The Brain Health Champion study: Health coaching changes behaviors in patients with cognitive impairment

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Abstract

Introduction: Converging evidence suggests that increasing healthy behaviors may slow or prevent cognitive decline.

Methods: We piloted a six-month, randomized, controlled investigation of 40 patients with mild dementia, mild cognitive impairment, or subjective cognitive decline. The intervention consisted of weekly motivational interviewing phone calls and three visits with a “Brain Health Champion” health coach, who guided participants to achieve personalized goals. Changes in behavior were measured using validated questionnaires.

Results: Compared with the standard-of-care control group, Brain Health Champion participants had statistically significant and clinically meaningful increases in physical activity (Cohen’s d = 1.37, P < .001), adherence to the Mediterranean diet (Cohen’s d = 0.87, P = .016), cognitive/social activity (Cohen’s d = 1.09, P = .003), and quality of life (Cohen’s d = 1.23, P < .001). The magnitude of behavior change strongly predicted improvement in quality of life.

Discussion: Our results demonstrate the feasibility and potential efficacy of a health coaching approach in changing health behaviors in cognitively impaired and at-risk patients.

Keywords: Health coaching; Behavior change; Risk reduction; Mild cognitive impairment; Dementia; Exercise; Mediterranean diet; Cognitive and social activity; Quality of life; Clinical care delivery

1. Background

Alzheimer’s disease and related dementias (ADRDs) are associated with substantial burdens on patients, families, and the health care system. The loss of independence and cognitive abilities is one of the most feared aspects of aging among healthy older adults, and this fear negatively impacts quality of life (QOL) [1,2]. Patients diagnosed with mild cognitive impairment (MCI) or dementia also report decreased QOL compared with their healthy peers, and they are more likely to experience comorbid neuropsychiatric symptoms, including depression and irritability [3–5].

In the United States alone, approximately 5.8 million people currently suffer from ADRDs and 15%–20% of adults over the age of 65 have MCI, which can be an early sign of a progressive neurodegenerative disease [6]. The total estimated global cost of treatment and care for ADRDs in 2018 was US $1 trillion, with predictions of a rise to US $2 trillion by 2030. In the U.S. alone, there is over $230 billion dollars of unpaid care provided by family members and other caregivers [6]. Compared with age-matched peers, older adults with MCI and dementia have worse health outcomes,
leading to increased health care utilization and higher out-of-pocket health care spending [7,8]. The transition from MCI to dementia is the most expensive step in the disease progression, and economic models demonstrate that delaying the transition from MCI to dementia by five years could result in an economic savings of more than $500,000 per patient [9,10].

In light of converging evidence linking brain healthy lifestyles to decreased risk of cognitive decline and dementia, recommendations from major health organizations have focused increasingly on behavior change in patients with or at risk for cognitive disorders [6,11–13]. Epidemiological research suggests that up to 35% of ADRD cases may be attributable to potentially modifiable risk factors [11]. Cohort studies provide strong evidence that lifestyle factors including physical activity, adherence to the Mediterranean diet, and social and cognitive stimulation are associated with a decreased risk of developing ADRDs [14–19]. Several small intervention trials have shown that behavior change in these domains can improve cognition in cognitively healthy older adults [20,21] and improve cognition or prevent decline in patients with cognitive impairment [22–24]. Adherence to recommendations for brain health are also associated with improved overall health and QOL for patients and caregivers [21,22]. The Finnish Geriatric Intervention Study to Prevent Cognitive Impairment and Disability (FINGER), a landmark nonpharmacological trial for cognitively normal adults with dementia risk factors, showed that a two-year, multimodal regimen of brain healthy behavior, including physical activity, dietary modification, and computerized cognitive training, improved cognition relative to a standardized education control group [25].

Despite growing support for brain healthy behavior change as a treatment strategy for ADRDs, there is a lack of research examining how to implement consensus-based lifestyle recommendations in clinical care. The Brain Health Champion (BHC) pilot study aimed to address the gap between knowledge and implementation by investigating the use of a health coaching intervention. There are several key barriers to changing patient behavior in routine neurological appointments, including limited time to interact with patients and lack of provider training in effective behavior change techniques [26]. To address these barriers, providers in other specialties have increasingly relied on health coaches, care managers, and other nonprovider personnel to help patients make behavior changes through increased contact with the clinical care system. For example, effective health coaching interventions have been used to manage cardiovascular risk factors in primary care and cardiology and opiate addiction in psychiatry [27–29]. Within the context of inconsistent provider counseling in dementia practice, the evidence supporting behavior change to mitigate cognitive decline, and the efficacy of health coaches to promote this change, the BHC pilot study was designed to investigate a promising model.

2. Methods

2.1. Participants

Forty participants were recruited from a subspecialty cognitive disorders practice in the Brigham and Women’s Hospital Alzheimer Center. Eligible participants had at least one prior appointment with one of two participating neurology providers. Study staff reviewed charts of patients who had upcoming, routine visits to identify potential participants. Neurologists excluded potential participants because of disabling medical conditions, prominent neuropsychiatric symptoms, or concerns about safety with moderate exercise. Potential participants approved by the neurologists were then contacted via mail, followed by a screening phone call.

To be eligible, participants had to be 50 years or older and have a diagnosis of mild dementia, MCI, or subjective cognitive decline (SCD), based on consensus criteria [30–32]. Of those with MCI or dementia, the assessed etiologies included AD, dementia with Lewy bodies, cerebrovascular disease, or mixed neurodegenerative/cerebrovascular disease pathology. Patients with moderate to severe dementia were excluded. Participants had to be sufficiently fluent in English to complete cognitive tests and behavioral questionnaires and to converse with the health coach.

Concurrent enrollment in pharmacological or observational studies was permitted. Five participants (three BHC interventions and two standard-of-care [SOC] arms) were involved in other research studies, three of which were pharmacological studies (two BHC interventions and one SOC arm). The study protocol was reviewed and approved by the Partners Human Research Committee (Protocol 2017P000384). It is registered with ClinicalTrials.gov (NCT03772977).

2.2. Study design and randomization

Participants were consented and enrolled by study staff after routine follow-up neurological visits at the Brigham and Women’s Hospital Alzheimer Center. Participants were randomized 1:1 into the BHC intervention or SOC arm. The randomization schedule was stratified by diagnosis of mild dementia, MCI, or SCD using random block sizes of two and four, generated in Stata 13.0 (StataCorp, College Station, TX).

2.3. BHC intervention

After randomization, participants in the BHC intervention met with a health coach for 45 minutes to assess baseline activity levels and areas for improvement in each of the three primary behavioral domains (physical activity, adherence to a Mediterranean diet, and social/cognitive stimulation). The health coach was a recent, pre-health college graduate embedded in the Alzheimer Center who received training on the evidence-based lifestyle factors that influence
cognitive decline and was introduced to techniques that facilitate behavioral change.

During the baseline assessment, the health coach reviewed standardized educational materials (see Supplement S.1). In a collaborative process, the health coach, participants, and study partners/caregivers (where applicable) worked together to set optimal brain health goals to be achieved in the short (one week), medium (before first follow-up visit at six weeks), and long term (by the end of the study, six months). Goals were guided by the overarching framework of maximizing adherence to recommendations for aerobic exercise for older adults [33], following the Mediterranean diet and participating in socially/cognitively stimulating activities. After the enrollment visit, participants committed to a weekly, 15-minute phone call with the health coach in addition to their standard neurological care.

During weekly phone calls, the health coach spoke with the participant and study partners/caregivers, if available. The phone calls followed a semistructured interview format to accomplish the following: (1) assess achievement of the previous week’s goals in each behavior domain; (2) discuss and troubleshoot any obstacles to achieving specific goals; and (3) adjust goals as necessary (see Supplement S.2).

In-person visits with the health coach occurred every six weeks, for a total of three additional visits outside of standard care. At the first in-person visit (6 weeks), participants and families met with the health coach and a research dietician for education and counseling on the Mediterranean diet. Participants completed a detailed food frequency questionnaire and received a handout describing the Mediterranean diet (see Supplement S.3). During the second (12 week) and third (18 week) in-person visits, participants and families met with the health coach to review progress and update goals.

Although goal-setting and contact with participants was personalized and dynamic, the health coach used a consistent overall approach that provided a common framework to the intervention. The intervention drew on techniques from evidence-based behavior change methods, including motivational interviewing [34], which aims to augment motivation, and behavioral activation, [23,35], which emphasizes setting concrete, attainable goals and changing habits/routines to promote sustained behavior change.

2.4. SOC control

After randomization to the SOC arm, participants and families received a standardized educational handout developed by a neurology provider at Brigham and Women’s Hospital, which is regularly used in clinical care (see Supplement S.4). SOC participants continued to receive routine care, which included general counseling on brain healthy behaviors, with in-person follow-up visits every three to six months as needed.

2.5. Outcome measures

Primary outcome measures were self-reported, validated behavioral scales assessing physical activity, diet, and social/cognitive activity: International Physical Activity Questionnaire (IPAQ) [36], Mediterranean Score (Med-Score) [37], and Florida Cognitive Activities scale (FCAS), respectively [38,39]. The secondary outcome measure was the Flanagan Quality of Life Scale (FQOL) [40], a 16-item Likert scale assessing satisfaction in subdomains of life including relationships, physical health, and independence [41]. Assessors administering the scales were not blinded to trial arm.

2.6. Statistical analyses

Treatment effect on self-reported questionnaires was assessed using mixed model analysis of variance (ANOVA) with time as a two-level within-participant factor and treatment assignment as a two-level between-participant factor. The primary analysis examined the time-by-treatment interaction using an F-test for each of the three primary outcome variables. P values were adjusted using the Holm-Bonferroni method for multiple comparisons. Demographic and cognitive variables at baseline by study arm were compared using two independent samples t-tests for age and Mini–Mental Status Examination (MMSE) and Mann-Whitney U tests for sex and diagnosis. For correlation analyses, changes in the three primary behavior domains and QOL were calculated as posttreatment minus pretreatment for each participant, and correlations between changes in the three primary outcomes and QOL were analyzed using Spearman’s rank correlation coefficients. A brain healthy behavior composite variable was calculated using the normed average change in each behavior domain (z-scored), with each behavior change domain weighted equally [42,43]. The relationship between the normalized composite score and normalized (z-scored) change in QOL was examined by linear regression using maximum likelihood estimation. Akaike’s Information Criterion (AIC) was used to assess the goodness of fit of the model using the composite behavioral score compared with that of a regression model using the three behavioral scores as independent predictors [44]. All analyses were completed using SPSS 23 for PC.

3. Results

3.1. Study recruitment, enrollment, and completion

Fig. 1 is a CONSORT flow chart that provides information about participant screening, recruitment, and enrollment. All patients with upcoming follow-up neurological care visits were reviewed by study staff. Ninety-one patients met inclusion criteria based on chart review and were referred for more detailed review by the two participating neurologists. Forty patients consented to participate, were randomized into BHC intervention or SOC control, and
completed baseline MMSE and self-report questionnaires. Of the 40 participants who began the study, three withdrew before six months (two from the BHC intervention and one from the SOC arm; all with mild dementia) for these reasons: (1) major medical illness (cancer); (2) severe cognitive decline; and (3) unwillingness to complete study procedures due to perceived burden. Age and cognition (baseline MMSE) of those who dropped out and those who completed the study were compared using Mann-Whitney U tests. There was no evidence of differences between the dropouts \((n = 3)\) and study completers with mild dementia \((n = 16)\) in baseline age \((P = .73)\) or MMSE \((P = .55)\).

### 3.2. Demographics and baseline characteristics

Table 1 summarizes demographic characteristics and baseline cognition (MMSE) by study arm. There were no significant differences in age, sex, diagnosis, or MMSE scores between the study arms at baseline. Mean baseline MMSE scores by diagnostic group were 19.5 (mild dementia), 25.8 (MCI), and 29.7 (SCD). There was no evidence that MMSE scores between the study arms at baseline. Mean baseline age \((P = .73)\) or MMSE \((P = .55)\).

### 3.3. Treatment effects on primary outcomes

Table 2 presents pretreatment and posttreatment mean scores and standard deviations of self-report questionnaire outcomes. Table 3 presents the results of the mixed model ANOVA analysis for time-by-treatment interactions. Compared with the SOC control group, BHC participants had statistically significantly improvement in physical activity \((\text{IPAQ}, P < .001)\), Mediterranean Diet \((\text{MedScore}, P = .016)\), and social/cognitive engagement \((\text{FCAS}, P = .006)\). Table 3 reports the mean change in each variable by group. SOC had negative change in all three behavior change domains. As only three participants of 40 withdrew from the study and the reasons for withdrawal suggest a missing completely at random missingness mechanism, a complete-case analysis was used. A sensitivity analysis with the three missing observations imputed with “worst-best-case” and “best-worst-case” response values was performed; this had a negligible effect on the reported \(P\) values (refer to Jakobsen et al. [45] for details of performing this sensitivity analysis).

Mixed model ANOVA with three-way interactions showed no statistically significant time-by-treatment-by-diagnostic group (mild dementia, MCI, or SCD) interactions in any behavior change domain \((\text{IPAQ}, P = .99, \text{MedScore} P = .74, \text{FCAS} P = .58)\). ANOVA models were re-run using baseline MMSE scores as a covariate, and all results remained statistically significant.

Table 3 reports the Cohen’s-d effect sizes for all significant intervention effects. Effect sizes were in the large to very large range [46] for IPAQ \((d = 1.37)\), MedScore \((d = 0.87)\), and FCAS \((d = 1.09)\). Changes in the three primary behavior change domains correlated with each other (Spearman’s correlation coefficient \(= 0.34–0.67\), \(P’ s < .05\)) (See Supplementary Table A1). A large intervention effect was also seen for the average behavior composite, where change in the composite was significantly greater in the BHC group than the SOC group \((P < .001)\) (Fig. 2).

The BHC intervention increased adherence to consensus-based recommended levels of physical activity and diet. By the completion of the study, 68% of the participants in the BHC arm, compared with 29% of SOC participants, reported spending \(>150\) min/week doing moderate or vigorous physical activity, consistent with Centers for Disease Control and Prevention recommendations for older adults [33]. Also by the study’s end, 78% of BHC participants reported a \(>50\%\) adherence to the Mediterranean diet, compared with 39% of SOC participants.

### 3.4. Treatment effects on QOL

Table 3 also includes the effect of the BHC intervention on QOL \((d = 1.23, P < .001)\). Compared with the SOC control group, BHC participants had significant improvement in QOL (FQOL). The SOC had negative change in QOL. Mixed ANOVA models with three-way interaction showed no time-by-treatment-by-diagnostic group interaction \((P = .97)\) for FQOL, indicating that diagnostic group did not modify

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**Table 1** Demographic characteristics and baseline cognitive scores by group

| Variables | BHC \((n = 19)\) | SOC \((n = 18)\) | \(P\) value |
|----------|----------------|----------------|-----------|
| Age \((y)\) | 74.7 (10.4) | 74.3 (8.0) | .90 |
| Sex \((M/F)\) | 10/9 | 6/12 | .41 |
| Diagnosis \((\text{SCD/MCI/MD})\) | 2/11/6 | 2/10/6 | .96 |
| MMSE | 23.2 (5.2) | 25.4 (4.3) | .23 |

**NOTE.** Values reported as mean (SD). Abbreviations: BHC, Brain Health Champion; SOC, standard of care; SCD, subjective cognitive decline; MCI, mild cognitive impairment; MD, mild dementia; MMSE, Mini–Mental Status Examination; SD, standard deviation.
intervention response. Change in self-reported brain healthy behavior was strongly related to QOL. Table 4 shows the results of Spearman’s correlation coefficients between change in FQOL and change in the three behavior domains (P’s ≤ .001—.004). The z-score behavior change composite score more strongly predicted improvement in QOL (R² = 0.69, AIC = 245, F-test P value: <.001) than the regression model using the three behavioral scores as independent predictors (R² = 0.57, AIC = 261, F-test P value: <.001) based on R² and AIC. Importantly, the AIC was 16 points lower for the composite score than the three individual scores, suggesting substantially improved fit [44].

4. Discussion

The results from this randomized clinical trial strongly demonstrate the potential efficacy of the BHC program for helping patients with MCI and mild dementia adopt consensus brain health recommendations. Compared with the SOC control group, BHC participants had statistically significant and clinically meaningful increases in physical activity, Mediterranean diet adherence, cognitive/social activity, and QOL. The success of the BHC intervention in increasing adherence to brain health recommendations provides support for a health coaching model to augment clinical care delivery for patients with cognitive decline.

Limited research has focused on how to provide cost-effective, scalable interventions in clinical care that are specifically aimed at changing behavior. The BHC study helps to bridge the treatment gap between understanding the health benefits of certain lifestyle behaviors and implementing them in the clinic. The intervention also provides support for the growing role of clinical precision medicine in ADRD care. Because dementia risk factors vary across individual patients, they cannot be adequately addressed by standardized, single-modality interventions but instead require a more personalized approach [47]. Single-domain interventions may also be less effective because they fail to account for the possible synergistic effects of multicomponent interventions [47].

Owing to the growing emphasis on multimodal interventions, this study used a z-score behavior health composite score as an exploratory outcome. There is a lack of consensus on how to combine lifestyle variables into a composite score that accurately reflects their respective effects on overall health and wellbeing. Methodological literature suggests that creating an equally weighted composite is appropriate when outcome variables are closely related [43]. In this study, changes in the three behavior change domains were highly correlated, and thus the composite behavior change score may accurately reflect combining the behaviors. Of note, the composite behavior score explained more of the variance in QOL improvement than a model in which each behavioral change was used as an independent predictor. This result suggests a potentially synergistic effect of multibehavior change on QOL, which may reflect the combined effects of increased self-efficacy and overall improved wellbeing. As emerging research continues to examine the potentially interdependent effects of multidomain behavior change, further work is needed to develop and validate composite lifestyle outcome measures.

The sample in this study included participants across a wide spectrum of cognitive disorders, from SCD to mild dementia. Epidemiological evidence suggests that nonpharmacological interventions may have the most potent effect before developing MCI, potentially delaying or preventing the onset of cognitive decline [14]. In light of these promising outcomes and the increased cost-saving effects of an earlier intervention, nonpharmacological research efforts are increasingly focused on these “preclinical” populations [11,25,48]. The BHC pilot cohort included three SCD subjects who represent this population at increased risk of
underlying ADRD pathology and developing decline [49,50]. Although the sample of SCD subjects was very small, limiting the conclusions that can be drawn, it is notable that the magnitude of the treatment effects was not modified by level of impairment (i.e., mild dementia, MCI, SCD). This result suggests possible effectiveness of the BHC program in cognitively normal, “preclinical” individuals with SCD and/or dementia risk factors. Planned research aims to examine the effects of the BHC intervention in cognitively normal, at-risk populations in primary care settings, for whom similar behavior changes may contribute to delaying or preventing the onset of cognitive impairment due to ADRDs.

4.1. Limitations

There are several limitations to the BHC pilot study that future research should address. First, the study used self-report behavior change questionnaires. This was an intentional design feature to mimic a “real-world” setting, as standard clinical practice often relies on questionnaire/survey data to assess risk and monitor patients. Although these questionnaires are validated and widely used in comparable studies and clinical care, there is the possibility of bias and error. Questionnaire bias might have affected the BHC and SOC arms in different ways depending on relationship with the coach or other motivations but likely does not account fully for the robust observed intervention effect. Future studies should include objective measures, such as wearable fitness trackers and photographed dietary intake, to corroborate self-reported behavior changes. Future studies should also use a detailed neurocognitive test battery and a longer duration to measure more granular changes in cognition and function.

Second, the SOC control group reflected “usual care,” rather than a standardized intervention. Although participants in the SOC group received the same handout, providers educated, treated, and followed up with patients according to their own clinical practice, which includes varied levels of lifestyle counseling. In this way, the study did compare a novel intervention to a realistic representation of current ADRD clinical care, and the results from this pilot study demonstrate the potential efficacy and feasibility of carrying out the intervention in real-world settings. However, future research should also compare the health coaching intervention to a standardized physician counseling and education control group to minimize potential variability of care delivery in that group.

Finally, the BHC intervention had multiple components that may have contributed to its impact on behavior, including weekly phone calls, in-person visits, nutritional counseling, and increased contact with the health care system overall. Within the therapeutic relationship between participant and health coach, factors contributing to behavior change could have included tangible goals, increased structure/routine, feedback/accountability, caregiver support, or motivational aspects of the personal relationship itself. In theory, these multiple factors of the BHC intervention may have all had an impact on its efficacy. However, to optimize the cost-effectiveness and implementation potential of a larger, clinic-based brain health initiative using
health coaches, it will be imperative to understand which components are critical and which may be eliminated. Future studies should vary the intervention to determine which aspects are most effective for different patient populations and care settings.

5. Conclusion

With converging evidence for the role of lifestyle factors in reducing risk and delaying cognitive decline, it is imperative to develop and test personalized, cost-effective programs to promote brain healthy behavior change in ADRD clinical care. The BHC intervention, a six-month health coaching intervention delivered through existing clinical infrastructure, improved adherence to consensus-based recommendations for physical activity, diet, and social/cognitive engagement in older adults with mild dementia, MCI, and SCD. Although large-scale investigations must be completed to address the limitations discussed previously, the BHC pilot demonstrates potential to change behavior and improve QOL, which may help reduce the burden of ADRDs on patients, caregivers, and the health care system.

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Authors’ contributions: K.R.D. and S.A.G. are responsible for project conceptualization. Funding acquisition was done by K.R.D., S.A.G., and H.E.M.S. were responsible for study design/methodology. The investigation was primarily performed by H.E.M.S. and S.A.G., with contribution from K.R.D. Data collection and preparation were done by B.M.M. and H.E.M.S. Statistical analyses were completed by C.P.B., H.E.M.S., and T.J.K. Original drafting of the article was done by H.E.M.S. Manuscript preparation was led by T.J.K. All authors participated in writing, reviewing, and editing the article for press.

Supplementary Data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.trci.2019.09.008.

RESEARCH IN CONTEXT

1. Systematic review: The authors searched PubMed for cohort studies and randomized controlled trials investigating modifiable dementia risk factors and behavior change interventions in patients with or at risk for cognitive impairment. To our knowledge, no trials have employed a clinic-embedded health coaching model within existing neurologic care to increase adherence to behaviors associated with brain health and improve quality of life in this population.

2. Interpretations: Our findings suggest that health coaches embedded in clinical care, who promote evidence-based recommendations for exercise, diet, and social/cognitive activities to reduce cognitive decline, may improve overall brain health and well-being.

3. Future directions: Future research will examine the effects of a health coaching model on behavior change in larger, varied populations, including patients at risk for cognitive impairment. Future studies will be of longer duration, include objective measures of behavior change, and aim to isolate which factors in the health coaching model most effectively contribute to behavior change.
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