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KSI Research Study Results

Sponsor: DHAMA USA

IRB Protocol Number: H16-257

IRB Name: Wrist Cooling Influence on Performance

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This report provides data that was collected for the above indicated project. This data does not reflect edits and screening from a peer review process that would be required prior to publishing these results. Any inquiries should be directed to the PI and/or co-PI for this study.

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Dates: Spring – Fall 2017

Location: Korey Stringer Institute, University of Connecticut

Researchers: Douglas Casa, PhD, ATC, Rebecca Stearns, PhD, ATC, Rachel Katch, MS, ATC, Ryan Curtis, MS, ATC, Andres Almeraya, BS, ATC

Main Research Questions / Objectives

Does using the DhamaSPORT wristband affect the:

1. Thermoregulatory, cognitive and cardiovascular functioning during exercise in the heat?
2. Perceptual responses during exercise in the heat?
3. Athlete's/subject's exercise performance when used during exercise?
4. Athlete's recovery following an exercise bout?

Design Overview: 14 subjects (cross over design)

Trials (Randomized and counter balanced order):

1. 1 wristband during exercise, and half of participants receiving a wristband during recovery (W_1)
2. 2 wristbands during exercise, and half of participants receiving wristbands during recovery (W_2)
3. No wristband during exercise, and no wristband during recovery (CON)
4. Wristband only during recovery (REC)

Exercise Protocol:

- 15-minute equilibration
- 135 minutes of biking (intervals of 30 minutes 50-55% VO_2 max; 15 minutes 70-75% VO_2 max)
- Blood lactate every 45 minutes of exercise
- 30-minute recovery period following exercise

Exercise Environment:

- 40°C (104°F)
- 30-50% Relative Humidity

Dependent Variables (collected at all trials):

Cardiovascular

1. Heart rate
2. VO_2 max
3. *Thermoregulatory*
4. Rectal temperature
5. Skin temperature

Perceptual scales

6. Thirst
7. Thermal
8. Rating of Perceived Exertion
9. Environmental symptoms questionnaire
10. Delayed onset muscle soreness (DOMS)
11. Recovery rating

Hydration & Sleep measures

- 12. Urine specific gravity, urine color
- 13. Body mass/Sweat rate
- 14. Total Quality Recovery (TQR)
- 15. Sleep/recovery analysis
- 16. Subject sleep measures using validated sleep quality scales

Performance (including cognitive)

- 17. Balance task (BESS)
- 18. Mental alertness, responsiveness, cognitive reasoning
- 19. Aerobic performance

Abbreviations List

Trec	Rectal Temperature
USG	Urine Specific Gravity
RPE	Rating of Perceived Exertion
BESS	Balance Error Scoring System
Tsk	Skin Temperature

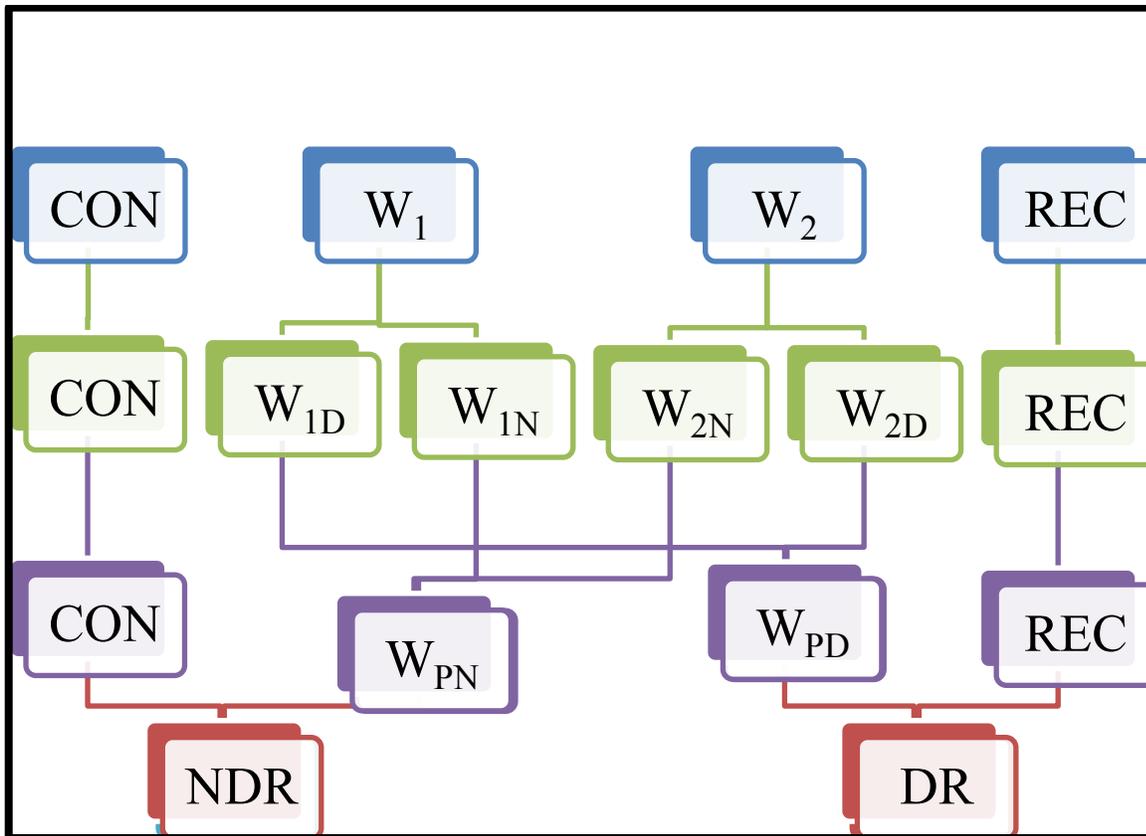


Figure 1. Flow Chart of Recovery Period Design and Trial Abbreviations.

First Level: Groups during exercise trials.

Second Level: Groups during the recovery period.

CON= Control of no wristband device

W₁= One wristband device

W₂= Two wristband devices

W_{1D}= One wristband device worn during recovery

W_{1N}= No wristband device worn during recovery

W_{2D}= Two wristband devices worn during recovery

W_{2N}= No wristband devices worn during recovery

REC= wristband devices only worn during recovery

Third Level: Groups pooled together for analysis.

W_{PD}= Groups wearing devices from exercise to recovery

W_{PN}= Groups wore devices during exercise and not during recovery.

Fourth level: Data pooled from all groups wearing and not wearing devices.

NDR= No device during recovery

DR= device during recovery

Abbreviations starting with W indicate wrist cooling and subscripts are arranged by:

(# of cooling units [1 or 2] OR Pooled recovery data [P], Recovery Intervention [D=wrist cooling, N=no cooling])

Therefore, W_{2D} means 2 cooling units during exercise that were worn into recovery

RESULTS

Table 1. Subject Demographic Information

Characteristics	Mean \pm SD
Age (years)	22 \pm 4
Height (cm)	181.6 \pm 6.9
Weight (kg)	75.4 \pm 8.7
Body Fat (%)	10.7 \pm 3.4
VO ₂ Max (mL/min/kg)	53.1 \pm 7.2
Watts VO ₂ Max (watts/kg)	367.9 \pm 76.9
55% Watts VO ₂ Max (watts/kg)	203.3 \pm 42.3
70% Watts VO ₂ Max (watts/kg)	275.5 \pm 53.8

Table 2. Trial information for all for four exercise interventions

Trial Information	CON	W1	W2	REC
Ambient Air Temperature (C)	39.3 \pm 0.6	39.7 \pm 0.4	39.5 \pm 0.4	39.5 \pm 0.3
Relative Humidity (%)	39.7 \pm 3.1	38.1 \pm 3.0	37.9 \pm 2.6	38.9 \pm 3.2
Water Intake (kg)	2.2 \pm 0.7	2.2 \pm 0.8	2.0 \pm 0.5	2.4 \pm 0.7
Body Mass Loss (% Kg)	-1.1 \pm 1.0	-1.2 \pm 1.3	-1.3 \pm 0.8	-0.9 \pm 1.0
Heat Production (kJ)	2058.8 \pm 435.8	2058.8 \pm 435.8	2058.8 \pm 435.8	2058.8 \pm 435.8
Heat Gain (kJ)	2084.2 \pm 435.7	2048.2 \pm 435.7	2048.2 \pm 435.7	2048.2 \pm 435.7
Heat Loss (kJ)	1.6 \pm 0.1	1.6 \pm 0.1	1.6 \pm 0.1	1.6 \pm 0.1

1. RESPONSES DURING EXERCISE:

Due to no statistical difference between groups W_1 and W_2 ($p = >0.05$) during exercise, the data from these groups were pooled together (W_p) when analyzing each variable during exercise.

Physiological Responses

Rectal Temperature: We observed no significant interaction between W_0 and W_p over time for T_{rec} during exercise ($p = >0.05$). See figure 1.1

Skin Temperature: No significant difference was observed between groups W_0 and W_p over time for mean body skin temperature during exercise ($p = >0.05$).

Heart Rate: We observed no significant interaction between W_0 and W_p for heart rate during exercise ($p = >0.05$).

Blood Lactate: No significant difference was observed between W_0 and W_p for blood lactate during exercise ($p = >0.05$).

Perceptual Measures

No group by time interactions were observed for the perceptual variables of RPE, thirst, or fatigue between groups during exercise ($p = >0.05$). However, the interaction between time points and groups for thermal perception approached statistical significance ($p = 0.053$), but ultimately failed to reach our set standard ($p \leq 0.05$).

Figure 1.1: Is there a difference in body temperature during exercise with and without wrist cooling? (no)

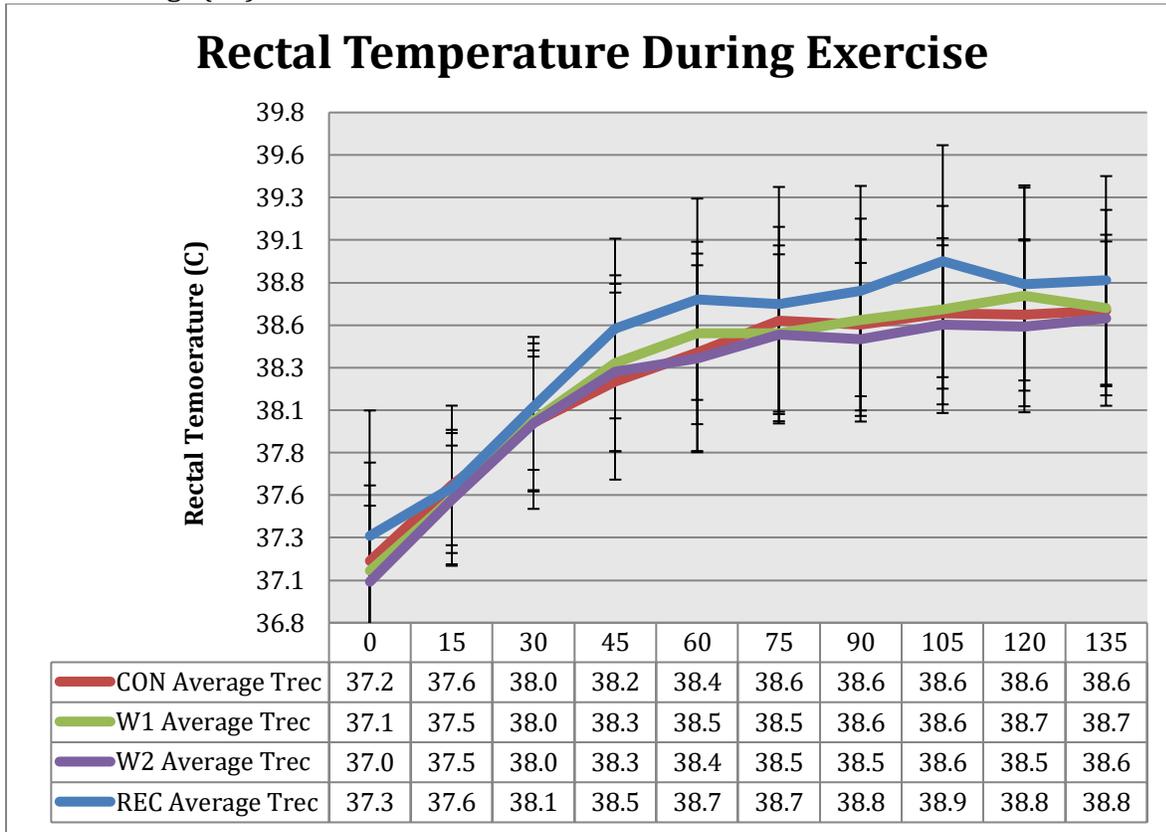


Figure 1.2: Is there a difference in heart rate during exercise with and without wrist cooling? (no)

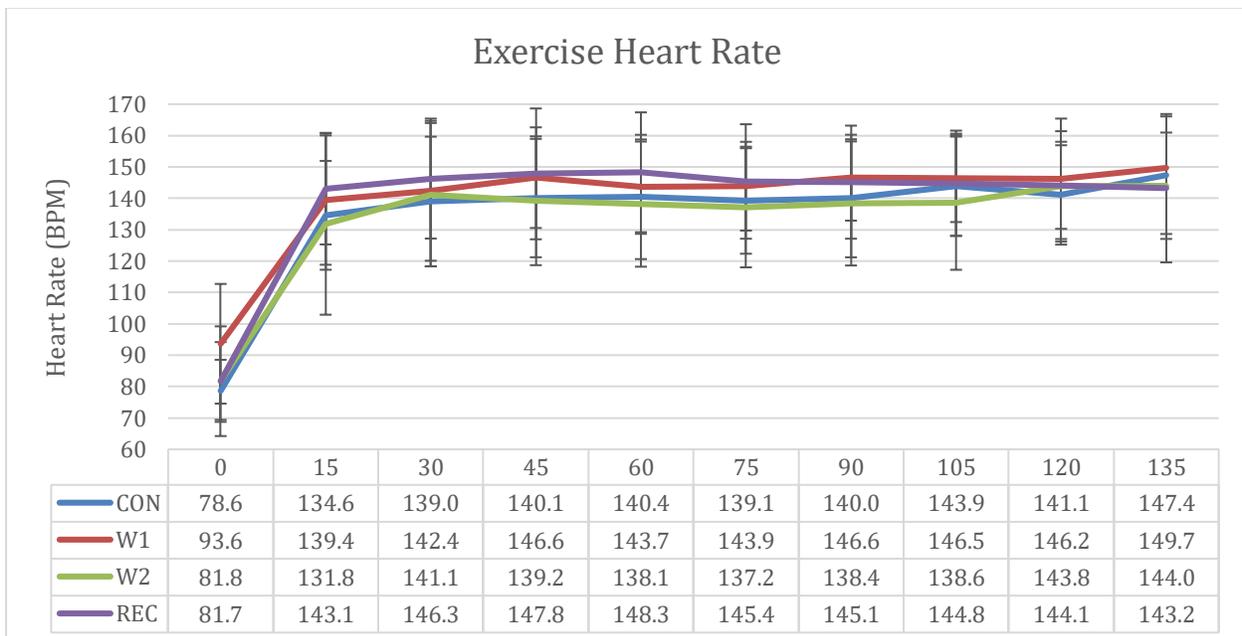


Table 1.1: Thermal Sensation During Exercise

THERMAL SENSATION	0	15	30	45	60	75	90	105	120	135
CON	5.1	5.5	5.9	6.0	6.2	6.4	6.4	6.4	6.5	6.5
SD	0.3	0.7	0.6	0.8	0.7	0.8	0.7	0.7	0.7	0.7
W1	5.1	5.7	6.0	6.3	6.3	6.2	6.4	6.5	6.3	6.4
SD	0.4	0.6	0.6	0.7	0.7	0.8	0.8	0.8	0.7	0.8
W2	5.1	5.8	6.0	6.0	6.2	6.3	6.2	6.1	6.3	6.5
SD	0.4	0.5	0.7	0.6	0.6	0.6	0.6	0.7	0.8	0.9
REC	5.1	5.9	6.0	6.1	6.3	6.3	6.4	6.2	6.3	6.3
SD	0.4	0.5	0.6	0.7	0.7	0.8	0.6	0.7	0.5	0.7

Table 1.2: Rating of Perceived Exertion During Exercise

RPE	0	15	30	45	60	75	90	105	120	135
CON	6.0	10.5	12.2	12.7	13.9	14.3	14.8	15.3	15.6	16.1
SD	0.0	2.4	2.8	2.9	2.8	2.3	1.8	1.7	1.6	1.7
W1	6.1	10.7	12.1	13.6	13.4	14.0	14.7	15.0	15.5	16.5
SD	0.4	2.9	2.7	3.0	3.0	2.4	2.2	1.8	1.9	1.6
W2	6.1	10.4	11.8	12.9	13.3	14.0	14.9	14.9	15.7	15.9
SD	0.3	2.9	3.5	3.1	2.8	2.1	2.1	1.7	2.0	1.9
REC	6.0	11.0	12.3	13.8	14.1	14.6	15.6	15.1	15.6	15.9
SD	0.0	2.0	2.0	2.6	2.5	2.4	2.2	2.2	2.0	1.7

Table 1.3: Skin Temperature During Exercise

SKIN TEMPERATURE	0	15	30	45	60	75	90	105	120	135
CON	35.9	36.7	37.0	37.2	37.2	37.2	37.3	37.3	37.3	37.4
SD	0.5	0.5	0.5	0.5	0.6	0.6	0.6	0.5	0.5	0.5
W1	35.9	36.8	37.1	37.1	37.1	37.1	37.1	37.0	37.2	37.2
SD	0.4	0.4	0.5	0.6	0.6	0.7	0.7	0.8	0.7	0.7
W2	35.9	36.8	37.1	37.2	37.1	37.1	37.1	37.1	37.2	37.3
SD	0.6	0.5	0.5	0.7	0.7	0.7	0.8	0.8	0.7	0.5
REC	36.0	36.9	37.2	37.4	37.4	37.4	37.3	37.3	37.4	37.5
SD	0.3	0.3	0.4	0.6	0.6	0.7	0.7	0.7	0.6	0.5

Table 1.4: Perceived Thirst During Exercise

THIRST	0	15	30	45	60	75	90	105	120	135
CON	2.0	2.8	2.9	3.2	3.2	3.1	3.3	3.3	3.4	3.4
SD	0.8	0.9	1.2	1.0	1.0	1.1	1.3	1.5	1.5	1.2
W1	2.1	2.7	3.3	3.7	3.5	3.4	3.5	3.3	3.9	3.6
SD	1.0	1.0	1.3	1.5	1.2	1.3	1.4	1.2	1.6	1.0
W2	2.5	2.8	3.4	3.6	3.1	3.1	3.3	3.8	3.4	3.8
SD	1.2	1.1	1.5	1.2	1.2	1.2	1.2	1.3	1.3	1.4
REC	2.0	3.1	3.4	3.6	3.7	3.6	3.6	3.9	3.5	3.5
SD	0.6	1.0	1.2	1.5	1.4	1.3	1.6	1.7	1.3	1.4

Table 1.5: Reported Fatigue During Exercise

FATIGUE	0	15	30	45	60	75	90	105	120	135
CON	0.8	1.7	3.1	3.9	4.8	5.2	5.4	6.0	6.5	7.0
SD	0.9	0.9	1.6	1.9	1.9	1.8	1.6	1.4	1.4	1.5
W1	0.9	2.0	2.9	3.8	4.6	4.8	5.4	6.0	6.9	7.5
SD	1.4	1.5	1.3	2.1	1.8	1.8	1.8	1.8	1.5	1.8
W2	0.8	2.4	3.1	3.8	4.1	4.9	5.4	6.0	6.3	6.9
SD	0.9	1.4	2.0	1.9	2.0	1.5	1.6	1.6	1.6	1.7
REC	0.5	2.5	3.8	4.5	5.2	5.7	6.4	6.4	6.6	7.0
SD	0.7	1.8	1.8	2.1	2.1	2.2	2.1	2.1	1.9	1.8

Table 1.6: Letter Digit Substitution Scores (Results in seconds)

LETTER DIGIT SUBSTITUTION	POST EXERCISE	POST RECOVERY
CON	62.4	64.6
SD	13.5	14.4
W1	60.4	61.3
SD	12.4	11.7
W2	60.6	64.1
SD	14.3	14.9
REC	60.4	63.0
SD	14.6	16.6

Table 1.7: Trail Making Scores (Results in seconds)

TRAIL MAKING		POST EXERCISE	POST RECOVERY
CON		30.5	24.3
	SD	14.7	10.3
W1		35.9	28.3
	SD	19.1	9.7
W2		29.7	25.0
	SD	15.9	10.8
REC		32.8	29.9
	SD	11.9	16.1

Table 1.8: Muscle Soreness (From 1-100)

MUSCLE SORENESS		POST EXERCISE	POST RECOVERY
CON		42.5	29.7
	SD	21.8	20.3
W1		43.5	26.6
	SD	21.8	20.9
W2		43.9	29.2
	SD	25.4	22.2
REC		43.7	30.6
	SD	20.5	21.3

Table 1.9: Blood Lactate During Exercise

BLOOD LACTATE		45 MIN	90 MIN	135 MIN
CON		1.9	1.6	1.5
	SD	1.0	0.9	1.0
W1		2.1	1.8	2.0
	SD	1.0	1.2	0.9
W2		2.1	1.6	1.7
	SD	1.6	0.9	1.1
REC		3.5	2.6	2.7
	SD	2.2	1.9	1.8

2. RECOVERY RESULTS

Physiological Responses

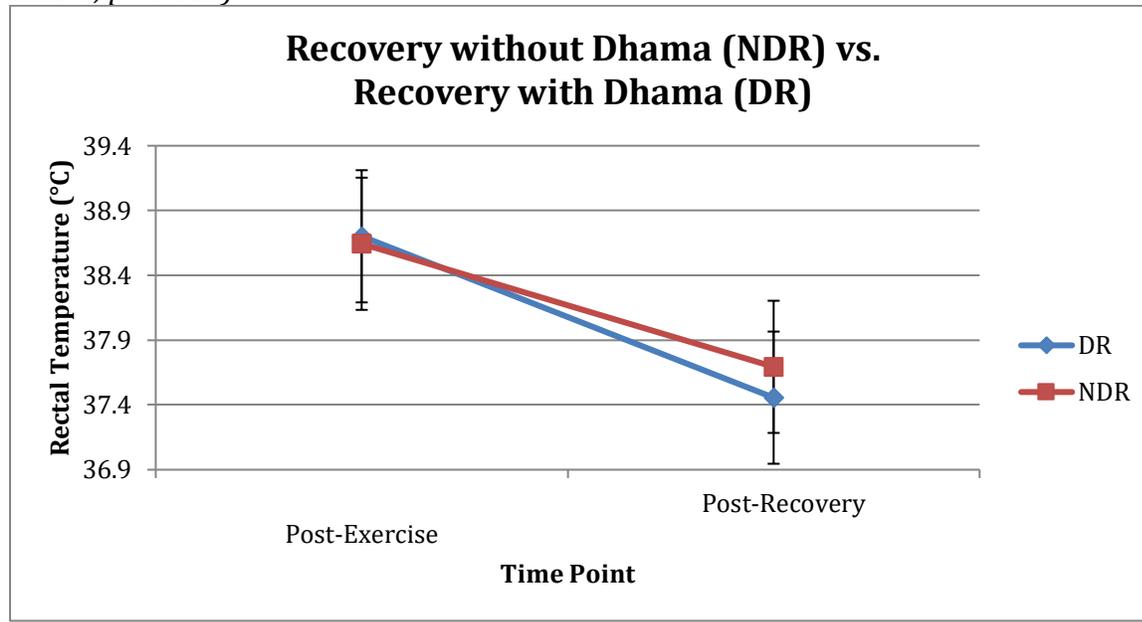
Rectal Temperature: Significant differences were found in the magnitude of cooling during the recovery period for DR vs. NDR (Figure 2.2.) (Mean $0.33^{\circ}\text{C} \pm 0.51^{\circ}\text{C}$, $p= 0.010$).

Additionally, differences were observed between W_{PN} and REC (Mean: $-0.27^{\circ}\text{C} \pm 0.31$, $P= 0.023$) (Figure 2.3.).

Skin Temperature: No differences were seen between groups when comparing skin temperatures during exercise. The comparison CON to W_{PN} approached significance (Mean: $0.60^{\circ}\text{C} \pm 0.88^{\circ}\text{C}$, $P= 0.06$).

See table 2.1 for remaining variable results

Figure 2.2: Is there a difference in rectal temperature from post exercise to post recovery when wrist cooling is utilized during recovery? (yes, Dhama use resulted in significantly lower temperatures during the post exercise recovery period. Mean difference = $0.33^{\circ}\text{C} \pm 0.51^{\circ}\text{C}$, $p= 0.010$)



	Post Exercise	Post Recovery	Delta
DR	38.70±0.54°C (101.6°F)	37.46±0.37°C (99.4°F)	1.24±0.54°C
NDR	38.64±0.50°C (101.5°F)	37.69±0.28°C (99.8°F)	0.93±0.46°C

Figure 2.3 Does wrist cooling only during recovery lower rectal temperature more after exercise than if wrist cooling is done only during exercise - if athlete were to wear Dhama during exercise or recovery, which has the greatest impact on post exercise temperature? (Results support Dhama during recovery, there was a significantly lower drop in temperature during recovery when Dhama was used during recovery vs only during exercise)

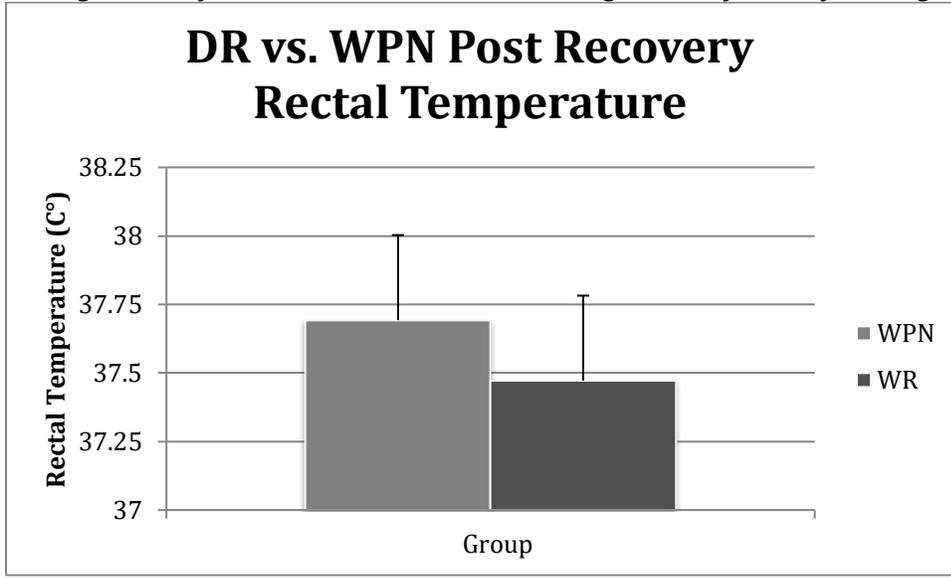


Table 2.1. Summary of sleep results between groups wearing (DR) and not wearing wristbands (NDR) during recovery period and exercise period only (no significant differences)

	Sleep Efficiency	Did you feel refreshed when you woke up? (1 = not at all, 5 = very much)	How many times did you wake up?
CON	85.4±5.3	3±1	1±1
WPN	84.0±4.6%	4±1	1±1
RECOVERY PERIOD COMPARISION			
DR	84.6±5.6%	3±1	2±1
NDR	85.5±5.4%	3±1	1±2

Note: WPN = Wrist cooling during exercise period only, DR = Wrist cooling during recovery and NDR = No wrist cooling during recovery, CON = control, no cooling at any time point

Table 2.2. Summary of recovery results between groups wearing and not wristbands for physiological, perceptual and mental performance tasks

1. REC vs. W_{PD}: Does wearing Dhama during exercise + recovery provide greater benefit than wearing Dhama only during the recovery period?
(no)
2. CON vs. W_{PN}: Does wearing Dhama during exercise but not during recovery impact the recovery period?
(no to all variables - skin temperature approached significance)
3. REC vs. W_{PN}: Does wearing Dhama during the just the recovery or just the exercise session provide a benefit over the other during the recovery period?
(no to all variables except rectal temperature)
4. NDR vs. DR: Does wearing Dhama during recovery provide a benefit to not wearing Dhama during recovery - even if it was or was not worn during exercise.
(no to all variables except rectal temperature)

	T _{Rec} (°C)	T _{Sk} (°C)	HR (bpm)	Thermal Sense (Avg. Rating)	Trail Making (Seconds)	Letter Digit Substitution (# of Letters)
1. REC vs. W_{PD} (Mean ± SD)	0.03 ± 0.41	-2.94 ± 10.30	6.70 ± 26.50	-0.10 ± 0.74	7.90 ± 21.60	-2.90 ± 7.87
	P > 0.05	P > 0.05	P > 0.05	P > 0.05	P > 0.05	P > 0.05
2. CON vs. W_{PN} (Mean ± SD)	-0.01 ± 0.27	0.60 ± 0.88	4.30 ± 15.81	0.10 ± 0.21	-5.56 ± 18.66	0.60 ± 6.36
	P > 0.05	P < 0.06	P > 0.05	P > 0.05	P > 0.05	P > 0.05
3. REC vs. W_{PN} (Mean ± SD)	-0.27 ± 0.31	0.42 ± 0.90	-8.40 ± 17.13	0.30 ± 0.79	1.13 ± 21.40	-0.10 ± 5.70
	P = 0.023*	P > 0.05	P > 0.05	P > 0.05	P > 0.05	P > 0.05
4. NDR vs. DR (Mean ± SD)	0.33 ± 0.51	0.16 ± 0.93	-1.70 ± 33.74	-0.38 ± 1.15	-0.21 ± 14.92	-1.3 ± 8.89
	P = 0.010*	P > 0.05	P > 0.05	P > 0.05	P > 0.05	P > 0.05

** “ denotes findings with significance.

W_R= DHAMAsport wristband during recovery period only.

W_{PD}= DHAMAsport wristband worn during both the exercise period and recovery period. W_{PN}= DHAMAsport wristband worn during exercise period, but not the recovery period.

CON= control trial, no DHAMAsport wristband worn at any time point.

DR= all DHAMAsport wristband recovery data across all groups.

NDR= data from trials without DHAMAsport wristband

Table 2.3 Balance Error Scoring System Results (*no significant differences*)

BESS TOTAL	BASELINE	POST EXERCISE	DELTA (BASELINE – POST EX)	POST RECOVERY	DELTA (POST EXERCISE – POST RECOVERY)
CON	17	14	3	11	4
SD	6	4	8	4	4
W1/W2	17	13	4	11	2
SD	6	4	7	3	2
REC	17	14	3	12	2
SD	6	7	6	4	5

Note: Data was pooled from W1 and W2 trials due to lack of differences post exercise

Table 2.4 Balance Error Scoring System Results By Stance Post Exercise

BESS TOTAL	SINGLE LEG FIRM	TANDEM FIRM	SINGLE LEG FOAM	TANDEM FOAM
CON	3	1	8	3
SD	2	1	1	1
W1/W2	3	0	7*	3
SD	2	1	1	1
REC	3	1	7	4
SD	2	1	3	2
BASELINE	3	1	8	5
SD	2	2	2	3

Note: Data was pooled from W1 and W2 trials due to lack of differences post exercise

*Indicates significant difference from control (CON)

Table 2.5 Balance Error Scoring System Delta By Stance: Post Exercise - Post Recovery

BESS TOTAL	SINGLE LEG FIRM	TANDEM FIRM	SINGLE LEG FOAM	TANDEM FOAM
CON	1*	0	2	1
SD	2	1	3	2
REC	-1	0	0	1
SD	2	1	3	2

Note: *Indicates significant difference from control (CON)

SUMMARY OF MAJOR RESULTS:

Dependent Variable	Exercise Session	Recovery Period (or Exercise to Recovery Delta)
Heart rate	No differences	No differences
Rectal temperature	No differences	Significantly lower temperature with Dhama
Skin temperature	No differences	No differences
Thirst	No differences	No differences
Thermal	No differences	No differences
Rating of Perceived Exertion	No differences	No differences
Muscle soreness	No differences	No differences
Fatigue	No differences	No differences
Balance task (BESS)	No differences	Some position specific differences
Letter Digit Substitution	No differences	No differences
Trail Making	No differences	No differences
Sleep measures	N/A	No differences

Claims:

1. Wearing Dhama after exercise in the heat can help lower body temperature up to 25% more than passive rest alone. (~0.5°F difference)
 - This has large implications for those who have rest breaks of 15-30 minutes in athletic, military and laborer scenarios (and are also expected to perform in the heat).
 - These cooling results for post-exercise, hyperthermic individuals at rest, may support the use of this device for passively warmed individuals, (such as those in heat waves) who might benefit from its use. Further research is required for this application.
 - Previous research has shown that differences in body temperature of as little as 0.35°C (~0.5°F) between 38-39°C (100.4°F to 102.2°F) have demonstrated differences in performance of up to 6% for a 2 mile race
2. Single leg foam stance is improve immediately post exercise when wrist cooling is utilized.
3. Wearing Dhama during exercise did not enhance nor hinder physiological functioning or performance.

APPENDIX

PERCEIVED THIRST

The thirst scale is meant to identify perceived thirst. Normal values for thirst vary based on setting. The higher the value from 1-9 the thirstier the individual feels.

PERCEIVED THERMAL SENSATION

The thermal scale is meant to identify how warm or cold someone is. Normal values for thermal sensation vary based on setting. The higher the value from 0-8, the warmer the person feels.

RATING OF PERCEIVED EXERTION (RPE)

This scale ranges from 6-20 and is an indicator of how hard or intense someone believes they are working. Normal values can range depending on the intensity and type of exercise.

FATIGUE

The fatigue scale is meant to identify how fatigued someone is. Normal values for vary based on exercise intensity and mode. The higher the value from 0-10, the more fatigued the person feels.

MUSCLE SORENESS

The muscle soreness scale is meant to identify how sore or how much muscular pain someone has on a 10cm scale ranging from “no soreness” to “unbearable pain.” Normal values for vary based on exercise intensity and mode. The higher the value, the more muscle pain the person feels.

BALANCE ERROR SCORING SYSTEM (BESS):

The BESS tests balance ability with participants in two different stances on two surfaces on both legs. Participants stand with their eyes closed and hands on hips during all four tests. The two stances include: Single Leg Stance, and Tandem Stance. The Single Leg Stance requires participants to stand on one foot with their contralateral hip flexed 30 degrees and knee flexed 45 degrees. Participants stand with the heel of one foot touching the toes of the other foot during the Tandem Stance. The two surfaces are a firm, flat surface and a foam pad.

Participants are instructed to assume the standard testing position and remain as still as possible for 20 seconds. Participants are scored based on the number of errors they perform during the 20-second time period. Errors include: Lifting hands off the iliac crest, opening the eyes, stepping, stumbling, or falling, moving the hip into more than 30 degrees of flexion or abduction, lifting the forefoot or heel, or remaining out of the testing position for more than 5 seconds. If a participant cannot maintain the standard position for at least 5 seconds, the score for that trial is a 10 (the maximum score for each trial).

LETTER DIGIT SUBSTITUTION TEST

The Digit Symbol Substitution Test is a paper and pencil tests that takes 90 seconds to complete. Each subject is given a digit-symbol code in which each digit is assigned a

specific symbol. The subject is instructed to write the number that corresponds to each symbol in order of appearance. The number of correct responses in 90 seconds is the score.

TRAIL MAKING TEST

The Trail Making Test is a paper and pencil test that takes less than 3 minutes to complete. The test consists of connecting numbers scattered around the paper in numerical order as quickly as possible without lifting the pencil. Time to complete the test and errors are tallied.