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Tai Chi in type 2 diabetes

Submission date 14/02/2026	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 16/02/2026	**Overall study status** Ongoing	
Last Edited 27/05/2026	**Condition category** Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims
This study looks at whether doing a gentle form of exercise called Tai Chi can help people aged 50 or older who have type 2 diabetes. It also tests whether a technique called ischemic preconditioning, which temporarily reduces blood flow to the legs using inflatable cuffs, can make the benefits of Tai Chi stronger. The main aim is to find out whether these approaches can help improve longterm blood sugar levels. The study will also look at blood vessel health, body measurements, how well people stick to the exercise plan, and safety.

Who can participate?
People can take part if they are aged 50 years or older, have had type 2 diabetes for at least six months, and have not changed their diabetes medication in the past three months. They must be able to walk on their own and safely take part in lowintensity exercise. They should not already be doing regular structured exercise. People cannot join if they have certain medical conditions such as unstable heart disease, recent stroke or heart attack, severe high blood pressure, advanced circulation problems, or other conditions that would make the procedures unsafe.

What does the study involve?
Participants will be randomly placed into one of four groups: usual care, Tai Chi only, Tai Chi with ischemic preconditioning, or Tai Chi with a sham (inactive) cuff procedure. Those in a Tai Chi group will attend three supervised sessions each week for 12 weeks. Each session lasts 45 minutes and includes warmup, Tai Chi movements adapted for older adults, and cooldown. In the ischemic preconditioning group, a 30minute cuff procedure will take place before each Tai Chi session. All participants will complete health and laboratory assessments at the start, after 12 weeks, and again four weeks later.

What are the possible benefits and risks of participating?
The study may help participants improve their fitness, balance, and blood sugar control, although this cannot be guaranteed. The risks are low because the exercises are gentle and supervised. The cuff procedure may cause temporary discomfort or pressure in the legs. All procedures are monitored by trained staff to keep participants safe.

Where is the study run from?
The study is being carried out in Żory, Poland, at Medical Center Provita and the Inżbud Octagon Sports Club.

When is the study starting and how long is it expected to run for?
The first participants are expected to join the study in March 2026. The exercise programme lasts 12 weeks for each person, with an extra followup check four weeks later. The whole study is expected to finish by November 2026.

Who is funding the study?
The study is funded by Centrum Medyczne Provita (Poland)

Who is the main contact?
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Contact information

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Public, Scientific, Principal investigator

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Study information

Scientific Title
The effect of Tai Chi exercises with ischemic preconditioning on glycemic control in individuals aged ≥50 years with type 2 diabetes – a randomized controlled trial

Acronym
Tai Chi - Dt2

Study objectives
Primary Objective
To determine whether ischemic preconditioning (IPC) applied prior to Tai Chi exercise leads to a greater improvement in glycemic control, as measured by glycated hemoglobin (HbA1c), in individuals aged ≥50 years with type 2 diabetes mellitus, compared to Tai Chi alone, sham IPC, or usual care

Secondary Objectives
1. To assess the effects of the intervention on microvascular function using the post-occlusive reactive hyperemia (PORH) test with laser Doppler flowmetry
2. To evaluate changes in anthropometric parameters, including body mass, BMI, and waist circumference
3. To assess exercise intensity, adherence to the training program, and safety outcomes, including adverse events
4. To determine whether the observed effects persist at a 4-week follow-up after completion of the intervention

The study aims to provide high-quality clinical evidence regarding the potential of combining a safe, low-intensity exercise modality (Tai Chi) with a non-invasive physiological intervention (IPC) to enhance metabolic and vascular outcomes in older adults with type 2 diabetes

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 04/01/2026, Research Ethics Committee of Physiotherapists at the Polish Physiotherapy Association (Correspondence Address: Centrum Rehabilitacji Funkcjonalnej ORTHOS ul. Z. Modzelewskiego 37, unit U8, Warsaw, 02-679, Poland; + 48 601 300 080; Email: biuro@fizjoterapeuci.org), ref: No. 4/01/2026

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Prevention, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Type 2 diabetes

Interventions
The intervention consists of a 12-week supervised exercise program with or without ischemic preconditioning (IPC), depending on group allocation

Tai Chi Program
Participants assigned to the Tai Chi groups will attend supervised group sessions three times per week for 12 consecutive weeks. Each session will last 45 minutes and will be conducted by a qualified physiotherapist or certified Tai Chi instructor under controlled conditions

Each session will include:
10 minutes of warm-up and mobility exercises,
30 minutes of modified Yang-style Tai Chi (therapeutic simplified form, 8–12 movements adapted for individuals aged ≥50 years, avoiding deep stances and rapid rotations),
5 minutes of cool-down and breathing exercises
Exercise intensity will be monitored using the Borg Rating of Perceived Exertion (6–20 scale), the talk test, and heart rate monitoring in a subgroup of participants

Ischemic Preconditioning (IPC)
In the IPC Tai Chi group, a 30-minute IPC session will be performed immediately before each Tai Chi session
IPC will be administered using a pneumatic tourniquet system (Delfi Personalized Tourniquet System). Occlusion cuffs (12 cm width) will be placed proximally on both lower limbs. Individual arterial occlusion pressure (AOP) will be determined for each participant prior to the intervention. The working IPC pressure will be set at 100% of the individually determined AOP
The IPC protocol will follow a standard ischemia–reperfusion sequence:
5 minutes of arterial occlusion,
5 minutes of reperfusion,
repeated three times (total duration: 30 minutes)

Participants will remain seated or supine during the procedure, and their well-being will be continuously monitored.

Sham IPC
In the SHAM Tai Chi group, a sham procedure will be applied before each Tai Chi session. The procedure will be identical in duration and setup; however, cuff pressure will be set at 20 mmHg, which does not induce arterial occlusion or physiological IPC effects

Usual Care Group
Participants assigned to the usual care group will maintain their habitual lifestyle and physical activity level without participation in the supervised Tai Chi program

All interventions are non-invasive, supervised, and conducted under standardized safety procedures.

Participants will be randomly allocated to study groups using a computer-generated randomisation sequence. The allocation sequence will be generated using an online randomisation tool to ensure true randomness.
Group assignments will be implemented using sealed, opaque, sequentially numbered envelopes prepared in advance by an independent member of the research team who is not involved in participant recruitment or outcome assessment. This procedure ensures allocation concealment and minimises selection bias.
Randomisation will follow a 1:1 allocation ratio between the intervention and control groups.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. 1. Glycated hemoglobin (HbA1c, %) measured using certified laboratory high-performance liquid chromatography (HPLC) method at baseline (T0) and after 12 weeks (T2) 2. Microvascular peak hyperemic response (PORH peak value) measured using laser Doppler flowmetry (PeriFlux System, Perimed) during the Post-Occlusive Reactive Hyperemia (PORH) test at baseline (T0), after 12 weeks (T2), and 4-week follow-up (T3) 3. Resting microcirculatory flow (REST FLOW) measured using laser Doppler flowmetry (PeriFlux System, Perimed) during the PORH test at baseline (T0), after 12 weeks (T2), and 4-week follow-up (T3) 4. Time to peak hyperemic response (PORH parameter) measured using laser Doppler flowmetry (PeriFlux System, Perimed) at baseline (T0), after 12 weeks (T2), and 4-week follow-up (T3) 5. Recovery time of microcirculatory flow (PORH parameter) measured using laser Doppler flowmetry (PeriFlux System, Perimed) at baseline (T0), after 12 weeks (T2), and 4-week follow-up (T3) measured using Primary Outcome Glycated hemoglobin (HbA1c, %) measured using a certified laboratory high-performance liquid chromatography (HPLC) assay, expressed as percentage (%), assessed at baseline (T0) and after 12 weeks of intervention (T2). Secondary Outcomes Peak hyperemic response (perfusion units, PU) measured using laser Doppler flowmetry (PeriFlux System, Perimed) during the Post-Occlusive Reactive Hyperemia (PORH) test, assessed at baseline (T0), post-intervention (T2), and 4-week follow-up (T3). Resting microvascular blood flow (perfusion units, PU) measured using laser Doppler flowmetry (PeriFlux System, Perimed) during the PORH protocol, assessed at T0, T2, and T3. Time to peak hyperemic response (seconds) measured using laser Doppler flowmetry (PeriFlux System, Perimed) during the PORH test, assessed at T0, T2, and T3. Microvascular recovery time (seconds) measured using laser Doppler flowmetry (PeriFlux System, Perimed) during the PORH test, assessed at T0, T2, and T3. at Time Points Description T0 – Baseline Assessment (Week 0) Conducted within 7 days prior to randomization and before initiation of any study intervention. All primary and secondary outcome measures are assessed at this time point. Participants are in a stable clinical condition and have not yet started the 12-week intervention program. T2 – Post-Intervention Assessment (Week 12 ± 7 days) Conducted immediately after completion of the 12-week intervention period. All primary and secondary outcome measures are reassessed to determine the effect of the intervention. Measurements are performed within 7 days after the final exercise session. T3 – Follow-Up Assessment (Week 16 ± 7 days) Conducted 4 weeks after completion of the intervention to evaluate the persistence of observed effects. No supervised exercise or IPC procedures are performed during this period. All secondary vascular and anthropometric outcomes are reassessed. HbA1c may also be measured to assess sustained glycemic changes.

Key secondary outcome(s)

1. Glycated hemoglobin (HbA1c, %) measured using a certified laboratory highperformance liquid chromatography (HPLC) assay at baseline (T0) and after 12 weeks (T2)

2. Peak hyperemic response (perfusion units) measured using laser Doppler flowmetry during the PostOcclusive Reactive Hyperemia (PORH) test at baseline (T0), after 12 weeks (T2), and at 4week followup (T3)

3. Resting microvascular blood flow (perfusion units) measured using laser Doppler flowmetry during the PORH protocol at baseline (T0), after 12 weeks (T2), and at 4week followup (T3)

4. Time to peak hyperemic response (seconds) measured using laser Doppler flowmetry during the PORH test at baseline (T0), after 12 weeks (T2), and at 4week followup (T3)

5. Microvascular recovery time (seconds) measured using laser Doppler flowmetry during the PORH test at baseline (T0), after 12 weeks (T2), and at 4week followup (T3)

6. Resting systolic and diastolic blood pressure (mmHg) measured using an automated validated sphygmomanometer at baseline (T0), after 12 weeks (T2), and at 4week followup (T3)

7. Body mass (kg) measured using a calibrated digital scale at baseline (T0), after 12 weeks (T2), and at 4week followup (T3)

8. Body mass index (kg/m²) measured using calculated values from measured height and body mass at baseline (T0), after 12 weeks (T2), and at 4week followup (T3)

9. Waist circumference (cm) measured using standard anthropometric tape at baseline (T0), after 12 weeks (T2), and at 4week followup (T3)

10. Perceived exercise intensity (Borg RPE 6–20 score) measured using the Borg Rating of Perceived Exertion scale at after each training session during the 12week intervention period

11. Heart rate (beats per minute) measured using wristworn smartwatch heart rate monitors at during selected training sessions throughout the 12week intervention period

12. Adherence rate (%) measured using attendance records at the end of the 12week intervention period (T2)

13. Adverse events (number and type) measured using standardized adverse event documentation forms at baseline (T0) through postintervention (T2) and followup (T3)

Completion date
30/11/2026

Eligibility

Key inclusion criteria
1. Individuals aged ≥50 years (no upper age limit, provided that clinical status allows safe participation).
2. Diagnosed with type 2 diabetes mellitus (T2DM) according to current diagnostic criteria.
3. Duration of diabetes of at least 6 months.
4. No changes in antidiabetic treatment (type of medication or dosage) for at least 3 months

prior to study enrolment.
5. No planned changes in pharmacological treatment during the 12-week intervention period.
6. No regular exercise habits, defined as:
6.1. No structured training-type physical activity ≥1 session per week during the past 3–6 months.
6.2. Occasional low-intensity recreational activity (e.g., walking) is permitted.
7. Ability to ambulate independently.
8. Ability to safely participate in low- to moderate-intensity exercise (Tai Chi) as assessed by a qualifying physician or physiotherapist.
9. Signed informed consent to participate in the study.
10. Consent to undergo laboratory testing and clinical measurements.

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
100 Years

Upper age limit
200 Years

Sex
All

Total final enrolment
120

Key exclusion criteria
1. Cardiovascular and Systemic Contraindications
1.1. Unstable coronary artery disease.
1.2. Myocardial infarction or stroke within <6 months prior to enrollment.
1.3. Uncontrolled arterial hypertension (resting SBP ≥180 mmHg or DBP ≥110 mmHg).
1.4. Severe heart failure (New York Heart Association [NYHA] class III–IV).
2. Vascular and Neurological Conditions
2.1. Diagnosed advanced peripheral artery disease (PAD) with symptoms of critical limb ischemia.
2.2. Active lower-limb ulcers, trophic changes, or infections.
2.3. Severe diabetic neuropathy with significant impairment of pain or pressure sensation.
2.4. Other neurological disorders that may interfere with the safe performance of exercise (e.g., advanced Parkinson's disease).
3. Contraindications to Ischemic Preconditioning (IPC)
3.1. History of deep vein thrombosis (DVT) or pulmonary embolism.
3.2. Known coagulation disorders.
3.3. Significant lower-limb vascular disease preventing the safe use of occlusion cuffs (e.g., advanced atherosclerosis; ankle–brachial index [ABI] <0.75 or >1.10).
3.4. Intolerance to limb compression or significant pain during the preliminary IPC procedure test.
4. Orthopedic and Functional Contraindications
4.1. Acute inflammation, injury, or exacerbation of musculoskeletal disorders.
4.2. Significant mobility limitations or deformities preventing the performance of Tai Chi

exercises, even in a modified form.
4.3. Recent surgery (<6 months).
5. Other Exclusion Factors
5.1. Active malignancy under current treatment.
5.2. Severe cognitive impairment or psychiatric disorders preventing informed participation.
5.3. Participation in another clinical trial or interventional study within the past 3 months.
5.4. Lack of informed consent or withdrawal of consent at any stage of the study.Adherence Criterion:
Participants are required to attend at least 70% of the scheduled exercise sessions. Individuals whose attendance falls below 70% of the total planned sessions during the 12-week intervention will be excluded from the final analysis.

Date of first enrolment
09/03/2026

Date of final enrolment
30/03/2026

Locations

Countries of recruitment
Poland

Study participating centre
Medical Center Provita
37 United Europe Avenue
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Study participating centre
Inżbud Octagon Sports Club
28 Szeroka Street
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Sponsor information

Organisation
Centrum Medyczne Provita

Organisation
Upper Silesian Academy in Katowice

Funder(s)

Funder type

Funder Name
Centrum Medyczne Provita

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	in Polish		16/02/2026	No	Yes
Protocol file			16/02/2026	No	No