JKGN
Journal of Korean Gerontological Nursing

Study Protocol

pISSN 2384-1877 | eISSN 2383-8086
J Korean Gerontol Nurs Vol. 26 No. 3, 248-256
https://doi.org/10.17079/jkgn.2024.00521

Effectiveness of a mobile app-based individualized non-pharmacological intervention on behavioral and psychological symptoms of dementia in community-dwelling older adults: Study protocol for a randomized control trial

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Received: July 9, 2024
Revised: August 7, 2024
Accepted: August 26, 2024

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Purpose: The manifestation of behavioral and psychological symptoms of dementia (BPSD) poses a considerable care burden and precipitates adverse health outcomes. Despite the increasing development of digital interventions, their application in the dementia population, specifically regarding their effectiveness in addressing BPSD, remains limited. Therefore, in this study, we aimed to describe a study protocol for evaluating the effectiveness of a mobile app-based individualized non-pharmacological intervention to improve BPSD in community-dwelling older adults. **Methods:** Employing a randomized control group pretest-posttest design, 36 dyads comprising people living with dementia (PLWD) and their family caregivers will be assigned to either an experimental or control group. The experimental group will engage in a 4-week regimen using a mobile app-based individualized non-pharmacological intervention, which includes recording and predicting BPSD. The control group will use the BPSD record system without accessing the individualized interventions. Both groups will continue with their usual care practices throughout the study period. **Results:** We hypothesize that the implementation of the mobile app-based individualized non-pharmacological intervention will alleviate BPSD. After the intervention, results will be analyzed to evaluate the effectiveness of the mobile app-based individualized non-pharmacological intervention on BPSD. **Conclusion:** The research team may encounter several challenges owing to the novelty of digitalized interventions. Nevertheless, the results of this study will provide robust evidence regarding the efficacy of mobile app-based individualized non-pharmacological interventions for community-dwelling older PLWD.
Trial registration: This trial has been registered with the Clinical Research Information Service in South Korea (CRIS No. KCT0008713; registered August 18, 2023).

Keywords: Behavioral and psychological symptoms of dementia; Dementia; Non-pharmacological interventions; Digital health; Randomized controlled trial

BACKGROUND

Dementia is an encompassing term encapsulating several types of cognitive impairment that commonly affects the cognitive functions of an individual [1]. Over 55 million people are presently affected by dementia globally [1], the prevalence of dementia in South Korea has seen a rapid surge and is projected to reach 1.95 million in 2050 [2]. Concurrently, the fi-

nancial outlay allocated to dementia care in 2019, estimated at 1.3 trillion US dollars, is also expected to more than double in 2030 globally [1]. People living with dementia (PLWD) generally experience memory loss and an escalating dependence on assistance for daily activities as the condition progresses, with family caregivers dedicating approximately 5 hours per day to aid in the execution of their daily activities [1]. Approximately 55% of PLWD reside at home and are taken care of by spouses and children in South Korea [3]. Given the cumulative impact of dementia, the forthcoming years are poised to witness an increase in care burden both on society and the family caregivers of PLWD.

Behavioral and psychological symptoms of dementia (BPSD) are prevalent features frequently observed in PLWD [1]. Although common manifestations of BPSD include apathy, depression, anxiety, irritability, agitation, nighttime behavior, and eating disorders, their prevalence can vary depending on the type and severity of dementia [4]. The progression of BPSD in PLWD is associated with the possible onset of physical and mental suffering [5] and adverse outcomes, such as falls [6]. Notably, the impact of BPSD extends beyond PLWD, as family caregivers can also endure significant stress and care burdens in cases of inadequately managed BPSD [7]. Therefore, the effective management of BPSD is essential in dementia care for PLWD and the quality of life of their caregivers.

Both pharmacological and non-pharmacological interventions stand as viable approaches to manage BPSD. Guidelines recommend applying non-pharmacological intervention as a first-line treatment, except in cases where BPSD poses a significant risk of inducing severe stress or harm to PLWD or others [8]. Non-pharmacological interventions such as music therapy, exercise, and reminiscence therapy have proven beneficial in alleviating BPSD symptoms [9]. Notably, the facilitation of these interventions through digital devices has been confirmed as effective in the management of BPSD [10]. Although concerns exist regarding the novel application of digital technologies in delivering non-pharmacological interventions to older adults, extant research has yielded favorable outcomes. Generally, older adults have exhibited positive attitudes toward digital technologies, recognizing their potential for improving healthy aging [11]. Moreover, non-pharmacological interventions delivered through digital devices have proven feasible and acceptable by PLWD and their caregivers [12].

Current studies on non-pharmacological interventions have yielded suboptimal effect sizes and failed to demonstrate significant improvement in BPSD care, partly because they do not fully reflect the diverse preferences of PLWD [9,10]. This highlights the necessity of incorporating an individualized approach, which emphasizes understanding and addressing an individual's basic needs, psychosocial and environmental factors, and personal preferences, to enhance the effectiveness of non-pharmacological interventions [9,13]. Individualized non-pharmacological interventions are crucial as they are tailored to meet the specific needs and preferences of each individual, and therefore, are expected to yield improved outcomes.

Mobile-based interventions, recognized for enhancing accessibility, facilitate easy access to non-pharmacological interventions [10,14]. Within the context of community settings, the implementation of individualized non-pharmacological interventions through a mobile app can emerge as a strategy for BPSD management [10]. To address this, our research team has developed individualized non-pharmacological interventions designed for implementation through a mobile app. In this study, we established a protocol to assess the efficacy of the mobile app-based individualized non-pharmacological intervention in reducing BPSD.

The aim of the study is to evaluate the effectiveness of a mobile app-based individualized non-pharmacological intervention in alleviating BPSD in community-dwelling older PLWD. The primary aim encompasses the evaluation of the effectiveness of this intervention on the frequency and severity of dementia-related symptoms, whereas the secondary aim is centered on assessing the effectiveness of the intervention on sleep patterns, physical activity level, and the degree of competence exhibited by family caregivers in managing BPSD.

METHODS

Ethic statement: This study has obtained ethical approval from the institutional review board of the Yonsei University Health System (IRB.4-2023-0660).

1. Design and Setting

This study is a parallel-group, randomized controlled trial designed to compare the effectiveness of mobile app-based non-pharmacological interventions with that of usual care. The study was registered with the Korean National Clinical

Trial Registry, Clinical Research Information Service (CRIS, KCT0008713), on August 18, 2023. Any necessitated amendments during the study will be publicly documented in CRIS before implementation. The study design is illustrated in Figure 1. The study will be conducted within community settings in South Korea. The current protocol is in line with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 Checklist [15].

2. Recruitment and Eligibility Criteria

The target population for this study is PLWD and their caregivers residing in domestic settings. The recruitment strategy will encompass a combination of convenience and snowball sampling methods. Potential participants will be recruited either from the neurology and psychiatric outpatient units of hospitals or from community-based long-term care centers for PLWD, such as dementia care centers, adult daycare centers, and home care centers in South Korea.

A systematic review reported the effect size (.25) of intervention using Information and Communication Technology on overall BPSD [10]. Therefore, the sample size, determined using the G-power program [16], was calculated based on a significance level of .05 (two-tailed), a statistical power of 80%, an effect size of 0.25, and repeated measures conducted thrice in a two-group comparison scenario. After considering a 30% dropout rate, a total of 36 dyads (experimental and control groups) will be recruited for this interventional experimental study.

Eligibility criteria for inclusion in the study encompass both PLWD and family caregivers living in community settings, contingent upon their express willingness to participate. Detailed inclusion criteria are as follows: PLWD candidates will be included if they are (a) aged 65 years or older, (b) diagnosed with dementia, (c) have a Korean version of Mini-Mental State Examination score < 24, (d) exhibit BPSD at least once a week (evaluated by the Korean version of the Neuropsychiatric Inventory [K-NPI]), and (e) reside in Seoul or Gyeonggi-do province with their family caregivers. Family caregiver candidates will be included if they are (a) the primary caregiver of PLWD and (b) exhibit proficiency in reading and writing Korean. The research team will hold continuous meetings to monitor participant enrolment and adherence to study protocols throughout the study period.

3. Randomization

PLWD and family caregiver dyads who meet the eligibility criteria will be randomly assigned into two groups by a researcher who maintains non-contact with the participants

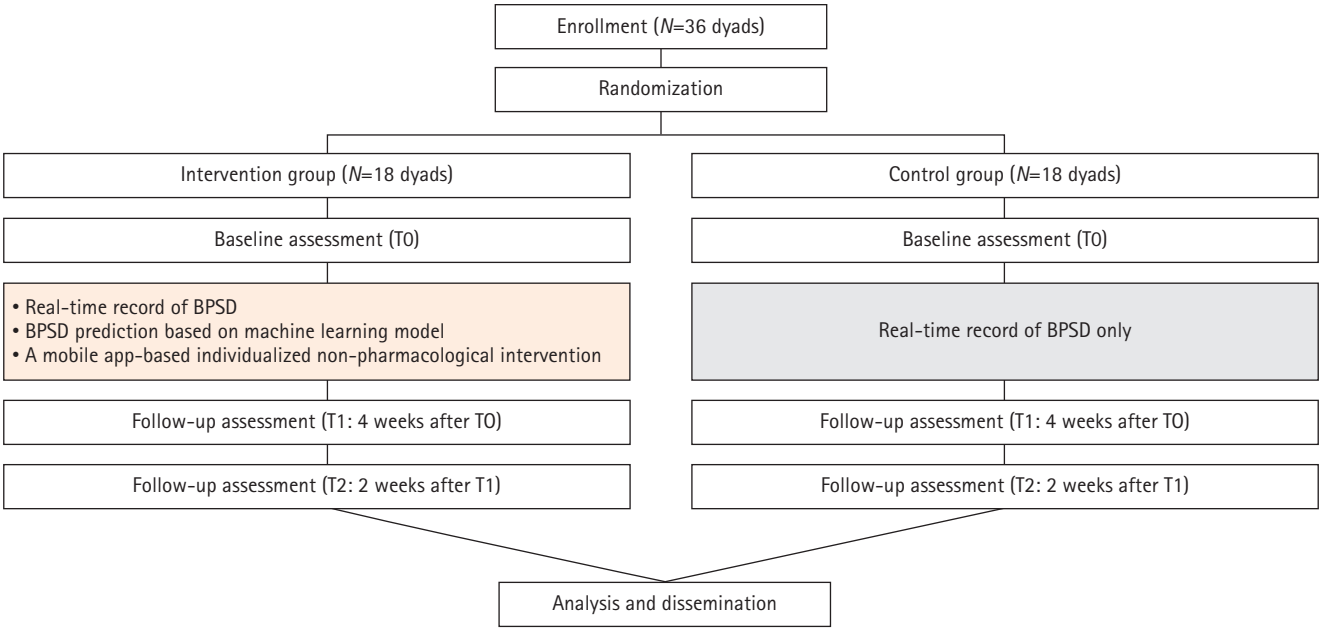

Figure 1. Overview of study design. BPSD=Behavioral and psychological symptoms of dementia.

https://doi.org/10.17079/jkgn.2024.00521

during the study. The groups include the experimental and control groups receiving a mobile app-based individualized non-pharmacological intervention and usual care, respectively. Randomization will be achieved using a computer-generated block randomization table to ensure a 1:1 allocation ratio between the experimental and control groups. The randomization process will involve the use of sequentially numbered, opaque, sealed envelopes and randomization software (STATA version 13.1; StatCorp LP). Given that this study employs a single-blind randomized control design, group allocation will be concealed from study participants.

4. Interventions

In our previous study, we developed machine learning models to predict the onset of BPSD in community-dwelling older adults. This involved training the models with data from 187 individuals with dementia and validating them with data from 35 additional individuals [17]. Our research team also reviewed the existing literature on non-pharmacological interventions for alleviating BPSD, which can be delivered through a mobile app [10]. Finally, we developed and tested an app designed to record and predict BPSD, and to provide individualized non-pharmacological intervention to manage BPSD [18]. In this study, participants assigned to the experimental group will engage in a 4-week regimen using all the features of the developed mobile app, including the individualized interventions. A tablet device (Galaxy Tab A8; Samsung) pre-downloaded with the app will be provided, and instructions for each menu in the app will be taught. PLWD and their caregivers will respond to inquiries in the user information and preference survey sections and concurrently record real-time BPSD manifestations using a diary through the app. In addition, PLWD will wear an actigraphy device to collect data on sleep and physical activity. Leveraging these initial data, future BPSD occurrence prediction can be implemented using a machine-learning model. Tailored non-pharmacological interventions will be administered according to the predicted or currently manifesting symptoms. Specifically, non-pharmacological interventions such as music therapy, exercise, and reminiscence therapy will be custom-developed for each PLWD based on their expressed preferences. Additionally, family caregivers can upload personal photos and videos for individualized reminiscence therapy. This comprehensive 4-week intervention, designed for implementation at home, exhibits the flexibility of being delivered in alternative locations as part of the mobile-centric feature of the intervention. The type and duration of individualized non-pharmacological interventions will be determined and provided by the family caregivers as needed. The frequency and duration of use will be logged and can be reflected in subsequent data analysis.

The control group will receive a similar tablet but will be instructed to record real-time BPSD manifestations using a diary and wear an actigraphy device as similar as possible to that of the experimental group to minimize potential bias. However, future BPSD occurrence prediction and individualized non-pharmacological interventions will not be provided to the control group. Both groups will not be restricted in their usual care practices, including existing non-pharmacological interventions employed at daycare centers, welfare facilities, or within their home setting, for the same study period. The research team will encourage the dyads in both experimental and control groups to contact the research team whenever technical issues arise during the study period and use the mobile app at least once a day or as needed.

5. Outcome Measures

Outcome variables regarding BPSD will be collected at baseline, immediately after the 4-week intervention, and 2 weeks post-intervention. Trained research assistants will conduct data collection under standardized conditions.

1) Primary Outcomes

(1) Agitation

The Korean version of the Cohen-Mansfield Agitation Inventory (CMAI-K) encompasses 29 behaviors categorized into physical aggressiveness, non-aggressiveness, and verbal agitation. Each behavior is rated on a scale from 1 (never) to 7 (several times per hour) [19]. The sum of each score ranges from 29 to 203, with a higher total score indicating a higher frequency of agitated behavior [19]. Cronbach's α of CMAI-K was .88 [19].

(2) Depression

The Korean version of the Cornell Scale for Depression (K-CSDD) contains 19 items on depressive signs and symptoms [20]. Each item is rated on a scale from 0 (absent) to 2 (severe), and the total sum of each item ranges from 0 to 38, and Cronbach's α of K-CSDD was .78 [20].

(3) Overall BPSD

K-NPI, developed to assess 12 domains of dementia-related behaviors, measures the frequency and severity of each domain, as well as the care burden [21]. The total NPI score is calculated by multiplying frequency and severity scores. Frequency scores are rated on a scale from 1 (less than once a week) to 4 (more than once a day), whereas severity scores are rated on a scale from 1 (mild) to 3 (severe) [21]. A higher K-NPI score indicates a higher overall BPSD and Cronbach's α of K-NPI was .85 [21].

2) Secondary Outcomes

(1) Sleep and physical activity

Data collection for sleep and physical activity will be facilitated through actigraphy using the wGT3X-BT activity monitor (ActigGraph, LLC). An actigraphy device collects data every 30 seconds when activated. The reliability of wrist actigraphy in measuring circadian rhythms among individuals with dementia has been demonstrated in previous studies [22].

(2) Competence in managing BPSD

The Competence Scale in Managing Behavioral and Psychological Symptoms of Dementia (CS-MBPSD) is a self-report tool used to measure the competence level of family caregivers in managing BPSD [23]. The CS-MBPSD comprises 28 questions on knowledge, skills, and attitudes in BPSD management, along with one general question [23]. The total scores on the CS-CMBPSD range from 28 to 140, with a higher score indicating a greater level of competence in managing BPSD [23]. Cronbach's α of CS-MBPSD was .92 [23].

6. Data Collection

Trained research assistants will visit homes or locations designated by study participants to collect data. The questionnaires will be self-reported by the PLWD and/or their caregivers. Information required for BPSD prediction according to the predetermined model [17], as well as the primary and secondary outcomes of the total population, will be collected at baseline and 6 and 8 weeks post-commencement (Table 1) [19-21,23-26].

During the first visit, the team will collect baseline information such as demographic data, BPSD symptoms, and competence in managing BPSD. Personal preferences for music and past experiences will be exclusively solicited from the intervention group to inform the establishment of individualized non-pharmacological interventions. Simultaneously, allocated mobile apps will be provided to dyads, with instructions to record real-time BPSD manifestations. Following a 4-week intervention period, the research assistants will visit to assess the

Table 1. Time Schedule of Assessments

	Assessments	Measurement	T0	T1	T2
Information for behavioral and psychological symptoms of dementia (BPSD) prediction	Sociodemographic	Self-reported	V		
	Cognitive function	The Korean version of the Mini-Mental State Examination-2 (K-MMSE-2) [24]	V		
	Daily living activities	The Korean version of activity of daily living (K-ADL) [25]	V		
	Personality traits	The Korean version of the Big Five Inventory (K-BFI) [26]	V		
Information for individualization of non-pharmacological interventions	Personal preferences for music and past experiences*	Self-reported	V		
Primary outcomes	Agitation	The Korean version of the Cohen-Mansfield Agitation Inventory (CMAI-K) [19]	V	V	V
	Depression	The Korean version of the Cornell Scale for Depression (K-CSDD) [20]	V	V	V
	Overall BPSD	The Korean version of the Neuropsychiatric Inventory (K-NPI) [21]	V	V	V
Secondary outcomes	Sleep and physical activity	Actigraphy	V	V	
	Competence in managing BPSD	The Competence Scale in Managing Behavioral and Psychological Symptoms of Dementia (CS-MBPSD) [23]	V	V	

*Experimental group only; T0=Baseline assessment; T1=4 Weeks after T0; T2=2 Weeks after T1.

https://doi.org/10.17079/jkgn.2024.00521

primary and secondary outcomes (T1). The last visit will transpire 2 weeks after the end of the intervention, and primary outcomes (T2) will be documented. In addition, the PLWD will wear an actigraphy device for the 2-week assessment period and throughout the 4-week intervention period. Two research assistants will independently conduct data encoding and double-check procedures on the collected data to ensure its accuracy.

7. Ethical Considerations

The study protocol has undergone review and evaluation by an Institutional Review Board (IRB.4-2023-0660). All participants will be assigned identification numbers to guarantee confidentiality at all times. Access to any data relevant to this study will be limited to the research team. All participants will be informed of the purpose and process of the study and their right to withdraw consent to participate at any point. Given the focus of the study on the dementia population, additional ethical awareness is required in the process of obtaining study consent. Dependency and vulnerability will be carefully considered when obtaining consent. First, the research team will examine the capacity for autonomous consent using the Evaluation to Sign to Consent protocol, consisting of four questions designed to evaluate the understanding of research information by participants with dementia or mild cognitive impairment [27]. Should the participants lack the capacity to provide consent, the research team will contact surrogates or their spouses and subsequently obtain written consent.

8. Data Analysis

The data obtained in this clinical trial will be analyzed following an intention-to-treat procedure. Stata (version 13.1; Stata Corp LP) or SAS (version 9.4; SAS Institute) will be used for data analysis. First, a comprehensive examination of the dyad demographics will be conducted. Baseline characteristics between the intervention and control groups will be compared using a two-sample t-test, Wilcoxon rank-sum test, or Fisher's exact test, depending on the nature of the variables. Differences in outcome variables between baseline and assessment points T1 or T2 will be analyzed using multilevel (mixed-effects) linear regression or multilevel (mixed-effects) logistic regression. The selected statistical threshold for significance for all analyses will be a two-tailed *p*-value of .05.

DISCUSSION

This study encompasses a description of the protocol of a randomized controlled trial poised to compare a mobile app-based individualized non-pharmacological intervention and usual care. The objective of the study is to evaluate the effectiveness of a mobile app-based individualized non-pharmacological intervention in improving BPSD. Previous research has highlighted the potential efficacy of digital interventions for PLWD in community settings [28,29]. Notably, within community settings, the availability of individualized non-pharmacological interventions can be restricted owing to limited access to therapists or healthcare providers. To address these constraints, the utilization of mobile app-based individualized interventions emerges as a practical means for delivering individualized non-pharmacological interventions.

Our mobile app-based individualized intervention stands out with notable strengths in comparison to existing digitalized non-pharmacological interventions for PLWD. To our knowledge, there is a dearth of apps providing a comprehensive array of non-pharmacological interventions, including music therapy, exercise, reminiscence therapy, or reminiscence with classical music. Moreover, our app incorporates a predictive feature for BPSD and subsequently recommends symptom-specific non-pharmacological interventions. Finally, an individual-centered approach, facilitated through a comprehensive survey of personal preferences, ensures the delivery of individualized interventions to each PLWD. If proven effective, these findings will provide robust evidence of BPSD improvement through our mobile app-based individualized non-pharmacological intervention.

Acknowledging inherent challenges associated with the use of a mobile-based intervention is essential within the context of our research. The vulnerability of older adults to the use of digital devices, owing to physical limitations and technological unfamiliarity [30], poses a significant challenge. Dyads may encounter several difficulties in app operation and troubleshooting technical issues. However, the feasibility of our app has undergone prior testing, yielding promising results [18]. Subsequent upgrades based on user feedback have been implemented. Surmounting these challenges will provide valuable insights into the potential benefits of digital healthcare for both PLWD and their caregivers.

Several limitations warrant acknowledgment. First, the study will be conducted in the natural world; thus, confounding fac-

tors such as personal activities in community settings, cannot be controlled. In addition, the dual role of the researcher, which includes both educating participants on mobile app usage and collecting data, could introduce potential biases. However, these potential problems could be controlled through random assignment of dyads, outcome assessment by family caregivers blinded to study allocation, and adherence to standardized data collection procedures for both groups.

Overall, this study will substantiate the effectiveness of the mobile-based individualized non-pharmacological intervention as well as the feasibility of this intervention for PLWD and their caregivers. Moreover, the findings of this study will provide empirical evidence for individualized non-pharmacological interventions for PLWD, particularly in the context of a digital approach using mobile apps.

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Authors' contribution

Study conceptualization, methodology, funding acquisition - EC; Data collection - MY, SH, EK, and JC; Data analysis - MY and MJK; Writing–original draft - EC, MY, MJK, SH, EK, and JC, Writing–review & editing - EC, MY, MJK, SH, EK, and JC

Conflict of interest

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

Funding

This research was supported by the Basic Science Research Program through the National Research Foundation of Korea (NRF), funded by the Ministry of Education (No. 2020R1 A6A1A03041989). The funding body of this study had no role in the study design, methods, development, recruitment, data collection, or preparation of the paper.

Data availability

Data sharing is not applicable to this article.

Acknowledgements

We are grateful to those who are arranging recruitment at the sites.

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