Official Title of Study:
Bingocize: A Novel Mobile Application for Older Adult Health

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Background & Objectives

Exercise interventions designed to improve physical and mental fitness have the potential to help reduce health care costs and maintain, or even improve, quality of life for older adults (Chodzko-Zajko et al., 2009). For example, interventions that reduce chronic disease risk and severity can decrease lifetime Medicare costs by as much as 60% (Rula et al., 2011). Despite this potential, however, adherence and retention of older adults to health promoting programs continues to be a challenge.Many facilities serving older adults are searching for creative ways to engage older adults in health enhancing and rehabilitative activities. The purpose of our trial was to test the effectiveness of using a new mobile application (Bingocize®) to improve functional performance, knowledge of health topics, dietary habits, and aspects of fluid cognitive abilities.

Design & Methods

Participant characteristics, recruitment, and sample size. In our past research, we have successfully worked with several agencies in the area, including state of Kentucky Area Development Districts (ADDs) and NHE, Inc. (a company that coordinates services for dozens of senior center/assisted living/independent living facilities throughout our region). For the current study, we have secured letters of support from Community Action of Southern Kentucky (CASOKY), which is responsible for running senior centers in a 17-county region in our area. We also have a letter of support from NHE, Inc. who will provide access to recruit participants from multiple low-income senior housing facilities. Both of these agencies will assist in recruiting participants from their facilities in Kentucky and Tennessee.

Flyers, newsletters, electronic communication, direct contact, and word of mouth will be used to recruit volunteers. Males and females who are over 60 and over will be eligible to participate. The Physical Activity Readiness Questionnaire (PAR-Q) will be used to determine the participant's health status based on responses to seven medical questions (Chodzko-Zajko et al., 2009). Participants answering "yes" to any of these questions will require a physician's release prior to participation in the study. Fall risk will be assessed using the STEADI algorithm, the Falls Efficacy Scale (Tinetti et al., 1990), and the four meter walk test from the Short Physical Performance Battery (SPPB; Stevens & Phelan, 2013; Ward et al., 2015). Diet/nutritional intake will be assessed using the Dietary Screener Questionnaire (DSQ; see Thompson, Midthune, Subar, McNeel, Berrigan, & Kipnis, 2005). Other criteria for inclusion in the research include: normal or corrected-normal vision, no history of severe neurological impairment, mobility (i.e., not wheel-chair bound), no history of colorblindness, English as their native language, and a minimum score of 17 on the tMMSE (telephone Mini-Mental Status Exam, scores of 17 or higher indicate no clinically significant dementia).

The research project has been reviewed and approved as a minimal risk project by WKU's Institutional Review Board (IRB) to ensure there are no ethical issues, and an approved safety monitoring plan is in place.

To calculate the needed sample size, we were conservative. Since physical outcome effect sizes due to the exercise intervention are generally larger than more distal cognitive outcome effect sizes, our calculations were based on examining cognitive outcome effect sizes (η_p^2) from interaction effects in our recently completed smaller study, as well as data from other published studies. With α=0.05 and power=0.8, (taking into account mean *r* among pre/post repeated measures and assumption of sphericity), the total sample size needed is 124. However, to adjust for the fact we are conducting a cluster randomized controlled trial (see Design section below; Murray, Varnell, & Blitstein, 2004) with an unknown intracluster coefficient, we will recruit a slightly larger sample - 160 - to better strengthen the overall validity of the study. This size is also comparable to other four-group exercise/cognition intervention studies published recently in the literature. (e.g., Loh et al., 2015).

Design. We expect sixteen senior centers in western Kentucky and Tennessee will serve as sites for the groups in our study (see the Inclusion of Women & Minorities attachment for details). We list some of the senior centers we have existing relationships with in other parts of our application (Performance Site/Location document; see our Letters of Support from NHE, Inc., and CASOKY). For both study control and feasibility reasons, we require a facility to have eight to twelve (8-12) older adults who consent to participate. This study will combine both between-group (condition) and within-subject (pre/post) comparisons. For logistical reasons, data will be collected in "waves" (i.e., 4 senior centers during one 12-week period, then another 4 senior centers during the next 12-week period, etc.).

Using a pre-/post-test cluster randomized clinical trial (CRCT) experimental design with two factors (exercise and health education) at two levels (present and absent), senior centers will be randomly assigned to one of four conditions in the study, as shown in **Table 1** below: (A) an experimental group that participates in Bingocize® (bingo, exercise, and health education) twice a week for 12 weeks, (B) a control/comparison group that participates in bingo+exercise only (the same exercises as the experimental group), (C) a control/comparison group that will participate in a bingo+health education program only (covering the same topics/materials as the experimental group), and (D) a control/comparison group that participates in bingo only. <u>All four groups will use our Bingocize® app on tablets, as the app is designed to accommodate the usage of all of these methods.</u> In addition to these between-group comparisons, within each individual we will take both pre- and post-intervention assessments of a variety of physical and cognitive outcome measures (described later).

Table 1: Design Layout of Participant Groups

	Plays Bingo Using App?	Exercises Using App?	Health Education Using App?
Group A (Experimental; Multimodal)	Yes	Yes	Yes
Group B (Exercise Control; Unimodal)	Yes	Yes	No

Group C (Health Education Control; Unimodal)	Yes	No	Yes
Group D (Bingo Control)	Yes	No	No

Statistical Analysis Plan

Planned statistical analyses. Although we expect missing data to be fairly minimal (based on our prior studies), we will use missing value analysis (MVA) to analyze those data, determine whether they are missing at random, and handle as appropriate (see next section; Handling participant attrition). We will also test normality assumptions using skewness and kurtosis analyses. Baseline differences will be assessed using generalized linear mixed models (GLMMs). Mixed models allow for additional flexibility to control for random effects across clusters (senior centers) and correlated data at the patient level, while controlling for covariates. With regard to our major questions regarding the efficacy of the multimodal intervention, we will examine Time (Pre/Post) x Group effects (four groups described above), applying Bonferroni corrections for multiple comparisons as needed. If the interaction of time and group or their main effects are significant, then post-hoc pairwise comparisons will be conducted using Least Squared Difference. Analyses will be conducted using lme4 in R.

Handling participant attrition. In all longitudinal studies, attrition is inevitable. However, we expect drop-out rates to be quite low in our study. In our most recent study, session attendance in each group was 93% or higher. We plan to use 80% attendance as the minimum participation level for inclusion in this study. However, as mentioned above, we will be analyzing missing values to ensure there is no bias in the data; statistically speaking, when handling selective attrition (e.g., someone who drops out or fails to meet the attendance requirement) in our study, we must take into account its effects on both within-group differences (i.e., pre/post-test differences within each of our four groups) as well as its effects on between-group differences (i.e., comparisons between the different groups in our study). With regard to within-group attrition effects, the most common approach is to systematically compare the drop-outs to the retained participants, to identify any pre-existing differences (e.g., in demographic variables, or on pre-test performance). If there are not any differences, then obviously, no further analysis is needed. If differences are found between drop-outs and the retained participants, we will include those variables which differed as covariates in the subsequent statistical analyses. For example, if we found differences in a pre-existing condition between drop-outs and retained participants in our experimental (Bingocize®) group, we can include that pre-existing condition as a covariate in the pre/post-test analysis to determine whether it statistically accounts for any of the improvements that the retained participants may show from baseline to post-test.