

## Development of an Intra-dialysis Yoga Protocol for Patients with End-Stage Renal Disease

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### Abstract

**Objective:** Patients with end-stage renal disease on maintenance haemodialysis are physically inactive. We describe the rationale and process of developing a targeted yoga therapy intervention to promote physical activity among this population.

**Methods:** An intra-dialysis yoga protocol was devised through a process of expert consensus. All yoga therapists were trained in the tradition of Tirumalai Krishnamacharya and his son T.K.V. Desikachar. Protocol development occurred in 4 stages: 1. Education of panel on end-stage renal disease and haemodialysis; 2. Discussion of potential therapeutic benefits of yoga for the population; 3. Identification of therapeutic goals for the population; and 4. Yoga protocol development. The protocol was subjected to critical feedback by other yoga therapists, clinical researchers, and nephrologists.

**Protocol:** A yoga practice was developed to be administered over 12-weeks during dialysis (intra-dialysis yoga; IDY) and offered during each dialysis session (3 times a week). The therapeutic goals of the practice were to improve physical function, reduce cardiovascular risk factors (hypertension, and cardiovascular disease), improve fatigue, reduce muscle cramps, improve mood, and help patients' cope with chronic medical illness and dialysis treatment. The yoga tools selected for use were movement, breathing, and meditation. Movements (asana) were designed to be done during dialysis sessions recognizing the limitations of patients having to remain in a chair. Breathing practices emphasized relaxation by utilizing deeper breathing (langhana) and other specific techniques (sitali). A water meditation (dhyana) was chosen to further support relaxation and enhances the experience of purification which is akin to dialysis treatment.

**Conclusion:** We developed a yoga intervention through a process of expert consensus of yoga therapists, researchers and clinicians. Therapeutic goals for the yoga practice were identified a priori to protocol development. This process may be useful in future research design and to help focus outcome selections for clinical trials.

**Keywords:** Haemodialysis; Complementary and alternative medicine; End-stage renal disease; Yoga; Meditation; Mind-body therapies

### Introduction

Chronic kidney disease is an important public health problem in the United States. Over half a million Americans suffer from ultimate progression of the disease with complete or near complete failure of kidney function termed end-stage renal disease (ESRD) [1]. In 2008, the cost to Medicare for the care of patients with ESRD was 39 billion dollars [1]. A majority of patients with ESRD receive dialysis (70%), with over 90% of these receiving maintenance haemodialysis (MHD). MHD consists of 9 to 12 hours of treatment a week divided into three sessions at local dialysis centres. The large amount of time required for MHD treatment restricts patients both functionally and socially from other potentially health promoting activities.

Patients with MHD have a drastically shorter 5-year survival rate (35%) than the general population, with cardiovascular disease accounting for 50% of their mortality [1]. Higher overall mortality is associated with hypertension [2] and poor physical functioning [3-5]. Increased mortality is also associated with psychosocial factors such as adherence to treatment and positive versus negative perceptions of illness [6]. Further, health-related quality of life (HRQOL) is significantly lower among patients on MHD than the general population [7], and associated with increased morbidity and mortality [5,8,9].

Exercise has been studied for patients on MHD based on the need to improve HRQOL and co-morbid medical conditions [10-13]. While data suggests exercise might be beneficial to patients [14,15-25]

implementation has been very limited in practice [11, 26]. In research studies, adherence to exercise interventions has varied widely from 43% to 99% [11].

Yoga, a mind-body practice that includes gentle exercise, may provide a novel intervention for patients with ESRD. Yoga has been practiced in India for over two millennia with the original purpose of personal and spiritual development. A recent phenomenon of the 20<sup>th</sup> century is the popular use of yoga for physical and mental health [27, 28]. In 2006, according to a U.S. national health survey, 6.1% of adults used yoga for health reasons, corresponding to over 13 million individuals [29]. With the growing interest of yoga for health, a burgeoning field of yoga therapy has emerged in the U.S. to treat medical conditions with yoga [30]. However, there exist few high quality data for the application of yoga for medical conditions [31]. As yoga becomes more popular in

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mainstream culture, and more individuals seek yoga as complementary or integrative medicine, systematic and rigorous research needs to be conducted to translate yoga into this modern therapeutic context.

While MHD prolongs the life of patients with ESRD, multiple comorbidities and intensive treatment drastically affect quality of life and survival. Extrapolating from the exercise literature, yoga has potential to be an effective adjuvant therapy that may improve the quality of life and physical functioning. As demonstrated in the exercise literature, haemodialysis sessions provide an opportune period to practice yoga that may result in higher adherence. As a form of exercise, yoga has been categorized as low intensity, [32,33] which may be ideal for the low physical function and exercise capacity of ESRD population. In addition, the cognitive component of attention and the emphasis on relaxation that characterizes mind-body practices, may have enhanced and/or different therapeutic effects than conventional forms of exercise studied to date.

Whereas many clinical research trials have utilized mind-body techniques in clinical studies, few have explained detailed development and rationale for the intervention a priori. Thoughtful description of how a complementary medicine therapy was integrated with conventional therapies may help generate hypotheses and inform study designs. The purpose of this paper is to describe the development of an intra-dialysis yoga (IDY) intervention for patients with ESRD.

## Methods

The IDY protocol was devised specifically for patients with ESRD through a process of expert consensus. The assembled expert panel consisted of a mind-body researcher/physician who is also a certified yoga instructor (GB) and three expert yoga therapists (CB, DW, AW). All expert yoga therapists had completed more than 500 hours of yoga teacher training in the tradition of Tirumalai Krishnamacharya and his son T.K.V. Desikachar. Each yoga expert also had more than 15 years' experience teaching yoga, and had completed training at a major global yoga therapy centre, the Krishnamacharya Yoga Mandiram (KYM) in Chennai, India. In addition, panellists had completed graduate studies in distinct fields producing a broad set of expertise including: 1. Internal Medicine and Haematology (DW); 2. Doctorate in Psychology (AW); and 3.) Masters in Religious Studies (CB).

The objective of the expert panel was to develop a yoga intervention specifically for patients with ESRD to be delivered during MHD. In the process, the rationale of the intervention from the perspective of yoga therapy and clinical medicine was documented. The panel met through bi-weekly phone meetings from 10/2008 to 3/2009 to develop the protocol. Protocol development by the panel occurred in four stages. In stage 1, the principal investigator (GB) provided education to expert yoga therapists on patients with ESRD, co-morbid conditions and symptoms, and conventional therapy. Stage 2 consisted of discussions

on potential therapeutic benefit of yoga for this population among the panel. This discussion led to Stage 3 where major therapeutic goals of the yoga practice were developed. Lastly, in Stage 4, a detailed initial protocol was developed through a process of consensus to fulfil the goals identified in Stage 3. The protocol also received critical feedback through a review process by expert yoga therapists at KYM in India and nephrologists and expert mind-body researchers at Harvard Medical School in the United States. Feedback was utilized to revise, and ultimately finalize, the initial protocol by the expert panel.

For the purposes of future clinical research, we identified health-related quality of life as the primary outcome. The Kidney Disease Quality of Life-36 instrument will be used to assess health-related quality of life. This instrument has been shown to be valid and reliable among patients with end-stage renal disease on haemodialysis. The primary outcome will be the Physical Component of this scale which assess physical function as it relates to quality of life [34,35].

## Protocol development

**Applying yoga tools and theory:** The yoga protocol consists of three fundamental techniques of yoga: 1.) physical postures and movement with focused breathing (*asana*); 2.) Breathing exercises alone (*pranayama*), and 3.) Meditation and visualization (*dhyana*). The selection of yoga techniques was based on a therapeutic approach of yoga based on an Indian cultural and ancient model of human mind-body processes and experiences termed *pancamaya*. A detailed description of *pancamaya* for the purposes of therapeutic yoga has been previously published [36]. Briefly, the *pancamaya* model views the human as an inter-related network of 5 dimensions which are: 1.) physical body (*annamaya*); 2.) Functional quality of physiological processes such as metabolism and homeostasis (*pranamaya*); 3.) Cognition (*manomaya*); 4.) Behavior and personality (*vijnanamaya*); and 5.) Emotional states (*anandamaya*). Each dimension affects another. For example, an emotional state of anger causes increased muscle tension, increase blood pressure, a lack of mental clarity, and aggressive behavior. In the application of *pancamaya*, therapeutic yoga conceptualizes disease as manifesting in these five dimensions. For therapy, yoga techniques are selected and delivered to target symptoms or disease by influencing dimensions directly or indirectly. The application of the *pancamaya* model for patients with ESRD is illustrated in Table 1. Based on the expert consensus process from Stage 3 of the protocol development, major therapeutic goals identified for this patient population were: low quality of life and physical function, hypertension, cardiovascular disease, depression and anxiety, fatigue, and coping with chronic medical illness and dialysis treatment.

**Yoga movements (asana):** The first tool, physical movements and postures, were selected with the goal of improving physical function (directly), and symptoms of depression and anxiety and fatigue (indirectly). In addition, physical movements, as a form of moderate

Symptoms/co-morbidities	Annamaya (Physical)	Pranamaya (Breath)	Manomaya (Cognitive)	Vijnanamaya (Personality/behavior)	Anandamaya (Emotional)
Hypertension	✓	✓		✓	✓
Cardiovascular Disease	✓	✓		✓	✓
Low physical function	✓	✓	✓	✓	✓
Muscle Cramps	✓	✓			
Depression/anxiety		✓	✓	✓	✓
Fatigue		✓		✓	✓
Coping with chronic medical illness and dialysis treatment			✓	✓	✓

Table 1: Target symptoms and co-morbidities of patients with end-stage renal disease categorized by pancamaya model.

exercise and physical activity, may provide therapeutic effects on blood pressure and cardiovascular disease. Further, by providing a structured activity during dialysis, patients may have increased satisfaction with dialysis treatment.

To increase overall physical function, yoga movements were selected to specifically improve the range of motion and strength of major musculoskeletal groups including back, lower extremities, and arm(s). These movements guide the patient’s torso through gentle extension, forward flexion, lateral flexion, and rotation. Limb movements focus on flexion and extension of hips, knees and ankles. Movements were introduced in progressive manner to engage patients with new challenges while maintaining safety (Table 2) for yoga movements in 12-week protocol).

As a mind-body practice, movements are intended to be performed with specific qualities. In particular, an emphasis on moving with attention (*sthira*) and ease (*sukha*) characterizes yoga movements and potentiates effects (Yoga Sutra 2.4). To maintain cognitive attention, movements are done slowly and coordinated with breath. According to yoga philosophy, these characteristics to movement produce effects on multiple dimensions, such as emotional, behavioral in addition to effects on the physical body (Yoga Sutra 3.9).

Yoga movements were also selected based on the functional limitations of MHD including protecting vascular access and remaining in the haemodialysis chair. Each movement was modified for the specific purpose of yoga practice during MHD. To avoid potential disruption or harm to the vascular access, none of the proposed exercises involved

movement of the vascular access site; any movements of the extremities only involved those extremities without vascular access. For example, patients who have vascular access in one arm will only be able to perform unilateral arm movements in the free arm and the legs. Patients with vascular access in the chest will be able to move both arms. The protocol that was designed anticipating minor modifications to the *asana* based on the individual capacity of patients, with the intention of maintaining the overall function and purpose of the yoga movement.

**Breathing (pranayama):** The breathing practice was designed to promote overall mental relaxation. Specifically, the breathing practice was developed to increase vital capacity and duration of breath with emphasis on lengthening the expiratory component. The term used for this type of breathing is *langhana*, which according to yoga therapy may reduce stress and stress-related conditions such as pain, fatigue, and depressed mood. Another function of rhythmic breathing is believed to be improvement in circulation due oscillating intra-thoracic pressure affecting cardiopulmonary venous return. In week 4, an additional *langhana* breathing technique is introduced termed *sitali*. *Sitali* breathing has the practitioner inhale through the mouth with a rolled tongue and exhale through the nose. *Sitali* breathing is believed to also enhance relaxation while keeping the mind attentive rather than dull or lethargic. With each inhale and exhale, there is a slight extension and flexion of the neck respectively, which may help with neck strain or tightness.

**Meditation (dhyana):** Water was selected as the object of meditation. Patients will be asked to visualized pleasant moving water. The meditation on water will evolve over 12 weeks as patients visualize

	Week 1	Week 2	Week 3	Week 4&5	Week 6&7	Week 8	Week 9 & 10	Week 11&12
<b>Postures</b>								
<b>Reclined chair</b>								
• Hip flexion		✓	✓	✓	✓	✓	✓	✓
• Hip twist		✓	✓	✓	✓	✓	✓	✓
• Anterior arm extension		✓	✓	✓	✓	✓	✓	✓
• Rest		✓	✓	✓	✓	✓	✓	✓
• Hip abduction		✓	✓	✓	✓	✓	✓	✓
• Knee extension			✓	✓	✓	✓	✓	✓
<b>Upright chair</b>								
• Knee extension			✓	✓	✓	✓	✓	
• Knee extension and foot flexion								✓
• Arm extension					✓	✓	✓	✓
• Foot flexion					✓	✓	✓	✓
• Forward bend					✓	✓	✓	✓
• Chest expansion						✓		
• Chest expansion and twist							✓	✓
<b>Breathing/ Inspiratory:Expiratory Ratio</b>								
• Free observed breath		✓						
• Controlled breath/Inspiration<expiration			✓	✓	✓	✓	✓	✓
• Cooling breath//Inspiration<expiration				✓	✓	✓	✓	✓
<b>Meditation</b>								
• Visualize pleasant moving water								
• Visualize pleasant moving water over body		✓						
• Visualize moving water with hand from abdomen to chest, and from chest away from body			✓	✓	✓	✓	✓	✓
• Visualize water moving with hand into body, up and down body, and then from chest away from body				✓	✓	✓	✓	✓

Table 2: Intra-dialysis yoga protocol.

water: 1.) moving before them; 2.) over them; and finally 3.) Into and through them. The water meditation was chosen as metaphor since patients receiving haemodialysis undergo purification of body fluids. Extending this metaphor further in the context of yoga therapy, the water meditation was designed to encourage removal of impurities on physical (annamaya), mental (manomaya), and deeper personal and emotional (vijñanamaya and anandamaya) dimensions. As a cognitive and emotional tool, the meditation was intended to provide mental support for the physical process of dialysis and minimize (or in the case of the water meditation “wash away”) negative attitudes or feelings associated with the treatment. By providing a positive association with water during dialysis, patients may develop positive feelings or attitudes with water that may increase patient satisfaction with dialysis treatment. Lastly, water as visualized in the meditation is believed to carry qualities of gentle power, which may give patients a sense of control (self-efficacy) with the treatment process and better cope with his/her chronic disease.

**Dose, timing, and setting of intervention:** The proposed intra-dialysis yoga protocol consists of yoga instruction and practice three times a week for 12 weeks. Since a large majority of patients receive MHD three times a week, this provides a maximal opportunity for practice. The duration of the protocol was determined based on the length of other exercise interventions studies in this patient population [10]. Patients will be offered an opportunity to practice yoga twice during each MHD session for 15 to 30 minutes for a total practice of 30 to 60 minutes. Each practice in a given MHD session will be the same. The length of each practice was based on the presumed capacity for patients to practice the yoga attentively and comfortably. Yoga will be practiced prior to the last hour of MHD to minimize potential adverse events from dialysis-related hypotension that tends to occur near the end of MHD treatment. The yoga program was designed to be gradual and progressive over the 12 weeks to increase patient safety and confidence to perform the yoga, while establishing sustainable behavioural and physical changes. Patients will be seated in their routine chair for dialysis during the entire yoga session. The yoga practice will occur both in upright and reclined positions while in the chair.

**Yoga teacher method:** The protocol was designed to be taught by a yoga teacher familiar with the tradition of Krishnamacharya and his son Desikachar. In the first 2 sessions, the yoga teacher will give a general background to yoga including importance of coordinated breath and movement, and developing qualities of attention (*sthira*) and ease (*sukha*) during practice. Instruction will be primarily through verbal structure, rather than demonstrative (i.e. teacher physically shows movements) to emphasize individual practice and empowerment. An attempt will be made to minimize verbal instruction to allow for patients to have their “own” experience and self-direction. Patients will be encouraged to practice at their own pace based on their physical capacity and comfort.

**Yoga teacher relationship building:** Yoga teachers will be encouraged build a consistent relationship with patients through: 1.) using the names of patient; 2.) incorporating social talk at the beginning of the visit; 3.) showing care and concern throughout the yoga practice non-verbally (e.g. head-nodding, sitting down, eye contact, thoughtful silence); 4.) Verbally offering positive reinforcement with patients regarding practice; 5.) Allowing patients to express questions or concerns regarding practice; and 6.) Engaging and maintain attention of all students.

**Safety:** We recognized that patients with ESRD are a high risk population and yoga may not be safe for all patients receiving MHD.

The protocol was designed to allow patients with various co-morbidities to participate. However due to higher risks associated with exercise, we do not advise or consider yoga during MHD for the following: patients with unstable cardiac disease, uncontrolled blood pressure or dramatic changes with movement, chronic lung disease that prevents gentle movement or deep breathing exercises, active cerebrovascular disease, and/or dizziness or light-headedness with movement.

## Discussion

We have described the rationale and process of developing a yoga intervention for patients with ESRD. The protocol was developed in 4 stages through expert consensus including education of the disease, discussion of potential benefits of yoga, identification of yoga practice goals, and creation of the protocol. This process utilized expert consensus among yoga therapists in the tradition of Krishnamacharya, mind-body researchers, and nephrologists. The protocol went through a series of refinements after receiving feedback from outside researchers and international yoga experts. Potential positive effects were identified a priori to protocol development to inform rationale of yoga techniques to be used. Traditional yoga therapy provided the basis of the protocol was developed based on yoga theory and translated into the conventional therapy of MHD.

Despite a growing number of yoga studies in the literature, few publications have explained the rationale and development of a yoga practice for a specific patient population [37-39]. There also is no available data or consensus on the optimal approach to developing a yoga intervention for clinical research. Other approaches have been described in the literature. For example in 2005, Sherman et al published a high quality randomized clinical trial of yoga among patients with chronic lower back pain. The yoga utilized was also within a single tradition (also within the tradition of Krishnamacharya), however, a single yoga expert developed the protocol, and the rationale or process of the protocol was not explained [40]. An alternative approach was used by Saper and colleagues in another clinical trial of yoga among minority patients with chronic lower back pain [41]. An expert panel was assembled consisting of yoga teachers and a mind-body researcher with the group representing 4 different yoga styles (Anusara, Ashtanga, Iyengar, and Kripalu). Materials on yoga and lower back pain were provided from the medical literature; books, periodicals, videos, and internet were collected and provided to the expert panel. Utilizing this information, panel members met and drafted a 12-week yoga protocol for lower back pain. The rationale for techniques used or if specific goals were identified was not reported.

There are limitations to our approach in the development of a yoga protocol for patients with end-stage renal disease. We developed a yoga practice on a single yoga tradition, and it is unclear if utilizing a different yoga style or multiple styles would provide a more feasible or effective intervention. In addition, this protocol development is based on the hypothesis that specific components of the yoga practice such as breathing techniques and meditation will have distinct effects. However, non-specific contextual effects of yoga practice such as attention from the yoga teacher, group effect, or expectation may be major factors driving potential benefits. Despite these limitations, our report is the first detailed description of a yoga intervention designed for study in clinical research.

## Conclusion

We have detailed our process for developing a therapeutic yoga intervention for clinical research. This process relied on the active participation of yoga therapists, clinical researchers, and clinicians to



develop a mind-body practice that integrates with conventional care. Importantly, the protocol was designed based on therapeutic goals specified *a priori*. This sequence helps design future clinical trials by identifying potential outcomes and mechanisms at the outset based on traditional yoga therapy theory.

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