Effects of remotely supervised physical activity (Tai Chi) on blood glucose, quality of life in overweight or obese women with T2DM: a randomized controlled trial

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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: We conducted a randomized controlled trial to assess the effectiveness and sustainability of the intervention.

Methods: The study design was a parallel randomized controlled trial. The participants were randomly paired and assigned to control and intervention groups. Patients assigned to the intervention group received online instruction in Tai Chi exercises three times a week for 12 weeks under the guidance of a physical therapist. The intervention group was asked to use the Tencent conference application, which provided online video instruction on Tai Chi exercises. Participants in the control group received a written Tai Chi exercise program and recommendations on a sheet of paper. All data were measured and recorded at baseline and after 12 weeks of intervention. The primary outcome indicator was HbA1c levels at 12 weeks post-intervention. Secondary outcome indicators were waist circumference (WC), body mass index (BMI), Fasting Plasma Glucose (FPG), 2-hour Plasma Glucose (2hPG), Salivary cortisol, Pittsburgh Sleep Quality Index ?PQSI?,and health-related quality of life (HRQOL).

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Conclusions: Providing patients with remote Tai Chi exercise intervention therapy may help improve outcomes for women with overweight or obese T2DM. In this exploratory study, the Tai Chi group consistently outperformed the control group on most endpoints. Clinical Trial: ChiCTR2200057863(19/03/2022)

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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. We conducted a randomized controlled trial to assess the effectiveness and sustainability of the intervention.

Material & methods: The study design was a parallel randomized controlled trial. The participants were randomly paired and assigned to control and intervention groups. Patients assigned to the intervention group received online instruction in Tai Chi exercises three times a week for 12 weeks under the guidance of a physical therapist. The intervention group was asked to use the Tencent conference application, which provided online video instruction on Tai Chi exercises. Participants in the control group received a written Tai Chi exercise program and recommendations on a sheet of paper. All data were measured and recorded at baseline and after 12 weeks of intervention. The primary outcome indicator was HbA1c levels at 12 weeks post-intervention. Secondary outcome indicators were waist circumference (WC), body mass index (BMI), Fasting Plasma Glucose (FPG), 2-hour Plasma Glucose (2hPG), Salivary cortisol, Pittsburgh Sleep Quality Index □PQSI□,and health-related quality of life (HRQOL).

Results: After 12 weeks, FPG (P□0.05), 2h PG ($P < 0.01$), and HbA1C levels (P□0.05) were significantly lower in the intervention group compared with baseline.

Conclusion: Providing patients with remote Tai Chi exercise intervention therapy may help improve outcomes for women with overweight or obese T2DM. In this exploratory study, the Tai Chi group consistently outperformed the control group on most endpoints.

KEYWORDS□Type 2 diabetes mellitus (T2DM), 24-style Tai Chi, overweight, obese, Health-Related Quality of Life (HRQoL)

Introduction

The increasing prevalence of obesity and related diseases at an alarming rate in both rich and low- and middle-income countries is indeed a serious concern [1]. Similar to the rising incidence of obesity, the prevalence of type 2 diabetes mellitus (T2DM) has also risen sharply over the past three decades [2].

In terms of the diagnosis of T2DM, women often face a higher burden of risk factors compared to men, including higher blood pressure and more outstanding overweight issues [3]. Women have a closer relationship with the incidence of T2DM. Factors such as sedentary behavior, anxiety and depressive symptoms, higher perceived stress, and lower self-efficacy are closely related to women and have a greater impact on female patients with T2DM [4].

With the increased prevalence of obesity and T2DM, sleep deprivation has indeed become a non-negligible part of the modern lifestyle [5]. Studies on the relationship between changes in sleep duration (from short to normal sleep or from normal to long sleep) and the development of T2DM do have inconsistent results [6] [7]. A growing body of research suggests that poor sleep quality is strongly associated with disease control and quality of life in T2DM [8]. Improving sleep duration can indeed be seen as an important strategy to reduce obesity and T2DM [9]. The relationship between sleep duration, obesity, and T2DM shows a bi-directionality, implying that they are causally related and may also influence each other [10].

The World Health Organization recently updated its physical activity guidelines to include increased physical activity and reduced sedentary behaviors as part of comprehensive weight management [11]. This will raise awareness of the benefits of an active lifestyle and help control the growing prevalence of overweight and obesity [12].

There is a strong correlation between physical activity and improved sleep quality. Regular physical activity has numerous benefits for sleep [13]. Long-term physical activity has a significant positive effect on sleep quality [14].

Therefore, Exercise is an important lifestyle management component for overweight or obese patients with T2DM, as it can help improve blood sugar control, reduce body weight, increase insulin sensitivity, and improve quality of life [15]. Several randomized controlled trials (RCTs) have reported the benefits of physical activity on HRQoL in overweight or obese women with T2DM, with little evidence of adverse effects[16] [17]. These benefits include improvements in specific symptoms such as fatigue, emotional functioning, mental health, and overall HRQoL. However, existing trial sample sizes are typically small and, in some cases, have failed to show clinically meaningful effects.

Tai Chi is a unique form of exercise that combines physical movement with mindfulness, making it a dual intervention with multiple benefits. Research has shown that mindfulness-based interventions, like Tai Chi, can positively impact glycemic control in individuals with T2DM. Specifically, these interventions have been linked to a reduction in hemoglobin A1c (HbA1c) levels by approximately 0.3% [18]. Tai Chi incorporates regulated breathing, mindfulness meditation, the intentional direction of thoughts, attention, imagery, and sensation. These elements collectively contribute to a holistic mind-body practice that promotes relaxation, enhances focus, and fosters inner calm [19].

Telemedicine is an effective and promising strategy, especially for the initial stages of a home-based therapeutic exercise program. It enables exercise techniques to be corrected for safety and allows personalized adjustments to an exercise program based on an individual's physical abilities and goals[20]. In a previous study, a 12-week telemedicine-based elastic band intervention, combined with regular follow-up via phone calls or communication software by clinical staff, improved muscle strength, dynamic balance, and physical function in patients with T2DM[21].

While telemedicine can improve diabetes management, few studies are truly representative of Asian diabetics.

Based on this rationale, we conducted a randomized controlled trial to assess the effectiveness and sustainability of the intervention. Our primary aim of this exercise intervention was to improve HbA1c. Our secondary aims were to improve waist circumference (WC), body mass index (BMI), Fasting Plasma Glucose (FPG), 2-hour Plasma Glucose (2hPG), Salivary cortisol, Pittsburgh Sleep Quality Index（PQSI）,and health-related quality of life (HRQOL).

Material and Methods

Study design

This study was a randomized, controlled, open clinical trial. All participants signed an informed consent form, and the Institutional Review Boards of all participating institutions approved the study (2024-013-01). The study was registered on the Chinese Clinical Trial Register, ChiCTR2200057863(19/03/2022).

Participants

Overweight or obese female patients with type 2 diabetes mellitus (T2DM) were recruited from January 2024 to March 2024 in our hospital. Figure 1 provides a flowchart of the recruitment and allocation of study participants.

The inclusion criteria of this study were: (1) BMI≥25kg/m2. (2) the age range of 55-75 years.

The exclusion criteria included: (1) Presence of a somatic condition that does not permit regular physical activity. (2) Body mass index (BMI) ≥ 35 kg/m². (3) Being pregnant at baseline. (4) Severe retinopathy. (5) Cognitive impairment.

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.

Calculation of Sample Size

Changes in HBA1c in the two groups were (-1.1 ± 0.8) and (-1.6 ± 0.6), respectively. According to the PASS 15.0 software calculations, a minimum of 20 participants per group is required, considering the 15% dropout rate. With a power of 80% and a two-sided significance level of 0.05, statistical variance tests were conducted on 41 participants.

Randomization and Blinding

Enrolled participants will be stratified by age and then randomly assigned to either control or intervention groups in a 1:1 ratio via a computer-generated randomization list. This task will be done independently by persons not involved in the research process. All researchers will be divided into two groups: one group will be responsible for instructing the intervention group, and the other group will conduct the routine education, neither knowing anything about each other's content. Neither the participants nor the researchers conducting the intervention or data collection will be aware of the grouping throughout the intervention. The study designers and staff responsible for assigning concealment and data processing are not allowed to participate in the entire intervention process.

Intervention methods

The control patients received traditional diabetes education. The content covered the basic knowledge of diabetes, dietary management, exercise therapy, drug treatment, and blood glucose monitoring. Each session lasted about one hour, and the teaching team consisted of endocrinologists, dietitians, and nurses.

Subjects in the Tai Chi group practiced 24-style Simplified Tai Chi through live video streaming under the guidance of professors and professionals. During the first week, Two professional Tai Chi instructors teach all the movements of 24-style Simplified Tai Chi via remote video. Starting from the second week, subjects practiced 24-style Simplified Tai Chi three times a week for 30 minutes, which included 5 minutes of warm-up and cool-down activities before and after.

The intervention group was asked to use the Tencent conference application, which provided online video instruction on Tai Chi exercises. Patients in the intervention group were able to clearly see the physiotherapist's demonstrations and explanations and perform Tai Chi in synchronization with the physiotherapist.

24-style Simplified Tai Chi has a total of 24 movements, which are more refined and standardized than the traditional Tai Chi routines, and can also fully reflect the movement characteristics of Tai Chi.

Outcomes

All data were measured and recorded at baseline and after 12 weeks of intervention. The primary outcome indicator was HbA1c levels at 12 weeks post-intervention. Secondary outcome indicators were waist circumference (WC), body mass index (BMI), Fasting Plasma Glucose (FPG), 2-hour Plasma Glucose (2hPG), Salivary cortisol, Pittsburgh Sleep Quality Index （PQSI）,and health-related quality of life (HRQOL).

Assessment of biomarker

A laboratory specialist collected blood samples between 8:30 and 9:00 a.m. after a 12-hour fast. 1 to 1.5 mL of venous blood specimens are collected in vacuum tubes containing sodium fluoride for measuring plasma glucose, lipids, and HbA1c.The insulin resistance (HOMR-IR) index was calculated as HOMR-IR = fasting insulin × fasting plasma glucose / 22.5.

Anthropometric Indicators

The researchers recorded detailed general information about the participants.
(including name, age, and medical history). Height, weight, and body mass index were measured by a scale (OMRON, HNH-318).

Circadian rhythms

Saliva was collected from each subject using a saliva collector at 0.5 h, 4 h, 8 h, and 12 h after the habitual wake-up time. Participants were instructed to collect salivary samples. At the time of sample collection, participants were asked to place the swab in their mouth, chew gently for 45-60 seconds, transfer it directly from their mouth to the test tube, and then place a pre-labeled sticker on the test tube. At the end of the test, the samples were stored in cryopreservation before being analyzed in the laboratory.

We calculated the area under the curve (AUC) for daytime cortisol using the trapezoidal formula introduced by Pruessner et al. [22].

Circadian rhythms are represented by the circadian cortisol slope, which was regressed by the time the samples were collected. Cortisol levels used for regression were log-transformed.

Normal peak circadian cortisol secretion occurs 30 minutes after awakening, then steadily declines during the day, reaching a nadir at bedtime. The flatter the diurnal slope and the greater the AUC, the more disrupted the circadian rhythm.

Assessment of sleep quality and quantity

Sleep quality and quantity were assessed before and after the training program (week 12) using the PSQI scale and a sleep monitoring bracelet.

The PSQI is a widely used and well-validated instrument for assessing sleep quality. The total PSQI score is calculated by summing the scores from seven domains, ranging from 0 to 21. A higher score indicates worse sleep quality. The PSQI has been extensively used in research and clinical settings to evaluate sleep quality in various populations, including patients with chronic diseases and the general population [23].

Objective characteristics of sleep-wake cycles were monitored with a sleep-monitoring bracelet. The bracelet automatically records the following data: total sleep time (minutes slept between bedtime and wake time), sleep efficiency (percentage of time asleep while in bed), and wake after sleep onset (minutes awake between sleep onset and wake time).

Assessment of health-related quality of life (HRQOL)

This study used the SF-12v2 tool to measure T2DM patients' HRQOL [24]. This tool is very useful in assessing the relationship between the quality of life of diabetic patients and other factors such as complications, age, occupation, gender, and treatment modalities. The tool contains 12 items to assess the following 8 domains: general health, physical functioning, social functioning, physical role, emotional role, physical pain, vitality, and mental health [25]. Their scores range from 0 to 100, with higher scores indicating better HRQOL. We also calculated the Physical Component Score 12 (PCS-12) and the Mental Component Score 12 (MCS-12) based on the participants' responses and the questionnaire.

Statistical analysis

Data were analyzed using SPSS 25.0. Continuous data are expressed as $\bar{x} \pm s$. Multiple group comparisons were analyzed using Analysis of Covariance (ANCOVA). Two independent sample t-tests were used to compare baseline and intervention data between groups. Changes in baseline were treated as dependent variables, while group, visit time, and the interaction of group and visit time (group × visit) were treated as independent effects. Differences were statistically significant at $P < 0.05$ and significant at $P < 0.01$.

Result

Baseline characteristics of participants

The participant flowchart is shown in Figure 1. A total of 80 participants were screened at baseline, of whom 50 met the inclusion criteria and agreed to participate in the trial. The 50 participants were equally divided into control and intervention groups of 25 each. In a 12-week trial, one people in the control group refused to cooperate, two had lost interest, and one lost contact and withdrew from the trial. Three people in the Tai Chi group had poor compliance, and two lost interest and dropped out of the trial. Finally, 20 people in the Tai Chi group and 21 people in the Control group completed the trial and were included in the analysis. As shown in Table 1, all baseline indicators were not significantly different between the two groups, and the balance was comparable.

Glucose-related indicators

The interaction effects of FPG ($P = 0.034$), 2h PG ($P = 0.022$), and HbA1c ($P = 0.012$) was statistically different (Table 2). After 12 weeks, FPG (P□0.05), 2h PG ($P < 0.01$), and HbA1C levels (P□0.05) were significantly lower in the intervention group compared with baseline (Table 2). The group main effect ($P = 0.035$) and time effect ($P = 0.001$) for HOMA-IR were significant. After 12 weeks, No significant difference in HOMA-IR was seen between the two groups before and after the intervention (Table 2).

Sleep-related indicators

Table 2 shows the PSQI global score, total sleep time, sleep efficiency, and wake-after-sleep onset before and after the intervention study. The Tai Chi group demonstrated a significant time effect ($P = 0.021$) for PSQI global scores. The time effects of Total sleep time ($P = 0.011$), Sleep efficiency ($P = 0.025$), and Wake after sleep onset ($P = 0.016$) were statistically different (Table 2). The Tai Chi group showed significantly higher total sleep time, higher sleep efficiency, and lower wake-after-sleep onset after the intervention program compared to the baseline. At the same time, no significant differences were found in the control group.

HRQoL-related indicators

The time main effects of PCS-12 ($P = 0.002$) and MCS-12 ($P = 0.015$) were statistically significant. After 12 weeks, PCS-12 (P□0.05) and MCS-12 levels (P□0.05) were significantly higher in the intervention group compared with baseline (Table 2). The salivary cortisol area under the curve and the diurnal cortisol slope did not show any significant difference in both groups before or after the intervention.

Changes of patients' exercise habits

Table 3 presents changes in patients' exercise habits from baseline to 12 weeks. In the intervention group, 10 patients (50%) did not have exercise habits when enrolled but insisted on exercising after 12 weeks. 1 patient (5%) in the intervention group had exercise habits but failed to keep them after 12 weeks. Other patients had no change in exercise habits. There was a statistically significant difference in changes in exercise habits between the two groups ($P = 0.016$).

Anthropometric indicators

The interaction effect of BMI ($P = 0.001$) was significantly different (Table 3). The time main effects of WC ($P = 0.021$) was statistically significant. After 12 weeks, both WC and BMI were not statistically significant in the intervention group compared with baseline.

Discussion

Traditional outpatient exercise interventions have affected patients' motivation to participate due to distance, time consumption, and space occupation and increased the healthcare economic burden. The development of Internet technology has made remote exercise instruction possible. Based on this foundation, we designed a randomized controlled trial to validate the effect of remotely supervised physical activity on overweight or obese women with type 2 diabetes mellitus (T2DM).

We hypothesized that Tai Chi exercise intervention in a mHealth model positively affects glycemic control, weight management, sleep quality and quantity, quality-of-life improvement, and circadian rhythms in overweight or obese patients with T2DM. This study found significant HbA1C, FBG, and 2hPG improvements in the intervention group at the end of 12 weeks. The intervention group showed slight improvements in HOMA-IR, TG, sleep quality and quantity, and HRQOL compared with the control group. Circadian rhythms and BMI appeared similar across the 2 groups.

Improvement in Blood Glucose Management

Tai Chi consists of slow dance movements integrating musculoskeletal, breathing, and meditative exercises [26]. Tai Chi integrates the mind and body and, therefore, seems suitable for treating T2DM [27]. Recently, several studies have shown that regular Tai Chi exercise significantly reduces fasting plasma glucose (FPG) [28] and glycosylated hemoglobin (HbA1C) levels [29], although normal levels are not achieved clinically.

Tsang et al. reported that insulin resistance and HbA1c did not significantly improve in patients with T2DM after practicing Tai Chi for 60 minutes daily [30]. This is slightly different from our current findings, where the Tai Chi intervention positively affected FBG, 2hPG, and HbA1C.

Some studies have also reported that Tai Chi can consume calories, promote glucose catabolism, facilitate weight loss in obese patients with T2DM, reduce insulin resistance, and improve insulin sensitivity [31]. In the present study, HOMA-IR levels were reduced by 7% in the intervention group at 12 weeks compared with the baseline, but the difference was not statistically significant.

Improvement in sleep quality and quantity

Tai Chi intervention improved the total Pittsburgh Sleep Quality Index (PSQI) score and objective sleep quality and quantity at baseline levels, including total sleep time, sleep efficiency, and wake after sleep onset. These findings are consistent with a meta-analysis that showed that different types of exercise, including single and combined exercise, were associated with improvements in the Pittsburgh Sleep Quality Index (PSQI) [32]. Exercise effectively in improving sleep may be related to reducing psychological stress (e.g., stress, anxiety, and depression) [33]. Tai Chi training may also indirectly improve sleep quality by enhancing physical fitness [34].

A meta-analysis of recent cross-sectional studies explored the relationship between sleep duration and HbA1c in patients with T2DM. According to the results of this meta-analysis, there was a significant association between sleep duration and HbA1c levels [35]. In the current study, we did not conduct further exploration of the correlation between glycated hemoglobin and sleep quality, and our data showed that both glycated hemoglobin and sleep quality in the Tai Chi group changed significantly from baseline, suggesting that Tai Chi exercise improved both indicators.

Improvement in HRQoL

Among the many methods of assessing quality of life, HRQoL is the one used worldwide and is an important measure of the impact of chronic diseases on people's quality of life [36]. Emerging evidence highlights that diabetes has a detrimental effect on HRQoL in older adults and that management of diabetes appears to be important in improving HRQoL in older adults [37]. Most exercise rehabilitation studies have focused on improving patients' physical fitness levels as the main research outcome, neglecting to some extent patients' subjective feelings and quality of life. When obesity coexists with diabetes, this dual distress may lead to more severe psychological problems, such as severe anxiety and depression in female patients [38]. Physical Component Score 12 (PCS-12) and Mental Component Score 12 (MCS-12) are two commonly used health-related quality of life (HRQoL) assessment tools, which are used to assess an individual's physical health status and mental health status, respectively [39]. Our trial data emphasize the importance of physical activity and mental health for overweight or obese women with T2DM.

Our study suggests that 12 weeks of Tai Chi exercise training is insufficient to affect patients' cortisol stress reactivity significantly. Several studies have shown that salivary cortisol levels are elevated during high-intensity exercise and do not always correlate significantly with low- and moderate-intensity training stress levels. This phenomenon may be explained by the fact that during low- and moderate-intensity training, the intensity of the body's stress response may be low, with little or insufficient change in cortisol secretion to be significantly detected in saliva. This also explains the results of the present experiment [40] [41] [42].

Improvement in Exercise Habits

The results showed a statistically significant difference in exercise habits between the two groups during the follow-up period ($P = 0.016$). Being overweight or obese can limit a patient's willingness to exercise, leading to a reduction in exercise and, therefore, becoming an important target for aerobic training interventions [43]. The use of mobile devices may improve adherence to exercise. In this study, over 90% of participants adhered well to exercise therapy using a mobile messaging app-based program. Previous studies have reported similar adherence rates to home exercise programs of approximately 50-70% [44]. We want to develop sustainable behavioral patterns for our patients to ensure they can incorporate these lifestyle changes into their daily lives. Studies have shown that remote monitoring improves patient adherence to exercise rehabilitation, and those patients who exercised before the intervention were more likely to maintain their exercise habits [45]. Similar results have been achieved in foreign studies.

Innovations in remote management of T2DM

Studies of diabetes management have shown that the use of remotely connected diabetes management systems is associated with increased treatment satisfaction, reduced diabetes distress, and improved glycemic control [46]. A study of telecommunication technology in T2DM management also showed that the application of tele-electronic technology to provide a virtual environment for psychotherapy was associated with increased treatment satisfaction and improved glycemic control [47]. These preliminary findings suggest that mobile health (mHealth) exercise interventions could be a practical and scalable solution for exercise therapy for people with T2DM.

Limitations

First, the sample size was limited and concentrated in one geographical area, making it impossible to assess cohort effects objectively. The sample size and recruitment area should be expanded to minimize geographic effects and limitations. Second, however, due to the limited number of physicians, we could not conduct large-scale remote management considering the cost. As a next step, we will establish a more complete remote management system and a mature team to help more DM patients.

Conclusion

Providing patients with remote Tai Chi exercise intervention therapy may help improve outcomes for women with overweight or obese T2DM. In this exploratory study, the Tai Chi group consistently outperformed the control group on most endpoints.

Declarations

Ethics approval and consent to participate

Research was conducted in accordance with the Declaration of Helsinki. The study protocol was approved by the Ethics Committee of Shanghai Yangpu District Shidong Hospital. All participants signed an informed consent form, and the Institutional Review Boards of all participating institutions approved the study (2024-013-01). The study was registered on the Chinese Clinical Trial Register, number ChiCTR2200057863(19/03/2022).

Human and animal rights

No animals were used for the study. All human procedures were followed in accordance with the Helsinki Declaration of 1975 as revised in 2013.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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Data availability

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

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Supplementary Files