Official Title: Evaluation of the Wits Workout Wellness Program for Older Adults

Document: Study Protocol and Statistical Analysis Plan

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Research Design
Wits Workout Program Evaluation

Background and Rationale

About 11% of the U.S. older adult population is at risk for or has subjective cognitive decline[1]. While some factors that affect brain health cannot be changed, research has shown that certain lifestyle changes such as participating in regular physical activity, staying socially engaged, and maintaining good heart health make a positive difference that can delay or reduce cognitive decline[1,2,3]. However, few cognitive brain health programs exist, and those that do are targeted to a specific audience (i.e., Alzheimer's and related dementias). Additionally, these existing programs primarily focus on one health domain (i.e. physical activity, diet)[4.5] without the additional focus on multi-health domains, which also includes elements such as intellectual engagement, social isolation, stress, sleep, and self-efficacy. **Thus, there is a need for a more holistic cognitive health program aimed toward the general older adult population and particularly those that are underserved (i.e., low income, racialized, rural)**.

Drawing on existing research conducted at the University of Illinois (UI) and other academic institutions, UI Extension Family Life Educators developed *Wits Workout*, a multi-modal workshop series designed to enhance brain health among people ages 50 and older. Wits Workout addresses multiple factors that affect cognitive health such as physical activity, stress, sleep, social isolation. The holistic workshop series is designed to be lay-leader led, interactive, and experiential. Preliminary evaluations demonstrate that this educational series serves a need in reducing isolation, increasing physical activity, promoting intellectual engagement, and enhancing overall brain health in older participants, all of which complement current aging brain health research.

Overall Aims

The aims of the study are to (1) Determine the feasibility and acceptability of Wits Workout among 120 intervention group recipients who receive the program at 8 locations in Illinois; and (2) Use a randomized trial to examine the preliminary efficacy of Wits Workout on changes in the primary outcomes of cognitive functioning, and secondary outcomes of self-efficacy, socialization, sleep, stress and physical activity levels following the 12-week intervention (3 months) and explore maintenance effects at 6 months (3-months post-intervention) compared to a waitlist control.

Hypotheses: At three and six-month posttests, intervention participants compared to controls will differentially improve with respect to (1) PROMIS[6,7] self-reported cognitive function measures; (2) scores on the Telephone Interview for Cognitive Screening (TICS); and (3) self-efficacy, socialization, sleep, stress and physical activity levels.

Research Design

We propose to conduct a two-arm randomized controlled trial with a treatment (workshop) group and wait-list control group. We will assess participant outcomes at baseline, immediately post-workshop (3-months) and at 6-months to assess maintenance of treatment effects.

Intervention. Wits Workout will take place over 12 weeks, one hour per week. The training will be delivered by 5 UI Extension faculty educators who were trained by the Extension faculty educators who developed the program. Each week includes a themed module with four activities and a training component featuring educational topics such as a) exercising regularly; c) engaging the brain with new and intellectually stimulating challenges; d) participating in social activities; e) getting enough sleep; and f) reducing stress. The workshop will be offered in-person in 8 areas with a target of 20 attendees per urban workshop and 12 attendees per rural workshop for a total of 120 workshop participants. The waitlist control participants (n=120) will be offered the workshop after the 6-month study period is completed. All COVID safety requirements will be in place at the workshop sites. A fidelity assessment tool will be developed by the research team and implemented at all program sites. All Wits Workout leaders will be observed teaching two sessions of the program by one of the study investigators. After the first observation occurs, the fidelity evaluator will debrief with the leader and the evaluator will follow up with a written evaluation that includes strengths, areas of improvement (including ways in which they adhered and/or strayed from the program content and facilitation techniques outlined in the Wits Workout Leader's Guide), and suggestions for increasing fidelity in their teaching. A second observation will occur within the several weeks of the first observation with the goal of continuous process improvement from the first to the second evaluation. UI faculty educators leading the workshops will record attendance over the 12 weeks and report to the investigative team. Attrition as well as completion rates will be documented based on workshop attendance.

Location	Urban/Rural	Numbers	Waitlist
Chicago Area	Urban	20	20
Chicago Area	Urban	20	20
Champaign	Urban	20	20
St. Joe/Paxton	Rural	12	12
Sterling	Rural	12	12
Mattoon	Rural	12	12
Macomb	Rural	12	12
Marion	Rural	12	12
Total Participants		120	120

Sample. We will offer Wits Workout to a minimum of 240 older adults (120 treatment and 120 delayed treatment controls) in three urban and five rural areas of Illinois (see

Table 1).

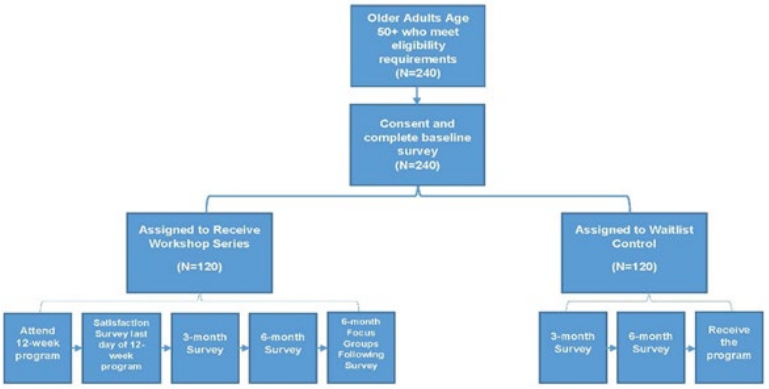
Qualitative Outcomes. We will conduct focus groups with participants 3 months after the conclusion of the workshops to learn more about the impact of the workshop on participant's health behaviors and their thoughts about how the program was delivered and evaluated.

Outcome Measures. We will examine the effects of participation in Wits Workout on the primary outcome of cognitive functioning and secondary outcomes of improved social satisfaction, self-efficacy, quality of life and sleep, reduced stress, and increased physical activity using the following measurements: Cognitive functioning will be assessed using the PROMIS Cognitive Function- Short Form 8a[6,7] and the Telephone Interview for Cognitive Status (TICS). [8,9] TICS is a brief, standardized test of cognitive functioning designed to be measured over the telephone. Social-satisfaction will be assessed using the Cutrona Social Provisions Scale[10]. Self-efficacy will be assessed using the PROMIS Item Bank v1.0 - General Self-Efficacy.[6] Sleep will be assessed using the Pittsburg Sleep Quality Index (PSQI).[13] Stress will be assessed using the Perceived Stress Scale.[14] Physical activity will be assessed using the Physical Activity Scale for the Elderly (PASE).[15]

Participant inclusion/exclusion criteria: 1) age 50+; 2) English speaking /understands English; 3) No self-reported serious mental illness or diagnosis of Alzheimer's or other dementia related disease, and a score of 27 or higher on the TICS cognitive assessment during the screening call.

Procedures

Participants will be recruited through UI Extension utilizing community partners, the Extension website, Extension newsletters, and multiple media outlets, including news releases, fliers, and social media. Upon registering for the program, participants will be contacted and invited to take part in the research study. Those interested will be screened for inclusion into the study with a brief telephone interview which includes the TICS assessment. Participants who are eligible will be sent a consent form and baseline assessment. University of Illinois at Chicago will provide institutional review board approval. All survey assessments will be administered online unless a participant is unable to complete the survey online in which case s/he will be offered the opportunity to take the survey via phone with a researcher or to receive a paper copy with a self-addressed, stamped return envelope. Once the baseline assessment is completed, participants will be randomized into two groups by a member of the research team. The treatment group will receive the 12-week workshop and the waitlist control group will receive the treatment after the six-month posttest is complete (see Figure 1). The first posttest and TICS will be administered by a member of the research team to both the workshop and control groups immediately following the end of the 12-week program (3 months). The 6-month follow-up assessment and TICS will be administered 3 months after the end of the program to both the workshop and control groups by a member of the research team. Reminders to complete the survey will be sent by a research team member by email and/or phone. Participants will be provided a $20 gift card upon completion of each survey that will be administered by a research assistant. A "reunion" event will take place three months after the last *Wits Workout* session for the workshop group only. The reunion will give participants an opportunity to reconnect informally and it will enable the research team to conduct the follow-up focus groups. Qualitative methods are particularly well suited for the assessment of simulated changes in behavior and will provide us richer detail than the surveys alone[16].



Power Analysis and Sample Size Estimation. In the cognition literature, a 1-3 point decrease in the Mini Mental State Exam score has been shown to be indicative of a meaningful decline. Our primary outcome, cognitive functioning, will be assessed using the TICS -- a telephone version of Mini Mental State Exam which is administered in person. Both measures correlate highly.[9,10] Among older adults with normal cognition, which is our target sample for this trial, an effect size of 0.29 was considered clinically meaningful.[11] With this more conservative effect size of .20, an alpha of .05/6 = 0.008 9adjusted for multiple outcome measures and comparisons across rural and urban samples), for 3 time points (0-12-24 weeks), power set to .80, and an estimated correlation of .50 among measures, we need a total of 208 participants. Accounting for ~15% attrition, we will target to recruit a total of 240 participants for this trial.

Data Analysis

Quantitative data. We will conduct 3x2 repeated measures ANOVAs to examine time (pre vs. post vs. follow-up),

group (intervention vs. waitlist control), and interaction effects. The quantitative measures that will be evaluated using this statistical model include measures of social satisfaction and support, perceived well-being and quality of life, physical activity and exercise, self-efficacy, and the cognitive functioning scores. Covariates such as demographics [age, biological sex, geographic location (rural vs. urban)], and attendance to the Wits Workout program will be accounted for in the analyses. As a secondary analysis, we will also examine correlations between the demographic characteristics and the study outcomes. Drs. Gothe and Payne have experience in analyzing similar large datasets from randomized controlled trials using these analysis strategies.

Qualitative data. Dr. Bobitt will conduct the focus groups using a guide to facilitate the discussion. The guide will include nine questions that will provide more in-depth detail about outcomes experienced by the participants (i.e. *In what ways did participating in Wits Workout impact your health behaviors?*) as well as questions that will provide details about their perception of the program (i.e. *What suggestions do you have to improve the program?*). We will audiotape and transcribe the focus groups. Three research team members will review all transcripts to develop an initial code book. We will then apply the codebook to a subsample of the transcripts individually then meet to discuss any areas where we are not coding consistently and adjust the codebook accordingly. We will then apply the same technique to another subsample of transcripts. Once we are certain that coding is consistent and the codebook is finalized, Dr. Bobitt will code the transcripts using NVivo QSR qualitative software. She will use an inductive thematic analysis process to analyze the data. Themes will be discussed and finalized with the research team.