Interventions to protect construction workers' health from heat exposure

Submission date 11/12/2024	Recruitment status Recruiting	[X] Prospectively registered [_] Protocol
Registration date 16/12/2024	Overall study status Ongoing	 Statistical analysis plan Results
Last Edited 13/12/2024	Condition category Signs and Symptoms	[] Individual participant data[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Extreme heat poses serious health risks, including heatstroke, heat stress, and mental health issues, affecting not only vulnerable groups like the elderly but also younger, active populations such as outdoor workers. These risks lead to reduced productivity, increased workplace injuries, and long-term health impacts.

In Spain, where hot summers and frequent heatwaves exacerbate these dangers, preventive measures are essential. Awareness campaigns, workplace initiatives, and updated legislation like Real Decreto 486/1997 aim to protect workers, but gaps in data and intervention effectiveness highlight the need for further research and comprehensive strategies to ensure worker safety. The main purpose of this study is to co-create, implement and evaluate the effectiveness of a co-created intervention in mitigating the potential adverse mental and physical health effects of heat exposure among outdoor construction workers in Spain. Secondary outcomes include: 1. To co-create a new intervention, or improvements on existing policies or plans, to mitigate the adverse mental and physical health effects of heat exposure of outdoor construction workers. The intervention will be co-designed by outdoor workers, employers, and researchers. 2. To evaluate the perceptions of outdoor construction workers of heat as a health risk, as well as their knowledge and attitudes towards current recommendations and preventive policies. 3. To get a first-hand insight into the influence of culture and gender identity on the

occupational behavior of workers when preventing heat exposure.

4. To characterize the exposure to heat of outdoor construction workers and the health impacts of heat exposure among outdoor construction workers, including physical and mental health outcomes.

Who can participate?

Outdoor construction workers aged over 18 years who have access to a smartphone and understand Spanish or Catalan.

What does the study involve?

This study will have two groups, an intervention group and a control group. Each participant will contribute information for 5 days.

The study will include two phases, a co-design phase and an implementation phase. In the codesign phase, workers, employers and researchers will participate in co-design activities with the aim of designing interventions to mitigate the adverse health effects of heat exposure in the workplace, to be implemented in their own company. In the implementation phase, the company will put in place the co-designed intervention in the intervention group only, and data will be collected on heat exposure, health outcomes and compliance. The control group will carry out their normal activities according to the procedures in place in their company for the entire period.

What are the possible benefits and risks of participating?

The INTERCAMBIO project supports companies in enhancing heat prevention plans, ensuring compliance with safety regulations like Real Decreto 486, and improving worker health and productivity. It provides expert guidance, tailored co-creation sessions for practical interventions, and offers anonymity or reputational benefits for companies. For workers, the project enables them to influence and improve workplace heat prevention measures, ensuring safer conditions. Participants benefit from health assessments and tailored interventions, with all personal data kept confidential. Participation is entirely voluntary, with no health risks or consequences for opting out, and no pressure from superiors is permitted.

Where is the study run from? ISGlobal (Barcelona Institute for Global Health) (Spain)

When is the study starting and how long is it expected to run for? January 2024 to December 2028

Who is funding the study? The European Union's Horizon Europe Research and Innovation programme under Grant Agreement No 101137149 (INTERCAMBIO)

Who is the main contact? Dr Xavier Basagaña, xavier.basagana@isglobal.org

Study website

https://intercambio-project.eu/

Contact information

Type(s) Public, Scientific, Principal Investigator

Contact name Dr Xavier Basagaña

ORCID ID http://orcid.org/0000-0002-8457-1489

Contact details C/ Doctor Aiguader 88 Barcelona Spain 08003 +34 (0)932147306 xavier.basagana@isglobal.org

Additional identifiers

EudraCT/CTIS number Nil known

IRAS number

ClinicalTrials.gov number Nil known

Secondary identifying numbers 101137149

Study information

Scientific Title

INTERCAMBIO WP4: Interventions to promote mental and physical health in changing working environments: Outdoor construction workers

Acronym

INTERCAMBIO WP4

Study objectives

1. Workers and employers are able to suggest preventive measures that can improve existing ones in terms of protecting workers' health from the effects of heat exposure.

2. There is a sizable percentage of construction workers who do not perceive heat exposure as a health risk.

3. Gender identity and cultural background have a significant influence on the preventive behavior of workers.

4. Heat exposure is associated with the presence of heat-related illness symptoms.

5. Implementing a preventive intervention is effective in reducing the prevalence of heat-related illness symptoms.

Ethics approval required

Ethics approval required

Ethics approval(s)

Not yet submitted, CEIm-PSMAR (Ethics Committee of Parc de Salut Mar) (Parc de Recerca Biomèdica de Barcelona (edificio PRBB) 1ª planta, oficina 163.05 C/ Doctor Aiguader, 88, Barcelona, 08003, Spain; +34 (0)93 316 06 79 – +34 (0)93 316 06 77; ceic-psmar@imim.es), ref: Reference number not provided

Study design

Controlled before-after intervention study (single-centre or multicentre depending on the recruited companies)

Primary study design Interventional

Secondary study design

Non randomised study

Study setting(s) Workplace

Study type(s) Efficacy

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Heat-related illness symptoms

Interventions

The study will not include randomization. All workers from the first company that accepts to participate in the intervention arm will be allocated to the intervention arm. The next company to be recruited, and their workers, will be allocated to the control arm.

The control group will carry out their normal activities according to the procedures in place in their company for the entire period. The implementation phase will run for 22 weeks, from the beginning of May 2025 to the last week of September 2025. The intervention will be implemented on the 12th week of the summer, only in the intervention arm. Thus, the intervention arm will have a before period (weeks 1-11) and an after period (weeks 12-22).

The intervention will be co-designed in collaboration with the relevant stakeholders of the study: employers, workers and occupational health scientists.

List of possible interventions:

Worker-level interventions:

- 1. Ask the worker to follow a specific hydration pattern during the work shift
- 2. Ask the worker to wear specific protective clothing (e.g. a hat or a cooling dress)
- 3. Use light-colored clothes (if work uniform is not provided by the company)

Company-level interventions:

- 1. Organize heat risk awareness campaigns or training
- 2. Change the schedule of activities in days of extreme heat
- 3. Impose mandatory rest periods
- 4. Engineering improvements in the workplace, e.g. to increase shade
- 5. Introduce strategies to improve worker's hydration
- 6. Provide ice slurry for workers
- 7. Provide cooling dressing for workers as part of their PPE

Intervention Type

Behavioural

Primary outcome measure

1. Heat-related illness symptoms measured using the Heat Illness Symptom Index at the end of the work shift using a validated scale that rates 11 symptoms (e.g., fatigue, cramps, dizziness) from 0 (no symptoms) to 10 (symptoms requiring cessation of work).

2. Average skin temperature during the shift will be monitored using four iButton devices placed at specific body locations (neck, scapula, hand, and shin) and calculated as a weighted average based on established guidelines.

Secondary outcome measures

Prevalence of individual heat-related illness symptoms (feeling tired, cramps, nausea, dizziness, thirst, vomiting, confusion, muscle weakness, heat sensations on the head or neck, chills, and feeling lightheaded) during each work shift. Variables will be dichotomized as less than 3 or greater or equal than 3 (presence of symptoms). If the frequencies are not too low, the researchers will also dichotomize at the value of 5 (presence of moderate or severe symptoms).
 Cognitive performance will be measured at the end of each work shift based on the Stroop test: 1) response time in milliseconds in the incongruent trials; 2) number of correct responses per minute; 3) inhibitory control, calculated as the difference between mean incongruent and congruent reaction time.

3. Self-reported sleepiness measured using the Karolinska Sleepiness Scale (KSS) at the end of the work shift

4. Sleep parameters obtained from Axivity (Ax3) sensor: sleep duration, sleep efficiency, awakenings, and wake after sleep onset. Sleep duration will be calculated as the duration between sleep onset and termination. Sleep efficiency will be defined as the proportion of time spent sleeping from onset to termination: (sleep duration–wake after sleep onset)/sleep duration. Sleep efficiency ranges from 0 to 1, where a score of 1 means the individual did not wake between sleep onset and termination. Awakenings were defined as the number of times a person was awake >5 minutes during the sleep period. Wake after sleep onset will be defined as the sum of the time a person was awake between sleep onset and sleep termination.

5. Time in moderate-to-vigorous physical activity at ambient temperatures greater than 28°C will be measured with the data provided by the accelerometer (physical activity) and the Wet Bulb Globe Temperature (ambient temperature) throughout the whole of the participation.

6. Perceived exertion (RPE) at the end of the shift measured using a scale: Not tired at all (0) - Extremely tired (almost maximal) (10)

7. Thermal sensation during the work shift (TS) will be self-reported by participants every day at the end of the work shift on a scale from 1 (cold) to 7 (hot)

8. Hydration frequency measured with the self-reported amount of liters of liquid ingested by participants during their work shift on a daily basis.

9. Hydration status will be measured with the self-reported urine color on a scale at the end of the work shift.

10. Perception of heat as a risk for health is measured with a baseline questionnaire at the beginning of the participation.

11. Perceptual Strain Index (PeSI) during work shift, calculated every day of participation, will be calculated based on the previously mentioned parameters (RPE: Perceived Extertion, TS: Thermal sensation) PeSI = 0.5*RPE + 5*(TS-1)/6), which will then be rescaled from 0 to 10. 12. Stress levels and mood measured at the end of the work shift with self-reported questions using a visual analogue scale from 0 to 100.

13. Heart rate variability during the work shift, obtained from the Polar H10 sensor that will be worn during the work shift.

Overall study start date

01/01/2024

Completion date 30/12/2028

Eligibility

Key inclusion criteria

Participants must be over 18 years
 Participants must have access to a smartphone

Participant type(s) Healthy volunteer, Employee

Age group Adult

Lower age limit 18 Years

Sex Both

Target number of participants 220

Key exclusion criteria Not being able to understand Catalan, Spanish or English

Date of first enrolment 01/01/2025

Date of final enrolment 01/01/2026

Locations

Countries of recruitment Spain

Study participating centre ISGlobal (Barcelona Institute for Global Health) Campus Mar C/ Doctor Aiguader, 88 Barcelona Spain 08003

Sponsor information

Organisation

Fundacion Privada Instituto De Salud Global Barcelona

Sponsor details

C/ Rosselló, 132, 7è Barcelona Spain 08003 Spain sara.lasuncion@isglobal.org

Sponsor type Research organisation

Website https://www.isglobal.org/en/home

Funder(s)

Funder type Government

Funder Name

The European Union's Horizon Europe Research and Innovation programme under Grant Agreement No 101137149 (INTERCAMBIO)

Results and Publications

Publication and dissemination plan Planned publication in a high-impact peer-reviewed journal

Intention to publish date

30/12/2027

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publicly available repository. Anonymised data will be published in the INTERCAMBIO ISGlobal Dataverse data repository, except when there is risk of re-identification of participants

IPD sharing plan summary

Stored in publicly available repository