

Tailored Occupational Therapy and Registered Dietitian Services for Home-Delivered Meal Clients: A Randomized Controlled Trial (SixtyPLUS)

I. OBJECTIVE

The purpose of this study is to determine which of the following four service models is most effective for improving the health outcomes of home-delivered meal clients: (1) meals alone, (2) meals + registered dietitian services, (3) meals + occupational therapy services, (4) meals + registered dietitian + occupational therapy services.

II. BACKGROUND AND RATIONALE

Home-delivered meal programs provide essential health and nutritional support to community-dwelling older adults in the United States.¹ Without this support, nearly three million older adults would be at even greater risk for malnourishment and subsequent health decline, leading to potential hospitalizations and nursing home placements.² Despite the reported value of home-delivered meals,³⁻⁵ the increasingly complex health needs of the older adult population warrant new, innovative approaches that enhance home-delivered meal services. In our prior work, we identified that the majority of home-delivered meal clients are living with diet-related health conditions, such as cardiovascular disease and diabetes,⁶ and require more specialized services – as provided by registered dietitians – to adequately address dietary needs.⁷ Additionally, our other work has identified that 80% of home-delivered meal clients are at elevated risk for falling,⁶ and over 40% have experienced a fall in the past year.⁸ The high prevalence of fall risk factors among home-delivered clients suggests that additional services – such as occupational therapy – are also needed to optimize clients' ability to safely remain living in their own homes and communities. In response to home-delivered meal clients' need for more enhanced and specialized services, the present study will test four different service models to determine which model is most effective for improving client health outcomes.

III. STUDY DESIGN

1. Experimental design: This is a single-blinded, four-arm randomized controlled trial that will compare health outcomes of home-delivered meal clients. Participants will be randomized into one of four study arms: In Arm 1, participants will receive home-delivered meals and basic nutrition education and fall prevention handouts. In Arm 2, participants will receive home-delivered meals plus dietitian services. In Arm 3, participants will receive home-delivered meals plus occupational therapy services, and in Arm 4, participants will receive home-delivered meals plus dietitian *and* occupational therapy services (See figure). Study activities will be conducted at LifeCare Alliance – Ohio's largest home-delivered meal provider.

2. Study population and sample size: LifeCare Alliance provides home-delivered meals to 6,200 older adults each year. Meals are funded through a combination of federal tax dollars, local tax levies, and private donations. To be eligible to receive meals, clients must be over the age of 60 and be "homebound," indicating that they are unable to safely and routinely leave their home to purchase or secure food. Clients also must *not* have a caregiver who can provide meals for them on a regular basis. We estimate enrolling 500 participants (125 participants per arm) for our trial.

