

**The Men's Eating and Living (MEAL) Study (CALGB 70807 [Alliance]):  
Recruitment Feasibility and Baseline Demographics of a Randomized Trial of Diet in Men on  
Active Surveillance for Prostate Cancer**

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**Background:** Diet may influence the risks of prostate cancer incidence and progression. However, large-scale randomized trials of dietary interventions for prostate cancer have yet to be completed.

**Methods:** The Men's Eating and Living (MEAL) Study (CALGB 70807 [Alliance]) is a phase 3 clinical trial testing the efficacy of a high-vegetable diet to prevent progression in prostate cancer patients on active surveillance. Participants were randomized to a validated diet counseling intervention or a control condition. Chi-Square and Kruskal Wallis analyses were used to assess between-group differences at baseline.

**Results:** From 2011 to 2015, 478 (103%) of a targeted 464 patients were randomized at 91 study sites. At baseline, mean (SD) age was 64 (6) years and PSA 4.9 (2.1) ng/mL. Fifty-six (12%) participants were African-American, 17 (4%) Hispanic/Latino, and 16 (3%) Asian-American. There were no significant between-group differences for age (p-value = 0.98), race/ethnicity (p-value = 0.52), geographic region (p-value = 0.60), time since prostate cancer diagnosis (p-value = 0.85), PSA (p-value = 0.96), clinical stage (T1c or T2a, p-value = 0.27), or Gleason sum (Gleason 6 or 3+4 = 7, p-value = 0.76). In a pre-planned analysis, the baseline prostate biopsy samples of the first 50 patients underwent central pathology review to confirm eligibility, with an expectation that <10% would become ineligible. One (2%) of 50 patients became ineligible.

**Conclusions:** The MEAL Study demonstrates the feasibility of implementing national, multi-institutional phase 3 clinical trials of diet for prostate cancer and of testing interventions to prevent disease progression in active surveillance.

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