

Pilot Mobile for Dementia and Frailty (Mindful Meals)

NCT05827094

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STUDY PROTOCOL

Objective

We conducted a pilot randomized controlled trial (RCT) to assess the feasibility and preliminary efficacy of an innovative, theory-driven mobile intervention specifically designed for older adults with frailty and dementia, aimed at increasing Mediterranean food consumption. Primary efficacy outcome was adherence to the Mediterranean diet score.

Design

This was a pilot randomized control trial (RCT) to test the feasibility and preliminary efficacy of a mobile intervention consisting of a patient-facing mobile app and a secure web-based administrative dashboard. Participants were randomly assigned to either the intervention group or the control group. Those randomized to the intervention received access to a mobile app, available for download by invitation only on the Apple App Store. Participants randomized to control received via email referral to National Institute on Aging (NIA) materials concerning healthy eating.

Methods

Participants

Eligibility criteria included: a) being age 65 years and older, b) having difficulty with at least one of the following activities: performing heavy housework; performing light housework; walking outside alone; managing money/paying bills; shopping for personal items; preparing meals, suggestive of frailty, 3) being diagnosed with early dementia or having memory symptoms suggestive of mild cognitive impairment. Exclusion criteria included: a) having difficulty with basic activities of daily living such as eating and getting

out of bed, suggestive of overt disability, b) having a 14-item Mediterranean Diet Adherence Screener (MEDAS) >8, suggestive of an optimal diet, d) severe hearing or visual impairment.

STATISTICAL ANALYSIS PLAN

Descriptive statistics were first calculated to compare demographic characteristics between the intervention and the control groups. Outcomes measures were analyzed by calculating the within-group pretest–post-test change scores and then comparing the change scores between the intervention and the control groups using Mann–Whitney U tests. To estimate the magnitude of the intervention's impact compared to the control group, we used Hedges' g to measure effect size. Hedges' g is a variation of Cohen's d that corrects for biases that may occur in small sample sizes, making it a more appropriate choice for our study. Hedges' g takes the difference in means between the intervention and control groups and divides it by the pooled standard deviation while applying a correction factor to account for potential biases. A larger absolute value of Hedges' g indicates a greater effect size, with values of 0.2, 0.5, and 0.8 generally considered small, medium, and large effect sizes, respectively. An R package, “BootES” was used to calculate 95% bootstrap confidence intervals for the effect sizes. The “BootES” package is designed specifically for this purpose, providing a robust and efficient method for estimating confidence intervals based on resampling techniques. Finally, descriptive statistics and visual analytics were used to describe app quality and to analyze log data of user interactions.

