

Food Intake REstriction for Health OUtcome Support and Education (FIREHOUSE): A Randomized Clinical Trial

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RATIONALE Particulate matter (PM) exposure and Metabolic Syndrome (MetSyn) are growing, global health concerns. FDNY first responders experienced a high exposure to PM following the collapse of the WTC, due to their detailed phenotyping we were able to observe that MetSyn characteristics were associated with higher risk of developing WTC-lung injury [WTC-LI; forced expiratory volume in 1 second (FEV₁) less than the lower limit of normal (LLN)]. Our prior metabolomics studies showed metabolites—polyunsaturated fatty acids and branched chain amino acids—rich in Mediterranean type diets were higher in subjects that didn't develop WTC-LI. Therefore, our objective was to investigate how a calorie-restricted Mediterranean dietary intervention could attenuate the adverse effects of WTC exposure among the affected FDNY population. **METHODS** Food Intake REstriction for Health OUtcome Support and Education (FIREHOUSE) RCT is a calorie-restricted Mediterranean 6-month dietary intervention of male firefighters with WTC-LI and BMI>27kg/m²; ClinicalTrials.gov Identifier: NCT03581006, NYU IRB # 17-00127. Power analysis and primary outcome assessment targeted at least a 1 kg/m² change of BMI (primary outcome) in the intervention group. Secondary outcomes include FEV₁, fractional exhaled nitric oxide (FeNO), pulse wave velocity (PWV), lipid profiles, targeted metabolic/clinical biomarkers, and quality of life measures. Change in outcomes from baseline to 6-months post-intervention will be compared between the two randomized groups. Interim analysis with an O'Brien Fleming boundary for a 3-look design was planned at the completion 30, 50, and 70 subjects in each group with an α spending rule of 0.001, 0.007, and 0.033, respectively. Subjects were randomized 1:1 to Low Calorie Mediterranean (LoCalMed), integrative technology-supported approach with social cognitive theory-based group counseling or Usual care. **RESULTS** Our interim analysis showed that LowCalMed resulted in a significant reduction in BMI compared to usual care (n=40/arm) (p<0.001 via independent two sample t-test). While we are continuing to analyze our data, so far we observed a decreased BMI in both groups; however, the intervention has a mean BMI reduction of 1.84 kg/m² while the controls' mean difference was only 0.61 kg/m², Figure 1. **CONCLUSIONS** While this study focuses on a population with a unique exposure, exposure to PM is a grave issue with global implications. Additionally, MetSyn is an increasing problem throughout the world. The findings of this study aim to not only improve the quality of life and lung health of the WTC-exposed population, but also be generalized to benefit a broader global context.

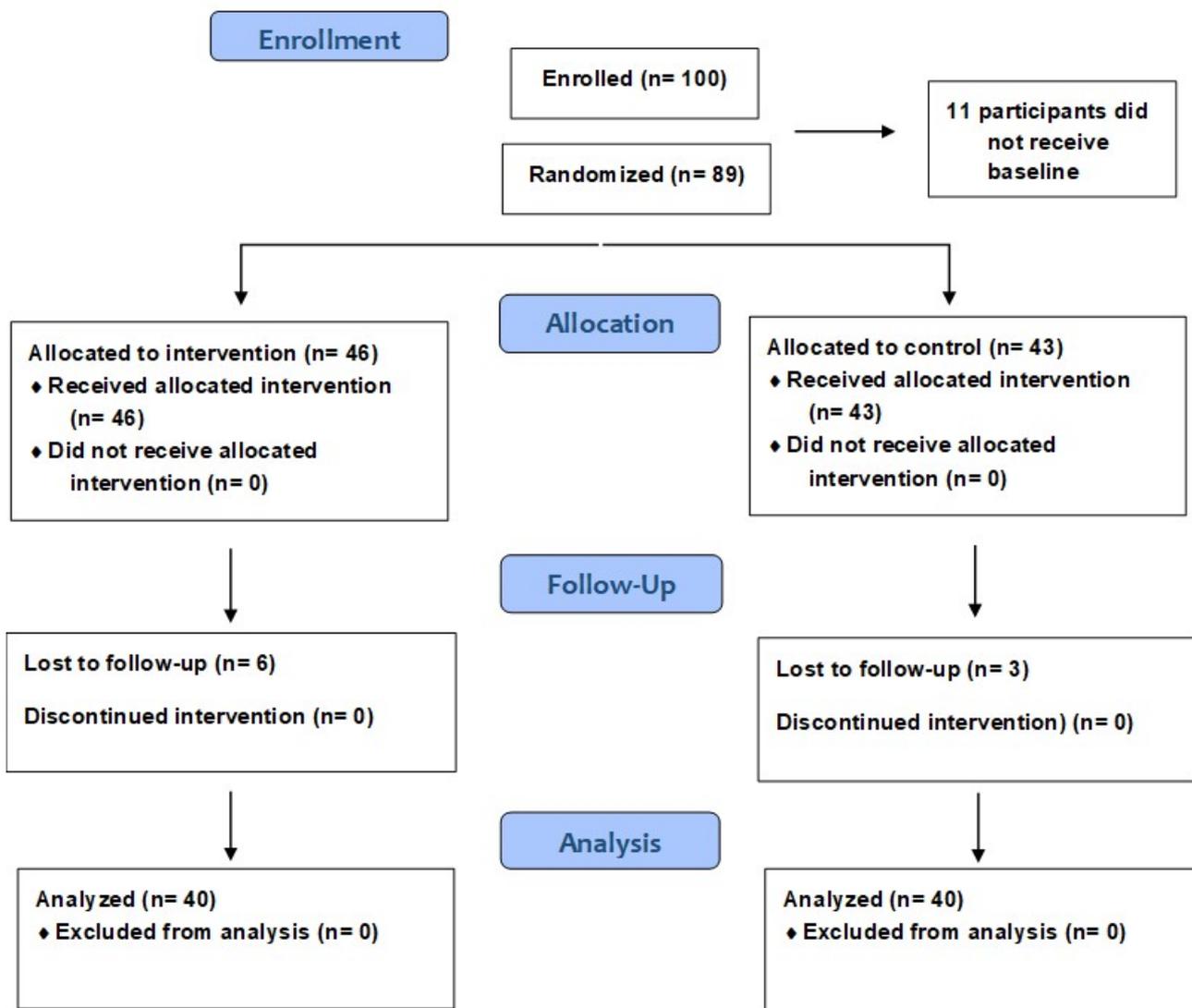


Figure 1. Enrollment CONSORT Diagram

This abstract is funded by: NHLBI, CDC/NIOSH, Stony-Wold Herbert Fund