Original Paper

Retracted: Effects of Tai Chi on Cognitive Function in Older Adults With Type 2 Diabetes Mellitus: Randomized Controlled Trial Using Wearable Devices in a Mobile Health Model

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Abstract

Background: Telemedicine is an effective and promising strategy, especially for the initial stages of a home-based therapeutic exercise program.

Objective: The objectives of this study were 2-fold: first, to assess whether Tai Chi practice combined with wearable device-based monitoring improves cognitive function in this population, and second, to explore the underlying mechanisms for any improvements observed, including changes in physical activity levels and sleep patterns.

Methods: The study was a randomized controlled trial in which participants were randomized (1:1:1) to receive usual care, fitness walking, or Tai Chi exercise. All indicators were assessed at baseline and 12-week follow-up. The usual care includes traditional diabetes education. Participants in the fitness walking group performed walking exercises on a treadmill under the supervision of a researcher 3 times a week for 12 weeks. Participants in the Tai Chi group practiced 24-style Simplified Tai Chi through live video streaming under the guidance of professors and professionals. In this 12-week program, participants underwent continuous glucose monitoring (CGM) using Guardian Sensors 3, CGM sensors attached to the upper arm. All participants carried bracelets to record their heart rate, sleep parameters, and steps. The primary outcome was the Montreal Cognitive Assessment (MoCA) at 12 weeks. Secondary outcomes included other cognitive subdomain tests and blood metabolic indices. The MoCA is a tool designed for rapid screening for mild cognitive impairment (MCI) and early dementia, with the core advantage of being more sensitive to early cognitive problems. The MoCA has a total score of 30. Lower scores may indicate the presence of cognitive dysfunction.

Results: After 12 weeks of intervention, the Tai Chi exercise group showed a significant improvement in MoCA scores from baseline (mean difference 23.83, 95% CI 17.79-25.66 vs 21.42, 95% CI 17.11-24.74; *P*=.03). The fitness walking exercise group showed an improvement in MoCA scores (22.94, 95% CI 18.05-23.98 vs 21.58, 95% CI 17.35-24.12*; P*.08), but this did not reach statistical significance. Furthermore, there was a statistical difference in the improvement of MoCA scores between the Tai Chi and fitness walking groups (2.65, 95% CI 0.34-4.41 vs 1.44, 95% CI 0.89-2.87; *P*<.05). The usual care group showed the least change in score at both points (0.23, 95% CI –0.02 to 1.39; *P*=.83). Compared with the MQ in the fitness walking group (91.93, 95% CI 77.83-97.47) vs 88.62, 95% CI 77.14-95.84; *P*=.45), Trail Making Test Part B (TMT-B) (220.81, 95% CI 210.03-233.49 vs 223.66, 95% CI 215.04-230.27; *P*=.33), the Tai Chi group was more effective in improving the MQ (99.23, 95% CI 80.55-107.69 vs 89.23, 95% CI 78.16-96.08; *P*=.001), TMT-B (207.33, 95% CI 200.26-220.82 vs 225.58, 95% CI 214.12-234.94; *P*=.001) scores, and there were significant differences between the two groups.

Conclusions: In summary, this study demonstrated that web-based exercise therapy for patients may enhance the effectiveness of exercise therapy in improving cognitive function among older individuals with type 2 diabetes mellitus. Tai Chi has significant advantages in improving cognitive function and sleep quality, while fitness walking, although also beneficial, is relatively weak in these areas.

Trial Registration: Chinese Clinical Trial Registry ChiCTR2200057863; https://www.chictr.org.cn/showproj.html?proj=159792

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Keywords: type 2 diabetes mellitus ; T2DM; 24-style Tai Chi; fitness walking; mHealth model; Montreal Cognitive Assessment (MoCA)

Introduction

Older patients with type 2 diabetes mellitus (T2DM) often suffer from cognitive decline, and some researchers have reported cognitive dysfunction in patients with diabetes [1]. As many as 60% of T2DM patients suffer from cognitive decline, which can lead to reduced quality of life, increased risk of dementia, and higher health care costs [2,3]. Considering these issues, it has become imperative to identify effective interventions to mitigate cognitive decline in this population.

It is well-documented that exercise can have both immediate and long-term effects on diabetes management [4]. The American College of Sports Medicine states that regular physical activity may have a positive impact on the psychological state and cognitive abilities of people with T2DM [4]. Tai Chi, characterized by slow, deliberate, and mentally focused movements, has been shown to improve physical performance, enhance balance, and reduce stress [5]. Importantly, Tai Chi also incorporates elements of cognitive engagement and social interaction, which may collectively contribute to the positive effects of Tai Chi on brain health [6]. However, it is rather challenging to select the optimal program from the available evidence-based cognitive interventions due to the considerable lack of relevant comparative effectiveness studies, especially for remote interventions.

The emergence of mobile health (mHealth) technologies, particularly wearable devices, presents new opportunities for more effective monitoring and management of chronic diseases, such as T2DM [7]. By integrating these devices into health care interventions, researchers and practitioners can collect real-time data on patient health parameters, enabling more personalized and data-driven health care.

With this in mind, we designed a randomized controlled trial (RCT) to investigate the effects of Tai Chi and walking on cognitive function in older adults with T2DM using wearable devices within a mobile healthcare model. The objectives of this study were twofold: first, to assess whether Tai Chi practice combined with wearable device-based monitoring improves cognitive function in this population, and second, to explore the underlying mechanisms for any improvements observed, including changes in physical activity levels and sleep patterns.

Methods

Study Design

The study was an RCT in which participants were randomized (1:1:1) to receive usual care, fitness walking, or Tai Chi exercise. All indicators were assessed at baseline and 12-week follow-up.

All participants signed an informed consent form, and the Institutional Review Boards of all participating institutions approved the study (IRB-AF37-V1.0). The study was registered on the Chinese Clinical Trial Register, ChiCTR2200057863 (March 19, 2022).

Participants

Participants were recruited from diabetic patients admitted to our hospital between January 2024 and March 2024. Textbox 1 lists the inclusion and exclusion criteria. The criteria for withdrawal are as follows: (1) loss of visits; (2) occurrence of a serious adverse event; (3) inability to adhere to the intervention medication as required by the trial.

Textbox 1. Inclusion and exclusion criteria.

Inclusion criteria
- Diagnosis of type 2 diabetes mellitus.
- HbA_{1c} 6.5%.
- Aged 60 years or older.
- The presence of mild cognitive impairment without dementia.
- Presence of type 2 diabetes mellitus lasting between 1 and 5 years.
- Informed consent and voluntary participation.

Exclusion criteria
- Amputations.

- Plantar injuries.
- Severe retinopathy.
- Dialysis.
- Malignant hypertension or history of falls and gait instability.

The following exclusion criteria were used: amputations, plantar injuries, severe retinopathy, dialysis, malignant hypertension, or history of falls and gait instability.

The criteria for withdrawal are as follows: (1) loss of visits; (2) occurrence of a serious adverse event; (3) inability to adhere to the intervention medication as required by the trial.

Acceptability

The acceptability of the intervention was evaluated using 2 primary metrics: adherence rate and participant satisfaction. Adherence was defined as completing ≥80% of scheduled group exercise sessions and submitting all end-of-study outcome measures. Satisfaction was assessed through a questionnaire administered after the study program, which covered participants' experiences and perceptions of the program. In addition, staff members called participants weekly to record their daily information and also encouraged them to continue exercising.

Calculation of Sample Size

Sample size calculations were performed using the G*Power program [8] and assumed a 0.5% difference in the elevated MoCA score. This assumption was based on the results of a previous randomized controlled trial examining the effects of Tai Chi on cognitive function in elderly patients [9]. This study found that at 36 weeks, the Tai Chi group had improved MoCA scores compared with the fitness walking group (mean [10], 24.67 [SD 2.72] vs 23.84 [SD 3.17]; between-group mean difference, 0.84 [95% CI 0.02-1.66]; P=.046). The amount of change at each time point, the difference between groups, and their 95% CI were calculated. The effect size within the F test family was set at 0.4.

Given a margin of error (d) of 0.27% and 95% CI, the study was designed with a hypothesized effect size of 0.55. A one-sided test was conducted at a significant level of 2.5%. To achieve a statistical power of 0.8 and detect a significant effect, a sample size of 50 participants was required for each group, resulting in a minimum total sample size of 150 participants. In addition, an anticipated attrition rate of 23% was factored into the planning.

Randomization and Blinding

After the baseline assessment, patients were randomized into 3 groups (usual care, fitness walking, and Tai Chi exercise groups). Patient grouping was determined by randomization of groups using a random allocation table combined with variable group size. Envelopes were prepared according to the randomized assignment table by an independent researcher not directly associated with the trial, and the assignment information was sealed in opaque envelopes. The envelopes were numbered and labeled in the order generated by the randomization table and then distributed to patients eligible for enrollment in the established order using an interactive voice response system.

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In exercise-intervention studies, it's impractical to implement blinding for the participants themselves since they are actively participating in physical activities. However, the study took steps to minimize potential biases by keeping the outcome evaluators and data analysts unaware of the group assignments. Once the statistical analyses were finalized, the researchers lifted the blinding.

Experimental Protocol and Interventions

The usual care includes traditional diabetes education. Education for this population included a proper diet, monitoring of blood glucose levels, and prevention of complications. The usual care group participants did not receive exercise interventions and maintained their original lifestyles. Participants in the fitness walking group performed walking exercises on a treadmill under the supervision of a researcher three times a week for 12 weeks. Each training session lasts 1 hour. Participants in the Tai Chi group practiced 24-style Simplified Tai Chi through live video streaming under the guidance of professors and professionals. Two professional Tai Chi instructors teach all 24-style Simplified Tai Chi movements via remote video. Participants practiced 24-style Simplified Tai Chi 3 times a week for 30 minutes, which included 5 minutes of warm-up and cool-down activities before and after each session. The 24-style Simplified Tai Chi consists of 24 movements, which are more refined and standardized than traditional routines and can fully reflect the movement characteristics of Tai Chi [11]. Tai Chi is a mind-body workout designed to integrate musculoskeletal, sensory, and cognitive systems. It focuses on controlled, self-initiated movement and synchronized breathing, encompassing movement patterns such as weight shifting, weight-bearing and lifting, trunk and pelvic rotation, and eye-hand coordination movements [12]. To control attendance, staff registered and monitored the training diaries of both groups of trainees.

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The exercise intensity of the 2 intervention measures was comparable and aligned with the World Health Organization (WHO) definition of moderate-intensity physical activity, which is defined as 3.0-5.9 metabolic equivalents (METs; 1 MET=resting metabolic rate during quiet sitting). A previous study using direct calorimetry to measure metabolic expenditure reported that Tai Chi has an intensity of 3.24 METs, placing it within the moderate-intensity range [13]. The exercise intensity of the fitness walking group was in the range of 3.3-5.5 METs, according to the Compendium of Physical Activities [14]. To monitor exercise intensity, we used heart rate (HR) as a key indicator. The target HR zone was set at 65%-75% of maximum heart rate (HR), calculated using the formula: Maximum HR=220−age.

In this 12-week program study, participants underwent continuous glucose monitoring (CGM) using Guardian Sensors 3, which are CGM sensors attached to the upper arm. All participants wore bracelets to record their heart rate, sleep parameters, and steps. Sleep parameters include the following data: total sleep time (the number of minutes slept between bedtime and wake time), sleep efficiency (the percentage of time spent asleep while in bed), and wake after sleep onset (the number of minutes awake between sleep onset and wake time).

Follow-Up

All indicators were assessed at baseline and 12 weeks of follow-up. Participants may request that the trial be discontinued. The trial should also be discontinued if the participant does not meet the study's requirements.

Outcomes

The primary outcome was the Montreal Cognitive Assessment (MoCA) administered at 12 weeks [15]. The Montreal Cognitive Assessment Scale has a total score of 30. Lower scores may indicate the presence of cognitive dysfunction. Secondary outcomes included other cognitive subdomain tests and blood metabolic indices. Cognitive subdomain tests included the Wechsler Memory Quotient (MQ), Digit Symbol Substitution Test (DSST), Trail Making Test Part B (TMT-B), Boston Naming Test (BNT), and Ray Complex Figure Test (ROCF), fasting blood glucose (FBG), HOMA-IR, and HbA_{1c}, the time in range (TIR) measured by CGM, and sleep parameters. Sleep quality and quantity were assessed using the Pittsburgh Sleep Quality Index (PSQI) scale and a sleep monitoring bracelet. The PSQI is a widely used and well-validated instrument for assessing sleep quality [16]. The self-rate questionnaire evaluates sleep quality and patterns. The 36-item Short Form Health Survey (SF-36) was used to measure health-related quality of life [17]. The blood samples were sent to our laboratory within 30 minutes for uniform testing and analysis using a fully automated biochemistry analyzer (BECKMAN COULTER AU5800).

All blood samples were collected after 12 hours of fasting and allowed to clot for 1-2 hours at room temperature. 1 to 1.5 mL of venous blood specimens are collected in vacuum tubes containing sodium fluoride for measuring plasma glucose, lipids, and HbA_{1c}. The insulin resistance (HOMA-IR) index was calculated as HOMA-IR=fasting insulin×fasting plasma glucose/22.5.

Statistical Analysis

We used SPSS 25.0 statistical software to analyze the collected data. For continuous data, we used mean (x) and standard deviation (s) to describe the data. Results were evaluated based on two datasets: intention-to-treat (ITT) and per-protocol set (PPS). All participants who completed the study and adhered to the protocol without major violations were included in the per-protocol set (PPS). The primary confirmatory analysis was based on the ITT (intention-to-treat) principle, which included all randomized patients with baseline data for the reported variable. The PPS dataset comprises patients who reached the study's final endpoint and strictly adhered to the trial protocol with no major deviations. According to the ITT analysis principle, all participants in the trial were maintained in their initially assigned treatment groups, and a sensitivity analysis was conducted to further validate the study results.

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To assess the robustness of the study findings, a sensitivity analysis was conducted. This involved assigning a negative outcome to participant attrition in the intervention arms and the best outcome to participant attrition in the control arm. The analysis was then repeated, with the outcomes reversed. The results of the sensitivity analysis were compared with the original analysis to evaluate the likely impact of participant attrition and to provide an unbiased estimate of the actual effect of the intervention.

Missing data were imputed using multiple imputation (based on the random forest algorithm, incorporating age, gender, baseline MoCA, and generating 50 datasets). Iterative trajectories showed that the model converged after 200 iterations (R-hat <1.1). The density plots of interpolated values align with observed values, and the intervention effect sizes across different interpolated datasets range from 1.4 to 1.7 (median =1.5), supporting the robustness of the results.

Primary and secondary outcomes were analyzed according to the ITT principle. To compare differences between multiple sets of data, we used the statistical method of analysis of covariance (ANCOVA). In this analysis, change from baseline became our dependent variable of interest. At the same time, group, visit time, and the interaction of group and visit time (ie, group×visittime) were set as independent influences. We used the Tukey test for between-group difference analysis. A one-way ANOVA model was used to assess continuity results.

We repeated the primary and secondary analyses (1) restricting the intervention group to participants who received the exercise intervention, which was self-reported by participants, (2) restricting the three cohorts to participants who were successfully followed up, and (3) estimating missing outcome data using multiple imputations.

For each primary and secondary endpoint, we ran a series of log-binomial regression models, incorporating two-way interactions between group, baseline MoCA scores, gender, age, and education. A post hoc subgroup analysis was conducted to further assess the effects of an exercise intervention on cognitive function in older adults with T2DM. The effect sizes were computed using Cohen d with the aid of the emmeans package. In line with the widely accepted standard for categorizing the magnitudes of effect sizes, a small effect is defined as d=0.2, a medium effect as d=0.5, and a large effect as d≥0.8.

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For sample size estimation, we assume a moderate effect size (Cohen d=0.5) for the primary outcome measure (MoCA scores). This effect size corresponds to an average between-group difference of 1.5 points, divided by the pooled SD of 2.0 points. This SD is derived from a meta-analysis of cognitive interventions in older adults [18], which reported a standard deviation range of 1.3-2.2 for MoCA scores. We considered differences to be statistically significant when the P value was less than .05, while such differences were considered significant when the P value was less than .01.

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In addition, we conducted post hoc subgroup analyses, stratified by sex, age (dichotomized as ≤67 or >67 years old based on the median age of the sample), educational level, BMI, disease duration, HbA_{1C}, and the number of comorbidities, to investigate potential differences among subgroups. Categorical variables were described using numbers and percentages and analyzed using the Fisher exact test.

Ethical Considerations

The research was conducted by the principles outlined in the Declaration of Helsinki. The Ethics Committee of Shanghai Yangpu District Shidong Hospital approved the study protocol. All participants signed an informed consent form, and the Institutional Review Boards of all participating institutions approved the study (IRB-AF37-V1.0). The study was registered on the Chinese Clinical Trial Register, number ChiCTR2200057863 (March 19, 2022). All subjects who fulfill the conditions of participation have voluntarily submitted individual written informed consent documents indicating that they voluntarily join this research project. During the study, participants' private information was strictly protected, and all personally identifiable data were deidentified. There was no monetary compensation provided.

Results

Baseline Characteristics of Participants

The flow of participants is illustrated in Figure 1. Initially, 203 individuals were evaluated at baseline, of whom 162 fulfilled the inclusion criteria and consented to participate in the study. These participants were then randomly assigned in a 1:1:1 ratio to three groups: usual care, fitness walking exercise, and Tai Chi exercise. In the usual care group, one participant refused to cooperate, one lost interest, and one became unreachable, resulting in their withdrawal from the study. Two participants in the fitness walking exercise group exhibited poor compliance, and 2 lost interest, resulting in their dropout. In the Tai Chi group, 1 participant showed poor compliance, and another refused to continue, resulting in their withdrawal. Ultimately, the trial was completed by 51 participants in the usual care group, 50 in the fitness walking exercise, and 52 in the Tai Chi exercise group. These participants were included in the subsequent analysis. As demonstrated in Table 1, all baseline indicators were comparable among the 3 groups, with no significant differences observed. "Poor compliance" was defined as refusing to wear an electronic wearable device or receiving fewer than 3 of the 12 scheduled telephone follow-up visits.

Figure 1. Flow diagram of the study participants.

PPS: per-protocol set . ITT: intention-to-treat

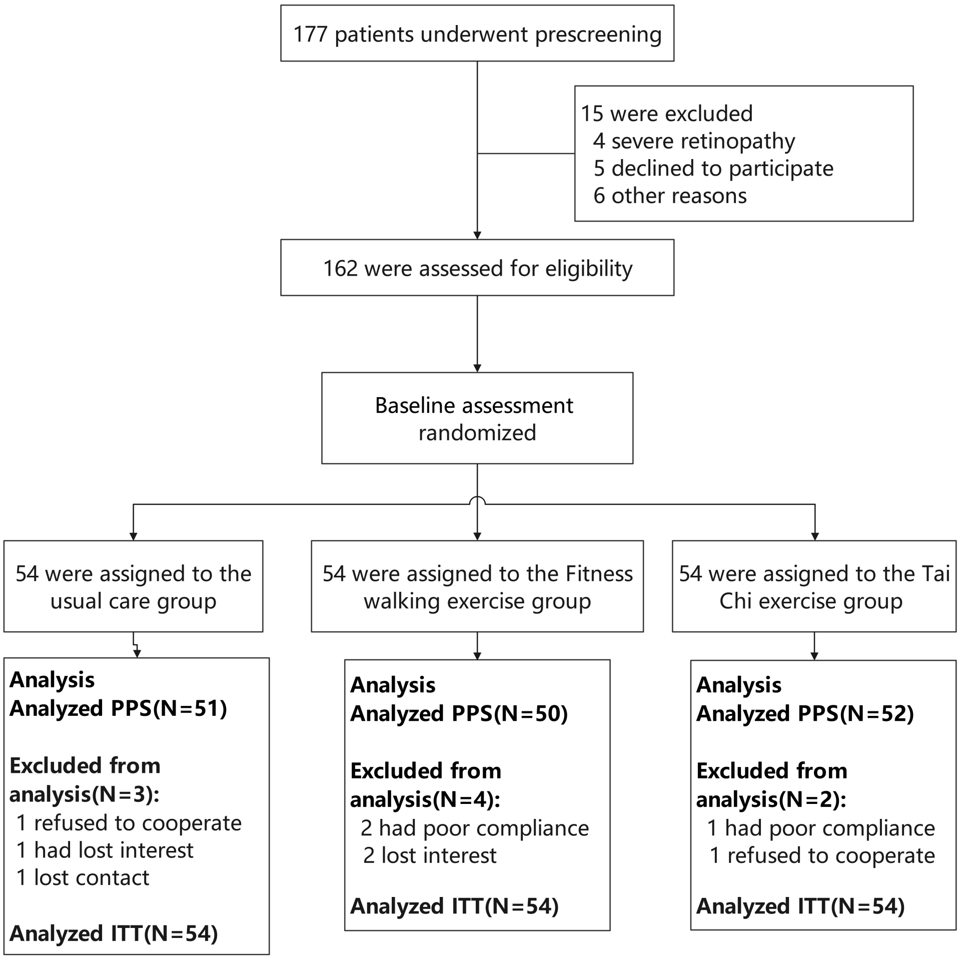


Table 1. Baseline characteristics of the participants. Data are presented as mean (SD).

Characteristic	Usual care (n=54)	Fitness walking exercise (n=54)	Tai Chi exercise (n=54)
Age (years), mean (SD)	64 (7)	65 (8)	66 (5)
Sex, n (%)			
Male	25 (49)	24 (48)	26 (50)
Female	26 (51)	26 (52)	26 (40)
Smoking status (smoker), n (%)	15 (29)	14 (28)	16 (31)
Educational background, n			
Compulsory school	10	9	11
High school	31	33	31
Higher education	10	8	10

In this study, the distribution of education levels among the 3 groups of participants showed some similarity, with those with high school education predominating, followed by those who had received compulsory education and those with higher education. Although the specific distribution of educational levels among the groups did not show statistically significant differences, educational level, as an important factor affecting cognitive reserve and cognitive function, may still have a potential impact on cognitive outcomes in subsequent research.

Gender distribution is likewise another important factor that may affect cognitive outcomes. In this study, the gender distribution of participants across the 3 groups was roughly balanced, with slightly more female participants than males; however, the differences in gender ratios among the groups were not statistically significant. Nonetheless, gender differences in cognitive functioning are a point of research interest. It has been demonstrated that there may be some differences in cognitive functions between males and females, which may involve memory, attention, language ability, and other aspects [19].

Primary Outcomes

The strengths of the Tai Chi exercise group can be demonstrated through a responder analysis that determined the percentage of participants who met the intended treatment goals with statistically significant (P<.05) MoCA scores (Table 2).

The primary analysis, which compared the 2 exercise treatments with the usual care group at posttreatment using the data set with multiple imputed data, showed that the Tai Chi exercise group was superior to the usual care group and fitness walking exercise group. The adjusted differences on the MoCA were 2.65 (95% CI 0.34-4.41; P=.03) for the Tai Chi exercise group (Table 3).

Table 2. Analyses of the Primary Outcome (Montreal Cognitive Assessment scores) at 12 weeks. Differences from the baseline are expressed as mean differences and 95% confidence intervals.

Analysis (number of patients included in the analysis)	Usual care		Fitness walking exercise		Tai Chi exercise		P value (Fisher test)
	Before the intervention, mean difference (95% CI)	After 12 weeks of intervention, mean difference (95% CI)	Before the intervention, mean difference (95% CI)	After 12 weeks of intervention, mean difference (95% CI)	Before the intervention, mean difference (95% CI)	After 12 weeks of intervention, mean difference (95% CI)	
Intention-to-treat analysis of the complete cases (n=162)	22.73 (18.75-25.04)	22.96 (19.31-24.17)	21.58 (17.35-24.12)	22.94 (18.05-23.98)	21.42 (17.11-24.74)	23.83 (17.79-25.66)	.03
Per-protocol analysis (n=153)	21.80 (17.66-26.51)	21.98 (15.39-26.47)	21.51 (15.91-25.92)	22.99 (17.05-26.41)	20.84 (16.38-27.84)	24.11 (16.59-27.35)	.03

Table 3. Between-group comparison of secondary and exploratory endpoints—intention to treat population. Differences from the baseline are expressed as mean differences and 95% CIs

Measurement	Usual care, unadjusted mean (P25-P75)	Adjusted difference, (95% CI)	P value	Fitness walking exercise, unadjusted mean (P25-P75)	Adjusted difference, (95% CI)	P value	Tai Chi exercise, unadjusted mean (P25-P75)	Adjusted difference, (95% CI)	P value
MQ[a]									
Baseline	89.01 (76.05-97.22)	—	.73	88.62 (77.14-95.84)	—	.45	89.23 (78.16-96.08)	—	.001
Postintervention	90.17 (76.86-96.17)	0.92 (0.35 to 1.05)		91.93 (77.83-97.47)	3.38 (1.14 to 4.66)		99.23 (80.55-107.69)[b,c]	10.01 (6.52 to 13.93)	
Digit Symbol Substitution Test score[d]									
Baseline	28.61 (19.77-27.51)	—	.66	29.72 (18.95-27.38)	—	.033	28.56 (19.08-28.14)	—	.001
Postintervention	29.74 (20.35-33.28)	1.13 (0.72 to 1.88)		33.92 (26.06-36.26)[b]	4.20 (2.79 to 6.93)[b]		37.84 (29.12-40.55)[b]	9.31 (5.51 to 12.84)[b]	
TMT-B[e] finding									
Baseline	227.19 (219.77-234.81)	—	.51	223.66 (215.04-230.27)	—	.33	225.58 (214.12-234.94)	—	.001
Postintervention	225.19 (218.85-235.97)	–2.06 (–3.48 to 0.67)		220.81 (210.03-233.49)	–2.88 (–3.92 to 0.95)		207.33 (200.26-220.82)[b,c]	–18.62 (–24.72 to 2.51)[b,c]	
Boston Naming Test score[f]									
Baseline	22.45 (19.17-25.37)	—	.63	23.84 (19.05-26.68)	—	.03	22.61 (18.94-25.06)	—	.004
Postintervention	22.97 (18.24-25.66)	0.52 (0.01 to 1.06)		25.94 (21.36-28.19)[b]	2.10 (1.38 to 3.85)[b]		26.61 (21.13-29.08)[b]	4.00 (1.82 to 6.79)[b]	
Rey-Osterrieth Complex Figure Test[g] score									
Baseline	32.21 (26.98-38.09)	—	.65	33.65 (27.13-39.11)	—	.41	32.64 (27.17-38.15)	—	.58
Postintervention	31.78 (27.04-39.83)	–0.58 (–0.89 to 1.94)		34.98 (26.63-39.93)	1.33 (0.64 to 2.98)		34.64 (29.45-38.38)	2.00 (1.38 to 4.59)	
Rey-Osterrieth Complex Figure Test delayed recall score									

Measurement	Usual care, unadjusted mean (P25-P75)	Adjusted difference, (95% CI)	*P* value	Fitness walking exercise, unadjusted mean (P25-P75)	Adjusted difference, (95% CI)	*P* value	Tai Chi exercise, unadjusted mean (P25-P75)	Adjusted difference, (95% CI)	*P* value
Baseline	13.81 (6.99-18.12)	—	.51	14.95 (7.24-19.03)	—	.26	14.58 (6.23-18.75)	—	.03
Postintervention	13.37 (6.02-19.42)	–0.44 (–0.80 to 1.50)		15.48 (6.91-20.11)	0.58 (–0.32 to 1.39)		18.39 (7.51-24.46)[b]	3.85 (2.66 to 4.59)[b]	
FBG[h] (mmol/L)									
Baseline	7.68 (5.13-8.59)	—	.47	8.08 (5.62-8.68)	—	.02	7.99 (5.63-8.92)	—	.02
Postintervention	7.73 (5.48-8.92)	0.05 (–0.62 to 1.39)		6.02 (4.89-7.33)[b]	–2.01 (–2.69 to 1.16)[b]		6.11 (4.51-6.94)[b]	–1.88 (–2.49 to 1.92)[b]	
HbA1c[i] (%)									
Baseline	7.37 (6.55-7.98)	—	.49	7.44 (6.78-7.92)	—	.01	7.23 (6.16-7.91)	—	.02
Postintervention	7.40 (6.92-7.91)	0.03 (–0.17 to 0.11)		6.99 (6.10-7.32)[b]	–0.45 (–0.95 to 1.07)[b]		6.52 (6.33-7.05)[b]	–0.71 (–1.58 to 0.82)[b]	
HOMA-IR[j]									
Baseline	3.6 (2.5-6.2)	—	.66	3.4 (2.6-6.0)	—	.38	3.8 (2.9-6.2)	—	.49
Postintervention	3.4 (2.2-6.0)	–0.2 (–0.4 to 0.1)		3.3 (2.1-5.7)	–0.1 (–0.3 to 0.1)		3.5 (2.6-5.9)	–0.3 (–0.4 to 0.1)	
Total sleep time (min)									
Baseline	412.7 (387.3-448.8)	—	.73	409.6 (385.1-444.3)	—	.01	402.6 (380.3-440.1)	—	.001
Postintervention	422.5 (390.8-445.5)	9.8 (5.3 to 12.8)		456.2 (399.0-479.5)[b]	47.7 (33.9 to 67.3)[b]		460.1 (396.4-489.6)[b,c]	57.7 (34.8 to 73.1)[b,c]	
Sleep efficiency (%)									
Baseline	76.7 (70.4-83.3)	—	.41	75.2 (71.9-82.0)	—	.32	74.1 (70.5-81.9)	—	.03
Postintervention	79.7 (72.8-85.1)	3.0 (1.7 to 5.5)		78.8 (72.9-83.7)	3.6 (1.7 to 5.5)		83.6 (76.6-89.0)[b,c]	9.5 (4.6 to 11.0)[b,c]	
Wake after sleep onset (min)									
Baseline	72.1 (56.5-89.1)	—	.42	70.7 (52.8-90.1)	—	.37	73.6 (55.0-88.3)	—	.02
Postintervention	76.8 (50.1-87.7)	4.7 (2.2 to 5.9)		62.8 (46.6-80.5)	–7.2 (–10.5 to 2.1)		50.4 (42.1-66.9)[b,c]	–23.2 (–31.6 to –15.8)[b,c]	
PSQI									
Baseline	6.88 (6.34-7.31)	—	.58	6.79 (6.28-6.98)	—	.32	6.90 (6.47-7.01)	—	.02
Postintervention	6.85 (6.76-7.02)	0.03 (–0.09 to 1.06)		6.05 (5.77-6.29)	–0.74 (–1.24 to 0.08)		5.43 (5.29-6.03)[b,c]	–1.47 (–1.99 to 0.14)[b,c]	
SF-36									
Baseline	76.36 (74.43-89.15)	—	.66	74.58 (71.82-88.27)	—	.02	76.03 (72.77-89.10)	—	.02
Postintervention	78.29 (75.77-88.03)	1.93 (0.84 to 2.12)		83.71 (76.96-98.12)[b]	9.13 (7.53 to 14.06)[b]		82.98 (77.58-99.52)[b]	6.95 (7.92 to 10.25)	
Total steps									
Baseline	8782 (7162-10899)	—	.38	7906 (7588-9834)	—	.001	8097 (7155-10561)	—	.02
Postintervention	9005 (8349-10772)	223 (109 to 336)		9902 (8951-11633)[b]	1996 (1238 to 2339)[b]		9938 (7980-10395)[b]	1841 (1052 to 2287)	
TIR[k] (%)									
Baseline	60.4 (54.1-73.9)	—	.37	62.5 (55.6-74.1)	—	.001	61.7 (50.9-78.0)	—	.001
Postintervention	62.1 (56.8-75.5)	1.7 (0.6 to 3.8)		80.1 (63.6-86.3)[b]	17.6 (11.4 to 25.5)[b]		84.2 (66.7-91.4)[b]	22.5 (17.9 to 29.0)	

[a]MQ: Wechsler Memory Quotient
[b]*P* <.05 compared with the Usual care group.
[c]*P* <.05 compared with the Fitness walking exercise group.
[d]DSST: Digit Symbol Substitution Test score.

[e]TMT-B: Trail Making Test part B.
[f]BNT: Boston Naming Test.
[g]ROCF: Ray Complex Figure Test.
[h]FBG: fasting blood glucose.
[i]HbA1C: glycated hemoglobin.
[j]HOMA-IR: homeostasis model assessment of insulin resistance.
[k]TIR: time in range.
[l]MoCA: Montreal Cognitive Assessment.

At posttreatment, the fitness walking exercise group did not show a significant difference in MoCA (adjusted difference 1.44, 95% CI 0.89-2.87; P=.083) compared with the baseline. The between-group effect sizes for the MoCA were d=0.79 (95% CI 0.44-1.26) and d=1.15 (95% CI 0.51-1.74) for the fitness walking and Tai Chi groups, respectively (Table 4).

Table 4. Comparison of treatment effects between the groups at posttreatment (intent-to-treat analysis). Differences from the baseline are expressed as mean differences and 95% confidence intervals

Measurement	Unadjusted mean (SD)			Adjusted difference (95% CI)				Between-group effect Size *d* (95% CI)		Within-group effect size *d* (95% CI)		
	Usual care	Fitness walking	Tai Chi	Fitness walking versus usual care	*P* value	Tai Chi versus Usual care	*P* value	Fitness walking versus usual care	Tai Chi versus usual care	Usual care	Fitness walking	Tai Chi
MoCA[a] score	22.96 (3.01)	22.94 (3.41)	23.83 (4.06)	–0.02 (–0.11 to 0.06)	.421	0.87 (0.25 to 2.31)	.002	0.79 (0.44 to 1.26)	0.98 (0.51 to 1.74)	0.15 (0.08 to 0.79)	0.46 (0.28 to 0.51)	0.71 (0.39 to 0.99)
MQ[b]	90.17 (11.26)	91.93 (10.59)	99.23 (17.08)	1.76 (0.84 to 2.04)	.582	9.06 (6.51 to 11.38)	.003	0.36 (0.24 to 0.65)	0.73 (0.58 to 0.95)	0.07 (0.02 to 0.13)	0.21 (0.15 to 0.42)	0.66 (0.32 to 0.85)
Digit Symbol Substitution Test[c] score	29.74 (8.05)	33.92 (4.48)	37.84 (5.59)	4.18 (2.83 to 6.53)	.011	8.10 (4.62 to 10.88)	.025	0.67 (0.33 to 0.89)	0.83 (0.20 to 0.95)	0.11 (0.09 to 0.22)	0.41 (0.18 to 0.72)	0.52 (0.31 to 0.67)
TMT-B[d] finding	225.19 (8.93)	220.81 (12.73)	207.33 (12.25)	–4.55 (–7.09 to –3.11)	.611	–17.94 (–25.89 to –13.51)	.022	0.21 (0.13 to 0.56)	0.77 (0.40 to 0.81)	0.21 (0.18 to 0.44)	0.20 (0.07 to 0.47)	0.77 (0.45 to 0.83)
Boston Naming Test[e] score	22.97 (4.02)	25.94 (4.11)	26.61 (4.18)	3.03 (2.01 to 4.69)	.026	4.34 (2.11 to 6.87)	.001	0.11 (0.05 to 0.49)	0.69 (0.42 to 0.89)	0.37 (0.24 to 0.59)	0.38 (0.12 to 0.52)	0.47 (0.33 to 0.68)
Rey-Osterrieth Complex Figure Test[f] score	31.78 (6.63)	34.98 (6.77)	34.64 (5.01)	3.02 (2.62 to 4.01)	.422	3.02 (2.62 to 4.01)	.417	0.25 (0.17 to 0.40)	0.33 (0.12 to 0.45)	0.10 (0.04 to 0.25)	0.39 (0.22 to 0.57)	0.41 (0.30 to 0.71)
Rey-Osterrieth Complex Figure Test delayed recall score	13.37 (7.01)	15.48 (7.11)	18.39 (7.83)	2.87 (1.55 to 4.24)	.477	5.01 (2.78 to 7.16)	.021	0.16 (0.07 to 0.33)	0.73 (0.56 to 0.81)	0.29 (0.10 to 0.47)	0.39 (0.11 to 0.68)	0.78 (0.66 to 0.94)

[a]MoCA: Montreal Cognitive Assessment.
[b]MQ: Wechsler Memory Quotient.
[c]DSST: Digit Symbol Substitution Test score.
[d]TMT-B: Trail Making Test part B.
[e]BNT: Boston Naming Test.
[f]ROCF: Ray Complex Figure Test.

Secondary Outcomes

Tai Chi versus Fitness Walking Groups

Compared with the fitness walking group (adjusted difference 3.38, 95% CI 1.14-4.66; P=.451), the Tai Chi group (adjusted difference 10.01, 95% CI 6.52-13.93; P=.001) showed greater effectiveness in improving MQ scores (Table 3). The adjusted differences on the MQ scores were 10.01 (95% CI 6.52-13.93; P <0.01) for the Tai Chi exercise group (Table 3). The within-group effect sizes for the MQ at posttest were d=0.21 (95% CI 0.15-0.42) for the fitness walking group and d=0.66 (95% CI 0.32-0.85) for the Tai Chi group. For the TMT-B finding, the corresponding between-group effect sizes were d=0.21 (95% CI 0.13-0.56) and d=0.77 (95% CI 0.40-0.81) for the fitness walking and Tai Chi group, respectively (Table 4). The Tai Chi exercise group experienced a significant increase in total sleep time compared to the fitness walking group. The two groups showed no significant differences in other secondary outcomes (DSST, BNT, ROCF scores, fasting glucose, HbA_{1c} levels, HOMA-IR, and TIR; Table 3).

The within-group effect sizes for the MQ at posttest were d=0.21 (95% CI 0.15-0.42) for the fitness walking group and d=0.66 (95% CI 0.32-0.85) for the Tai Chi group.

For the TMT-B finding, the corresponding between-group effect sizes were d=0.21 (95% CI 0.13-0.56) and d=0.77 (95% CI 0.40-0.81) for the fitness walking and Tai Chi group, respectively (Table 4).

The Tai Chi exercise group experienced a significant increase in total sleep time compared to the fitness walking group. The two groups showed no significant differences in other secondary outcomes (DSST, BNT, ROCF scores, fasting glucose, HbA1c levels, HOMA-IR, and TIR). (Table 3)

Sensitivity Analyses

The baseline characteristics of the 3 groups (usual care, fitness walking exercise, and Tai Chi exercise) were similar to the results of the per-protocol analysis. After multiple imputations of missing outcomes, the improvement in MoCA scores in the Tai Chi exercise group was significantly greater than that in the usual care group (adjusted difference 0.87, 95% CI 0.25-2.31; P=.002; Table 4). Consistent with the results of the per-protocol analysis and multiple imputation analysis. A total of 102/108 participants (94.4%) in the fitness walking exercise and Tai Chi exercise groups self-reported or confirmed participation in the exercise intervention.

Consistent with the results of the per-protocol analysis and multiple imputation analysis. A total of 102/108 participants (94.4%) in the fitness walking exercise and Tai Chi exercise groups self-reported or confirmed participation in the exercise intervention.

Tai Chi versus Usual Care Groups

At 12 weeks, the tai chi group showed significant improvement in MQ, DSST, TMT-B, BNT, ROCF score, FPG, and HbA_{1c} compared with the control group, and the difference between the groups was statistically significant (Table 3).

Fitness Walking versus Usual Care Groups

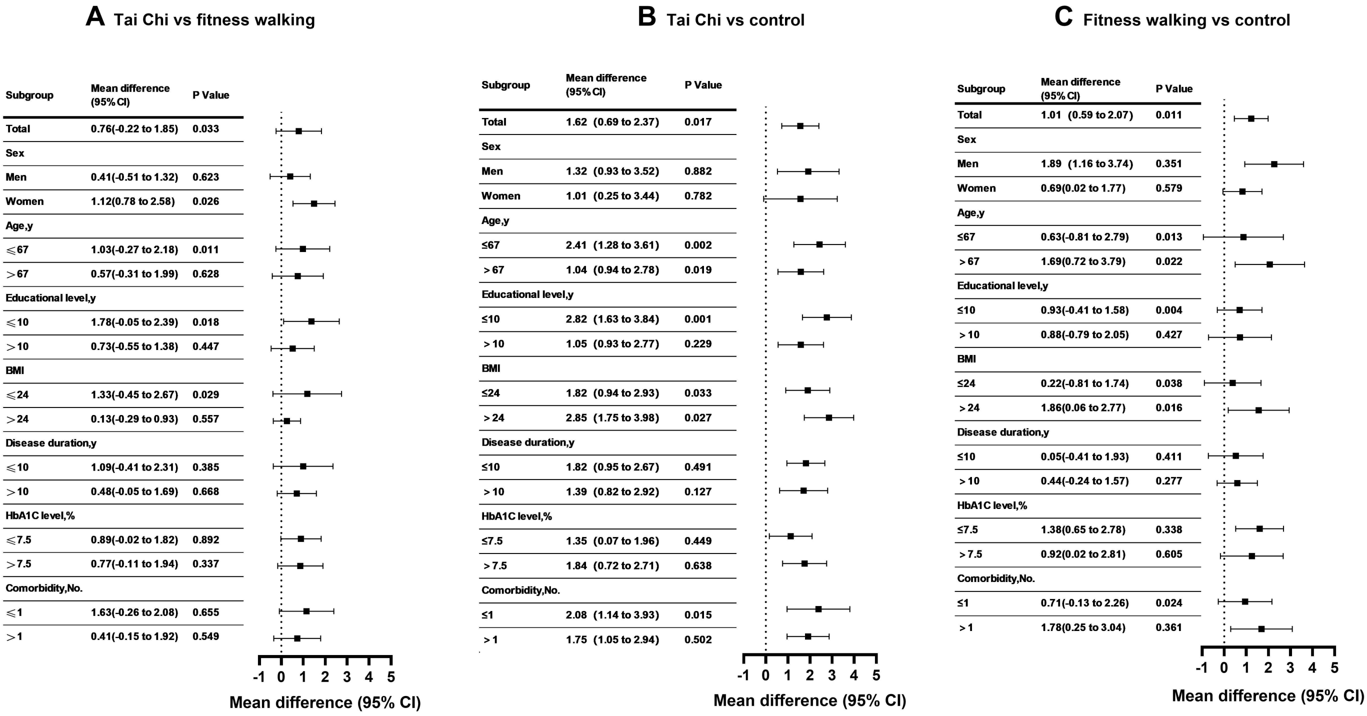
At 12 weeks, the fitness walking group showed significantly greater improvement in DSST and BNT scores compared with the usual care group (Table 3). Fitness walking effectively reduced HbA_{1c} and FBG levels, with no significant change in HOMA-IR (Table 3). Regarding sleep parameters, the fitness walking group only showed improvement in total sleep time compared with the usual care group (Table 3). The total steps and TIR differ significantly in time between the two groups (Table 3).

Regarding sleep parameters, the fitness walking group only showed improvement in total sleep time compared to the usual care group (Table 3). The total steps and TIR differ significantly in time between the two groups (Table 3).

Subgroup Analysis

Subgroup analyses at 12 weeks showed that in females (mean difference 1.12, 95% CI, 0.78-2.58), age ≤67 years (mean difference 1.03, 95% CI, –0.27 to 2.18), educational level ≤10 years (mean difference 1.78, 95% CI, –0.05 to 2.39), BMI of 24.00 or less (mean difference 1.33, 95% CI –0.45 to 2.67), and one or fewer comorbidities (mean difference 1.25, 95% CI, 0.30 to 2.21) in the subgroups, the Tai Chi group, compared with the walking group, had a better effect on improving the MoCA scores (Figure 2).

Figure 2. Subgroup analysis of Montreal cognitive assessment at 12 weeks. FBG: fasting blood glucose; HOMA-IR: homeostasis model assessment of insulin resistance; MQ: Wechsler Memory Quotient; TMT-B: Trail Making Test part B; TIR: time in range (calculated as weight in kilograms divided by height in meters squared; to convert to proportion, multiply by 0.01).



Self-Report Questionnaires

After adjusting for baseline severity, the scores on the PSQI and self-report measures of the SF-36 for both the walking group and the Tai Chi group were significantly different following the exercise intervention (Table 3).

Adherence and Dose Information

According to our criteria, participants were considered to be exercising consistently if they completed ≥70% of the total number of exercise sessions. In the fitness walking exercise group and the Tai Chi exercise group, 45 (83.3%) and 43 (79.6%) participants, respectively, completed ≥70% of the total number of exercise sessions. According to the heart rate monitored by the bracelet in the fitness walking exercise group and the Tai Chi exercise group, the median heart rates were 120 (IQR 98-145) beats/minute and 128 (IQR 94-140) beats/minute, respectively.

Adverse Events

Adverse event records were collected from the experience and satisfaction questionnaire at the end of the research project. No serious adverse events occurred during the trial. However, three cases of minor musculoskeletal discomfort were reported among participants in the 2 exercise groups: the Fitness walking exercise group (1/3, 33%) and the Tai Chi group (2/3, 67%); *P*=.11.

Discussion

Principal Findings

This randomized clinical trial demonstrated that Tai Chi exercise enhances cognitive function more effectively than fitness walking in older adults with T2DM. Specifically, after 12 weeks, cognitive benefits were obtained with both exercise modalities; however, the effects on specific cognitive domains differed. Participants in the Tai Chi group exhibited significantly higher scores on the MoCA, Memory Quotient (MQ), and Trail Making Test Part B (TMT-B) compared with both the fitness walking group and the usual care group. Furthermore, the Tai Chi group also showed significantly improved total sleep time and reduced wake after sleep onset compared with the fitness walking group.

The MoCA is a tool designed for rapid screening for mild cognitive impairment (MCI) and early dementia, with the core advantage of being more sensitive to early cognitive problems than traditional scales such as the Mini-Mental State Examination (MMSE) [20]. In investigations where the primary goal is to identify patients with potential cognitive impairment, especially in the early stages, a MoCA cutoff score of <26 achieved 87% sensitivity and 72% specificity in identifying cognitive impairment [21].

Previously, the efficacy of Tai Chi for patients with T2DM was uncertain. Although physical exercise is generally considered beneficial for cognitive function in individuals with diabetes, randomized clinical trials have shown inconsistent effects on overall cognitive function and specific cognitive subdomains [22,23]. Their findings show similarities with ours.

Previous studies have shown that the MoCA decreases yearly in patients with T2DM [21], and our study demonstrated an improvement in MoCA after the Tai Chi intervention. Our randomized clinical trial revealed that Tai Chi improves overall cognitive performance and memory function. This finding is consistent with a recently published meta-analysis. This meta-analysis showed that overall cognitive function was significantly enhanced when Tai Chi was increased from 20 to 40 minutes to 60 minutes [24]. Findings on T2DM, body mass index (BMI), and comorbidities suggest that interventions may be more effective in the early or mild stages of T2DM [25].

The exploratory analysis of secondary outcomes, including DSST, TMT-B, sleep, and metabolic indices, as presented in Table 3, should be interpreted with caution, as these analyses are exploratory and have not been corrected for multiple testing. Independent replication studies are needed to validate these findings. Specifically, the MQ scores of the Tai Chi group increased by almost 10 points on average, while the fitness walking group showed a minor improvement; in terms of TMT-B, the average score of the Tai Chi group was lower than that of the fitness walking group, implying that the Tai Chi group was faster and more efficient in performing the complex task, which reflected the unique advantage of Tai Chi in improving cognitive function. These results support the idea that Tai Chi, as an effective form of physical and mental exercise, enhances physical function and significantly improves cognitive ability [26].

Protection of prefrontal-hippocampal neural circuits is crucial in intervention strategies aimed at preventing cognitive decline [27]. A randomized controlled trial showed that 12 weeks of standardized Tai Chi training (5 sessions/week) significantly improved functional coupling of the medial prefrontal cortex to the bilateral hippocampus in healthy older adults, which was accompanied by an 18% increase in the Logical Memory subscale of the Wechsler Memory Scale (P=.003) [28]. Most studies have found that Tai Chi consistently increases frontal lobe activity, frontotemporal lobe functional connectivity, and hippocampal volume. Tai Chi-related improvements in memory and cognitive control associated with Tai Chi are driven by increased activity in the medial prefrontal cortex, dorsolateral prefrontal cortex, and the frontoparietal network [29].

In addition, improving sleep quality at night enhances daytime cognition by enhancing the flow of the brain's lymphatic system, which facilitates the removal of neurotoxic metabolites such as beta-amyloid and tau proteins [30]. As the top center for regulating cognitive and emotional activity, the prefrontal cortex is highly susceptible to the effects of aging [31]. Studies have shown that participation in Tai Chi exercise significantly enhances resting-state functional connectivity between the medial prefrontal cortex and the bilateral hippocampus [32]. There is a positive correlation between this enhancement of connectivity and improvements in memory function, as assessed by the Wechsler Memory Scale [33]. In addition, another study showed that 8 weeks of Tai Chi training were more effective than regular aerobic exercise in improving the nodal clustering coefficient of the left thalamus, which reflects the effectiveness of information processing and transmission between this brain region and its peripheral regions [34]. This finding is consistent with the higher cognitive flexibility demonstrated by Tai Chi practitioners [35]. Given the key role of the thalamus in attention regulation, working memory maintenance, and sleep regulation, Tai Chi is particularly beneficial in slowing the natural decline of cognitive function with age [10].

In addition, the study found that the Tai Chi group showed a significant increase in total sleep time, which may be related to Tai Chi's ability to relieve stress and enhance sleep quality [36]. A good night's sleep is a critical factor in maintaining physical and mental health; therefore, this additional benefit of Tai Chi deserves further attention and exploration [37].

DSST, BNT, fasting blood glucose (FBG), HbA_{1c}, and total sleep time were clinically significantly lower in both Tai Chi and fitness walking groups compared to the usual care group. These findings suggest that remotely monitored exercise with wearable digital devices and glucose monitoring is more effective than unsupervised management [38]. T2DM patients are monitored and managed through wearable digital devices and continuous glucose monitoring, and remote exercise guidance is provided through the Tencent Meeting app. Mobile devices collect users' health data (eg, steps and sleep quality) and provide customized interventions tailored to each individual's situation. Compared with traditional interventions, mobile device-based interventions can significantly reduce labor and material costs [39].

Subgroup analyses in our study showed that the Tai Chi group outperformed the fitness walking group in terms of overall cognitive and memory function in women and patients with a BMI of 24.00 or less who had T2DM for more than 10 years and had one or fewer comorbidities. This compares with previous studies showing a higher prevalence of dementia in women [40]. Findings on T2DM duration, BMI, and comorbidities suggest that interventions may be more effective in the early or mild stages of T2DM [25].

Limitations

First, although the study was designed as a randomized controlled trial with data monitoring through wearable devices, it required patients to be proficient in operating electronic devices, which may have limited the accuracy and generalizability of the findings. Second, although the sample size exceeded the minimum requirements for statistical analysis, it was still relatively small and concentrated in one geographic area, making it impossible to objectively assess cohort effects. The sample size and recruitment area should be expanded to minimize geographic effects and limitations. Third, although it's impossible to eliminate potential expectation biases in the Patient-Reported Outcomes (PROs) collected, the primary outcomes assessed through objective laboratory parameters are unlikely to be influenced by the participants' or physicians' awareness of the interventions received. Fourth, a limitation of this study is the unequal duration of exercise interventions (30 min of Tai Chi vs 60 min of fitness walking), which may confound comparisons of total energy expenditure and physiological stress. Although both interventions were matched for intensity (40%-59% of heart rate reserve), the longer duration of fitness walking may have contributed independently to the outcomes. Future studies should standardize exercise volume (eg, MET hours per week) or directly measure energy expenditure to isolate the effects of exercise type on outcomes. Fifth, the duration of the intervention in this study was only 12 weeks, which is shorter than the durations of 6 months, 12 months, or even 2 years in other studies [41,42]. One of the significant challenges for patients is maintaining their exercise habits over a year or more. Therefore, we will develop follow-up strategies based on the study's results to support participants after the study period.

Ultimately, this study recommends the use of remote exercise instruction via wearable digital devices and smartphones. This may have excluded individuals of lower socioeconomic status. In the future, it will be crucial to develop strategies that enhance access to the necessary technology and ensure all individuals have equal access to these programs. Remote design hinders clinical assessment and the collection of data on disease states or injuries.

Conclusions

In summary, this study demonstrated that web-based exercise therapy for patients may enhance the effectiveness of exercise therapy in improving cognitive function among older individuals with T2DM. Tai Chi has significant advantages in improving cognitive function and sleep quality, while fitness walking, although also beneficial, is relatively weak in these areas. These findings provide a scientific basis for promoting Tai Chi as a form of exercise that benefits both body and mind and also suggest that we should consider comprehensive individual needs and health conditions when choosing an exercise method. Future studies could further investigate the specific benefits of Tai Chi for various populations and explore the potential effects of combining it with other exercise modalities.

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Data Availability

The data that support the findings of this study are available on request from the corresponding author.

Authors' Contributions

XSC, HZL, and YXH had full access to all the data in the study and took responsibility for the integrity of the data and the accuracy of the data analysis. The first authors (XSC and HZL) contributed equally. SJW, FH, and JM conceived the study. YH, HMZ, and QG designed the study. XH and QWM collected the data. JXF, YXH, and SJW contributed to data analysis and interpretation. XSC, HZL, and YXH wrote the first draft of this manuscript. All authors critically reviewed and approved the final version of the manuscript. SJW and YXH supervised this study.

Conflicts of Interest

None declared.

Checklist 1

CONSORT checklist.
[PDF File (Adobe File), 390 KB-Checklist 1]

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Abbreviations

2hPG: 2 hour plasma glucose
BNT: Boston Naming Test
CGM: continuous glucose monitoring
DSST: Digit Symbol Substitution Test score
FPG: fasting plasma glucose
HDL-C: high-density lipoprotein cholesterol
HOMA-IR: homeostasis model assessment of insulin resistance

LDL-C: low-density lipoprotein cholesterol
MCI: mild cognitive impairment
MoCA: Montreal Cognitive Assessment
MQ: Wechsler Memory Quotient
PSQI: Pittsburgh Sleep Quality Index
RCT: randomized controlled trial
ROCF: Ray Complex Figure Test
T2DM: type 2 diabetes mellitus
TC: total cholesterol
TG: triglyceride
TIR: time in range
TMT-B: Trail Making Test part B
WC: waist circumference

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