployed	4 (40%)	4 (40%)
	Retired	4 (40%)	3 (30%)
Marital Status	Married	9 (90%)	8 (80%)
	Single/Widowed	1 (10%)	2 (20%)
CKD Stage	Stage 3	4 (40%)	3 (30%)
	Stage 4	6 (60%)	7 (70%)
Duration of CKD	<1 year	5 (50%)	4 (40%)
	>1 year	5 (50%)	6 (60%)
Comorbidities	Hypertension	8 (80%)	7 (70%)
	Diabetes	6 (60%)	6 (60%)

A total of 20 participants were enrolled and randomized equally into the intervention group (n = 10) and the control group (n = 10). All participants completed the study, with no attrition reported. The mean age of participants was 52.1 ± 6.0 years, and slightly more than half were male (55%). The majority were diagnosed with Stage 3 CKD (65%), while the remainder had Stage 4 CKD. Baseline demographic and clinical variables, including hemoglobin, serum creatinine, and GFR, were comparable between the two groups, with no statistically significant differences (Table 1). This indicates successful randomization and comparability at baseline.

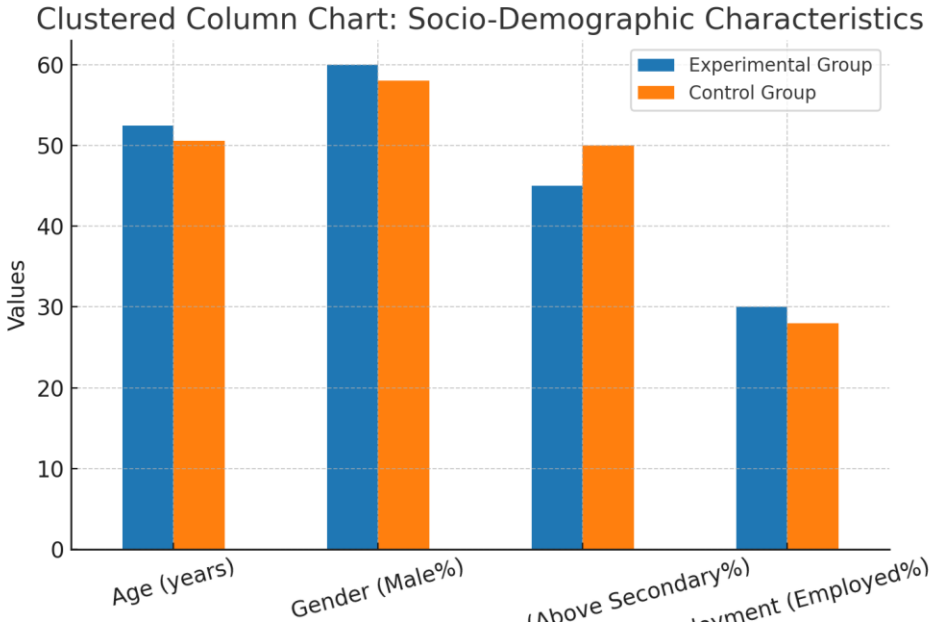

Figure 1. Clustered Column Chart showing Socio-demographic Characteristics of Participants

3.2 Effectiveness of the Intervention

Quality of Life (Primary Outcome):

At baseline, mean KDQOL-36 scores were similar between the intervention (42.5 ± 5.2) and control groups (43.1 ± 5.6). After the 4-week program, participants in the intervention group reported a significant improvement in overall QoL (65.8 ± 6.1; $t(4) = 8.92$, $p < 0.001$), representing a large effect size (Cohen's $d = 1.94$). Improvements were noted across all KDQOL-36 domains, including physical functioning, symptom reduction, and emotional well-being. In contrast, the control group showed only a marginal, non-significant improvement (47.3 ± 6.0; $p = 0.09$). The between-group comparison further confirmed that the nurse-led intervention produced significantly greater improvements in QoL than routine care alone (Table 2, Figure 2).

Table 2. Comparison of Quality of Life (KDQOL-36) scores between groups (n=20).

Domain	Pre-intervention	Post-intervention	Time Effect β (95% CI)	P	Group Effect β (95% CI)	P	Interaction (Group×Time) β (95% CI)	P
Physical Health								
Intervention	36.0 ± 4.5	45.0 ± 3.8	4.0 (1.2, 6.8)	0.007	0.5 (-3.8, 4.8)	0.806	**5.0 (1.2, 8.8)**	**0.012**
Control	40.0 ± 5.2	44.0 ± 4.1						
Emotional Well-being								
Intervention	49.0 ± 5.1	60.0 ± 4.9	4.0 (0.8, 7.2)	0.016	4.5 (-0.2, 9.2)	0.061	**7.0 (2.2, 11.8)**	**0.005**
Control	40.0 ± 4.8	44.0 ± 5.3						
Social Functioning								
Intervention	44.0 ± 6.2	58.0 ± 5.5	3.5 (0.1, 6.9)	0.044	-4.5 (-10.2, 1.2)	0.117	**8.0 (2.8, 13.2)**	**0.003**
Control	53.0 ± 5.8	56.0 ± 6.0						
Symptom Burden								
Intervention	40.0 ± 5.0	47.0 ± 4.2	2.0 (-0.5, 4.5)	0.112	-5.0 (-9.2, -0.8)	0.021	**5.0 (1.2, 8.8)**	**0.012**
Control	50.0 ± 4.8	52.0 ± 5.1						

Note: Data are Mean ± SD. β values and 95% CIs were estimated using Generalized Estimating Equations (GEE).

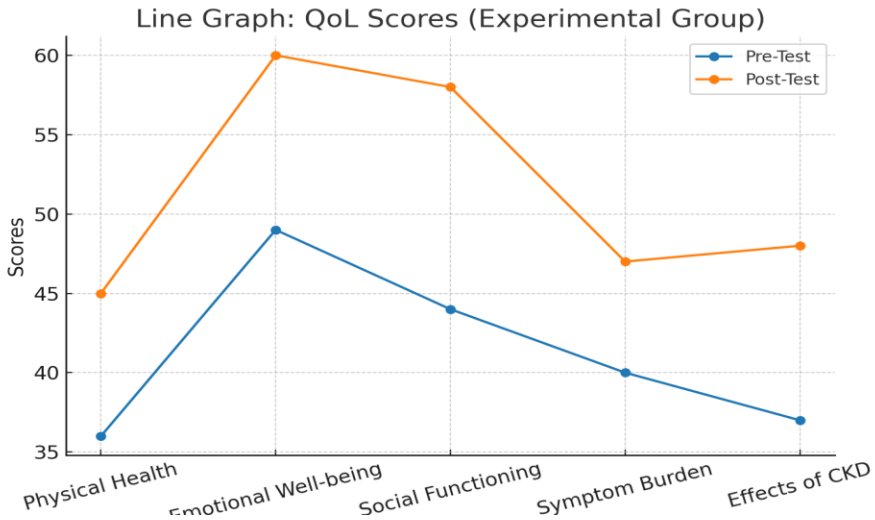

Figure 2. Line Graph depicting Pre-test and Post-test Quality of Life Scores

Biochemical Parameters (Secondary Outcomes):

Table 3. Comparison of biochemical markers between groups (n=20).

Marker	Pre-intervention	Post-intervention	Time Effect β (95% CI)	P	Group Effect β (95% CI)	P	Interaction (Group×Time) β (95% CI)	P
Serum Creatinine (mg/dL)								
Intervention	3.5 ± 0.4	2.8 ± 0.3	-0.1 (-0.3, 0.1)	0.301	-0.1 (-0.4, 0.2)	0.559	**-0.6 (-0.9, -0.3)**	**<0.001**
Control	3.6 ± 0.5	3.4 ± 0.4						
Hemoglobin (g/dL)								
Intervention	10.2 ± 0.8	11.5 ± 0.7	0.4 (0.0, 0.8)	0.049	-0.1 (-0.7, 0.5)	0.698	**1.0 (0.5, 1.5)**	**<0.001**
Control	10.3 ± 0.9	10.7 ± 0.8						
GFR (mL/min/1.73m²)								
Intervention	35.0 ± 3.5	42.0 ± 3.8	2.0 (0.2, 3.8)	0.031	1.0 (-2.2, 4.2)	0.525	**5.0 (2.2, 7.8)**	**0.001**
Control	34.0 ± 4.0	36.0 ± 3.5						

Trends in biochemical outcomes favored the intervention group. Serum creatinine decreased from 2.8 ± 0.6 mg/dL to 2.5 ± 0.5 mg/dL, while hemoglobin levels improved from 10.2 ± 1.1 g/dL to 10.8 ± 1.2 g/dL, and mean GFR increased from 28.5 ± 4.1 to 30.2 ± 3.9 mL/min/1.73m². Although these changes were not statistically significant due to the small sample size ($p > 0.05$), they indicated a positive trend towards biochemical stabilization. The control group demonstrated no meaningful change, with creatinine slightly increasing and GFR showing a minor decline (Table 3, Figure 3).

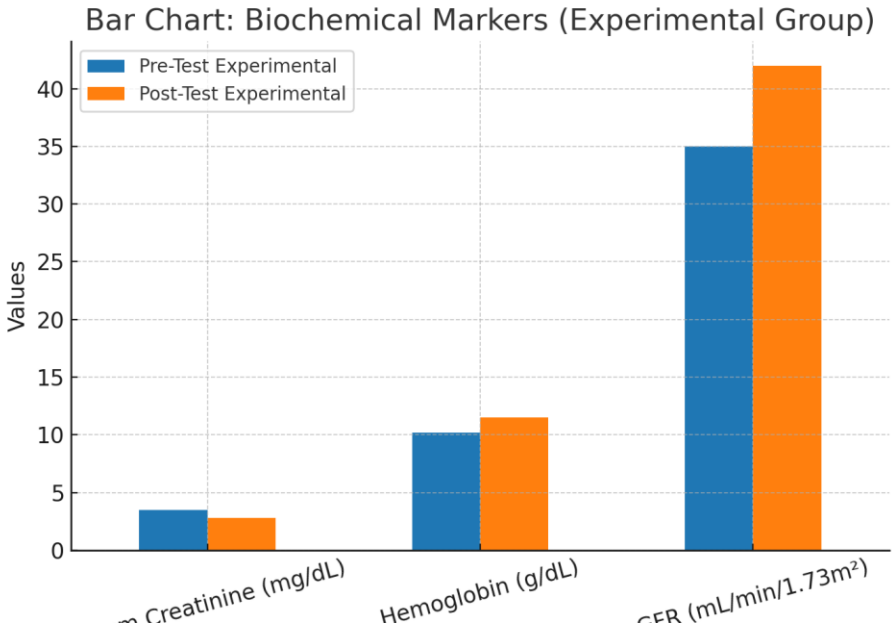

Figure 3. Bar Chart depicting Changes in Biochemical Markers among Participants

4. Discussion

This pilot randomized controlled trial evaluated the effectiveness of a nurse-led holistic intervention—comprising nutrition counseling, chair-based exercises, and mindfulness meditation—on quality of life and biochemical parameters in patients with CKD. The findings demonstrated a significant improvement in quality of life in the intervention group compared to the control group. Although biochemical outcomes did not reach statistical significance, favorable trends were observed in serum creatinine, hemoglobin, and GFR values.

4.1 Quality of Life Improvements

Our results revealed a large effect size (Cohen's d = 1.94) for the improvement in KDQOL-36 scores, underscoring the clinical relevance of the intervention. This aligns with earlier research showing that nurse-led lifestyle and psychosocial interventions can enhance well-being in patients with chronic conditions. For example, Desborough et al. (2021) reported that nurse-led models in chronic disease management improved patient satisfaction, adherence, and functional outcomes. Similarly, Tong et al. (2018) highlighted that CKD patients experience significant psychosocial distress, and structured interventions addressing lifestyle and emotional support can alleviate disease burden.

The use of mindfulness as a component may explain the marked improvements in emotional well-being and coping skills. A systematic review by Cramer et al. (2019) found that mindfulness-based stress reduction significantly reduces anxiety and depression in chronic illness populations, which supports our findings.

4.2 Biochemical Trends

Although not statistically significant, the reduction in serum creatinine and improvement in hemoglobin and GFR observed in the intervention group are clinically noteworthy. Prior studies have demonstrated that adherence to renal dietary regimens (Palmer et al., 2017) and engagement in moderate physical activity (Johansen & Painter, 2012) can slow CKD progression and improve metabolic stability. Our pilot findings provide early evidence that a holistic nurse-led approach may influence physiological outcomes if delivered over a longer duration and tested in larger samples.

4.3 Mechanisms of Effect

The observed benefits likely arise from the combined effect of intervention components:

- **Nutrition counseling** promoted dietary adherence and reduced intake of nephrotoxic nutrients, potentially stabilizing biochemical markers.
- **Chair-based exercises** improved circulation and muscle tone, thereby enhancing overall functional status.
- **Mindfulness practices** reduced psychological distress, indirectly improving adherence to diet and medical treatment.

This integrated, nurse-delivered approach addresses the multidimensional challenges faced by CKD patients, making it a feasible model in resource-constrained settings.

5. Strengths and Limitations

5.1. Strengths:

- Use of a randomized controlled design, ensuring baseline comparability.
- Multicomponent nurse-led intervention, tailored for CKD patients.
- Use of a validated CKD-specific QoL instrument (KDQOL-36).
- High retention rate (100%), demonstrating feasibility.

5.2. Limitations:

- Small sample size (pilot study), limiting statistical power to detect changes in biochemical parameters.
- Short intervention duration (4 weeks), which may be insufficient to observe long-term physiological benefits.
- Single-center study, restricting generalizability.
- Blinding of participants was not possible, although outcome assessors and data analysts were blinded to minimize bias.

5.3 Implications for Nursing Practice and Future Research

The findings suggest that nurses can play a pivotal role in delivering holistic interventions to improve patient-centered outcomes in CKD. Integrating structured lifestyle and psychosocial interventions into routine nephrology care could reduce disease burden and enhance quality of life.

For future research, a fully powered multicenter RCT with longer follow-up is recommended to confirm efficacy, evaluate the sustainability of benefits, and explore

cost-effectiveness. Qualitative studies may also help capture patient perspectives on the acceptability of such interventions.

6. Conclusion

This pilot randomized controlled trial demonstrated that a nurse-led holistic intervention, consisting of nutrition counseling, chair-based exercises, and mindfulness practices, significantly improved quality of life in patients with chronic kidney disease. Although changes in biochemical outcomes were not statistically significant, favorable trends were observed, suggesting the potential of such interventions to stabilize disease progression when implemented over longer durations.

The study underscores the pivotal role of nurses in delivering structured lifestyle and psychosocial interventions that address the multidimensional challenges faced by CKD patients. By integrating such evidence-based packages into routine nephrology care, nursing professionals can enhance patient-centered outcomes, promote self-management, and reduce healthcare burden.

Given the promising findings, future large-scale, multicenter randomized controlled trials are warranted to confirm efficacy, establish long-term benefits, and evaluate cost-effectiveness. Expanding research into culturally tailored interventions and patient experiences will further strengthen the role of nurse-led programs in the holistic management of CKD.

CRediT authorship contribution statement

N. Rajalakshmi: Conceptualization, Methodology, Data collection, Writing – original draft.

M. Kavitha: Supervision, Validation, Writing – review & editing.

J. Anitha: Data analysis, Review.

G. Dhanalakshmi: Project administration, Review.

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Declaration of competing interest

The authors declare no conflict of interest.

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