

In-bedroom renewed air as anti-inflammatory adjuvant therapy in cancer survivors: BREATHS trial.

Eva Hernandez-Garcia, Andrew Edkins, Evangelia Chrysikou, Jose M. Ordonez-Mena, Larissa Nekhlyudov, Juyong Brian Kim, Gary McLean, Hannah Frost; The Bartlett School of Sustainable Construction, University College London (UCL), London, United Kingdom; University College London (UCL), London, United Kingdom; Clinical Informatics and Health Outcomes Research Group, Nuffield Department of Primary Care Health Sciences, University of Oxford, Oxford, United Kingdom; Department of Medicine, Brigham & Women's Hospital, Harvard Medical School, Boston, MA; Division of Cardiovascular Medicine, Department of Medicine, Stanford Cardiovascular Institute, Stanford University, Stanford, CA; Faculty of Medicine, National Heart and Lung Institute, Imperial College London, London, United Kingdom; Cancer Research UK Manchester Institute, Manchester, United Kingdom

Background: Inflammation plays a pivotal role in both cancer progression and adverse cardiovascular (CV) effects of anticancer treatments. Cardio-oncology rehabilitation with inflammatory pathways-targeting therapies is emerging as a promising approach for cancer survivors at high risk of CV toxicity. In-home air filtration interventions effectively lower interleukin-6 levels in high-risk populations for CV and respiratory events and significantly impact C-reactive protein (CRP) levels in patients with atherosclerosis. Evidence indicates that CRP can serve as a reliable clinical indicator of residual inflammatory risk and cardiotoxicity after cancer therapy. Concurrent administration of purified air therapy along with conventional pharmacological agents—including statins, cyclooxygenase inhibitors, and beta-blockers—may potentiate the desired therapeutic effect, yet the underlying interactions are not fully understood. We investigate whether overnight in-bedroom air filtration effectively reduces inflammation and cardiac markers in survivors of adult-onset cancer at high risk of CV toxicity.

Methods: This is a series of N-of-1 randomized, adaptive, blinded, and placebo-controlled trials conducted in the homes of adult survivors residing in densely populated urban areas of Valencia, Spain, with the poorest air quality levels, as evidenced by particulate matter concentrations exceeding the WHO and EU Directive limits. Inclusion criteria are age ≥ 18 years, prior history of breast, colorectal, prostate, lung, or hematologic cancer, exposure to cardiotoxic cancer therapy, and CRP level ≥ 3 mg/L. Participants will be randomly assigned to three treatment sets, each comprising a 14-day period of active therapy (portable air purifier at 275 m³/h) and a 14-day period of placebo (sham purification). In-bedroom air filtration treatment and placebo will be administered nightly for a minimum of 7 consecutive hours. The blinded sequence will last between 4 and 12 weeks per participant, depending on the clinical efficacy evidenced after each treatment set (CRP < 2 mg/L or CRP reductions $\geq 35\%$). Participants who fail to achieve the clinically meaningful change in the last treatment set will undergo an open-label phase: 14 days of no treatment and 14 days of active therapy administered nightly and daily (air purifier operating continuously at 275 m³/h). Participants will be asked to keep a daily in-bedroom time log. The primary endpoint is defined as the change in blood CRP levels after each cycle. Secondary outcomes include changes in D-dimer, serum amyloid A and glycated hemoglobin A1c concentrations, and blood pressure. Exploratory endpoints include the feasibility of at-home point-of-care testing to monitor residual inflammatory toxicity. Ten participants will be enrolled in the trial. No enrolled participants at the time of abstract submission. Clinical trial information: NCT06778122. Research Sponsor: None.