Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effectiveness of Cooling Strategies (Neck Cooling and Menthol Mouth Rinse) on Thermo-Perceptual and Physiological Responses in Hijab-Wearing Female Futsal Players

Protocol summary

Study aim

To investigate the effect of neck cooling and menthol mouth rinse, both independently and in combination, on repeated-sprint performance, physiological responses, and perceptual indicators in hijab-wearing female futsal players under hot and dry indoor conditions.

Design

A randomized, semi-experimental, 2x2 factorial crossover trial with block randomization and placebo control.

Settings and conduct

The study will be conducted in an indoor futsal hall under controlled hot and dry environmental conditions (temperature: 34 ± 1°C, relative humidity: 20-30%) at the Islamic Azad University, Shahrekord Branch.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Female; Aged 18-30 years; Minimum 2 years regular futsal training; Consistent sports hijab use; General health confirmed by sports physician. Exclusion Criteria: Menthol intolerance or skin irritation from cooling; Acute illness during study; Incomplete test sessions; Medications affecting cardiovascular/respiratory/thermoregulatory systems.

Intervention groups

1. Menthol Mouth Rinse (MEN): 25 mL of 0.1% L-Menthol solution, rinsed for 10 seconds and expectorated. 2. Neck Cooling (NEC): Application of a phase-change material (PCM) cooling pack (initial temperature ~2-4°C) to the neck area. 3. Combined Intervention (MEN+NEC): Simultaneous application of both menthol mouth rinse and neck cooling. 4. Control (CON): Placebo mouth rinse (non-menthol) and a non-cooling neck pack.

Main outcome variables

Performance Variables: Best sprint time; Performance decrement index. Physiological Variables: Skin temperature; Heart rate; Sweating rate; Body weight loss. Perceptual Variables: Rating of perceived exertion (Borg 6-20 scale); Thermal sensation; Thermal comfort.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251112067968N1**
Registration date: **2025-12-25, 1404/10/04**
Registration timing: **prospective**

Last update: **2025-12-25, 1404/10/04**
Update count: **0**

Registration date

2025-12-25, 1404/10/04

Registrant information

Name

Ali Haghighati borujeni

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-12-31, 1404/10/10

Expected recruitment end date

2026-03-01, 1404/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effectiveness of Cooling Strategies (Neck Cooling and Menthol Mouth Rinse) on Thermo-Perceptual and Physiological Responses in Hijab-Wearing Female Futsal Players

Public title
Effectiveness of Cooling Strategies (Neck Cooling and Menthol Mouth Rinse) on Thermo-Perceptual and Physiological Responses in Hijab-Wearing Female Futsal Players

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion criteria:
Female sex Age range of 18 to 30 Years Minimum of two years of regular futsal training experience Consistent use of sports hijab during training and competitions General health confirmed by a sports medicine physician
Exclusion criteria:
Intolerance to menthol mouth rinse or occurrence of skin irritation from neck cooling Suffering from an acute illness during the research execution period Failure to complete at least one test session Use of medications affecting the cardiovascular, respiratory, or thermoregulatory systems

Age
From **18 years** old to **30 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
This study employed a randomized, counterbalanced crossover design. To determine the order of participation in the four intervention conditions, including menthol MEN, NEC, MEN+NEC, and control, the intervention sequences were randomly and counterbalanced using a Latin-square design, ensuring that each condition was equally distributed across different time positions to minimize order and period effects. The intervention sequences were generated by an independent researcher prior to the start of the study, and allocation was concealed using sealed, opaque envelopes.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Crossover

Other design features
Quasi-experimental crossover trial with repeated measures and a 2×2 factorial structure, in which each participant completes four conditions: menthol mouth rinse (MEN), neck cooling (NEC), combined (MEN+NEC), and control (CON). The order of conditions is determined by block randomization, with at least 72 hours between sessions. The protocol is conducted in an indoor futsal hall under controlled hot-dry conditions (34±1°C, 20–30% RH).

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Islamic Azad University, Shahrekord Branch
Street address
No. 10, 75th Alley, Ba Honar Street, Shahrekord
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Province
Chahar-Mahal-va-Bakhtiari
Postal code
881863003

Approval date
2025-12-20, 1404/09/29

Ethics committee reference number
IR.IAU.SHK.REC.1404.321

Health conditions studied

1

Description of health condition studied
Exercise in heat condition

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Best sprint time

Timepoint
Calculated post-protocol after data collection

Method of measurement
Calculated using a standard formula based on the sprint times recorded across the 10 repetitions

2

Description
Performance Decrement Index

Timepoint
Upon the completion of the protocol and the collection of all temporal data

Method of measurement

Statistical analysis was performed using the standardized performance decrement formula, derived from the recorded times across 10 sprint repetitions.

3

Description
Skin Temperature
Timepoint
Pre, during, and post-activity phases.
Method of measurement
Measured using skin thermistors placed on specific body sites.

4

Description
Heart Rate
Timepoint
With smartwatch-integrated sensors
Method of measurement
Longitudinal monitoring across the pre-, intra-, and post-activity phases

5

Description
Sweat Rate & Body Mass Loss
Timepoint
Body weight measured immediately before the protocol and immediately after completion.
Method of measurement
Calculated by comparing pre- and post-activity body weight (without fluid intake during the test)

6

Description
Rating of Perceived Exertion
Timepoint
After the exercise protocol.
Method of measurement
Measured using the Borg Scale (range 6–20)

7

Description
Thermal Sensation & Thermal Comfort
Timepoint
Before, during, and after the exercise protocol.
Method of measurement
Measured via standardized thermal sensation and comfort questionnaires.

Secondary outcomes

empty

Intervention groups

1

Description
First group: Menthol Mouth Rinse (MEN): Rinsing with 25 mL of 0.1% L-Menthol solution for 10 seconds and then expectorating.
Category
Other

2

Description
Second group: Neck Cooling (NEC): Application of a phase-change material (PCM) cooling pack (initial temperature approximately 2-4°C) to the neck area.
Category
Other

3

Description
Intervention group: Third Intervention (MEN+NEC): Simultaneous application of both the menthol mouth rinse and the neck cooling.
Category
Other

4

Description
Control group: Placebo mouth rinse (non-menthol solution with similar taste) and application of a non-cooling neck pack.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Islamic Azad University, Shahrekord Branch
Full name of responsible person
Akram jafari
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Shahrekord, Islamic Azad University, Shahrekord Branch
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Sponsors / Funding sources

1

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Name of organization / entity

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Islamic Azad University

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Akram Jafari

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Sport Medicine

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data without participant names

When the data will become available and for how long

6 months after publication of the article

To whom data/document is available

University students and professors

Under which criteria data/document could be used

For future research

From where data/document is obtainable

To the researchers of this study

What processes are involved for a request to access data/document

By email to researchers

Comments