STUDY PROTOCOL

Title

The Effect of Tai Chi Exercises Combined with Ischemic Preconditioning on Glycemic Control in Individuals Aged ≥50 Years with Type 2 Diabetes – A Randomized Controlled Trial

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1. Background and Rationale

Type 2 diabetes mellitus (T2DM) is associated with chronic hyperglycemia, insulin resistance, endothelial dysfunction, and microvascular impairment. Regular physical activity is a cornerstone of non-pharmacological management; however, adherence to moderate- or high-intensity exercise programs is often low among adults aged ≥50 years.

Tai Chi is a low- to moderate-intensity mind–body exercise characterized by slow, controlled movements and high safety profile. It has been shown to modestly improve glycemic control and functional capacity in individuals with T2DM.

Ischemic preconditioning (IPC) is a non-invasive procedure consisting of brief cycles of vascular occlusion and reperfusion. IPC may enhance vascular responsiveness, endothelial function, and metabolic adaptation. The combination of IPC and Tai Chi may potentially amplify metabolic and microcirculatory benefits while maintaining high tolerability.

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2. Objectives

Primary Objective

To determine whether IPC applied prior to Tai Chi training results in greater improvement in glycated hemoglobin (HbA1c) compared with Tai Chi alone, sham IPC, or usual care.

Secondary Objectives

- To assess changes in microcirculatory function using the PORH test.
- To evaluate changes in anthropometric parameters.
- To assess exercise intensity, adherence, and safety.
- To determine persistence of effects at 4-week follow-up.

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3. Study Design

Prospective, randomized, controlled, parallel-group clinical trial with four arms.

Allocation

Participants will be randomly assigned (1:1:1:1) to:

1. **Usual Care (UC)**
2. **Tai Chi (TC)**
3. **IPC → Tai Chi**
4. **SHAM → Tai Chi**

Randomization will use block randomization with variable block sizes, stratified by sex and baseline HbA1c. Allocation concealment will be ensured.

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4. Study Setting

The study will be conducted in Żory, Poland, at:

- Medical Center Provita
- Inżbud Octagon Sports Club
- “Badajto” Certified Laboratory

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5. Sample Size

Total planned sample: 200 participants (50 per arm).
Minimum acceptable recruitment: 35 participants per arm.

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6. Participants

Inclusion Criteria

- Age ≥50 years
- Diagnosed T2DM (≥6 months)
- Stable pharmacological treatment (≥3 months)
- No regular structured exercise
- Ability to safely perform low–moderate intensity exercise
- Signed informed consent

Exclusion Criteria

- Unstable cardiovascular disease
- Recent MI or stroke (<6 months)
- Severe heart failure (NYHA III–IV)
- Advanced peripheral arterial disease
- Active lower-limb ulcers
- Contraindications to IPC (e.g., DVT history, coagulation disorders)
- Severe musculoskeletal limitations
- Active cancer treatment
- Severe cognitive impairment

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7. Intervention

Tai Chi Program

- Frequency: 3 times per week
- Duration: 45 minutes/session
- Total duration: 12 weeks
- Modified Yang-style therapeutic form (8–12 movements)

Session structure:

- 10 min warm-up
- 30 min Tai Chi
- 5 min cool-down

Ischemic Preconditioning (IPC)

Performed 30 minutes before each Tai Chi session.

- Device: Delfi Personalized Tourniquet System
- Cuff width: 12 cm
- Location: proximal lower limbs
- Pressure: 100% individually determined Arterial Occlusion Pressure (AOP)
- Protocol: 5 min occlusion / 5 min reperfusion × 3 cycles
- Total duration: 30 minutes

Sham IPC

- Pressure: 20 mmHg
- Same timing and setup
- No arterial occlusion

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8. Outcome Measures

Primary Outcome

- HbA1c (%) measured at:
    - T0 (baseline)
    - T2 (12 weeks)

Secondary Outcomes

Microcirculation (PORH Test – Laser Doppler Flowmetry)

- Rest flow
- Biological zero
- Peak hyperemic response
- Time to peak
- Recovery time

Anthropometric Parameters

- Body mass
- BMI
- Waist circumference

Training Intensity

- Borg RPE scale
- Talk test
- Heart rate (subgroup)

Safety and Adherence

- Adverse events
- Attendance rate
- Completion ≥80% sessions (per-protocol analysis)

Follow-Up

- T3 (4 weeks after intervention)

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9. Safety

All sessions will be supervised by qualified physiotherapists.
Participants' general condition will be assessed before each session.
IPC pressure will be individually calibrated.

Risk is considered low and comparable to supervised exercise.

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10. Statistical Analysis

Data will be analyzed using intention-to-treat and per-protocol approaches.
Between-group differences will be evaluated using repeated-measures ANOVA or mixed models.
Significance level: $p < 0.05$.

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11. Ethical Considerations

The study will be conducted in accordance with the Declaration of Helsinki.
Participation is voluntary.
Written informed consent will be obtained.
Participants may withdraw at any time without consequences.

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12. Expected Outcomes

It is hypothesized that IPC combined with Tai Chi will produce greater improvements in HbA1c and microvascular function compared to Tai Chi alone, sham IPC, or usual care.

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