

A PROTOCOL FOR TESTING THE EFFICACY OF YOGA INTERVENTION IN MANAGING CHRONIC KIDNEY DISEASE OF UNKNOWN ETIOLOGY IN THE UDDANAM REGION

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ABSTRACT

Chronic Kidney Disease of Unknown Etiology (CKDu), a distinct form of CKD lacking traditional risk factors, has severely affected the Uddanam region of India, with a staggering 40-60% prevalence. Despite multiple investigations, the underlying causes remain elusive, highlighting the urgent need for complementary therapeutic approaches. Yoga, an ancient Indian practice with proven efficacy in various chronic illnesses, offers promising potential for CKDu management. This study aims to validate a yoga program for CKDu, assess its feasibility, and evaluate the efficacy of a three-month yoga intervention in alleviating symptoms and complications through comprehensive biochemical, physiological, and psychological assessments. Primary outcomes include biochemical markers, physiological parameters (e.g., blood pressure, body composition), and psychological assessments (quality of life, anxiety, stress). The validated and feasible yoga module is anticipated to demonstrate significant improvements in biochemical, physiological, and psychological outcomes in the intervention group compared to the control group. Positive results support the integration of yoga as an adjunctive therapy for CKDu management.

INTRODUCTION

Chronic Kidney Disease of Unknown Etiology (CKDu), identified by the World Health Organization in the early 2000s, is a distinct form of CKD that lacks the traditional risk factors associated with CKD, such as diabetes, hypertension, cardiovascular disease, and obesity. A unique characteristic of CKDu is its geographical restriction to specific regions, including Mesoamerican nephropathy in Central American countries, Balkan endemic nephropathy in the Balkan states, aristolochic acid nephropathy in regions using herbal medicines (e.g., Belgium, China), Sri Lankan nephropathy, and Uddanam endemic nephropathy in India. The highest prevalence of CKDu has been reported in Uddanam, India, with unpublished cross-sectional estimates suggesting a prevalence between 40% and 60% (Praveen Gadde, *et al.*, 2017), significantly higher than the highest CKD prevalence reported in Nicaragua, Central America, where 10-20% of the adult population have been affected (Torres *et al.*, 2010; Ramirez-Rubio *et al.*, 2016).

The Uddanam region, comprising over 100 villages in north-coastal Andhra Pradesh, has been severely affected by CKDu. As of 2015, it was estimated that more than 4,500 people had died from CKDu, and around 34,000 people were diagnosed with kidney diseases in the preceding 10 years in this region (Abraham *et al.*, 2016). Kaviti is one of the worst-affected areas, and the high incidence of CKDu has led to social stigma, with neighboring villagers hesitating to visit affected areas while the underlying

causes remain elusive, drinking water sourced from bore wells, hand pumps, and dug wells has been suspected as a potential contributor to the high CKDu prevalence (Reddy, D.V. Gunasekar, A, 2013). Despite multiple expert committees studying the situation from 2003 to 2013, proposing factors such as nitrate and silica contamination, dehydration, tobacco chewing, seafood consumption, pesticide exposure, and analgesic use, no concrete conclusions have been drawn, highlighting the need for further studies to determine the exact causes of CKDu in the Uddanam region (Reddy, D.V., Gunasekar, A, 2013).

CKDu shares similarities with CKD (Chronic Kidney Disease), which represents a critical global health challenge due to its substantial impact on morbidity and mortality rates. However, awareness among patients and healthcare providers remains remarkably inadequate (Tatapudi *et al.*, 2019). CKDu and CKD initially lack symptoms. However, as kidney function deteriorates due to a complex interaction of several aggravating factors, symptoms related to impaired regulation of water and electrolyte balance, waste clearance, and red blood cell production become apparent. If unrecognized or untreated, kidney failure may manifest with symptoms such as lethargy, weakness, shortness of breath, generalized swelling (oedema), loss of appetite, fatigue, congestive heart failure, metabolic acidosis, hyperkalemia, fatal arrhythmias including ventricular tachycardia, uremia leading to brain encephalopathy, pericarditis, or hypocalcemia (Narasimha Rao, Y., Prasada Rao M, 2018).

The ancient Indian practice of yoga, encompassing meditation, relaxation, breath control, and physical postures (*asanas*), has gained recognition as a therapeutic intervention for various chronic illnesses. Regular yoga practice promotes harmony and functional balance among organ systems, leading to improved health and well-being. Notably, yoga has demonstrated efficacy in enhancing the quality of life (QoL) for patients with chronic conditions such as lupus nephritis with CKD, cancer, Parkinson's disease, chronic lower back pain, and depression. The mechanisms underlying yoga's benefits involve decreasing oxidative stress and inflammation while boosting antioxidant defense mechanisms, resilience, mood, and metabolic regulation (Büssing, A., et al., 2012). Despite yoga's proven efficacy in CKD management, there is a dearth of research evaluating its potential in CKDu. Given the nature of CKDu's spread and the need for health promotion at individual and community levels, it is crucial to explore complementary therapies alongside conventional treatment approaches. Yoga offers promising avenues for alleviating symptoms and comorbidities of CKDu, owing to its established benefits in reducing oxidative stress, and inflammation, improving insulin sensitivity, controlling cardiovascular risk factors, and enhancing QoL (Levey, A.S., et al., 2012). Larger-scale and rigorous research is warranted to Fig. 1.

establish yoga as a safe, beneficial, and cost-effective adjunct treatment for slowing disease progression, reducing complications related to decreased estimated glomerular filtration rate (eGFR), mitigating cardiovascular risks, and improving QoL and survival in CKDu patients. Our proposed yoga-based lifestyle protocol aims to evaluate its effectiveness in managing CKDu, its symptoms, and complications, with the belief that positive outcomes could motivate self-motivated exploration of alternative therapies.

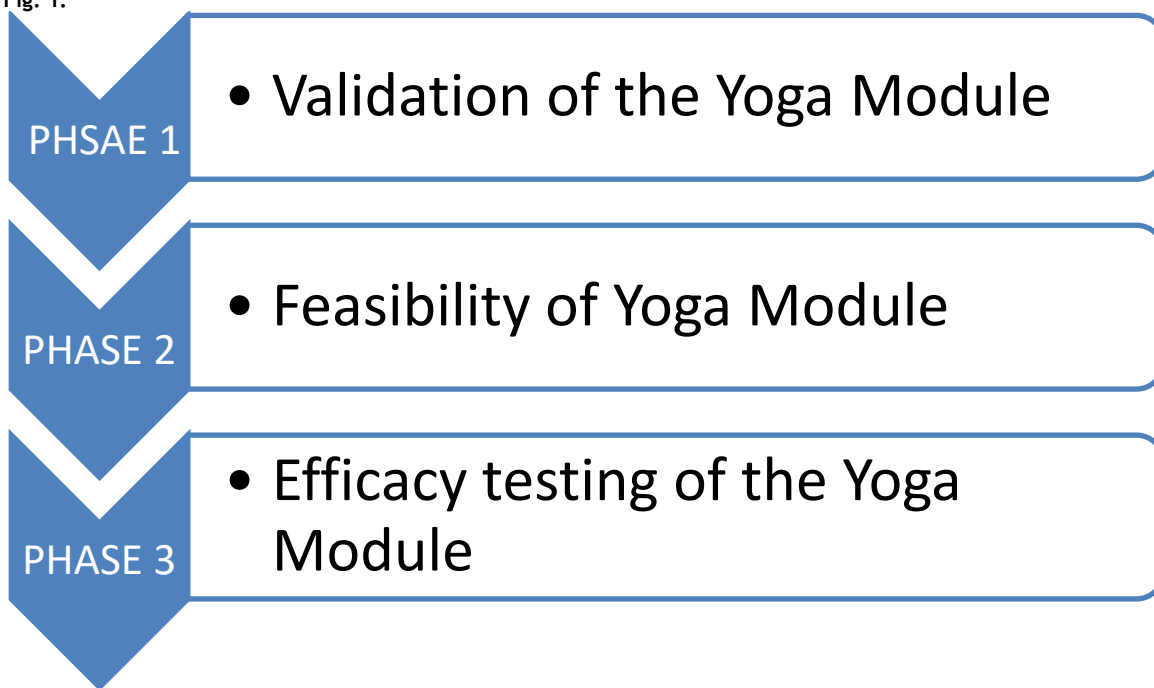
Aim and Objectives:

The study aims to develop, perform content validation, and assess the feasibility of a Yoga Module for patients with Chronic Kidney Disease of Unknown Etiology (CKDu).

1. To develop a comprehensive Yoga Module specifically designed for patients diagnosed with CKDu.
2. To validate the content of the Yoga Module, ensuring the inclusion of key components essential for designing and reporting interventions for CKDu.
3. To assess the feasibility of implementing the Yoga Module in a clinical setting for CKDu patients.

Study Design:

The validation, feasibility, efficacy testing of the Yoga module for CKDu will be conducted in three phases (Fig. 1).



Phase 1: Validation of the Yoga Module

The initial list of yoga practices will be compiled using a combination of traditional texts and published scientific studies about kidney diseases. This would be taken to experts (Yoga) and asked to rate each practice on a scale of 0-3 (0 - Not essential, 1 - Essential, 2 - Useful but not essential, 3 -Not Necessary). Based on the data obtained, (Lawshe's 1975) content validity ratio (CVR) will be calculated. Items that score above the calculated CVR score would be retained in the list and the module would be finalised.

Phase 2: Feasibility of the Yoga Module

The feasibility of implementing the proposed yoga module will be evaluated in a sample of approximately 20-30 randomly recruited CKDu patients from the Uddanam region who meet the eligibility criteria. The yoga intervention will be conducted over 4 weeks, with sessions scheduled 5 days per week. A self-structured questionnaire comprising both open-ended and closed-ended questions will be administered to the participants. The questionnaire will explore various aspects such as acceptability, adherence, logistical consideration, participant satisfaction, adverse effects and qualitative feedback suggestions. Based on

the feasibility assessment results, necessary modifications to the yoga module's design, delivery, or implementation strategies would be made for the third phase of the study.

Phase 3: Efficacy testing of the Yoga Module

Participants: A total of 100 participants would be randomly allocated equally to the intervention group and the control group based on convenience sampling. Patients diagnosed with CKDu (or CKD) will be identified from medical records at the District Medical Health Office (DMHO), Srikakulam, Uddanam region. Eligible participants will be recruited after attending an informational session conducted by the primary investigator, where informed consent will be obtained. Recruitment will continue until the target sample size is reached. Enrolled participants will then be randomly allocated to either the yoga intervention group or the control group using computer-generated random numbers to ensure unbiased group assignment. The selection criteria for the study would be as follows:

Inclusion criteria:

- A. Individuals diagnosed with CKDu between Stage 1 to Stage 4.
- B. Participants of both genders aged 20 years to 70 years.

C. Willingness to participate in a 12-week Yoga program.

Exclusion criteria:

- A. Individuals diagnosed with genetic kidney diseases, renal carcinoma, polycystic kidney disease or acute kidney pathologies
- B. Pregnancy
- C. Those who had undergone renal replacement therapy
- D. Those identified with severe cognitive impairment
- E. Individuals who are immobilized or have severe mobility restrictions
- F. Individuals diagnosed with metabolic, neurological or psychological problems
- G. Alcoholic or addiction to any other recreational drug(s)
- H. Recent surgery

Intervention:

The intervention group will receive the structured yoga program (as developed in phase 2). The program will be conducted under the supervision of a certified yoga trainer. Participants will attend one-hour sessions, five days per week, for 12 weeks.

Control Group:

The control group will receive standard care and education regarding CKDu management. Participants will be instructed to maintain their usual lifestyle and dietary habits during the study period.

Outcome Measures:

A comprehensive assessment will be conducted at baseline and post-intervention (12 weeks) for both groups. The primary outcomes will include the following:

Biochemical parameters:

This would comprise of Complete Blood Count, Renal Function Test, Liver Function Test, Thyroid Profile and Lipid Profile tests.

Physiological measures:

This includes Hand Grip Strength (for overall body strength & functioning) and Bio Scan (a non-invasive tool used to assess various physiological parameters such as body composition, hydration levels, and metabolic rate)

Psychological assessment:

These will include the 36-Item Short Form Survey Instrument (SF-36) Cronbach's α coefficient of the SF-36 questionnaire was 0.791, (Zhang, Y., et.al., 2012.), a patient-reported survey used to measure health-related quality of life across eight domains internal consistency Cronbach's $\alpha > 0.90$ (Linde, L., et.al., 2008.), Fatigue Assessment Scale (FAS) questionnaire designed to measure the severity of fatigue in individuals the test – retest reliability was .89. (De Vries, J., et.al., 2004), Perseverative Thinking Questionnaire (PTQ) tool to assess repetitive negative thinking patterns internal consistency α of 0.93 (Dereix-et.al., 2019.) such as worry and rumination, and Hamilton Rating Scale for Anxiety (HAM-A) for measuring the severity of anxiety symptoms. Additionally, a self-administered Vedic Personality Inventory (VPI) which assesses *Sattva* (gentle and controlled), *Rajas* (violent and uncontrolled) and *Tamas* (dull and uncontrolled) would be used along with the *Vata Pitta Kapha* Questionnaire to determine the individual's dominant body constitution (*doshha*) and related health attributes.

Statistical Analysis:

Appropriate statistical analyses will be performed to evaluate the efficacy of the yoga module intervention. Within-group and between-group comparisons will be conducted for the primary and secondary outcomes. Intention-to-treat analysis will be employed to handle missing data and assess the robustness of the findings.

DISCUSSION

This study protocol outlines a structured method for developing, validating, and assessing a yoga module designed for individuals with Chronic Kidney Disease of Unknown Etiology (CKDu), with a focus on areas with high prevalence, such as Uddanam, India. Chronic Kidney Disease of Unknown Etiology (CKDu) (Gunasekara, T. S. C., De Silva, P. M. C., Herath, C., Siribaddana, S., Siribaddana, N., Jayasumana, C., ... & Jayasundara, N. 2020) remains unique challenges due to its unclear causes and the absence of conventional risk factors typically associated with

Chronic Kidney Disease (CKD), such as diabetes and hypertension (Nistala, R., & Savin, V. 2017). Exploring this condition through complementary therapies like yoga provides a distinct viewpoint that resonates with earlier research highlighting the advantages of yoga in managing chronic diseases (McCall, et.al., 2013) Yoga has shown effectiveness in lowering oxidative stress, inflammation, and cardiovascular risks, all of which are important for managing chronic kidney disease (CKD). The protocol's strategy for creating a yoga module designed for CKDu responds to the pressing demand for supplementary therapies that work alongside conventional treatment, ultimately improving patients' quality of life (QoL).

The study employs a well-organized approach that includes content validation, feasibility testing, and efficacy evaluation, ensuring that the intervention is carefully designed to meet the unique needs and preferences of CKDu patients. Comparable phased approaches have shown effectiveness in interventions for numerous chronic conditions, where it is crucial to validate and assess feasibility as essential preliminary steps to ensure appropriate design and implementation. The integration of diverse outcome measures, such as physiological, biochemical, and psychological assessments, is consistent with the biopsychosocial model of health, facilitating a comprehensive evaluation of the intervention's impact on the physical and mental well-being of CKDu patients.

A possible constraint of the study lies in the challenge of maintaining participant involvement, given the dedication required for consistent yoga practice. Studies on yoga interventions for chronic disease management have noted variations in adherence rates, particularly among those who are not well-acquainted with the practice. The feasibility phase will assess acceptability, adherence, and logistical factors, allowing for crucial adjustments to the module's design or delivery before efficacy testing takes place. The study's limitation lies in its concentration on a particular region, potentially restricting the applicability of the findings to other populations that exhibit varying CKDu risk factors.

If successful, this study could help incorporate yoga as a cost-effective complementary therapy for CKDu. The yoga module provides CKDu patients with a proactive self-care approach that improves their quality of life and may help slow the progression of the disease, while having few negative effects. This initiative promotes resilience and self-management within an underserved community. Future research could explore broadening the module's use in more CKDu-affected areas or investigating the precise mechanisms through which the intervention reduces oxidative stress and improves metabolic health. This study presents a valuable chance for comprehensive management in CKDu, tackling existing knowledge gaps and promoting advancements in integrative methods for kidney health. Upon completion of the findings will be disseminated in journal and this dissemination strategy seeks to involve the scientific community in the development, validation, and feasibility of integrative CKDu treatment. Based on the literature review we assumed that this study presents comprehensive results and novel methodologies aimed at advancing future research, clinical practices, and policy-making to improve care and quality of life for CKDu patients globally.

CONCLUSION

This study protocol provides a method for creating, validating, and evaluating a yoga module specifically designed for patients with Chronic Kidney Disease of Unknown Etiology. This protocol focuses on the critical requirement for supportive, non-invasive strategies aimed at enhancing standard care and the quality of life for patients in Uddanam, India, where CKDu is widespread. Validating content, testing feasibility, and assessing efficacy offer a structured method for developing and implementing interventions that could be relevant to similar populations around the globe. This study has the potential to validate yoga as a supportive therapy for CKDu if it proves successful. The findings will be shared and showcased to promote holistic therapeutic approaches for CKDu and associated chronic kidney diseases.

Safety Monitoring:

Participants' safety will be closely monitored throughout the study. Any adverse events or side effects reported during or after the yoga sessions will be carefully documented and addressed.

Ethical Consideration:

The study protocol will undergo a comprehensive review and receive approval from the institutional review board and ethics committee RES/IEC-SVYASA/218/2021 to guarantee adherence to ethical standards. This trial is registered under the Clinical Trials Registry - India (CTRI), ensuring compliance with ethical standards and transparency in research practices CTRI/2022/02/040564. We will prioritize confidentiality and data privacy by implementing stringent measures to safeguard participant information. Data will be stored securely and will be accessible only to authorized research personnel, ensuring the protection of participant privacy throughout the study.

Consent:

Informed consent will be obtained from all participants before enrollment, incorporating both written and oral consent formats. The consent form will provide comprehensive details about the study, including its purpose, objectives, methods, and procedures. It will clearly state that participants have the freedom to withdraw from the study at any time without any repercussions. To enhance accessibility, the consent form will be available in both English and the local language, and the research team will clearly explain its contents in the local language to ensure participant understanding.

Confidentiality and Data Access:

All participant information will be treated with strict confidentiality by the research team. Data will be securely stored and accessible only to authorized researchers directly involved in the study, ensuring that participant privacy is upheld throughout the research process.

Declaration of Competing Interest:

The authors declare that they have no known financial interests or personal relationships that could have influenced the work reported in this paper.

Potential Implications:

If the yoga intervention significantly improves biochemical, physiological, and psychological outcomes in CKDu patients, it could support integrating yoga as an adjunct therapy in CKDu management. Positive outcomes may also encourage the adoption of yoga-based lifestyle interventions for other chronic kidney diseases, contributing to improved patient care and quality of life. This study design aims to provide robust evidence for the efficacy of the yoga module intervention, addressing the current research gap and expanding the therapeutic options available for individuals affected by CKDu.

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