

Development of an Internet of things-based treatment adherence program among older adults with mild cognitive impairment using Intervention Mapping: A developmental study

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Purpose: Dementia and altered cognitive function are highly prevalent among older adults with mild cognitive impairment (MCI); hence, prevention is necessary before it develops into dementia. Treatment adherence—medication adherence and physical activity—is essential to prevent and delay dementia; however, comprehensive interventions to promote it in this population are lacking. This study aimed to develop a program for treatment adherence utilizing an Internet of Things (IoT) device. **Methods:** The six-step mapping protocol was used to develop the IoT-based treatment adherence intervention (ITAI). The intervention was based on a literature review, expert opinions, and input from older adults with MCI. **Results:** In Step 1, a needs assessment was conducted to gain insights into health problems and their underlying determinants. In Steps 2 and 3, performance objectives were identified for behavior change and selected theoretical and evidence-based methods were linked to the intervention outcomes. In Step 4, the ITAI was designed with components and materials consistent with the identified change goals and methods, and specific intervention components were developed. In Step 5, implementation plans and solutions to barriers to its application were identified. In Step 6, the plan to evaluate intervention effectiveness was outlined. **Conclusion:** The Intervention Mapping provided a systematic procedure for developing an ITAI for older adults with MCI and preparing a randomized controlled trial. Utilizing Intervention Mapping is useful as ITAI systematically processes treatment adherence for MCI using the IoT and is acceptable and valid. ITAI is expected to increase medication adherence and physical activity in older adults with MCI.

Keywords: Cognitive dysfunction; Treatment adherence and compliance; Internet of things; Methods; Aged

INTRODUCTION

1. Background

Mild cognitive impairment (MCI) is a transitional stage between normal aging and dementia, characterized by subjective

memory impairment, maintenance of normal cognitive function, and active daily living [1]. MCI increases the risk of dementia and cognitive function change, but it is reversible. Hence, prevention is necessary to avoid its development into dementia. The prevalence of MCI is increasing worldwide, and one out of five Korean older adults (20.2%) suffer from MCI

[1]. The annual morbidity of dementia is 1%~2% and 10%~15% in normal older adults and those with MCI, respectively [2]. Hypertension, diabetes, hyperlipidemia, and atherosclerosis increase the risk of cognitive decline. Diabetes accelerates age-related cognitive decline [3], and increases the risk of dementia among older adults. Diabetes can also lead to complications in the central nervous system and cognitive function processes [3]. Additionally, decreased cerebral blood flow due to aging disrupts mechanisms regulating the brain and enhanced by hypertension. Furthermore, the severity of atherosclerosis in the arteries likely associates hypertension with cognitive decline [4]. People with MCI have a higher prevalence of hypertension, diabetes, and stroke [5]. According to the dementia prevention guidelines, the early detection of chronic diseases, treatment and management of chronic diseases, and regular exercise can prevent dementia [6]. Therefore, people with MCI need chronic disease treatment and regular exercise to reduce and prevent dementia. To manage chronic diseases, it is necessary to understand and follow experts' instructions on drug use, diet, and exercise therapy [7]. Treatment adherence consists of taking medication and complying with a specialist's prescription for chronic disease management [8]. Compliance with medication is essential for treatment adherence. Non-adherence to medication is a major barrier to safe and cost-effective health care delivery among providers. Medications and dosages are key factors in successful healthcare delivery, yet adherence in older adults remains low [9]. Cognitive decline in older adults is a risk factor for medication non-adherence [10]. It also affects instrumental daily activities, including medication use and treatment adherence [11]. For this reason, medication adherence intervention was implemented to solve the problem of medication non-adherence in older adults with MCI [12]. As with previous interventions, it helped people with MCI with medication adherence [12,13]. The mechanism of action associated with physical activity improves cognitive function, stimulates nerve growth, and encourages survival [14]. Physical activity decreases the risk of cerebrovascular diseases by reducing cardiovascular risk factors such as hypertension and hyperlipidemia [15]. Older adults with MCI have lower exercise levels than those with normal cognitive function [5]. A physical activity intervention study revealed that participants who adhered to medication reported improved cognitive function and decreased risk of cerebrovascular and cardiovascular diseases [16], suggesting that both regular physical activity and medication adherence are important

in preventing cognitive decline.

The fourth industrial revolution brought in healthcare innovation through the development of information technology and biotechnology, with diseases being prevented using the Internet of things (IoT) platforms, and wearable devices and customized healthcare services showing significant growth [17]. The IoT indicates that each object connects to the Internet and enables communication through technology [17]. Research using the IoT has been conducted on individual interventions to provide educational information tailored to patients' needs and technology-based reminders for patients and medical institutions [18]. Healthcare provider interventions are being developed based on IoT devices [19]. Notably, technology-based interventions improve patient outcomes, costs, and treatment effectiveness. Furthermore, technology-based interventions are employed for early recognition of inadequate performance; reducing complications; and alerting, rewarding, and providing feedback on the patient's progress. A systematic review reports that regular visit strategies (telehealth, home monitoring, and telephonic counseling) have been widely employed to enhance medication adherence [20]. Interventions using periodic visits to improve medication are being challenged because sustained adherence could not be achieved. Considering that individuals with MCI experience memory deterioration, medication adherence intervention strategies are required to ensure continued use. For people with MCI, exercise not only prevents and delays dementia but also assists in managing chronic diseases [21]. However, a well-developed integrated approach for physical activity among older adults with MCI that ensures medication adherence, prevents and delays dementia and manages chronic diseases is unavailable. Technology-based exercises and physical activity rates record, and information and aid supervision are necessary strategies to support care managers' and patients' decisions when developing target programs.

The provision of healthcare through the convergence of the IoT and information and communication technology is recently adopted in managing chronic diseases because of their role in promoting treatment adherence through reminders. Smart health devices are developed and released to aid treatment methods for older adults with MCI [12,22]. IoT also allows immediate institutionalization of interventions by identifying the state and providing prompts for care and to medication adherence leading to desired treatment adherence, and these technologies can help patients with MCI adhere to treatment. This paper describes the methods used and outcomes

obtained from developing and refining a theory- and evidence-based program to facilitate the IoT-based treatment adherence intervention (ITAI). The study aimed to develop an ITAI program to improve treatment adherence (medication adherence and physical activity) using Intervention Mapping steps (development of an intervention) among older adults with MCI.

METHODS

Ethic statement: The study was approved by the Institutional Review Board (IRB) of Yonsei University Health System prior to conducting the study (IRB No. 4-2019-1317).

1. Developing the ITAI

The development of the ITAI followed the Intervention Mapping protocol comprising six steps. The Intervention Mapping protocol is a systematic outline for the development, implementation, and evaluation of intervention for health behavior change [23]. It is considered useful for constructing

programs grounded in both theory and empirical data. The Intervention Mapping facilitates the effective development of behavioral change interventions, and many healthcare programs have successfully used it for various interventions [24]. Table 1 shows the six steps of Intervention Mapping and their purpose and methods. The implementation as conducted in each step is presented below.

Step 1 required obtaining insight into the health problems and underlying determinants of older adults with MCI. We developed a complex intervention focused on behavioral support for MCI. Moreover, we first sought to understand the kind of support needed by an individual for their problem. Through this step, we gained insight into the health problems and underlying determinants of treatment adherence among older adults with MCI. To identify training and methods for providing them with the necessary support, we reviewed literature on the health problems associated with MCI. We searched PubMed and Cumulative Index to Nursing and Allied Health Literature (CINHAL) for English articles, and Korean studies Information Service System (KISS), KoreaMed, and Research Information Sharing Service (RISS) databases for Korean arti-

Table 1. The Intervention Mapping Steps Process of the ITAI

Steps	Objectives	Methods
1 Needs assessment	<ul style="list-style-type: none"> Gain insight into health problems and underlying determinants of older adults with MCI 	<ul style="list-style-type: none"> Review of evidence <ul style="list-style-type: none"> Systematic literature review related to the older adults with MCI Target population Analysis of behavior Behavioral determinants
2 Formulation of the change objectives	<ul style="list-style-type: none"> Specify performance objectives and changeable determinants 	<ul style="list-style-type: none"> Intervention outcomes settings <ul style="list-style-type: none"> Goal of outcomes Proximity objectives identification <ul style="list-style-type: none"> Specific performance goals for behavior change
3 Selection of the theory-based methods and practical strategies	<ul style="list-style-type: none"> Identify and select theoretical models Select methods that address change objectives Select evidence-based and design of practical implications 	<ul style="list-style-type: none"> Analysis of prior interventions to select health belief model <ul style="list-style-type: none"> A research framework constructed based on the health belief model Selection of intervention strategies and methods
4 Producing program components and materials	<ul style="list-style-type: none"> Intervention content and method composition 	<ul style="list-style-type: none"> Draft development of the ITAI program with the experts Content validity test by the experts
5 Planning program adoption and implementation	<ul style="list-style-type: none"> Preparing for intervention implementation 	<ul style="list-style-type: none"> Adoption and implementation planning of the developed program considering its sustainability <ul style="list-style-type: none"> Constructing the ITAI Pretest
6 Planning for evaluation	<ul style="list-style-type: none"> Setting up an evaluation plan 	<ul style="list-style-type: none"> Application of the ITAI program through a quantitative pilot study

ITAI=Internet of things-based treatment adherence intervention; MCI=Mild cognitive impairment.

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The literature review search terms were “mild cognitive impairment OR mild cognition impairment OR mild impairment of cognition OR mild impairment of cognitive function OR cognitive decline” AND “medication adherence OR medication compliance” AND “activity or activities OR walk OR walking OR exercise” AND “program OR programs OR intervention OR interventions OR treatment OR treatments.” The following criteria were used to select studies for analysis: (1) research published in English and Korea, (2) experimental or quasi-experimental studies, (3) research conducted for older adults with MCI, and (4) research with medication adherence and physical activity program. Finally, we analyzed 16 of 237 studies after excluding those irrelevant to the topic (Table 2, Appendix 1) [12,13,25-38].

In Step 2, we formulated the outcomes for health behavior change, dividing them into broad and specific performance objectives. We conducted a comprehensive literature review on medication adherence and physical activity among older adults with MCI in Step 1; based on this, overall behavioral goals and specific interventions for older adults with MCI were finalized.

In Step 3, a theoretical analysis was performed to identify effective health behaviors. A research framework was constructed based on the health belief model [39]. The performance strategy based on the health belief model was determined through the literature for health behavioral belief promotion education, self-efficacy improvement, cue to action trigger, cue to action trigger and reminder, and individualized coaching.

In Step 4, we designed the ITAI with components and materials consistent with the identified change goals and methods, described the components, and determined real-world applications. A discussion with six experts was conducted. Some of the experts had participated in the problem analysis in Step 1. To verify the validity of the expert group, the members were three nursing professors with expertise in health-related research and intervention program development, two gerontological nurse practitioners with more than 20 years of experience, and one neurologist.

In Step 5, after a week of pre-testing with participants with MCI, the research team met to discuss the implementation barriers and mitigation action plans.

In Step 6, we designed a randomized control trial pilot study to evaluate interventions. The program includes a nurse’s assessment of medication adherence and physical activity, weekly phone visits, and education. Major outcome measurement

Table 2. Literature Review of Studies Related to Medication Adherence and Exercise Intervention

NO.	Author (year)	Design	Population	Intervention	Strategies	Duration	Outcomes measured	Results
1	Insel and Cole (2005) [13]	Before-after study	-27 community-dwelling adults self-administering one prescription medication -Mean age 78 years, range 67~89 years	Use of medication monitoring system (MEMS) as reminder to take medication	-The cues were individually tailored (nurse-instigated individualized) -Provide cues to support remembering with MEMS	8 weeks	Mini-Mental State Examination (MMSE) scores	Medication adherence improved from 64.5% to 78%
2	Kamimura et al. (2012) [12]	Before-after study	-18 community-dwelling adults with a history of non-adherence -Age 81.2±6.2 years	Use of an automatic pill dispenser as reminder to take medication	-Automatic pill dispenser with daily alarms -Caregiver monitoring	12 weeks	Medication adherence: percentage of days that the correct number of doses was taken according to MEMS	-55.5% of users showed 100% improvement in self-administration medication rate (SAMR) values at 1 month -49.9% maintained SAMR values of 100% at 3 months

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Table 2. Continued

NO.	Author (year)	Design	Population	Intervention	Strategies	Duration	Outcomes measured	Results
3	Hawkins and Firek (2014) [25]	Before-after study	-27 outpatients from a veteran administration clinic -Age 65.3±8.2 years	-Pictorial medication sheet with brief instruction on use -An optional CADEX Pocket -Pill Box (ePill LLC) with 4 alarms daily	-Optional alarmed pillbox -Pictorial medication sheets and education -Optional CADEX Pocket Pill Box (ePill LLC) with four vibrating daily alarms -30 day pill counts at visit four time	16~48 weeks	Medication adherence: at each monthly visit, pill counts	Improvement adherence pre- (79.74±16.98) to post intervention (84.74±10.00)
4	Smith et al. (2007) [26]	Randomized controlled trials (RCT)	-Intervention group (n=8) -Control group (n=6)	-Intervention group: video-monitoring phase and/or plain ordinary telephone service (POTS) monitoring phase and/or a standard unmonitored care phase (n=8) -Control group: only POTS and/or unmonitored care as match controls to video participants that could not serve as their own control in all 3 phases (n=6)	-Televideo monitoring equipment was installed in the homes: -Telephone service (POTS) monitoring -Video monitoring -Visited once per month by the study coordinator	12~24 weeks	Medication adherence: SAMR, i.e., ratio of the number of doses taken independently to the number of all prescribed doses during 1 week (pill count of the pill dispenser)	-Initial compliance rates (1 month into the phase) were 80% for video, 85% for phone, and 75% for controls -End-of-phase values of 81, 80, and 62%, for video, phone, and no monitoring respectively
5	Vervloet et al. (2014) [27]	RCT	Diabetes type 2 patients -Short message service (SMS) group (n=56) -Non-SMS group (n=48) -Control group (n=57)	Real time medication monitoring system offers (real time at a central database)+SMS reminders	-Realtime medication monitoring dispenser -Real time SMS reminders	24 weeks	Pharmacy refill data, pill counts	-SMS group (79.5% vs. 64.5%, +16.3%) -Non-SMS group reached 73.1% (+7.3%)

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Table 2. Continued

NO.	Author (year)	Design	Population	Intervention	Strategies	Duration	Outcomes measured	Results
6	Marek et al. (2013) [28]	RCT	Older adults Medication-certified self-managing medications (N=414)	Pharmacy screens medication-dispensing machine or a medplanner visited the participants at least every 2 weeks	<ul style="list-style-type: none"> -Advanced practice nurse reviewed all medications identified -Received a medplanner (nurse care coordination) -Provided prompts for medication administration as well as feedback on missed doses -Medication-dispensing system with alarm -The nurse creates a treatment plan specific to each participant's clinical condition -Nurse visits every 2 weeks -The care plans included monitoring of specific signs and symptoms related to medical diagnoses, medications, and other individualized problem areas 	12~48 weeks	Health status outcomes: Geriatric Depression Scale, MMSE, Physical Performance Test, Mental Component Summary, SF-36 Physical Component Summary	The time by group interventions were significant for outcome variables
7	Suzuki et al. (2013) [29]	RCT	-Exercise group (n=50) -Control group (n=50)	Aerobic exercise, strength training, balance, dual tasking 2x90 min/wk		24 weeks	MMSE, logical memory scores	MMSE, logical memory scores improved in the exercise group
8	Lam et al. (2011) [30]	RCT	-Tai Chi group (n=171) -Control group (n=218)	-Tai Chi exercise: ≥3x30 min/wk -Control group: stretching ≥3x30 min/wk, group intervention	Tai Chi exercise	12 weeks	Memory Inventory for the Chinese, cognitive subscale (Alzheimer's Disease Assessment Scale [ADAS-Cog]), Clinical Dementia Rating (CDR), Neuropsychiatric Inventory, The Berg Balance Scale (BBS)	Improvements in attention and the CDR scores in the exercise group

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Table 2. Continued

NO.	Author (year)	Design	Population	Intervention	Strategies	Duration	Outcomes measured	Results
9	Baker et al. (2010) [31]	RCT	-Exercise group (n=23) -Control group (n=10)	-High-intensity exercise: treadmill, stationary bicycle, elliptical trainer, 4x45-60 min/wk -Control: stretching 4x45-60 min/wk, group intervention	High-intensity exercise	24 weeks	Symbol digit verbal fluency, Stroop and task switching, Story Recall	-Improved for women in the exercise group -Delayed recall: no difference
10	Lautenschlager et al. (2008) [32]	RCT	-Physical activity group (n=85) -Control group (n=85)	-Physical activity program: walking, strength training 3x50 min/wk -Usual care control: educational material individual intervention	Walking, strength	24 weeks	Scale-Cognitive subscale (ADAS-Cog) scores	Intervention group improved ADAS-Cog
11	Shin (2011) [33]	Non-equivalent control group pre-post test	-Exercise group (n=17) -Control group (n=17)	Swiss Ball exercise program: performed 2 times/wk	Swiss ball exercise	12 weeks	One Legged Stand (OLS), Timed Up & Go (TUG), Sit-to-Stand (STS), Active Daily Living (ADL)	Improvement OLS, TUG, STS, ADL
12	van Uffelen et al. (2008) [34]	RCT	-Group 1 (n=77) -Group 2 (n=75) -Group 3 (n=78) -Group 4 (n=74)	-Group 1: aerobic walking, 2x60 min/wk and vitamin B supplementation -Group 2: placebo activity, 2x60 min/wk and vitamin B supplementation -Group 3: walking 2x60 min/wk and placebo supplementation -Group 4: placebo activity, 2x60 min/wk and placebo supplementation, group intervention	Aerobic walking	24-48 weeks	Neuropsychological tests, MMSE	-No improvement in MMSE or verbal fluency -Women with good attendance in aerobic walking improved delayed recall
13	Scherder et al. (2005) [35]	RCT	-Walking group (n=15) -Hand and face exercises (n=13) -Control group (n=15)	-Walking group: walking 3x30min/wk -Hand and face exercises, bending and stretching the fingers, producing different facial expressions 3 x 30 min/week -Control group: social visits or normal social activities individual intervention	Walking, bending and stretching	6 weeks	Executive Functions (EF)	Improvement in tasks appealing to EF walking group and the hand/face group

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Table 2. Continued

NO.	Author (year)	Design	Population	Intervention	Strategies	Duration	Outcomes measured	Results
14	Kim et al. (2010) [36]	One group pre- post test	Exercise group (n=16)	Combined exercise: walk, Yoga three times/wk	Walking yoga	8 weeks	Cognition Scale for Older Adults (CSOA)	Improvement CSOA
15	Kim et al. (2019) [37]	One group pre- post test	Internet of things (IoT)- based exercise group (n=30)	IoT-based exercise program (upper exercise 3 content and lower exercise contents): twice weekly exercise	IoT-based upper, lower exercise	12 weeks	Grip strength, Gait speed, Five chair, standing time Short Physical Performance Battery (SPPB), MMSE	Improvement Grip strength, Gait speed, Five chair standing time, SPPB score, MMSE exercise group
16	Jung (2018) [38]	One group pre- post test	Square-stepping exercise (n=26)	Square-stepping exercise: twice weekly exercise	Square-stepping	8 weeks	Montreal Cognitive Assessment (MoCA-K), BBS, TUG	Improvement MoCA, BBS

consists of items for treatment adherence; medication adherence, and physical activity level (gait phase and physical activity assessment) and additionally measures perceived health beliefs and self-efficacy.

2. Patient and Public Involvement

There are inadequately developed integrated approach for physical activity among older adults with MCI that ensures medication adherence, prevents and delays dementia and manages chronic diseases. This paper describes the methods used and outcomes obtained from developing and refining a theory- and evidence-based program to facilitate the ITAI. During the development process, the researcher was trained to conduct the intervention. The researcher participated in a one-day training course on the components of developing IoT interventions targeting older adults. The nurse involved in the intervention implementation received supervision and feedback from the first author, patients, and relatives on delivering the post-implementation interventions. Also, a trained nurse examined the pre-test of the intervention in five older adults with MCI from a neurology outpatient clinic who met the predetermined inclusion criteria. After ITAI was initially completed, five older adult patients with MCI tested the usability of the developed intervention. The patients and caregivers were informed that by signing this consent form, they consent to the collection and use of their information, and the data collected during the research will be used for research purposes. They were also informed that the findings would be published in international journals or through conferences without directly linking personal data to the collected information.

3. Delimitation of the Study

This study used Intervention Mapping to develop an ITAI for the management of MCI. Results from Steps 5 and 6 of the Intervention Mapping steps will be published in a future paper. We have applied only pre-testing using a feasibility test for the development of an intervention plan that can be implemented in future studies.

4. Ethics Approval and Consent to Participate

The study was approved by the IRB of Yonsei University

Health System prior to conducting the study (IRB No. 4-2019-1317).

RESULTS

1. Step 1: Needs Assessment

In the first step of the needs assessment, we reviewed and analyzed the health problems and behaviors of MCI to identify the determinants. Furthermore, the final participation criteria were as follows: aged 65 years or older, diagnosed with MCI by a neurologist, no previous history of any psychiatric disease, taking medications for a chronic disease, using a smartphone, and those who have a primary caregiver. People with a diagnosis of dementia and severe respiratory and cardiovascular disease were excluded.

1) Analysis of Behavior

Compared to older adults in general, those with MCI suffered from more chronic diseases such as hypertension and diabetes [3]. Medication adherence among community-dwelling individuals with MCI was reportedly between 64.8% and 75.0% [13,26]. As most participants with MCI lived in their homes, the need for an integrated intervention to improve the adherence of doctor-prescribed medication and physical activity (hereafter referred to as treatment adherence) for dementia prevention was necessary.

We found that older adults with MCI perceived difficulties in performing healthy behaviors. Although they could perform normal activities, they had memory impairment due to cognitive decline, which means that even though they thought of implementing healthy behaviors, they could not practice them due to a decline in memory. Cognitive decline in such individuals, therefore, acts as a risk factor for lower medication adherence [40] and affects instrumental activities of daily living, rendering it difficult to comply with treatment [11]. Although exercise is recommended for those at risk or individuals who are living with dementia, many are inactive [41]. Older adults with MCI are less active than those without it, and few meet the recommended physical activity for maintaining their health and functioning [42]. The tendency for low physical activity and fitness in people with MCI or dementia may be due to different barriers concerning exercise participation. Because these people are generally older, they must fight the perceived age-related barriers to exercise

participation, such as fear of falls, increased risk of injury, and a perception of limited benefits of exercise [42]. Education is needed to overcome these barriers. Moreover, it is essential to improve the perceived health beliefs related to physical activity [39].

2) Analysis of Behavioral Determinants

In this study, we confirmed the theoretical definition and developed an operational definition of treatment adherence. The former refers to the degree to which an individual performs behaviors consistent with a clinical prescription [8]. The latter entails the adherence to prescribed medication for chronic diseases and physical activity. We considered the major behavioral determinants of individuals with MCI based on the health belief model to identify the factors that could change behaviors for treatment adherence. The main factors affecting the health behavior of participants with MCI are problems of cognitive impairment, which do not allow behaviors to be practiced owing to the lack of perceived health beliefs (threats and expectations) [43] and memory deterioration. Exercise providers promote movement in these groups by recognizing and responding to the needs of people with MCI or dementia in exercise programs [41]. Furthermore, cue to action interventions have been implemented to help memory by focusing on strategies that trigger actions [13]. However, even if the perceived health beliefs are enhanced, it is difficult to practice them due to memory impairment. Specifically, we recognized the need for a method that could help improve health beliefs and memory for people with MCI to practice health behaviors.

2. Step 2: Outcomes and Objectives

The second step was to identify intervention outcomes based on needs assessment. The intervention goal was treatment adherence by improving the patients' medication adherence and performance of physical activities, to reduce the risk of dementia. We defined behavioral outcomes as an "increase in treatment adherence." As perceived health beliefs and behavioral triggers cause these treatment adherence behaviors, the performance goals should be devised around them. Subsequently, we established objectives by selecting important and modifiable determinants of behavior, taking medication based on perceived health beliefs and creating cues to action for behavior leading to reaching or maintaining medication adherence. To achieve these, we formulated the change goals (Table 3).

Table 3. Definitions of Elements in the Conceptual Framework

Concept	Theoretical definition	Operational definition	Component of this study	Behavioral outcomes	Personal determinants	Performance objectives	Change objectives
Older adults with MCI	Individual demographic and sociological characteristics.	Demographic and health-related characteristics of the older adults with MCI.	Education, evaluation	Treatment adherence	Perceived health beliefs	The patient decides to practice taking medication based on perceived health beliefs.	To improve perceived health beliefs and self-efficacy, the experts develop and apply health belief improvement education.
Threat	The combination of perceived severity and susceptibility is referred to as perceived threat. Perceived severity and perceived susceptibility to a given health condition depend on knowledge about the condition.	Personalized nursing education makes individuals more aware of perceived severity and susceptibility of dementia; they are more likely to participate in dementia-related health prevention actions.	Education, self-efficacy, demonstration, and evaluation		Cue to action (reminder, personal influence)	Cue to action for behavior leading to reaching or maintaining medication adherence.	Provide a reminder strategy, an opportunity for action, to prevent memory impairment in patients to promote medication adherence.
Expectations	The expectation (perceived benefits, barriers, and self-efficacy) is that a certain health action could prevent the condition for which people consider they might be at risk.	Perceived benefits and barriers can be strengthened through personal nursing education with nurses. Use of self-efficacy strategies for program content.	Telephone calls and counseling, education, and Internet of things (IoT) device	Physical activity	Perceived health beliefs (reminder, personal influence)	The patients' perceived health beliefs and behavioral triggers help them adhere to or maintain physical activity.	To enhance perceived health beliefs and self-efficacy, the experts develop and apply perceived health belief improvement education. - As a strategy for promoting physical activity, strategies such as feedback from the experts are provided.
Cue to action	The cue or trigger is necessary to increase engagement in health-promoting behaviors.	IoT device-based cue or trigger and personal nursing coaching.	Medication adherence, physical activity, and self-efficacy				
Behavior	Behavior to reduce threats based on expectations. Health outcome that changes positively through modifications in health behaviors.	Medication adherence and physical activity among older adults with MCI.	Pre-post evaluation				

MCI=Mild cognitive impairment.

3. Step 3: Theoretical Methods and Practical Strategies

In the third stage, we identified and selected theoretical models and evidence-based methods to address the change objectives described earlier. The health belief model was found to be appropriate because it accounted for health behavior changes, including key motivational factors and individual perceptions, to explain preventive health behaviors. The health belief model is divided into risk and expectation factors in the perceived health beliefs; based on this classification, health behaviors can be practiced using a cue to action. Health beliefs refer to behaviors regarding disease control that help in behavior change and function as prerequisites for action [39]. The health belief model consists of five concepts of behavioral change: perceived severity, susceptibility, benefit, barriers, and self-efficacy [39]. To develop the interventions, we confirmed the theoretical definition of the health belief model, established an operational definition, identified the components of this study (Table 3), and constructed a framework.

1) Behavior Change Techniques

After identifying the patient and ITAI target behaviors, interventions were developed for older adults with MCI; an intervention method using the IoT to provide reminders was selected for action trigger strategies [25]. Additionally, perceived health beliefs promotion education and self-efficacy enhancement strategies were developed. Recently, devices that help medication adherence can prompt and monitor drugs based on the IoT, enabling the use of technology-oriented reminders [18]. As a strategy to promote physical activity, recommended walking (cardio exercise) that is not limited by time and space was selected as it could easily induce regular exercise in older adults [32]. Regarding the IoT, wrist-worn devices promoted walking. We further developed personalized goals and contents for their achievement as follows: the ITAI based on perceived health beliefs improvement education and the self-efficacy enhancement strategy; the IoT smart pillbox, wrist-worn devices, and action trigger strategies as reminders [25]; and personalized nursing coaching strategies [26].

4. Step 4: Developing Intervention Components

1) Development of the ITAI Content

The fourth stage involved designing an ITAI with components and materials consistent with the change goals and

methods identified in Step 3, which was discussed with the expert group. The individual components and the real-world applications that were developed were described. First, design problems were identified by reviewing the literature on interventions based on the health belief model [39] and those using the IoT. Second, data on communication technology information about the device were obtained. Finally, educational programs on the perceived severity, susceptibility, benefit, and barriers (perceived health beliefs) were developed as a strategy for improving health behavior beliefs. The intervention strategy consisted of self-efficacy enhancement approaches, including achievement experience, proxy experience, and verbal persuasion [44]. To improve an individual's perceived health beliefs, participants and their primary caregivers were educated on disease knowledge, dementia risk factors, the importance of medication adherence and physical activity, how to exercise walking, and how to practice drug use. Personalized training methods were implemented via handouts, and pre-intervention training was provided to participants lasting approximately 20~30 minutes. During the intervention period, for customized nursing coaching, an IoT-based smart pillbox alerted the user to take medicines, and a wrist wearable device reminded the user to go walking. In the introductory step, we trained a researcher (registered nurse) in prescription recommendations, IoT smart pillbox, and wrist wearables, using handouts, educational material, and demonstrations. Personalized nursing coaching, which is conducted via weekly telephone consultation, lasting about 20 minutes enquired about feedback on the patient's medication adherence rates, the average weekly steps, and then the weekly steps goals for the ensuing week. Additionally, in real-time, the researcher immediately checked the medication adherence status through the data transmitted from the smart pillbox. If the patients failed to take medication more than twice, the researcher instantaneously contacted them via phone and sent a text message to the primary caregiver. Primary caregivers provide the most care for older adults with MCI, mainly daughters, sons, and daughters-in-law in Korea. When the primary caregivers received the text message, they were instructed to visit or call the older adults with MCI or help them take their medications. During the maintenance period, a reminder strategy was implemented, excluding customized nursing coaching, to maintain a reminder set for a personalized smart pillbox and a wearable alarm set as a maintenance strategy to promote physical activity.

2) Content Validation

The panel of five experts (comprising physician, nursing professors, and geriatric practitioners with at least 10 years of experience) evaluated the education and program content validity, and the relevance of the ITAI using the Polit and Beck methods [45]. We measured the content validity index of the overall ITAI program using the scale content validity index. The proportion of education and program content that reported a rating of 3 or 4 by all content experts (scale content validity index/universal agreement), the average of the item content validity index for all items on the scale (scale content validity index/average proportion), and the content validity index of ITAI individual content items (item content validity index) [46]. The scale content validity index is a composite score that requires key components like the scale content validity index/universal agreement, scale content validity index/average proportion, and the item content validity index. Each item was rated on a 4-point scale to avoid having an ambivalent midpoint: 1, not relevant; 2, somewhat relevant; 3, quite relevant; and 4, highly relevant. The experts' scores are assigned relevance when they score 3 to 4 on the Likert-type scale. When the assigned score is deemed as relevant then a 1 is assigned and when it is deemed not to be relevant then a 0 is assigned. The individual item content validity index ratio was computed as the number of relevant ratings, therefore, dichotomizing the scale into either relevant (1) or not relevant (0). As a result, the scale content validity index/universal agreement, scale content validity index/average proportion, and scale content validity index/universal agreement ranged from 1.00. The criteria of the dimensions that indicated sound content validity were item content validity index > 0.78 and scale content validity index/average proportion > 0.90 (Appendix 2).

5. Step 5: Implementation Plan

The ITAI will be planned as a pre-post design with a control group, comprising an intervention period of 6 weeks, and a maintenance period of 4 weeks based on the 16 articles included in the literature review. We discussed the potential issues and barriers to intervention implementation and devised a plan to ensure the execution with the expert group. Additionally, the researcher was trained to conduct the intervention. The researcher who provided the intervention participated in a one-day training course on the components. Subsequently, the nurse received supervision and feedback on how they deliv-

ered the post-implementation interventions. A trained nurse examined the pre-test of the intervention in five older adults with MCI. After ITAI was initially completed, five older adults tested its usability. During the pre-test, the project leader supervised the nurse to ensure that the assessment was carried out as described. After a week of pre-testing, the five older adults with MCI and a research team met to discuss the barriers to implementation to develop an action plan to overcome the barriers. The main difficulty identified during the testing phase was that older adults with MCI forgot to use the device due to memory impairment. To solve this problem, we created a poster with an illustration and provided a description of the device, and placed it in the patients' homes where they could observe it while taking medications.

6. Step 6: Evaluation Plan

The evaluation of the intervention is part of the implementation process. We conducted a pre-test and designed a randomized controlled trial to assess the feasibility of the intervention, and investigated the delivered practice. The goal of the intervention is to enhance medication adherence, physical activity, perceived health beliefs, and self-efficacy. The final IATI for older adults with MCI is presented in Table 4 and Figure 1. In the first week, which is the start of the intervention, the patients are given a demonstration of the IoT device in their homes. The nurse evaluates the physical activity assessment and medication adherence. Thereafter, the researcher provides face-to-face education for medication adherence and physical activity. The patients implement daily activity (steps count), which is monitored through a wearable device. For 1 to 6 weeks, the nurse researcher performs daily checks through real-time monitoring of medication adherence through the web-server. If medication non-adherence happens twice in a row, the nurse makes an immediate call to the participant and sends a text message to the caregiver. Furthermore, nurses provide weekly phone visits to provide feedback and motivation. For seven to 10 weeks, the participants themselves implement medication adherence and physical activity enhancement with the help of an IoT device. The primary outcomes are medication adherence rates and the average weekly step count. This study will have a duration of 10 weeks, and the outcome variables will be assessed at baseline, 6 weeks, and 10 weeks. Outcome assessment measures will include perceived health beliefs, self-efficacy, medication adherence, and physical activity

Table 4. Contents of the Internet of Things (IoT)-Based Treatment Adherence Intervention Program

Week	Health beliefs cue to action sources		Intervention	Strategy
	Reminder	Personal influence		
1		√	IoT-based smart pillbox setting in patient home; Training on the use of smart pillbox, and wrist-worn wearables and app (initial weeks)	Demonstration and patient performance
		√	Check how to take the medication and assess the remaining number	Registered nurse (RN) evaluation
		√	Physical activity assessment	RN evaluation
		√	Education on preventing and delaying dementia; the importance of medication adherence and physical activity	Face-to-face education
		√	Check the correct usage performance of the smart pillbox and wearable	Patient performance
		√	Wearable alarm settings to promote physical activity: check the weekly average step count and set target steps	RN and patient performance
1-6		√	Real-time monitoring of medication adherence through the web server	RN evaluation (every day)
		√	Daily physical activity (step count) monitoring through wearable apps	RN evaluation (every day)
	√		Wearable alarm settings to promote physical activity: check the weekly average step count and set target steps	Patient performance
	√	√	Medication non-adherence twice in a row: Immediate phone call; a text message sent to a caregiver	RN evaluation; Telephone calls by RN
	√	√	Weekly phone visit: feedback and motivation	Telephonic counselling by RN
7-10	√		Keep using smart medicine boxes and wearables	
	√		Follow personalized smart medicine box alarm settings	
	√		Follow the wearable alarm settings	

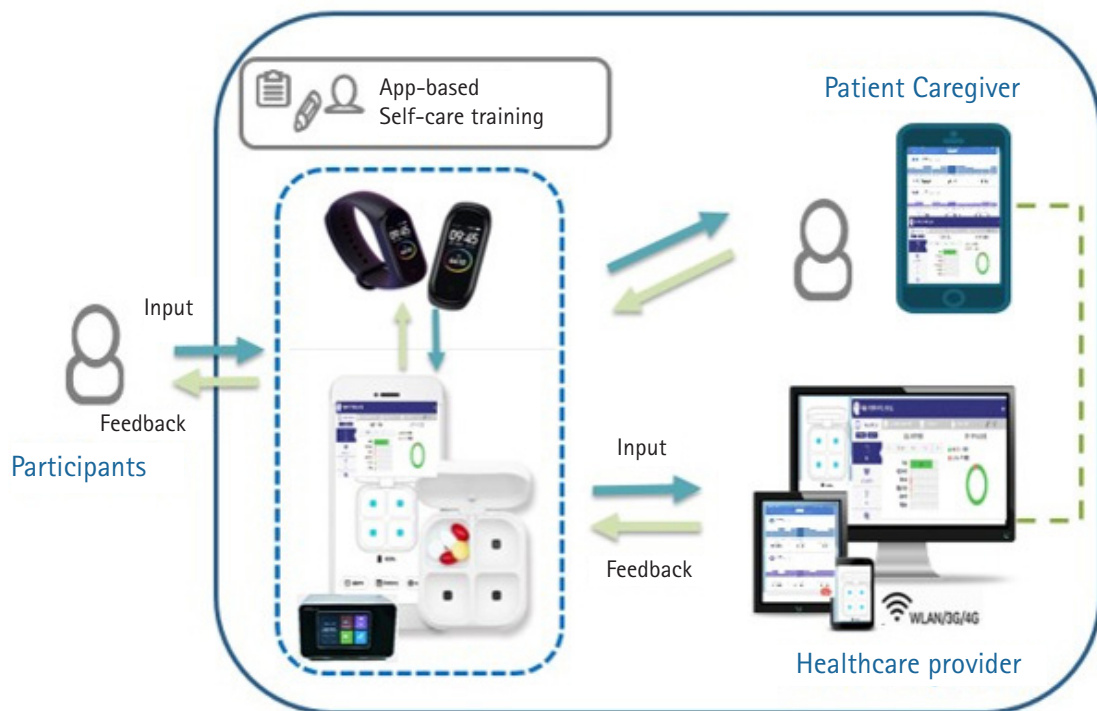


Figure 1. Structure of Internet of things-based treatment adherence intervention.

levels. The outcomes will be analyzed using a linear mixed-effects model with random effects and repeated measures effects.

DISCUSSION

The use of Intervention Mapping ensured an efficient approach to intervention development, including the participation of the target population. It was ascertained that the intervention was systematically approached and based on the available evidence and theories. It was grounded in theory so that the project planner could specify the essential determinants and outcome factors. This framework also made it easy to determine what needed to be changed due to the intervention. In this study, we described the systematic evolution of the ITAI interventions according to the Intervention Mapping.

The goal of our intervention was to improve treatment adherence by enhancing medication adherence and physical activity so that dementia could be prevented or delayed in people with MCI in the long term. Previous interventions to promote medication adherence [10,18] and physical activity [32] exist, but relatively few interventions include a real-time approach and feedback. The program developed in this study is useful as it is an ITAI with a real-time approach focusing on treatment adherence and fully considers the environment in which the technology-based healthcare service influence has grown. This program is based on the theory of health belief behavior designed to increase treatment adherence and prevent cognitive decline in older adults with MCI. The ITAI will help improve treatment adherence outcomes, and ultimately, prevent or delay dementia and improve health status among community-dwelling older adults with MCI. Community health workers, healthcare providers, and administrators can easily access older adults with MCI living at home or in institutions and improve treatment performance.

The Intervention Mapping enabled us to describe and design our intervention using selected strategies that are essential for older adults with MCI. The Intervention Mapping was found to be a beneficial and systematic way to describe interventions; however, to ensure standardization using the IoT, we spent extensive time identifying and using IoT-based Korean products. This was done to select a product that would suit the patients' individual needs. This paper explained the interventions in detail and with transparency to inspire other programs that are being developed using different methods.

Community-dwelling older adults with MCI have been observed to have varying impairments and considerable comorbidities. The ITAI is intended to provide support to older adults with MCI with some degree of independence who live in communities rather than those who receive institutional care or depend on domiciliary carers. Older adults with MCI within some communities may have considerable physical function limitations or debilities and may be depressed. Therefore, our intervention might not entirely meet their needs and treatment adherence. As a result, those with specific difficulties (e.g., comorbid chronic illnesses, physical function limitations, behavioral and psychological symptoms) may require some tailored goal adherence support from a nurse, doctor, or pharmacist.

The possibility of accepting IoT devices for older adults with MCI was confirmed. The ITAI in this study can be managed at the patient's home in real-time, and the health manager can check the patient's treatment progress anytime, anywhere, making immediate intervention possible, reducing cost and time, and increasing the effect. However, older adults with MCI needed several educational sessions and demonstrations as one or two sessions were insufficient. The nurse researcher had to visit the participants' homes several times because they forgot to use the device due to a malfunction or memory loss. Thus, the extent to which the provider intervention contributed to increased treatment adherence rates is unclear. For this reason, during the intervention period, older adults with MCI were asked to identify additional barriers by identifying the number of training and demonstration sessions required. Provider training was designed for providers serving older adults with MCI and might not be effective in diverse settings or contexts as the materials used may not resonate with other populations. Additionally, the Coronavirus disease 2019 (COVID-19) pandemic began after our intervention was developed, with accompanying restrictions on physical activity and interaction due to social distancing. In future programs, it is necessary to develop exercise interventions that can be applied within the COVID-19 context.

Nevertheless, Intervention Mapping can serve as a blueprint for adapting the intervention to different populations and environments while retaining the core program components. It is possible to reorganize and utilize training tailored to the target audience before the application of ITAI. Furthermore, as a strategy to increase utilization in practice, it is necessary to establish a web-based system that allows the target person to be linked

from the hospital to the community dementia prevention center for healthcare providers as a form of management. It can be used for patient treatment by establishing a system in which the patient management results are linked to the hospital for future use.

CONCLUSION

In conclusion, the Intervention Mapping was used as a methodical procedure for developing the ITAI for older adults with MCI. Healthcare providers can use this program to improve treatment adherence for chronic disease management and dementia prevention in older adults with cognitive impairment. Further studies are warranted to evaluate the effectiveness of this intervention. Efficacy assessment would contribute to strategies for improving treatment outcomes in older adults with MCI.

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Authors' contribution

Study conceptualization and methodology - JS, EC, GSK, HK, BSY, and CGP; Data collection and analysis - JS and EC; Drafting and critical revision of the manuscript - JS, EC, GSK, HK, BSY, and CGP; Supervision - JS and EC; All authors have read and agreed to the published version of the manuscript.

Conflict of interest

No existing or potential conflict of interest relevant to this article was reported.

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Data availability

All data generated or analyzed during this study are included in this published article.

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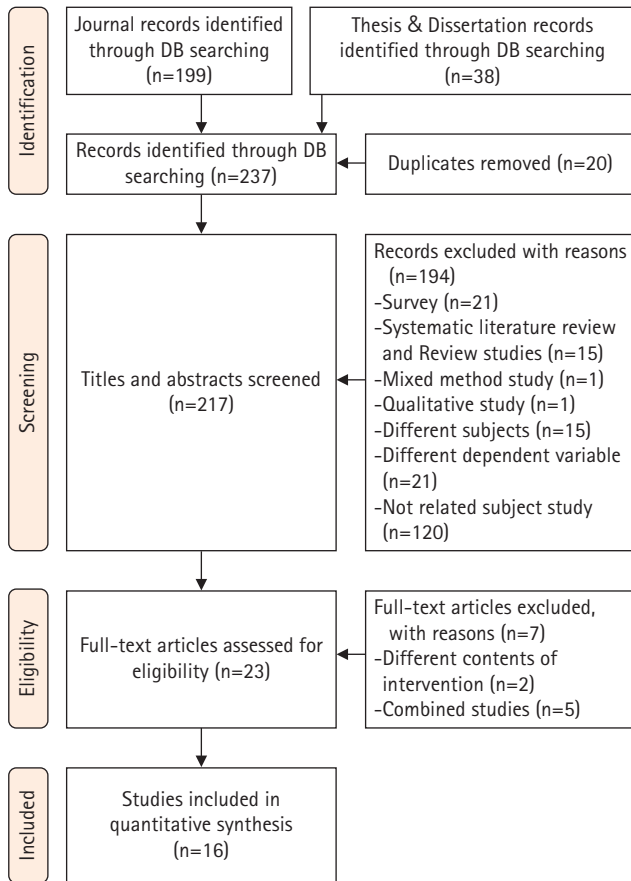
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Appendix 1. Systematic literature review process of the study. DB=Database.



Appendix 2. Rating on an Internet of things-based treatment adherence intervention program of program content and education by five experts: Rated 3 or 4 on a 4-point relevance scale. CVI=Content validity index; I=Item-level.

Category	Expert 1	Expert 2	Expert 3	Expert 4	Expert 5	Experts in agreement	Item CVI
Contents of Program							
1	√	√	√	√	√	5	1.0
2	√	√	√	√	√	5	1.0
3	√	√	√	√	√	5	1.0
3-1	√	√	√	√	√	5	1.0
3-2	√	√	√	√	√	5	1.0
3-3	√	√	√	√	√	5	1.0
4	√	√	√	√	√	5	1.0
5	√	√	√	√	√	5	1.0
6	√	√	√	√	√	5	1.0
7	√	√	√	√	√	5	1.0
8-1	√	√	√	√	√	5	1.0
8-2	√	√	√	√	√	5	1.0
					Average I-CVI=		1.0
Proportion relevant	1.0	1.0	1.0	1.0	1.0		
Contents of Interventions Program by Week							
1	√	√	√	√	√		1.0
2-6	√	√	√	√	√		1.0
7-10	√	√	√	√	√		1.0
					Average I-CVI=		1.0
Proportion relevant	1.0	1.0	1.0	1.0	1.0		
Contents of Education							
1	√	√	√	√	√	5	1.0
2	√	√	√	√	√	5	1.0
3	√	√	√	√	√	5	1.0
4	√	√	√	√	√	5	1.0
5	√	√	√	√	√	5	1.0
6	√	√	√	√	√	5	1.0
7	√	√	√	√	√	5	1.0
8	√	√	√	√	√	5	1.0
					Average I-CVI=		1.0
Proportion relevant	1.0	1.0	1.0	1.0	1.0		