


A Non-Randomized Pilot Trial of Brain-WISE: A Group-Based Program for Brain Health and Dementia Risk Reduction in Community Settings

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Abstract

Background: Addressing modifiable risk factors can potentially prevent 45% of cases of dementia. Here, we present the development of Brain-WISE, a low-intensity, group-based intervention to improve brain health in community settings. We conducted preliminary testing to refine intervention materials and procedures, assess acceptability and adherence, and evaluate preliminary effects. **Methods:** 143 community-dwelling adults aged 56–93 completed the non-randomized pilot trial. The 6-session intervention included psychoeducation, discussion/activities, and health screenings. Adherence was measured by attendance and acceptability was measured with questionnaires. Brain health knowledge and motivation to improve brain health were assessed before and after the program. **Results:** Across 6 cohorts, attendance was 80%–97% and 96% of participants agreed that the program was worthwhile. Knowledge ($d = 0.83$, $P < .001$) and motivation ($d = 0.43$, $P < .001$) increased significantly. **Conclusions:** The Brain-WISE program displayed good adherence and acceptability and evidence of an effect on knowledge and motivation. Further testing is warranted.

Keywords

dementia prevention, non-pharmacological intervention, lifestyle, risk reduction behavior, dementia, Alzheimer's disease

Introduction

There is rapidly growing interest in primary and secondary prevention of dementia, encouraged by recent epidemiological data indicating that up to 45% of cases of dementia may be delayed or prevented by addressing fourteen potentially modifiable risk factors throughout the lifespan.¹ In 2015, results were published from the Finnish Geriatric Intervention Study to Prevent Cognitive Impairment and Disability (FINGER), a randomized controlled trial of an intensive multidomain lifestyle intervention to prevent cognitive decline in at-risk older adults.² Based on its success, over a dozen similar studies have been initiated worldwide in the last decade. These evaluate the efficacy of various combinations of exercise, diet, cognitive training, vascular risk factor management, and other components to improve cognition or slow cognitive decline.^{3,4}

Results from FINGER and similar studies offer robust evidence for the efficacy of intensive, multi-domain,

behavioral interventions for cognitive benefit and dementia risk reduction. However, the feasibility and effectiveness of these interventions in mainstream community settings remains uncertain. The FINGER protocol involved periods

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of frequent aerobic training (5-6 times per week), resistance training (2-3 times per week), and cognitive training (3 times per week), as well as nutritional counseling and routine visits to a nurse and physician.⁵ Because of the intensity, complexity, and cost, FINGER and similar protocols may be challenging to implement in mainstream community settings. Even with substantial resources and structure provided by the FINGER study, only 40% of participants adhered to at least half of the intervention sessions, which amounted to 80 in-person physical training sessions and 144 at-home computer-based cognitive training sessions.⁶

Conversely, it is possible that the effectiveness of multicomponent interventions in community settings could exceed expectations, as the control groups in experimental settings have typically received more comprehensive clinical care than what is typically provided to most older adults in the U.S. For example, participants in the FINGER control group met regularly with a nurse (every 6 months) and a physician (every 12 months) for a detailed health history, physical exam, and routine laboratory tests and received oral and written information about their clinical findings and personalized advice for reducing dementia risk factors.⁵ In contrast, the standard of cognitive care in the U.S. for adults age 65 or older is a Medicare Annual Wellness Visit (assuming the person can access a primary care provider, which many cannot).⁷ This annual visit may only involve screening of cognitive function "...by direct observation or reported observations from the patient, family, friends, caregivers, and others."⁸ Indeed, a recent survey of Medicare recipients found that only 31% of patients received a performance-based cognitive screening, 35% were asked about memory problems, and 15% received both.⁹ Although the FINGER intervention group improved more than the control group, the control group also improved their health and cognitive test scores, and many of these benefits persisted 5 years later.¹⁰

Since the FINGER study, there is growing evidence that relatively simple psychoeducation about brain health and risk reduction, as well as person-centered goal-setting, might be efficacious for improving brain health and reducing dementia risk.¹¹ For example, the Brain Body Life for Cognitive Decline study randomly assigned 119 participants in their 70s to an intervention or control (passive health education) group.¹²⁻¹⁴ The 8-week intervention provided the same health education as the control group, but with personalized advice from a dietician (1 visit) and exercise physiologist (3 visits), and online cognitive training (2 hours/week). Compared to the control group, the intervention group showed modest but significantly greater reductions in their composite dementia risk score and increases in cognitive test scores at 3 and 6 months post-intervention.¹³ Similarly, the Systematic Multi-Domain Alzheimer Risk Reduction Trial (SMARRT)

recruited 172 people in their 70s from primary care and randomly assigned them to a 2-year control group (generic health education) or a more personalized intervention that involved routine nurse visits and virtual sessions with a health coach who helped participants form and pursue personalized risk-reduction goals (eg, diet and exercise).¹⁵ Although effect sizes were modest, the intervention group exceeded the control group in reducing their composite dementia risk score, increasing cognitive test scores, and improving quality of life scores.¹⁵

Many multidomain interventions are being developed, but directly comparing or building upon them is challenging. A key limitation of almost all multicomponent interventions is that they are rarely studied mechanistically or within the context of a theoretical framework of behavior change. The underlying psychological and behavioral mechanisms of successful or unsuccessful dementia risk reduction, as well as moderating factors, remain poorly understood. The lack of mechanistic understanding limits the field's ability to understand differences in efficacy and adherence, and to adapt potentially effective interventions to new populations and contexts.

In response to the strengths and limitations of previous dementia risk reduction interventions and the needs of our local community in Delaware, we developed the *Brain Wellness Information, Support, and Empowerment* (Brain-WISE) program, a group-based intervention delivered over 6 weekly sessions in community settings. The goal of Brain-WISE is to improve older adults' knowledge about brain aging and dementia, enhance their brain health, and reduce their risk of dementia. The development of this program was inspired by several key factors. First, the program was modeled on the successes and limitations of our previous community program called Memory Ambassadors.^{16,17} This program provided psychoeducation (~1-hour lecture) to groups of ~25-75 people in community settings (eg, senior centers; retirement communities), along with optional cognitive screenings with brief feedback and counseling. Between 2017-2022, approximately 800 older adults in and around the state of Delaware participated in a Memory Ambassadors event in person or by Zoom. Program team members observed, and participants informally reported the benefits of the group-delivery format, such as allowing participants to listen to each other's questions, offer advice, make connections, normalize dementia-related concerns, and reduce stigma. Forty-five percent of participants who elected to complete a cognitive screening screened positive for mild or more severe impairment, and 81% of those people elected to have their results sent to their primary care provider for further discussion of brain health and dementia risk reduction.¹⁸ This percentage of people who elected to follow up with their primary care provider was much higher than what has been reported by more passive screening methods

(eg, 34%),¹⁹ suggesting that the counseling approaches used, such as the principles of motivational interviewing, were effective. When developing Brain-WISE, we decided to include the same counseling approaches along with the group delivery format. As with Memory Ambassadors, Brain-WISE was developed to be delivered by multiple interventionists to optimize future uptake and implementation. In particular, we considered speech-language pathologists (SLPs), who are a large and underutilized brain health workforce.¹⁷

Second, the development of Brain-WISE was informed by the Health Belief Model (HBM) and other influential determinants of behavior change. The HBM is a well-established theoretical model that has been used to understand a wide array of older adults' health behaviors and health behavior change, including multiple behavior change,²⁰ and is the model most frequently used to conceptualize dementia risk reduction.²¹⁻²³ Applied to dementia risk reduction, the HBM posits that a person's dementia risk behaviors are influenced by at least 6 factors: (1) their general health motivation; (2) the perceived threat of dementia, which is a combination of a person's perceived susceptibility and the perceived severity of dementia; (3) the perceived benefit of risk reduction behaviors; (4) the perceived barriers to risk reduction behaviors; (5) the person's self-efficacy for risk reduction; and (6) the presence and effectiveness of cues to take action. These factors are hypothesized to influence a person's initial engagement with a risk reduction program (eg, the decision to respond to an advertisement) and serve as mediating factors.

Finally, the development of Brain-WISE was also influenced by other individual and social-structural determinants of behavior and behavior change, which have been described by a recent synthesis of meta-analyses.²⁴ This review found that the most consequential determinants of across behaviors and behavioral interventions were *social support*, *access*, and *habits*. Specifically, *social support* was defined as “informational, instrumental or financial help to facilitate a

particular behavior” (p. 380). *Access* meant “material or logistic resources to facilitate the performance of a behavior” (p. 380). *Habits* were defined as “repeated behaviors that exhibit automaticity, occur without awareness, and are difficult to stop even when they no longer provide benefits to the individual” (p. 380).

The Brain-WISE program is a community-based group “boot camp” that aims to educate people about cognitive aging, brain health, and dementia while also helping them make a person-centered plan and give them tools for success that will change health behaviors and lead to reduced risk of dementia (Figure 1). It is delivered to groups of people who have some degree of proximity/connection with one another, such as those residing in the same retirement community or attending the same church or senior center, to leverage social support and address local access issues. Each Brain-WISE session includes: instruction about the benefits of particular health behaviors, emphasizing both brain health and dementia risk reduction benefits,²⁵ and identification of personal perceived benefit; promotion of access to local and person-centered resources; activities or discussions to problem-solve ways to overcome individual and common barriers to risk reduction; tips or discussions about individual and collective ways to maintain or grow social support related to each risk/protective; tips or discussions about how to convert brain-healthy behaviors into person-centered habits, including generating daily cues for action; and opportunities to grow self-efficacy by recalling individual past successes and encouraging one another.

Taken together, these components make the Brain-WISE program a community implementable lifestyle intervention that provides group education and personalized counseling to help adults make a personalized plan to change health behaviors and ultimately reduce their dementia risk. To evaluate whether a future definitive trial of Brain-WISE is warranted, we conducted a non-randomized pilot study, as defined by Elderidge et al.²⁶

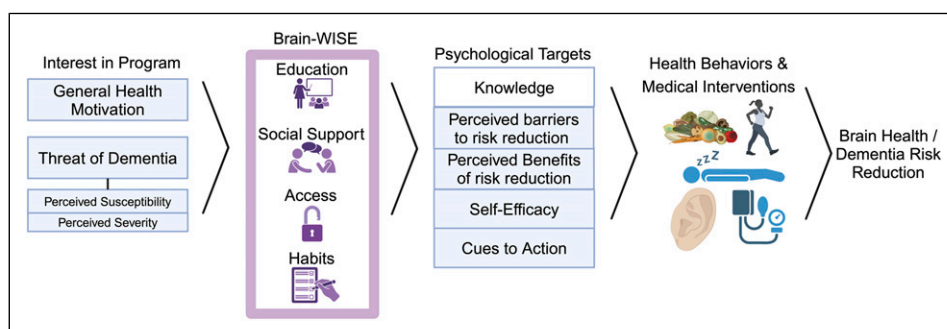


Figure 1. Conceptual Model of Brain-WISE based on the Health Belief Model (shaded blue) and other influential determinants of behavior (purple).

This allowed us to refine study materials and processes, assess the feasibility (ie, acceptability and adherence) of the intervention, and evaluate its preliminary effects on its psychological targets.

Methods

Participants

To deliver the intervention in community settings, we first identified and partnered with prospective community sites, and identified a site liaison (eg, church elder, activities director) who helped direct participant recruitment from that site (eg, with emails, flyers, social media) and plan trial logistics. Participants were midlife and older adults who lived independently (ie, not in assisted living), could read and understand English, and self-reported not having significant daily challenges with thinking or memory. Study procedures were approved by the University of Delaware's Institutional Review Board, and participants provided written informed consent.

Intervention

Intervention Structure and Procedures. The Brain-WISE program consisted of 6 sessions, delivered to cohorts of 20-30 people. After the first cohort, based on participant acceptability data, the program transitioned from meeting twice a week to once a week. Each session lasted approximately 90 minutes. The format for all sessions included watching a pre-recorded lecture as a group for 30-45 minutes, followed by individual or smaller group activities, reflection, or discussion for 30-45 minutes. Participants sat in groups of 3-6 people where everyone could see the facilitator and presentation screen and could also engage in the smaller group discussions. Each small group had a facilitator (eg, graduate student clinician) trained in motivational interviewing techniques by three experienced clinicians, a clinical psychologist (author M.L.C.) and two speech-language pathologists (authors K.V.B. and M.J.M.), both relational and content-based techniques (using the taxonomy of Hardcastle et al).²⁷ Relational techniques included asking open-ended questions; providing statements of affirmation, reflection, and summary; mapping an agenda; emphasizing autonomy; and offering emotional support. Content-based techniques included looking forward; hypothetical thinking; identifying past successes; identifying strengths; brainstorming; troubleshooting; values exploration; considering change options; reviewing outcome goals; and summarizing the plan. At least two of the three clinical supervisors were present for every session to ensure the effective use of these strategies.

Participants had a workbook containing the recorded lecture slides with space for notes, as well as reflection activities, information about accessing resources, and examples

of tools that promote healthy habits (eg, paper-based exercise and diet trackers). In response to acceptability data from the first wave, closed captions were added to the recorded lectures, and minor design changes were made to the workbook (eg, larger slides and fewer per page; adding tabs between sections). Additionally, a program website was developed with links to all relevant URLs (eg, links to local and national resources). Initially, the program included homework assignments following each session, but this component was removed after the first cohort's acceptability feedback. Over the course of the six sessions, participants also had the option of completing cognitive and hearing screenings.

Intervention Content. The risk/protective factors addressed during the sessions followed the DANCERS mnemonic (ie, Disease Management, Activity, Nutrition, Cognitive Stimulation, Social Engagement, Relaxation, and Successful Sleep),^{16,17} with the addition of hearing health and proactive use of compensatory memory aids and strategies.

Session 1 introduced the program and allowed cohort members to connect interpersonally. It provided psychoeducation about normal cognitive aging, mild cognitive impairment (MCI), and dementia; common causes of MCI and dementia; modifiable and nonmodifiable risk factors; the importance of disease management and primary care for addressing many risk factors; and discussions to consider having with a primary care provider.

Session 2 focused on physical activity and provided recommendations from authoritative sources and organizations such as the National Institute on Aging, which were congruent with the recent global consensus on optimal exercise recommendations for enhancing health longevity in older adults.²⁸ The session educated participants about the benefits of endurance, strength, flexibility, and balance activities, with a particular emphasis on endurance and strength training because these are most associated with brain health and dementia incidence.^{28,29} Participants were encouraged to engage in 150 minutes per week of moderate physical activity and strength training twice a week for 45 minutes. The program offered examples of free, home-based exercise programs. Participants also learned how to create physical activity "SMART" goals (ie, goals that are specific, measurable, achievable, realistic, and timebound) and to use a paper or electronic tracker.

Session 3 focused on nutrition, teaching participants about the Mediterranean-DASH diet intervention for neurodegenerative delay (MIND) diet, as this diet has shown promise for slowing cognitive decline and dementia.³⁰⁻³² This session provided examples of recipes and behavioral strategies to help participants adhere to the diet, including food-tracking tools. Additionally, a registered dietitian joined the session to answer questions.

Session 4 focused on hearing health and the importance of cognitive and social engagement because of the association

between these risk factors and dementia.³³⁻³⁵ This session covered when to get one's hearing tested, the benefits of over-the-counter vs prescription hearing aids, and behavioral strategies for better hearing and communication. Additionally, it was discussed what types of activities are cognitively and socially stimulating and suggestions were provided for finding new ways to stay socially and cognitively active.

Session 5 focused on the importance of using memory aids and strategies proactively so that they become habits (ie, procedural memories) that can persist even if episodic memory declines over time.^{36,37} The session covered internal strategies (eg, mental rehearsal, mnemonics), external strategies (eg, use of a notes app), and environmental strategies (eg, use of a "memory station" in the home). Participants practiced using these strategies in the session and problem-solved ways to customize these approaches to their needs.³⁸

Session 6 covered the importance of sleep,³⁹ stress management, relaxation, and mental well-being.¹ Participants learned sleep hygiene strategies, how to find a Cognitive Behavioral Therapy for Insomnia (CBTi) provider, and when to talk to a doctor about possible sleep apnea or other sleep disorders. Participants learned about mindfulness and diaphragmatic breathing (with demonstrations) and how and when to find a mental health provider if needed. This session initially taught CBT principles (e.g., identifying automatic thoughts and challenging them), but this was removed after the first cohort and replaced with mindfulness content because participants found the CBT content to be unnecessary and not actionable.

Intervention Fidelity. The intervention's fidelity was enhanced by using pre-recorded psychoeducational content, following the structure and content of the workbook, and by virtue of the primary interventionists being the intervention developers. More formal fidelity checks will be included in future stages of the intervention's development and evaluation.

Study Design

This report follows the extension to the Consolidated Standards of Reporting Trials (CONSORT) guidelines for

developing and reporting pilot randomized controlled trials,⁴⁰ excluding irrelevant items. A non-randomized pilot trial like this one is a type of feasibility study "...in which all or part of the intervention to be evaluated and other processes to be undertaken in a future trial is/are carried out (piloted) but without randomization of participants.... in which only the intervention, and no other trial processes, are piloted."^{26(p15)} We enrolled six cohorts of participants to pilot the intervention materials, content, and procedures and make iterative improvements based on acceptability data, assess adherence, and estimate preliminary effects (Figure 2).

Outcomes and Data Analysis

The primary outcomes for this feasibility trial were adherence and acceptability. Secondary outcomes included brain health awareness (eg, identification of risk and protective factors) and motivation (ie, elements of the Health Belief Model).

Adherence and Acceptability. Adherence was operationalized as percent attendance at sessions. Any participant who attended at least one session was counted. For example, if 30 participants attended at least one of the six sessions, the denominator for that cohort would be 180. We used an a priori definition of 70% attendance being acceptable based on what is typical for community-based behavioral interventions.^{41,42}

Acceptability of the content, procedures, and materials was assessed with bespoke questionnaires - one completed after each session and specific to that session, and another completed at the end of the program and about the acceptability of the program as a whole. The session-specific acceptability measure (Appendix A) was composed of 20 items for Cohort 1 (when homework was a component of the intervention) and 15 items thereafter when homework was removed as a component: five items about psychoeducation content, five items about psychoeducation delivery, and five items about discussion/activities. Participants rated each item on a scale from 1 (strongly disagree) to 5 (strongly agree). The a priori benchmark for

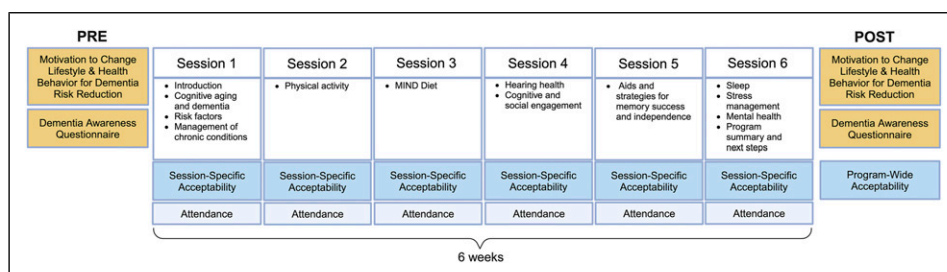


Figure 2. Intervention and Study Overview. **Note:** light blue boxes indicate recording of attendance. Dark blue boxes indicate measurement of acceptability. Gold boxes indicate assessment of outcomes.

acceptability was for median scores in each domain to be at least 4 across participants and domains, indicating that most participants at least “agreed,” if not “strongly agreed,” with the positively phrased items.

The program-wide acceptability measure (Appendix B) contained items about the overall value of the program, the number and length of sessions, the most and least effective components, suggestions for additional components, and whether participants thought the program would be effective if delivered online (an option we have considered). Our only a priori benchmark for this survey was for the item, “Overall, this program was worthwhile” to have a median score of at least 4, indicating that most participants at least “agreed,” if not “strongly agreed.” The remaining items were interpreted as supporting information without pre-determined benchmarks.

Motivation. Initially, components of motivation were assessed with the Dementia Worry Scale⁴³ and Self Efficacy for Managing Mild Cognitive Impairment Scale.⁴⁴ However, participants in Cohort 1 reported that the phrasing of the items in these scales presumed current cognitive impairment or was about dementia rather than brain health. Subsequently (Cohorts 2-6), we used the Motivation to Change Lifestyle and Health Behaviors for Dementia Risk Reduction (MCLHB-DRR) scale.²² This measure has seven subscales that assess elements of the HBM related to dementia risk reduction: perceived susceptibility (four items), perceived severity (five items), perceived benefits (four

items), perceived barriers (four items), cues to action (four items), general health motivation (four items), and self-efficacy (two items). The scale uses a 5-point Likert scale from 1 (strongly disagree) to 5 (strongly agree). A repeated-measures *t* test was used to assess pre-post changes in the MCLHB-DRR total score.

Brain Health Knowledge. Initially, we used a bespoke measure to assess participants’ knowledge of the most up-to-date information about brain health and dementia risk reduction. However, after discovering an existing measure that contained up-to-date information, we switched to the Dementia Awareness Questionnaire⁴⁵ (Cohorts 2-6). This measure assesses respondents’ ability to identify risk and protective factors and includes foils. The total score reflects the number of correct items minus the number of foils endorsed. A repeated-measures *t* test was used to assess pre-post changes. Cohen’s *d* effect size estimates were interpreted as follows: a small effect size around 0.2, a medium effect size around 0.5, and a large effect size around 0.8.⁴⁶

Participant motivation and brain health knowledge were assessed within two weeks pre and post treatment. Those with email addresses received a REDCap link to complete the measures. Participants without an email address or who did not complete the measures online did so in person prior to the first session. After the final session, participants could complete the measures via REDCap, telephone, or in person.

Table 1. Participant Demographics.

Age (mean, SD)	77.6 (7.8)	Min = 56, Max = 93
Sex		
Male	32	22%
Female	111	78%
Race/Ethnicity		
White	126	91%
Black/African American	9	6%
Asian	1	1%
Hispanic	2	1%
Other	1	1%
Education		
< Bachelor’s degree	35	28%
Bachelor’s degree	47	38%
>Bachelor’s degree	42	33%
Likely cognitive status*		
Cognitively unimpaired	62 / 91	68%
MCI	27 / 91	30%
Early-stage dementia	2 / 91	2%
Elected not to complete MoCA	52 / 143	36% of total

Note: *Ninety-one participants out of 143 elected to complete the Montreal Cognitive Assessment (MoCA) and receive feedback about their score. Likely classification (CU, MCI, dementia) was based on the cutoff scores of Milani et al.,⁴⁷ which are adjusted for age, race/ethnicity, and education.

Table 2. Session-Specific Acceptability Ratings.

Session #	Psychoeducation content							Psychoeducation delivery							Discussion/Activities						
	1	2	3	4	5	6	+	1	2	3	4	5	6	+	1	2	3	4	5	6	+
Cohort 1 (retirement community)	4	5	5	4.5	5	5	5	5	5	5	5	5	5	5	4	4	5	5	5	5	5
Cohort 2 (retirement community)	4	5	5	4.5	5	4	5	5	5	5	5	5	5	5	5	5	*	5	5	5	5
Cohort 3 (church)	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Cohort 4 (senior center)	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Cohort 5 (senior center)	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Cohort 6 (Jewish C.Ctr.)	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
+	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5

Note: The median response was computed for each session across participants and the five items related to content, delivery, and discussion/activities. Each cell reports the median values for each session: session 1 median, session 2 median, etc. The row labeled + indicates the median value for that item across sessions. The columns labeled + indicate the median value across item categories (ie, psychoeducation content, psychoeducational delivery, discussion/activities). *The session was interrupted, and there was not time for the activities/reflection/discussion portion.

Table 3. Program-Wide Acceptability.

	<i>n</i>	%
Overall, the program was worthwhile		
Strongly agree	101	86%
Somewhat agree	12	10%
Neutral	0	0%
Somewhat disagree	2	2%
Strongly disagree	3	2%
Overall, how did you feel about the number of sessions?		
6 sessions was the right number	109	92%
6 sessions was too few	6	5%
6 sessions was too many	3	3%
Overall, how did you feel about the length of each session?		
90 minutes was about right	108	93%
90 minutes was not long enough	4	3%
90 minutes was too long	4	3%
Overall, how much did you benefit from the lecture content (the recorded portions) of the program?		
5 = benefitted a lot	62	49%
4	33	26%
3	19	15%
2	11	9%
1 = did not benefit at all	1	1%
Overall, how much did you benefit from the reflection activities and small-group discussions?		
5 = benefitted a lot	57	49%
4	30	26%
3	22	19%
2	8	7%
1 = did not benefit at all	0	0%
Knowing what you know now about the program, if we were to offer a similar program by Zoom rather than in person, how do you think that would go? Do you think it would be better, worse, or about the same?		
In person would be A LOT more effective than Zoom	95	81%
In person would be A LITTLE more effective than Zoom	11	9%
In person would be about as effective as Zoom	7	6%
Zoom would be A LITTLE more effective than in person	4	3%
Zoom would be A LOT more effective than in person	0	0%

Table 4. Motivation and Knowledge Data.

	Pre		Post		Paired samples test	Cohen's d (95% CI)
	Mean	SD	Mean	SD		
MCLHB-DRR	88.6	12.5	93.8	12.2	$t(82) = 3.87, P < .001$	0.43 (0.20 - 0.65)
Dementia Awareness Scale	4.7	3.8	7.6	3.4	$t(83) = 7.57, P < .001$	0.83 (0.57 - 1.07)

Note: The MCLHB-DRR score was the total raw score with all subscales coded such that a higher value reflected more motivation. The Dementia Awareness Scale score is all correct items endorsed minus all sham items endorsed.

Results

Sample Characteristics

The six cohorts of the pilot trial were conducted at four community sites in Delaware and Pennsylvania: a continuing care retirement community (Cohorts 1 and 2), a church (Cohort 3), a senior center (Cohorts 4 and 5), and a Jewish Community Center (Cohort 6). Enrollment began in July, 2023 and concluded in December, 2024. A total of 150 adults responded to recruitment efforts. Of those, 143 participants provided informed consent and attended at least one study session. Five withdrew or stopped responding before providing informed consent. Two provided informed consent but never completed the study measures or attended any session. Participant demographics are listed in Table 1.

Adherence and Acceptability

Attendance across the six cohorts was 97% (Cohort 1; retirement community), 93% (Cohort 2; retirement community), 90% (Cohort 3; church), 83% (Cohort 4; senior center), 84% (Cohort 5; senior center), and 80% (Cohort 6; Jewish Community Center). The median session-specific acceptability ratings across intervention domains (psychoeducation content, psychoeducation delivery, and discussion/activities), sessions, and cohorts were scores of 4 ("agree") or higher (Table 2). Program-wide acceptability ratings (Table 3) revealed that 96% of participants agreed or strongly agreed that the program was worthwhile. The vast majority (92%) reported that six was an appropriate number of sessions and that 90 minutes was an appropriate duration (93%). Seventy-five percent of participants said they benefitted from the psychoeducational component, and the same percentage reported benefitting from the activities/discussion components. Ninety percent of participants believed the in-person version of this program (ie, the version that they completed) would be more effective than an online version, primarily due to the value of social interaction for increasing attention, accountability, and interest, as well as a distaste for technology or videoconference technology specifically. Open-ended

responses about course content did not consistently report any content being missing or unnecessary.

Motivation and Knowledge

There were 83 (71%) complete records (ie, data for pre and post) for the MCLHB-DRR scale and 84 (72%) complete records of the Dementia Awareness Scale in Waves 2-6. After the program, MCLHB-DRR and Dementia Awareness Scale scores increased significantly (Table 4).

Discussion

The Brain-WISE program received high acceptability ratings across session domains (psychoeducation content, psychoeducation delivery, and discussion/activities), session content, and cohorts, particularly after Cohort 1, when we made the most substantive modifications to materials and procedures. Participants reported that the program was worthwhile, its overall structure (eg, length and number of sessions) was appropriate, and no content was missing or unnecessary. The effect sizes for knowledge (large) and motivation (small-medium) were similar to the BRAIN BOOTCAMP intervention,^{48,49} which used the same measures. The BRAIN BOOTCAMP intervention is less intensive and more easily scalable than Brain-WISE, for example, by being remotely delivered, unproctored, and individual (rather than in-person, proctored, and group-based). However, the authors reported significant challenges with attrition (41.6% completion), defined as failing to complete both pre- and post-measures, particularly for participants with less education and lower baseline motivation. By this same definition of attrition, Brain-WISE had 71% completion.

The mechanisms of adherence and preliminary effects remain to be evaluated with a larger investigation with a control condition, but we hypothesize that the social connection aspects of the program will be significant. These aspects may promote positive social pressure to attend, engage, jointly overcome local barriers to brain health, and sustain health behavior changes. We can

illustrate this hypothesis with a few anecdotes. Our participants at the retirement community phoned or physically retrieved their neighbors who were not present at the beginning of a session. In this same community, residents formed a morning walking group and banded together to petition their caterer to offer more MIND Diet-friendly options. At the senior center, participants invited one another to their favorite activities (eg, pickleball) and taught one another how to navigate the free shuttle service to engage with more brain-healthy programming. At the church, participants considered new ways to engage their socially isolated parishioners and serve healthier food options at church functions.

Social engagement is important for brain health, as it leads to neurogenesis, neuronal rejuvenation, and improved neuroendocrine system function, while also buffering against hypothalamic-pituitary-adrenal axis dysfunction.⁵⁰ Furthermore, social connection, accountability, and positive peer pressure may also be important strategies for engaging with and adhering to other health behaviors and brain resilience factors. As multidomain interventions are increasingly adapted or developed for community settings, it may be important to balance feasibility and scalability with these social mechanisms, as they can contribute to adherence, satisfaction, and sustained behavior change, particularly for individuals with low education and motivation. When participants were asked whether this program would be effective online (eg, over Zoom), their open-ended responses overwhelmingly highlighted the importance of social connection and accountability (as well as dislike of technology). While the Brain-WISE program is primarily based on the Health Belief Model, which focuses on individual perceptions and thought processes, future development of this and other interventions might also consider incorporating principles from Social Cognitive Theory, which emphasizes the interaction between individuals and their environment.⁵¹ Although our current participants overwhelmingly preferred an in-person format, we hope to engage younger participants in the future, who might be more open to a virtual format or need one because they are not retired. If the program becomes adapted for online delivery, it seems important that group members share a community, and extra attention would need to be paid to ensure the opportunity for social connections.

The main limitations of the current study are its relatively homogenous (ie, White, non-Hispanic,

female) sample and reliance on patient-reported outcomes, although these limitations are common to many multidomain interventions. Future development and evaluation of the program would benefit from more testing in diverse communities, for example, by partnering with and hosting Brain-WISE groups at churches, senior centers, and other organizations in Black, Hispanic, and rural communities. Future evaluation of the program would also benefit from direct assessment of health outcomes (eg, physical activity with actigraphy) or performance-based measures, and extended follow-up assessments. Given the acceptability and preliminary evidence for the effects of the Brain-WISE intervention, further development and testing are warranted. Testing multidomain interventions against a passive health education control group is most typical, but a waitlist control group might be more feasible and ethical in community settings, especially because the intervention itself is relatively brief (six weeks). Future testing could also evaluate the relative contributions of each program element and the potential value of booster sessions. This program might also benefit from being evaluated with a multiphase optimization strategy (MOST) optimization study.⁵²

Alongside the intensive FINGER-network protocols, there is a growing number of less-intensive, multidomain interventions that are intended to be more feasible and implementable in clinical and community settings,^{25,53-58} and these, too, are showing evidence for being able to improve brain health and reduce dementia risk. If evidence continues to support the efficacy and effectiveness of the Brain-WISE program, it adds to the literature on less intensive multidomain interventions by (1) being informed by the Health Belief Model and other influential determinants of behavior; (2) being conducted in person and with groups of people who share a community; (3) including the formation of person-centered health goals; (4) addressing hearing health and proactive instruction of cognitive aids and strategies; and (5) being conducted by a variety of interventionists, including speech-language therapists. Overall, the results of this pilot trial suggest that the Brain-WISE program shows promise as an engaging and acceptable approach for improving motivation and knowledge related to brain health and dementia risk reduction among adults and older adults in community settings.

Appendix

Appendix A: Session-Specific Acceptability Survey

Prompt	Please answer the following questions about the most recent session that you completed. Please only answer questions about that session
Lecture content	<p>The information presented today was new to me</p> <p>I understood the information presented today</p> <p>The information presented today was useful to me and my health</p> <p>The amount of information was about right (ie, not too much, not too little)</p> <p>I am likely to do something based on the information presented today, for example, change a health habit or talk to my doctor</p>
Lecture delivery	<p>I could hear the speaker</p> <p>The speaker talked at a good pace</p> <p>I could read the slides (for example, the font was the right size)</p> <p>The slides were easy to understand</p> <p>The lecture today kept my attention</p>
Discussion, activities	<p>I enjoyed the small group discussions and activities</p> <p>The small group activities were relevant to the topic of the day</p> <p>The small group discussions and activities helped me understand and think about the topic today</p> <p>The small group discussion and activities took about the right amount of time</p> <p>I felt comfortable with the other members of my small group</p>
Homework (wave 1 only)	<p>The homework that I did in preparation for today was easy to understand</p> <p>The homework that I did in preparation for today helped me understand something about my health</p> <p>The homework that I did in preparation for today took about the right amount of time (ie, not too long)</p> <p>I understand the score or feedback that was given to me today about my homework responses</p> <p>I am likely to do something based on the homework feedback that was given to me today. For example, change a health habit or talk to my doctor</p>

Note: the response options were 1 = strongly disagree, 2, 3, 4, 5 = strongly agree, Cannot say/Not applicable.

Appendix B: Program-Wide Acceptability Survey

Prompt Previous satisfaction surveys were about each session individually. This survey is about the program overall		
1	Overall, this program was worthwhile	Strongly disagree somewhat disagree neutral somewhat agree strongly agree
2	Overall, how did you feel about the number sessions?	6 sessions was about the right amount 6 sessions was too many 6 sessions was too few
3	Overall, how did you feel about the length of each session?	90 minutes was about right 90 minutes was too long 90 minutes was not long enough
4	What was the best or most effective part of this program?	[Free response]
5	What was the worst or least effective part of this program?	[Free response]
6	If you were to add content or sessions, what would you add?	[Free response]
7	If you were to remove content or sessions, what would you remove?	[Free response]
8	Overall, how much did you benefit from the lecture content (the recorded portions) of the program?	1 = did not benefit at all 2 3 4 5 = benefited a lot
9	Overall, how much did you benefit from the reflection activities and small-group discussions?	1 = did not benefit at all 2 3 4 5 = benefited a lot
10	Knowing what you know now about the program, if we were to offer a similar program by Zoom rather than in person, how do you think that would go? Do you think it would be better, worse, or about the same?	-In person would be A LOT more effective than Zoom -In person would be A LITTLE more effective than Zoom -In person would be as effective as by Zoom -Zoom would be A LITTLE more effective than in person -Zoom would be A LOT more effective than in person
11	Why do you think that?	[Free response]
12	Is there anything else that you would like to tell us about the program?	[Free response]

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Ethical Statement

Ethical Approval

This study was approved by the University of Delaware Institutional Review Board.

Informed Consent

All participants provided written informed consent.

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Data Availability Statement

De-identified data are available for sharing upon reasonable request.

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