

Perspectives and Issues in Yoga Therapy

Yoga Therapy Research: A Whole-Systems Perspective on Comparative Effectiveness and Patient-Centered Outcomes

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Abstract

For the yoga research community to capitalize on its current momentum, it is critical to consider certain developments in research theory and innovative methodologies. The concept of *model validity* must be incorporated in yoga therapy research so that explanatory constructs employed and outcome measures chosen reflect the principles of traditional yogic science. Focusing on *effectiveness research* will ensure maximum generalizability of study results and reflect real-world therapy delivery settings, thereby increasing the relevance of outcomes. Whole systems of healing require research methodologies that address complex relationships between multi-target therapies with multiple potential treatment results. *Complex, dynamic systems theory* provides the theoretical and methodological innovations necessary to design studies, choose outcomes, and analyze data in a way that can account for charting complex, cyclical, therapeutic trajectories across time. Emphasizing *patient-centered outcomes* is aligned with the patient-oriented and tailored nature of yoga therapy delivery. Increasing the quality and quantity of *comparative effectiveness research* to analyze the harms and benefits of contrasting therapies can provide an infrastructure for designing studies that can have significant practical impact. The creation of *practice-based research networks* within the yoga research community will incentivize links between mainstream clinical researchers and yoga therapy delivery settings, ultimately developing collaborative networks. Yoga therapy centers can facilitate patient recruitment for studies and inform standards for yoga researchers. Collaborative efforts between the yoga and ayurvedic research communities will streamline efforts, solidify expertise, cross-pollinate theoretical and methodological innovation, and consolidate efforts to secure research funding and increase publication and dissemination of study findings.

Overview of Yoga Research

Research on yoga therapy is growing in volume, breadth, and scope (Field, 2011). A recent bibliometric analysis found 122 clinical trials of yoga have been conducted in the U.S. to date with a threefold increase in yoga research publications in the last decade (Jeter et al., 2015). Yoga research has documented the efficacy of yoga in addressing mental health, cardiovascular, respiratory, and musculoskeletal disorders, and in mitigating cancer symptoms (ibid). Researchers have also found therapeutic yoga beneficial for numerous chronic and lifestyle-related conditions, including diabetes (Innes & Vincent, 2007), cardiovascular health (Jayasinghe, 2004; Mamtani & Mamtani, 2005), metabolic syndrome (Anderson & Taylor, 2011; Corey et al., 2014; Innes, Bourguignon, & Taylor, 2005; Innes, Selfe, & Taylor, 2008; Kanaya et al., 2014), anxiety (Khalsa, Shorter, Cope, Wyshak, & Sklar, 2004; Telles, Gaur, & Balkrishna, 2009), and depression (Kamei et al., 2000; Khumar, Kaur, & Kaur, 1993; Uebelacker et al., 2010), sleep (Beddoe, Lee, Weiss, Kennedy, & Yang, 2010; Khalsa, 2004; Manunath & Telles, 2005), and low back pain (Saper et al., 2009; Sherman, Cherkin, Erro, Miglioretti, & Deyo, 2005; Tekur, Singhpow, Nagendra, & Raghuram, 2008; Williams et al., 2005; Williams, 2009). Therapeutic yoga has also demonstrated promising results in treating pre-pathological conditions like stress (Brisbon & Lowery, 2011; Hartfiel, Havenhand, Khalsa, Clarke, & Krayner, 2011) and inflammation (Dhananjai et al., 2013; Kiecolt-Glaser et al., 2010; Pullen et al., 2008; Sarvottam, Magan, Yadav, Mehta, & Mhapatra, 2012; Yadav, Magan, Mehta, Sharma, & Mahapatra, 2012), thereby serving the goals of health promotion and disease prevention. Yoga may also be useful as a risk-reduction strategy in ameliorating the results of negative lifestyle habits that lead to conditions such as obesity that reduce quality of life and wellbeing (Benavides & Caballero, 2009; Bera & Rajapurkar, 1993; Jain & Talukdar, 1995; Littman et al., 2012; Mahajan, Reddy, & Sachdeva, 1999; Manchanda et al., 2000; McCaffrey, Ruknui, Hatthakit, & Kasetsomboon, 2005; Murugesan,

Govindarajulu, & Bera, 2000; Raju, Prasad, Venkata, Murthy, & Reddy, 1997; Rioux & Ritenbaugh, 2013; Rioux, Thomson, & Howerter, 2014, Tran, Holly, Lashbrook, & Amsterdam, 2001; Thomley, Ray, Cha, & Bauer, 2011; Yang et al., 2009; Satyanarayana, Rajeswari, Rani, Krishna, & Rao, 1992; Schmidt, Wijga, Von Zur Muhlen, Brabant, & Wagner, 1997; Sivasankaran et al., 2006; Telles, Nagarathna, Nagendra, & Desiraju, 1993; Telles, Naveen, Balkrishna, & Kumar, 2010), and encouraging positive lifestyle habits like mindful eating and self-awareness (Carei, Fyfe-Johnson, Breuner, & Brown, 2010).

Most yoga studies focus on biomedical outcomes and very few studies include outcome measures that could be considered yogic in nature in that they emanate from the internal logic and causal theory of yogic science or its associated medical discipline, ayurveda. However, yoga randomized controlled trial (RCT) designs often do not account for the multiple outcomes that are likely due to the complex therapeutic pathways associated with yoga therapy. Current research on the mechanistic pathways of yoga focus on how specific aspects of yoga contribute synergistically to self-regulation in terms of cognitive, emotional, behavioral, and autonomic responses to stress (Gard et al., 2014). Recent developments in research theory and methodology have produced approaches that may be better suited to yoga as a healing discipline and these include: (1) an emphasis on model validity; (2) an emphasis on effectiveness rather than efficacy research in complementary and integrative medicine (CIM), including increased focus and funding for *comparative effectiveness research* in real-world settings; (3) prioritizing research focused on patient-centered outcomes; (4) advancements in the practical application of complex dynamic systems theory for CIM clinical trials; and (5) initiatives aimed at creating *practice-based research networks* as an alternative to the single-site academic medicine research setting.

Yoga as a Whole Practice and Complex Systems Research

Therapeutic yoga is a multi-factorial and complex intervention that is tailored to the condition of the individual being treated. Most current yoga research defines conditions and outcomes of interest in biomedical terms for a standardized diagnosis. Although these terms and outcomes are salient and useful, they do not reflect the internal logic of yogic philosophy, nor do they reflect the etiology or nosology associated with ayurveda, which serves as an appropriate medico-therapeutic context for yoga therapy. Frawley and others have argued for the intertwined origins and combined practical application of yoga and ayurveda as vedic sciences with the shared goal of somatic and psycho-spiritu-

al wholeness and balance. *Prana* and the subtle energetics of the body-mind serve as the primary causal link between yoga and ayurveda and their shared therapeutic practices include asana, pranayama, mantra, meditation, and therapeutic diet (Frawley, 1999, 2001).

Yogic philosophy and the causal models of ayurvedic medicine share a number of factors in common. These factors indicate a strong need for innovative research designs. Recognizing that yoga therapy fits a complex-systems model of therapeutic intervention necessitates appropriate research methods. In addition, there is a call across the holistic medical systems that relevant outcomes should be portrayed simultaneously in biomedical terms and through the indigenous logic of the system itself.

Yogic philosophy entails concepts of the body and bodily processes that differ from typical western conceptions of anatomy and physiology. (1) Yogic philosophy emphasizes flows of energy and substances through networks, channels, and pathways; thus, the body-mind and its anatomy-physiology are conceived as *processual* in nature. (2) The individual is portrayed as a set of simultaneously interacting nested systems (i.e., the *koshas*), thus emphasizing the interplay between the individual, the environment, and what they exchange on a material and energetic level—food, breath, sensory input, etc., all contextualized by time and space (Figure 1). Yoga therapy does not focus on isolated organs or tissues in the body as much as it holistically attempts to simultaneously rebalance and structurally integrate the individual's physical body, psycho-emotional states, and spiritual conditions. Yoga therapy is designed to address structural/functional conditions while improving vitality in the physiological, emotional, and subtle-energetic realms.

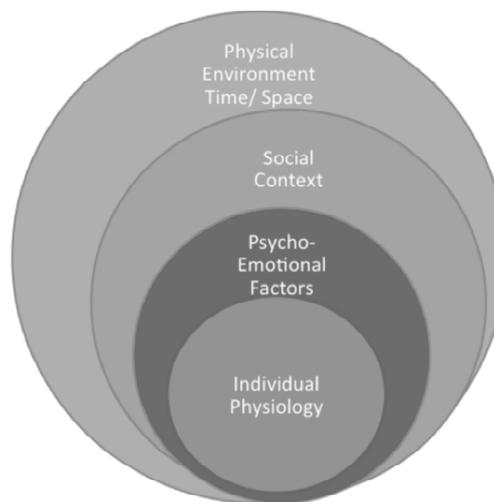


Figure 1. Considerations in developing a therapeutic yoga regimen.

Yoga therapy is typically a tailored form of treatment, specific to the condition as well as the unique characteristics

of the individual. The results of yoga therapy typically occur gradually and accumulate over time; maximum therapeutic effectiveness is associated with sustained, long-term practice. Frequency, duration, and intensity of practice may be modified to fit the specific circumstances of a particular therapeutic situation. Yoga therapy may have sustained or delayed effects that occur after a session, between sessions, or even some period of time after yogic practices have been temporarily or permanently suspended. The individualized application of yoga therapy is cyclical rather than linear in that it involves feedback loops and interactions between different layers of change and phases of therapy (Figure 2). Therapeutic rationales are modified based on the perceived causal roots of the condition(s). The treatment approach may change periodically in tandem with the response of the patient to therapy or modifications to the composition of and relationships between identified causative factors. Emphasizing the individual over the symptom(s) affects ideas about causal process and how change is created. Consideration of how internal and external factors related to the individual's life may contribute to his or her condition becomes a primary factor in determining the most potentially effective therapeutic approach. As a complex multi-target therapy with diachronic outcomes, yoga as a therapeutic practice can be characterized as holistic, systemic, nonlinear, and dynamic (Ahn, Tewari, Poon, & Phillips, 2006a, 2006b; Ahn et al., 2010; Bar-Yam, 2003; Bell et al., 2002; Bell & Koithan, 2006; Bell, Koithan, & Pincus, 2012; Capra, 1996; Guastello & Liebovitch, 2008; Koithan, Bell, Niemeyer, & Pincus, 2012; Laslo, 1996; Rioux, 2012; Ritenbaugh, Fleischman, Boon, & Leis, 2003; Verhoef et al., 2005; Verhoef, Koithan, Bell, Ives, & Jonas, 2012; West, 2006; Zimmerman, Lindberg, & Pisek, 2001).

The key features of practice, process, and outcomes noted above provide the context for yoga therapy delivery; thus, the distinction in conventional research between specific and non-specific effects becomes a point of focus. In conventional research, specific or characteristic effects are unique to the particular framework of therapy, identifiable as related to the application of the therapy via its own internal logic, and are invoked as the causal explanation for the achieved outcome (Price, Long, Godfrey, & Thomas, 2011). Non-specific or incidental effects have been previously defined as including the placebo effect where belief, expectation, and patient-healer interaction impact the therapeutic outcome. These are assumed to be distinct from the chosen therapy. However, this logic does not necessarily apply within a therapeutic framework such as yoga therapy, which emphasizes energetic exchanges and control of thought patterns and emotional states as primary avenues of therapeutic impact. These categories need to be re-examined in light of yogic philosophy and redefined for the purposes of yoga

research in order to convey an authentic and causally accurate model of yoga therapy practices and their outcomes.

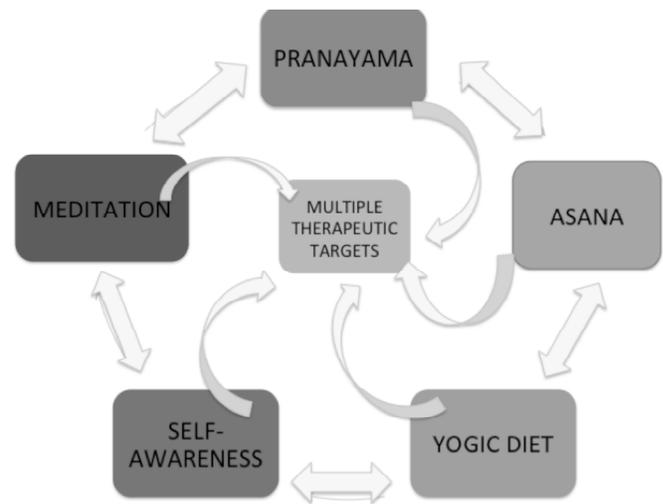


Figure 2. Whole-system yoga therapy as nonlinear and dynamic.

Key Research Design Concepts.

When considering research approaches that will be most appropriate for investigating the practices and outcomes associated with yoga therapy, yoga therapists should utilize terminology typically used by the conventional research community. This will require that yoga therapists become conversant in the terminology and concepts associated with clinical research in mainstream settings. Key terms include:

- **Efficacy:** Studying the effects of a standardized intervention under “ideal conditions,” (e.g., randomized controlled trials comparing a drug to placebo) and attempts to address the causal mechanism within a homogenous population. Outcome measures in efficacy studies are chosen to be constant and objective. These types of studies are associated with *internal validity* in which the focus is on maintaining *comparability* between experimental and control groups and attempts are made to control all extraneous variables.
- **Effectiveness:** Studying the effects of an intervention in a real-world setting, representative of routine care, with a defined but more heterogeneous population. Measures may be patient-centered and subjective, but they are considered to have more *generalizability* to a wider population because experimental conditions have not been as tightly controlled. Effectiveness studies focus more on external validity.
- **Pragmatic Trials/Observational Studies:** Studying the results of a complete treatment system in a real-world

setting, with or without a control group. This may or may not involve randomized treatment assignment or blinding. These types of trials are associated with *model validity* because they focus on investigating the therapy as it is delivered and on its own terms.

- **Comparative Effectiveness Research:** Comparing the results of an alternative intervention to routine care or comparing the effects of two contrasting alternative approaches, both as typically delivered. This approach is also associated with *model validity* as it focuses on maintaining the internal structure of the therapeutic system and evaluating the outcomes according to an internally consistent model (Methodology Committee of the Patient-Centered Outcomes Research Institute (PCORI), 2012; Witt, Huang, Lao, & Berman, 2010; Witt et al., 2012a, 2012b).

It may help to look at the different forms of experimental validity associated with the research process in terms of examples related to yoga research.

- **Internal Validity:** Usually refers to the *comparability* of test and control groups and focuses on collecting objective measures and controlling extraneous variables. In yoga therapy research, maintaining the comparability of test and control groups must be balanced with other considerations. Some examples of control groups utilized in yoga therapy research have included usual care, physical therapy, stretching exercises, or health education classes. Certain phenomena associated with yogic practice are not reflected in objective measures. In particular, increases in self-awareness, personal relationships, or changes in decision-making can impact areas of daily living not identified as causal factors of the condition in question. These patient-centered outcomes may be pertinent and impactful for study participants, though not always considered relevant or causally related by mainstream conventional research standards. Yoga researchers must explicitly consider the balance between internal and external validity in the research design process and detail their reasoning when discussing study results, outcome measures chosen, and implementation of the therapeutic framework (Rioux & Ritenbaugh, 2013).
- **External Validity:** Refers to *generalizability* or the comparability of the study population and the general population of interest. This may involve the use of differential diagnosis, (e.g., ayurvedic constitutional types informing inclusion criteria) to: (a) demonstrate the principles of tailoring the therapy to the individual; (b) to replicate how yoga therapy would be applied in a real-world clinical setting; or (c) to illustrate how ther-

apies and expected outcomes are individualized. The recent trend toward manualized study protocols and standardized teacher training in yoga interventions is a meaningful attempt to convey the rationale behind therapeutic decision-making and maintain the rigor of standardization in clinical research while allowing for some flexibility in implementation (Sherman et al., 2010, 2011).

- **Model Validity:** The research must fit the medical paradigm being studied. Research design and outcome measures should be consistent with the philosophical frameworks and healing theories of the system and in sync with the realities of current clinical practice (Bornhoft et al., 2006; Price et al., 2011; Rioux, 2012; Witt et al., 2010, 2012a, 2012b). Theories of causality and mechanism should be provided to support intervention designs, outcomes measures chosen, implementation strategies, and to account for any discrepancies in results that can be illuminated by yogic/ayurvedic theories of differential response. Some factors deemed relevant in a yoga/ayurveda paradigm may include age and health status; strength of the disease or condition (e.g., critical nature/chronicity of illness) versus resilience and immunity of the individual; contributing genetic factors; quality of metabolic fire versus toxicity in tissues; compromise of organ function; or psychological outlook and compliance. Intervention design rationales should address how, why, and according to what frequency and intensity of dosage a specific therapy might bring about predetermined outcomes. The use of biomedical theory alone to contextualize yoga research outcomes compromises the potential benefit of the research by limiting its explanatory capacity. Incorporating model validity into research study designs clarifies the underlying therapeutic rationale of an intervention and should include five key pieces of information:
 - 1) Theory of etiology, diagnosis, and treatment
 - 2) Rationale for how the treatment works
 - 3) Components and process of the intervention
 - 4) Assumed causal pathway for change
 - 5) Anticipated outcomes of treatment and determinants of variability

One Recent Example

A recent study of yoga therapy and ayurveda for weight loss (Rioux, Thompson, & Howerter, 2014) utilized a dual-diagnosis design (biomedical AND ayurvedic) to establish inclusion and exclusion criteria, thereby creating a study population that was coherent according to BOTH paradigms. This same study implemented a semi-standardized

protocol including diet and lifestyle guidelines and yoga practice protocol, but maintained tailored features of treatment based on each individual's circumstances. This kind of study design maintains the model validity of yoga while simultaneously adhering to the standards of conventional Western research. Semi-standardized protocols with tailored features are reasonable approaches to designing clinical trials of yogic interventions. This type of study design does not detract from a conceptually consistent approach to a well-defined population, even if it may mean that every single causal factor cannot be addressed. Careful selection of the most salient outcomes for any defined condition (in biomedical and yogic terms) will allow for maximum explanatory potential and an optimal and *clinically relevant* contribution to the evidence base.

Clinical Trial Design and the Efficacy-Effectiveness Continuum

Conventional clinical trials test simple action, single entity, fixed interventions (e.g., pharmaceutical drugs), based on a straightforward biomedical, disease-based approach to treatment. The designs are based upon theoretical frameworks in which causality is presumed to be unchanging and linear. In contrast, yoga therapy trial designs should focus on nonlinear, interactive, dynamic quality-of-life assessments (physical-sensorial-mental-spiritual), consistent with a multi-target/multi-outcome therapeutic paradigm. This would include assessment of graded remission of complex sets of indicators (including symptoms) per flexible, semi-standardized diagnostic criteria. Yoga therapy trial designs should also collect data on reversal of the disease state (e.g., rebalancing of the *doshas* or other causal factors noted above) rather than simple absence of symptom profiles (Singh, 2010; Rioux & Ritenbaugh, 2013; Rioux, Thomson & Howerter, 2014).

Conventional randomized controlled trials (RCTs) that are focused on investigating treatment *efficacy* typically have the following features: (1) narrow inclusion and exclusion criteria for recruitment and patient eligibility; (2) standardized treatment protocols that do not account for patient variation, co-morbidities, or individualized care; (3) objective outcome measures, such as laboratory parameters; and (4) a controlled setting such as a medical research clinic. Clinical trials investigating the *effectiveness* of treatments focus on: (1) real-world settings, such as a community-based clinic or yoga therapy center; (2) a sample of typical patients with individualized health histories, co-morbidities, and concurrent therapies; (3) flexible, semi-standardized treatment protocols, incorporating some individualized tailoring, to account for variation in the condition and circumstances of patients throughout the intervention; (4) patient-centered outcome measures that reflect the priorities of patients in terms of preferred treatment results and health goals; and (5) detailed descriptions of the treatment

setting and context, including practitioner credentials (Methodology Committee of the PCORI, 2012; Witt et al., 2010, 2012a, 2012b).

Conventional pharmaceutical research has focused on creating targeted drugs in cellular and animal systems, then moving to human safety/efficacy trials and sometimes to pragmatic trials of drug-treatment effectiveness. Research on traditional whole systems of medicine would be well-served to move in the opposite direction in five phases: (1) context, paradigms, philosophical understandings; (2) utilization and safety; (3) comparative effectiveness; (4) component efficacy; and (5) biological mechanisms. These phases have been discussed by Fonnebo et al. (2007) and Singh (2010). Each phase is best pursued with the understanding that yoga therapy represents a complex, dynamic system involving multiple interacting therapeutic components and multiple possible intersecting outcomes. To appropriately reflect the implementation of yoga therapy and its therapeutic principles, studying components and mechanisms can most appropriately be done within the context of a whole-systems approach. To investigate the true effectiveness of yoga therapy, study designs should utilize broad but well-defined inclusion criteria, flexible protocols, potential concurrent therapies, and should reflect real-world settings in a typical therapeutic context (Methodology Committee of the PCORI, 2012; Rioux, Thomson, & Howerter, 2014; Rioux, 2012; Witt et al., 2010, 2012a, 2012b). Intervention design rationales should include details on the components and procedures of the intervention and dosing—in terms of frequency, intensity, and duration of practice (see Figure 3). Publication of detailed study protocols allows for evaluation by clinicians and researchers and for replication of the study in larger or divergent populations (Rioux & Ritenbaugh 2013). Anticipated outcomes may differ according to individual and contextual factors and data collection methods may be more or less appropriate according to population differences.

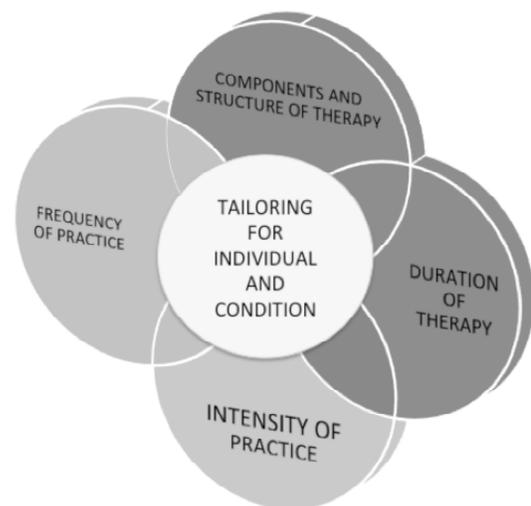


Figure 3. Factors influenced by rationale and proposed mechanism in yoga therapy.

YOGIC ELEMENT	Individualized by	Therapeutic Target	Tailoring Technique
ASANA	Constitution/ Imbalance Profile/ Age/Fitness/Injury	Physiological, Psychoemotional and Energetic Balance	<i>Dosha/Agni/Ama</i> -Specific Effect on Tissues, Organs, Ojas, Tejas, Prana
PRANAYAMA	Psycho-Emotional State/Detoxification	Nervous System/ Allostatic Load	Pacify/Enervate/Stabilize/ Clarify
YOGIC DIET	Quantitatively/ Qualitatively Appropriate	Metabolic Activity, Toxicity, Vitality, Immunity, Cognition	Increase/Decrease/Regulate Variability/per Sattva, Rajas, Tamas
MEDITATION	Spiritual Outlook/ Ritual Preferences	Self-Regulation/Stress Response/Restoration	Sensory Input/Mudra/ Mantra/Visualization
SELF-AWARENESS	Temperament/ Interactional Style	Relationships (with Self and Others)/Integration	Solitude/Engagement/ Service/Community

Table 1: Yoga therapy protocol design: Components, therapeutic rationale, and tailoring.

Table 1 provides a sample yogic protocol that includes: (1) a selection of yogic components that could be included in a therapeutic yoga regimen; (2) some foundational principles that could inform their individualization; (3) some possible intended therapeutic targets; and (4) a sample of tailoring techniques that could be used in modifying a therapeutic protocol. The tailoring techniques described are a few of numerous options. Any of the elements in the table could be changed to reflect a different approach and although this is an oversimplified representation, it offers one potential means of organizing and thinking through the intervention and research design processes. A critical factor in research is to demonstrate that the explanatory logic and causal relationships between the therapeutic rationale, yogic components, and tailoring techniques are clear and consistent. These considerations should be examined in detail when designing a research question and intervention, and when choosing and analyzing study outcomes.

Yogic theory addresses the individual in context as an open complex system. In yoga therapy, the emphasis is on the entire simultaneous spectrum of actions in multiple, interdependent subsystems of the individual as a whole, at numerous points in time. The nature of yoga therapy as a healing modality is such that it looks at the cumulative effects of multiple agents acting simultaneously on the individual as a bio-psycho-social whole in active energetic exchange with its environment (Rioux, 2012). As a result of the philosophical foundations of this approach, the yoga therapist recognizes multiple possible causes and multiple potential manifestations of the identified disorder and the physiological and psycho-emotional imbalances that may be

the causal roots of the condition being addressed. These imbalances thus possess potentially mutual and bidirectional causality. The concept of monolithic causality is thus not applicable to yoga therapy in theory or in its practical application.

Outcome Measures: Generic and Yoga-Specific

Outcome measures and evaluation parameters should be relevant to both patient and practice. They should account for tailored treatment strategies and the specifics of the environment in which the intervention is implemented. Studies of yogic therapy should include both biomedical outcomes and outcomes emanating from the indigenous philosophy of yogic science, regardless of the condition being treated. Current studies show consistent changes in a number of areas not typically associated with the symptom-complex of the condition being treated. These change areas may include: (a) psycho-emotional; (b) stress; (c) sleep quality and duration; (d) energy and vitality; (e) quality of life and wellbeing; and (f) improved relationships or self-awareness. These categories of change are often classified as part of the *overall benefit* of a treatment approach, even when causality cannot be determined. However, in yogic science a great body of theory on the mechanisms of change in these areas exists and should be explored to its fullest potential in clinical trials on yoga therapy. Bornhoft et al. contended that “insufficient external validity and model validity can distort statements concerning the efficacy or effectiveness of certain treatments and whole systems medical approaches” (Bornhoft et al., 2006, p.3). Likewise, research and data on

yogic outcomes should be collected, analyzed, and translated into accessible concepts and terminology that can be understood and appreciated by mainstream researchers, clinicians, public health workers, and potential patients. A complex systems approach may make this possible.

When selecting yoga-specific outcome measures, it is useful to consider the iconic features of yoga therapy and how they may individually and cumulatively influence potential health benefits. According to Rioux (2012), some of these iconic features may include:

- A simultaneous multi-target approach, affecting physiology, organs, tissues, spirit, psyche, feeling states, relationships, and sensory processing.
- The ritualized self-awareness that is the cornerstone of yogic practice. Adjustments must be made in the study design and the outcome measures chosen to account for the cyclical, recursive nature of self-awareness cultivated through yogic practice that initiate, support, and sustain change over time.
- *Reverberations*: Particular, persistent effects echoing on multiple levels that possess similar properties. These serve as continual reflections of initial impact.

These features must then be specified by the condition under study, the characteristics of the sample population, the relationships between therapeutic components and expected treatment response, according to yogic scientific principles. Thus, it will be necessary for yoga therapy researchers to develop tools and strategies that incorporate the rigor of conventional medical research while maintaining the complex, nonlinear systems approach that is consistent with yogic science. It will be important to collect both quantitative and qualitative data, as well as process measures that reflect the components, flow, structure, and tailoring of yoga therapy delivery. These data collection instruments and strategies will ideally account for the pathological and therapeutic features of time, space, and circumstance, and why and how therapeutic effects shift as the patient responds and changes. It will be important for yoga therapy researchers to identify *therapeutic thresholds* and collect data at these specific time points (Rioux, Thomson & Howerter, 2014; Rioux, 2012). Researchers will need to include both scientifically relevant and objective barometers of change, as well as patient-centered, subjective experiences of change. Patient-oriented outcomes and self-report should focus on both incidental and specific effects, as well as the overall benefits of yoga therapy beyond conventional psycho-social measures. It will also be important to account for transformative change that takes place either gradually or suddenly, the magnitude of which may be greater than the intended effect of the therapy. Data collection instruments should be developed to collect interactive, multi-scale data involving

feedback loops, bidirectional causality, and clinical intuition (Rioux, 2012).

Comparative Effectiveness Research and Yoga Therapy

Comparative Effectiveness Research (CER) is defined by the Institute of Medicine as “the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat and monitor a clinical condition or improve the delivery of care” (Methodology Committee of the PCORI, 2012, p. 1584; Witt et al., 2010, 2012a, 2012b). CER has the potential to inform, influence, and improve patient decision-making, clinician treatment approaches, and healthcare policy in a way that RCTs cannot because of their lack of generalizability to a wide variety of patients and their non-comparability to real-world healthcare contexts. One of the key tenets of CER is that outcome measures chosen to reflect effectiveness of treatment are patient-centered. CER also focuses on dynamic aspects of care that affect outcomes at the individual level and explain variations in patient response to treatment that would be present under typical conditions of care. CER attempts to include a broad range of patients with individual characteristics that will impact treatment tailoring, implementation, and associated health outcomes. CER can also be designed—combined with a whole-systems approach—to account for multiple, interacting, and potentially synergistic outcomes, encompassing simultaneous improvement in several areas. Outcome measures are linked with patient priorities and objectives for treatment, as opposed to the RCT model of one primary outcome associated with the condition under study that may not reflect patient values or encompass the entire spectrum of possible treatment results, which vary according to individual patient characteristics (Methodology Committee of the PCORI, 2012; Witt et al., 2010, 2012a, 2012b).

Comparative effectiveness research is increasingly recognized for its capacity to investigate the complex and tailored therapies associated with complementary and integrative medicine. In the field of acupuncture, standards and criteria for the design and implementation of comparative effectiveness studies are being proposed and evaluated in an attempt to advance the discipline and ensure that studies are both comparable to one another and reflective of real-world practice in typical clinical settings (Witt et al., 2010, 2012a, 2012b). Additionally, development of standardized data collection instruments and procedures for some CIM fields is underway and being evaluated by experts to maintain fidelity to conventional scientific precepts, ensuring that model validity is balanced with internal and external validity, as associated with conventional medical research (Horn

& Gassaway, 2007; Johnson, 2010; Rioux, 2012; Witt et al., 2012b). Similar efforts are being initiated in the field of ayurvedic medicine and the yoga therapy research community can capitalize on the shared knowledge base to promote its own efforts, as the two therapeutic frameworks are commonly utilized together, employing common theoretical and therapeutic constructs, as well as principles related to causality and mechanism.

Next Steps in Whole-Systems Yoga Therapy Research

There are a variety of measures that can be taken to advance yoga therapy research that are consistent with yogic science and reflect its therapeutic premises and ideas about causality. Training in the basic premises of conventional and whole systems research as they relate to yoga therapy is an essential tool that should be made available to all serious students of yoga therapy. This training will result in yoga therapists with an educated perspective on yoga therapy research and the ability to evaluate and critique research that does not reflect the scientific principles of yoga therapy as a healing modality. Yoga therapists should have the ability to refer their clients to well-done studies that are relevant to their care and to critique those with inappropriate study designs or outcome measures.

Schools and independent clinics can offer to serve as satellite research centers and data collection sites for research projects with these primary features: (a) flexible, semi-protocolized treatment interventions; for (b) well-defined populations with dual diagnosis of a western disease category and a yoga therapy/ayurvedic diagnosis; and (c) well-defined guidelines regarding training and evaluation of yoga therapists involved in research design, treatment implementation, or data analysis. Developing this type of research infrastructure across the holistic healing disciplines comes under the rubric of practice-based research networks (PBRN) and can serve as an excellent model for yoga therapy trials in which it may be difficult to get large numbers of study participants to convene in an academic medicine setting, where research is typically conducted (Horn & Gassaway, 2007; Sauer, Valovich-McLeod, 2012). Developing this kind of infrastructure must then be supported by the availability of normative tools and strategies for data collection, as discussed above. It will also involve an acceptance within the yoga therapy community of certain research conventions that may be unfamiliar or counterintuitive but also necessary for successful completion of the research enterprise. Some of these may include: (1) standardized templates for patient intake and data collection, reflecting categories of assessment specific to yoga therapy as well as biomedical terms; (2) manualized protocols for

identified conditions that are nevertheless flexible enough to account for tailoring and differential diagnosis; and (3) consistent guidelines and oversight in the training of yoga therapists involved in the implementation of clinical trials research and practice-based research networks. Yogic categories of assessment, treatment, and outcomes used for normative purposes by yoga researchers should be translated into terms that are accessible to mainstream health professionals and researchers for maximum utility.

To conclude with a practical example, Table 2 provides details on how contrasting conditions with different root causes may lead to different study designs or interventions, with the theory of therapeutic mechanism potentially informing different data collection procedures and choice of outcome measures. These two examples represent combined physical and psycho-emotional disorders than can be prototypically associated with therapeutic yoga approaches and ayurvedic doshic imbalances. The table represents an oversimplification of some principles in order to provide a framework for thinking through intervention and research design issues. Causality is often complex and may involve multiple doshic imbalances, which vary among individuals. However, it is possible through use of dual-diagnosis recruitment procedures and careful selection of inclusion/exclusion criteria to amass a cohesive sample population for studies of yoga therapy and ayurveda, despite the centrality of tailoring in both paradigms. Table 2 is not meant to imply a direct correlation between western disease categories and doshic imbalances, as root causes can vary. It nevertheless serves as an illustrative tool for some of the concepts discussed above and may serve to link causality to intervention and study design considerations.

The goal of the researcher is to develop sound and comprehensive rationales for each feature of their intervention and relate these back to aspects of study design and selection of outcome measures. The tables and figures in this article are not offered as definitive prototypes; they are meant to serve as fodder for discussion within the yoga research community. Subsequent discussion can focus on how to incorporate the complex, nonlinear, and tailored qualities of yoga therapy and its therapeutic logic into clinical trial designs and how to develop concrete, distinct criteria for the choice of intervention components and outcome measures that are comprehensible for laypeople and mainstream researchers. It is the contention of this article that a whole systems approach, focused on comparative effectiveness and emphasizing patient-centered outcomes, will inform the kind of research that can lead to an expansion of yoga therapy in mainstream settings, eventual reimbursement by insurance, and acceptance of yoga therapy as a low-cost, non-invasive alternative for health promotion, disease prevention, risk reduction and collaborative treatment/self-care for many chronic and lifestyle-related conditions.

DESIGNING A THERAPEUTIC REGIMEN	(VATA IMBALANCE) Anxiety/Fatigue/Insomnia	(KAPHA IMBALANCE) Depression/Obesity/Congestion
Yogic Elements	Emphasize Subtle Components	Emphasize Physical Components
Structure of Therapy	Flexible, Soft, Fluid	Consistent, Disciplined
Duration of Therapy	Shorter duration	Longer Duration
Frequency of Practice	3–5x per week	5–7x per week
Intensity of Practice	Reduced Intensity	Increased Intensity
Therapeutic Approach	Encouraging Warmth	Authoritative Support
Rationale	Conserve Energy/ Stabilize	Expend Energy/ Detoxify

Table 2: Elements to consider in designing interventions for contrasting conditions.

Conclusions

Yoga therapy research is poised for expansion and yoga therapists may have the potential to play a far more significant role in health promotion, disease prevention, risk reduction, and treatment of chronic, lifestyle-related conditions. For the yoga research community to capitalize on its current momentum, it will be critical to consider certain developments in research theory and innovative methodologies. It is crucial to incorporate the concept of *model validity* in yoga therapy research so that explanatory constructs employed and outcome measures chosen reflect the principles of traditional yogic science. Focusing on *effectiveness research* will ensure maximum generalizability of study results and reflection of real-world therapy delivery settings, and will increase relevance for a wider sector of the population. Whole systems of healing require research methodologies that can address the complex relationships between multi-target therapies, with multiple potential treatment results. *Complex, dynamic systems theory* provide the theoretical and methodological innovations necessary to design studies, choose outcomes, and analyze data in a way that can account for charting complex, cyclical, therapeutic trajectories across time. Emphasizing *patient-centered outcomes* research is aligned with the patient-oriented and tailored nature of yoga therapy delivery.

Initiatives aimed at increasing the quality and quantity of *comparative effectiveness research*—to analyze the harms

and benefits of contrasting therapies—can provide an infrastructure and impetus for yoga therapy researchers to design studies that can have significant practical impact. The creation of *practice-based research networks* within the yoga research community will incentivize links between mainstream clinical researchers and yoga therapy delivery settings, ultimately developing collaborative networks. Yoga therapy schools and centers can facilitate patient recruitment for studies, help inform standards and credentials for yoga researchers, and gain access to resources available at mainstream research centers. Likewise, collaborative efforts between the yoga research and ayurvedic research communities are essential to streamline efforts, solidify expertise, cross-pollinate theoretical and methodological innovation, and consolidate efforts to secure research funding and increase publication and dissemination of study findings.

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