

The Enabling Reduction of Low-Grade Inflammation in Seniors (ENRGISE) Pilot Study: Screening Methods and Recruitment Results.

Cauley JA¹, Manini TM², Lovato L³, Talton J³, Anton SD², Domanchuk K⁴, Kennedy K³, Stowe CL³, Walkup M³, Fielding RA¹, Kritchevsky SB³, McDermott MM⁴, Newman AB¹, Ambrosius WT³, Pahor M²; ENRGISE Investigators.

Author information

Abstract

BACKGROUND: The Enabling Reduction of Low-grade Inflammation in Seniors (ENRGISE) Pilot Study is a multicenter randomized clinical trial examining the feasibility of testing whether omega-3 fish oil (ω -3) and the angiotensin receptor blocker losartan alone or in combination can reduce inflammation and improve walking speed in older adults with mobility impairment. We describe recruitment methods and results.

METHODS: Eligible participants were 70 years and older, had elevated interleukin-6 levels (2.5-30 pg/mL) and mobility impairment.

RESULTS: Of those who responded to recruitment, 83% responded to mailings. A total of 5,424 telephone screens were completed; of these, 2,011 (37.1%) were eligible for further screening. The most common reasons for ineligibility at the telephone screens were lack of mobility impairment or use of angiotensin receptor blockers or angiotensin-converting enzyme inhibitors. Of the 1,305 initial screening visits, 1,087 participants had slow gait speed (<1 m/s). Of these, 701 (64%) had elevated interleukin-6 and were eligible for second screening visits. Of the 582 second screening visits, 335 (57.6%) were eligible to be randomized. A total of 289 participants (96% of goal) were randomized: 180 in the ω -3 stratum (240% of goal); 43 in the losartan (57% of goal), and 66 in the combination (44% of goal). The telephone screen and first screening visit to randomization ratio was 19 to 1 and 4.5 to 1, respectively. The estimated cost of recruitment per randomized participant was \$1,782.

CONCLUSION: Recruitment for ω -3 exceeded goals, but goals for the losartan and combination strata were not met due to the high proportion of participants taking angiotensin receptor blockers or angiotensin-converting enzyme inhibitors.

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