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Virtual Tai Chi program for patients with irritable bowel syndrome with constipation: proof-of-concept feasibility trial

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Abstract

Background: Satisfaction with current treatment options for irritable bowel syndrome with constipation (IBS-C) is low, with many patients turning to complementary treatments. Tai Chi is a mind-body medicine practice with proven efficacy in other functional disorders. As a proof-of-concept, we tested the feasibility and preliminary clinical outcomes associated with a Tai Chi program designed for IBS-C.

Methods: A total of 27 IBS-C patients participated in a single-arm trial of 8 sessions of Tai Chi delivered weekly over 7 weeks via live videoconferencing in group format. Clinical improvement was assessed via change in IBS Symptom Severity Score (IBS-SSS) from baseline to 4 weeks post-treatment (week 11) with secondary outcomes exploring symptom ratings, IBS-related quality of life (IBS-QOL), GI-specific anxiety, abdominal distention, and psychological factors.

Key Results: Despite substantial dropout (n=7; 26%), the treatment protocol had moderate to excellent feasibility for other criteria. Treatment satisfaction was excellent. Exit interviews confirmed high satisfaction with the program among completers, but a high burden of data collection was noted. One participant experienced an adverse event (mild, exacerbation of sciatica). There was a significant improvement in intra-individual IBS-SSS between baseline and post-treatment (average change −66.5, 95% CI −118.6 to −14.3, P=0.01). Secondary outcomes

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AUTHOR CONTRIBUTIONS KS, RR, and BK planned and designed the study; MP recruited participants and administered the study; IGF collected patient-specific data. MP, HBM, and EM analyzed the data; KS drafted the manuscript; all authors interpreted the results and contributed to critical review of the manuscript; KS had full access to all of the data in the study and takes responsibility for the integrity of the data and accuracy of the data analysis.

were notable for improvements in other IBS symptom scoring measures, IBS-QOL, measured abdominal diameter, and leg strength.

Conclusions and Inferences: Our data provide preliminary evidence of the feasibility of a Tai Chi intervention for IBS-C, show promise for improving outcomes, and identify more streamlined data collection as an area for further program improvement.

INTRODUCTION

Irritable bowel syndrome (IBS) is a chronic and common condition with a global prevalence of more than 11%[1] and significant effects on sufferers' quality of life. Despite the availability of both over-the-counter and prescription options for treatment, satisfaction with current treatment options remains low. In irritable bowel syndrome with constipation (IBS-C), only 25% of individuals surveyed were satisfied with available over-the-counter and prescription agents.[2] With treatment dissatisfaction so prevalent, between 30–50% of patients with chronic gastrointestinal (GI) conditions turn to complementary and alternative medicine (CAM) treatments for their symptoms.[3] In fact, younger women and those with poor treatment satisfaction are independent predictors of CAM use, such that there is a striking overlap with the demographics of the IBS population, who may see these treatments as safer and more natural than pharmacotherapeutic options.[4]

Tai Chi is an ancient mind-body medicine practice originating in China that integrates physical elements with psychosocial, spiritual, and behavioral components.[5] Meditation is combined with deep breathing and slow, graceful movements to move vital energy (*qi*) throughout the body. Tai Chi has demonstrated benefit in randomized trials for fibromyalgia,[6–8] a condition with a similar demographic and pathophysiologic overlap with IBS.[9] In both cases, chronic pain with central sensitization and psychosocial factors play an important role in disease presentation and quality of life and are hypothesized mechanistic targets in Tai Chi.[8] Moreover, Tai Chi appears to improve overall psychological well-being, specifically reducing stress, general anxiety, and depression—all modulating factors in IBS.[10]

Tai Chi may also be particularly acceptable to patients with IBS, a population seeking out alternative treatments for their symptoms. Because exercise already has an established place in the IBS treatment paradigm,[11,12] the integrative use of exercise and meditation techniques used in Tai Chi may be viewed as particularly credible to both providers and patients with IBS. In addition, patients seeking CAM alternatives for IBS symptoms seem to be most bothered by abdominal pain and bloating,[4] symptoms where some IBS therapies may be less satisfactory. Given that patients with IBS-C have disproportionate abdominal pain, bloating, and life interference than those with IBS with diarrhea (IBS-D),[13] patients with IBS-C may be a prime candidate population for Tai Chi with its integration of both mind (psychological) and body (physical).

We developed a novel Tai Chi program designed to meet the specific needs of patients suffering from IBS-C and tested its feasibility and preliminary outcomes using a nonrandomized, open proof-of-concept design. Our Tai Chi Program differed from traditional Tai Chi programs by its focus on the internal organs, with self-massage

specifically focused on the abdominal muscles and viscera. Additionally, the IBS-C Tai Chi program adapted 10 movements from both the Yang and Chen Tai Chi styles that combined rotations to target massage to the digestive tract. We analyzed the study with the ORBIT model for behavioral interventions in chronic disease[14] in mind—specifically determining feasibility of the intervention in preparation for an efficacy trial. The primary objectives were to evaluate feasibility and engagement in this novel mind-body treatment and evaluate post-treatment changes in IBS symptom severity. We also explored factors that may contribute to therapeutic benefit as well as underlying mechanisms of change. We hypothesized that virtual Tai Chi sessions would be an acceptable and feasible means of treating IBS-C with associated markers of symptom improvement. We hoped this study would set the stage for a future fully powered RCT to test the efficacy of our intervention.

METHODS

Participants

We conducted the trial from 7/20/2020 to 4/27/2021 at Massachusetts General Hospital (MGH), a tertiary care center in Boston. Inclusion criteria included: 1) aged 18–70 years, 2) Rome IV criteria for IBS-C, 3) continued IBS-C throughout a 2-week run-in period, and 4) willingness to complete the program and study assessments. Exclusion criteria included: 1) inability to stand without assistance for 20 minutes, 2) current opioid use, 3) BMI > 35 kg/m^2, 4) severe osteoarthritis, 5) severe abdominal pain (measured as a “4” on a 0–4 visual analog scale (VAS)) at screening, 6) severe constipation (defined as <1 bowel movement/week without laxatives), and 7) concurrent inflammatory bowel disease or celiac disease diagnosis. We recruited participants through referrals from the GI clinic at MGH, through a hospital-based study recruitment website, and using a Facebook advertisement. A trained research coordinator (MP) conducted phone screens followed by a virtual appointment with one of the investigators (KS or BK) for confirmation of Rome IV IBS-C diagnosis, virtual exam using videoconferencing technology, and adherence to inclusion and exclusion criteria.

Procedures

This study was a single-site, open-label intervention study evaluating the effects of Tai Chi among patients with IBS-C according to the Rome IV criteria.[15] The study was approved by the Institutional Review Board of MGH (IRB#2019P000361) and registered with ClinicalTrials.gov (NCT04132804). All participants signed informed consent. Participants were allowed to continue all medications, including laxatives, prokinetics, and antidepressants/neuromodulators as long as the doses were stable in the preceding three months. Similarly, participants were asked to avoid any major lifestyle changes including starting a new diet or changing their exercise pattern. The study consisted of three periods: run-in, treatment, and post-treatment follow up. After phone screening, patients met virtually with investigators for further confirmation of eligibility and consent. Eligible participants enrolled in a two-week run-in period during which they needed to continue to meet Rome IV criteria for IBS-C and complete 80% of daily symptom diaries. Participants completed a daily stool diary to ensure they met criteria for IBS-C, a daily GeoPain diary (a mobile phone application that allows participants to enter the precise location and severity of their pain, along with alleviating and exacerbating factors) as well as

complete a daily VAS pain scale (see “Assessments” below). The study schema is presented in Supplementary Figure 1. Surveys were completed online using REDCap, a secure web platform for building and managing online databases and surveys.

Tai Chi Intervention—Participants meeting final eligibility criteria during the two-week run-in period started eight weekly, one-hour group-based Tai Chi lessons. Lessons were led by a Tai Chi master (RR) with specific experience with delivering other group-based protocols for other health conditions.[6,8] Lessons occurred on Days 0, 7, 14, 21, 28, 35, 42, and 49. As this study ran during the COVID-19 pandemic, lessons were administered virtually using a secure Zoom platform (Zoom Video Communications, Inc., San Jose, CA), a collaborative, cloud-based videoconferencing service offering online meetings. Virtual lessons were also thought to improve the scalability and practicality for future, larger treatment trials.

Classes were limited to 10 participants per session, and participants were asked to keep their cameras on so that the instructor could monitor their form and ensure adherence to the protocol. Lessons were conducted in three groups with Group 1 containing 10 enrolled participants and running from 08/18/2020 to 09/30/2020, Group 2 containing 14 enrolled participants and running from 10/27/2020 to 12/08/2020, and Group 3 containing 7 enrolled participants from 02/09/2021 to 03/30/2021. Participants earned $150 for completion of the study in its entirety (if they completed 7/8 Tai Chi classes and 80% of the diaries).

In the first session, the instructor explained the theory behind Tai Chi and its procedures and provided participants with emailed materials on its principles and techniques. In subsequent sessions, participants practiced 10 forms from the classic Yang style of Tai Chi with self-massage, meditation, and visualization tailored to IBS-C under his instruction (see Appendix for Tai Chi protocol). Each session included a warm-up and self-massage to the abdominal area with a focus on the digestive tract, followed by a review of principles, movements, breathing techniques, and relaxation in Tai Chi. The Tai Chi protocol was partially adapted from those used in previous fibromyalgia studies[6,8] with significant modification to suit IBS-C patients. In order to target abdominal symptoms, participants were instructed on various meditations and visualizations with a strong focus on relaxing the abdominal and lower back area as well as the internal organs (i.e. participants were instructed in deep breathing with gentle movements of the abdominal wall and back muscles while visualizing a healing energy ball two inches below the navel). Throughout the intervention period, participants were instructed to practice Tai Chi at home for at least 20 minutes each day and keep track of practice in their daily diaries. At the end of the 8-week intervention, participants were encouraged to maintain their Tai Chi practice, using printed and digital resources.

Measures

Feasibility Measures—Feasibility measures were determined to be consistent with the guidelines for intervention development.[14] We assessed the following measures:

1. *Feasibility of recruitment*: This was assessed as the proportion of potential participants successfully contacted who agreed to participate. We considered a proportion ≥70% good and ≥80% excellent.

2. *Program acceptability*: This was assessed as the proportion of participants who started treatment who attended at least 7 out of the 8 Tai Chi sessions. We considered a proportion ≥70% good and ≥80% excellent.

3. *Feasibility of quantitative measures*: This was assessed as the proportion of participants who started treatment who completed at least 80% of their daily diary entries. We considered a proportion ≥70% good and ≥80% excellent.

4. *Adherence to home practice*: This was assessed as the proportion of participants who started treatment who practiced Tai Chi at home at least 80% of days during the treatment period. We considered a proportion ≥70% good and ≥80% excellent.

5. *Program satisfaction*: This was assessed as the proportion of participants who completed follow-up who rated their treatment satisfaction (“How satisfied were you with your treatment?”, 5-point (1–5) scale upper anchor “very satisfied” and lower anchor “very dissatisfied”) and likelihood of continuing treatment satisfaction (“How much do you agree with the following statement: I will continue practicing Tai Chi after the end of the trial?”, 5-point (1–5) scale upper anchor “strongly agree” and lower anchor “strongly disagree”). We considered a proportion ≥70% rating 4s/5s good and ≥80% excellent.

6. *Instructor assessment of Tai Chi mastery*: This was assessed as the proportion of participants who completed all sessions who were rated by the instructor (“Did the student master the Tai Chi?”, 6-point (0–5) scale upper anchor “most mastered”). We considered a proportion ≥70% rating 4s/5s good and ≥80% excellent.

7. *Instructor assessment of participant enthusiasm*: This was assessed as the proportion of participants who completed all sessions who were rated by the instructor (“How enthusiastic or motivated was the student?”, 6-point (0–5) scale upper anchor “very enthusiastic/motivated”). We considered a proportion ≥70% rating 4s/5s good and ≥80% excellent.

8. *Program safety*: This was assessed as the proportion of participants who started treatment who self-reported no treatment-related adverse events. Participants were instructed to contact study personnel if they experienced worsening symptoms, including 5 consecutive days without a bowel movement specifically. Outside of bowel movement frequency, specific adverse events were not elicited unless reported by subjects. Safety was considered excellent if there were no treatment-related adverse events and good if there were minimal to mild adverse events linked to program participation, which occurred in no more than 10% of participants.

Quantitative Measures—The primary quantitative outcome was change in the IBS Symptom Severity Scale (IBS-SSS)[16] from pre-treatment (before the first treatment session) to follow-up (4 weeks after the last treatment session). The IBS-SSS contains five questions: the severity of abdominal pain, the frequency of abdominal pain, the severity of abdominal distention, dissatisfaction with bowel habits, and interference with quality of life. Questions addressing severity of pain and distention, dissatisfaction, and interference are each collected using a visual analog scale (VAS) with four or five anchors. Frequency of abdominal pain is collected as the number of days over the previous 10 that the individual experienced abdominal pain. Each of the five questions is scored from 0 to 100 and summed for a total score from 0–500, with higher scores indicative of worsening symptom severity. A score decrease of ≥50 has been shown to indicate clinically-significant improvement in clinical symptoms.[17]

Secondary outcomes included the Gastrointestinal Symptom Rating Scale—IBS version

(GSRS-IBS), an IBS symptom severity scale with 5 symptom clusters scored from 1–7 with 7 representing more severe discomfort;[18] IBS Quality of Life Scale (IBS-QoL), range from 0–100 with higher scores indicating poorer quality of life;[19] Visceral Sensitivity Index (VSI), range from 0–75 with higher scores indicating more severe GI-specific anxiety;[20] irritable bowel syndrome-behavioral responses questionnaire (IBS-BRQ), range from 26–182 with higher scores indicating greater IBS avoidance and control behaviors (e.g. avoidance of or hypervigilance around social eating);[21] Fear of Food Questionnaire, range from 0 to 90, with higher scores indicating greater food fears;[22] and the Hospital Anxiety and Depression Scale (HADS), with anxiety and depression subscales that range from 0–21, and subscale scores ≥8 suggestive of anxiety or depression.[23] All scales were collected at screening, pre-treatment, at session 4, immediately after completing the last Tai Chi session, and at 4 weeks post-treatment.

Participants also completed daily VAS scales evaluating abdominal pain (4-point scale), abdominal discomfort, bloating, and constipation severity (10-point scale for abdominal bloating, discomfort, and constipation severity; higher scores indicating more severe symptoms).

Because of the predominance of abdominal distention as a primary complaint in the IBS-C population, we measured anthropomorphic measures at the first, middle, and last session as well as 4 weeks post-treatment including weight (with calculation of body mass index (BMI)) and abdominal circumference. Abdominal circumference, self-reported by participants due to the virtual nature of the study, was measured at the point just below the belly button (using a flexible tape measure mailed to each participant on enrollment) at 3:00 PM each day. Leg strength was assessed throughout the study as in previous interventions[24] as an alternative surrogate for Tai Chi mastery in that leg strength represents confidence, security, and self-esteem, as a means of “awakening healing from within.” Leg strength was assessed by patient report by having participants sit up against a wall, knees bent at a 110-degree angle with no support for as long as possible to measure progression over the course of the treatment.

Participants recorded both complete spontaneous bowel movements (CSBMs) and spontaneous bowel movements (SBMs) in daily diaries throughout the run-in, study period, and 4-week follow up period. Data from the GeoPain diary will be analyzed and reported in a separate publication due to the novel nature of this instrument.

We conducted semi-structured exit interviews by phone after the final post-treatment visit or at study withdrawal for all participants whom we were able to contact. Interviews were audio-recorded while responses were simultaneously entered into an online, secure database. Key themes were later extracted from interview findings using a form of rapid analysis.

Statistical Analysis

Baseline patient characteristics were summarized using descriptive statistics. Feasibility markers were evaluated based on the proportion of participants who achieved each benchmark, as detailed earlier in the Feasibility Measures. The primary quantitative endpoint, IBS-SSS, was analyzed in a mixed model repeated measures analysis with unstructured within-person covariance among the repeated assessments. Adjusted means for IBS-SSS at each study timepoint change in IBS-SSS from pre-treatment (baseline, 1st class) to post-treatment follow-up (11 weeks, 4 weeks after study completion) were estimated by linear contrasts. A group-level random effect was considered, but zero variance was estimated. The mixed model accounted for missing data when participants withdraw. Similar analyses were used for our secondary outcome measures.

RESULTS

Participant Characteristics

A total of 130 patients were referred and completed a phone screen for eligibility with 38 patients agreeing to undergo screening and 31 IBS-C patients completing the virtual screening visit and run-in (Figure 1). Patient characteristics are summarized in Table 1. The sample was predominantly middle-aged (mean age 41 years), female (25/27, 93%), and white (22/27, 82%), with higher levels of comorbid general anxiety (78% scored above the cutoff for anxiety). Six participants (22%) reported chronic musculoskeletal conditions (e.g., chronic back pain, arthritis, or fibromyalgia). The majority of participants (23/27, 85%) had used laxatives to treat their IBS-C symptoms, but 17/27 (63%) had never seen a provider for their symptoms. Recruitment was relatively evenly distributed across clinical (GI clinic) and non-clinical sources (advertising). At baseline, patient symptom severity was moderate (IBS-SSS score 236±21.9) and mean IBS-QOL score was 91±6. Participants rated their abdominal pain as a 1.8 on a 0–4 VAS, while bloating was the most severe symptom (over constipation and abdominal discomfort) by VAS (5 on a 0–10 scale).

Feasibility and Acceptability Markers

Four participants withdrew during the run-in period, one due to lack of a bowel movement for eight days not responding to rescue treatment requiring an ED visit and three due to the cumbersome nature of the symptom diaries, questionnaires, electronic recording, and class attendance as the primary reason for withdrawal (see qualitative data below). Seven participants (26%) did not complete the study after initiating treatment. One

subject experienced a treatment-related adverse event, exacerbation of sciatica, that required physical therapy, but the event did not lead the subject to drop out of the study. Sixty-seven percent (18/27) of participants attended ≥7 of 8 classes (moderate program acceptability) and 56% (15/27) completed ≥80% of the daily diaries, while patient adherence to other quantitative measures and home practice was less robust (Table 2). Feasibility of recruitment was excellent, with 31 out of 38 (82%) meeting study criteria agreeing to participate. Satisfaction among participants who completed follow-up was excellent.

Quantitative Outcomes

Data for each quantitative outcome are presented in Table 3.

Primary Outcome: Change in IBS Symptom Severity Score—Participants showed significant improvements from pre-treatment to follow-up (adjusted mean difference of −66.5, 95% CI −118.6 to −14.3, P=0.01)(Figure 2). 41 (11/27) percent of participants exceeded the 50-point improvement considered clinically-significant for the IBS-SSS.[17] Change in IBS-SSS was similar among the subset who completed follow-up.

Secondary Quantitative Outcomes: Other Patient-Reported Outcomes—Participants experienced significant improvements in quality of life (IBS-QOL) and several GSRS-assessed symptoms (constipation, bloating, and satiety). Pre- to post-treatment VAS scales significantly improved for abdominal discomfort and bloating. Changes in constipation and abdominal pain were not significant. There were significant improvements in the Fear of Food Questionnaire and most subscales. Anxiety and depression (by HADS) and GI-specific anxiety (by VSI) did not improve significantly from pre- to post-treatment.

Secondary Quantitative Outcomes: Physical Measurements—Peak abdominal distention significantly decreased by 6.2 cm from pre- to post-treatment, which was accompanied by an increase in measured leg strength. Average weight and BMI dropped over the course of the study, but the magnitude of the decrease was limited.

Secondary Quantitative Outcomes: Bowel Movement Frequency—Participants reported 2.2±3.2 CSBMs at baseline which increased marginally to 2.8±2.9 at week 8, whereas SBMs decreased from 8.5±5.8 at baseline to 8.0±4.3 at week 8. Patients did not complete daily CSBM/SBM diaries after completing the class.

Exit Interviews

Three main themes emerged across semi-structured exit interviews across 14 participants, including 5 who withdrew from the study or during run-in.

Theme 1: perceptions of program benefits—Participants spoke highly of the program skills and how practicing them provided hope for the power of the mind-gut connection. Participants identified abdominal massage, meditation, and breathing as specific beneficial aspects of the intervention. However, one participant felt that the program was not as effective because it attempted to target a mixed audience (with respect to level of physical ability).

Theme 2: online format—Opinion on the use of the video-based format was split. Multiple participants cited the ease of the video-based format, which offered flexibility and greater individual participation. Others cited a desire for in-person treatment to ensure proper positioning and movement and inability to follow along in the video-based format. One participant preferred more interaction with other participants during sessions.

Theme 3: process and barriers—All three participants who withdrew from the study during run-in or during the study itself noted difficulties with the data collection process, which they noted was difficult to keep up with and not user friendly. Similarly, some participants found the data entry too time consuming. One participant felt that the daily diary reporting helped identify symptoms more clearly. Three participants (including one who withdrew from the study) felt that the program required a large amount of memorization, which took away from the meditative aspect of the practice.

DISCUSSION

In this proof-of-concept feasibility study of Tai Chi for the treatment of IBS-C, we demonstrated overall feasibility of a virtually-delivered platform for this mind-body intervention. We also demonstrated improvements in multiple IBS-C patient-reported parameters with significant improvement in symptom severity during the study. The current study adapted a virtual, group-based Tai Chi program for the specific needs of patients with IBS-C.

These findings, combined with previous randomized studies on the effect of Tai Chi in fibromyalgia,[6,8] suggest that using a virtual Tai Chi program for IBS-C may be both feasible and effective for a biopsychosocial illness such as IBS-C. Consistent with the ORBIT feasibility model, however, our preliminary outcome data should be interpreted with caution. Specifically, the trial was neither designed or powered for efficacy and lacked a control arm. Nevertheless, these results demonstrate proof-of-concept and motivate evaluation of the intervention in a larger, future trial. The other issue with relevance to any future trial designs is the significant attrition rate seen in the current study. Although most attrition occurred in the early phases of the trial, all withdrawing participants—regardless of timing—cited the burdensome nature of the data collection as the primary reason for withdrawal. We also collected many exploratory outcomes that participants may have found onerous. Importantly, we would ensure that a follow-up trial decreases the questionnaire burden now that relevant parameters have been established. Moreover, if an in-person option is feasible, it may improve subject retention and satisfaction—though virtual sessions make future, larger treatment trials more scalable and enable delivery of the intervention to locations beyond major urban areas and academic centers.

The rationale for improvement of IBS-C symptoms with this multicomponent Tai Chi intervention is likely multifactorial, though the biologic mechanisms by which the intervention may work are largely theoretical. As a complex, multicomponent intervention, the mechanism of action may reflect effects on intermediate variables that ultimately improve overall health outcomes.[6] IBS is recognized as a true biopsychosocial illness, where visceral hypersensitivity is modulated by a patient's psychosocial milieu. Thus,

by improving psychological wellbeing, coping, and self-efficacy, Tai Chi mind-body may help patients with IBS engage in behaviors that help more effectively manage symptoms.[8] Indeed, Tai Chi has been demonstrated to improve indicators of psychosocial well-being, with specific benefit on anxiety, depression, and stress.[25]

IBS is associated with abnormalities in autonomic nervous system function,[26] with IBS-C specifically characterized by lower parasympathetic tone relative to IBS-D.[27] Tai Chi has been associated with enhanced vagal modulation,[28,29] which may preferentially benefit IBS-C patients. Sleep disturbances are also common in IBS,[30] and Tai Chi has been associated with improvement in sleep quality in randomized, controlled trials.[31] Thus, the benefits of Tai Chi in this population may occur across central and peripheral mechanisms, which is of specific benefit in a disease like IBS with such heterogenous pathophysiology. Interestingly, the benefits seen with Tai Chi occurred despite minimal impact on bowel movement frequency (CSBMs or SBMs), suggesting that symptom perception (particularly with pain and or bloating/distention) may have driven some of the changes over time. Future investigations may benefit from formal measurement of autonomic function and sleep quality.

Our Tai Chi intervention was specifically designed with the abdominal complaints prevalent in IBS-C in mind. Abdominal bloating and distention are some of the most refractory symptoms in IBS-C relative to IBS-D with substantial impacts on quality of life.[32] Over time, participants experienced less bloating which continued over the 4 weeks after the intervention was completed. Importantly, this subjective improvement in bloating was accompanied by an objective decrease in abdominal circumference of 6.1 cm. Bloating and distention may be a potent driver of dietary restriction—both as a legitimate means of symptom avoidance and as disordered eating pathology.[33] In fact, food avoidance and restriction is a marker of IBS disease severity and reduced quality of life[34] that may be a marker of pathologic disordered eating, or avoidant restrictive food intake disorder (ARFID).[35–37] In our study, participants reported decreases in abdominal distention and decreased fear of foods and decreased avoidance and control behaviors related to food and eating, thus offering a unique potential treatment benefit of Tai Chi specifically that merits further investigation.

Despite the novelty of this trial, we acknowledge some limitations. Importantly, we saw a high attrition rate as described above, and the trial was not designed to assess efficacy. While the mixed model analysis avoids some sources of bias in the estimated symptom improvements, the study provides only proof-of-concept. In any trial of an intervention for IBS, the lack of a control arm is a significant limitation because of high placebo response rates in this population.[38] However, the changes in symptom severity remained stable 4 weeks after completing treatment, suggesting an ongoing benefit even after the intervention was complete. We did not elicit subject experience with Tai Chi or related practices during screening, which may have affected our results. Our study sample was also predominantly white, female, and skewed toward middle age. While this reflects the demographics of many IBS sample sets, this group may be more motivated to participate in a mind-body intervention. Interestingly, despite only 35% of individuals having had GI evaluation, symptoms were moderate in severity, suggesting that these types of interventions

may be more acceptable to the large number of IBS patients who do not typically seek care.[39]

In summary, we developed a novel Tai Chi program designed to meet the specific needs of patients suffering from IBS-C via live videoconferencing and tested its feasibility using a nonrandomized, proof-of-concept design. Our results show this novel mind-body intervention is both initially feasible and potentially effective and motivate a larger, randomized efficacy trial. Because IBS is a disease associated with substantial impacts on quality of life in the absence of mortality,[40] focusing on interventions with patient acceptability is key. With the growing interest and acceptability of CAM treatments for chronic disease, further work is needed to create an evidence base for these therapies.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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DISCLOSURES

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DATA AVAILABILITY

The data that support the findings of this study are available from the corresponding author, KS, upon reasonable request.

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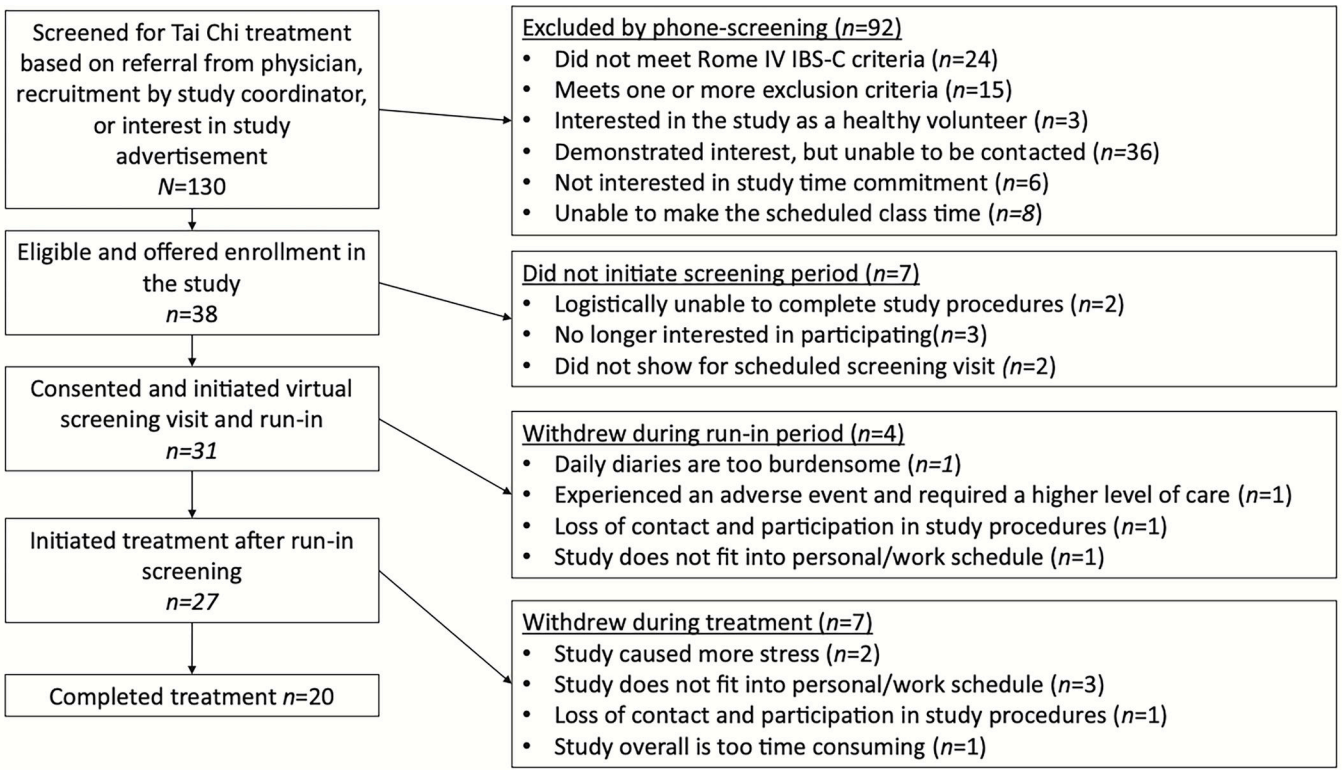

Figure 1:
Study flow

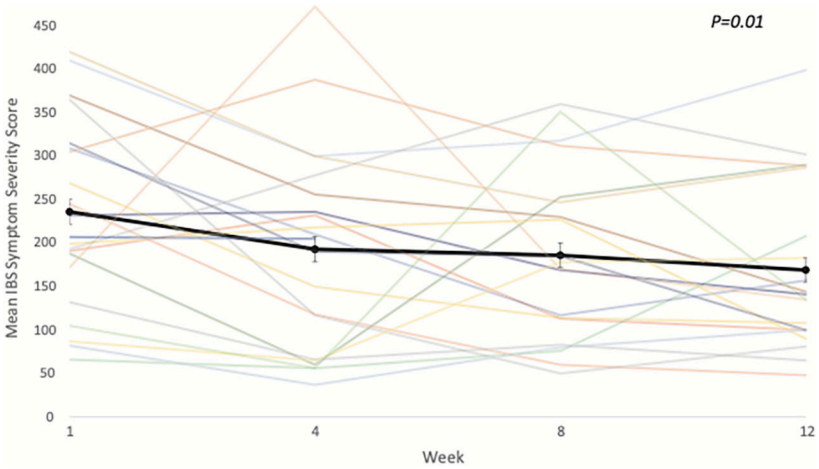

FIGURE 2 IBS Symptom Severity Score (IBS-SSS) change over time; mean group change in bold

Figure 2:
IBS Symptom Severity Score (IBS-SSS) change over time; mean group change in bold

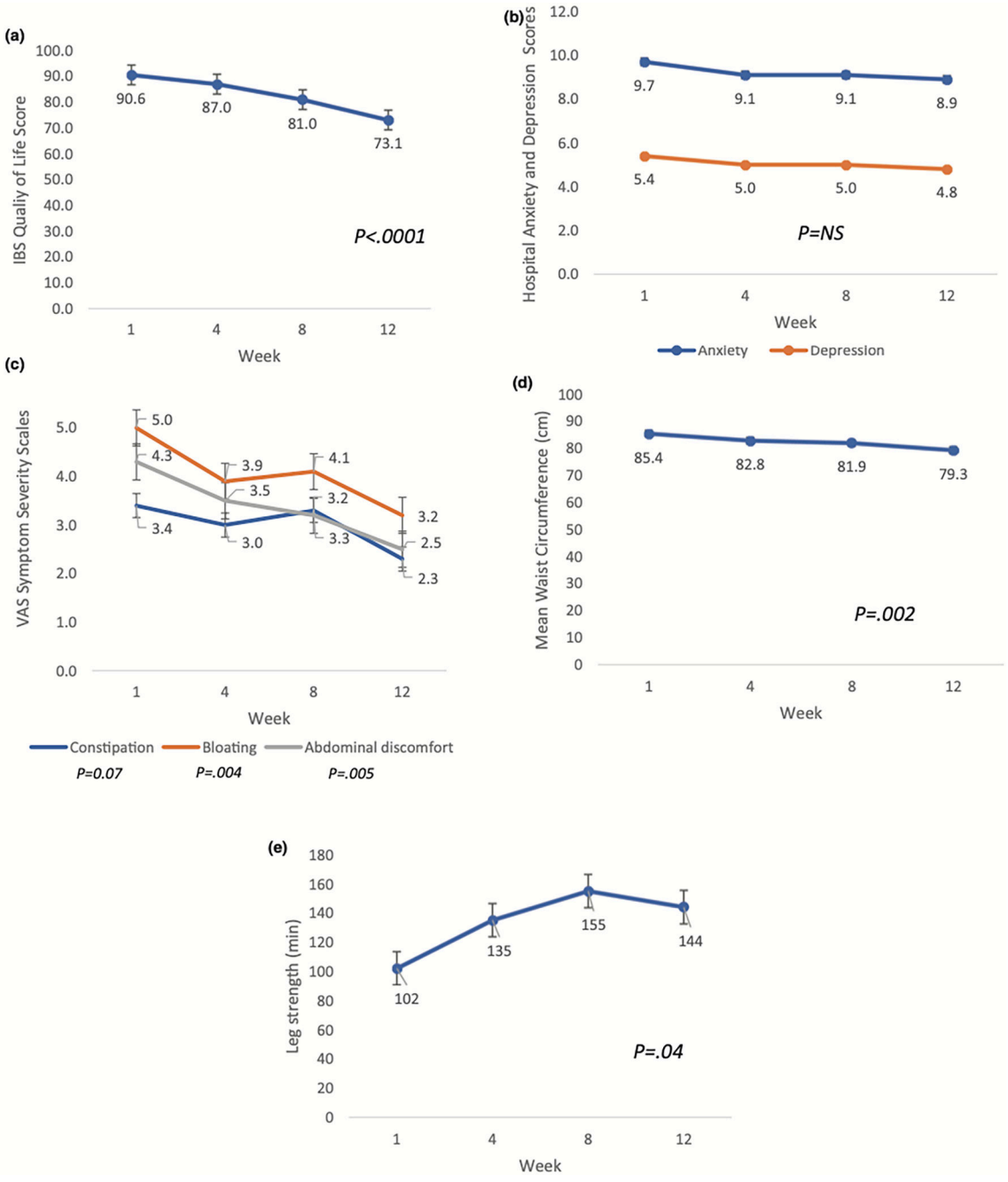

Figure 3:

Change in selected secondary measures over time; For leg strength, participants were asked to sit against a wall without support, legs bent at a 110 degree angle for as long as they could, at 80 percent of their maximum effort, using a self-timer.

VAS, visual analog scale

TABLE 1

Demographics and baseline characteristics[a]

Characteristic	Tai Chi intervention group (N = 27)
Demographics	
Age, mean (SD), years	41.1 (16.2)
Female	25 (92.6)
BMI, mean (SD), kg/m^2	23.5 (3.6)
Race	
American Indian/Alaska Native	0 (0)
Asian	4 (14.8)
Native Hawaiian/Pacific Islander	3 (11.1)
Black/African Americana	1 (3.7)
White	22 (81.5)
More than one race	0 (0)
Hispanic/Latinx	2 (7.4)
Psychological comorbidities	
HADS anxiety, mean (SD)	9.7 (3.7)
HADS depression, mean (SD)	5.4 (3.4)
HADS total, mean (SD)	15.1 (6.2)
Concomitant medications	
Laxatives	23 (85.2)
Miralax	6 (22.2)
Dulcolax	6 (22.2)
Sennosides	2 (7.4)
Enema	3 (11.1)
Linaclotide	3 (11.1)
Magnesium	3 (11.1)
Neuromodulators	9 (33.3)
SSRIs	5 (18.5)
SNRIs	1 (3.7)
Tricyclic antidepressant	2 (7.4)
Gabapentin	1 (3.7)
Seen GI provider for symptoms	10 (37.0)
Referral source	
MGH GI clinic	12 (44.4)
Recruitment website	12 (44.4)
Facebook ad	1 (3.7)
Word of mouth	2 (7.4)

Abbreviations: SD, standard deviation; BMI, body mass index; HADS, hospital anxiety and depression score; SSRI, selective serotonin reuptake inhibitor; SNRI, serotonin-norepinephrine reuptake inhibitor; MGH, Massachusetts General Hospital

[a]Data are shown as number (percentage) unless otherwise noted. Percentages are rounded.

TABLE 2

Feasibility and acceptability benchmarks

Outcome	Tai Chi intervention group
Feasibility of recruitment	31/38 (82%) screened and eligible participants agreed to participate (*excellent*)
Feasibility of study completion	20/27 (74%) participants successfully completed the entire study (*moderate*)
Participant satisfaction	19/20 participants (95%) rating 4s/5s (*excellent*) on treatment satisfaction and 19/20 (95%) participants rating 4s/5s out of 5 (scale 1-5) on likelihood of continuing Tai Chi (*excellent*)
Acceptability of treatment	18/27 participants (67%) attended ≥7 out of 8 Tai Chi lessons (*moderate*)
Adherence to daily diary	15/27 participants (56%) completed ≥80% of the daily diaries (*moderate*)
Adherence to Tai Chi practice	11/20 participants (55%) practiced Tai Chi ≥80% of days during the treatment period (*moderate*)
Instructor assessment of Tai Chi mastery	14/20 participants (70%) were rated as 4s/5s out of 5 (scale 0-5) (good)
Instructor assessment of Tai Chi enthusiasm	19/20 participants (95%) achieved an enthusiasm level of 4s/5s out of 5 (scale 0-5)(*excellent*)
Treatment-related adverse events	1/20 participants (5.0%) had an adverse event (good)

TABLE 3

Primary and secondary outcome data over time

Measure	Baseline (*n* = 27)	Midtreatment (*n* = 21)	Posttreatment (*n* = 20)	4-week follow-up (*n* = 20)	Estimated change[a]	p-value[a]
IBS-SSS (1° measure)	236 (21.9)	193 (25.4)	186 (22.0)	169 (21.3)	−66.5 (26.2)	0.01
Secondary IBS survey measures						
IBS-QOL	90.6 (6.3)	87.0 (6.9)	81.0 (6.5)	73.1 (5.7)	−17.5 (3.6)	<0.0001
Visceral sensitivity index	42.1 (3.5)	42.4 (4.2)	36.2 (4.0)	37.3 (4.3)	−4.9 (4.2)	0.25
IBS-BRQ score	92.6 (5.6)		82.2 (5.8)	82.8 (5.6)	−9.8 (5.0)	0.05
GSRS score						
Constipation	4.0 (0.22)		3.7 (0.31)	3.3 (0.26)	−0.73 (0.31)	0.02
Bloating	4.1 (0.28)		3.5 (0.29)	3.2 (0.30)	−0.85 (0.33)	0.01
Pain	3.8 (0.23)		3.3 (0.24)	3.4 (0.24)	−0.44 (0.30)	0.16
Diarrhea	2.4 (0.25)		2.2 (0.27)	1.9 (0.24)	−0.51 (0.30)	0.10
Satiety	3.9 (0.31)		3.2 (0.32)	2.9 (0.29)	−1.0 (0.39)	0.01
VAS scales[b]						
Abdominal discomfort	4.3 (0.46)	3.5 (0.65)	3.2 (0.56)	2.5 (0.50)	−1.8 (0.63)	0.005
Constipation	3.4 (0.52)	3.0 (0.60)	3.3 (0.66)	2.3 (0.44)	−1.1 (0.59)	0.07
Bloating	5.0 (0.46)	3.9 (0.60)	4.1 (0.61)	3.2 (0.67)	−1.8 (0.60)	0.004
Abdominal pain[c]	1.8 (0.16)	1.5 (0.26)	1.2 (0.22)	1.5 (0.14)	−0.32 (0.20)	0.12
Physical measures						
Weight, kg	66.3 (2.8)	65.9 (2.7)	65.6 (2.8)	65.7 (2.8)	−0.65 (0.30)	0.03
BMI, kg/m^2	23.5 (0.72)	23.4 (0.70)	23.3 (0.71)	23.3 (0.72)	−0.20 (0.11)	0.06
Waist circumference, cm	85.4 (2.2)	82.8 (2.5)	81.9 (2.4)	79.3 (2.2)	−6.2 (1.9)	0.002
Leg strength, min	102 (17)	135 (20.1)	155 (22.5)	144 (23.9)	+38.8 (18.7)	0.04
Fear of food questionnaire score	44.3 (4.1)		39.7 (4.5)	35.6 (4.3)	−8.7 (3.2)	0.008
GI fears	3.2 (0.23)		2.9 (0.27)	2.6 (0.26)	−0.61 (0.24)	0.01
Food fears	3.1 (0.24)		2.5 (0.29)	2.3 (0.32)	−0.76 (0.25)	0.003
Food avoidance	3.1 (0.27)		3.2 (0.27)	3.0 (0.30)	−0.18 (0.26)	0.48
Social impairment	1.4 (0.27)		1.1 (0.22)	0.67 (0.14)	−0.72 (0.22)	0.002
Distress/loss of pleasure	2.4 (0.34)		2.3 (0.32)	2.3 (0.32)	−0.16 (0.28)	0.56
HADS score						

Measure	Baseline (*n* = 27)	Midtreatment (*n* = 21)	Posttreatment (*n* = 20)	4-week follow-up (*n* = 20)	Estimated change[a]	p-value[a]
Anxiety score	9.7 (0.73)	9.1 (0.95)	9.1 (1.01)	8.9 (1.1)	−0.79 (0.87)	0.37
Depression score	5.4 (0.6)	5.0 (0.71)	5.0 (0.76)	4.8 (0.76)	−0.59 (0.46)	0.21

Note: Pretreatment: at first Tai Chi class (Day 0); Midtreatment: 4weeks into Tai Chi program (Day 28); Posttreatment: after last Tai Chi class (Day 49); Follow-up: 4weeks after completing program (Day 77).

Abbreviations: GSRS-IBS, Gastrointestinal Symptom Rating Scale—IBS version; HADS, Hospital Anxiety and Depression Scale; IBS-SSS, IBS Symptom Severity Scale; IBS-QOL, IBS Quality of Life Scale; VAS, Visual Analog Scale.

[a]Data are shown as estimated means (SE) from mixed model repeated measures analysis with unstructured covariance among the repeated measures to determine adjusted means for a measure at each study timepoint and whether there was a significant difference in measure over time from pretreatment to 4-week follow up Day 77.

[b]Participants were asked to rate the severity of their constipation, bloating, or abdominal discomfort on a visual analog scale (VAS) scale from 0 to 10, 0 being no symptom and 10 being the worst severity.

[c]The VAS asked participants to rate their average level of abdominal pain in the past week, 0 being the least amount of pain and 4 being the most amount of pain.