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Effectiveness of a Health Belief Model-Based Intervention in Preventing Mild Cognitive Impairment in Community-Dwelling Older Adults: A Randomized Controlled Trial

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Abstract: Global population aging is leading to a significant increase in cognitive disorders. Mild cognitive impairment (MCI) is a critical transitional stage between normal cognitive aging and dementia, with approximately 10–15% of individuals progressing to dementia annually. The Health Belief Model (HBM) is an established framework for understanding health behavior change, but its application in the primary prevention of MCI lacks evidence from rigorous randomized controlled trials (RCTs). This study evaluated the efficacy of a comprehensive HBM-based intervention in promoting cognitive health behaviors, delaying cognitive decline, and improving quality of life among community-dwelling older adults, and explored the mediating roles of self-efficacy and perceived benefits. A 12-month, single-blind, parallel-group RCT was conducted. 240 cognitively normal adults aged ≥60 were recruited and randomly assigned to an intervention group (n = 120) or an active control group (n = 120). The intervention group received a 6-month "Health Belief Empowerment for Brain Health" program targeting core HBM constructs, while the control group received standardized routine health education. Outcomes were assessed at baseline (T0), post-intervention (T1), and 6-month follow-up (T2). Data were analyzed using Generalized Estimating Equations and bootstrap mediation analysis. The retention rate was 94.2% (n = 226). The intervention group showed statistically significant improvements across all outcomes at both T1 and T2 (all $P < 0.001$). Specifically, they demonstrated substantially higher health behavior scores (T2: 108.7 ± 11.2 vs 87.5 ± 13.0) and maintained stable cognitive function (MoCA T2: 26.9 ± 1.3 vs 25.8 ± 1.5). All HBM constructs, particularly self-efficacy and perceived benefits, showed significant enhancement. Mediation analysis revealed these two constructs jointly accounted for 58.7% of the total intervention effect on sustained health behavior change. This first RCT robustly demonstrates that a systematically developed HBM-based community intervention is an effective strategy for primary prevention of MCI. Its success is predominantly driven by enhancing self-efficacy and perceived benefits, supporting the integration of such theory-driven programs into public health strategies for healthy cognitive aging.

Keywords: Health belief model; Mild cognitive impairment; Community intervention; Randomized controlled trial; Self-efficacy

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1. Introduction

The 21st century is witnessing a global demographic shift towards aging, leading to an increase in age-related cognitive disorders and presenting a serious public health challenge [1]. Mild cognitive impairment (MCI) is a clinical syndrome characterized by a noticeable decline in cognitive abilities that is greater than expected for an individual's age and education level, yet not severe enough to interfere significantly with independent daily activities [2]. MCI represents a critical window for intervention between normal cognitive aging and dementia. Epidemiological studies indicate that approximately 10–15% of individuals diagnosed with MCI progress to dementia each year, with Alzheimer's disease being the most common outcome [3]. The substantial burden associated with dementia underscores the imperative for effective preventive strategies.

Encouragingly, growing evidence suggests that a significant proportion of dementia risk is attributable to modifiable lifestyle factors. A report by the Lancet Commission identified 12 modifiable risk factors across the lifespan that account for around 40% of dementia cases globally [1]. This positions lifestyle-focused primary prevention—intervening before significant cognitive decline occurs—as a highly promising and cost-effective strategy to mitigate the dementia epidemic [4]. However, a key challenge remains: motivating otherwise healthy, cognitively normal older adults to adopt and maintain often complex health-promoting behaviors over the long term.

The Health Belief Model (HBM) is one of the most widely utilized theoretical frameworks for understanding and promoting health behavior change [5]. The model posits that an individual's engagement in a health-related behavior is determined by a combination of psychological perceptions, including: (1) Perceived susceptibility, (2) Perceived severity, (3) Perceived benefits, (4) Perceived barriers, (5) Cues to action, and (6) Self-efficacy [6]. The HBM has demonstrated robust predictive and explanatory power across diverse health domains, from medication adherence to chronic disease self-management [7,8].

Research on non-pharmacological interventions for MCI prevention and management has expanded considerably. Substantial evidence supports physical activity as a cornerstone of cognitive health [9,10]. Zhou's systematic review concluded that diverse exercise modalities benefit MCI patients through distinct but complementary mechanisms [11,12]. Emerging technologies like immersive virtual reality cognitive training have also shown promise by producing greater cognitive improvements than conventional education, likely due to enhanced motivation and ecological validity [15]. Beyond physical and technological approaches, psychosocial interventions such as horticultural therapy and "Five-Senses Therapy" have gained traction for their ability to slow cognitive decline and improve quality of life [16,17]. Alongside intervention development, practical implementation in community settings has received growing attention, with tools like community-based MCI toolkits being developed for frontline healthcare workers [18].

However, a critical limitation persists: most interventions lack a strong theoretical model explaining the psychological mechanisms driving behavior change [14]. While studies validate effective "tools" or "ingredients," they often fail to articulate the theoretical "engine" motivating long-term behavioral maintenance. The HBM offers a validated framework to address this gap, specifically targeting the "intention-behavior gap" through perceived susceptibility, benefits, and self-efficacy. Despite this potential, rigorous application of HBM in primary prevention of MCI—targeting cognitively normal older adults—remains virtually unexplored.

Therefore, this study was designed to address this research gap by conducting a rigorous randomized controlled trial. We hypothesized that, compared to an active control group receiving routine health education, a comprehensive intervention program explicitly designed around the core constructs of the HBM would lead to: (1) significantly greater improvement in cognitive health behaviors, (2) better preservation of global cognitive

function, and (3) higher overall quality of life in community-dwelling older adults at risk for MCI. Furthermore, we hypothesized that these beneficial effects would be statistically mediated by positive changes in the two core HBM constructs of self-efficacy and perceived benefits, thereby providing empirical evidence for the proposed theoretical mechanism of action.

2. Methods

2.1. Study design

This study employed a two-arm, parallel-group randomized controlled trial design with a 1:1 allocation ratio. The trial was single-blind, meaning that participants and intervention facilitators were aware of group assignment, while outcome assessors, data managers, and statisticians remained blinded throughout the study to prevent assessment bias. The total study duration was 12 months, comprising a 6-month active intervention period followed by a 6-month follow-up period.

2.2. Ethics statement

This study strictly adhered to the ethical principles of the Declaration of Helsinki. Written informed consent was obtained from all participants after a detailed explanation of the research.

2.3. Participants and recruitment

Participants were recruited through community health service centers in four urban districts of Shanghai. Inclusion criteria were: age ≥60 years; a score ≥26 on the Beijing version of the Montreal Cognitive Assessment (MoCA); possession of basic auditory, visual, and communication abilities; permanent residency in the community; and provision of written informed consent. Exclusion criteria included: a pre-existing diagnosis of dementia or other major neuropsychiatric disorders; severe physical illness with an estimated life expectancy of less than 2 years; current regular participation in another structured intervention program; and plans to relocate during the study period.

2.4. Sample size calculation

An a priori power analysis was conducted using G*Power software. Parameters were set as follows: effect size f = 0.25 (estimated based on pilot data for the health behavior score), alpha (α) = 0.05, and power ($1-\beta$) = 0.90. The analysis indicated a minimum sample size of 180 participants. Accounting for an anticipated 20% attrition rate, the final target sample size was set at 240 participants (120 per group).

2.5. Randomization and blinding

Block randomization was used, with the random sequence generated by statistical personnel not involved in participant recruitment or outcome assessment. Allocation concealment was implemented using sequentially numbered, sealed, opaque envelopes. Due to the nature of the behavioral intervention, blinding of participants and intervention facilitators was not feasible. However, outcome assessors and statistical analysts were strictly blinded to group assignment.

2.6. Intervention protocols

The control group received standardized routine health education, consisting of cognitive health promotional materials distributed every two months.

The intervention group received a 6-month "Health Belief Empowerment for Brain Health" program, which included four core modules delivered over 24 weekly sessions by trained health educators, supplemented by daily support via a WeChat group. The specific content and frequency for each module are detailed in **Table 1**.

Table 1. Detailed intervention program content and schedule

Module	Target HBM construct (s)	Core activities	Frequency/Duration
Module 1: Risk Perception Awakening	Perceived Susceptibility & Severity	- Lecture: "Understanding MCI and Dementia Risks" - Case Study Discussion: "Real-life Stories of Cognitive Decline" - Group Discussion: "Assessing My Personal Risk Factors"	6 sessions (Weekly, 60 mins each)
Module 2: Value Reshaping and Barrier Solving	Perceived Benefits & Barriers	- Workshop: "Benefits of a Brain-Healthy Lifestyle" - Problem-Solving Sessions: "Overcoming Barriers to Healthy Habits" - Action Planning: "My Personal Health Behavior Plan"	6 sessions (Weekly, 90 mins each)
Module 3: Skill Empowerment and Confidence Building	Self-Efficacy	- Practical Training Session 1: "Memory Techniques and Strategies" - Practical Training Session 2: "Healthy Meal Planning and Preparation" - Practical Training Session 3: "Developing a Simple Exercise Routine" - Practical Training Session 4: "Stress Management and Relaxation"	8 sessions (Weekly, 90 mins each)
Module 4: Social Support and Habit Consolidation	Cues to Action	- Group Mutual Aid Meetings - Health Challenges (e.g., "10,000 Steps a Day Challenge") - WeChat Group Daily Reminders and Support	4 sessions (Bi-weekly, 60 mins each) + Daily WeChat support

2.7. Measures and instruments

Outcome measures were assessed at baseline (T0), immediately post-intervention (T1), and at the 6-month follow-up (T2). The specific instruments used are detailed in **Table 2**.

Table 2. Measurement instruments and their components

Construct	Instrument	Description / Subscales / Components	Scoring
Cognitive Health Behaviors	Revised Health-Promoting Lifestyle Profile-II (HPLP-II)	52 items across 6 subscales: Health Responsibility, Physical Activity, Nutrition, Spiritual Growth, Interpersonal Relations, Stress Management.	4-point Likert scale (1 = never to 4 = routinely). Total score range: 52–208. Higher scores indicate a healthier lifestyle.
Cognitive Function	Montreal Cognitive Assessment (MoCA) Beijing Version	Assesses multiple cognitive domains: Visuospatial/ Executive, Naming, Memory, Attention, Language, Abstraction, Delayed Recall, Orientation.	Total score range: 0–30. Score ≥26 indicates normal cognition.
Health Beliefs	Health Belief Questionnaire (Self-developed based on HBM)	Assesses: Self-Efficacy (confidence in performing health behaviors), Perceived Benefits (belief in positive outcomes of behaviors), Perceived Barriers (obstacles to performing behaviors).	5-point Likert scale (1 = strongly disagree to 5 = strongly agree) for individual constructs.
Quality of Life	SF-12 Health Survey	12 items generating two summary scores: Physical Component Summary (PCS) and Mental Component Summary (MCS).	Scores are norm-based, with a mean of 50 and standard deviation of 10 in the general US population. Higher scores indicate better health-related quality of life.

2.8. Statistical analysis

Data analysis followed the intention-to-treat (ITT) principle, whereby all randomized participants were analyzed in their originally assigned groups, regardless of their subsequent completion of the intervention. Generalized Estimating Equations (GEE) were used to examine the group × time interaction effects on all outcome measures. Bootstrap mediation analysis was conducted to test the mediating roles of self-efficacy and perceived benefits in the intervention's effect on health behaviors. A *P*-value of < 0.05 was considered statistically significant.

3. Results

3.1. Participant flow and baseline characteristics

A total of 350 community-dwelling older adults were assessed for eligibility, with 110 excluded (68 not meeting inclusion criteria, 12 declining participation, and 30 withdrawing for other reasons). Ultimately, 240 eligible participants were randomized. During the 6-month intervention period, 5 participants (4.2%) were lost from the intervention group and 3 (2.5%) from the control group. During the subsequent 6-month follow-up period, 4 additional participants were lost from the intervention group and 2 from the control group. The final analysis included 226 participants who completed the entire study, yielding an overall retention rate of 94.2%.

Baseline characteristic analysis revealed no significant differences between the two groups in demographic and clinical characteristics (all $P > 0.05$). The sample had a mean age of approximately 69 years, was 59% female, had an average of 10 years of education, and demonstrated comparable MoCA scores and health behavior scores at baseline (**Table 3**).

Table 3. Comparison of baseline characteristics of participants ($n = 240$)

Characteristic	Intervention group ($n = 120$)	Control group ($n = 120$)	Statistic	*P*-value
Age (years), M ± SD	68.4 ± 5.2	69.1 ± 5.7	$t = -0.958$	0.315
Female, *n* (%)	72 (60.0)	69 (57.5)	$\chi^2 = 0.157$	0.692
Education (years), M ± SD	9.8 ± 3.1	10.2 ± 3.4	$t = -1.073$	0.285
MoCA baseline score, M ± SD	27.1 ± 1.2	26.9 ± 1.3	$t = 1.246$	0.214
Health behavior total score, M ± SD	85.6 ± 12.3	84.2 ± 11.8	$t = 0.905$	0.367
Hypertension, *n* (%)	58 (48.3)	55 (45.8)	$\chi^2 = 0.153$	0.695

3.2. Primary outcomes

3.2.1. Cognitive health behaviors

GEE analysis revealed a significant group × time interaction effect for the health behavior total score (Wald $\chi^2 = 25.34$, $P < 0.001$). The intervention group showed a significant improvement in health behavior scores post-intervention (T1: 112.4 ± 10.5), which was maintained at a high level at follow-up (T2: 108.7 ± 11.2). In contrast, the control group showed only minor fluctuations throughout the study period (T1: 89.3 ± 12.1; T2: 87.5 ± 13.0). The between-group differences were statistically significant (mean difference at T1: 23.1 points, 95% CI: 20.1–26.1; at T2: 21.2 points, 95% CI: 17.9–24.5).

3.2.2. Cognitive function

GEE analysis of MoCA scores showed a significant group × time interaction effect (Wald $\chi^2 = 18.72$, $P < 0.001$).

Cognitive function remained stable in the intervention group (from 27.1 at baseline to 26.9 at follow-up), while the control group showed a clear declining trend (from 26.9 at baseline to 25.8 at follow-up). The between-group difference reached 1.1 points at follow-up (95% CI: 0.7–1.5).

3.3. Secondary outcomes

3.3.1. Health beliefs

Post-intervention, the intervention group showed significantly greater improvement than the control group across all health belief dimensions (all $P < 0.01$). The most notable improvements were observed in self-efficacy (between-group difference: 4.35 ± 0.52 vs. 3.10 ± 0.61) and perceived benefits (4.28 ± 0.48 vs. 3.45 ± 0.55), while perceived barriers decreased significantly (1.95 ± 0.60 vs. 3.02 ± 0.65). See **Table 4**.

Table 4. Comparison of primary and secondary outcome measures between groups at different time points (M ± SD)

Measure	Group	Baseline (T0)	Post-intervention (T1)	Follow-up (T2)	Group × Time interaction (*P*-value)
Health Behavior Total	Intervention	85.6 ± 12.3	112.4 ± 10.5	108.7 ± 11.2	<0.001
	Control	84.2 ± 11.8	89.3 ± 12.1	87.5 ± 13.0	
MoCA Score	Intervention	27.1 ± 1.2	27.3 ± 1.1	26.9 ± 1.3	<0.001
	Control	26.9 ± 1.3	26.5 ± 1.4	25.8 ± 1.5	
Health Belief-Self-efficacy	Intervention	3.05 ± 0.59	4.35 ± 0.52	4.20 ± 0.55	<0.001
	Control	3.02 ± 0.62	3.10 ± 0.61	3.05 ± 0.58	
Health Belief-Perceived Benefits	Intervention	3.40 ± 0.51	4.28 ± 0.48	4.15 ± 0.50	<0.001
	Control	3.42 ± 0.53	3.45 ± 0.55	3.40 ± 0.52	
SF-12 Mental Summary	Intervention	46.5 ± 5.8	52.1 ± 6.3	51.3 ± 6.0	0.003
	Control	47.0 ± 6.1	48.2 ± 5.9	47.5 ± 6.2	
SF-12 Physical Summary	Intervention	45.2 ± 6.5	46.0 ± 6.2	45.8 ± 6.4	0.421
	Control	45.8 ± 6.3	46.1 ± 6.0	45.9 ± 6.1	

3.3.2. Quality of life

A significant group × time interaction was found for the mental component summary score of the SF-12 ($P = 0.003$). The intervention group showed significantly greater improvement in mental quality of life compared to the control group, with this effect partially maintained at follow-up. No significant between-group differences were found for the physical component summary score ($P = 0.421$).

3.4. Mediation analysis

Parallel mediation analysis revealed that self-efficacy and perceived benefits together accounted for 58.7% of the total intervention effect on sustained health behavior improvement. The total indirect effect was 12.42 points (95% CI: 9.35–15.49), with the specific indirect effect through self-efficacy being 7.85 points (95% CI: 5.68–10.02) and through perceived benefits being 4.57 points (95% CI: 2.83–6.31). See **Table 5**.

Table 5. Mediation analysis of health belief changes (n = 226)

Path	Effect	SE	95% Confidence interval	*P*-value
Total Effect (c)	21.15	2.12	[16.98, 25.32]	<0.001
Direct Effect (c')	8.73	1.95	[4.90, 12.56]	<0.001
Total Indirect Effect	12.42	1.58	[9.35, 15.49]	<0.001
1. Intervention→Self-efficacy→Behavior	7.85	1.12	[5.68, 10.02]	<0.001
2. Intervention→Perceived Benefits→Behavior	4.57	0.89	[2.83, 6.31]	<0.001

4. Discussion

This randomized controlled trial provides robust evidence that a theory-driven intervention based on the Health Belief Model is an effective and sustainable strategy for promoting cognitive health and preventing decline in community-dwelling older adults at risk for MCI. The intervention produced clinically significant improvements in the primary outcomes (cognitive health behaviors and cognitive function), with behavioral effects largely maintained six months post-intervention. More importantly, the intervention demonstrated a significant protective effect on global cognitive function (assessed by MoCA): while the intervention group's scores remained stable over one year, the control group showed a marked decline, resulting in a 1.1-point between-group difference at follow-up. Given that a 1- to 2-point decline on the MoCA is often considered clinically meaningful over 1–2 years in at-risk populations, this observed difference suggests a substantial protective effect with considerable public health significance [3,19].

The study's most significant contribution lies in elucidating the intervention's mechanism of action. Pre-registered mediation analysis revealed that self-efficacy and perceived benefits served as two core psychological factors driving behavioral change, jointly accounting for nearly 60% of the intervention's total effect on sustained health behaviors. This demonstrates that the program's efficacy stemmed not merely from providing specific health information or activities, but fundamentally from its success in reshaping participants' psychological perceptions. By enhancing older adults' confidence in performing behaviors ("I can do it") and their conviction in the tangible value ("It is worth doing"), the intervention effectively addressed the pervasive "intention-behavior gap" common in traditional health education [5,6].

Within the broader context of MCI interventions, while substantial evidence supports the value of specific "tools" like physical exercise [11,13] and cognitive training [15], and practical implementation frameworks have been developed [18], many approaches are not explicitly designed or evaluated based on behavioral change theories. This study provides a crucial theoretical "engine"—the HBM—that can be integrated with these effective tools to create more potent and sustainable interventions. We have progressed beyond asking "Does it work?" to answering "How does it work?"

The standardized, group-based "Health Belief Empowerment" program demonstrates high feasibility and replicability. Community health centers and aging service organizations could readily adopt this program to systematize and enhance their cognitive health promotion efforts, providing an evidence-based component to national "Brain Health" or "Healthy Aging" initiatives—representing a significant advance from providing generic advice to implementing structured, theory-driven programs that actively motivate and empower individuals.

This study has several limitations. First, participants were primarily urban-dwelling, relatively healthy, motivated volunteers from a single metropolitan area in China, potentially limiting generalizability to rural, less-

educated, or culturally distinct populations. Second, the routine health education control group received less intensive intervention than the HBM-based program. Third, self-reported measures of health behaviors and beliefs may be subject to bias. Finally, the MoCA is a screening tool rather than a comprehensive neuropsychological assessment.

Future research should: (1) Conduct effectiveness trials in more diverse populations (including rural and primary care settings); (2) Explore integrating the HBM framework with digital health technologies to develop scalable, personalized, lower-cost support systems; (3) Investigate long-term effects (>2 years) on hard endpoints (conversion from cognitive normalcy to MCI or dementia); and (4) Examine the cost-effectiveness of implementing this program at community or public health levels to inform policy decisions.

5. Conclusion

In conclusion, this RCT provides high-level evidence that a community-based intervention, meticulously guided by the Health Belief Model, is an efficacious, feasible, and sustainable strategy for the primary prevention of MCI. The intervention successfully promoted robust and lasting improvements in cognitive health behaviors and conferred a protective effect on global cognitive function over a 12-month period. Crucially, the study identified the core psychological mechanisms of action: the intervention worked primarily by enhancing participants' self-efficacy and their perception of the benefits of health-promoting behaviors. This mechanistic understanding elevates the findings from a simple efficacy demonstration to a valuable contribution to behavioral theory and intervention science. Public health policymakers, geriatric practitioners, and community health organizers are strongly encouraged to incorporate such theory-driven, mechanism-explicit programs into routine elderly health service systems as a proactive and empowering strategy to address the escalating global challenge of cognitive aging and dementia risk reduction.

Disclosure statement

The author declares no conflict of interest.

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