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Outcomes from a Whole-Systems Ayurvedic Medicine and Yoga Therapy Treatment for Obesity Pilot Study

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Abstract

Objectives: To determine the feasibility and acceptability of an Ayurveda/Yoga intervention for weight loss, using dual-diagnosis inclusion criteria, dual-paradigm outcomes, and a semistandardized protocol with tailoring according to the Ayurvedic constitution/imbalance profile of each participant.

Design: Seventeen participants enrolled in a weekly intervention for 3 months. Outcome measurements were performed at baseline, postintervention, and 3 and 6 months follow-up.

Setting: The intervention was conducted through the University of Arizona, Department of Family and Community Medicine from April through December 2012.

Subjects: Participants included 2 men and 15 women recruited from the community of Tucson, AZ using flyers and hospital message boards. Seventeen enrolled and 12 participants provided complete follow-up data.

Intervention: Participants met with an Ayurvedic practitioner twice monthly (six times) and followed semistandardized dietary guidelines with individual tailoring to address relevant psychophysiological imbalances obstructing weight loss and a standardized protocol of therapeutic yoga classes three times weekly with recommended home practice of two to four additional sessions.

Outcome measures: Primary outcome was weight loss. Other biomedical outcomes included body mass index, body fat percentage, waist and hip circumference, waist to hip ratio, and blood pressure. Unique instruments were designed to collect data on outcomes associated with the Ayurvedic medical paradigm, including dietary changes by food qualities, mood/affect, relationships, and changes in Ayurvedic imbalance profiles.

Results: Participants lost an average of 3.5 kg during the 3-month intervention. Weight loss at 3 and 6 months postintervention increased to an average of 5.6 kg and 5.9 kg, respectively. Participants who lost 3% of their body weight during the 12 week intervention, lost on average an additional 3% during the follow-up period. Psychosocial outcomes also improved. No additional services were provided to participants during the follow-up period.

Conclusions: A whole-systems Ayurvedic medicine and Yoga therapy approach provides a feasible promising noninvasive low-cost alternative to traditional weight loss interventions with potential added benefits associated with sustainable holistic lifestyle modification and positive psychosocial changes.

Keywords: Ayurveda, yoga, whole system, obesity, East Asian medicine, integrative medicine

Introduction

Obesity is an epidemic in the U.S. population and has been designated as a research priority by the National Institutes of Health.[1] The CDC reports that the prevalence of obesity was 39.8% and affected about 93.3 million of U.S. adults in 2015–2016, with an estimated annual medical cost of obesity in the United States at $147 billion in 2008 U.S. dollars.[2,3] Obesity is a primary causal factor in many diseases, including type 2 diabetes, hypertension, cardiovascular disease, dyslipidemia, stroke, and liver disease.[4] Worldwide obesity has nearly tripled since 1975. In 2016, more than 1.9 billion adults, 18 years and older, were overweight. Of these >650 million were obese. Thirty-nine

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percent of adults aged 18 years and over were overweight in 2016, and 13% were obese. Most of the world's population lives in countries where overweight and obesity kill more people than underweight.[5]

According to a systematic review of 33 studies, the 4 highest quality studies calculated the per-person annual direct medical cost of obesity in 2008 as $1,723.[6] A 2014 study estimated that obese individuals may lose as much as 8 years from their life span due to comorbid conditions associated with obesity.[7] Obesity and metabolic syndrome are preventable.[5] Conventional care paradigms for obesity and metabolic syndrome treatment are expensive and may involve surgery and medications with side effects.[8–10] Conventional medical approaches have demonstrated limited success in the treatment or prevention of obesity.[11–13] Some trials have shown that even moderate weight loss of 5%–10% can significantly modify risk profiles for obesity-associated disease; thus, novel approaches to treat obesity are needed.[14]

Inter- and multidisciplinary care have been shown to reduce weight and body mass index (BMI)[15,16] with enhanced effects when combined with cognitive behavioral therapy.[17] Obesity researchers now commonly acknowledge that tailored multimodal integrated interventions demonstrate the best outcomes.[8–10] A 2005 study of numerous holistic healing modalities for which data were accessible showed that they appeared to be a good value,[18] whereas a 2006 lifetime cost-use analysis from a societal perspective of outpatient weight loss strategies in overweight and obese U.S. women demonstrated that a multidisciplinary weight loss program consisting of diet, exercise, and behavior modification also provides good value for money.[19]

A 2018 analytic review of obesity management, diabetes prevention, and cardiovascular risk reduction concluded that, as a society, more is paid for disease management than disease prevention, and in failing to provide sufficient insurance coverage for weight management, the more costly management of a type 2 diabetes epidemic is funded.[20]

This whole-systems (WS) Ayurvedic medicine and Yoga therapy pilot intervention combined comprehensive lifestyle change; a first-time use of an Ayurvedically consistent cognitive-behavioral therapy approach (coined herein as Ayurvedic CBT) to addressing maladaptive emotions, behaviors, and cognitions associated with weight gain; and ritualized self-awareness practices with alternative diet and activity modification for overweight/obese adults. This intervention integrates the two complementary Vedic healing disciplines of Ayurveda and Yoga, which are linked through *Samkhya* philosophy and particular consideration of how disturbances of the mind inform disorders in the body and affect the *doshas*.

Particular portions of the classical text *Charaka Samhita*[21] relevant to the discipline of Ayurvedic Yoga therapy include (1) appropriate/inappropriate use of the senses and mental faculties, which are the essence of yogic practice and central to psychological and experiential aspects of disordered eating and sedentary lifestyle (Sa1 No. 118–132) and (2) the central role of yogic practice in pursuing self-understanding and escaping the cycle of attachment/aversion, relevant to food cravings as well as addressing impulsive behavior and stagnation (*rajas/tamas*) (Sa1 No. 133–155). Thus, this application of whole-systems Ayurveda and Yoga therapy (WSAY) has been applied in a manner consistent with traditional practice as described in *Charaka Samhita*[21] and studies published in Indian medical journals that utilize asana to promote metabolic activity and affect *doshic* expression.[22,23]

This is the first published study to test the feasibility of a tailored WSAY weight loss intervention and presents promising preliminary results in terms of conventionally recognized outcomes for assessing obesity. This pilot study is also the first to collect standardized Ayurvedic outcomes in an academic medicine setting in the United States. Preliminary data analysis suggests that a whole-systems Ayurveda/Yoga approach to obesity offers an acceptable, noninvasive, and low-risk treatment option for obesity, through a semistandardized treatment protocol that is feasible to replicate, and potentially generalizable to broader populations.

A previous article on the study design and protocol discussed basic weight loss measures, adherence measures, participant demographics, and satisfaction with the intervention.[24] This article covers additional biomedical and Ayurvedic health outcomes and those related to process, context, and whole-systems features of the design, implementation, and analysis.

Ayurvedic theory, obesity, and weight loss

Ayurvedic medicine for treating obesity has not been rigorously studied in clinical trials, but other complex multimodal Ayurvedic treatments have been studied for efficacy and effectiveness in chronic conditions such as osteoarthritis,[25] fibromyalgia,[26] and hepatic cirrhosis.[27] This intervention design offered an innovative and personalized obesity treatment approach focused on lifestyle changes, and diet and exercise modification, delivered according to the constitution/imbalance profile of the patient.[28] This study utilized *Ayurvedic Yoga Therapy*, which integrates causal and therapeutic principles shared by these historically intertwined disciplines and is designated as a category of professional practice by the National Ayurvedic Medical Association.[29]

Yoga is inexpensive, noninvasive, and has been determined by two comprehensive reviews of clinical trials to be a safe effective intervention to reduce BMI and effective as primary or supplemental self-care for weight loss, weight maintenance, and prevention of obesity and metabolic syndrome.[30,31] Other studies of yoga for weight loss/metabolic syndrome/diabetes have found significant reductions in abdominal obesity,[32] positive alterations in ghrelin axis,[33] and a reduction in cardiometabolic risk factors.[34] The specific mind–body approach of yoga therapy has also been found to spur psychosocial changes associated with durable weight loss, including ''yoga culture'' social support and reports that a yogic experience of weight loss was ''easier'' and ''subjects felt more confident in their ability to maintain lasting weight loss.''[35]

The practice of Ayurvedic medicine entails the application of individualized, multimodal, and multitarget therapies and holds potential for the effective treatment of obesity due to its comprehensive approach. A 2015 commentary from the *Lancet-Diabetes and Endocrinology* provides clinical recommendations for obesity prevention and treatment, which

specifically suggest ''a multifaceted treatment strategy'' and ''individualized treatment.''[36] An unrelated 10-week yoga program for weight loss, including ''Ayurveda-inspired components'' in a nonacademic setting, reported improvements in psychosocial outcomes and self-reported weight loss but was less comprehensive as an intervention, reported no objective measures, and included no Ayurvedic outcomes.[37]

Ayurvedic theory focuses on the relationship between balanced and imbalanced expression of the five elements—air, space, fire, water, and earth—in the human body, mind, and spirit, as expressed in the *doshas*. The *doshas* are three bioenergetic systems that comprise pairs of elements and referred to as *vata* (air and space), *pitta* (fire and water), and *kapha* (water and earth). Ayurveda refers to obesity as *Sthaulya* (or *Medoroga*). *Sthaulya* is defined as a metabolic disorder stemming from lack of exercise, poor diet, stress, genetic predisposition, and ultimate increase in *kapha dosha* leading to excessive accumulation of adipose tissue, associated with accumulation of water and earth elements in the body–mind, poor digestive fire, and accumulation of toxins in the digestive tract.[38–40]

Overeating and a sedentary lifestyle contribute to the accumulation of earth and water elements in the body, as does excess sleep, steroid medications, and psychoemotional conditions such as depression and anxiety. Earth and water are associated with the heavy, dense, slow, and cold qualities and are antagonistic to strong metabolic fire, which is sharp, light, and hot, thus contributing to slow metabolism and obesity.[41]

A multimodal tailored synergistic protocol

The protocol utilized semistandardized treatment consistent with Ayurvedic medical theory, including isolated features of tailoring. This is consistent with real-world Ayurvedic clinical practice in which treatment implementation is responsive to patient feedback. Tailored implementation of the standardized intervention according to participant feedback is a hallmark of the Ayurvedic clinical approach, and is a consistent feature of holistic/integrative health care delivery.[42] Ayurveda and Yoga are complex interventions, including multifactorial components, which mutually enhance one another to achieve synergistic therapeutic effects. As healing modalities, Ayurveda and Yoga focus on the cumulative effects of multiple agents—diet, lifestyle, self-awareness, postures, breathing techniques, and meditation—acting simultaneously on the individual as a biopsychosocial network.[43]

Ayurvedic and Yogic treatments are consistent with systems-based models of obesity causality that inform optimal treatment frameworks.[15–17] Multiple causal factors mutually enhance and reinforce one another in a synergistic manner in the overweight/obese individual. Ayurveda and Yoga provide exercise, stress reduction, nervous system balance, shifting of metabolic function, and anti-inflammatory effects to address many of the root causes associated with obesity.[44] The match between a systems approach to addressing the multiple causal factors of obesity and the systems approach to treatment inherent within Ayurvedic medicine and Yoga therapy may provide optimal therapeutic effects (Fig. 1).

Materials and Methods

Study design and sample

This study was a prospective single-arm pre/post design with longitudinal follow-up at 3 and 6 months after the intervention. The study design incorporated a protocolized approach to diet modification and yoga therapy, as appropriate for the predetermined Ayurvedic constitution of primary or secondary *kapha dosha* and a concomitant imbalance of elevated *kapha dosha.* Study participants were subjected to dual-diagnosis assessment that included a BMI of 25–45, indicating overweight through morbid obesity. The intervention

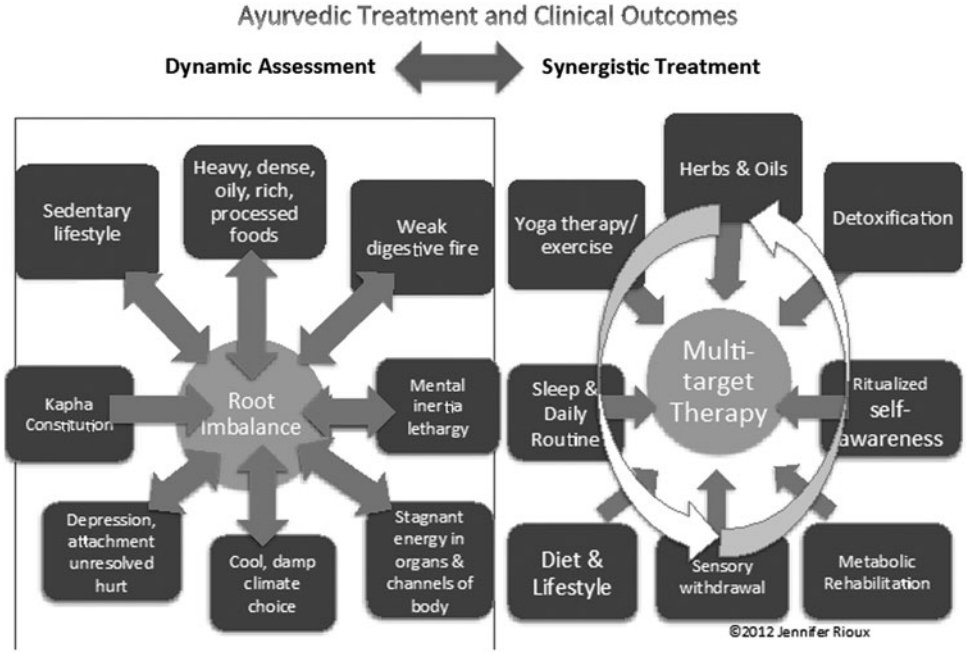

FIG. 1. Systems approach to Ayurvedic treatment and clinical outcomes.

was semistandardized, in that diet and yoga protocols for reducing *kapha* were further tailored to the needs of the individual based on variance in constitutional type, particular food habits/needs, and physical functionality as related to yoga.

Recruitment for the study included posting notices for a ''holistic weight loss program'' on university hospital message boards and through flyers in the community. Participants were overweight/obese adult community members, naive to Ayurveda and Yoga, and were paid no fees for the intervention. If interested, participants were told they would participate in a 3-month intervention combining Ayurvedic diet, lifestyle modification, and yoga therapy, and would have follow-up assessments after the intervention was complete. This pilot feasibility study was approved by the University of Arizona Institutional Review Board. All study participants provided consent before participation.

Inclusion/exclusion criteria

Study participants met both biomedical and Ayurvedic inclusion and exclusion criteria. Inclusion criteria consisted of a biomedical diagnosis of obesity through BMI between 25 and 45 and a traditional Ayurvedic pulse analysis demonstrating either primary or secondary prominence of *kapha dosha* in the constitution and aggravated *kapha dosha* (increased water and earth elements) as primary in the imbalance. Ayurvedic pulse analysis is a traditional diagnostic method by which a trained clinician assesses pulse characteristics—movement, rate, rhythm, force, volume, tension, temperature, consistency—under the index, middle, and ring fingers, associating these with *doshic* qualties, such as cold/hot, light/heavy, and mobile/slow.[45]

To ensure consistency, constitution/imbalance profiles were assessed through pulse by 1 Ayurvedic doctor with 12 years experience in pulse assessment. This pilot study represents the first time that Ayurvedic pulse diagnosis was collected as an outcome in a clinical trial. Pulse assessment subsequently appeared in an unrelated pilot study of Ayurveda for coronary heart disease.[46] Exclusion criteria included insulin-dependent diabetes; arthritis or osteoporosis compromising functionality; current cardiovascular disease; issues with balance/equilibrium or mobility; yoga practice within the past 2 years; other type of current weight loss treatment; and age >70 years.

Intervention

The intervention was designed as a comprehensive diet, activity, and lifestyle modification program based on principles of Ayurvedic medicine and Ayurvedic Yoga therapy. This intervention combined several features, which have subsequently been identified as essential to weight loss interventions: (1) personalized nutrition, (2) a problem-solving and motivational approach to lifestyle adherence, and (3) targeted strategies for reducing food cravings. Tailored nutrition prescription, defined as ''comprehensive and dynamic nutritional recommendations based on shifting, interacting parameters in a person's internal and external environment'' (47:93), closely matches the Ayurvedic approach to personalized dietary modification based on constitution/imbalance profiles.

Precision nutrition has been shown through a systematic review to be promising for the prevention and management of metabolic disorders.[47] This WSAY intervention combined Ayurvedic CBT as individualized solution-focused coaching with motivational social support delivered in group yoga classes. A subsequent pilot study of a coaching approach to weight loss delivered through group visits in primary care led to significant weight loss and was found to be efficient and cost effective.[48] Ayurvedic strategies for identifying and addressing food cravings and aversions, according to the science of food qualities, were an important aspect of the intervention, presented graphically in Figure 2. Cravings and aversions have recently been described as ''food cue reactivity'' by neurobiologists citing their critical role in obesity.[49]

Ayurvedic CBT involved significant ritualized self-awareness and self-monitoring of lifestyle behaviors. Combining practitioner-led patient education and individualized coaching reinforced group social support provided in yoga classes. Intervention components were the semi-standardized Ayurvedic diet approach, three 75 min group yoga classes per week supplemented by home practice, and twice monthly visits over 12 weeks with an Ayurvedic Doctor (AD). The AD utilized Ayurvedic CBT and traditional Ayurvedic diagnostic methods, including assessment of *doshic* imbalances through pulse and tongue analysis to chart physiological and psychosocial changes in response to treatment over time.

The Ayurvedic diet reduced or eliminated foods that aggravate earth and water elements and increased the use of spices and freshly prepared foods to stoke metabolic fire and remove toxins from the digestive tract (Appendix A). The Ayurvedic doctor/Ayurvedic Yoga therapist with 12 years' experience provided patient care and some yoga instruction with support from another yoga professional trained in the protocol. Both researchers were blinded to all outcomes until follow-up data collection was complete.

Tailored advice during Ayurvedic consultations included therapeutic recommendations regarding sleep, food cravings, daily routine, sensory input, relationships, and self-awareness informed by participant feedback and discussion of barriers to adherence protocol. The implementation, sequencing, and specific instructions for Ayurvedic Yoga therapy were delivered in a stepped approach as yoga-naïve participants increased their endurance. Yoga instruction was also tailored to participant functionality, using well-established props and modifications to make postures accessible (Appendix B).

Yoga therapy treats obesity through postures, breathing techniques, and meditation that improve muscle tone, reduce fat, regulate the nervous system and psychoemotional states, and detoxify tissues/improve metabolism.[30–34] Ayurvedic Yoga further addresses obesity by counteracting the slow, static, cold, heavy, and dense qualities.[22,23] The intervention was designed to change eating and activity patterns and to improve self-efficacy, quality of life/well-being, vitality, stress management, self-awareness around food choices, and barriers to weight loss. A comprehensive multimodal Ayurvedic approach, including CBT and tailoring treatment to the physiology and psychoemotional profile of the individual, potentially increases therapeutic impact and maximizes the accessibility and sustainability of change for the participant.[8–10,15–17]

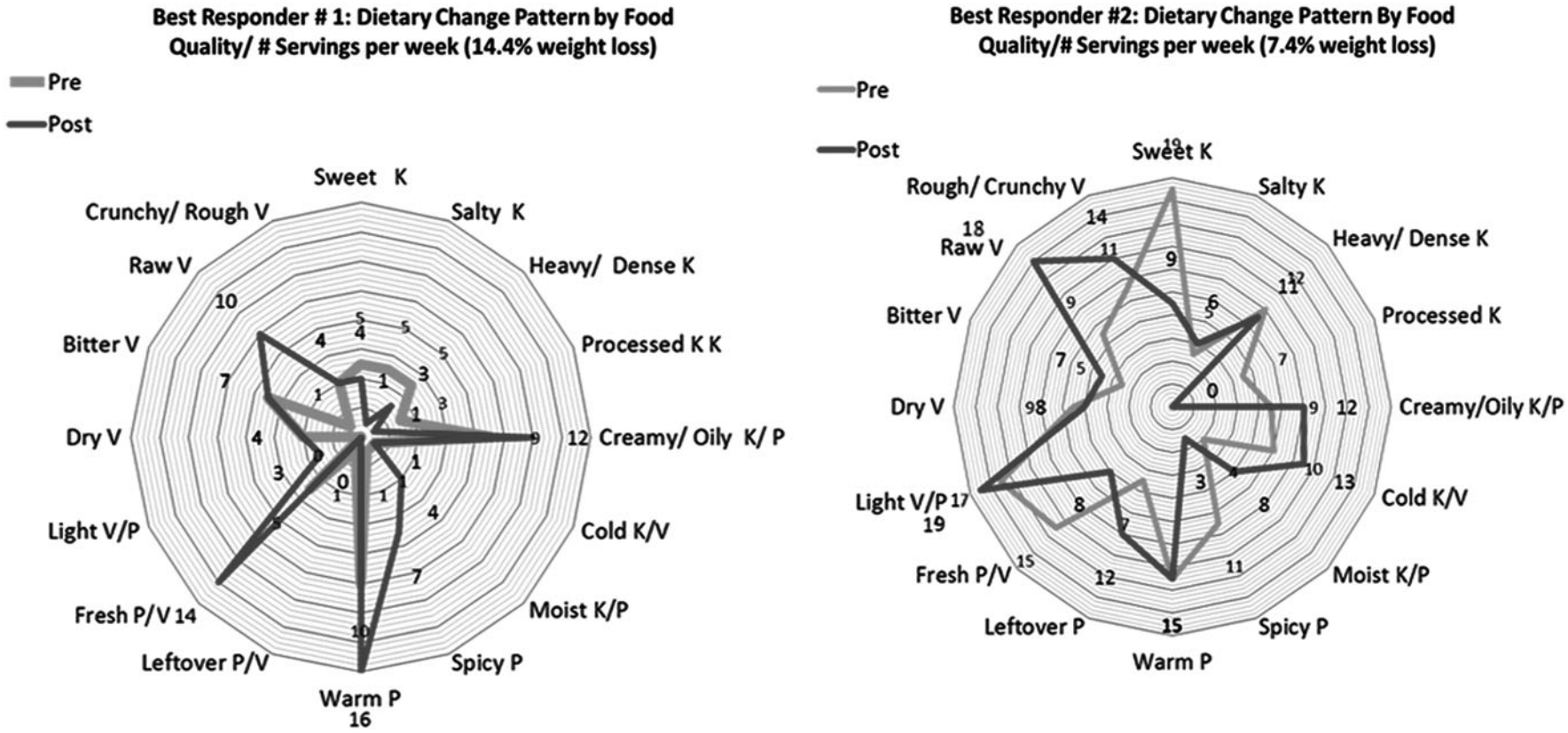

FIG. 2. Post-Ayurvedic dietary change outcomes by food quality and number of servings per week. Using the AGNI (Ayurvedic Gauge of Nutritional Information)© tool developed for this intervention, participants charted the qualities of the food they ate weekly (light, heavy, etc.) through a color-coded wheel making a note of the number of servings per week and used the changing color map to track their progress with the dietary protocol. The graphic shows K for foods that increase *kapha dosha*, P for *pitta dosha*, and V for *vata dosha.* The diet protocol focused primarily on decreasing *kapha* food qualities and increasing *vata* and *pitta* food qualities.

Data collection procedures

Standardized Ayurvedic outcome instruments were developed to collect data on diet, use of senses and relationships to reflect model validity, and explore connections between physiological and psychosocial outcomes of Ayurvedic treatment. Other Ayurvedic outcomes such as pulse analysis, hydration, strength of appetite, and elimination patterns were practitioner collected and did not require unique instruments, but were critical in understanding paradigm-specific causality.[42,43] Ritualized self-awareness practices of the WSAY intervention were integrated into data collection processes. Participants used the diet data collection tools to enhance their experience and understanding of food qualities and how they contribute to weight gain/loss, supporting increased motivation and self-efficacy. (Fig. 2).

Recording frequency and duration of yogic practices such as breath work, meditation, and postural practice supported self-regulation. Participant-led data collection increased five traits that a 2015 review found to predict long-term weight loss success: (1) autonomous motivation, (2) self-efficacy, and (3) self-regulation for weight and physical activity outcomes, and (4) positive body image and (5) *flexible eating restraint* for sustainable effects on weight control (50:84). Ayurveda-consistent self-monitoring and data collection procedures were consistent with noted psychological mediators of successful outcomes in obesity-related lifestyle-change interventions.[50]

Self-report instruments were designed to capture data in five lifestyle-related areas identified by Ayurvedic medicine as potential contributors or impediments to weight loss: (1) dietary intake based on food qualities, including cravings and aversions (Fig. 2); (2) changes in mood associated with *kapha* aggravation; (3) media usage and excess sensory stimuli; (4) frequency, content, and intensity of yoga, breathing, and meditation; and (5) changes in relationship quality and interaction.[22,23,38–40] Data were also collected through visual analog scales (VAS) with a range of 1–100 on appetite, energy, and self-awareness to represent nonspecific effects of the intervention or overall benefit.[51] Data were collected through Ayurvedic practitioner assessment, as well as patient self-report, across many time points.

This multireporter multitime-point strategy of data collection allows for a layered description of health outcomes, which contain both objective and subjective measures, as well as process outcomes and contextualizing information. This has been referred to as the evidence mosaic,[52] characterized by overlapping analyses of data sets and sources. The evidence mosaic also resonates with the concept of *topographical* data collection intentionally used in this study design,[24] which includes multiple overlapping sources of data that form a composite picture of the overall phenomena and do not dismiss or exclude data that are emergent within the research process, rather than predetermined.

These data combine to encompass both patient and provider priorities and provide a rich frame of reference for understanding aspects of the health care experience, the treatment paradigm, or environmental variables that arise as *emergent properties* of the whole system. One example of an emergent property resulting from comprehensive Ayurvedic diet and lifestyle change is that family members notice increased vitality or weight loss in the study participant, thus developing an affinity for the new habits of their family member or an interest in yoga. This change in perspective increases social support for change, thus creating an impetus for greater adherence to the protocol, begetting additional improvements in weight loss and vitality.

Provider-reported outcomes included changes in body weight, BMI, body fat percentage, fat/lean mass, waist/hip circumference and ratio, and blood pressure. Patient-reported outcome measures included diet and exercise self-efficacy scales adapted from Bandura's work on health promotion through social cognitive means[53] and modified to include Ayurveda-consistent categories of analysis associated with *kapha dosha*; the Perceived Stress Scale (PSS-10) 10 items rated from 0 never to 4 very often[54]; Pittsburgh Sleep Quality Index (PSQI); 100 mm line VAS of energy, appetite, stress, quality of life, well-being, and program satisfaction at all time points.[51]

Uniquely designed instruments were used to collect data on diet by food qualities (Fig. 2), sensory input (e.g., frequency, duration and intensity of TV or music), changes in *kapha* mood/emotions (e.g., confused, stuck, joyous, content), primary relationships (% of time experienced as positive vs. negative), and sleep patterns (No. of hours sleep per night/No. of sleep interruptions). Adherence to thrice weekly yoga classes, home yoga practice, and bimonthly consultations with an Ayurvedic medicine practitioner was recorded by study staff. Anthropometric, psychosocial, and Ayurvedic outcomes were analyzed to highlight relationships between variables, including therapeutic context.[24]

Data analysis

In this feasibility study, the dual-diagnosis design provided a diagnostic rubric that informed the development of the standardized intervention, whereas the psychosocial context of each patient and their response to treatment informed the individualization of the intervention as it proceeded. The patient population represented a cohesive whole (through similarity of constitutional/imbalance profiles), whereas tailored treatment features provided the opportunity to maximize patient response to, and compliance with, the intervention. Intensive multilayered (e.g., topographic/mosaic) collection of clinical outcomes provided insight into individualized features of the treatment regimen, whereas the density of data on any given feature of the intervention, or treatment response, allowed for optimal interpretation of outcomes in relation to a predetermined causal model.

Outcomes were analyzed to explore synergy of therapeutic components and patient priorities shaped how the flexible features of the intervention were implemented. For instance, as participants changed their dietary habits, their elimination improved; better elimination led to less toxicity in the body; less toxicity in the body informed better moods; better moods encouraged optimal decision making around food; optimal decision making around food increased the potential for weight loss; weight loss increased energy and activity levels, thereby improving yoga attendance and intensity; and so on. Figure 3 shows the principle of mutual causality, an iconic feature of whole systems in which change is bidirectional, with any therapeutic improvement having the potential to positively impact another salutogenic process.

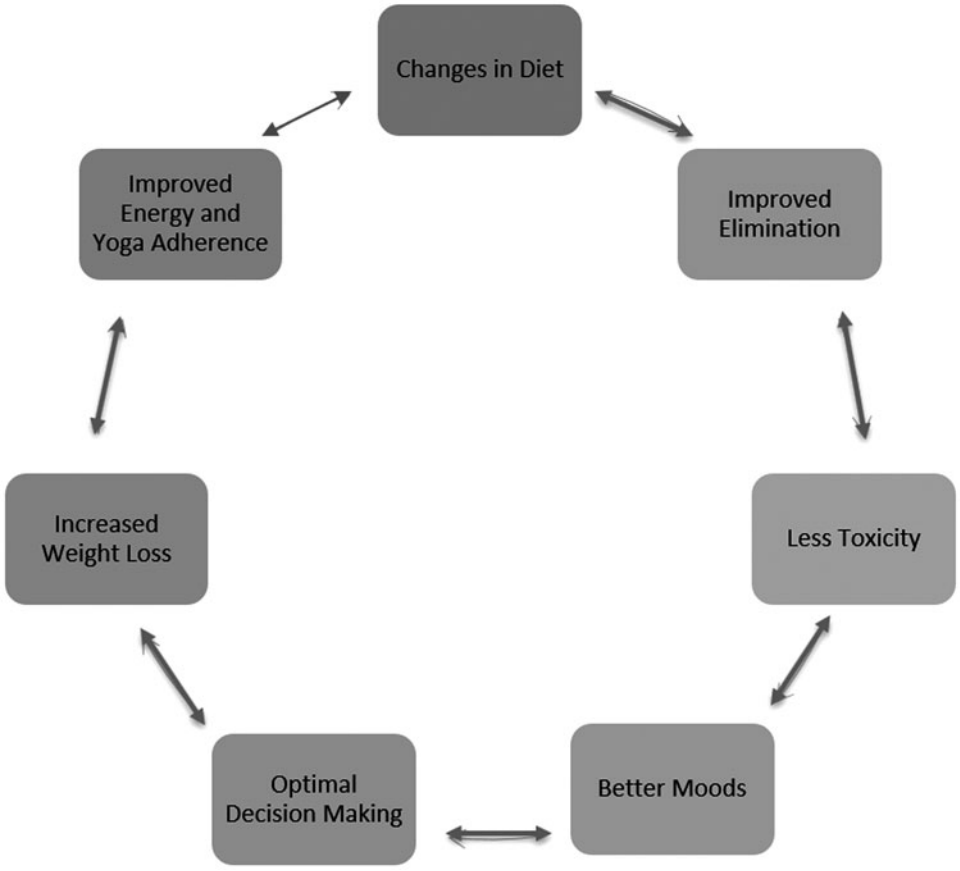

FIG. 3. Multimodal Ayurvedic approach to obesity. Demonstrates the mutual causality and bidirectionality that is an iconic feature of whole systems of medicine, necessitating certain research design and analysis features to accurately represent the therapeutic process.

As this is a pilot study with 17 participants enrolled, within-person difference scores were calculated for each time point and descriptive statistics are provided, but an a priori decision was made by the research team to not perform statistical comparisons as this is a pilot study with a small sample size. Descriptive statistics included mean, standard deviations, frequency, percentage, and change scores. Analysis of the follow-up period was designed to evaluate the durability of the effect, that is, maintenance/continuation of weight loss and lifestyle changes. Exploratory and visualization analyses were performed to measure synergy between outcomes and comparisons of Ayurvedic concepts that do not lend themselves to traditional computational analysis.

WS concepts, such as tipping points of behavioral change, or identification of thresholds for intervention effectiveness, are explored here through visual analysis using the relationship between adherence, lifestyle changes, and yoga practice. Ayurvedic lifestyle outcomes such as profiles of constitution and imbalance are graphically displayed. All computations were performed using Stata 12 and graphics were created in Stata 12 and Microsoft Excel.

Results/Outcomes

Seventeen participants enrolled in the study. Participants were 41.3 years of age on average with 2 men and 15 women. Overall, participants lost an average of 3.5 kg. during the duration of the intervention (Table 1). Weight loss had increased to an average of 5.6 kg and 5.9 kg. at 6 and 9 months, respectively, with no additional services provided. Mean weight loss at 6 months postintervention was 6%. It has been noted by biomedical clinicians that weight loss as minimal as 5%–10% of initial weight is sufficient for clinically meaningful reductions in weight-related biomarkers.[8,13] Aggregate blood pressure (practitioner-reported) was 123/81 at baseline, 114/74 postintervention, 113/74 at 6 months, and 118/81 at 9 months.

On average, self-efficacy around dietary change and exercise improved in all categories from baseline to 3 months with continued improvement at 6 months and minimal decline at 9 months, indicating a need for additional support during the follow-up period. Changes in perceived stress improved from baseline to 3 months and ability to maintain positive outlook was sustained at 6 and 9 months. Participant self-report of stress indicated reduced stress levels at every time point after enrollment. Continued weight loss and maintenance of improved psychosocial outcomes were sustained at 9 months, indicating durability of health outcomes over time. Participants reported increased energy, well-being, and quality of life, at 3 and 6 months, with measures above baseline values at 9 months.

Intervention adherence and weight loss

To explore the relationship between adherence to the program and weight loss, each participant's weight was triangulated on a graph (Fig. 4) with yoga program adherence (x axis) and dietary recommendation adherence (y

Table 1. Anthropometric and Conventional Outcomes

	Baseline Mean (SD)	*3 Month Mean (SD)*	*6 Month Mean (SD)*	*9 Month Mean (SD)*
Anthropometric				
Weight (lbs.)	205.1 (42.0)	197.4 (39.5)	192.0 (40.3)	184.9 (69.6)
Weight change (lbs.)		−8.3 (10.0)	−13.1 (13.8)	−13.0 (17.9)
Weight change (%)		−3.8% (0.04)	−5.6% (0.07)	−6.2% (0.09)
BMI	33.2 (5.2)	31.9 (4.8)	31.2 (5.6)	31.3 (5.4)
Body fat %	43.2 (5.6)	39.4 (4.7)	39.7 (6.7)	39.4 (6.1)
Waist circumference (cm)	112.4 (15.1)	107.0 (14.3)	106.5 (17.2)	103.2 (15.8)
Waist circumference change (cm)		−5.4 (7.1)	−5.8 (8.4)	−9.0 (10.5)
Hip circumference (cm)	121.4 (13.8)	117.7 (10.5)	116.0 (12.1)	115.7 (12.2)
Hip circumference change (cm)		−3.7 (5.9)	−5.4 (6.2)	−4.7 (6.6)
Waist to hip ratio	0.91 (0.05)	0.89 (0.06)	0.91 (0.08)	0.89 (0.08)
WHR change		−0.18 (0.03)	0.00 (0.04)	−0.02 (0.05)
*11 people total at 6 months: 1 dropout (surgery); 10 people at 9 months: +1 dropout (relocation)				
Blood pressure				
Blood pressure—systolic	123 (19)	114 (13)	113 (15)	118 (12)
Blood pressure—diastolic	81 (9)	76 (10)	74 (6)	81 (9)
Psychosocial/stress				
Well-being	66.3 (12.9)	78.8 (7.8)	77.3 (17.2)	73.1 (12.8)
Quality of life	75.2 (12.8)	82.1 (6.2)	85.3 (10.5)	76.1 (11.5)
Energy	67.9 (13.6)	74.5 (8.4)	68.2 (21.2)	63.6 (21.1)
Self-efficacy				
Eating				
Relationship with others/self	60.8 (12.9)	66.5 (15.5)	67.5 (15.3)	58.8 (23.7)
Adapt to routine/circumstance	68.8 (14.3)	74.4 (10.4)	75.4 (12.3)	69.3 (13.6)
Internal/emotional regulation	65.5 (16.2)	74.7 (9.6)	73.1 (12.4)	65.1 (19.6)
Exercise				
Relationship with others/self	65.8 (20.2)	67.2 (12.7)	69.1 (20.6)	59.8 (18.9)
Adapt to routine/circumstance	64.9 (16.4)	68.5 (12.2)	65.6 (18.4)	59.9 (22.8)
Internal/emotional regulation	56.3 (16.9)	66.5 (13.4)	60.9 (15.9)	52.9 (18.8)
Secondary outcomes				
Water intake (oz. per day)	42.3 (27.6)	62.8 (26.2)	51.8 (27.7)	52 (30.2)
Appetite (VAS 0–100)	75.8 (14.1)	69.2 (11.8)	73.8 (10.9)	75.8 (12.7)
Elimination (BM/×per day)	1.3 (0.77)	2.0 (1.2)	1.8 (1.2)	1.5 (0.52)

*denotes change in *N* during follow up.
BM, bowel movement; BMI, body mass index; VAS, visual analog scales; WHR, wait-to-hip ratio.

axis). Each participant's weight change was displayed for the 3, 6, and 9 month follow-up periods. Those with negative change scores indicate weight loss, and those with positive scores indicate weight gain. Visual analysis of the pattern clustering indicates a positive relationship with a minimum of 55% adherence to both yoga and dietary components and weight loss.

Ayurvedic constitution and imbalance data

There are a number of ways in which *doshic* expression through the constitution and imbalance profiles of the patient can be expressed. The Ayurvedic doctor/researcher in this intervention was trained to characterize the expression of the *doshas* in the patient constitution as a ratio of 3:2:1, with the most prominent *dosha* as 3, the second most prominent *dosha* as 2, and the least prominent *dosha* as 1.[41] *Doshic* expression in the patient imbalance through this method is characterized as quantitatively above the baseline measures of the patient's constitution, and is measured by assessing qualities of the pulse under index, middle, and ring fingers including movement, rate, rhythm, force, volume, tension, temperature, and consistency, as noted above. All study participant pulse analysis was conducted by one Ayurvedic doctor to maintain consistency and the doctor was blinded to changes in patient pulse analysis until data collection was complete.

Analysis of the aggregate constitutional pulse in Figure 5 shows that the study sample was predominantly *pitta* with secondary *kapha* and tertiary *vata*. Individuals with any constitution may develop disorders of any *doshic* type; however, it is more common for individuals who have primary or secondary *kapha* to develop a *kapha* imbalance. An individual's original constitution represents a state of balance or health for that person. The numbers associated with the constitutional baseline hereunder (column 1) represent therapeutic targets of *doshic* balance or health, expressed as numbers.

Analysis of the aggregate imbalance (column 2) shows that in the study participant group as a whole, there was evidence of aggravation in all three *doshas* with *kapha* (earth and water) being most elevated (+1.08), *vata* second

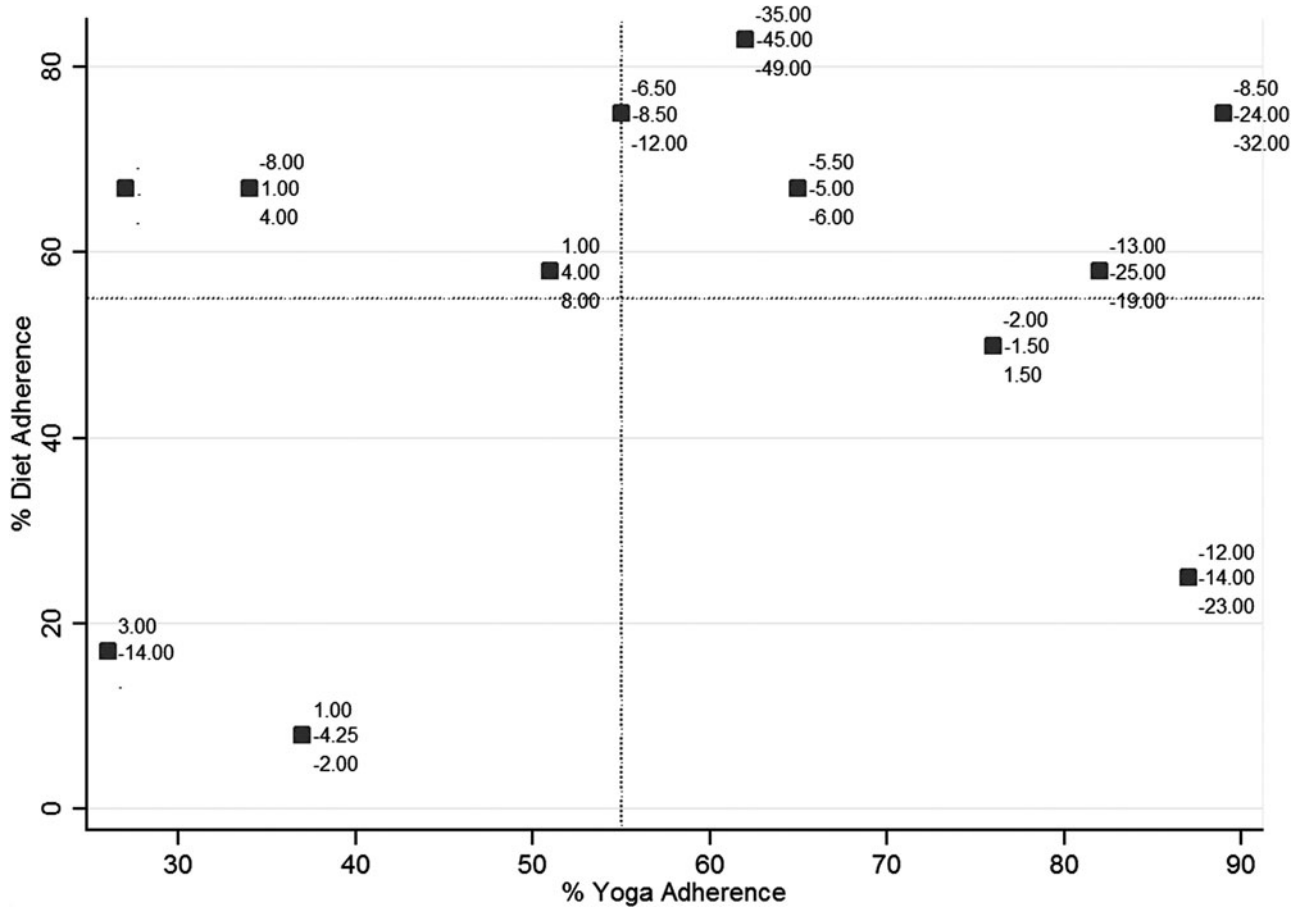

FIG. 4. Weight loss as a function of diet and yoga adherence. Weight loss (lbs.) is displayed for 3 months (*top*), 6 months (*middle*), and 9 months (*bottom*) for each participant. Participants with >55% adherence in both diet and yoga demonstrate the greatest levels of weight lost and maintained after the intervention. Numbers associated with each box show weight loss in pounds at the three data collection time points. This graph shows the tipping point of 3% loss of baseline body weight ($N = 11$). (One participant's data excluded due to multiple surgeries during intervention.)

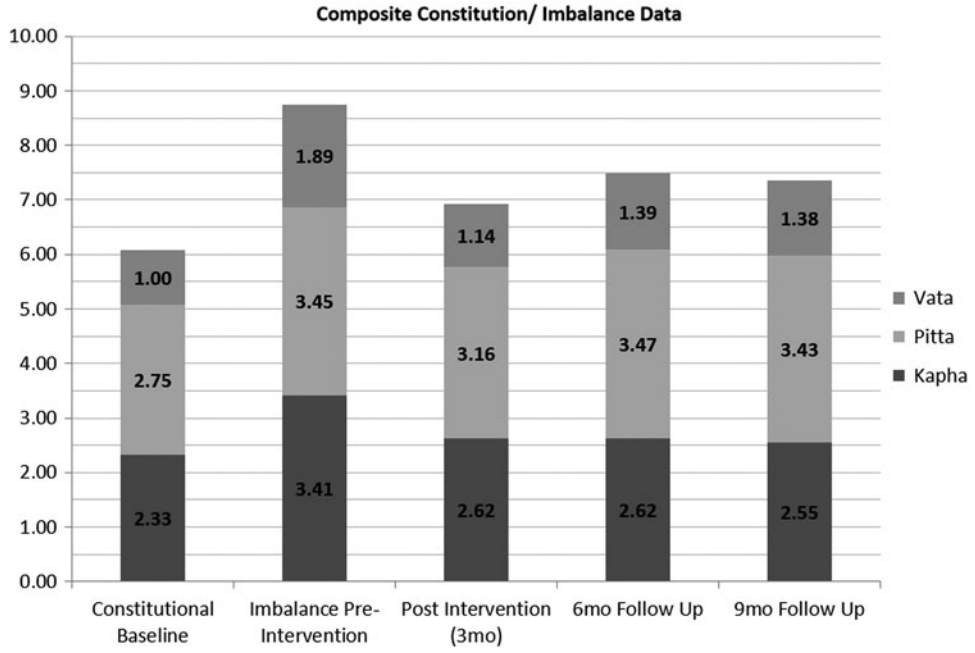

FIG. 5. Composite constitution/imbalance data.

Table 2. Ayurvedic Outcomes

Doshic *change (pulse analysis)*	*Vata*	*Pitta*	*Kapha*
Aggregate constitutional baseline	1	2.75	2.33
Aggregate imbalance baseline	1.89	3.45	3.41
Aggregate imbalance 3 months	1.14	3.16	2.62
Aggregate imbalance 6 months	1.39	3.47	2.62
Aggregate imbalance 9 months	1.37	3.42	2.55

Sleep quantity/awakenings	*Pre*	*Post*
Average No. of hours slept per night	7.06 (0.69)	7.58 (0.29)
No. of subjects waking in night $N=12$	12 (0.63)	6 (0.58)
Ayurvedic mood/affect scale		
Imbalanced *kapha* emotions		
Frequency of reporting ($N=12$)	5.75 (1.71)	2.75 (0.96)
Magnitude (0–20 scale)	8.81 (0.98)	7.38 (3.33)
Imbalanced *kapha* cognitive dysfunction		
Frequency of reporting ($N=12$)	7.66 (1.16)	4.33 (1.53)
Magnitude (0–20 scale)	8.82 (0.66)	9.16 (1.35)
Balanced *kapha* internal/emotional regulation		
Frequency of reporting ($N=12$)	8 (1.83)	7.25 (2.5)
Magnitude (0–20 scale)	11.43 (2.57)	12.8 (1.93)
Balanced *kapha* relationships with others/self		
Frequency of reporting ($N=12$)	5.5 (1.0)	5.25 (1.71)
Magnitude (0–20 scale)	7.8 (2.66)	13.5 (1.24)

Quality of relationships: changes pre to post	*Positive % per week*	*Negative % per week*	*Intensity, %*	*Nonintentional interaction, %*
Family/personal	+7.07	−9.96	+11	−30
Work/school	+9.9	−3.38	−19.5	−9
Health/food	+3.21	−28.23	−22.5	−6
Self	+6.77	−11.50	−5	−13

most elevated (+0.89), and *pitta* least elevated (+0.7). This is consistent with the understanding of obesity as a *kapha* disorder, with underlying stress and nervous system aggravation (*vata*) that disrupts optimal metabolic activity (*pitta*). Columns 3, 4 and 5 represent an assessment of aggregate imbalance at 3 (postintervention), 6, and 9 months, respectively. Postintervention, *kapha* was reduced (–0.79) to within 0.29 of balance and further reduced at 9 months post (–0.86) to within 0.22 of balance. *Vata dosha* was reduced (–0.75) to within 0.14 of balance postintervention and *pitta* was reduced (–0.29) to within 0.41 of balance postintervention.

Other Ayurvedic outcomes

Table 2 represents key Ayurvedic outcomes. The data show an additional 30 min of sleep per night on average, increasing from 7.06 to 7.58 h, and a reduction in instances of waking by 50% (12–6) for study participants. Scales were developed to measure *kapha*-type moods such as depression, confusion, and feeling ''stuck'' or hurt with postintervention measures showing a reduction in frequency of *kapha*-negative moods of 48%, as well as reduced severity of moods. Scales measuring *kapha*-negative cognitive patterns such as confusion, difficulty making decisions, and cloudy thinking showed a reduction of 57%, with negligible increase in severity.

According to Ayurvedic theories of metabolism, adequate water intake is important for supporting metabolic activity and regular bowel movements promote detoxification. Both of these measures improved among study participants, who also reported a reduction in appetite at 3 and 6 month time points. All of these outcomes would be consistent with pacification of aggravated *doshas* and a hewing of *doshic* expression closer to the constitutional baseline.

Both Ayurveda and Yoga place a high emphasis on self-awareness and intentionality as keys to positive health and self-regulation. Study participants were given both standard (in yoga classes) and tailored tools for increasing self-awareness, positivity, and intentionality in their relationships with self and others. Ayurveda and Yoga consider these strategies to be critical to developing a positive affinity for behavior change and creating social support for new habits. A self-report instrument was designed to measure positive versus negative interactions on a weekly basis, intensity of interaction (either positive or negative), and whether they were intentional or involuntary.

Data in Table 2 show that postintervention, negative personal/family interactions were down 7% and positive personal/family interactions were up 10%, the intensity of these interactions had increased by 11%, and nonintentional interactions had decreased by 30%. Positive work/school interactions increased 10% and decreased 3% with increased intensity of 20% and nonintentionality reduced by 9%. Positive interactions with health and food increased 3% postintervention and negative interactions with health and food were reduced by 28%, whereas intensity increased by 23% and involuntary

interaction reduced by 6%. Data were also collected on positive and negative interactions with self, showing that postintervention positive interactions with self were up by 7%, negative interactions with self were reduced by 12%, intensity was down 5%, and nonintentional interaction was down 13%. It is possible that these variables may be partially responsible for the improvements in psychosocial measures and lower perceived stress displayed in Table 1.

Discussion

This was the first known whole-systems Ayurvedic medicine and Yoga therapy intervention for obesity, including innovative instruments designed to collect Ayurvedic outcomes and incorporating dual diagnosis and dual outcomes collection from the perspectives of both Ayurveda and biomedicine. Data from the study demonstrate that the intervention was well tolerated by participants, with a satisfaction rate averaging >90% at all time points. The study protocol included collection of both conventional and Ayurvedic outcomes, without presenting undue burden for participants.

Attendance at yoga classes averaged 75%, combined yoga and home practice averaged 60%, whereas adherence to dietary advice averaged 55%. Thrice weekly yoga classes were well tolerated by individuals with a BMI up to 42. Participants reported that the Ayurvedic outcome instruments promoted self-awareness around food and lifestyle choices. There was evidence of weight loss in 75% of participants, with percentage of weight loss increasing with combined yoga and dietary adherence.

Weight loss was correlated with adherence to yoga classes, home yoga practice, and compliance with dietary change suggestions. Participants reported overall benefits of the program two times as often as challenges associated with the program.[18] Psychosocial outcomes and self-efficacy data contextualized the differential responses of completers versus dropouts and inform refinement of the program to address identified challenges to establishing and maintaining lifestyle change.

The semistandardized dietary modification encompasses a *flexible eating restraint* approach, de-emphasizing rigid dietary rules in favor of implementing self-care-oriented knowledge grounded in a commitment to a value-based goal. An Ayurvedic focus on experiential knowledge of food qualities and mindful healthy eating, rather than portions and calorie control, led participants to feel more competent and independent in maintaining protocol adherence and able to establish durable integration of lifestyle changes. Identified challenges included lack of family support, and a desire for assistance transitioning to community yoga classes during the follow-up period, to promote sustained practice over time. No adverse events associated with the dietary changes or yoga practices were reported.

Limitations

This study did not include a control group, randomization, or blinding. The unique study instruments developed to collect data on Ayurvedic medical features of the intervention will need to be validated in future studies. The small sample size of this pilot study means that this study was not powered to detect statistical significance for quantitative outcomes. Data collection and protocol adherence were estimated to be 65%. Based on participant feedback, it is anticipated that retention and adherence rates will increase with refinement of the instruments and protocol, and flexibility in yoga class scheduling. On exit interview, participants cited the desirability for postintervention support groups to facilitate continued diet and lifestyle changes and booster yoga classes during follow-up (>3 months) to promote home yoga practice. This integrated WSAY approach reflects a highly innovative clinical trial design, which may not be replicated in all Ayurvedic practices.

Conclusions

An Ayurveda-/yoga-based lifestyle modification program is an acceptable and feasible approach to weight management. Data collection, including self-monitoring and conventional and Ayurvedic outcomes, did not unduly burden participants, with attrition similar to that of other weight loss studies. Weight loss of 3.5 kg postintervention and 5.9 kg at 6 month follow-up shows proof of promise for a sustainable weight loss associated with well-integrated lifestyle changes that also increased self-reported vitality, psychosocial well-being, enhanced quality of life, and positive aspects of self-awareness and relationships. Integrated WSAY for obesity shows promise of durable health benefit and potential prevention or risk mitigation of other chronic conditions based on known comorbidities of obesity/obesity sequela.

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Author Disclosure Statement

No competing financial interests exist.

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Appendices

Appendix A: Ayurvedic Dietary Guidelines for Weight Loss Study

Emphasize lightly cooked or raw vegetables, whole grains and fresh fruits, and light proteins (legumes, fish, or poultry).

Please avoid sweet, salty, oily, heavy, rich, and dense foods. Gradually work toward eliminating processed and packaged foods, white flour and sugar, alcohol and dairy.

Drink 4–6, 8 oz glasses of *room-temperature* water per day. Drink one immediately upon waking and one glass with every meal. Please do not put ice in your drinks.

When eating, the stomach should be filled with 1/3 food, 1/3 water and 1/3 space. Eat your biggest meal at midday.

Separate fruit from other foods by 30 min and do not eat meat and dairy together.

Please note any craving or avoidance of certain foods on your food wheel and your lifestyle change log.

Approach food intake as an act of self-love. Do not eat when feeling emotional or upset. Take a few minutes to focus on your breathing, perhaps reading the 5-element meditation. Consider your food as the source of your energy and vitality. Eat with awareness, focusing on the tastes and qualities of the foods you are eating, and how they make you feel.

Cook at least five meals at home per week and use the following spices: cumin, coriander, fennel, cardamom, ginger, cinnamon, turmeric, basil, oregano, mustard seeds, garlic, and black pepper.

Appendix B: Yoga Sequence for Weight Loss Study (In-class and Home Practice)

- In all poses, the light quality through suspension, distance from the ground, and lifting in limbs and trunk were emphasized. As sessions progressed, focus was on lengthening the duration of balance poses, increasing endurance in strength poses, more rapid transitions between poses, and maintaining longer pose sequences in a continuous flow. The slow, static, grounded, heavy, dense, and cool properties of *kapha dosha*, and increased oppositional qualities through speed of movement and raising heat in the body were de-emphasized.
- Beginning in week 5 of the study, sun salutations were added to the beginning of the sequence, as increased strength and endurance of participants made this practice accessible. The number of sun salutation repetitions was gradually increased over time to a maximum of four, preceding the start of the regular yoga sequence.
- Participants were instructed to practice *Ujjayi* pranayama throughout the yoga sequence and they were provided with a manual of all yoga poses, including photos.

Mountain
Mountain with arms overhead
Mountain with bound arms overhead

Mountain with eagle pose arms
Mountain with cow face arms
Mountain with reverse namaste arms
Tree pose
Triangle
Warrior II
Extreme side angle
Half moon pose
Mountain
Chair
Straight-legged standing forward bend
Plank
Upward dog
Down facing dog
Warrior I
Wide legged standing forward bend
Downward facing dog
Straight-legged standing forward bend
Sitting on heels, toes bent under
Hero
Twisted hero
Seated twist
Spinal twist seated on floor
Upward facing head to knee
Wide legged seated forward bend
Cobbler pose
Camel pose
Reclining hand to foot pose
Bridge pose
Alligator twists
Legs up the wall (hips on blanket)
Corpse pose—10 min
5 Min SO/HUM meditation