Mobile Health Intervention to Support Healthful Diet

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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, aimed at increasing Mediterranean food consumption. Feasibility was determined by the number of participants enrolled and retained. Primary efficacy outcomes included adherence to the Mediterranean diet score and insulin resistance measures. Secondary and theoretical mechanistic variables involved in behavioral change were food groups, social cognitive theory constructs, and anthropometric and functional measures. Usability and mobile app analytics provided deeper insights into participants' experiences and engagement with the app, identifying potential areas for improvement.

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

Study participants were recruited between January and October 2022 through listserv emails, presentations, and flyers in retirement communities and other places frequented by older adults in Seattle, WA. 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. 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 Memory Impairment Screen for Telephone (MIS-T) score of <3, suggestive of memory impairment or cognitive difficulties, c) having a 14-item Mediterranean Diet Adherence Screener (MEDAS) >8, suggestive of an optimal diet, d) severe hearing or visual impairment.

Data Collection Procedures

A study coordinator (SC) collected data during in-person assessments and remotely using standardized procedures at two time points. At the baseline in-person assessment, the SC administered clinical and demographic questionnaires, collected functional and anthropometric measures, and conducted a blood draw using dried blood spot collection methods ([DBS] described later). The second in-person visit occurred about twelve weeks later and included a similar battery of assessments and a recording of a semi-structured exit interview. Moreover, to better understand user engagement and interaction with the mobile health intervention, we collected and analyzed user log data. User log data was automatically captured and stored by the app's backend system, ensuring an accurate and comprehensive collection of user interactions. This data comprised a record of users' actions within the app, including the frequency and duration of use, features accessed, and progress through various intervention components.

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.