Invitation statement: We invite you to participate in this human subject study. This consent form provides information related to this research. The principal investigator or research staff will explain the content to you in detail and answer any related questions.

Study title: Heat Acclimation and Innovative Cooling Systems: Optimizing Athletic Performance and Reducing Heat-Induced Performance Impairments in Hot Environments Under Climate Change Conditions.

IRB number: KMUHIRB-E(II)-20250212

Research implementation period: From June 30, 2025 to December 31, 2027. (This indicates the overall
execution period of the study, not the duration of each individual participant's involvement.)

Study site / responsible unit: Department of Sports Medicine

Sponsor / commissioning unit: None

Study type checkboxes: Drug / Medical device / New medical technology / Human subject research / Other

Participant name: _____ Medical record number (leave blank if none): _____

Collection sites: Department of Sports Medicine (Kaohsiung Medical University), Kaohsiung Medical University Hospital, Siaogang Hospital, Cijin Hospital, Kaohsiung Medical University Gangshan Hospital, Other.

Research team:

- Principal Investigator: Guo Lan-Yuan — Department of Sports Medicine — Tel: #2646 #614
- Co-Principal Investigator: Zhang Nai-Ren — Department of Sports Medicine — Tel: #2646 #625 Research Staff: Xu Min — Department of Sports Medicine — Tel: #2646 #624
- Research Staff: Chen Zhang-Hua — Department of Sports Medicine — Tel: #2646 #624 Research Staff: Lin Wei-Cheng — Department of Sports Medicine — Tel: #2646 #625 Research Staff: Ayesha Ariba — Department of Sports Medicine — Tel: #2646 #624
- Research Staff: Gan Pin-Yi — Department of Sports Medicine — Tel: #2646 #624
- **24-hour emergency contact:** Guo Lan-Yuan **Mobile:** 0958722770

1. Current worldwide marketing status of the drug / medical device

Not applicable.

2. Research background / purpose of the experiment

"Weekend athletes" refers to irregular exercisers who usually have a low routine exercise volume but perform training on holidays or weekends. Differences in heat-acclimation training frequency between such individuals and regularly trained athletes can substantially affect athletic performance in hot environments.

Exercise in high temperatures increases skin blood flow and sweating to promote heat dissipation, but it also increases physiological stress, causes dehydration, and reduces aerobic exercise capacity. Therefore, athletes are generally advised to perform heat-acclimation training before competition to reduce physiological burden and improve performance. However, heat-acclimation training itself is a high-intensity load and may cause fatigue that affects performance; in particular, weekend athletes may be more vulnerable to the added, risk of sudden increases in high-intensity exercise.

To reduce heat load, athletes may adopt cooling strategies such as ice packs, cooling materials, or a pre-cooling vest. The temperature-regulating vest used here applies selective cooling mainly to the back/trunk, avoiding cooling of the limb muscles, thereby reducing trunk thermal load and cardiovascular pressure. Compared with cold-water immersion, its core-temperature reduction may be smaller, but it can effectively lower skin temperature. The purpose of this study is to investigate, in non-regularly trained endurance exercisers under high-temperature conditions, how active cooling intervention influences peripheral circulatory regulation mechanisms, such as sympathetic activation and skin peripheral blood flow, so as to reduce subjective exertion and improve exercise comfort and safety.

3. Main inclusion and exclusion criteria

3.1 Inclusion criteria (participants meeting all of the following are eligible)

• Age between 20 and 50 years.

• During the past 6 months, endurance-type exercise performed fewer than 3 times per week, with each exercise session lasting about 40–60 minutes.

• No cardiovascular disease, metabolic disease (such as diabetes), neurological disease, or any disease affecting vascular regulatory function.

• No use within the past 3 months of medication affecting vascular regulation.

• No major sports injury or musculoskeletal disease within the past 3 months that would affect exercise performance.

3.2 Exclusion criteria (those with any of the following may not participate)

• Diseases affecting circulation or vascular function, such as diabetes, hypertension, or peripheral vascular disease.

• Long-term work in high-temperature environments.

• BMI greater than 30 kg/m², or excessive alcohol use. (Excessive alcohol use was defined in the form as more than 70 g alcohol for men or 56 g alcohol for women within a weekly period, or daily drinking behavior persisting for more than 30 consecutive days.)

• Known hypersensitivity to increases or decreases in temperature (for example, urticaria / hives).

4. Experimental methods and related tests

This study plans to conduct the experiment using four items: a temperature-regulating vest, a human exercise-function assessment system, a skin blood-flow measurement device, and an infrared thermal imager.

(1) Temperature-regulating vest

The temperature-regulating vest is equipped with heat-dissipation plates and cooling fans. The system can automatically adjust circulating-water temperature according to ambient temperature so that the water temperature in the vest remains stable and not excessively cold, while maintaining an appropriate temperature difference from the surrounding environment to enhance heat-dissipation efficiency. This helps promote cooling in hot outdoor environments and improves the participant's thermal comfort. The design schematic is shown in Figure 1.

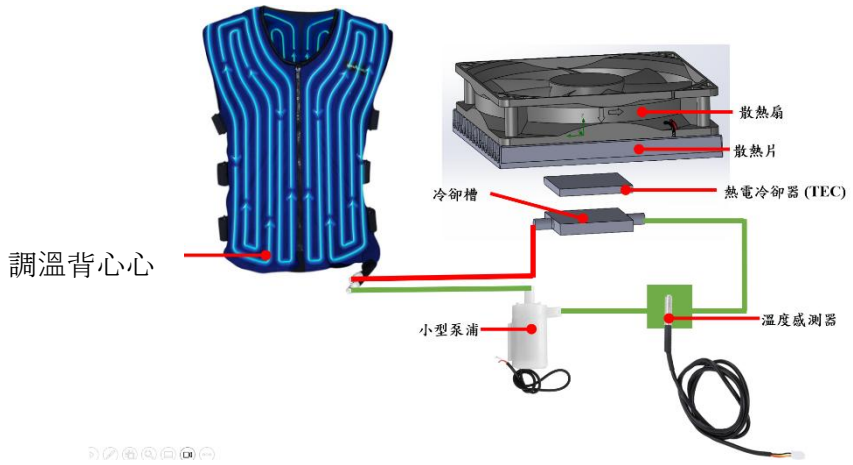

Figure 1

In addition, a small display module is installed at the front of the vest to show ambient temperature, circulating-water temperature, and the temperature difference between the water and the environment. The user can manually set the desired temperature-difference range (0–10°C). If the water temperature is too close to the environmental temperature, pressing the yellow button increases the temperature difference and accelerates cooling; pressing the red button reduces the temperature difference and increases comfort.

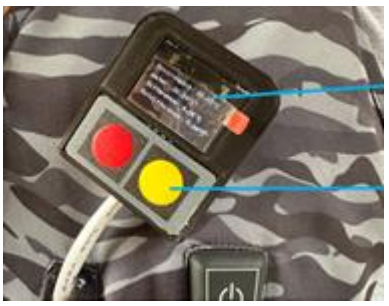

Figure 2: OLED display and control buttons.

(2) Human exercise-function assessment system

The assessment includes the following: (1) lower-limb explosive power (single vertical jump), (2) upper-limb muscle strength (30-second push-up test), (3) core muscle strength (30-second bent-knee sit-up test), (4) flexibility (single seated forward bend), (5) agility (15-second rapid stepping in place), (6) balance (30-second one-leg standing test), and (7) cardiorespiratory endurance (30-second high-knee stepping test). This instrument is used to assess overall exercise-performance ability (Figure 3).

Figure 3: Human exercise-function assessment instrument

(3) Skin blood-flow measurement device

This study uses a skin blood-flow monitor to record changes in five frequency bands at the peripheral region of the upper limb, in order to explore how cooling strategies affect different physiological regulatory mechanisms. Data collected include vascular endothelial function and vasomotion-related information, and the study is intended to observe the effects of autonomic regulation of blood vessels, respiratory fluctuations, and cardiac pulsation on circulation.

Figure 4: Skin blood-flow monitor.

(4) Infrared thermal imager

The thermal imager can measure skin-surface temperature and distinguish different temperatures by different colors. In this study it is used to assess body-surface temperature before and after exercise and to clearly observe changes in surface temperature.

Study procedure: All participants will perform treadmill exercise testing in a simulated indoor summer environment (temperature: 32–35°C; humidity: 60 ± 5%). The cooling-intervention group will wear the temperature-regulating vest for 30 minutes before the test for pre-cooling. Before

warm-up, all participants will undergo baseline measurements using the upper-limb skin blood-flow monitor and the thermal imager. After this, a 5-minute warm-up period will be completed, followed by a 50-minute treadmill/walking exercise test (including the progression from warm-up to cool-down). Exercise intensity will mainly be maintained at about 70–80% of maximal heart rate. During the exercise test, heart rate and rating of perceived exertion will be recorded every 15 minutes. Five minutes after completion, post-test measurements will be performed to compare temperature changes and blood-flow changes between the cooling-intervention group and the control group.

5. How your data / specimens will be handled, storage location and retention period, and who may use your samples

To ensure the proper use of research data/specimens and protect the rights and interests of the providers, the data/specimens collected in this study will not be used for other purposes outside this research. All research data will be stored in the Department of Sports Medicine / Exercise Biomechanics Laboratory of Kaohsiung Medical University. Relevant materials will be kept with the study records for 5 years and then destroyed. After the research ends, if the participant terminates consent for continued use of data/specimens, the collected data/specimens will be destroyed and will not continue to be retained. During the research period, coded identifiers rather than personal identity information will be used in order to protect participant privacy.

6. Possible side effects, frequency of occurrence, and how they will be handled

• Before testing begins, the experimenters will provide complete safety instruction and ensure that the participant can use the equipment correctly and appropriately.

• During testing, adequate rest time will be provided between different test items, and the participant will be asked whether any discomfort has occurred. If any unsuitable sensation or phenomenon appears, the test will be stopped immediately.

• If physical discomfort occurs, for example muscle soreness or weakness in the limbs, the experiment will be stopped immediately, and whether to continue will be decided according to the participant's wishes. If the participant experiences urgent discomfort and wishes to seek medical attention promptly, the research personnel will assist with medical referral.

7. Other alternative treatments and explanation

This research does not involve treatment; therefore this item is not applicable.

8. Expected benefits of the trial

Participation in this trial is not expected to provide any direct benefit to the participant.

9. Participant obligations / restrictions / matters requiring cooperation during the trial

• Before testing begins, complete safety instruction will be provided and it will be confirmed that the participant can operate appropriately.

• During testing, suitable rest time will be arranged between different test items, and the participant will be asked whether any discomfort has occurred. If any unsuitable sensation or phenomenon appears, the test will be stopped immediately.

10. Handling of data / specimens after the study

Not applicable — explanation requested on the form. Checkbox options shown on the form:

■ I agree that, in de-identified form, my specimens may continue to be provided to Kaohsiung Medical University, its affiliated institutions, and related enterprises for other research. If future use exceeds the scope to which I originally agreed, my further consent must first be obtained through my attending physician, and the new use must also be approved by the relevant human-subject research ethics review body.

■ I agree to donate them to the human biological databank of Kaohsiung Medical University and its affiliated institutions / related enterprises for storage. After de-identification, they may be used for subsequent medical research and will not involve personal privacy.

■ Destroyed by Kaohsiung Medical University and its affiliated institutions / related enterprises.

■ Returned. (Because remaining specimens may be pathological tissue, storage and transport may carry infectious risk; if there is no special need or appropriate storage equipment, the form recommends destruction on your behalf by the above institutions.)

11. Ethical considerations for the trial

The researchers state that, before conducting the study, approval has been obtained from the Human Subject Research Ethics Committee / IRB, and the principles of autonomy, non-maleficence, and justice will be followed.

After confirming eligibility, the researchers will again explain the study topic, purpose, and procedures to you in detail, ensuring that you receive sufficient information and can consider participation rationally. Under circumstances free from coercion or undue control, you will voluntarily participate, and only after giving consent will you enter the study. During the research period, you retain full autonomy and may decide to withdraw at any time, and this will not affect your medical rights or the quality of care you receive.

Regarding non-maleficence, this study gives priority to respect for human rights and ethical considerations. Any personally identifiable information will be processed by coding to preserve confidentiality. All materials collected in the study are only for academic research reference and will be disclosed publicly only with your permission. The study consent form and research results will be managed openly and properly stored to avoid leakage of the data you provide. Regarding justice, participants will not receive different treatment because of social or economic status, personal characteristics, race, sex, or health condition. During the study, you will be promptly provided with relevant information related to your health or disease, as well as ways to ask research-related questions and the relevant contact telephone numbers, in order to maintain fairness.

12. Confidentiality

Professor Guo Lan-Yuan will handle your information confidentially in accordance with the law. During the study, coded identifiers rather than personal information will be used to protect privacy. You also understand that clinical-trial monitors, auditors, competent authorities, and members of this hospital’s Human Subject Research Ethics Committee may inspect the research records (including electronic records) in order to ensure that the trial process and data comply with relevant laws and regulations, and they will observe the confidentiality obligations.

13. Use of research results

If the results of this research lead to academic publication, intellectual property, or practical benefit, you agree to donate them without compensation to Kaohsiung Medical University / Kaohsiung Medical University Chung-Ho Memorial Hospital / Kaohsiung Municipal Siaogang Hospital for medical uses such as disease diagnosis, prevention, treatment, and research.

14. Subsidy, required expenses, compensation for injury, and insurance

• **A. Subsidy for participation:** After the participant completes the experiment, NT$500 may be received.

• **B. Expense burden:** You do not need to pay any expenses related to this study.

• **C. Compensation for injury:** If an adverse reaction causes harm according to the clinical-trial plan, the trial-executing institution (checkboxes on the form list KMU Hospital / Siaogang Hospital / Cijin Hospital / KMU Gangshan Hospital / Other) shall bear compensation and indemnity responsibility in accordance with the law. However, foreseeable adverse reactions already described in this consent form are not compensated.

• **D. Medical care:** If an adverse reaction or injury occurs according to the clinical-trial plan, the hospital is willing to provide professional medical care and medical consultation.

• **E. Other compensation:** Other than the preceding medical compensation and medical care, this study provides no other form of compensation. If you are unwilling to accept such risk, you should not participate.

• **F. Legal rights:** You will not lose any legal rights because you signed this consent form.

• **G. Insurance:** This research has not purchased liability insurance.

15. Participant rights

• During the trial, any important new finding related to your health or disease that may affect your willingness to continue participating will be provided to you immediately and proactively.

• To conduct this research, you will receive the care / explanation of Teacher Guo Lan-Yuan. If you have any questions or concerns while you are participating, you may contact the principal investigator, Teacher Guo Lan-Yuan (24-hour contact number: 0958722770). This consent form is prepared in duplicate, and a signed copy has already been provided to you. The nature and purpose of the research have been completely explained. Research staff Lin Wei-Cheng / Ayesha Ariba / Gan Pin-Yi can answer your questions related to the study.

• If, during the trial, you have questions about the conduct of the research work, or if you have opinions or concerns about participant rights that affect your willingness to continue, you may contact the hospital's Human Subject Research Ethics Committee at 07-3121101 ext. 6646 or 07-3133525.

D. This research plan may be carried out only after review and approval by the Human Subject Research Ethics Committee / Institutional Review Board (IRB). In accordance with regulations of the Ministry of Health and Welfare, the IRB is composed of professionals from relevant academic backgrounds together with
non-medical members of the public, and operates independently to review, approve, and supervise

human research in order to protect the rights, safety, and welfare of research participants.

E. The IRB reviews research plans and comprehensively evaluates the appropriateness of the research methods and procedures, respects participant autonomy, ensures a balance of research risk and benefit, minimizes harm to participants, and considers fair distribution of research burdens and outcomes so as to protect participant rights.

F. Any research carries risk. Please evaluate carefully.

16. Withdrawal from and termination of the trial

You are free to decide whether to participate in this trial. During the trial process, you may also withdraw your consent and leave the trial at any time, without giving any reason, and this will not cause any inconvenience or affect the future medical care your physician provides to you. Teacher Guo Lan-Yuan (the principal investigator) may also stop the trial when necessary. If the trial is suspended or terminated, Teacher Guo Lan-Yuan (the principal investigator) will immediately inform you and ensure that you receive appropriate treatment and follow-up.

17. Handling of data / specimens after mid-trial withdrawal

Not applicable — explanation requested on the form. Checkbox options shown on the form:

■ I agree that, in de-identified form, my specimens may continue to be provided to Kaohsiung Medical University, its affiliated institutions, and related enterprises for other research. If future use exceeds the scope to which I agreed, my renewed consent must first be obtained and the new use must also be reviewed and approved by the relevant ethics committee.

■ I agree to donate them to the human biological databank of Kaohsiung Medical University and affiliated institutions / related enterprises for storage. After de-identification they may be used for subsequent medical research and will not involve personal privacy.

■ Destroyed by Kaohsiung Medical University and its affiliated institutions / related enterprises.

■ Returned. (Because remaining specimens may be pathological tissue, and storage / transport may involve infectious risk, destruction on your behalf is recommended if there is no special need or proper storage equipment.)

18. Possible commercial benefits arising from the research

Information obtained from this trial may lead to discoveries, inventions, or the development of commercial products. All such rights belong to the trial sponsor. You and your family will not obtain any financial benefit or monetary compensation from the research results, inventions, or other discoveries derived from this information, nor will you own any rights to such developed results.

19. Signatures

1. The principal investigator, co-principal investigator, or authorized person has explained in detail the nature and purpose of the research methods in this study, and the possible risks and benefits.

Signature of principal investigator / co-principal investigator: _____

_____ Signature date: Common Era

_____year _____month _____day

Signature of other research personnel involved in the consent explanation / discussion: _____

Signature date: Common Era ____year _____month _____day

2. After receiving the explanation, I have fully understood the above research methods and the possible risks and benefits. I have also had my questions about this trial answered in detail. I agree to participate voluntarily and will keep a copy of the consent form.

Participant signature: [handwritten

signature] Date signed: 2026 / 2 / 4

Date of birth: 2002 / 2 / 5

Telephone: 0972380538

Contact address (handwritten): No. 38, Ding'an Road, Sanmin District, Kaohsiung City. (Best-effort reading of the handwritten address.)

■ If the participant is a person without legal capacity to act (a minor under 7 years of age) or a person under guardianship declaration, consent must be obtained from the legal representative or guardian.

■ If the participant is a person with limited capacity to act (a minor over 7 but under 18 years of age) or a person under assistance declaration, consent must be obtained from both the participant and the legal representative / assistant.

■ If the participant is neither a person without capacity, nor with limited capacity, nor under guardianship or assistance declaration, but is unconscious or mentally disordered and unable to express intent, consent shall be provided by the person authorized to consent. The order of priority listed on the form is: (1) spouse, (2) adult children, (3) parents, (4) siblings, (5) grandparents.

Note: The following fields are provided for the legal representative / guardian / assistant / authorized consenter:

Name: _____ Signature date: Common Era __year _____month _____

_____day Relationship to the participant: _____ Contact

telephone: _____

Mailing address: _____

A. Witness statement

This certifies that the principal investigator has completely explained the content of this research to the participant.

Witness name: _____ Signature date: Common Era ____year _____month _____day

Notes

1. If the participant, legal representative, guardian, assistant, or other authorized consenter is unable

to read, a witness should be present for all discussions relating to the participant consent form. The witness should read the consent form and provide any other written materials to the participant so as to certify that the principal investigator or designated person has clearly explained the contents and that the participant or authorized consenter fully understands them.

2. The participant, legal representative, guardian, assistant, or authorized consenter should still personally sign the participant consent form and record the date, but a fingerprint may be used instead of a signature.

3. After completing the oral explanation and confirming that the participant's or authorized consenter's
agreement is entirely voluntary, the witness should sign the participant consent form and record the date.

4. Personnel related to the trial may not serve as the witness.