



Contents lists available at ScienceDirect

## North American Spine Society Journal (NASSJ)

journal homepage: [www.elsevier.com/locate/xnsj](http://www.elsevier.com/locate/xnsj)

## Clinical Studies

## A Tai chi and qigong mind-body program for low back pain: A virtually delivered randomized control trial



Yang Yang, PhD<sup>a,\*</sup>, Sydne McCluskey, PhD<sup>b</sup>, Mohamad Bydon, MD<sup>c</sup>, Jaspal Ricky Singh, MD<sup>d</sup>, Robert D. Sheeler, MD<sup>e</sup>, Karim Rizwan Nathani, MBBS<sup>c</sup>, Ana C. Krieger, MD, MPH<sup>f</sup>, Neel D. Mehta, MD<sup>g</sup>, Joshua Weaver, MD<sup>h</sup>, Libin Jia, MD<sup>i</sup>, Sharon DeCelle, MS, PT, LPC<sup>j</sup>, Robert C. Schlagal, PhD<sup>k</sup>, Jay Ayar, DrPH (c), MPH, BDS<sup>l</sup>, Sahar Abduljawad, DrPH (c), MPH<sup>m</sup>, Steven D. Stovitz, MD, MS<sup>m</sup>, Ravindra Ganesh, MBBS, MD<sup>n</sup>, Jay Verkuilen, PhD<sup>o</sup>, Kenneth A. Knapp, PhD<sup>l</sup>, Lin Yang, PhD<sup>p</sup>, Roger Härtl, MD<sup>q</sup>

<sup>a</sup> Center for Taiji and Qigong Studies, 151 E 81st St 7D, New York, NY 10028, United States

<sup>b</sup> Educational Psychology Program, CUNY Graduate Center, 365 Fifth Av, New York, NY 10016, United States

<sup>c</sup> Department of Neurological Surgery, Neuro-Informatics Laboratory, Mayo Clinic, 200 1st St SW, Rochester, MN 55905, United States

<sup>d</sup> Department of Rehabilitation Medicine, Weill Cornell Medicine, 525 E. 68th St, New York, NY 10065, United States

<sup>e</sup> Department of Family Medicine, Mayo Clinic, College of Medicine, Rochester, Minnesota, Next Level Concierge Care, 10250 N 92nd St Suite 210, Scottsdale, AZ 85258, United States

<sup>f</sup> Weill Cornell Center for Sleep Medicine, Department of Medicine, Weill Cornell Medical College, 425 East 61st St - 5th floor, New York, NY 10065, United States

<sup>g</sup> Department of Anesthesiology, Division of Pain Management, Och Spine at Weill Cornell Medicine/NewYork-Presbyterian Hospital, 240 East 59th St, 2nd Floor, New York, NY 10022, United States

<sup>h</sup> Department of Neurology, Weill Cornell Medicine, 1305 York Ave, Floor 2, New York, NY 10021, United States

<sup>i</sup> Office of Cancer Complementary and Alternative Medicine, Division of Cancer Treatment and Diagnosis, National Cancer Institute, 9609 Medical Center Dr. 1W704, Rockville, MD 20850, United States

<sup>j</sup> Private Practice, 309 E Holmes St, Urbana, IL 61801, United States

<sup>k</sup> Department of Reading Education and Special Education, Appalachian State University, Boone, North Carolina, 4717 Valero Ct, Laredo, TX 78046, United States

<sup>l</sup> Department of Public Health, School of Health Sciences and Practice, New York Medical College, 40 Sunshine Cottage Road, Valhalla, NY 10595, United States

<sup>m</sup> Department of Family Medicine and Community Health, University of Minnesota Medical School, Minneapolis, Minnesota, Mill City Clinic, 901 South 2nd St, Minneapolis, MN 55415, United States

<sup>n</sup> Division of General Internal Medicine, Mayo Clinic College of Medicine, 200 1st St SW, Rochester, MN 55905, United States

<sup>o</sup> Educational Psychology Program, CUNY Graduate Center, 365 Fifth Ave, New York, NY 10016, United States

<sup>p</sup> Department of Cancer Epidemiology and Prevention Research, Cancer Care Alberta, Alberta Health Services, Calgary, Alberta, Canada; Departments of Oncology and Community Health Sciences, Cumming School of Medicine, University of Calgary, 5th Floor, Holy Cross Centre, Box ACB, 2210 - 2 St. SW, Calgary AB T2S 3C3, Canada

<sup>q</sup> Department of Neurological Surgery, Division of Spine Surgery, Och Spine at Weill Cornell Medicine/NewYork-Presbyterian Hospital, 525 East 68th St, Box 99, New York, NY 10065, United States

FDA device/drug status: Not applicable.

Author disclosures: **YY**: Nothing to disclose. **SMC**: Nothing to disclose. **MB**: Nothing to disclose. **JRS**: Nothing to disclose. **RDS**: Nothing to disclose. **KRN**: Nothing to disclose. **ACK**: Nothing to disclose. **NDM**: Nothing to disclose. **JW**: Nothing to disclose. **LJ**: Nothing to disclose. **SDC**: Nothing to disclose. **RCS**: Nothing to disclose. **JA**: Nothing to disclose. **SA**: Nothing to disclose. **SDS**: Nothing to disclose. **RG**: Nothing to disclose. **KAK**: Nothing to disclose. **LY**: Nothing to disclose. **RH**: Nothing to disclose.

\* Corresponding author. Research Department, Center for Taiji and Qigong Studies, 151 E 81st St, 7D, New York, NY 10028, USA.

E-mail address: [yang@centerfortaiji.org](mailto:yang@centerfortaiji.org) (Y. Yang).

<https://doi.org/10.1016/j.xnsj.2024.100557>

Received 23 July 2024; Received in revised form 26 August 2024; Accepted 5 September 2024

Available online 8 September 2024

2666-5484/© 2024 The Author(s). Published by Elsevier Inc. on behalf of North American Spine Society. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>)

## ARTICLE INFO

## Keywords:

Back pain  
Telerehabilitation  
Randomized controlled trial  
Tai chi  
Qigong  
Meditation  
Mind-body  
Nonpharmacological intervention

## ABSTRACT

**Background:** Mind-body treatments have the potential to manage pain, yet their effectiveness when delivered online for the treatment of low back pain (LBP) is unknown. We sought to evaluate whether a virtually delivered mind-body program integrating tai chi, qigong, and meditation (VDTQM) is effective for treating LBP.

**Methods:** This randomized controlled trial compared VDTQM (n=175) to waitlist control (n=175). Eligible participants were at least 18 years old, had LBP for at least 6 weeks, were not pregnant, had not previously taken tai chi classes, and had not undergone spine surgery within 6 months. The treatment group received a 12-week VDTQM program in live online 60-minute twice-weekly group classes from September 2022 to December 2022. All participants continued their usual activities and care. Primary outcome was pain-related disability assessed by the Oswestry Disability Index (ODI) score. Secondary outcomes included pain intensity, sleep quality, and quality of life (QOL). Intent-to-treat analyses were conducted.

**Results:** Of the 350 participants 278 (79%) were female, mean age was 58.8 years (range: 21–92), 244 (69.7%) completed the 8-week survey, 248 (70.9%) the 12-week, and 238 (68%) the 16-week. No participants withdrew due to adverse treatment effects. Compared with control group, treatment group experienced statistically and clinically significant improvement in ODI score by  $-4.7$  (95% CI:  $-6.24$  to  $-3.16$ ,  $p < .01$ ),  $-6.42$  (95% CI:  $-7.96$  to  $-4.88$ ,  $p < .01$ ), and  $-8.14$  (95% CI:  $-9.68$  to  $-6.59$ ,  $p < .01$ ) points at weeks 8, 12, and 16, respectively. Treatment group also experienced statistically significant improvement at all time points in the other outcomes.

**Conclusions:** Among adults with LBP, VDTQM treatment resulted in small to moderate improvements in pain-related disability, pain intensity, sleep quality, and QOL. Improvements persisted 1 month after treatment concluded. These findings suggest VDTQM may be a viable treatment option for patients with LBP.

**Trial registration:** [clinicaltrials.gov](https://clinicaltrials.gov) Identifier: NCT05801588.

## Background

Low back pain (LBP) remains the leading cause of disability worldwide [1], impacting 619 million individuals [2] in 2020 and a projected 843 million [3] in 2050. Safe, effective, and accessible treatment at a low cost is needed. Increasing evidence demonstrates the promise of nonpharmacologic treatments such as those that focus on body movement and/or mental retraining [4] to attenuate pain and improve disability in individuals with LBP [5]. Nonpharmacologic approaches are often recommended as an initial LBP treatment [6].

Social distancing requirements during the COVID-19 pandemic complicated matters for nonpharmacologic therapies. Increased telemedicine availability spurred by the COVID-19 pandemic allowed patients to continue receiving care and provided an opportunity to investigate telerehabilitation effectiveness for patients with LBP. In-person therapies can be difficult for patients to access due to a dearth of available facilities, cost, scheduling, or physical condition [7]. Preliminary research indicates digitally delivered physiotherapy may be effective treatment for improving disability and reducing pain [8]. However, evidence is mixed [9] and further research regarding the effectiveness of virtually delivered therapies is needed.

Qigong is an ancient Chinese healing art for nurturing vital energy. Tai chi, a series of bodily movements incorporating qigong practice, has healing and martial art function with demonstrated benefits to sleep [10], immune function [11], fall prevention [12], cardiac rehabilitation [13,14], and overall well-being [15], as well as increasing the likelihood of return to work [5]. Recently, 2 tai chi studies [16,17] and 1 qigong study [18] demonstrated short-term small to moderate effects on improving LBP and disability.

Qigong practice emphasizes both stillness and movement, 2 essential components for LBP relief and injury prevention according to Chinese healing and martial arts. Stillness meditation (adaptable for standing, sitting, and lying down) is thought to promote calmness, resilience, body awareness, deeper relaxation, and strength. Slow, simple movements are thought to further cultivate relaxation, flexibility, energy flow, and proper body alignment in motion [19]. A curriculum integrating stillness and movement has the potential to serve as a feasible nonpharmacologic treatment option for adults with LBP. To our knowledge, this is the first investigation of a virtually delivered integrated tai chi, qigong, and meditation program (VDTQM) with a balanced focus on stillness and movement.

The principal aim of this study was to assess the effectiveness of a VDTQM program integrating stillness and movement among adults living with LBP. Our hypothesis was that participants engaged in the treat-

ment would experience greater improvement in pain-related disability, pain intensity, sleep quality, and health-related QOL compared to the waitlist control group.

## Methods

## Study design, settings, and participants

In this prospective randomized controlled trial, adults with LBP were assigned into 1 of 2 groups: a VDTQM (treatment) group and a waitlist control group. Of 417 recruited individuals recruited from July 2022 to September 2022, a total of 350 participants primarily from the New York City Metropolitan Area and Portland, Maine met inclusion criteria and were enrolled and randomized. Participants were recruited through a variety of routes, such as: emails to mailing lists of a podcast of the Comprehensive Spine Care Center at Weill Cornell Medicine for people with LBP; referrals from physicians of primary care, geriatrics, and osteopathic medicine; and an employee wellness program newsletter that went to approximately 80,000 employees at Northwell Health in the New York area.

Participants in the treatment group received free live online sessions for 12 weeks from September 2022 to December 2022. The waitlist control group had the option to participate in the free VDTQM program 1 week after the final study follow-up, from January 2023 to April 2023. Outcome measures were collected electronically from both groups at baseline, 8 weeks, 12 weeks (at the conclusion of the treatment), and 16 weeks (4 weeks after the conclusion of the treatment). The research protocol was approved by the Institutional Review Board of the New York Medical College (IRB approval number: GMB 15574, see protocol in Supplementary 1). Informed consent was obtained from all participants before randomization.

## Inclusion and exclusion criteria

Participants were eligible to participate if they were at least 18 years old, had experienced LBP for at least 6 weeks prior to study enrollment, understood written and spoken English, were not pregnant, had not previously taken tai chi classes, and had not undergone spinal surgery within the last 6 months.

## Randomization and blinding

After completing the baseline survey, eligible participants were assigned a value between 0 and 1 with a random number generator in

Stata [20], then sorted by this random number. The first half of the participants were assigned to the treatment group and the second half to the control group. Due to the nature of this behavioral treatment, it was not possible to blind the participants.

### Intervention

The VDTQM program is a treatment developed to reduce LBP and associated disability. The practice follows foundational principles of Chinese medicine for healing and pain relief: cultivating a tranquil mind and relaxed body [19]. The program is based on tai chi and qigong exercises and meditation developed by the first author. Each session lasted approximately 60 minutes, comprising six 10-minute segments: energy cultivation, standing meditation, spinal flexibility, lying down meditation, core strength, and sitting meditation (a link to a typical class is provided in Supplementary 2). Approximately every 4 classes, 1 of 6 acupuncture points for back, neck, sciatica, energy, and sleep were taught: Ling Gu (22.05), Cheng Shan (BL 57), Feng Chi (GB 20), Huan Tiao (GB 30), Yong Quan (KD 1), and Lao Gong (PC 8). A member of the administrative team manually took attendance for each class. A link to a recording of a typical class is available in Supplementary 2.

The first author taught and streamed the class content to all treatment participants via Zoom twice weekly for 12 weeks from September 22, 2022 to December 19, 2022. Participants received guidelines and suggestions for home practice and were encouraged to complete a practice log for each class. Class recordings were available for viewing at any time to facilitate home practice. To facilitate continued participation and minimum discomfort, participants were taught tools (such as modifying range of motion and altering number of repetitions) to tailor their practice based on their needs. Individuals in both treatment and control groups continued their usual medical care throughout the study.

### Measures

Baseline information included self-reported sociodemographic characteristics, height, weight, and cigarette smoking history. All primary and secondary outcome measures (described below) were collected at the baseline, 8-, 12-, and 16-week surveys via the Qualtrics platform. Adverse events were identified through feedback, phone calls, and during treatment sessions.

### Primary outcome

The Oswestry Disability Index (ODI [21]) is a 10-item questionnaire assessing pain-related disability due to LBP (range 0-100; higher scores reflect increasing disability). A 5-10 point between-group difference is considered clinically small, while a 10-20-point difference is moderate, and any difference greater than 20 points is large [5].

### Secondary outcomes

Pain intensity was measured using 2 visual analog scale questions (VAS [22]), one focusing on back pain and another on leg pain. Scores range from 0 to 10; higher scores indicate worse pain. Scores on the 2 pain measures were averaged to compute a total score on a 0-10-point scale. Clinically meaningful between-group differences were defined as small (0.5-1 point), moderate (1-2 points) and large (greater than 2 points) [5].

Sleep quality was measured using the Pittsburgh Sleep Quality Index (PSQI [23]). The 19 questions are used to compute 7 "component" scores, the sum of which yields 1 global score (range 0-21; higher scores correspond to poorer sleep quality). A minimal clinically important difference on the PSQI global score is 4.4 points [24].

QOL was measured using the 36-item Short Form Health Survey questionnaire (SF-36) [25]. The SF-36 assesses 8 scales, which are summed to create a global score (range 0-100; higher scores reflect

greater well-being). A minimum clinically important difference on the SF-36 is 5 points [26].

### Sample size

With an assumed effect size of  $d=0.6-0.7$  and a total of 100 participants randomly assigned to either treatment or control groups, we expected to achieve power ranging from 70% ( $d=0.6$ ,  $\alpha=.016$ , 2-tailed, conservative correction for multiple testing) to 85% ( $d=0.7$ ,  $\alpha=.016$ , 2-tailed). Assuming an attrition rate of 50%, we initially aimed to recruit 200 participants. During the recruitment phase, there was greater interest in participation than the research team had anticipated, with 417 responses to the baseline and eligibility survey (of which 350 met eligibility criteria and consented to image, voice, or data collection). The online delivery platform enables us to recruit more participants without significantly increasing costs. Because of this, and to increase our safety margin against dropouts, we ultimately recruited 350 participants to facilitate a balanced design.

### Statistical analysis

All analyses were conducted on the full sample with 2-sided tests and  $\alpha=0.05$ . Intent-to-treat analyses were conducted (all available responses at each time point were included in analyses, regardless of treatment adherence). The baseline sociodemographic characteristics of the sample were compared between randomization groups using 2-sample t-tests. Linear mixed models (LMM) were fitted to each outcome (ODI, VAS, PSQI, and SF-36) to compare scores across randomization groups at baseline and 8, 12, and 16 weeks (Supplementary 2). Fixed effects were estimated for randomization group (treatment or control), time, and a group-by-time interaction. Random effects were estimated for participants to capture individual-level variation. Contrasts were calculated to test adjusted group mean differences at each time point. The t-tests and LMM analyses were conducted in the R programming language [27]. LMM analyses were conducted using the nlme package [28]. We performed multiple imputation and re-fit the models to the complete data sets. Bayesian sensitivity analyses were conducted to test the impact of priors reflecting no or adverse effect of treatment. Sensitivity analyses adding sex as a predictor were conducted. Multiple imputation and sensitivity analyses were performed in Version 8.8 of Mplus [29].

### Results

The baseline survey was completed by 417 individuals, of which 350 met eligibility criteria and were randomly assigned to either the treatment or control group (175 participants assigned to each group, see Fig. 1). The 2 groups were similar on all baseline demographic and clinical variables (Table 1). Of the 175 participants assigned to treatment, 51 (29%) attended no classes, 94 (54%) 25% or fewer classes, 70 (40%) at least half of the classes, 50 (28%) 75% or more classes, and 13 (7%) all 24 classes. Of the 162 treatment group participants who attended fewer than 24 classes, 3 (2%) were due to family issues, 2 (1%) to health issues, 1 (1%) to loss of interest, 22 (14%) to scheduling conflicts, 1 (1%) to other reasons, 3 (2%) to lack of progress, and 130 (80%) did not provide a reason. At 8 weeks, 91 (52%) participants in the treatment group and 153 (87%) in the control completed assessments. At 12 weeks, 93 (53%) participants in the treatment group and 155 (89%) in the control completed assessments. At 16 weeks, 90 (51%) participants in the treatment group and 148 (85%) in the control completed assessments.

Over half the treatment group participants with missing data attended less than 25% of the classes; further, most participants who gave reasons for dropping out of the study cited scheduling conflicts. None of the demographic characteristics in Table 1 were predictive of missing data, nor were the baseline outcome measures. These findings suggest our data are likely missing at random (MAR). Therefore, we present results based on the data set with missing observations for participants

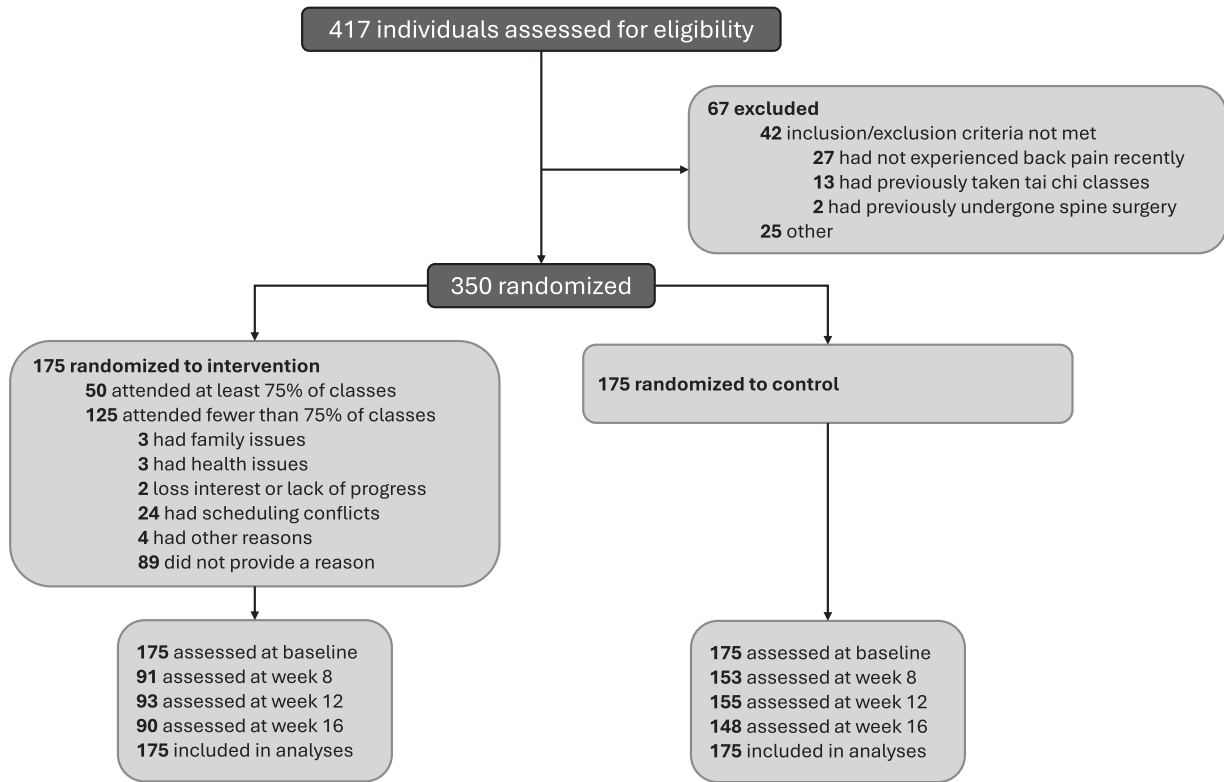


Fig. 1. CONSORT diagram of study participation.

Table 1  
Participant baseline demographic and clinical characteristics by randomization status\*.

Characteristic	Treatment (N=175)	Control (N=175)
Age (y)	57.9 (15.6)	59.7 (14.0)
BMI (kg/cm <sup>2</sup> )	27.7 (7.1)	28.6 (7.5)
Weight (pounds)	163.1 (37.6)	165.6 (44.7)
Height (inches)	64.5 (5.3)	634.0 (5.0)
Sex:		
Female	138 (79%)	140 (80%)
Male	35 (20%)	35 (20%)
Did not respond	2 (1%)	0 (0%)
Hispanic	11 (6%)	23 (13%)
Race:		
Asian	18 (10%)	17 (10%)
Black	16 (9%)	11 (6%)
Other	6 (3%)	12 (7%)
White	122 (71%)	126 (72%)
Did not respond	13 (8%)	9 (9%)
Education level:		
College	141 (81%)	144 (82%)
High School or Less	7 (4%)	3 (2%)
Some College or Higher	22 (13%)	25 (14%)
Did not respond	5 (3%)	3 (2%)
Work Status:		
Employee	93 (53%)	87 (50%)
Not Working	13 (7%)	16 (9%)
Retired	52 (30%)	53 (30%)
Self-Employed	15 (9%)	18 (10%)
Did not respond	2 (1%)	1 (1%)
Smoked Cigarette <sup>†</sup>	69 (39%)	54 (31%)
ODI <sup>‡</sup>	24.1 (11.7)	23.0 (12.3)
VAS <sup>§</sup>	4.5 (2.1)	4.5 (2.0)
PSQ <sup>  </sup>	7.3 (2.7)	7.1 (2.9)
SF3 <sup>¶</sup>	57.4 (15.2)	59.6 (16.8)

ODI, Oswestry Disability Index; VAS, Visual Analog Scale; PSQI, Pittsburgh Sleep Quality Index; SF36, 36-Item Short Form Health Survey.

\* Data are means (SD) for continuous variables and numbers (%) for categorical variables.

<sup>†</sup> Participants who currently or ever smoked cigarettes are included in this count.

<sup>‡</sup> Scores range from 0-100, with higher scores indicating increasing disability.

<sup>§</sup> Scores range from 0-10, with higher scores indicating worse pain.

<sup>||</sup> Scores range from 0-21, with higher scores indicating worse sleep quality.

<sup>¶</sup> Scores range from 0-100, with higher scores indicating greater health-related quality of life.

**Table 2**  
Model-derived mean outcomes by randomization group<sup>a</sup>.

ODI <sup>†</sup>				
Wk	Treatment (N=175)	Control (N=175)	Adjusted between-group difference <sup>‡</sup> (95% CI)	p-value
0	22.9	24.2	NA	NA
8	19.3	24.0	-4.7 (-6.2, -3.2)	<.01
12	17.4	23.8	-6.4 (-8.0, -4.9)	<.01
16	15.6	23.7	-8.1 (-9.7, -6.6)	<.01
VAS <sup>§</sup>				
0	4.5	4.5	NA	NA
8	3.6	4.2	-0.7 (-1.0, -0.3)	<.01
12	3.2	4.1	-0.9 (-1.3, -0.6)	<.01
16	2.7	3.9	-1.2 (-1.5, -0.9)	<.01
PSQI <sup>  </sup>				
0	7.0	7.3	NA	NA
8	6.4	7.0	-0.6 (-1.1, -0.1)	.02
12	6.0	6.9	-0.8 (-1.3, -0.3)	<.01
16	5.7	6.7	-1.0 (-1.5, -0.5)	<.01
SF-36 <sup>¶</sup>				
0	59.9	57.5	NA	NA
8	66.5	57.9	8.6 (6.6, 10.7)	<.01
12	69.8	58.0	11.7 (9.7, 13.8)	<.01
16	73.1	58.2	14.9 (12.8, 16.9)	<.01

ODI, Oswestry Disability Index; VAS, Visual Analog Scale; PSQI, Pittsburgh Sleep Quality Index; SF36, 36-Item Short Form Health Survey.

<sup>a</sup> Estimates from linear mixed models with fixed effects for randomization group (treatment or control), time, and a group-by-time interaction and random effects for participants.

<sup>†</sup> Scores range from 0-100, with higher scores indicating increasing disability.

<sup>‡</sup> Calculated with orthogonal contrasts.

<sup>§</sup> Scores range from 0-10, with higher scores indicating worse pain.

<sup>||</sup> Scores range from 0-21, with higher scores indicating worse sleep quality.

<sup>¶</sup> Scores range from 0-100, with higher scores indicating greater health-related quality of life.

who did not complete outcome measures at all time points (see Outcomes Section below regarding results of analyses based on imputed data and sensitivity analysis).

### Outcomes

Model fit statistics and parameter estimates for the LMMs are presented in eTables 1-5 in Supplementary 2. Compared with the control group, the treatment group experienced statistically and clinically significantly greater improvement on the ODI at all time points, with a 4.7-point between-group difference at 8 weeks, 6.42-point difference at 12 weeks, and 8.14-point difference at 16 weeks ( $p < .01$  for all differences, Table 2). The overall change on the ODI from baseline to 16-week follow-up within the control group was 0.45 points, while within the treatment group it was 7.31 points.

Compared with the control group, the treatment group experienced statistically and clinically significantly greater improvement on the VAS at all time points, with a 0.65-point between-group difference at 8 weeks, 0.93-point difference at 12 weeks, and 1.22-point difference at 16 weeks ( $p < .01$  for all differences). The overall change on the VAS from baseline to 16-week follow-up within the control group was 0.6 points, while within the treatment group it was 1.74 points. Compared with the control group, the treatment group experienced statistically significantly greater improvement on the PSQI at all time points, with between-group differences of 0.62, 0.82, and 1.02 points at 8, 12, and 16 weeks, respectively ( $p = .02$  for 8 weeks and  $p < .01$  for the remaining comparisons). On the PSQI, the overall change within the treatment group was 1.35 points, while it was 0.55 points within the control group. Results for the PSQI subscales are presented eTable 12 in Supplementary 2. Compared with the control group, the treatment group experienced statistically and clinically significantly greater improvement on the SF-36 at all time points, with between-group differences of 8.62, 11.74, and 14.86 points at 8, 12, and 16 weeks ( $p < .01$  for all differences). The overall change within the treatment group on the SF-36 was 13.14 points, while within the control group it was 0.66 points. Results for the

SF-36 subscales are presented in eTable 13 in Supplementary 2. Mean scores on each outcome at each time point are displayed in Fig. 2 by randomization group.

Detailed outcomes from sensitivity analyses and multiple imputation procedures are available in Supplementary 2, see eTables 6-11. Results from analyses on the complete data set from multiple imputation were generally similar to those from analyses on the data set with missing data. Sensitivity analysis testing the impact of priors reflecting no or adverse effects of treatment also produced consistent results. Sex did not exhibit a modifying effect on the treatment's impact concerning ODI, SF-36, or VAS measures. However, regarding PSQI, the effect of the treatment varied based on sex, showing that females experienced more significant improvements compared to males.

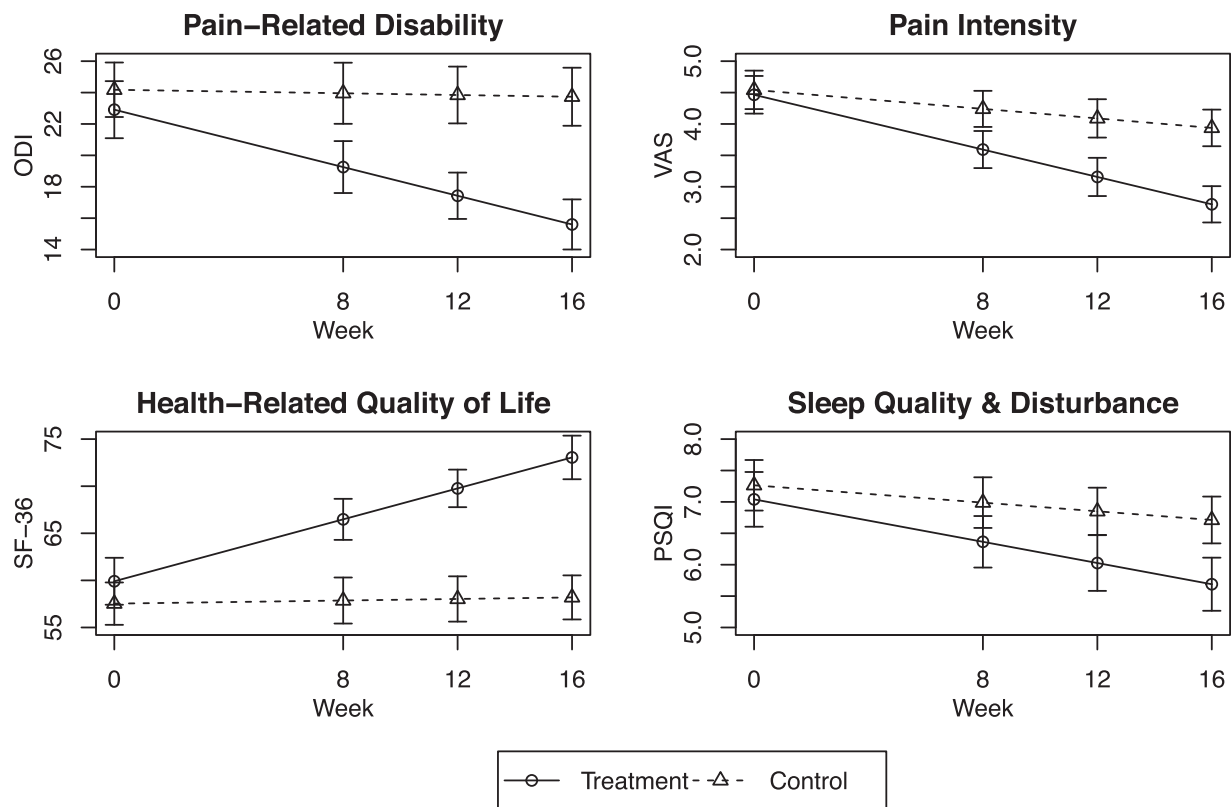
### Adverse events

During the treatment period, 2 (1.6%) of 124 participants attending 1 or more of the 24 sessions reported an adverse event: one started having pain in the forearm after treatment started; the other had shoulder pain possibly due to overdoing shoulder rotations. The pain in both cases was minor and transient.

### Discussion

Our randomized controlled trial found that a 12-week VDTQM treatment was effective in improving pain-related disability, pain intensity, sleep quality, and QOL in adults with LBP. Participant outcomes continued to improve 1 month after treatment was completed and reached both clinical and statistical significance for all outcomes except for sleep quality, which only reached statistical significance. Subjective experiences also mirrored these findings [41]. Given our study duration of 16 weeks, we are unable to evaluate if the effects are longer lasting. To our knowledge, this is the first study demonstrating the effectiveness of a VDTQM program for treating LBP.





**Fig. 2.** Outcomes by randomization group. Abbreviations: ODI, Oswestry Disability Index; VAS, Visual Analog Scale; PSQI, Pittsburgh Sleep Quality Index; SF36, 36-Item Short Form Health Survey. Scores on ODI range from 0-100, with higher scores indicating increasing disability. Scores on VAS range from 0-10, with higher scores indicating worse pain. Scores on PSQI range from 0-21, with higher scores indicating worse sleep quality. Scores on SF-36 range from 0-100, with higher scores indicating greater health-related QOL. Error bars indicate 95% Confidence Intervals.

The VDTQM program was delivered remotely, allowing people with a wide range of pain intensity, physical conditions, ages (21-92) and locations to participate. It yielded benefits beyond pain-related disability and pain relief, including sleep and QOL; pain and pain-related disability continued to improve even after the conclusion of treatment. These findings align with previous randomized controlled trials using in-person tai chi, qigong, and meditation integrated curricula which have demonstrated significant effects on sleep, anxiety, strength, force control, immune function, cognition and overall well-being [10,11,15,30-32].

Our between-group differences reflect small (ODI) to moderate (VAS) but clinically and statistically significant effects of the VDTQM program. These findings are consistent with the conclusions of a 2017 review [5], which found the effects of nonpharmacological intervention on back pain are small in pain related disability (ODI 5-10), and moderate in pain intensity (VAS 1-2). These conclusions are also in line with the system used in a review by the American College of Physicians and American Pain Society [33,34]. Two prior studies of adults [16] and retired athletes [17] with LBP exclusively included movements in their curriculum and found that tai chi reduced pain compared to control groups; Hall et al. [16] additionally reported moderate improvement in disability. One qigong study of office workers with LBP [18] focused on meditative stillness (standing and sitting) during the treatment and found it led to greater pain relief and improved disability compared to the control. The VDTQM participants demonstrated clinically significant short-term improvement in both pain and pain-related disability. A distinctive feature of our study was the focus on integrating both movement and stillness within the treatment. It was also delivered online, setting it apart from the previous studies.

Our study had limitations. First, the participants were primarily from the New York Metropolitan area and were recruited based on participation in a webinar and wellness program. All major US ethnic groups were represented with a moderate degree of over-representation of Non-Hispanic Whites and a significant over-representation of college educated individuals. Female participants outnumbered males by roughly 4:1. Only 28.5% of the treatment group participants attended 75% or more of the 24 sessions. Many participants with low adherence reported scheduling issues as the reason, and it became clear in qualitative interviews that it was not made clear enough to the participants that the sessions would be held twice (rather than once) weekly. In future studies, the research team needs to clarify the schedule of the treatment beyond email communication. Due to low adherence, there was missing data at all time points. It is possible that those who dropped out of the study experienced less improvement in their outcomes compared to those who completed the program, which could potentially make the treatment appear more effective than it truly was. However, we believe that this bias may be limited, as most participants who provided reasons for dropping out cited scheduling conflicts rather than a lack of motivation or perceived effectiveness of the treatment. Nevertheless, we cannot be certain about the reasons for dropout among those who did not provide feedback. LMMs yield unbiased results if data are MAR – that is, the missingness is independent of unobserved measurements [35]. Although sensitivity analysis suggested our data are MAR, this is ultimately impossible to determine. Readers can find multiple imputation procedures and results in section 4 of Supplementary 2 and sensitivity analysis procedures and results in section 5 of Supplementary 2. There is no consensus among statistical experts regarding how to define and conduct ITT of longitudinal randomized control trial data with missing

values. Various strategies such as complete-case analysis and multiple imputation have been proposed and implemented [36]. We chose to include all available observations in our models, with participants analyzed within their assigned randomization group regardless of compliance or loss to follow up. As Detry and Ma explain [35], LMMs produce relatively unbiased estimates of treatment effects in the presence of MAR data “and additional methods for handling missing data, such as multiple imputation, are generally not required.” Pain medication use was not captured in this study and should be included in future investigations. Outcome measures were collected for 1 month post treatment. Future investigations should follow participant outcomes for a longer period after treatment concludes to understand whether the short-term improvements were limited to temporary syndrome relief. Finally, given the nature of the study, it was impossible to blind participants to group membership; however, the data analyst should be blinded in future research. We did not directly compare the effects of VDTQM to those of other evidence-based nonpharmacologic treatments. Although there are examples of other nonpharmacologic and tai chi studies which use waitlist controls [5] and the utilization of inactive controls is a common practice in behavioral interventions [37], it would be informative to include a comparison treatment that facilitates an expectation of improvement. Future investigations should include a comparison treatment in addition to a waitlist control group, as well as including an activity for the control group to create a similar expectation of improvement. In general, tai chi/qigong programs used in research are highly heterogeneous in terms of curriculum composition and instructor qualification which are essential for the quality and efficacy of the research [38]. The VDTQM program has demonstrated positive effects on various health outcomes in several controlled trials [10,11,30–32]. In addition, a sample class video is provided in the supplemental materials to allow other researchers to replicate the study. The instructor is a master teacher of traditional tai chi and qigong with a PhD in Kinesiology.

The growing prevalence of LBP places a burden on individuals, society, and the healthcare system [2]. This safe, adaptable, low-cost, and scalable treatment can help surmount common barriers to timely care for LBP: absence of facilities, scheduling problems, costs, and the like [3,39]. A VDTQM program could be an important nonpharmacologic resource for LBP treatment, potentially helping ease the burden on the healthcare system and expanding access to timely care, especially to people in underserved areas [8,40]. By focusing on both physical and mental modalities, VDTQM was designed with an aim to alter how individuals perceive and manage their LBP, with the goal of increasing functionality and overall well-being.

## Conclusions

A 12-week virtually delivered integrated tai chi, qigong, and meditation program resulted in small to moderate improvement in pain-related disability, pain intensity, QOL and sleep quality in adults with LBP. Improvements in all outcomes were sustained for at least 1 month after the conclusion of the treatment. The results of our study indicate that VDTQM may be a viable treatment option for patients with LBP.

## Role of the funder/sponsors

Funding came from Qi Balance LLC. The curriculum was designed and taught by Dr Y. Yang, and is based on Chen Style Tai Chi and Hunyuan Qigong. The scientific design of the study was done by Dr Knapp, Dr Hartl, Dr Sheeler, Dr L. Yang, Dr Stovitz, Dr Krieger, Dr Singh, Dr Mehta, Dr Weaver, Dr Jia, Dr Verkuilen, Dr Schlagal, DeCelle, and Dr Y. Yang. Dr Knapp was responsible for the submission of the IRB at New York Medical College. The data collection was done at New York Medical College by Dr Knapp, PhD candidates Ayar, and Abduljawad. Data analysis was done by Dr McCluskey. All authors contributed to the writing and editing of the manuscript and approved the final version.

## Disclaimer

The content is solely the responsibility of the authors and does not necessarily represent the official views of the Center for Taiji and Qigong Studies and Qi Balance LLC.

## Declaration of competing interests

Funding came from Qi Balance LLC. The curriculum was designed and taught by Dr Y. Yang, and is based on Chen Style Tai Chi and Hunyuan Qigong. Dr Y. Yang is the director of both Qi Balance LLC which funded the study, and the Center for Taiji and Qigong Studies, a not for profit 501(c)(3) organization with a focus on researching the health benefits of Chinese healing and martial arts. Dr Y. Yang teaches tai chi/qigong for a living but received no remuneration for designing and teaching the tai chi/qigong exercises reported herein; he is the author of the book *Taijiquan: The Art of Nurturing, the Science of Power*, and tai chi/qigong instructional videos, reports professional fees for teaching tai chi/qigong for a cancer research project at University of Oakland and a cancer research project at University of Calgary, honorarium from Andrew Weil Center for Integrative Medicine for lecturing, teaching fee from Kripalu Center for Yoga and Health outside the submitted work; Dr. Schlagal reports professional fees for teaching tai chi/qigong for cancer research at University of Calgary outside the submitted work. The authors report no other conflicts of interest.

## CRediT authorship contribution statement

**Yang Yang:** Conceptualization, Methodology, Investigation, Resources, Writing – original draft, Writing – review & editing, Supervision, Project administration, Funding acquisition. **Sydne McCluskey:** Methodology, Validation, Formal analysis, Investigation, Resources, Writing – original draft, Writing – review & editing, Visualization. **Mohamad Bydon:** Methodology, Validation, Formal analysis, Investigation, Writing – review & editing. **Jaspal Ricky Singh:** Conceptualization, Investigation, Resources, Writing – review & editing. **Robert D. Sheeler:** Conceptualization, Methodology, Investigation, Resources, Writing – original draft, Writing – review & editing, Supervision. **Karim Rizwan Nathani:** Methodology, Validation, Formal analysis, Investigation, Writing – review & editing. **Ana C. Krieger:** Conceptualization, Methodology, Investigation, Writing – original draft, Writing – review & editing. **Neel D. Mehta:** Conceptualization, Investigation, Resources, Writing – review & editing. **Joshua Weaver:** Conceptualization, Investigation, Resources, Writing – review & editing. **Libin Jia:** Conceptualization, Methodology, Investigation, Writing – review & editing, Supervision. **Sharon DeCelle:** Conceptualization, Methodology, Investigation, Resources, Writing – review & editing, Supervision. **Robert C. Schlagal:** Conceptualization, Methodology, Investigation, Resources, Writing – original draft, Writing – review & editing. **Jay Ayar:** Investigation, Resources, Data curation, Writing – review & editing, Project administration. **Sahar Abduljawad:** Investigation, Resources, Data curation, Writing – review & editing, Project administration. **Steven D. Stovitz:** Conceptualization, Methodology, Investigation, Resources, Writing – review & editing, Supervision. **Ravindra Ganesh:** Validation, Investigation, Writing – review & editing. **Jay Verkuilen:** Methodology, Validation, Formal analysis, Investigation, Resources, Writing – review & editing, Visualization, Supervision. **Kenneth A. Knapp:** Conceptualization, Methodology, Validation, Formal analysis, Investigation, Resources, Data curation, Writing – original draft, Writing – review & editing, Supervision, Project administration. **Lin Yang:** Conceptualization, Methodology, Validation, Investigation, Writing – original draft, Writing – review & editing. **Roger Härtl:** Conceptualization, Methodology, Investigation, Resources, Writing – review & editing, Supervision, Project administration.

## Acknowledgments

We acknowledge: Stephen Kaufman, PhD, Professor Emeritus at University of Illinois at Urbana-Champaign for insightful guidance on the study concept and design, and his critical revision of this manuscript, the assistance of Ian Shrier, MD, PhD who provided valuable insights on an early version of this manuscript, Karen Caldwell, PhD for reviewing the manuscript critically. We thank the participants in the study, all of the physicians and therapists who recruited participants, and the research coordinating team from the Center for Taiji and Qigong Studies.

## Supplementary materials

Supplementary material associated with this article can be found, in the online version, at [doi:10.1016/j.xnsj.2024.100557](https://doi.org/10.1016/j.xnsj.2024.100557).

## References

- [1] Knezevic NN, Candido KD, Vlaeyen JWS, Zundert JV, Cohen SP. Low back pain. *The Lancet* 2021;398(10294):78–92.
- [2] Ferreira ML, de Luca K, Haile LM, et al. Global, regional, and national burden of low back pain, 1990–2020, its attributable risk factors, and projections to 2050: a systematic analysis of the Global Burden of Disease Study 2021. *The Lancet Rheumatol* 2023;5(6):e316–29.
- [3] Murray CJL, Atkinson C, Bhalla K, et al. The state of US health, 1990–2010: burden of diseases, injuries, and risk factors. *JAMA* 2013;310(6):591–608.
- [4] Ashar YK, Gordon A, Schubiner H, et al. Effect of pain reprocessing therapy vs placebo and usual care for patients with chronic back pain: a randomized clinical trial. *JAMA Psychiatry* 2022;79(1):13–23.
- [5] Chou R, Deyo R, Friedly J, et al. Nonpharmacologic therapies for low back pain: a systematic review for an American College of Physicians Clinical Practice Guideline. *Ann Intern Med* 2017;166(7):493–505.
- [6] Qaseem A, Wilt TJ, McLean RM, et al. Noninvasive treatments for acute, subacute, and chronic low back pain: a clinical practice guideline from the American College of Physicians. *Ann Intern Med* 2017;166(7):514–30.
- [7] Carvalho E, Bettger JP, Goode AP. Insurance coverage, costs, and barriers to care for outpatient musculoskeletal therapy and rehabilitation services. *N C Med J* 2017;78(5):312–14.
- [8] Cui D, Janela D, Costa F, et al. Randomized-controlled trial assessing a digital care program versus conventional physiotherapy for chronic low back pain. *npj Digit Med* 2023;6(1):1–10.
- [9] Seron P, Oliveros MJ, Gutierrez-Arias R, et al. Effectiveness of telerehabilitation in physical therapy: a rapid overview. *Phys Ther* 2021;101(6):pzab053.
- [10] Caldwell KL, Bergman SM, Collier SR, et al. Effects of Tai Chi Chuan on anxiety and sleep quality in young adults: lessons from a randomized controlled feasibility study. *Nat Sci Sleep* 2016;8:305–14.
- [11] Yang Y, Verkuilen J, Rosengren KS, et al. Effects of a Taiji and Qigong intervention on the antibody response to influenza vaccine in older adults. *Am J Chin Med* 2007;35(4):597–607.
- [12] Li F, Harmer P, Fitzgerald K, et al. Effectiveness of a therapeutic Tai Ji Quan intervention vs a multimodal exercise intervention to prevent falls among older adults at high risk of falling: a randomized clinical trial. *JAMA Intern Med* 2018;178(10):1301–10. doi:10.1001/jamainternmed.2018.3915.
- [13] Yeh GY, McCarthy EP, Wayne PM, et al. Tai chi exercise in patients with chronic heart failure: a randomized clinical trial. *Arch Intern Med* 2011;171(8):750–7.
- [14] Yang Y, Decelle S, Reed M, Rosengren K, Schlagal R, Greene J. Subjective experiences of older adults practicing taiji and qigong. *J Aging Res* 2011;2011:650210.
- [15] Li X, Chang P, Wu M, et al. Effect of tai chi vs aerobic exercise on blood pressure in patients with prehypertension: a randomized clinical trial. *JAMA Netw Open* 2024;7(2):e2354937.
- [16] Hall AM, Maher CG, Lam P, Ferreira M, Latimer J. Tai chi exercise for treatment of pain and disability in people with persistent low back pain: a randomized controlled trial. *Arthritis Care Res (Hoboken)* 2011;63(11):1576–83.
- [17] Weifen-Wu WW, Muheremu A, Chaohui C, MD L, Lei S. Effectiveness of Tai Chi practice for non-specific chronic low back pain on retired athletes: a randomized controlled study. *J Musculoskel Pain* 2013;21:37–45.
- [18] Phattharasupharkerk S, Purepong N, Eksakulkla S, Siriphorn A. Effects of Qigong practice in office workers with chronic non-specific low back pain: a randomized control trial. *J Bodyw Mov Ther* 2019;23(2):375–81.
- [19] Yang Y. *Taijiquan: the art of nurturing, the science of power*. Champaign, IL: Zhenwu Press; 2005.
- [20] StataCorp Stata Statistical Software: release 17. College Station, TX: StataCorp LLC; 2021.
- [21] Fairbank JC, Couper J, Davies JB, O'Brien JP. The Oswestry low back pain disability questionnaire. *Physiotherapy* 1980;66(8):271–3.
- [22] Haynes MH, Patterson DG. Experimental development of the graphic rating method. *Psychol Bulletin* 1921;18:98–9.
- [23] Buysse DJ, Reynolds CF, Monk TH, Berman SR, Kupfer DJ. The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. *Psychiatry Res* 1989;28(2):193–213.
- [24] Longo UG, Berton A, De Salvatore S, et al. Minimal clinically important difference and patient acceptable symptom state for the Pittsburgh Sleep Quality Index in patients who underwent rotator cuff tear repair. *Int J Environ Res Public Health* 2021;18(16):8666.
- [25] Ware JE, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. *Med Care* 1992;30(6):473–83.
- [26] Ogura Y, Ogura K, Kobayashi Y, et al. Minimum clinically important difference of major patient-reported outcome measures in patients undergoing decompression surgery for lumbar spinal stenosis. *Clin Neurol Neurosurg* 2020;196:105966.
- [27] R Core Team. *R: A Language and Environment for Statistical Computing*. Published online; 2021. <https://www.R-project.org/>. Accessed June 1, 2023.
- [28] Pinheiro J, Bates D, and R Core Team, *nlme: Linear and Nonlinear Mixed Effects Models*, 2023. Published online <https://CRAN.R-project.org/package=nlme>. Accessed June 1, 2023.
- [29] Muthen LK, Muthen B. *Mplus version 8 user's guide*. Los Angeles, CA: Muthen & Muthen; 2017.
- [30] Yang Y, Verkuilen JV, Rosengren KS, Grubisich SA, Reed MR, Hsiao-Weckler ET. Effect of combined Taiji and Qigong training on balance mechanisms: a randomized controlled trial of older adults. *Med Sci Monit* 2007;13(8):CR339–48.
- [31] Christou EA, Yang Y, Rosengren KS. Taiji training improves knee extensor strength and force control in older adults. *J Gerontol A Biol Sci Med Sci* 2003;58(8):763–6.
- [32] Burgener SC, Yang Y, Gilbert R, Marsh-Yant S. The effects of a multimodal intervention on outcomes of persons with early-stage dementia. *Am J Alzheimers Dis Other Demen* 2008;23(4):382–94.
- [33] Chou R, Qaseem A, Snow V, et al. Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society. *Ann Intern Med* 2007;147(7):478–91.
- [34] Ostelo RW, Deyo RA, Stratford P, et al. Interpreting change scores for pain and functional status in low back pain: towards international consensus regarding minimal important change. *Spine (Phila Pa 1976)*. 2008;33(1):90–94.
- [35] Detry MA, Ma Y. Analyzing repeated measurements using mixed models. *JAMA* 2016;315(4):407–8.
- [36] Baraldi AN, Enders CK. An introduction to modern missing data analyses. *J School Psychol* 2010;48(1):5–37.
- [37] Tock WL, Maheu C, Johnson NA. Considerations of control conditions designs in randomized controlled trials of exercise interventions for cancer survivors. *Can J Nurs Res* 2022;54(4):377–91.
- [38] Yang GY, Sabag A, Hao WL, et al. Tai Chi for Health and well-being: a bibliometric analysis of published clinical studies between 2010 and 2020. *Complement Ther Med* 2021;60:102748.
- [39] Foster NE. Barriers and progress in the treatment of low back pain. *BMC Medicine* 2011;9(1):108.
- [40] Greco CM, Gaylord SA, Faurot K, et al. The design and methods of the OPTIMUM study: a multisite pragmatic randomized clinical trial of a telehealth group mindfulness program for persons with chronic low back pain. *Contemp Clin Trials* 2021;109:106545.
- [41] Yang Y, Caldwell K, Schlagal R, et al. No pain, more gain: Subjective responses to a t'ai chi and qigong program for back pain. Submitted for publication. 2024.