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Journal of Geriatric Medicine
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RESEARCH ARTICLE

One-Year Impact of a Multidomain Brain Health Intervention on Cognition and Behavior Change for Midlife and Older Adults: A Pilot Clinical Trial

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ABSTRACT

Objectives: At one-year follow-up, this study explored whether a multidomain brain-health intervention resulted in maintained behavior change, provided cognitive benefits, increased self-efficacy for behavior change, and whether participants intended to continue with these changes. **Methods:** One-hundred thirty midlife and older adults were assigned to one of three conditions: brain fitness (B-Fit) intervention utilizing education and goal setting, education-only, or waitlist control. Questionnaires and cognitive measures were administered. **Results:** Both B-Fit and education-only participants maintained increased levels of health behavior changes at follow-up testing. There were no clinically meaningful cognitive benefits nor impact on self-efficacy. B-Fit participants reported greater intention to increase health behaviors in the coming year compared to education-only. **Discussion:** The B-Fit intervention helped participants change their behaviors and maintain these changes over time; however, it was not more effective than the education-only condition. Although, B-Fit participants self-reported a greater likelihood to increase these behavior changes over time.

Keywords: Brain health, dementia prevention, self-efficacy, behavior change

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ARTICLE INFO
Article Received: 21 March 2024 | Article Accepted: 11 April 2024 | Article Published: 19 April 2024
DOI: 10.30564/jgm.v5i1.6303

CITATION
Boyd, B., Schmitter-Edgecombe, M., 2024. One-Year Impact of a Multidomain Brain Health Intervention on Cognition and Behavior Change for Midlife and Older Adults: A Pilot Clinical Trial. Journal of Geriatric Medicine. 6(1): 18–34. DOI: 10.30564/jgm.v5i1.6303

1 Introduction

Alzheimer's disease (AD) is one of the most expensive disorders in the United States [1]. While disease modifying agents are being investigated, we must target known risk factors for AD and dementia to prevent or delay new cases. Delaying the onset of new AD cases by even just one year can result in a decrease of approximately 11.8 million fewer cases after 50 years [2]. Therefore, seemingly small delays in the onset of dementia could have profound effects on AD case numbers. Most prior intervention studies have focused on modifying only a single risk factor for dementia. Given that the etiology of dementia is heterogeneous, this unitary factor approach is likely not sufficient for dementia prevention [3, 4]. Recently, a growing body of work has focused on developing and studying multidomain interventions for dementia prevention.

1.1 Results from Prior Multidomain Studies

Findings from published multidomain brain health interventions have been mixed regarding cognitive benefits. The FINGER study [5], the Agewell trial [6], and the study by Lee and colleagues [7] all reported positive cognitive findings thereby providing preliminary support for the use of multidomain brain health interventions. Comparatively the MAX trial [8] and the MAPT [9] study did not report significant cognitive benefits from the multidomain intervention compared to controls. Given the variability in methodology and differing cognitive measures used, it is unclear at this time what factors influence a successful multidomain intervention.

In prior work with a pilot multidomain intervention, called B-Fit (Brain Fitness), we found that, unlike waitlist controls, the B-Fit and education-only conditions self-reported engaging in significantly more healthy brain aging behaviors post-training. Furthermore, compared to waitlist controls, B-Fit participants self-reported significantly higher post-training engagement in positive health behaviors [10]. In the current study, we focused on whether behavior change was sustained at one-year and any cognitive benefits associated with the intervention. The multidomain intervention targeted seven risk factors: cardiovascular risks physical activity, nutrition, stress, social engagement, cognitive engagement, and sleep. Factors were selected based on prior research indicating a relationship between these factors and risk for dementia [11, 12, 13, 14, 15, 16]. Several of the risk factors were identified by the 2020 Lancet Commission's recommended targets for dementia prevention [4]. The intervention also included a lesson on teaching implementation of compensatory strategies as research suggests effective utilization of compensatory strategies may improve management of dementia symptoms [17, 18, 19].

The B-Fit arm of the intervention was grounded in Self-Determination Theory (SDT) to create an environment for behavior change that would help participants sustain behavior change even after the intervention ended. According to the SDT model, individuals are more likely to engage in health behavior change if the needs of autonomy, relatedness, and competence are met [20, 21, 22, 23]. As such, rather than providing prescriptive goals that participants must follow, an intervention that allows for autonomy-supportive individualized goal setting (e.g., one individual may choose a nutrition goal of eating more fish while another may choose to drink more water, each will develop a plan and consider barriers to achieving there personalized goal) may lead to more sustained change. In addition, the program should include a focus on social support and collaboration to foster a greater sense of relatedness. Finally, the program should foster a sense of competency by providing necessary information, strategies for change, and encouraging realistic goal setting.

In addition to grounding the intervention in SDT, the current intervention sought to teach participants how to engage in effective behavior change strategies for themselves. Evidence suggests that, regardless of the targeted behavior, goal setting and self-monitoring are effective strategies to promote behavior change [24, 25, 26, 27]. Data also suggests that creating a specific action plan for when, where, and how the goal will be completed increases the likelihood of goal completion [28, 29, 30].

1.2 Intention for Sustained Change

An area that has yet to be assessed in prior multidomain brain health interventions, to the best of our knowledge, is assessment of participants intention to sustain and/or increase health behavior change post-training. Correlational research supports an association between intention and behavior with multiple meta-analyses reporting a moderate correlation between intention and behavior [31]. While there are some promising results from early multidomain studies, these interventions often required costly clinician input, health care provider assistance, and/or expensive treatment regimens. Once the external motivation to complete the prescriptive goals for the purpose of a study is removed, the newly established health behaviors may fade [32]. Although intention alone is not sufficient for behavior change, it would be telling if participants report no intention to continue with these health behavior changes following the intervention [33].

As there is a gap between intention to change and successful behavior change, some researchers have proposed additional factors to assess that provide further predictive power for behavior change initiation and success. Action planning, action control, and self-efficacy have emerged as potentially useful factors from this literature [30, 34]. Not only are the constructs of planning and self-efficacy useful for predicting behavior change outcomes, but interventions that have sought to improve either construct have resulted in increased behavior change [34]. As such, interventions designed with an emphasis on improving either planning or self-efficacy could help reduce the intention-behavior gap.

1.3 Current Study Objectives

The study purpose is to assess for (a) sustained behavior change as a result of the intervention, (b) cognitive benefits of the intervention, (c) intention to continue or increase health behaviors at follow-up testing, and (d) changes in self-efficacy for engaging in healthy brain aging behaviors. Although both the B-Fit and education-only participants demonstrated significant behavior change immediately post-training [10], we hypothesized that there would be differences between these groups at one-year follow-up. Given that B-Fit participants were provided with psychoeducation on goal setting, goal monitoring, and goal modifying, we hypothesized that participants in the B-Fit condition would self-report engaging in more health behaviors at one-year post-intervention compared to both the education-only group and the waitlist control condition. We also hypothesized that participants in the B-Fit condition would experience improved cognitive performance on a fluid composite measure of cognitive abilities and self-report increased self-efficacy for health behaviors compared to both the education-only condition and the waitlist control condition. Additionally, compared to the education-only condition, we hypothesized that participants in the B-Fit condition would report greater engagement in healthy brain aging behaviors in the prior year as a result of the intervention, as well as greater intent to continue with healthy brain aging behaviors, and a stronger desire to increase healthy brain aging behaviors.

2 Method

2.1 Participants

Participants were individuals aged 40 years and older who reside within the community. Participants were recruited from three neighboring counties: Whitman and Spokane counties in Washington and Latah county in Idaho. Study participants were recruited in partnership with community agencies, including Pullman Regional Hospital. Individuals were excluded from participating if they met any of the following criteria: a clinical diagnosis of dementia, inability to provide own consent, unstable or severely disabling disease (e.g., organ failure), and inability to complete assessment and intervention protocols due to communication, vision, hearing, or other medical difficulties. To assess for the presence of these criteria, all participants completed a phone interview, which included a medical history and the Telephone Interview of Cognitive Status (TICS).

Any participant who met study exclusion criteria or fell within the Impaired range on the TICS (score < 26) was ineligible to participate. Approximately 200 participants completed the phone interview. After applying exclusion criteria and confirming that participants could attend sessions, 131 participants were enrolled. One participant dropped after completing baseline testing. Therefore, 130 participants completed baseline testing and were assigned to a condition. A total of seven participants dropped from the study prior to completing post-training testing. Of those who dropped, 4 had been assigned to the B-Fit condition and 3 to the education-only condition. An additional 10 participants were lost between post-training testing and follow-up testing. Of these, 5 had been assigned to the B-Fit condition, 2 to the education-only condition, and 3 to the waitlist control. See ***Figure 1*** for flowsheet.

Of the initial 130 participants, 65 participants completed the pilot intervention during 2016-2017 and the remaining 65 participants during 2018-2019. For the 2016-2017 cohort, the intervention included 9 weeks of material and final feedback session for a total of 10 weeks. For participants in the 2018-2019 cohort, the intervention was truncated to 7 sessions by combining related topics into a single session (i.e., exercise and cardiovascular disease; sleep and stress) and removing the feedback session. Despite this change, both cohorts were provided with the same educational information that focused on the same eight topics. No meaningful cohort differences were found in data from this study nor in Boyd and colleagues study [10].

As participants were located in different counties, participants were blocked into groups of 8-13 participants based on location and available group meeting times. These groups were randomly assigned to either the B-Fit or education-only intervention in a 2:1 format such that for every one education-only group there were two B-Fit groups. When participants were unable to be blocked (e.g., group meeting time did not work), they were asked about their interest in being put on a waitlist and serving as a waitlist control participant. After blocking, 68 participants were assigned to the B-Fit intervention, 36 to the education intervention, and 26 were waitlist controls.

2.2 Measures

2.2.1 Primary Outcome Measures

The *Healthy Aging Activity Engagement (HAAE) questionnaire* [35] is a validated self-reported measure wherein participants indicate level of engagement in various healthy brain aging behaviors. The measure includes 32-items and participants rate their engagement with each behavior on a scale from 1 (strongly disagree) to 5 (strongly agree), with higher scores indicating higher levels of engagement. Factor analysis revealed three subscales: biological health (e.g., questions about exercise and diet), social and cognitive strategies (e.g., questions about social and cognitive engagement), and health safeguard behaviors (e.g., not smoking) [35]. Each subscale demonstrated excellent internal consistency (Rasch reliability .94 to .98). Test-retest reliability for the total score was acceptable with a strong correlation (r = .83).

The *NIH Toolbox Cognition Battery (NIHTB-CB)* is a well validated assessment instrument that provides a comprehensive, yet brief, measure of multiple domains of cognitive functioning [36, 37]. The NIHTB-CB is composed of seven tests: flanker inhibitory control and attention, picture sequence memory, list sorting working memory, picture vocabulary, oral reading recognition, dimensional change card sort, and pattern comparison processing speed. In this study, the Crystalized Cognition Composite and the Fluid Cognition Composite, which were derived from the NIH toolbox tests, were used to measure cognitive abilities that are dependent upon stored knowledge and past learning and cognitive abilities for learning, processing, and responding to novel information/situations, respectively.

2.2.2 Secondary Measures

A *One-year Post-Intervention Questionnaire (OPQ)* was created for this intervention to assess three things: the participants behavior change as a result of the intervention, the participants intention to continue with the health behavior changes they started during the intervention, and the participants intention to further increase their positive health behaviors over the course of the next year. Items include questions like "As a result of the brain health intervention I am practicing better nutrition," "During the course of the next year, I intend to continue to use stress reduction techniques," and "During the course of the next year, I intend to begin engaging in additional behaviors that lower cardiovascular risk factors." For each item, participants rated each statement on a scale from 1-5 with 1 being "not at all," 3 being "somewhat," and 5 being "very much." An average score for each of the three subscales was created by adding together the individual responses for each item in a subscale and dividing by the number of questions. Only participants in the B-Fit and education-only condition completed this questionnaire; waitlist control participants had no specific references for completing the questionnaire as they did not engage in an intervention.

The *Self Rated Abilities for Health Practices (SRAHP)* scale is a validated measure of self-efficacy wherein participants rate their ability to perform specific health behaviors [38, 39]. For each item, participants rate on a 0 (not at all) to 4 (completely) scale how well they would be able to perform certain tasks. Items assess for self-efficacy related to behaviors of exercise, nutrition, general well-being (e.g., "Change things in my life to reduce my stress"), and general health practices (e.g., "Use medication correctly").

2.3 Procedure

All procedures and methods were approved by the Washington State University institutional review board. Before the first day of the intervention, participants completed a standardized baseline assessment that included a questionnaire packet a brief battery of neuropsychological tests in the lab. Then, after completing the intervention, participants returned to the lab to complete the post-training testing and re-take several questionnaires; of note, the NIH Toolbox was not administered at post-training as cognitive performance is unlikely to change in a few months. Post-training testing occurred for all participants, including waitlist participants, approximately 2.5 months after the baseline testing. Participants returned to the lab for follow-up testing approximately 12 months after the initial baseline testing session for re-administration of the neuropsychological battery; questionnaire data was also collected at this time. The OPQ was only administered at follow-up testing. As we have previously published results from the data collected immediately following the intervention (i.e., post-training), the current study focuses on the data collected at the 1-year follow-up. The examiners who administered the neuropsychological battery to participants and collected questionnaire data were blind to participant condition and study hypotheses. No questionnaires were completed during groups and no testing occurred outside the lab to ensure independence of observations.

2.3.1 B-Fit and Education Condition

Participants in the B-Fit and education-only conditions engaged in weekly, two-hour group sessions that centered on one or two learning topic(s) each week. For both conditions, the sessions focused on providing education about brain health that was accompanied by a bound educational booklet containing all presented material. When discussing each topic, clinician educators provided empirically supported information in a manner that was comprehensible for participants. During the first session, clinician educators oriented participants to the intervention and presented information on the brain, cognitive aging, mild cognitive impairment and dementia. Each following session introduced a new topic or two in the following order: cognitive engagement, cardiovascular risk factors, physical activity, nutrition, social engagement, sleep, stress, and compensatory strategies/assistive technologies.

2.3.1.1 B-Fit Condition.

For participants in the B-Fit condition, the first session also included an overview of how to successfully utilize goal setting and goal monitoring. No goal was set during this first session. For all subsequent sessions, participants set an autonomous, intrinsically motivating, and manageable goal that was related to the educational topic(s) discussed and was designed to increase engagement in healthy brain aging behavior. See ***Table 1*** for outline of a typical session. Participants were instructed to work on each goal for all remaining weeks of the intervention. During the goal setting process, participants collaboratively identified how to integrate the selected goal into their daily life and problem-solve for potential barriers to goal completion. Time was allotted during each session for the following tasks in this order: brief socialization, discussing successes and challenges with goal implementation during the prior week, didactics, new goal setting, group problem solving for new and past goals, and a few minutes to socialize or ask questions at the end. As participants simultaneously worked on several goals, all goals were kept to a short time commitment of 5-10 minutes. Participants utilized standardized goal tracking sheets for the purpose of recording goal progress. During each session, participants provided an overall rating of their progress on each goal for the prior week.

2.3.1.2 Education-Only Condition

The session format for participants in the education-only condition included time to socialize, didactics, and socializing at the end. To keep the session lengths equal between the education-only and B-Fit conditions, clinician educators facilitated discussions around pre-selected discussion prompts related to the sessions didactics without providing new content. For example, the clinician educator may ask a question like "How do you feel when you exercise regularly" or "Did we discuss modifiable risk factors you were not aware of?" These discussion questions adequately filled time without discussing information related to goal setting or goal implementation.

2.4 Analysis

2.4.1 Sample Size and Missing Data

For all analyses, pairwise deletion was used for participants with missing data. To calculate composite scores for the NIH toolbox data, participants must have completed all subtests; therefore, an additional data loss came from participants who were unable to complete all subtests. Furthermore, some of the measures used in this study were only administered to certain conditions or were added part way through our pilot study. The SRAHP and the OPQ were only administered to participants starting in 2018, which means approximately half of participants were not given these measures. Furthermore, the OPQ was only administered to B-Fit and education-only participants, given that the waitlist group did not receive an intervention. As a result of this, the number of participants utilized in each analysis varied; exact sample size used is reported for each analysis in the results section separately as well as in ***Tables 3 and 4***.

Of note, this study was negatively impacted by the COVID-19 pandemic. We had started additional groups prior to the COVID-19 stay at home orders that had to be stopped. As such, the overall sample size for this study was lower than originally planned. Despite this, a priori power analyses indicated that we have adequate power to detect moderate effect sizes for our analyses using HAAE and NIH Composite Scores. For the SRAHP and OPQ data, we are underpowered to detect anything smaller than a large effect size. Effect sizes are presented for all analyses.

2.4.2 Primary Outcomes

To assess for differences in the HAAE across conditions (i.e., B-Fit, education-only, waitlist) and time points (baseline, post-training, follow-up), a 3x3 mixed factorial analysis of variance (ANOVA) was completed. To examine for differential impact of the three conditions on cognition between baseline and follow-up, 3x2 mixed factorial ANOVAs were run separately on the Crystalized and Fluid Composite scores. Follow-up ANOVAs and *t*-tests were conducted to examine significant ($p < .05$) main effects and interactions.

2.4.3 Secondary Outcomes

To assess for differences in self-efficacy (i.e., SRAHP) between the three conditions across baseline, post-training and follow-up data, a 3x3 mixed factorial ANOVA was run. Follow-up tests were conducted for significant findings ($p < .05$). Prior to analysis of the one-year post-intervention questionnaire data (i.e., OPQ), inter-class correlation statistics were run. As this survey was created for the intervention, interclass correlations assessed for how well the items within each subscale resemble each other. Three independent sample *t*-tests were run comparing data from the B-Fit and education-only conditions to identify whether there was a difference in reported behavior change, intention to maintain healthy brain aging gains, and intention to increase healthy brain aging behaviors.

3 Results

As can be seen in ***Table 2***, one-way ANOVAs revealed that the age, $F(2, 115) = 0.83$, $p = .44$, $\eta^2 = .01$, education, $F(2,115) = 0.57$, $p = .57$, $\eta^2 = .01$, and TICS scores, $F(2,111) = 0.35$, $p = .70$, $\eta^2 = .01$, of study participants did not differ across conditions. Chi-square analyses revealed that the gender, χ^2 $(2, n = 116) = 2.91$, $p = .23$, $V = .12$, and race, χ^2 $(10, n = 115) = 11.25$, $p = .34$, $V = .22$, of study participants also did not differ across conditions. The sample was predominantly white and highly educated. Descriptive statistics for all analyses are presented in ***Tables 3 and 4***; all variables were normally distributed. ***Table 3*** includes the measures that were administered to all participants. ***Table 4*** includes the measures that were only administered to participants starting in 2018; therefore, these analyses represent a smaller subsample of the participants.

3.1 Analyses Using Entire Sample

3.1.1 HAAE Mixed Factorial ANOVA

For the HAAE analysis, the overall sample size was 92 including 49 B-Fit participants, 23 education-only participants, and 20 waitlist control participants. A 3 (condition) x 3 (time) mixed factorial ANOVA revealed a significant main effect of time, $F(2, 178) = 14.32$, $p < .001$, $\eta^2_p = .14$, that was modified by a significant time by condition interaction, $F(4, 178) = 2.77$, $p = .03$, $\eta^2_p = .06$. There was no significant main effect of condition, $F(2, 89) = .16$, $p = .85$, $\eta^2_p = .004$. Follow-up repeated measures ANOVAs showed a simple effect of time for both the B-Fit condition, $F(2, 96) = 24.58$, $p < .001$, $\eta^2_p = .34$, and for the education-only condition, $F(2, 44) = 5.31$, $p = .01$, $\eta^2_p = .19$. For the B-Fit condition, in comparison to baseline (M = 114.98), pairwise comparisons showed that participants reported engaging in more healthy brain aging behaviors at post-training (M = 124.72), $M_D = -9.74$, $p < .001$, and at follow-up (M = 122.78), $M_D = -7.80$, $p < .001$. There was no significant difference between post-training and follow-up, $M_D = 1.94$, $p = .13$. A similar pattern was found for the education-only condition. In comparison to baseline (M = 113.20), engagement in healthy brain aging behaviors was higher at both post-training (M = 121.30), $M_D = -8.11$, $p = .01$, and follow-up (M = 121.96), $M_D = -8.77$, $p = .02$, and there was no significant change between post-training and follow-up, $M_D = -0.66$, $p = .83$. There was not a significant difference across baseline (M = 119.94), post-training (M = 120.99) and follow-up (M = 120.14) for the waitlist control, $F(2, 38) = 0.11$, $p = .89$, $\eta^2_p = .006$.

3.1.2 NIH Mixed Factorial ANOVA

Two 3 (condition) x 2 (time) mixed factorial ANOVAs were conducted with NIH toolbox cognitive data composite scores as the dependent variables. For the Crystalized Composite Score analysis, there were a total of 88 participants including 50 from the B-Fit condition, 19 from the education-only condition, and 19 from the waitlist control condition. The analysis revealed a significant main effect of time, $F(1, 85) = 19.83$, $p < .001$, $\eta^2_p = .19$, that was modified by a significant time by condition interaction, $F(2, 85) = 10.55$, $p < .001$, $\eta^2_p = .20$. Follow-up paired sample *t*-tests unexpectedly revealed higher mean Crystallized Composite scores pre-intervention compared to follow-up for both the education-only condition (M = 121 vs. 118), $M_D = 2.68$, $t(18) = 2.45$, $p = .03$, $d = .56$, and waitlist controls (M = 124 vs. 115), $M_D = 8.58$, $t(18) = 4.88$, $p < .001$, $d = 1.12$. There was no significant change across time (M = 122 vs. 123) for the B-Fit condition, $M_D = -0.14$, $t(49) = -0.13$, $p = .89$, $d = .02$. The main effect of condition was also not significant, $F(2, 85) = 0.46$, $p = .63$, $\eta^2_p = .01$.

For the Fluid Composite Score analysis, there were a total of 87 participants, including 49 from the B-Fit condition, 19 from the education-only condition, and 19 from the waitlist control condition. For the Fluid Composite Score, there was a significant main effect of time, $F(1, 84) = 14.50, p < .001$, $\eta^2_p = .15$, indicating lower mean Fluid Composite scores pre-intervention (M = 100) compared to follow-up (M = 105). There was also a significant main effect of condition, $F(2, 84) = 3.51, p = .03$, $\eta^2_p = .08$. Follow-up pairwise comparisons revealed that the B-Fit participants (M = 98) had a significantly lower score on the Fluid Composite compared to the waitlist controls (M = 106), $M_D = -7.47$, $p = .02$. The interaction was not significant, $F(2, 84) = 1.66, p = .20$, $\eta^2_p = .04$.

3.2 Analyses Using the Partial Sample

3.2.1 SRAHP Mixed Factorial ANOVA

For this analysis the overall sample size was 43, including 21 from the B-Fit condition, 13 from the education-only condition, and 9 from the waitlist control condition. A 3 (condition) x 3 (time) mixed factorial ANOVA indicated that there was not a significant main effect of time, $F(2, 80) = 2.06, p = .13$, $\eta^2_p = .05$, indicating no significant difference in SRAHP scores between baseline (M = 90.05), post-training (M = 94.36) and follow-up (M = 92.91). There was also no significant main effect of condition, $F(2, 40) = 0.17, p = .85$, $\eta^2_p = .01$, indicating no significant difference in SRAHP scores between the B-Fit (M = 90.94), education-only (M = 93.33), and waitlist controls (M = 93.04). Additionally there was not a significant time by condition interaction, $F(4, 80) = 0.67, p = .61$, $\eta^2_p = .03$.

3.2.2 One-year Post-group Questionnaire (OPQ) Analysis

For this analysis the sample size was 36, including 23 from the B-Fit condition and 13 from the education-only condition. Cronbach's alpha was calculated for the OPQ as well as all three subscales of the measure. For the entire measure, $\alpha = .95$. For the 8 questions related to behavior change as a result of the intervention, $\alpha = .87$. For the 8 questions assessing for intentions to sustain these behavior changes, $\alpha = .87$. Finally, for the 8 questions assessing for intentions to increase health behaviors in the coming year, $\alpha = .95$. This data suggests that the reliability of each subscale and the questionnaire as a whole is in the good to excellent range.

Three independent sample *t*-tests were run on the three subscales of the OPQ. For these analyses, one tailed *p* values are provided to account for the directional hypothesis. The *t*-test showed that the intervention condition (M = 3.40, SD = 0.81) self-reported greater change attributed to the intervention compared to the education-only condition (M = 2.93, SD = 0.73), $t(34) = 1.73, p = .047, d = .60$, 95% CI[-0.08, 1.03]. Self-reported intention to continue with health behavior changes during the course of the next year did not significantly differ between the intervention (M = 3.99, SD = 0.78) and education-only (M = 3.61, SD = 0.73) conditions falling within the somewhat to quite a bit range, $t(34) = 1.46, p = .08, d = .51$, 95% CI[-0.15, 0.92]. However, the intervention condition (M = 3.70, SD = 0.84) endorsed greater intention to further increase positive brain health behaviors in the coming year compared to the education-only condition (M = 3.08, SD = 0.98), $t(34) = 2.00, p = .03, d = .69$, 95% CI[-0.01, 1.25].

4 Discussion

This study expanded analysis of the pilot multi-domain brain-health intervention by investigating whether participants were able to maintain self-reported behavior change at follow-up testing and whether there were any cognitive benefits of the intervention. Furthermore, we assessed whether participants intended to continue with the self-reported behavior changes, and to identify whether the intervention had an effect on self-efficacy.

The results demonstrated a similar pattern on the HAAE for the B-Fit and education-only conditions across time such that there was an increase in self-reported health behaviors between baseline and post-training and relatively stable health behaviors between post-training and follow-up testing. This pattern contrasts with the lack of change for the waitlist control condition across time points. Although these results fit well within the context of our prior study, we had expected that the B-Fit participants would be better able to maintain health behaviors across time given that the intervention was grounded in good health behavior change practices including SDT, goal setting, and goal monitoring. The ability of the education-only participants to engage in self-reported behavior change and maintain the behaviors speaks to the benefit of receiving relevant health information. This was unexpected given previous studies highlighting that education is typically insufficient for behavior change to occur [40].

A recent study by Solomon and colleagues [41] noted the variability in methodology in multidomain interventions as a particular problem for making comparisons across studies. While the FINGER trial and Agewell study both demonstrated behavior change benefits for the intervention, as this study did, aspects of the designs (e.g. length of intervention, lack of long-term follow-up) make it challenging to compare results [6, 5]. Neither Lee and colleagues [7], the MAPT trial [9], nor the MAX trial [8] reported on change in health behaviors following the intervention nor did they follow participants after the active intervention supports were removed.

However, a MAPT PLUS study is underway with the goal of examining participants' abilities to keep up with health behavior change for an additional few years without the structure of the intervention. Our findings add to the literature by demonstrating participants' ability to maintain self-reported health behavior changes once study supports end, which is necessary given prior work finding that once the active intervention phase is over individuals rarely maintain their behavior change gains for the long-term [42]. Furthermore, when compared to the relatively brief, sometimes as brief as a single visit, education conditions in some of the trials, it makes sense that the study multi-hour, multi-week education-only condition had a meaningful impact on self-reported behavior change. Likely such an intensive condition sufficiently increased participant's risk perception for not engaging in health behavior change, which previous research indicates would increase the likelihood for behavior change to occur [43].

Given the lack of difference between the B-Fit and education-only conditions, one could conclude that the goal setting component of the B-Fit intervention is not necessary to encourage self-reported behavior change. However, this claim would not be well supported given the vast amount of research highlighting the benefits of goal setting for behavior change [25]. As such, we should consider two more probable interpretations. First, the characteristics of the education-only condition created an environment where the education-only participants were inspired to create their own health related goals. Second, there could be benefits from the goal-setting component of the intervention that were not captured by the data collected.

This study also looked at intentions to maintain and intentions to increase behavior change in the coming year after participants completed the study. At the one-year follow-up, both education-only and B-Fit participants self-reported being equally as likely to continue with the changes made with average responses falling in the high end of the "somewhat" to "quite a bit" range. However, compared to the education-only condition (responses falling close to the "somewhat" range), the B-Fit participants (responses falling close to the "quite a bit" range) endorsed a stronger desire to increase their positive brain health behaviors in the coming year. This finding suggests that the B-Fit intervention could have a longer-term impact on behavior change. On the OPQ, B-Fit participants also self-reported significantly more change attributed to the intervention ("somewhat" to "quite a bit" range) compared to the education-only participants ("a little bit" to "somewhat" range). Given the lack of difference between these two conditions as self-reported on the HAAE, this may suggest that the B-Fit participants were better able to link any behavior change they made during this period of time directly to the intervention itself.

Although there was a significant change across time for both the Crystalized and Fluid Composite Scores, one must not confuse statistical significance with clinically meaningful change. The slight differences in scores are likely more reflective of expected minor variability in performance or practice effects. As such, these results did not align with our hypothesis that B-Fit participants would experience cognitive benefits from the intervention as demonstrated by the Fluid Composite Scores. In general, multidomain brain health interventions have shown mixed results in terms of the cognitive benefits of these interventions. Studies that have demonstrated cognitive benefits from their interventions include the FINGER trial [5], the MAX trial [8], the Agewell trial [6], and Lee and colleagues [7]. Studies that did not demonstrate cognitive benefits from the intervention include the MAPT trial [9]. Given the varying assessment tests used, ages of study participants, health domains focused on, and lengths of studies, it is difficult to identify what aspect(s) allowed some studies to have a positive impact on cognition.

Finally, we assessed for change in self-efficacy following the intervention with an expectation to find improved self-efficacy for health behavior for the B-Fit participants. However, there was not a significant difference across time or among groups on self-efficacy for health behaviors and therefore our hypothesis was not supported. A possible reason for limited change is that all participants started with a baseline that indicated relatively good self-efficacy; therefore, we would not expect to see as much change after the intervention. Although the effect sizes were small and the analyses were not significant, it would still be fruitful for future researchers to assess whether self-efficacy for health behaviors is impacted by other multidomain brain health interventions given the critical link between self-efficacy and successful behavior change [30, 34].

In addition to simply furthering this line of research, this study possessed some critical strengths. We assessed for our participants' abilities to maintain self-reported health behavior change once study supports were removed, we used a very active education control condition, and we sought to understand whether participants intended to continue with their goals after the study ended. Our pilot intervention was also created to be completed with little cost, no expensive equipment, or costly clinician involvement. Finally, the materials created for the B-Fit intervention (PowerPoint slides, booklets, etc.) could be distributed to other health care providers or agencies quickly and easily to facilitate implementation to the general public.

Our study included some limitations. Our sample was non-clinical, predominately white, and well-educated with most having college degrees, which reduces the generalizability of our findings. Participants in the B-Fit condition may have more resources to implement the requested health behavior changes on their own and the education-only participants may have been in a better position to uptake the provided information and directly apply this information. A second limitation is that our analyses were underpowered due to this being a pilot study conducted in a rural area that was also impacted by COVID-19. In general, more research is needed to identify what characteristics make up a successful multidomain brain health intervention.

Although we cannot say our intervention had a clinically meaningful effect on cognitive functioning nor significantly increased self-efficacy for behavior change, both the B-Fit intervention and education-only conditions helped midlife and older adults engage in more self-reported health behaviors that will likely benefit their brain health in the long-term. We also know that our participants intend to keep up with the changes they made as a result of the study, at least for the coming year, which may further increase the odds of them experiencing long-term brain health benefits. Additionally, there is a possibility that the goal setting component of the B-Fit intervention provided some benefits for behavior change that were not adequately assessed for by the current study design. Although the current body of work is small and many questions remain about what factors may lead to a successful multidomain intervention, several more trials are currently underway that may help answer some of the questions that remain for this important area of study [44, 45].

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Tables and Figures

Table 1 *- B-Fit Intervention Structured Session Format*

Group Meeting Component	***Group Meeting Component Purposes***
Initial Socializing (10 min): Group socializes before formal work begins.	Builds social support and group connections, provides an opportunity to practice social engagement.
Go-Round (20 min): Group members reports on successes and challenges in implementing their plan.	Allows clinicians to see how each group member is progressing with their goals and for group members to learn from the successes and challenges of others
Didactics/Brain Health Education (40-50 min): Clinician provides group members with information.	Provides group members with scientific evidence and a basis for choosing a health behavior change goal.
Individualized Goal Setting (10-15 min): Clinician guides group members to set realistic goals.	Each group member completes a goal-setting planning sheet including answering when, where, with whom, and how will I accomplish the goal.
Problem-solving (30-40 min): Group members assist each other in problem-solving potential barriers.	Facilitates breaking goals into a manageable form, draws on experiences of group members, and models effective problem-solving and goal setting.
Final Socializing (5-10 min)	Strengthens group connections, opportunity for social engagement.

Table 2 - *Demographics of Participants by Condition*

	Condition		
	B-Fit (N = 63)	Education-only (N = 29)	Waitlist (N = 24)
Age (in years)	63.36 (8.96)	64.41 (8.94)	66.23 (11.54)
Education (in years)	16.19 (2.35)	16.52 (1.99)	15.87 (1.96)
% Female	69.84	62.07	83.33
% White/Not Hispanic or Latino	87.30	89.66	100.00
TICS Average	35.22 (2.81)	34.68 (3.24)	35.25 (3.12)

Note. Standard deviations in parentheses. There are no statistically significant group differences.

Table 3 - *Descriptive Statistics for Analyses Using the Entire Sample*

	Condition					
	B-Fit	n	Education-only	n	Waitlist	n
HAAE T1	114.98 (17.98)	49	113.20 (14.15)	23	119.94 (12.71)	20
HAAE T2	124.72 (15.81)	49	121.30 (11.54)	23	120.99 (13.45)	20
HAAE T3	122.78 (15.73)	49	121.96 (14.41)	23	120.14 (16.61)	20
NIH Crystalized T1	122.39 (13.65)	50	120.95 (13.43)	19	123.67 (16.65)	19
NIH Crystalized T3	122.53 (16.06)	50	118.26 (13.86)	19	115.08 (14.53)	19
NIH Fluid T1	96.73 (10.07)	49	102.84 (12.41)	19	101.69 (13.11)	19
NIH Fluid T3	100.16 (13.91)	49	105.79 (13.30)	19	110.15 (17.02)	19

Notes. HAAE = Healthy Aging Activity Engagement questionnaire. NIH Crystalized = NIH Toolbox Crystalized Cognition Composite. NIH Fluid = NIH Toolbox Fluid Cognition Composite. T1 is baseline, T2 is post-training, and T3 is follow-up. Standard deviations in parentheses.

Table 4 - *Descriptive Statistics for Analyses Using the Partial Sample*

	Condition					
	B-Fit	n	Education-only	n	Waitlist	n
SRAHP T1	86.92 (18.28)	21	95.53 (9.31)	13	90.69 (20.05)	9
SRAHP T2	93.24 (15.42)	21	96.17 (5.92)	13	93.67 (19.22)	9
SRAHP T3	92.66 (15.34)	21	91.30 (12.29)	13	94.76 (13.97)	9
OPQ						
Change after intervention	3.40 (0.81)	23	2.93 (0.73)	13	--	
Plans to continue	3.99 (0.78)	23	3.61 (0.73)	13	--	
Plans to increase	3.70 (0.84)	23	3.08 (0.98)	13	--	

Notes. SRAHP = Self Rated Abilities for Health Practices. OPQ = One-Year Post-Intervention Questionnaire. T1 is baseline, T2 is post-training, and T3 is follow-up. Standard deviations in parentheses. OPQ and SRAHP only administered to participants starting in 2018. Waitlist control participants did not take the OPQ because questions were related specifically to the intervention.

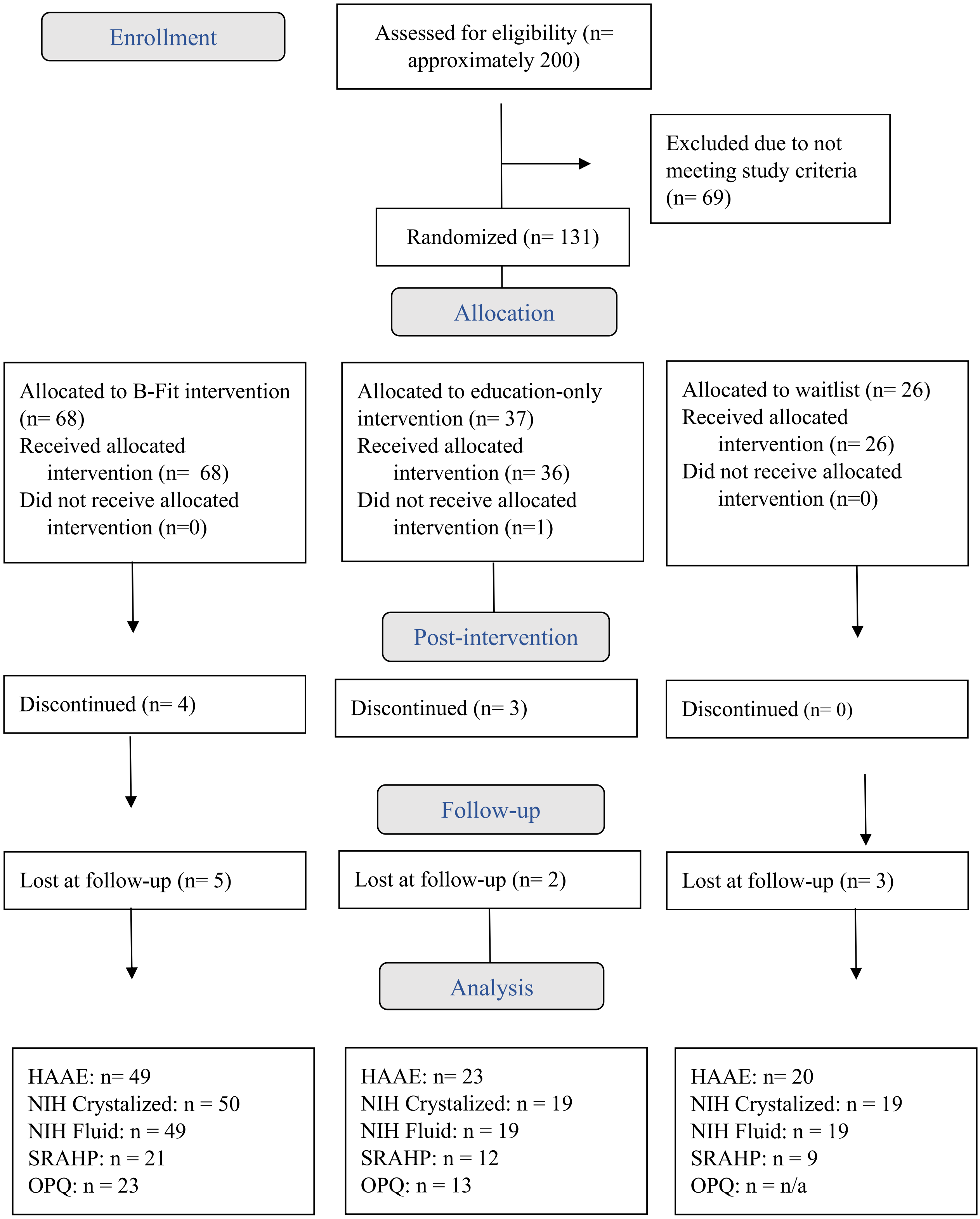

Figure 1: Participant Allocation and Loss Flowchart