

Official Title of Study:

Bingocize: A Novel Mobile Application for Older Adult Health

NCT Number:

NCT03629912

Date:

10/11/22



*INSTITUTIONAL REVIEW BOARD  
OFFICE OF RESEARCH INTEGRITY*

DATE: October 11, 2022

TO: Matthew Shake, Ph.D.  
FROM: Western Kentucky University (WKU) IRB

PROJECT TITLE: [1116174-18] Bingocize: A Novel Mobile Application to Help Maintain or Improve Older Adults' Health, Function, and Cognition

REFERENCE #: IRB 18-048

SUBMISSION TYPE: Continuing Review/Progress Report

ACTION: APPROVED

APPROVAL DATE: October 11, 2022

EXPIRATION DATE: March 31, 2023

REVIEW TYPE: Expedited Review

Thank you for your submission of Continuing Review/Progress Report materials for this project. The Western Kentucky University (WKU) IRB has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a project design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

This submission has received Expedited Review based on the applicable federal regulation.

Please remember that informed consent is a process beginning with a description of the project and insurance of participant understanding followed by a *signed/implied* consent form. Informed consent must continue throughout the project via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the consent document.

Please note that any revision to previously approved materials must be approved by this office prior to initiation. Please use the appropriate revision forms for this procedure.

All UNANTICIPATED PROBLEMS involving risks to subjects or others and SERIOUS and UNEXPECTED adverse events must be reported promptly to this office. Please use the appropriate reporting forms for this procedure. All FDA and sponsor reporting requirements should also be followed.

All NON-COMPLIANCE issues or COMPLAINTS regarding this project must be reported promptly to this office.

This project has been determined to be a MINIMAL RISK project. Based on the risks, this project requires continuing review by this committee on an annual basis. Please use the appropriate forms for this procedure. Your documentation for continuing review must be received with sufficient time for review and continued approval before the expiration date of March 31, 2023.

Please note that all research records must be retained for a minimum of three years after the completion of the project.

If you have any questions, please contact Robin Pyles at (270) 745-3360 or Robin.Pyles@wku.edu. Please include your project title and reference number in all correspondence with this committee.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within Western Kentucky University (WKU) IRB's records.

## INFORMED CONSENT DOCUMENT

**Project Title:** Bingocize: A Novel Mobile Application to Help Maintain or Improve Older Adults' Health, Function, and Cognition

**Investigators:** Dr. Matthew Shake, Western Kentucky University, Department of Psychological Sciences; [matthew.shake@wku.edu](mailto:matthew.shake@wku.edu),  
Dr. Jason Crandall, Western Kentucky University, School of Kinesiology, Recreation, and Sport; [Jason.crandall@wku.edu](mailto:Jason.crandall@wku.edu) or 270-745-2077

You are being asked to participate in a project conducted through Western Kentucky University. The University requires that you give your signed agreement to participate in this project.

**You must be 60 years old or older to participate in this research study.**

The investigator will explain to you in detail the purpose of the project, the procedures to be used, and the potential benefits and possible risks of participation. You may ask any questions you have to help you understand the project. A basic explanation of the project is written below. Please read this explanation and discuss with the researcher any questions you may have.

If you then decide to participate in the project, please sign this form in the presence of the person who explained the project to you. You should be given a copy of this form to keep.

### 1. Nature and Purpose of the Project:

The benefits of physical activity participation in older adults include slowing the physical changes related to aging, promoting psychological and cognitive well-being, managing chronic diseases, improving health-related quality of life, and increasing longevity. Exercises that specifically focus on functional fitness variables, such as balance, strength and flexibility, are important factors for preventing falls and improving health in older adults. Although the benefits of physical activity have been well documented, very few older adults participate in recommended amounts for preventing falls and improving quality of life.

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Expedited  
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Given the need to develop programs that increase physical activity, cognition, and health education in older adults, the purpose of the study is to test the effectiveness of a 12-week Bingocize® program for improving functional fitness (e.g., upper body and lower body strength, endurance, and flexibility), cognitive ability, and knowledge of health topics like fall risk and good dietary habits.

## 2. Explanation of Procedures:

If you agree to be in this study, you will be asked to do the following BEFORE and AFTER the study.

- Complete six (6) questionnaires
- Have your height, weight, and blood pressure measured
- Complete six (6) physical tests of upper and lower body muscular strength, endurance, and flexibility
  - (a) lower body muscular strength (e.g., number of times you can stand up and sit down in a chair in 30 seconds),
  - (b) upper body muscular strength (e.g., number of bicep curls you can do with a light dumbbell in 30 seconds),
  - (c) lower body flexibility (e.g., chair sit and reach test--the distance you can reach forward toward your toes while sitting in a chair,
  - (d) upper body flexibility (e.g., back scratch test--how far your hands can reach behind your neck),
  - (e) cardiovascular fitness (e.g., stepping in place) and a (f) balance test.
- Complete several cognitive tasks assessing aspects of your attention, memory, and thinking. These tasks will be given either on paper or on a computer.

Once you complete the testing above, you may be asked to attend twice-weekly Bingocize sessions during a 12-week period. Bingocize is a mobile application that

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combines exercise, health education, and bingo in a fun game format! These sessions will last approximately 60 minutes and will occur twice a week. Because we need to compare older adults who exercise to some who do not, there is a possibility that you will not be selected to participate in the exercise portion of the project, and instead be in a group that plays Bingo and learns health-related information, or even a group that only plays Bingo. However, after the project is over, if your group wishes to play an exercise version of the game, we will provide that opportunity to you.

### 3. **Discomfort and Risks:**

Emotional stress may occur due to not being able to complete exercises, answer health education questions losing in bingo. Physical injury is possible with any type of physical exercise/exertion, but every effort will be made to use proper progressions and exercises with participants, and we will talk to you about your health history before you begin. The exercises you may do are not greater in magnitude or duration than things people do regularly in daily life (e.g., getting up and down from a chair, raising arms, walking in place, etc.).

### 4. **Benefits:**

The potential direct benefits include improved fitness level, including improved cardiorespiratory fitness, muscular strength, balance, flexibility, and aspects of cognitive function. In addition, there are social benefits from participating in community based exercise programs. You may also see improvement in the knowledge and understanding of the health education information presented and then the subsequent use of that information. Finally, we will also pay participants \$40 if they (a) complete both the before and after tests described above, and (b) attend at least 20 of the 24 Bingocize game sessions at their facility. We will also provide small prizes at each game session for the winners of each Bingocize game.

### 5. **Confidentiality:**

The answers you provide on the surveys, the fitness data, your health history, and the cognitive data we collect are ALL confidential, which means that your

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responses/results will only be known by Dr. Crandall, Dr. Shake, and their team of trained and ethics-certified investigators. Your identity as a participant in this research study will be kept confidential and will never be reported in any publication of the results of this study. The material will be maintained for up to 3 years.

**6. Refusal/Withdrawal:**

Refusal to participate in this study will have no effect on any future services you may be entitled to from the University. Anyone who agrees to participate in this study is free to withdraw from the study at any time with no penalty.

*You understand also that it is not possible to identify all potential risks in an experimental procedure, and you believe that reasonable safeguards have been taken to minimize both the known and potential but unknown risks.*

\_\_\_\_\_  
Signature of Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Witness

\_\_\_\_\_  
Date

THE DATED APPROVAL ON THIS CONSENT FORM INDICATES THAT  
THIS PROJECT HAS BEEN REVIEWED AND APPROVED BY  
THE WESTERN KENTUCKY UNIVERSITY INSTITUTIONAL REVIEW BOARD  
Robin Pyles, Human Protections Administrator  
TELEPHONE: (270) 745-3360

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## PHYSICIAN'S RELEASE

Patient's Name \_\_\_\_\_

**Project Title:** Bingocize: A Novel Mobile Application to Help  
Maintain or Improve Older Adults' Health, Function, and Cognition

**Investigators:** Dr. Matthew Shake, Western Kentucky University,  
Department of Psychological Sciences; [matthew.shake@wku.edu](mailto:matthew.shake@wku.edu),

Dr. Jason Crandall, Western Kentucky University, School of Kinesiology,  
Recreation, and Sport; [Jason.crandall@wku.edu](mailto:Jason.crandall@wku.edu) or 270-745-2077

This page will give you the information you will need to understand why this program is being done and why your patient is being invited to participate. It will also describe any known risks, inconveniences or discomforts that your client may have while participating. We encourage you to ask questions at any time, including via email or phone.

### ➤ PURPOSE AND BACKGROUND

The benefits of physical activity participation in older adults include slowing the physical changes related to aging, promoting psychological and cognitive well-being, managing chronic diseases, improving health-related quality of life, and increasing longevity. Exercises that specifically focus on functional fitness variables, such as balance, strength and flexibility, are important factors for preventing falls in older adults.

Although the benefits of physical activity have been well documented, very few older adults participate in recommended amounts for preventing falls and improving quality of life. Various reasons for this lack of participation in physical activity include discomfort, fear of injury, social isolation, and fear of falling. Fortunately, researchers have identified factors that will motivate older adults to participate in physical activity. Some of these factors are moderate intensity exercise, group-based interventions, and increasing self-confidence, improving attitudes toward physical activity, and providing social support for activity.

Given the need to develop programs that increase physical activity in older adults, the purpose of the program is to improve functional fitness (e.g., upper body and lower body strength, endurance, and flexibility).

### ➤ PROCEDURES

Participants will be asked to do the complete physical tests of upper and lower body muscular strength, endurance, and flexibility. These tests include, but are not limited to: (a) lower body muscular strength (e.g., number of times you can stand up

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and sit down in a chair in 30 seconds), (b) upper body muscular strength (e.g., number of bicep curls you can do with a light dumbbell in 30 seconds), (c) balance tests, and (d) a gait test. Each session will last approximately 60 minutes and will occur two times per week. During the sessions, gentle exercises will be alternated with bingo number calling. Participants who win BINGO and those who excel during the exercise sessions (e.g., best attitude, most reps completed, etc.) will receive small prizes at the end of each session.

➤ RISKS

Potential risks from participation in the program are typical of those related to participating in physical activity. Specifically, there is a risk of physical injury or discomfort, including muscle soreness. However, we will do our best to ensure that the program progresses gradually and that you are given ample instructions as to how to perform exercises safely or how to perform modifications if your patient cannot do specific exercises.

➤ BENEFITS

The direct benefits to your patient include the potential to improve physical health, including your cardiorespiratory fitness, muscular strength, balance, and flexibility. In addition, there are social benefits to participating. Finally, we will award small prizes to bingo winners and participants \$40 for being in the study.

➤ QUESTIONS

If you have any questions or concerns about your patient's participation in this program, please call Dr. Jason Crandall at 270-745-2077 or Dr. Matthew Shake at 270-745-4312.

**Physician's Signature** \_\_\_\_\_ **Date** \_\_\_\_\_

**Printed name** \_\_\_\_\_

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