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Effects of Heat Stress Prevention Training on the Knowledge of Construction Students

Mehdi Torbat Esfahani¹, Ibukun Awolusi², and Yilmaz Hatipkarasulu³

¹Ph.D. Student, School of Civil & Environmental Engineering, and Construction Management, The University of Texas at San Antonio, San Antonio, TX 78249, E-mail: mehdi.torbatesfahani@my.utsa.edu

²Assistant Professor, School of Civil & Environmental Engineering and Construction Management, The University of Texas at San Antonio, San Antonio, TX 78249, E-mail: ibukun.awolusi@utsa.edu (corresponding author).

³Associate Professor, School of Civil & Environmental Engineering and Construction Management, The University of Texas at San Antonio, San Antonio, TX 78249, E-mail: yilmaz.karasulu@utsa.edu

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Abstract: Construction workers exposed to extreme heat in hot and humid climates are at risk of heat stress and heatrelated illnesses. Although several studies have been conducted on heat stress research in the construction industry, only a few have focused on safety training and its effects on improving the knowledge of the construction workforce. This study examines the effects of training on the knowledge of the future construction workforce for heat stress prevention. The training was conducted for the future construction workforce (i.e., undergraduate construction senior students). Pre-tests and post-tests were administered before and after the training to determine the trainees' knowledge. In addition, selfassessment surveys were administered after the training to evaluate trainees' perception of knowledge improvement through the training. The questions of the tests and assessment were designed to ascertain the participants' knowledge of the risk factors, types of heat-related illnesses, and prevention strategies. The results illustrate an overall significant positive impact of training on the participants' knowledge and ability to protect themselves from heat stress.

Keywords: Construction, heat-related illness, heat stress, knowledge, prevention, training.

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1. Introduction

Construction is a high-hazard industry comprising various types of work, including new construction, alteration, and/or repair activities (OSHA, 2015). Construction workers engage in many activities in unpredictable conditions that may expose them to severe hazards, such as extreme heat in hot environments, that put workers at risk of heat stress (OSHA, 2015). Moreover, increasing global temperatures, and more frequent and longer-lasting periods of extreme heat place worker populations at higher risk for heat-related illnesses (HRI) and injuries (Runkle et al., 2019; Acharya et al., 2018). Heat or extreme temperature can result in severe health-related hazards and HRI, and injuries (Lugo-Amador et al., 2004). Several factors, including but not limited to air temperature, movement, humidity, health conditions, clothing, job types, and working times, can increase the risk of heat stress or HRI on the construction job site.

Generally, environmental, individual, demographic, and occupational factors severely impact workers' health and contribute to heat stress or HRIs like rashes, cramps, syncope, exhaustion, rhabdomyolysis, or heat stroke, which can result in death (NIOSH, 2016). Heat stress could also have direct and indirect consequences, affecting projects' costs, time, and scope. Several heat stress control and prevention procedures have been developed for workers in construction, including hydration, active cooling methods, acclimatization, rest breaks, the use of PPEs, and other engineering and administrative controls. In addition, heat stress risk can be managed in several ways to control heat stress exposure through an action-triggering threshold system, control of continuous work time with mandatory work-rest regimens and enable self-paced working by empowering employees (Rowlinson et al., 2014). The employer should institute a training program conducted by persons qualified by experience or training in occupational safety and health (Awolusi et al. 2017) to ensure that all workers who are potentially exposed to heat stress are adequately trained (NOSH, 2016). In addition, the worker's lack of appropriate knowledge on health actions to take when exposed to heat-related hazards can annihilate the effects of the prevention strategies (Jacklitsch et al., 2019).

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Research indicates that the state of knowledge about heat stress is at the general level, and prevention strategies such as training can exert essential effects (Hancock and Vasmatzidis, 2009). Studies have shown links between educational outcomes, such as enhancing knowledge, and health-related behaviors (Rasberry et al., 2017). According to El-Shafei et al. (2018), significant improvement was achieved in construction workers' knowledge by conducting exertional heat illness training as a health education program. Similarly, the results of the study conducted by Bonafede et al. (2022) highlighted the need to increase workers' perception of heat stress in the workplace to safeguard their health and productivity. In addition, research demonstrated that it is necessary to raise construction workers' knowledge and awareness of heat-related illnesses, their symptoms, and prevention methods (Song and Zhang, 2022).

This study evaluates the effects of training on the knowledge of the future construction workforce about heat hazards, heat-related illnesses, their signs and symptoms, risk factors, and prevention strategies. This evaluation will answer the research question: "Does heat stress prevention training enhance the knowledge of the future construction workforce?" Training sessions were conducted, and the results of the analysis of the effects of the training using an objective assessment (pre-and post-tests) and a subjective (self-evaluation) assessment are presented and discussed.

2. Background

2.1. Heat Stress Risk Factors, Heat-Related Illnesses, and Prevention Strategies

Generally, the main risk factors of heat stress are categorized into environmental, individual, demographic, and occupational. Four critical environmental risk factors include air temperature, humidity, radiant heat, and wind speed (Rowlinson et al., 2014). Individual factors include physical and health conditions, metabolic heat generated by physical activities, alcohol or caffeine consumption, clothing materials, layers, and colors, hydration, sweating, acclimatization, and age (Chan et al., 2013; NIOSH, 2016). Vulnerability, built environment characteristics (like the type of dwellings and heat insulations), and population adaptation capacity related to health problems and heat stress perceptions are a few of the demographic heat stress risk factors (Hatvani-Kovacs, 2016). Working times, spending hours outdoors, daily working hours, spatial characteristics of work, maximizing productivity pressure (Jia et al., 2019), workload, work pace, physical task activities, position types, experiences, and types of construction projects are the most critical occupational risk factors (Rowlinson and Jia, 2015).

Assessing the level of heat stress, physiological heat strain, individual factors, and type of work can generate useful information that can be used to develop guidance for eliminating or mitigating heat stress (Malchaire et al., 2001, ISO 2005; Yi and Chan, 2015; Shakerian et al., 2021). First, to evaluate the heat stress level, the causation of heat stress, like total heat, which is loaded by environmental factors, metabolic heat, or clothing impacts, should be assessed, and its extravagance of human tolerance limits should be analyzed. Furthermore, metabolic heat is the energy produced by chemical processes in the body during physical activities or by converting food to energy (Koojiman et al., 2010). Moreover, increasing the number of layers, clothing colors, and clothing materials can increase heat stress hazards (Parsons, 2006). Second, heat strain is the physiological response that dissipates excess heat from the body caused by heat stress, which can lead to serious injury (Yang and Chan, 2015). These risk factors may result in HRIs and injuries.

Heat stroke, rhabdomyolysis, exhaustion, cramps, syncope, or rashes are the main HRIs (NIOSH, 2016). Although heat stress can cause HRIs directly, it tends to induce other construction accidents indirectly through physical fatigue, impaired mental capacity, and misuse of inconvenient personal protective equipment (PPE) (Rowlinson et al., 2014). Just like other safety and health hazards, engineering controls, administrative controls, as well as using personal protective equipment, clothing, and auxiliary body cooling are principal categories of heat stress prevention and control strategies. While engineering controls include convective radiant, evaporative heat controls, water and air-cooled garments, cooling vests, wet overgarments, phase-changed systems, ice vests, and encapsulating ensembles can protect the workforce from heat stress hazards, administrative controls involve changing effective procedures like limiting exposure time and temperature, reducing metabolic heat, enhancing tolerance to heat, health and safety training, screening for health intolerance, and a heat alert program (NIOSH, 2016).

2.2. Training and Knowledge of Heat Stress Risk Factors, Heat-related Illnesses, and Prevention Strategies

Hazard recognition depends on workers' ability to detect hazards, and safety training by enhancing workers' hazard awareness can reduce the rate of accidents in construction. Safety training is a significant factor that impacts safety during construction projects. Over the years, injury and accident prevention through education and training has proven to be successful (Awolusi et al., 2022). According to Li et al. (2019), project management teams can reduce safety risks among workers on new projects by conducting training, such as training in safety operations and using PPEs. Training also can increase knowledge and improve cognitive performance during heat stress (Hancock and Vasmatzidis, 2003). Training could be in traditional face-to-face, online, or artificial intelligence-based eye-tracking (Zhu et al., 2022), and the effectiveness of safety training procedures is a critical component of construction site safety management (Awolusi et al. 2017). Lucas et al. (2014) concluded in their study that raising awareness among workers and the administration about heat stress prevention strategies is critical to effectively protect the workers. According to El-Shafei et al. (2018), educational programs can significantly impact adherence to healthy behaviors in preventing heat illness or managing any signs or symptoms. The study also illustrated a significant improvement in workers' knowledge about heat illness and behavioral action for prevention after health education. Construction workers are at high risk of exposure to heat illnesses, and therefore, the need to provide training and educational programs is very critical to improve their knowledge about heat illnesses and behavioral actions for prevention (El-Shafei et al., 2018). Moreover, the risk of experiencing HRI could be compounded by a lack of knowledge about HRI first aid, suboptimal hydration measures, and increased response time by emergency medical services (Smith et al., 2021). Workers' risk perception of heat stress is often low, negatively affecting their health and productivity. Bonafede et al. (2022) evaluated workers' knowledge base and awareness of the health effects of environmental thermal stress conditions, and highlighted the need to increase workers' knowledge and perception of heat stress in the workplace to safeguard their health and productivity.

Researchers have found that most construction companies allocate the highest discretionary safety funding to safety training (Song et al., 2017). It was suggested that increasing the amount of discretionary safety funding in a construction company can improve its incident record. Companies can improve their safety record by investing in safety programs, training, and employee incentives (Song et al., 2017). Furthermore, research results indicated that awareness of heat-related illnesses is vital to prevention and heat-related training should focus more on heat-related illness prevention strategies, first aid, and symptom identification (Song and Zhang, 2022; Zhu et al., 2022). Studies also pointed out that training techniques could be different for migrant to native workers and that migrant workers get informed mainly through written or oral communications, while native workers through training courses (Messeri et al., 2019). Song and Zhang (2022) assessed the effects of demographic characteristics of construction workers on their awareness of the danger of heat, knowledge of symptoms of heat-related illnesses, prevention, and first aid. Manning et al. (2023) also stated that heat training twice a week following heat acclimatization may improve and maintain adaptations in environmental symptoms.

Although research results point to how knowledge about heat stress varies among workers based on experiences, nature of work and other demographic characteristics (Song and Zhang, 2022), there is still a need to evaluate the impact of training on the knowledge of the construction workforce. In this study, the effects of training in heat stress hazards and HRIs prevention strategies on improving the knowledge of the future construction workforce knowledge are investigated.

3. Research Method

The study presents the evaluation of the effects of a training program on extreme temperatures and heat stress prevention for construction workers which is part of the Susan Harwood Training Grant Program sponsored by the Occupational Safety and Health Administration (OSHA) and the United States Department of Labor (U.S. DOL). Each training session of the program is 3 hours in length. Five learning objectives (LOs) were defined to achieve the study purpose, and pre-and post-tests together with a self-assessment survey were designed to evaluate the effects of training on the participants' knowledge of each of the LOs. Knowledge of the factors associated with heat stress and HRI, recognition of heat-related hazards, identification of signs and symptoms of heat-related illnesses, prevention or control options, and plans for heatrelated medical emergencies were defined as LOs one to five, respectively. The training materials used were prepared based on the material originally developed by the University of Houston Clearlake through a previous Susan Harwood Training Grant Program for material development. Pre-tests and post-tests were also administered to determine the trainees' knowledge before and after the training. In addition, self-assessment surveys were issued to evaluate trainees' perception of knowledge improvement through the training. This section describes the design of the tests, self-assessment survey, data gathering, measurement process, and data analysis. Fig. 1 depicts the summary of the research process.

3.1. Design of Pre-and Post-Tests and Self-Assessment Survey

A total of eighteen questions were designed for pre- and post-test. There are thirteen multiple choice questions (MCQ) and five true or false questions (TFQ) to assess all five learning objectives. The learning objectives, number, type, and description of the questions addressed by each learning objective are shown in Table 1. In addition, a self-assessment survey was developed to ask trainees about their knowledge of each LO before and after the training. It was designed based on a Likert scale of 1-low to 5-high. In other words, trainees could answer this survey by selecting two numbers associated with their knowledge of each LO: the first related to their pre-knowledge before the training, and the following related to their post-knowledge after the training.



Learning objectives	Type of questions	Question details				
Knowledge of the factors associated with heat stress and HRI (LO1)	MCQ	Selection of the environmental risk factors associated with heat stress				
	MCQ	Selection of the personal risk factors associated with heat stress				
	MCQ	Selection of physiological measurement of heat stress indicators				
	TFQ	Identifying acclimatization risk factors for workers not working under hot conditions for less than one week				
Knowledge and skill	MCQ	Selection of the risk associated when the air temperature is above 95°F				
to recognize heat- related hazards (LO2)	TFQ	dentifying the hazard associated with air temperature, clothing, and work condition				
	TFQ	Identifying the hazard associated with air temperature, clothing, and work condition				
Knowledge and skill to identify signs and symptoms of heat- related illnesses (LO3)	MCQ	Selection of the sign of heat cramp				
	MCQ	Selection of the sign of heat exhaustion				
	MCQ	Selection of the sign of heat stroke				
	TFQ	Identifying the heat stress hazard associated with high heart rate				
Knowledge of the different types of HRI prevention control options (LO4)	MCQ	Selection of the benefits of drinking water, taking rest, and avoiding caffeine				
	MCQ	Selection of the preferred heat stress control option				
	MCQ	Selection of the more effective heat stress control option				
	MCQ	Selection of the effective usage of evaporative coolers as an engineering control				
	TFQ	Identifying the benefits of air movement and reduced clothing layers				
Knowledge to plan for heat-related medical emergencies (LO5)	MCQ	Selection of the first aid supplies to prevent heat stroke				
	TFQ	Identifying emergency preparation options				

Table 1. Learning objectives, type, and description of the pre-and post-tests

3.2. Data Collection and Measurement

This section describes the training and data-gathering process. Two training sessions were conducted. Fifty-one undergraduate students studying construction science and management participated in the training. Participants were junior and senior students who were preparing to join the construction workforce either for internships or full-time positions where heat stress hazards and illnesses are applicable. The pre-test and post-test were administered before and after the training. Before starting the session, a pre-test was given to evaluate the trainees' knowledge. After around three hours of training, the post-test and self-assessment survey were administered.

Each trainee was given an ID number based on their name taken in order to distinguish their results in a data table. Answers were entered into a Microsoft Excel spreadsheet and recorded. The correct answer to each question will get one point, while incorrect answers will get 0. The summation of the results for each trainee will give us his or her score in each LO. For example, if trainee #1 answers all four questions of LO1 correctly, that trainee would get 4 points for this section. This procedure was repeated for all LOs, initially for the pre-test and subsequently for the post-test. The 51 rows are associated with trainees' ID and columns related to 5 LOs calculations for each pre- and post-tests. The LO1 result calculation would be out of 4 and 3, 4, 5, and 2 for LO2, LO3, LO4, and LO5. Finally, these ten data sets are available to test the effects of the training on the knowledge of each LO from before and after the training sessions. Moreover, the answers to the self-assessment survey will be measured by the indicated and scaled numbers associated with each LO, the first being the trainees' pre-knowledge scale and the second being their post-knowledge indicator.

3.3. Data Analysis

The paired student's t-test statistical method was chosen because of the data's normal distribution and known estimated scaling term. It compares the differences in the mean responses of the same group of people on one variable versus another before and after (pair sample) the training intervention. The one-tailed directional hypothesis was selected for a dependent test. This analysis was chosen because our variables are independent, with two categories and the same participants in each category. The mean differences with 95% confidence intervals and effect size were analyzed to evaluate the significance or non-significance improvement between pre to post-test results. A p-value less than 0.05 would be a criterion to indicate the knowledge improvement as significant. The p-value was calculated using the cumulative distribution function of the t-student distribution with degrees of freedom of the number of trainees minus one. In addition, mean, standard deviation, T-ratio, and effect size will be compared for each LO.

4. Results

4.1. Objective Assessment

According to the data gathering and statistical test procedures described in the last sections, the statistical analysis is conducted on the pre-and post-test responses, and the results can be found in Table 2. It illustrates the statistic values, degrees of freedom (df), p-values, mean differences, standard error (SE) differences, confidence interval values, the result of significant or insignificant improvement after training in this table, and effect sizes. Each row compares the results of each LO between the pre-and post-test. The improvement obtained in all LOs is based on a positive effect size. The results indicate improvement in all LOs except LO2. Among these improvements, LO1, LO3, and LO4 are significant improvements (p-value < 0.05) while improvement in LO5 is insignificant (p-value =0.5 > 0.05). LO4, knowledge of the different types of HRI prevention or control options, shows the most significant knowledge improvement (statistic value =

7.961, effect size =1.1148), and LO5, knowledge of how to plan for heat-related medical emergencies, shows the least knowledge improvement (statistic value=0, effect size=0). The negative value for effect size (-0.0651) and statistic value (-0.465) in LO2 illustrates no improvement in knowledge of heat-related hazard recognition.

	LO 1 Factors 4 questions		LO 2 Hazards 3 questions		LO 3 Signs/Symptoms 4 questions		LO 4 Controls 5 questions		LO 5 Emergency Plan 2 questions		TOTAL 18 questions	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Number of Samples	51	51	51	51	51	51	51	51	51	51	51	51
Mean Score	3.71 93%	4.00 100%	2.61 87%	2.55 85%	3.22 81%	3.61 90%	2.43 61%	3.78 76%	1.94 97%	1.94 97%	13.9 77%	15.88 88%
Standard Deviation	0.61	0.000	0.635	0.61	1.006	0.603	0.944	1.172	0.238	0.238	1.628	1.785
Degree of Freedom	50		50		50		50		50		50	
Mean Difference	0.2941		-0.0588		0.3922		1.3529		0		1.98	
SE Difference	0.0854		0.1265		0.1561		0.1699		0.0485		0.288	
<i>p</i> -value	< .001		0.678		0.008		<.001		0.5		<.001	
Significance p < 0.05	significant		not significant		significant		significant		not significant		significant	
Effect Size Cohen's <i>d</i>	small to medium 0.4824		<i>small</i> -0.0651		small to medium 0.3517		<i>large</i> 1.1148		small to medium 0		<i>large</i> 0.964	

Table 2. The results of the student's t-test statistical analysis

Moreover, this table compares the number of samples, mean, median, standard deviation, and standard error for each determination and provides information to analyze the differences between pre- and post-test responses. The results indicate 7%, 9%, 15%, and 11% improvements for LO1, LO3, LO4, and overall training, respectively. There was no change in this value for LO5 while there was a 2% decrease in LO2. Also, statistical results obtained after testing the data with the student's t-test indicated that this training program could improve the knowledge associated with each LO, which was defined and examined under the effects of heat stress and HRI prevention training. To investigate the overall results obtained from the pre-and post-test, total responses to all eighteen questions were analyzed, and the statistical values of this comparison are also shown in a highlighted column in Table 2.

4.2. Subjective Assessment

After the training, trainees answered a self-assessment survey. The self-assessment survey was designed to rate the students' knowledge of each LOs from low to high on a 5-point Likert scale before and after the training. In other words, students selected a number based on their perception to rate their knowledge before and after the training. Table 3 illustrates the results of a simple means of survey responses. It shows each LO's mean responses (out of 5) and standard deviation before and after the training.

 Table 3. Self-assessment survey statistical results

LEARNING OBJECTIVE	Assessment Average (1=Low, 5=High)					
	Before Tra	ining	After Training			
Knowledge of the factors associated with heat stress and heat-related illnesses (LO1)	2.76/5.0		4.75/5.0			
Knowledge and skill to recognize heat-related hazards (LO2)	2.69/5.0	in and a second s	4.75/5.0	4.74/5.0		
Knowledge and skill to identify signs and symptoms of heat-related illnesses (LO3)	2.63/5.0	2.58/5.0	4.8/5.0			
Knowledge of the different types of heat-illness prevention control options (LO4)	2.33/5.0	an a	4.65/5.0			
Knowledge to plan for heat-related medical emergencies (LO5)	2.47/5.0		4.76/5.0			

5. Discussion

According to objective assessment results, significant improvements were achieved in LO1, LO3, and LO4. However, the results indicate that no enhancement was obtained on LO2 and LO5 by training intervention. The analysis of the effect size of the training intervention on LO5 yielded a statistically insignificant result, indicating a null effect size. This means that the training intervention did not bring about any change or improvement in the trainees' knowledge of medical emergency planning. This observation suggests that students had adequate knowledge about medical emergencies before undergoing the training program. This can also be attributed to people's general knowledge about the procedure for medical emergency planning which can be similar across different domains. It is also plausible that the assessment questions posed were general or a different form of assessment approach such as the demonstration of skills might be a more appropriate measure of the impact of the training on medical emergency planning. In addition, the slight negative size of the mean value (-0.0588) for LO2 shows a small decrease in the mean value between pre- and post-tests. The questions in this part asked participants to select the best answer choice for the question, "What is the risk associated when the air temperatures are above 95 °F?". The participants were also asked to select if the following statements were true or false: "An outdoor worker wearing multiple layers of clothing is lifting and carrying heavy equipment. She is working in the sun. The air temperature is 75 °F, and the relative humidity is 80%. Assuming no other factors are an issue, this worker is likely at risk of heat stress," and "An outdoor worker wearing light clothing, operating a saw. He is working under the shade. The air temperature is 75 °F, the relative humidity is 30%, and there is a light breeze. Assuming no other factors are an issue, this worker is likely at risk of heat stress." The participants may have found this set of assessment questions a little complex and challenging after an intensive and inclusive training program on concepts new to them. The cognitive demands inherent in these questions, coupled with the cumulative nature of the training content, may engender some inconsistency, and diminish the clarity of responses from learners. This points to the importance of evaluating critically the formulation and phrasing of questions to ensure they align with the pedagogical objectives and the students' cognitive capacities, thus optimizing the effectiveness of the assessment process.

According to the outcomes illustrated in Table 2 about the overall results from pre- to post-tests, the mean value of correct responses increased from 13.9 out of 18 to 15.88, showing the overall critical improvement in the knowledge of heat stress prevention. Results indicated significant knowledge improvement (p-value < 0.05) after training for the future construction workforce. The effect size (0.964) indicates a large size effect of the training to enhance the knowledge of the factors associated with heat stress and HRI, knowledge, and skill to recognize heat-related hazards, knowledge, and skill to identify signs and symptoms of heat-related illnesses, knowledge on the different types of HRI prevention or control options, and knowledge to plan for heat-related medical emergencies. In addition, the effect size is more significant than 0.5 and close to 1, and a high statistical value (6.88) indicates the significant impact of training on students' knowledge.

The self-assessment survey results also reveal a significant improvement in all LOs. The mean knowledge rating before the training was 2.58 and critically increased to 4.74 after the training. Furthermore, the decrease in standard deviation between post- to pre-tests shows a minor variation, indicating a significant improvement for most participants. These findings reflect the efficacy of the training program in enhancing the knowledge of the students in the targeted LOs.

6. Conclusion

This study evaluated the effects of heat stress prevention training on the knowledge of the future construction workforce. Five LOs were defined, pre-and post-tests with eighteen questions associated with each LOs, and a self-assessment survey was designed to evaluate the effects of training on the knowledge improvement of students as the future construction workforce. A total of 51 students answered them, and the responses were collected and measured based on the number of questions for each LO in pre-and post-tests and a 5-point Likert scale (low to high-rate knowledge) in the self-assessment survey. The student's t-test was conducted to analyze the responses statistically. The results indicated that training causes a significant improvement in students' knowledge of heat stress risk factors, HRI, and prevention strategies. However, the results do not show a critical enhancement in LO2 and LO5; critical knowledge enhancement was obtained by training in LO1, LO3, and LO4. According to the overall results from the tests and responses to the self-evaluation survey, either the objective assessment survey established the significant positive impacts of heat stress prevention training on the knowledge of the future construction workforce. Therefore, heat stress prevention training remarkably impacted the knowledge improvement of the construction workforce. Furthermore, the findings of this study underscore the importance of targeted training programs in enhancing the knowledge and understanding of heat stress risk factors, HRIs, and prevention strategies among the construction workforce, contributing to safer and healthier practices in the construction industry.

The findings of this study may be beneficial to construction workers to acknowledge the importance of training in improving their safety and health performance. Also, it could be helpful for health professionals and safety educators, especially those passionate about construction safety science, regarding their knowledge of heat stress, HRIs, and heat hazards. Future studies could evaluate the effects of training on the health-related behavior of the construction workforce. Several behavior change models, including the health belief model, and explain health behavior in individuals, and could be considered to examine how knowledge and perception can influence behavior modification concerning health problems such as heat hazards and HRIs. To further reinforce the significant knowledge improvements achieved by training, future studies could investigate the impacts of using some training tools, such as virtual reality, to enhance knowledge of the construction workforce and guide and promote heat stress prevention programs.

Author Contributions

Mehdi Torbat Esfahani contributes to conceptualization, methodology, analysis, investigation, data collection, and draft preparation. Ibukun Awolusi contributes to conceptualization, methodology, investigation, manuscript editing, supervision, project administration, and funding acquisition. Yilmaz Hatipkarasulu contributes to conceptualization, methodology, analysis, manuscript editing, supervision, project administration, and funding acquisition. All authors have read and agreed with the manuscript before its submission and publication.

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Institutional Review Board Statement

The data collection instruments were submitted for Institutional Review Board (IRB) approval which determined that the project did not meet the DHHS or FDA criteria as regulated research. It was stated that under the determination the project, as written, requires no further IRB oversight.

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Mehdi Torbat Esfahani is currently a Ph.D. Student in the School of Civil & Environmental Engineering, and Construction Management at The University of Texas at San Antonio (UTSA). His research focuses on construction safety management, technology, and automation in construction.



Ibukun Awolusi, Ph.D., is an Assistant Professor in the School of Civil & Environmental Engineering, and Construction Management at The University of Texas at San Antonio (UTSA). Dr. Awolusi's research interests and expertise are in construction safety, safety in manufacturing, innovation, technology integration, sustainable materials and infrastructure, construction education, and workforce development.



Yilmaz Hatipkarasulu, Ph.D., is an Associate Professor in the School of Civil & Environmental Engineering, and Construction Management at The University of Texas at San Antonio (UTSA). Dr. Hatipkarasulu's research interests are in the areas of data analysis and modeling, cone penetration testing (CPT) analysis and modeling, occupational safety, construction education, and decision making and applied professional ethics.