

Randomized Trial of Two Mind–Body Interventions for Weight-Loss Maintenance

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ABSTRACT

Objective: Regain of weight after initial weight loss constitutes a major factor contributing to the escalating obesity epidemic. The objective of this study was to determine the feasibility and clinical impact of two mind–body interventions for weight-loss maintenance.

Design: Randomized, balanced, controlled trial.

Setting: Large-group model health maintenance organization.

Participants: Overweight and obese adults were recruited to a 12-week behavioral weight-loss program. Participants meeting threshold weight loss and attendance requirements were eligible for randomization.

Interventions: The three weight-loss maintenance interventions were *qigong* (QI), Tapas Acupressure Technique® (TAT®) (registered trademark of Tapas Fleming, L.Ac.), and a self-directed support (SDS) group as an attention control.

Outcomes: The main outcome measure was weight loss maintenance at 24 weeks postrandomization. Patient interviews explored additional benefits of the interventions, as well as barriers and facilitators to compliance.

Results: Eighty-eight percent (88%) of randomized patients completed the study. There were no significant study-related adverse events. At 24 weeks, the TAT group maintained 1.2 kg more weight loss than the SDS group did ($p = 0.09$), and 2.8 kg more weight loss than the QI group did ($p = 0.00$), only regaining 0.1 kg. A separation test (0.05 level, 0.95 power) indicated that TAT merits further study. A secondary analysis revealed that participants reporting a previous history of recurrent unsuccessful weight loss were more likely to regain weight if assigned to the SDS arm, but this effect was suppressed in both the QI and TAT groups ($p = 0.03$). Although QI participants reported important general health benefits, the instruction sequence was too brief, given the complexity of the intervention.

Conclusions: TAT warrants further research for weight-loss maintenance. Any further research on *qigong* should use a modification of our protocol.

INTRODUCTION AND BACKGROUND

Obesity is the second leading cause of preventable death in the United States, primarily because of cardiovas-

cular and cancer risk.¹ Extensive research has documented that weight loss is achievable, at least in the short term.² In response to this overwhelming evidence, the Surgeon General, the National Institutes of Health, the medical research

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community, and professional organizations recommend weight control and increased physical activity as core components of treatment guidelines for hypertension, hyperlipidemia, type 2 diabetes, and cancer prevention.^{3,4} Despite these efforts, however, the obesity epidemic continues to affect more than 100 million Americans.

A major factor contributing to this escalating epidemic is weight regain after initial weight loss, which is disappointingly common. The most promising traditional strategies to prevent regain involve continued behavioral intervention with frequent contacts,⁵ which is a high-cost strategy that is unlikely to be widely implemented and one that is not acceptable to many patients. To combat successfully the obesity epidemic, clinicians and health care systems need effective and feasible options to help individuals maintain weight loss.

Traditional Chinese Medicine (TCM) offers a variety of mind–body approaches to health maintenance and promotion. In theory, such approaches could reduce stress, control cravings, and improve mental focus. In addition, complementary and alternative medicine (CAM) approaches remain popular and appealing among patients. There is, however, scant evidence to support the use of such modalities for weight-loss maintenance.⁶

We conducted an early-phase feasibility study of two mind–body interventions from the TCM tradition: Tapas Acupressure Technique® (TAT®; a registered trademark, of Tapas Fleming, L.Ac.), and *qigong* (QI). We sought to determine which intervention might warrant further phase 2–3 studies by addressing the following issues: (1) feasibility, recruitment, adherence, and barriers; (2) delivery of the interventions, and modifications to enhance efficacy and compliance; (3) possible effect size compared with attention control, and modulation of other common predictors of weight maintenance; and (4) any additional benefits.

MATERIALS AND METHODS

Study design

The overall study design is summarized in Figure 1. Participants attended a 12-week weight-loss intervention. Those meeting threshold weight-loss requirements and adherence targets were then randomized to one of three weight-loss maintenance interventions. These interventions were delivered during a 12-week period immediately postrandomization. Data collection for outcomes took place at 12 and 24 weeks after randomization.

Participants

Participants were recruited from the community using local community advertising and e-mail contact with Kaiser Permanente Northwest employees. Interested participants attended an information and screening session. The study inclusion criteria allowed for men and women ages 18–80. Women eligible for the study had a body–mass index (BMI) of 25–35 kg/m² at screening, while men had a BMI of 25–40 kg/m². To be eligible for randomization, participants had to live in the Portland metropolitan area, complete the weight loss program, attend 75% of weight-loss sessions, lose at least 3.5 kg in the weight-loss program, and be willing to accept random assignment to any of the three weight-loss maintenance arms. Participants were excluded because of medical conditions or treatments that might contraindicate using a diet and exercise weight-loss treatment including cancer; significant gastrointestinal disease inappropriate for diet and physical activity intervention; diabetes; taking prescription medication for high blood pressure or high cholesterol; psychiatric hospitalization during the past 2 years;

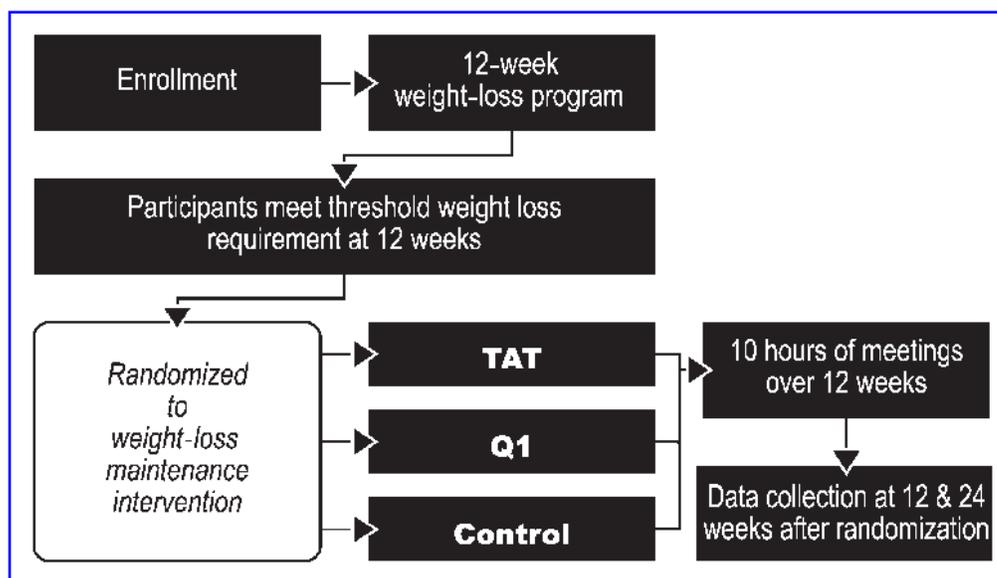


FIG. 1. Study design. TAT®, Tapas Acupressure Technique® (registered trademarks of Tapas Fleming, L.Ac.).

taking medication for psychosis or manic-depression; congestive heart failure; cardiovascular disease (stroke, myocardial infarction, coronary artery bypass graft, arteriosclerotic cardiovascular disease); taking weight-loss medications currently or within the past 6 months; liposuction in the past 12 months; and previous history of bariatric surgery. Participants were also excluded because of a previous history of CAM weight-loss treatment; current acupressure; *qigong*; or acupuncture treatment; reported consumption of more than 21 alcoholic drinks per week; weight change of more than 10 pounds during the 6 months prior to the initial screening; pregnancy; current breast-feeding or planning pregnancy prior to the end of participation; current participation in another clinical trial; or household member of another participant in the study.

Participants signed consent forms and filled out baseline questionnaires at the first screening visit. Patients who qualified were then randomized to a weight-loss maintenance intervention based on their scheduling preferences at the second screening visit.

Participants were weighed for a second measurement at the completion of the 12-week weight-loss class. Those participants who lost at least 3.5 kg were invited to participate in the treatment phase of the study. Participants completed questionnaires and were randomized to one of three weight maintenance arms. The Kaiser Permanente Committee for the Protection of Human Subjects approved this study.

Interventions

Weight-loss program. All participants received the same initial 12-week group weight-loss intervention, called “Freedom from Diets.” Freedom from Diets is a program of the Kaiser Permanente Northwest Health Education Department and is currently delivered to about 700–1000 individuals per year. This state-of-the-art program incorporates behavioral, social support, and motivational theories into the curriculum. It is delivered in a group setting and utilizes group discussion and peer support. Sessions last approximately 1½ hours. The program includes problem-solving skills; food preparation and shopping; self-monitoring of diet, activity, weight, and behaviors; social support; self-efficacy; and physical activity. Center for Health Research investigators originally developed this program.⁷ From available data, mean weight loss is approximately 1.2 lb per week, or 10 to 14 pounds during 12 weeks; average attendance at each group session is about 80%. These data are comparable to results reported in the literature.⁵

Weight-loss maintenance study interventions. For the weight-loss maintenance portion of the study, eligible participants were randomized to one of three weight-loss maintenance interventions: QI, TAT, or self-directed support (SDS). The three arms were matched for intensity of con-

tact, with each maintenance intervention providing 10 hours of group-based contact time distributed during the first 12 weeks of the maintenance phase.

Qigong Intervention (QI). *Qigong* is an ancient healing discipline and in China is referred to as the jewel of TCM. It is a discipline consisting of breathing and mental exercises; these are usually combined with physical exercises. *Qigong* balances the subtle energy system in the body described in the theories of TCM.⁸ *Qi* is the term for the vital energy and life force in our bodies, as well as for breath. *Gong* can be translated as “work” or “discipline.” *Qigong* has been defined in many ways, including “air energy,” “breath work,” and “energy work.” According to TCM theories, a vital energy system exists in the body, through which flows *qi*, the life force. The system’s pathways are called meridians or channels. When energy is flowing through this system at normal levels and in balance, the body stays healthy and resistant to disease, and can activate its own healing. When imbalances or blockages occur, the physiology is affected. If a person is healthy, various TCM approaches can be practiced to maintain health. If a person is ill, the person can regain health by reestablishing a normal balance in the energy system. All of the treatment modalities in TCM are designed to achieve this harmony, and *qigong* is considered to be its most powerful method.

For this protocol (Qigong Intervention (QI)), the specific Qigong techniques included:⁹

1. **Shaking** (5 minutes)—Participants learned how to begin opening the body’s meridians and connect with universal energy.
2. **Movements** (18 minutes)—Movements were focused on increased communication and exchange with universal energies, thereby enhancing an individual’s vitality. These included a seven-step protocol for opening the five directions, as well as instruction in “flying dragon” and “playing with the wave” movements.
3. **Harvest the energy method** (5 minutes)—Participants learned basic *qigong* closing methods (involving *qi* massage) to consolidate and maintain the results of the exercises. The steps included nourishing the eyes, washing the face, combing the hair, nourishing the ears, strengthening the teeth, and harmonizing the *qi*.

The protocol was developed and taught by Zhongxian Wu, 17th-generation lineage holder of the Wudang Dragon Gate and 7th-generation lineage holder of the *Emei Zhen Gong* style of *qigong*.

Tapas Acupressure Technique (TAT). Acupressure was developed as a system of treatment more than 5000 years ago. Acupressure points are places on the skin that are especially sensitive to bioelectrical impulses in the body and conduct these impulses readily. Asian cultures envision

these points as junctures of special *qi*-carrying pathways. Stimulating these points with pressure, needles, or heat produces changes in the energy flows within and around the body that promote healing, relieve pain, and alter the chemical balance within the body and mind.

The TAT procedure¹⁰ combines acupressure with specific mental focuses, altering the energy patterns stored in the body.

For the purposes of this trial, the general instructions to patients were to:

1. Identify the belief or action that is hindering weight loss/maintenance.
2. Focus on that negative image while holding the TAT pose: specifically, applying pressure to acupuncture points GB21, BL1, and *Yin Tang* for 30 seconds. These points are located just medial to the eyes, above the nose, and behind the head.
3. Transition the focus onto the opposite positive image while holding the same points for an additional 30 seconds.
4. Hold the TAT pose while focusing on, "all the origins of this problem are healing now."
5. Hold the TAT pose while focusing on, "all the parts of me that got something out of having this problem are healing now."
6. Forgive everyone you have blamed for the problem, and ask forgiveness of everyone who has been hurt because of the problem.

Daily practice as needed was advised.

The protocol was developed by Tapas Fleming, L.Ac., and was taught by a licensed acupuncturist.

Control intervention: Self-Directed Support (SDS). In the control group, the first maintenance session reviewed written materials providing a general overview of weight-loss maintenance strategies. Subsequent sessions consisted of maintenance support groups, providing opportunities to ask questions of the class leader and share experiences. Although these support meetings were facilitated, the participants largely directed the content of these sessions.

Outcome measures

The main quantitative outcome measure was weight change, with weight assessed at randomization, and at 12 and 24 weeks postrandomization. Weight was measured with subjects wearing light indoor clothes and without shoes by a high-quality digital scale at each measurement visit. Scales are calibrated annually by the Bureau of Weights and Standards and quarterly by study personnel using standard weights. Staff are trained and certified to use the scale and measure weight according to study protocol.

Several additional psychosocial constructs, discussed in the following sections, were measured prior to randomiza-

tion to determine whether the CAM interventions might modulate their potential impact on weight.

Absorption. Absorption¹¹ can be defined as an openness to experiencing emotional and cognitive alterations across a variety of situations. We used the Tellegen Absorption Scale,¹² a widely used research measure.

Expectancy. Patients were asked to rate (on a scale of 1–5) how helpful they thought each of the CAM interventions would be for managing weight prior to enrollment in the weight-loss class.

Social support. Social support was measured using a scale adapted from the Medical Outcomes Study, which assesses the individual's perception of how supportive others are being and how available they are to aid in coping with stressful life events, strain, and hassles. This shortened version was also used in the Women's Health Initiative.¹³

Depression. Depression was assessed using the Center for Epidemiologic Studies Depression Scale, a general measure of depressive symptoms used extensively in research studies.¹⁴

Weight loss history. Patients were asked to report how often they had previously attempted weight loss, and how much weight they had been able to lose in the past, prior to enrollment in the weight-loss class.

Sample size, blinding, and randomization

The sample size of approximately 90 was determined by funding limitations and other practical considerations, as is typical for an early-phase clinical trial. Generally, a comparison-of-means test with 30 individuals per group would have power 85% to detect a relatively large effect size of 0.77, although the method we used here was somewhat more powerful. The study was single-blinded from the standpoint of the main clinical outcomes. Although it was not possible to blind patients to their treatment assignment, personnel weighing the patients were blinded to the treatment assignments.

Treatment was determined by design-adaptive allocation,^{15,16} with balance obtained for gender, age, race, weight at enrollment, and first-stage weight loss. The Consolidated Standards of Reporting Trials (CONSORT) statement¹⁷ has asserted that such a balancing scheme is equivalent to randomization. The allocation was done by a project manager who was blinded to participant identity, and the project staff arranging the subsequent visits were completely blinded to the allocation process.

Statistical methods

The primary descriptive analyses presented means and standard deviations of weights at the start and end of each

study period (enrollment to randomization, randomization to 12-week follow-up, and randomization to 24-week follow-up). This display was necessary for clarity, because the number of analyzable participants over each segment differed. The inferential analysis employed the conditional-change model (analysis of covariance),¹⁸ in which change in weight during one of the above periods is regressed on weight at the start of the period, on indicators of the TAT and QI treatment groups, and on the balancing factors. We investigated whether the TAT or QI treatments modulated the effects of other factors on weight change in a secondary, exploratory analysis. The statistical model was

$$dw = \beta_0 + \beta_1 w_0 + \beta_T TAT + \beta_Q QI + \beta_X X + \beta_{XT} X * TAT + \beta_{XQ} X * QI + e$$

where dw is weight change, w_0 is weight at the start of the period, X is the predictive factor in question, and TAT and QI are indicators of the CAM treatment groups. Thus, β_{XT} and β_{XQ} measure change in the slope of X in predicting dw , relative to the slope in the controls, which is β_X .

Because this was a Phase I study, statistical significance of treatment effects may be less important than a determination of whether there is a sufficient indication to carry out further research on the treatment. For this analysis, we used separation tests.¹⁹ This amounts to computing a value $\Delta = 1.645 * SDE$ (where SDE is the standard deviation of the treatment effect), and then declaring an indication for (or against) further research if the estimated effect lies above $+\Delta/2$ or below $-\Delta/2$, with no indication if it lies between them. This is a test of the hypothesis of an effect of $-\Delta/2$ versus $+\Delta/2$ with both statistical errors set at the 0.05 level.

Qualitative methods

In-depth, semistructured, face-to-face interviews were conducted with a subsample of participants in the study. Interviews were conducted at the end of the weight loss maintenance interventions. The goal of the interviews was to explore broadly participants' experiences in the two CAM weight-maintenance protocols.

Participants were consented for the in-depth interviews when they consented to the original study. Upon completion of the maintenance interventions, a list of participants who had completed either the TAT or QI sessions was produced. Participants were contacted from this list for an in-depth interview with the goal of obtaining a total of 10–12 interviews. We preferentially interviewed those with the highest attendance rates to gain insight as to what enabled their compliance. Based on the literature and the authors' prior experience designing and conducting in-depth interviews,^{20–22} we estimated that conducting approximately 10–12 in-depth interviews with study participants would generate an adequate quantity of data for comparing and contrasting participants' experiences with the QI and TAT protocols.

The interviews were held either at the Center for Health Research or at a location identified as convenient by the participant. Interviews lasted about 1 hour and were conducted by a trained qualitative interviewer. Every interview used a similar interview guide. Questions were intended to elicit discussion about individuals' overall experiences with either the TAT or QI class, including their sense of the interventions' utility and the barriers and facilitators to learning and practicing the techniques.

Interviews were audiotaped and professionally transcribed for analysis. The analysis of the interviews was guided by the overall analytical approach of representing, describing, and interpreting, and was conducted by a trained qualitative researcher. Content analysis was guided by a specific set of data reduction and reconstitution techniques.^{23–28} The interview transcripts were coded to identify responses to specific questions and to capture emergent themes. A coding dictionary was developed to aid in this process, with some codes denoting questions posed to interview participants during the discussion (e.g., barriers to learning technique), whereas others represented issues raised by the participants that emerged during the discussions. ATLAS.TI 5.0 (Scientific Software Development, Berlin, Germany, 1997) was used to electronically code and manage the data and generate reports for analysis.

RESULTS

Recruitment, adherence, and participant flow

From May through September 2004, 223 participants were recruited to the study in two approximately equal size cohorts. Figure 2 summarizes the aggregate recruitment data.

Of the 11 randomized participants who dropped out of treatment, information as to reason for discontinuation was obtained from 9. Three (3) participants either never attended or discontinued attending the weight-loss maintenance sessions primarily because of scheduling conflicts, whereas 6 discontinued because of unclear expectations of the classes or discomfort with some aspect of the class.

Baseline data

Table 1 shows baseline clinical and demographic data for all randomized patients.

Compliance

QI participants attended a mean of 5.8 (standard deviation [SD] 5.8) hours of instruction, TAT participants attended a mean of 7.2 (SD 2.6) hours of instruction, and SDS participants attended a mean of 4.8 (SD 3.1) hours of instruction. Attendance was significantly higher for TAT than for SDS.

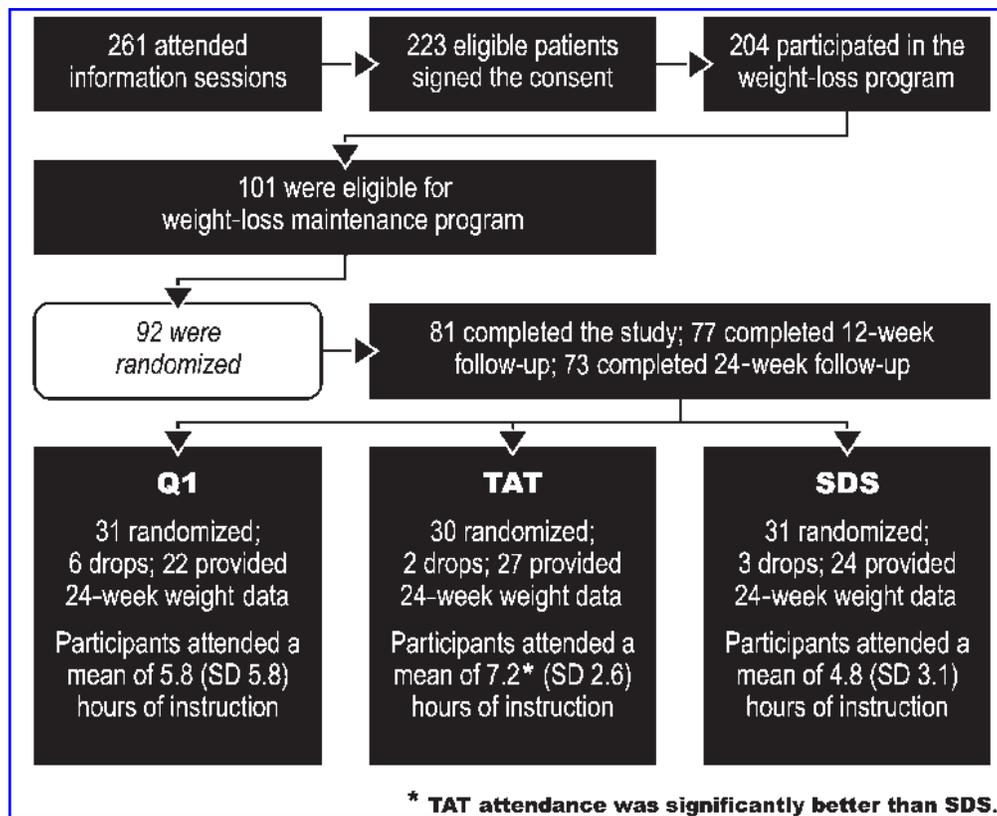


FIG. 2. Participant flow. TAT,[®] Tapas Acupressure Technique[®] (registered trademarks of Tapas Fleming, L.Ac.); SDS, self-directed support; QI, *qigong*; SD, standard deviation.

Participants provided questionnaire data detailing home compliance and practice. In response to the question, “How often did you use TAT,” of 25 respondents at 24 weeks, 6 reported using the technique at least daily, 11 reported using the technique at least weekly, and 8 reported using the technique at least monthly. In response to the question, “How many days per week did you practice *qigong* at least once,” of 17 respondents at 24 weeks, 4 reported practicing 3–4 days per week, 4 reported practicing 1–2 days per week, and 9 reported practicing less than 1 day per week. For TAT, 10/25 responded that they were somewhat or very likely to continue using TAT, compared to 3/17 for QI. Thirteen TAT respondents thought the number of group sessions was “just right,” whereas 12 recommended an increase in the number of TAT sessions. For QI, 3 thought the number of sessions was “just right,” whereas 14 recommended an increase in the number of QI sessions.

Quantitative analysis

Primary analysis. Table 2 shows the unadjusted results for all treatment groups and all study periods. The groups were well matched for loss over the weight-loss stage of the study, which was guaranteed by the design-adaptive alloca-

tion. The TAT group was nearly stable throughout the 24 weeks, whereas the SDS group showed a usual weight gain pattern, and the QI group showed a significant weight gain.

The adjusted results are shown in Table 3. TAT had a small advantage over SDS at 12 weeks, which could be attributed to chance. At 24 weeks, however, TAT showed a more substantial benefit over control ($p = 0.09$). The QI results are in the wrong direction at both 12 and 24 weeks, and show significant differences from both other groups at both time points.

The purpose of this Phase I study was to seek an indication for further research. To evaluate the indication for further research, a separation test¹⁹ was used of TAT versus control. The TAT–SDS SDE was 0.71, so the resulting $\Delta = 1.645 \times 0.71 = 1.17$ at 24 weeks, and because the observed effect of -1.22 kg difference exceeds $1.17/2 = 0.59$, the indication is for further research on TAT. The separation test at 12 weeks does not give an indication for or against further research on TAT. Because the QI results are in the wrong direction, there is no indication for further research using this protocol.

Secondary analysis. In all cases, we found that the modulatory effects of TAT and QI on the relationship of pre-

TABLE 1. BASELINE CHARACTERISTICS

	<i>SDS</i>	<i>TAT</i>	<i>QI</i>	<i>Total</i>
Gender				
Male	5	3	5	13
Female	26	27	26	79
Age (years, mean and SD)	46.2 (11.3)	47.6 (10.6)	47.5 (10.5)	
Education				
Did not complete high school	1	0	0	1
Completed high school	1	0	0	1
Some college	14	11	13	38
College degree	7	13	6	26
Postgrad. work	7	6	12	25
Unknown	1	0	0	1
Marital status				
Never married	8	5	6	19
Married	18	16	18	52
Widowed	0	1	1	2
Divorced	4	8	4	16
Separated	0	0	1	1
Unknown	1	0	1	2
Annual household income (U.S. dollars, thousands)				
29 or less	4	3	4	11
30–44.9	6	9	9	24
45–59.9	3	7	5	15
60–74.9	8	6	6	20
75–89.9	0	0	1	1
90 or more	9	4	5	18
Unknown	1	1	1	3

SDS, self-directed support; TAT[®], Tapas Acupressure Technique[®] (registered trademarks of Tapas Fleming, L.Ac.); QI, *qigong*; SD, standard deviation.

dictors to weight change was the same, and so we pooled them in Table 4. Although there is some tendency for the CAM treatments to reduce the effects of the predictors, the only rows in Table 4 showing statistical significance are the last two, involving weight loss history (number of previous tries) and historical weight loss (maximum) in lbs. In these

cases, the effect of the CAM treatment was to mostly remove the deleterious effect of the weight history variable. Stated another way, patients reporting a previous history of repetitive unsuccessful weight loss regained more weight in the study only if assigned to the SDS intervention ($p = 0.034$).

TABLE 2. WEIGHT CHANGES OVER THREE STUDY PERIODS: MEANS (KG), SDs, AND SAMPLE SIZES

	<i>SDS</i>			<i>TAT</i>			<i>QI</i>		
	<i>Start</i>	<i>End</i>	<i>Change</i>	<i>Start</i>	<i>End</i>	<i>Change</i>	<i>Start</i>	<i>End</i>	<i>Change</i>
Enroll to randomization									
Mean	85.3	80.3	−5.0	82.5	77.0	−5.5	84.6	79.1	−5.5
SD	14.0	14.2		10.7	10.3		10.3	10.2	
<i>N</i>		31			30			31	
Randomization to 12 weeks									
Mean	81.2	81.5	+0.3	76.6	76.5	−0.1	77.2	78.7	+1.5
SD	14.9	15.3		10.8	11.0		10.0	10.4	
<i>N</i>		26			26			25	
Randomization to 24 weeks									
Mean	81.1	82.3	+1.2	76.5	76.6	+0.1	78.0	80.8	+2.8
SD	14.7	15.3		10.7	10.8		9.7	10.2	
<i>N</i>		24			27			22	

SDs, standard deviations; SDS, self-directed support; TAT[®], Tapas Acupressure Technique[®] (registered trademarks of Tapas Fleming, L.Ac.); QI, *qigong*.

TABLE 3. TREATMENT GROUP COMPARISONS OF WEIGHT CHANGE (KG) DURING WEIGHT MAINTENANCE STAGE^a

Effect	TAT-SDS		QI-SDS			TAT-QI		
	SDE	p	Effect	SDE	p	Effect	SDE	p
Randomization to 12 weeks -0.36	0.51	0.479	1.03	0.51	0.047	-1.39	0.50	0.006
Randomization to 24 weeks -1.22	0.71	0.089	1.58	0.74	0.034	-2.79	0.71	0.000

^aAdjusted for enrollment weight; weight change over weight-loss stage, age, and gender.

TAT[®], Tapas Acupressure Technique[®] (registered trademarks of Tapas Fleming, L.Ac.); SDS, self-directed support; QI, *qigong*; SDE, standard deviation of effect; *p*, two-sided *p*-value.

Qualitative analysis

A total of 12 completed and transcribed interviews were conducted. Of these, 6 represented participants (5 female and 1 male) assigned to TAT arm, and 6 represented participants (5 female and 1 male) assigned to the QI arm. The following describes participants' three key domains of experience reflected upon in the interviews: effect of the intervention on weight maintenance; effect of the intervention on their general health and wellness; and facilitators and barriers to learning/practicing the techniques.

Effect on weight-related behaviors. TAT: For the TAT arm, 5 of the 6 participants commented on how the technique impacted their weight maintenance or weight loss efforts. Participants reported almost immediate help in curbing cravings, controlling overeating, and sticking to a "good eating plan" directly after the use of TAT for these purposes:

I did it for eating and cravings. In particular, I have this brownie habit. At the afternoon break at work at

3 o'clock, the cafeteria has this chocolate brownie that calls to me every single day! So we worked at one of the classes on this brownie craving and it went away. I mean 3 o'clock came and went and I didn't think about it!

Three (3) participants also used TAT for improving their sleep and relaxation as a means to help with their weight maintenance. These participants felt that using TAT for improving sleep and increasing relaxation would assist them in their efforts to eat well and continue to maintain or lose weight:

I knew before I started this study that when I'm stressed, I eat. Because of that I have to have things in place to help relieve that stress. This technique helps with relieving stress, and therefore I don't reach for food quite so often. So it's had a big impact.

QI: Most of the participants interviewed in the QI arm reported either maintaining their weight during the class or

TABLE 4. IMPACT OF CAM INTERVENTIONS ON MODULATION OF WEIGHT CHANGE (KG) BY BASELINE FACTORS

	12 Weeks post randomization			24 Weeks post randomization		
	TAT & QI	SDS	p	TAT & QI	SDS	p
Age	0.002	0.014	0.771	0.024	0.020	0.959
BMI	-0.630	-1.00	0.385	-0.924	-0.873	0.935
Male	1.385	0.427	0.497	2.629	0.542	0.370
Original weight loss	-0.046	0.278	0.447	-0.015	-0.015	0.997
Baseline weight	0.015	0.022	0.872	0.017	0.033	0.796
Absorption	0.040	-0.094	0.083	0.063	-0.043	0.370
Social support	-0.024	-0.054	0.651	-0.042	-0.115	0.525
Depression	-0.010	0.106	0.592	-0.112	0.283	0.203
Expectancy	0.097	1.359	0.518	0.777	2.582	0.537
Weight loss hx (freq)	0.150	1.119	0.048	0.262	1.279	0.185
Weight loss hx (lb)	-0.075	0.711	0.0006	0.023	0.767	0.034

Entries are modulatory effects of the group indicated by the column (the effect of a one-unit change in the variable on the left on weight change over the period, within the column group). *p*, *p*-value for testing difference between the groups; CAM, complementary and alternative medicine; TAT[®], Tapas Acupressure Technique[®] (registered trademarks of Tapas Fleming, L.Ac.); SDS, self-directed support; QI, *qigong*; BMI, body mass index; hx, history.

gaining slightly. Additionally, one participant reported losing weight during the QI class, which the participant directly attributed to QI. Although the participant considered the effect of QI on her weight loss a “bit of a mystery,” the participant recognized a distinct pattern of frequent urination after each class session or personal practice:

I actually did better with my weight loss when I added in the *qigong*—I lost an additional 10 pounds. . . . I don’t know how it works or why it works but it seemed to have a diuretic effect. I noticed that on a regular basis over and over again. . . . And I do think the movement is a good energy burner and the meditation definitely helps focus your thoughts away from snacking and eating.

Although participants’ experiences varied as to whether they found the specific QI techniques for weight loss or hunger management helpful, they all seemed to *philosophically* believe that the practice of *qigong* could help them with their overall health, and thus their weight-loss maintenance efforts:

I think it’s got potential. If somebody wants to step out of the ordinary and take responsibility for their own health a little bit, I think it’s got strong possibilities.

Effect on overall health and well-being. TAT: In addition to the positive impact of TAT on eating behaviors, the five participants who actively used TAT reported using it specifically and successfully for stress reduction and relaxation:

It’s almost an immediate effect and getting into the pose makes a difference. With my disease I know my lungs pretty well, so breathing is not effortless. . . . I could tell it just as soon as I got into the position. My [breathing] slowed and got deeper.

Other participants had success applying the technique in the following specific ways: to decrease hot flashes at night (2 participants); to lessen an allergic reaction (2 participants); and to decrease heartburn symptoms (1 participant). For these conditions, participants reported fairly immediate positive effects.

I applied it to a time when I got into poison oak and it’s actually quite toxic to me when I get it. I get it quite easily. So I immediately did TAT so that my body wouldn’t absorb the oils of the poison oak, and then cleansed, and then did TAT again and never broke out. I swear that mental state on whether or not the body is going to absorb the oils worked. That was a very good success story that I was real happy with.

QI: Although participants’ experiences varied as to the impact of the QI on weight-loss maintenance, participants had more to say about how they perceived *qigong* positively benefiting their overall health and well-being. All of the participants interviewed reported feeling energized after the class or personal practice sessions. This was often the first thing participants would describe when asked about how the QI impacted them:

You feel invigorated. . . . You can feel the effect of the *qi* building up in your body. I don’t sense much in my abdomen, in general, but I do sense a lot around my hands, around my head and around my face. There were times when I felt this overwhelming energy around my forehead. . . . and it would actually like lift you and you would be a little bit brighter going into whatever you are doing for your day. You would kind of expect things to go a little easier for you.

Participants also described feeling an increased level of calmness, peace, and relaxation after the classes or personal practice sessions. They would describe a shift in their outlook that included an increased ability to cope with stress, an elevated mood, and a sense of being more positive and easygoing about life. Descriptive words that repeatedly came up when participants were describing the health benefits of the class included “more energy,” “positive,” “peaceful,” “relaxed,” and “less stress.”

Positive thinking and self-affirmation and all of that positive energy. That’s what it amounted to. . . . I don’t know about weight loss or weight maintenance, but I did find a more positive outlook and peace. It would take the stress right out of you. I know that stress causes a lot of health problems. From that standpoint alone it’s beneficial.

Facilitators and barriers to learning or using the technique. TAT: Participants described two primary facilitators that increased the chances of success. One facilitator to success was applying TAT to very specific, focused issues, such as specific food cravings (i.e., brownie) or concrete health issues (i.e., hot flashes or allergic reactions). Another facilitator was being fully present, focused, and mentally committed to the process when applying the technique:

I believe that you need to be totally committed and in a full mental state even if it’s only 30 seconds long or 4 seconds long, whatever you take for that moment. I think your body is very powerful and able to overcome many, many things.

Most participants found the technique easy to use and practice outside of the class sessions. Participants thought the number of classes for learning the technique was ap-

appropriate. Overall, participants felt that TAT was easy to learn, very portable and flexible, and, most importantly, that you could experience almost immediate positive benefit:

I couldn't believe how easy it was. It's a very easy technique to use. The difficulty is remembering to use it when you need it! Surprisingly, it works.

For the most part, participants shared only very mild barriers to learning and using TAT. Barriers to success included experiencing life stressors such as new jobs or the holidays; being too broad in their focus or application of the technique; or being too mentally distracted when applying the technique.

QI: Participants interviewed from the QI identified three areas that facilitated their understanding, learning, and practice of *qigong*. A primary facilitator for these participants was the instructor. Participants found the instructor to be highly authentic, skilled, and knowledgeable. Participants commented on how the instructor was obviously a "master" of *qigong* because he embodied health, vitality, and energy from the participants' perspective:

What continued to keep me interested is the instructor was absolutely awesome. You could tell he was consumed with the fact that this was such a wonderful healing exercise for the body. His commitment kind of walked me through this awkward new place that *qigong* was for me. Every time I went I continued to be impressed with it.

Participants described two other facilitators to learning and practicing the technique. Participants felt that learning this technique in a group setting was beneficial, and that the experiential nature of the class facilitated understanding and learning of the technique:

I liked the feeling of all of the energy. I liked actually being able to feel what he was explaining to us. . . . I liked that fact that he was teaching *qigong* and he was explaining things to us. I liked the fact that I could actually get a sense or taste of what he was teaching us as opposed to it being more ambiguous. . . . I actually got to *experience* what he was talking about.

Participants in the QI tended to have more to say about the barriers to understanding, learning, and practicing *qigong* than about the facilitators. Participants' described experiencing barriers in three main areas: understanding the concept/philosophy behind *qigong*; learning the movements; and practicing outside of class sessions.

Several participants noted that one of the main barriers to understanding the concept and philosophy of *qigong* was overcoming the "Westerner hurdle" or "mindset" that was

quite different from the instructor's Eastern/Oriental culture and belief system:

A lot of his explanation is very general Oriental kind of belief that the *qi* energy is universal. The *yin* and the *yang* pull together. In a Western culture, that just was sort of "plop" to me and I needed a little more. I would be fascinated to learn more of a "nuts and bolts" approach to why it works.

In addition to wanting a more basic Western-style introduction and explanation of *qigong*, participants also found learning the movements of the technique to be challenging. Participants described learning *qigong* as a "complicated process" that initially looked simple or obvious but was deceptively hard once they started applying the movements. In part this was because of learning something so "foreign" and "new." As an example, the movement of "shaking" was repeatedly brought up by participants as something that looked easy, but was actually experienced as difficult and uncomfortable:

I think this exercise, which is basically just shaking, there was no instruction of how you were supposed to shake, I could feel in myself and see it in other people that people were unsure how to shake. It wasn't just the first week but even later on I sensed some discomfort about that.

Additionally, participants also felt that the overall goal of the class might have been "unrealistic." They felt that too much was being taught in a limited timeframe. Participants repeatedly mention that there were not enough classes to help them feel like they truly "ingrained" or "solidified" the movements.

Participants identified several challenges to *qigong* practice at home: space, time, and privacy. Participants felt that the movements required space to do them in, so finding an appropriate place at work, home, or while traveling was difficult. Participants also felt that completing a *qigong* session takes time—around one half hour—that participants described as difficult to accommodate into their busy schedules. For some participants, the time to complete the *qigong* practice at home interfered with their available time to engage in other Western-style exercises. Participants also spoke frequently again of the "oddness" of the movements, such as shaking, and how they felt that *qigong* is not sufficiently known or "socially acceptable" for them to feel comfortable practicing it in a public setting such as a park or at work:

The barrier that I saw was that you sort of need a place to do it. You need to make a commitment of a place and time. You know, where walking is socially ac-

cepted—you can do it anywhere and anytime. But this I felt you had to make arrangements to do it.

Summary. A synopsis of the qualitative data is provided in Table 5.

Adverse events. No significant study-related adverse events were reported.

DISCUSSION

Our results suggest that TAT warrants further research as a potential intervention for weight-loss maintenance. TAT participants demonstrated superior adherence and compliance, with qualitative data suggesting that patients found the technique easy to learn, easy to apply, and helpful for managing food cravings and stress. Additionally, TAT was relatively inexpensive to administer (costing approximately \$150/participant), and quantitative data showed that TAT potentially may be effective for achieving weight-loss maintenance, compared to controls.

TAT participants maintained on average 5.4 kg of their original 5.5-kg weight loss at 24 weeks. Pooled data² from previous studies show that among participants receiving long-term behavioral weight-loss maintenance treatments, averaging 41 sessions during 54 weeks, patients maintained on average 10.3 kg of their initial 10.7-kg weight loss. Despite the relatively low intensity of the intervention, the weight-loss maintenance data for TAT appear competitive. In addition, patients in previous trials have generally maintained their weight loss only as long as they continued attending maintenance sessions, whereas the TAT group maintained weight loss at week 24 despite ces-

sation of the intervention at week 12. Interventions in previous trials have also suffered from the perceived difficulty that they may be monotonous or boring, whereas patient interview data for TAT showed that participants found the technique engaging and useful. Our secondary analysis suggested that patients reporting a previous history of repetitive unsuccessful weight loss regained more weight in this study only if they were assigned to the control intervention ($p = 0.034$). Thus, the mind–body approach may provide participants with a compelling tool that can be successfully applied after instruction has ended.

Weight-loss data for the QI was significantly worse than those of both other groups at 12 and 24 weeks. Qualitative data suggested that although patients found the technique promising, particularly in terms of effects on overall well-being, there were many barriers to successful implementation. It appears likely that the QI offered in this study was structurally insufficient. We attempted a QI of only 10 hours in order to match contact hours among groups, thus dramatically limiting the QI to fit the methodological requirements of the study design. In this case, the experimental constraint may have proven highly detrimental to the clinical intervention. Interview data suggested that future studies of *qigong* should be carried out with consideration to the following protocol modifications:

- Offer more classes, over a longer timeframe
- Teach a minimum set of movements initially as a basic instruction
- Provide during the first meeting a “Western nuts and bolts” explanation of *qigong*
- Create opportunities for participants to practice together outside of class

TABLE 5. SYNOPSIS OF PATIENT INTERVIEW DATA

	<i>QI</i>	<i>TAT</i>
Effect on weight	Theoretically could help with weight control, but the instruction sequence offered to study participants was too brief and lacked clear explanations of the concept and related movements.	Helpful tool for curbing food cravings and controlling overeating. Also perceived to be a helpful stress management technique in relation to eating and exercising behaviors.
Other effects	Participants felt more energetic, calm, and relaxed immediately after the class sessions and also experienced an increased sense of peacefulness and optimism after practicing the technique.	Used effectively by some participants for other medical conditions, including hot flashes, allergies, and esophageal reflux. Helpful for improving sleep, restfulness, and relaxation.
Compliance	Perceived as somewhat foreign and complex. Not enough classes were offered to adequately teach the technique. Home practice difficult because it potentially requires space, privacy, and time.	Portable, practical, and relatively easy to learn and use. Ongoing practice of TAT facilitated by the fact the technique can be applied quickly (less than 15 minutes).

SDs, standard deviations; SDS, self-directed support; TAT,[®] Tapas Acupressure Technique[®] (registered trademarks of Tapas Fleming, L.Ac.); QI, *qigong*.

CONCLUSIONS

The study was designed as an early-phase pilot to assess whether either of two mind–body interventions to assist in weight-loss maintenance should move forward into Phase II trials. The results for *qigong* did not support further research on our intervention protocol, but the qualitative results provide guidance for future revised approaches. In contrast, results for TAT at 24 weeks indicate superior weight-loss maintenance (1.2-kg greater weight loss maintenance than control, and virtually no weight regain on average.) This result is strong for an early-phase trial, designed to evaluate feasibility, acceptability, and effect size. The results here support further research on this intervention; planning for a larger study is under way.

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