Study Protocol: Hand Ice-Pack Cryotherapy vs Thermoneutral Water Pack in Healthy Volunteers

Version 1.0 — 2025-10-03

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1. Administrative Information

1.1 Short title

Hand Ice-Pack vs Thermoneutral Pack RCT

1.2 Trial registration

Not prospectively registered (laboratory, minimal-risk, non-therapeutic investigation).

1.3 Protocol version and date

Version 1.0; 2025-10-03.

1.4 Roles and responsibilities

Sponsor/Institution: Poznań University of Physical Education (Department of Physical Therapy and Sports Recovery).

Scientific lead: [Paweł Korman], PhD. Data management/statistics: [Ewa Śliwicka], MSc. Thermal imaging lead: [Manuel Sillero-Quintana], MSc.

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2. Background and Rationale

Local cryotherapy with ice packs is widely used to alleviate pain and modulate cutaneous temperature and sensation. However, the short-term time-course of rewarming and contemporaneous changes in subjective thermal perception and somatosensory thresholds are not fully characterised in controlled, randomized settings. This study compares a 15-minute hand ice-pack application with a thermoneutral water-pack control, using infrared thermography (IRT) and a resistance thermometer (RT) alongside validated subjective scales and quantitative sensory testing (QST).

3. Objectives

Primary objective:

• To compare the effect of ice-pack vs thermoneutral pack on dorsal hand skin temperature (Tsk) during early rewarming after a 15-minute application.

Secondary objectives:

• To compare immediate post-cooling changes in mechanical detection threshold (MDT) and vibration detection threshold (VDT).

• To compare trajectories and peaks of subjective thermal sensation (TSS), thermal comfort (CS), and pain (VAS) during cooling and immediately post-cooling.

• To characterise agreement and systematic offset between ROI-averaged IRT and single-site RT across matched time points.

4. Trial Design

Randomized, parallel-group, two-arm laboratory experiment with a 1:1 allocation ratio (ice vs thermoneutral water). Single-centre. No blinding of participants; thermal image analysis performed offline by a rater not involved in data collection.

5. Study Setting

Single air-conditioned laboratory (Department of Physical Therapy and Sports Recovery, Poznań University of Physical Education). Ambient conditions monitored throughout (target ~22.5 ± 1.0 °C, 55 ± 7% RH).

6. Participants

6.1 Eligibility criteria

Inclusion: healthy males, university students, good general health, no history of neck/upper-quadrant pain.

Exclusion: diabetes; thyroid or other endocrine disorders; significant spinal pain; generalised neurological/rheumatological disorders; regular analgesic or psychotropic medication use.

6.2 Recruitment

Oral announcements among university student population.

6.3 Informed consent
Written informed consent obtained prior to any procedures.

7. Interventions

7.1 Cooling intervention (experimental)
Commercial plastic ice bag (Ø 22.86 cm; capacity ~946 ml). Filled with 400 g of pre-portioned cylindrical ice cubes (20 g each). Applied to the dorsal hand, ~1 cm proximal to the wrist joint line, covering fingers. Duration: 15 minutes.

7.2 Thermoneutral control
Same bag, filled with water at thermoneutral temperature (equal to current limb temperature ± 0.5 °C), mass-matched to 400 g. Same placement and duration.

7.3 Concomitant care
Participants refrained from topical agents on hands 24 h prior; abstained from smoking, alcohol, coffee, intense exercise on test day. Hands washed/degreased ≥ 1 h before data collection.

8. Outcomes and Endpoints

8.1 Primary endpoint
• Minimum dorsal hand Tsk during the 30-minute rewarming window (IV–X) measured by IRT (ROI mean); between-group difference (ice vs control).

8.2 Key secondary endpoints
• Dorsal hand Tsk at matched time points (I, IV–X) by IRT and RT; between-group differences and IRT–RT offsets.

• MDT change (post-cooling minus baseline; IV–I).

• VDT change (IV–I).

• Subjective scales: TSS (−4 very cold … +4 very hot), CS (1 comfortable … 5 extremely uncomfortable), VAS pain (0–100 mm). Outcomes include peak during cooling (II/III) and immediate post-cooling (IV).

8.3 Safety/harms

Monitoring for intolerance to cold (excess pain, numbness), skin irritation, or adverse events (e.g., frostbite risk). None anticipated under protocol; record and report any events.

9. Time Schedule of Enrolment, Interventions, and Assessments

Acclimatisation: 15 minutes (supine, hand supported on insulating mat).

Measurements at the following time points:

I – end of acclimatisation (baseline)

II – 7th minute of cooling

III – 15th minute of cooling

IV – immediately after removing the pack

V – 5th minute of rewarming

VI – 10th minute of rewarming

VII – 15th minute of rewarming

VIII – 20th minute of rewarming

IX – 25th minute of rewarming

X – 30th minute of rewarming

Schedule (✓ = administered):

• IRT (ROI mean Tsk): I, IV–X (eight images total)

• RT (single-site Tsk): continuous at 1-min; aligned to I–X for analysis

• TSS, CS, VAS: I, II, III, IV

• QST (MDT, VDT): I and IV

10. Data Collection Methods

10.1 Infrared thermography (IRT)

FLIR SC640 (NETD < 30 mK, 640×480, ±2% accuracy). Perpendicular camera mounting at ~90 cm. Emissivity set to 0.98; ambient control per guidance. ROI template on dorsal hand up to the wrist line. Software: Thermacam Researcher Pro 2.10. Images analysed offline by trained rater; 10% re-analysed for intra-rater consistency.

10.2 Resistance thermometer (RT)

Contact sensor (~15 mm^2) affixed between 3rd–4th metacarpals, mid-distance between wrist and MCP joints, secured with medical tape. 1-min sampling from acclimatisation start to end of rewarming. Two-point check vs reference thermometer before each session.

10.3 Quantitative sensory testing (QST)

MDT: Semmes–Weinstein monofilaments (1.65–6.65; 0.008–300 g), vertical application until bending, ~1 s contact; up-down method, threshold from central tendency.

VDT: Rydel–Seiffer tuning fork (64 Hz; 0–8/8 scale), three trials over a bony landmark; mean of three readings.

10.4 Subjective scales

TSS (−4…+4; anchors from very cold to very hot), CS (1…5; comfortable to extremely uncomfortable), VAS pain (0–100 mm; no pain to worst pain imaginable). Scripted instructions by the same assessor.

11. Sample Size

An a priori power analysis (G*Power 3.1.9.7) for a two-tailed independent-samples t-test ($\alpha = 0.05$, power = 0.80, anticipated effect size $d = 0.80$) indicated a required sample of 26 participants per group (total n = 52). In practice, 39 participants were enrolled and randomised (experimental n = 20; control n = 19). Of 40 individuals assessed, one was excluded at screening for a health condition. No participants discontinued the intervention or were lost to follow-up. With the achieved sample size, post-hoc power to detect $d = 0.80$ was approximately 0.68; accordingly, findings are interpreted as exploratory/hypothesis-generating.

12. Randomization and Allocation

12.1 Sequence generation

A simple 1:1 computer-generated randomization sequence (no blocking or stratification; superiority framework) was prepared by Paweł Korman to map numeric study IDs to groups (ice pack vs thermoneutral control). Korman had no access to personal identifiers.

12.2 Allocation concealment and implementation

At registration, participants received numeric study IDs (ID001–ID039) assigned by Piotr Szałański. The identity–ID linkage was held by the registrar. Group assignments were concealed until completion of baseline assessments and were disclosed immediately before the intervention. No sequentially numbered opaque sealed envelopes or centralized web-based randomization system were used.

12.3. Blinding

Participants and interventionists were not blinded. Thermal image analysis was performed offline by an assessor not involved in data collection. Raw-data preprocessing/curation (Manuel Sillero-Quintana) and statistical analyses (Ewa Śliwicka) were conducted by team members who did not take part in the experimental procedures and were blinded to group allocation.

13. Statistical Analysis Plan (SAP)

- **Descriptives:** values as mean ± SD; Table 1 additionally reports min–max where shown.
- **Normality:** Shapiro–Wilk test.
- **Between-group comparisons at prespecified time points:** Student's t test (normal) or Mann–Whitney U test (non-normal).
- **Within-group pre–post comparisons:** paired Student's t test (normal) or Wilcoxon signed-rank test (non-normal).
- **Repeated measures:** two-way repeated-measures ANOVA for Tsk (group × stage; and IRT vs RT within groups), with Bonferroni-adjusted post hoc tests. Effect size: partial η^2 for RM-ANOVA.
- **Significance:** $\alpha = 0.05$; tests two-sided.
- **Analysis set / missing data:** all randomised participants analysed; no imputation (no losses).

14. Data Management and Sharing

De-identified individual participant data (IPD) and the de-identified summary datasets underlying all tables and figures are openly available in Zenodo (DOI: 10.5281/zenodo.17255092) under a CC BY 4.0 license, with no access restrictions or data-use agreement required. The Zenodo record also includes Supplementary File S1 (exact questionnaire wording/anchors) and the full Research Protocol and prespecified Statistical Analysis Plan. De-identified IPD comprise participant-level values for prespecified outcomes and baseline characteristics; direct identifiers, dates, free-text fields, and rare categories were removed or aggregated to minimise re-identification risk. The dataset will be preserved for at least 5 years; enquiries may be directed to the corresponding author.

15. Ethics

Approved by the Bioethics Committee of the Poznań University of Medical Sciences (Resolution No. 360/11). Conducted in accordance with the Declaration of Helsinki. Minimal risk expected.

16. Monitoring and Harms

Adverse events (e.g., excessive pain, skin irritation) monitored throughout; any event recorded with timing, severity, relatedness, and action taken. No interim analyses; trial duration per session ~60–75 minutes.

17. Amendments and Deviations

Any protocol deviations or amendments will be documented with rationale, date, and potential impact on outcomes; none planned at this stage.

18. Dissemination

Results to be submitted to a peer-reviewed journal and presented at scientific meetings. Participants can request a lay summary.