CONSORT 2025 Checklist

Regional tissue oxygenation during high-intensity exercise following voluntary isocapnic hyperpnea versus inspiratory threshold loading in endurance–trained individuals: a randomized controlled trial

Hopewell S, Chan A-W, Collins GS, et al. CONSORT 2025 statement: updated guideline for reporting randomised trials. PLoS Med. 2025;22(4):e1004587.

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Title and Abstract				
Title	1a	Identification as a randomised trial	Title includes 'randomized controlled trial'. [Title]	1
Structured abstract	1b	Structured summary of the trial design, methods, results, and conclusions	Structured abstract reports parallel-group RCT design, VIH vs. ITL comparison, n = 20, NIRS outcomes, three-way ANOVA, and main findings. [Abstract]	1
Open Science				
Trial registration	2	Name of trial registry, identifying number (with URL) and date of registration	Retrospectively registered in ReBEC on February 10, 2026 (RBR–5rysw9w, https://ensaiosclinicos.gov.br/rg/RBR-5rysw9w). [Methods – Study Design]	3
Protocol and SAP	3	Where the trial protocol and statistical analysis plan can be accessed	Study protocol approved by Ethics Committee (protocol n° 210525001). Protocol document available as supplementary material. Statistical analysis plan prespecified in protocol. [Methods – Study Design; Data Availability]	3
Data sharing	4	Where and how the individual de-identified participant data, statistical code and any other materials can be accessed	Processed and anonymized participant-level NIRS data and Python analysis code available from corresponding author upon reasonable request. [Data Availability]	16
Funding	5a	Sources of funding and other support, and role of funders	Funded by ANID Fondecyt de Iniciación 2025 (No. 11250867), UTEM LPR23-17 and LE24-03. Funders had no role in design, conduct, analysis, or reporting. [Protocol of Study]	–
Conflicts of interest	5b	Financial and other conflicts of interest of the manuscript authors	Not explicitly stated in the manuscript. Should be included per journal requirements.	–
Introduction				
Background and rationale	6	Scientific background and rationale	Background covers RMT modalities (ITL vs. VIH), respiratory muscle metaboreflex, NIRS methodology, PFC oxygenation during exercise. [Introduction, paragraphs 1–4]	1–2
Objectives	7	Specific objectives related to benefits and harms	To contrast effects of 5 weeks VIH vs. ITL on tissue oxygenation (PFC, m.Intercostales, m.Vastus Lateralis) during high-intensity CLT. Hypothesis: RMT would attenuate exercise-induced deoxygenation. [Introduction, last paragraph]	3
Methods				
Patient and public involvement	8	Details of patient or public involvement in the design, conduct and reporting of the trial	Participants were not involved in the design, conduct, or reporting of this trial. Their role was limited to participation as study subjects. [Methods – Participants]	4
Trial design	9	Description of trial design including type of trial, allocation ratio, and framework	Parallel-group RCT, 1:1 allocation ratio, superiority framework comparing VIH vs. ITL. [Methods – Study Design]	3
Changes to trial protocol	10	Important changes to the trial after it commenced, with reason	No protocol modifications were made after trial initiation. [Methods – Study Design; Protocol]	3–4
Trial setting	11	Settings and locations where the trial was conducted	Laboratory of Exercise Physiology, Pontificia Universidad Católica de Chile, Santiago, Chile. June to November 2024. [Methods – Protocol; Participants]	3–4
Eligibility criteria	12a	Eligibility criteria for participants	Age 19–45 years, BMI < 25 $kg \cdot m^{-2}$, no chronic disease or injuries within 3 months, regular endurance training (≥3 sessions/week, ≥30 min/session) for ≥6 months. No special diets or performance-enhancing substances. [Methods – Participants]	3–4
Eligibility criteria (sites/personnel)	12b	If applicable, eligibility criteria for sites and for individuals delivering the interventions	VIH sessions supervised by trained personnel. ITL: participants trained by laboratory personnel; correct technique confirmed weekly. [Methods – RMT]	5–6

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Intervention and comparator	13	Intervention and comparator with sufficient details to allow replication	VIH: SpiroTiger™, 3×12 min/week, 70% FVC, 30 bpm. ITL: POWERbreathe™ Plus, 5×30 breaths/week, 60% MIP. Both: 1,080 cycles/week. Detailed protocols based on Leddy et al. and Johnson et al. [Methods – RMT]	5–6
Outcomes	14	Prespecified primary and secondary outcomes	Primary: TSI at PFC, m.Intercostales, m.Vastus Lateralis across 6 CLT epochs (Group × Training interaction). Secondary: Δ[O_2Hb], Δ[HHb], Δ[tHb]. Exploratory: $\dot{V}O_2$max, $\dot{V}$Emax, MIP, TTE. [Methods – Outcomes]	7
Sample size	15	How sample size was determined	A priori: G*Power, Cohen's $f \geq 0.30$, $\alpha = 0.05$, $1-\beta = 0.80$, 2 groups, 6 measurements. Minimum n = 18; enrolled n = 20 (~10% dropout). [Methods – Sample Size Calculation]	4
Interim analyses and stopping rules	16	Any interim analyses or stopping rules (or explain why not done)	No interim analyses or stopping rules were applied due to the short duration and low-risk nature of the trial. [Methods – Protocol]	4
Randomisation: sequence generation	17a	Method used to generate the random allocation sequence	Computer-generated random allocation sequence (Microsoft Excel RAND function). [Methods – Participants]	4
Randomisation: type	17b	Type of randomisation; details of any restriction	Stratified by sex, 1:1 ratio, no additional blocking. [Methods – Participants]	4
Allocation concealment	18	Mechanism used to implement the random allocation sequence	Allocation sequence prepared and held exclusively by an independent investigator not involved in enrollment or data collection. [Methods – Participants]	4
Implementation	19	Who generated the allocation sequence, who enrolled participants, and who assigned participants to interventions	Sequence generated by independent investigator. Group assignment revealed after baseline assessments. [Methods – Participants]	4
Blinding	20a	Who was blinded after assignment to interventions and how	Participant blinding not feasible. Artefact rejection/event marking by 2 blinded investigators. NIRS preprocessing by 2 additional blinded investigators (different lab). Statistical analyses by blinded investigators. Unblinding after all analyses completed. [Methods – Protocol]	4–5
Blinding (similarity)	20b	If relevant, description of the similarity of interventions	Not applicable. VIH and ITL are inherently distinct modalities (endurance vs. strength-based); blinding was not feasible. Acknowledged as limitation. [Discussion, Limitation 1]	12
Statistical methods	21a	Statistical methods for comparing groups for primary and secondary outcomes	Three-way RM-ANOVA: Time (6 levels) × Training (2 levels) × Group (2 levels). Greenhouse–Geisser correction. Bonferroni post-hoc. η^2p reported. Paired t-tests for within-group changes (Cohen's d). ITT framework. $\alpha = 0.05$. [Methods – Statistical Analysis]	7–8
Statistical methods (additional)	21b	Definition of who is included in each analysis, and in which group	All 20 randomized participants included (ITT). No participants or data points excluded. [Methods – Data Analysis; Statistical Analysis]	7–8
Results				
Participant flow	22	For each group, the numbers of participants randomly assigned, receiving intended treatment, completing follow-up, and analysed	20 enrolled: VIH (n = 10), ITL (n = 10). All 20 completed intervention and post-training assessments. All 20 analysed (ITT). CONSORT flow diagram in Supplementary Materials. [Results – Participant Characteristics]	8
Recruitment	23	Dates of recruitment and follow-up	Conducted June to November 2024. University teams and recreational athletics clubs. [Methods – Participants]	3–4
Baseline data	24	A table of baseline demographic and clinical characteristics for each group	Table 1: No significant between-group differences in anthropometric variables, pulmonary function, or CPET outcomes. [Results – Table 1]	8
Numbers analysed	25	For each group, number of participants included in each analysis and whether the analysis was by original assigned groups	All 20 randomized participants analysed per original group assignment (ITT). VIH n = 10, ITL n = 10. [Methods – Statistical Analysis; Results]	7–8
Outcomes and estimation	26	For each primary and secondary outcome, results for each group, and estimated effect size and its precision	Primary: No significant Group × Training interactions. Training effect on VL TSI ($p = 0.036$, $\eta^2p = 0.22$; mean Δ 3.2%, 95% CI: 0.3–6.1%). Time effects for most NIRS	8–10

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			variables. Results for all sites (PFC, Intercostales, VL) with η^2p. [Results – Tissue Oxygenation Responses; Figures 2–4]	
Binary outcomes	27	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Not applicable. All outcomes are continuous NIRS-derived variables.	–
Harms	28	All important harms or unintended effects in each group	No adverse events observed in any participant during the 5-week training period. Adherence: VIH 97.3%, ITL 98.0%. [Methods – Adverse Event Monitoring; Results]	6, 8
Discussion				
Interpretation	29	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	VIH and ITL elicit distinct respiratory adaptations without modifying regional tissue oxygenation. VL TSI training effect interpreted cautiously (measurement variability, no concomitant Δ[HHb]/Δ[tHb] changes). Discussed: metaboreflex, training duration, trained status. [Discussion]	10–15
Limitations	29	Sources of potential bias, imprecision, and relevant concerns about multiplicity of analyses	Nine limitations detailed: (1) no sham control, (2) sample size, (3) menstrual cycle self-report, (4) no RMF verification, (5) retrospective registration, (6) differential supervision, (7) volume-matching limitations, (8) no device calibration, (9) CLT duration variability. [Discussion – Limitations]	12–15
Generalisability	30	Generalisability (external validity) of the trial findings	Results specific to endurance-trained individuals ($\dot{V}O_2max$ ~46–48 $mL \cdot kg^{-1} \cdot min^{-1}$). Future work recommended in untrained, older adults, or clinical populations. [Discussion, last paragraph]	15