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Widely Integrated Services in Home (WISH) for homebound older adults: a study protocol for a randomized encouragement trial

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Abstract

Background Home-based primary care (HBPC) is an emerging patient-centered, interprofessional healthcare service model that can address unmet medical needs and care burdens for homebound older adults. In December 2022, the Ministry of Health and Welfare in South Korea launched the *Home-Based Medical Center Demonstration* project to provide a new bundle payment for physician home visits. In this study, we seek to determine whether the recently introduced HBPC services in South Korea have been associated with a reduction in long-term care (LTC) facility admissions and acute hospitalizations among homebound older adults.

Methods The study is a community-based, multicenter, two-arm, randomized encouragement design trial with a 12-month follow-up period (n = 600). Eligible study participants are community-dwelling LTC recipients with multimorbidity and functional deterioration. Study participants are recruited from five HBPC centers located in urban areas (Northeast Seoul, West Seoul, Daejeon, Wonju, and Paju). The study participants are randomly assigned to either the HBPC group or the usual care group with a 1:1 allocation ratio. Those assigned to the HBPC group receive longitudinal home visits at least once a month by an interprofessional HBPC team according to the Widely Integrated Services in Home (WISH) intervention protocol. This protocol adheres to the *Integrated Care for Older People* principles, which call for a person-centered assessment and broader integration of health and LTC services at the micro-, meso- and macro-levels. Primary outcomes of the trial are 1) between-group community survival days and 2) between-group potentially avoidable hospitalizations. Results of the treatment are estimated by both modified intention-to-treat and complier average causal effect analytic methods.

Discussion This study aims to investigate the real-world effectiveness of HBPC on the reduction of LTC facility admissions and acute care hospitalizations in the community setting. The findings may inform healthcare policy decisions to expand HBPC services in South Korea and other countries.

Trial Registration CRIS KCT0007921.

Keywords Home-based primary care, Long-term care facility admission, Geriatric syndrome, Caregiver burden, Interprofessional collaboration, Post-randomization consent design, Complier average causal effect

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Background

Care failure refers to situations in which care needs essential for daily life such as personal hygiene, diet, sleep, and mobility are not met by family members or paid caregivers. Important causes of care failure are the so-called "geriatric syndromes," which are health problems that usually have more than one cause and affect various parts of the body. When geriatric syndromes occur, the burden of care on the family increases substantially due to an increase in actual care time and psychological burden. Delayed or limited access to medical care for homebound older adults is another important factor that results in unnecessary long-term care (LTC) facility admission. Mounting care dependency and caregiver burden accelerate care failure at home and prompt admission to LTC facilities. However, nearly 70% of South Korean older adults hope to remain in their homes rather than relocate to LTC facilities even if their physical and cognitive capacities decline [1].

Home-based primary care (HBPC) is an emerging patient-centered, interprofessional healthcare service model that can address unmet medical needs and care burdens for homebound older adults with multiple comorbidities and high care dependency [2, 3]. HBPC increases access by providing a different route to health care for people who face barriers to outpatient primary care. A number of studies in the United States, Canada, and Denmark have evaluated the impact of HBPC, showing a reduction in avoidable use of hospital and emergency services and cost-saving effects [3–13]. In addition, HBPC had a positive impact on patient and caregiver experience, including satisfaction and quality of life [2–4, 14–16]. However, the association between HBPC service and LTC facility admissions among homebound older adults is unclear. Moreover, few studies from non-Western countries have investigated the effects of HBPC services.

A healthcare system that facilitates a complex spectrum of interventions with an extensive degree of coordination among healthcare and home and community-based service (HCBS) workers is critical to meet the complex needs of homebound older adults [17, 18]. However, current home healthcare services in South Korea are fragmented and disconnected. Physician house calls were legally prohibited in South Korea due to conservative interpretation of the Medical Service Act (Article 33) up until 2019. This provision was abolished after December 2019, when the National Health Insurance Act was amended to allow home-based medical care services. In addition, the *Community Integrated Care Initiative* was introduced in June 2018 so that residents in need of care could receive HCBS tailored to their individual needs [19]. Since then, the Korean Ministry of Health and Welfare has launched several pilot projects (including the *Home-Based Medical Center Demonstration* project) to provide new bundled payments for physician home visits. However, only a small number of physicians are participating in home-based medical care services, with a national participation rate in the pilot projects of 0.4% [20].

In this study, we describe a study protocol focusing on LTC outcomes of the *Home-Based Medical Center Demonstration* project newly launched in South Korea. Although several observational studies have suggested that the need for skilled nursing facilities and nursing home care is reduced after implementing HBPC programs, there is a paucity of empirical studies that provide definitive real-world evidence of the effects of HBPC programs on community-dwelling homebound older adults. This study protocol was designed to determine whether an HBPC program that provides interprofessional team interventions based on the results of the comprehensive geriatric assessment (CGA) for 12 months can delay admission to LTC facilities and reduce the hospitalization rate. Additional analyses will be conducted to provide answers to the following questions: (1) Are there patient or organizational characteristics for which HBPC intervention is more effective? (2) Through which mechanism(s) does HBPC produce beneficial effects?

Study Hypotheses

We hypothesize that homebound older adults will eventually follow one of two pathways until they are relocated to LTC facilities: (1) the symptom burden pathway and (2) the caregiver burden pathway. The first potential pathway for entering a facility is *"because I am very sick."* When symptoms such as fever, dyspnea, vomiting, diarrhea, poor oral intake, general weakness, and pain occur and the patients require help (illness experience), older adults and family will seek help (help-seeking behavior). However, the first barrier is the difficulty of accessing a hospital because of patient weakness. It is common for such patients to endure symptoms (unmet medical care) or rely on multiple medications (prescribing cascade) and visit the emergency room only after the disease worsens. Even after hospitalization, all problems are not easily solved. The individual's health is likely to deteriorate rather than recover because hospitalization itself can act as an allostatic stressor and cause various geriatric syndromes such as sleep disorders, mood disturbances, delirium, sarcopenia, malnutrition, pressure sores, and an intubated state. At the time of discharge, physiological systems are prone to impairment, physical resilience is depleted, and the body cannot effectively avoid or mitigate health threats (post-hospital syndrome) [21–23]. Ultimately,

no matter what type of symptoms result in hospitalization, functional decline intensifies along the path of 'emergency room → intensive care unit → general ward → skilled nursing facility (LTC hospital) → assisted living facility (LTC facility).' In this process, discharge back home is unlikely.

The second pathway for admission to an LTC facility is *"because there is no one to take care of me."* The family structure in South Korea has changed in recent years, and only 20.1% of elders live with their children [24]. According to the 2020 Older Adults Living Profile Survey, the proportion of older adults living by themselves or with a spouse is 78.2%, a significant increase from 66.8% in 2008 [23, 25]. This means that most Korean older adults have no choice but to receive basic personal care from paid caregivers (i.e., home helpers). However, the use of home-help services does not resolve all problems. National Long-Term Care Insurance (NLTCI) provides only up to 4 h/day of care even for homebound older adults with the highest LTC grade (i.e., Grade 1). In South Korea, if an individual needs care for more than 4 h, they may consider the 24-h care of an LTC facility. If such a decision is made by family members who bear the burden of care rather than the older adult themselves due to cognitive or economic deficits, admission to an LTC facility is a reasonable choice.

One way to address care failure is to provide interprofessional collaborative interventions focused on geriatric syndromes. Interestingly, care failure almost always co-occurs with geriatric syndromes, which include poor oral intake, general weakness, depression, sleep disorders, cognitive deficits, delirium, repeated falls, urinary incontinence, dehydration, and chronic pain. These are not simply symptoms but are deeply related to the burden of care. For example, poor oral intake will more than double the time required to eat and prepare a meal. Urinary incontinence will increase the actual care burden for toileting. Delirium, which may be expressed as sudden fits of anger, is a major cause of family members no longer being willing to care for an aging adult. It is, therefore, necessary to implement a multidimensional approach to reduce not only the symptoms but also the burden of care to prevent institutionalization.

To this end, we developed a Widely Integrated Services in Home (WISH) intervention protocol for homebound older adults, which consists of eight components. This protocol adheres to the *Integrated Care for Older People* principles proposed by the World Health Organization, which call for a person-centered assessment and broader integration of health and LTC services at micro-, meso- and macro-levels [17, 26]. Part of this protocol (1–5) was applied to the *Home-Based Medical Center Demonstration* project promoted by the Ministry of Health and Welfare of the Korean government in December 2022. The eight components are listed below.

1) Build an interprofessional care team composed of a physician, nurse, and social worker.
2) Identify major issues that increase both symptom and caregiver burden in the physical, mental, cognitive, and social domains by conducting a CGA based on a list of 20 problems of decreased gait ability, chronic undernutrition, depression, cognitive decline, multimorbidity, caregiver stress, socioeconomic vulnerability, high-risk for LTC facility admission, activities of daily living (ADL) disability, instrumental activities of daily living (IADL) disability, end-of-life stage, falls, pain, dehydration, delirium, polypharmacy, incontinence, behavioral and psychological symptoms of dementia, pressure sores, and tube inserted state.
3) Hold regular interprofessional care team meetings to review new patients and update individualized care plans to solve problems.
4) Designate a primary case manager to conduct longitudinal home visits at least once a month to provide healthcare (including medication management) and family counseling (including caregiver support) services.
5) Conduct a CGA (including complete medical history, physical examination, and laboratory blood tests) every 6 months to monitor for changes in the patient's intrinsic capacity.
6) Organize interagency interdisciplinary team meetings with HCBS providers to integrate healthcare and social services within NLTCI (optional).
7) In situations when short-term hospitalization is required, provide a transitional care program in cooperation with local partner hospitals (optional).
8) In response to emergency situations, conduct after-hours telephone counseling or urgent house call services (optional).

Methods

Study design

This study protocol is for a community-based, multicenter, prospective, two-arm, parallel-group, outcome assessor-blinded, pragmatic, randomized encouragement design trial with a 12-month follow-up period. The primary research center of the study is the Institute for Community Care and Health Equity of Chung-Ang University. The study has been designed following the SPIRIT Statement.

Eligibility criteria and recruitment

Study participants are recruited through community screening of residents in five urban areas (Northeast Seoul, West Seoul, Daejeon, Wonju, and Paju). The recruitment process is carried out according to the following two strategies. First, in the process of requesting HCBS services from the NLTCI system, potential subjects who meet the eligibility criteria are selected. Second, in the process of using the HCBS of the NLTCI, potential subjects who meet the criteria and have unmet healthcare needs are referred. These strategies are meaningful because they reflect the actual path of home-based medical service use among South Korean older adults. To this end, the five HBPC centers participating in the study should establish cooperative relationships with NLTCI corporations and a variety of HCBS providers. In this study, the construction of a collaborative network in the community is included in the WISH intervention protocol and is a major task of the social workers.

The recruitment period during which study participants are to be enrolled in the trial is between January 1, 2023, and June 30, 2024. Study participants are recruited via two referral pathways depending on whether they are newly entered (NLTCI route) or are already in the NLTCI system (HCBS route). Accordingly, only those who receive an LTC certificate are invited to participate in the trial and are contacted by social workers to schedule the initial home visit by telephone triage. Study subjects are recruited as follows. First, a frailty screening of those referred by NLTCI and HCBS partners is conducted. The Clinical Frailty Scale (CFS), which was developed and verified with high-predictive validity in South Korea, is used to select potential subjects [27]. Second, social workers conduct a pre-enrollment home visit or telephone triage to affirm the following inclusion criteria using a standard procedure: (1) older adults living at home (age $\geq$ 65 years); (2) LTC recipients certified as Grade 1 to 5 (registration score $\geq$ 45); (3) those experiencing functional deterioration (CFS $\geq$ 4); (4) those with multimorbidity with unmet healthcare needs (e.g., self-medication, medicating 'by proxy,' forgone medical care); and (5) individuals who provide consent to receive longitudinal intervention services. Exclusion criteria of the study are listed as follows: (1) expected survival time less than 1 month; (2) who prefer to be admitted to an LTC facility; (3) those participating in any kind of other home-based medical service.

Randomization, allocation concealment, and blinding

Study participants are randomly assigned to either the HBPC group or the usual care group at a 1:1 allocation ratio. The randomized sequence is generated by a simple randomization procedure within each of the five HBPC centers by an independent third party (Artificial Intelligence Institute, Seoul National University, Seoul, South Korea). Random assignment is performed after screening but before the initial home visit. Information about subject allocation is centrally transferred to social workers at each HBPC center. In an HBPC intervention, complete blindness of the study participants is almost impossible. This is an open-label trial where both the study participants and healthcare providers have knowledge of the assignment group. However, outcome assessor is blinded to the treatment assignment.

Randomized controlled trial (RCT) has long been the gold standard for clinical research but is not always feasible. Public health researchers are increasingly addressing questions for which the RCT may not be a practical (or ethical) option or for which the RCT can be complemented by alternative designs that enhance generalization to participants and contexts of interests [28]. For example, in interventions about which prospective study participants (e.g., patients, healthcare providers) are likely to have strong preferences, they would not choose to be randomized. In this case, only an atypical population (e.g., extremely poor or highly educated people) may be willing to be participated [28, 29]. When RCT is infeasible or unjustifiable, there are several alternative intervention designs [28–30]. One flexible example is the randomized encouragement design, in which individuals are randomly assigned to receive encouragement to take up the program [29–31]. Figure 1 depicts the process of randomization, request to participate in the study, informed consent, intervention, follow-up, and analysis according to the randomized encouragement design. In this study, participants assigned to the HBPC group are instructed to engage in longitudinal home visits according to the WISH intervention protocol by social workers. On the other hand, participants assigned to the usual care group are not provided with any specific information about the HBPC program by social workers. Effective encouragement leads to higher take-up of HBPC services in the intervention group than in the usual care group [30]. However, patients and their families have the right to refuse such offers. Patients who are assigned to the intervention group but who do not want or are not willing to pay for HBPC services may receive usual care. Likewise, if patients and their families are assigned to the control group but request to participate in the *Home-Based Medical Center Demonstration* project, HBPC services will be provided for ethical and/or practical reasons. As this is a natural process that occurs in the real world, we will not consider it a protocol violation. Randomized encouragement trials retain the core benefits of traditional RCT while offering considerable flexibility to efficiently meet the unique needs of patients [31].

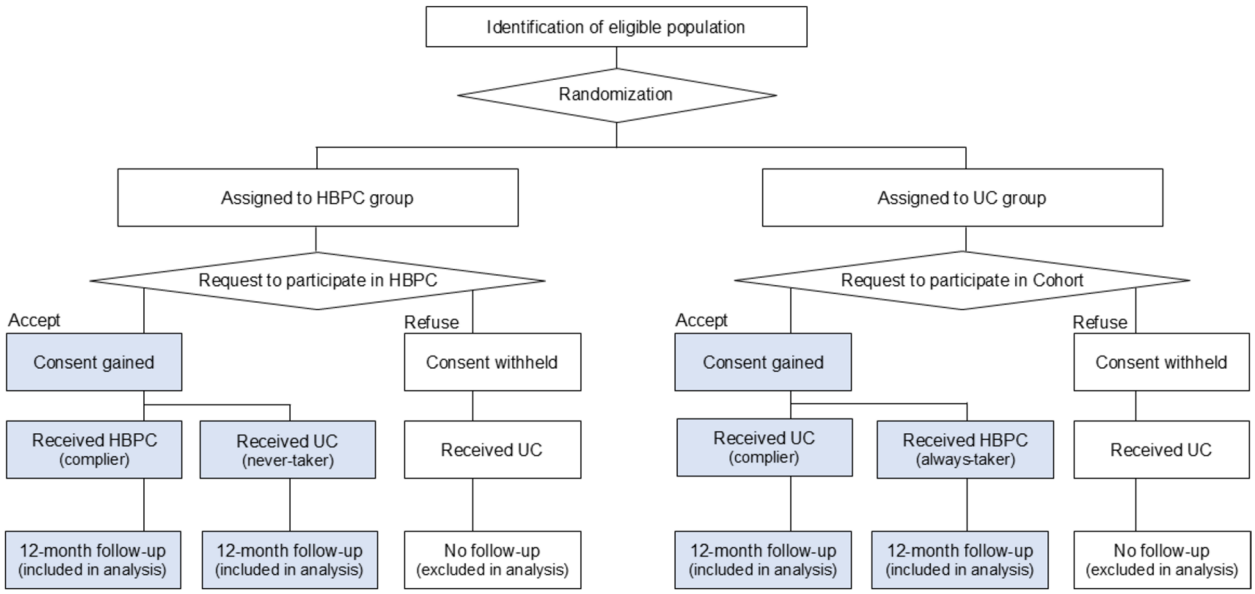

Fig. 1 Design of the randomized encouragement trial. HBPC = home-based primary care, UC = usual care

Informed consent

The post-randomization consent design (Zelen's design) is used [29, 32, 33]. The informed consent process of a traditional clinical trial is not always ethical from the patient's point of view. It is often the case that a proposed trial with a randomized process exhaust patients and detailed explanations may cause psychological difficulties. This can damage the doctor-patient relationship and, in some cases, negatively impact the treatment effect. In this study, by using a double consent design, participants are informed with respect to only the intervention to which they are randomly assigned. In other words, participants assigned to the HBPC group receive solely the information about the HBPC supported by an interprofessional care team without disclosing what type of interventions are provided to the control group. Likewise, participants assigned to the control group are informed only about the usual care that they receive during the trial. Although ethical limitation exists, post-randomization consent design has often applied to questions regarding real-world treatment or intervention effects under conditions of incomplete adherence [29, 33].

Development of the WISH intervention protocol

Study participants are recruited and receive treatment from five HBPC centers located in urban areas. Table 1 summarizes the organizational characteristics of the five centers participating in this study. These centers have

Table 1 Organizational characteristics of HBPC centers (as of January 2023)

Site	Organization Type	Full-time[a] staff making home visits	Part-time staff making home visits	Visits per staff member per day	Other staff involved in care
Northeast Seoul (Gangbuk)	Private clinic	2 Physicians, 3 NPs	-	5 to 7	1 clerk
West Seoul (Mapo)	Private clinic	1 Physician, 2 RN, 1 SW	2 Physician	8 or 9	1 clerk
Paju, Gyeonggi	Private clinic	2 Physicians, 5 NPs, 6 RNs, 2 SWs	1 Physician	8 or 9	2 clerks
Daejeon	Cooperative	1 Physician, 4 NPs, 3 RN, 1 SW(OT)	4 Physicians	3 to 6	-
Wonju, Gangwon	Cooperative	2 NPs, 3 RN, 1 SW	3 Physicians	3 to 6	1 clerk

NP Nurse practitioner, *RN* Registered nurse, *SW* Social worker, *OP* Occupational therapist

[a] Work more than five days per week or make more than 100 home visits per month

already been providing home-based medical care services from the beginning of the pilot project initiated by the Ministry of Health and Welfare in 2019. However, the organizational characteristics of these centers differ, and there are large gaps in how to implement HBPC intervention components. For example, in some centers, nurses play a major role in assessment and intervention as case managers. Another center uses a 24/7 telephone call system and physicians (rather than nurses) to conduct urgent home visits. Four of the centers have social workers that play an active role. Two centers are owned by cooperatives, and three centers are private clinics. These differences are partly due to the prohibition of home-based medical services in South Korea before 2019.

To minimize the heterogeneity of HBPC practices among centers, we developed a WISH protocol to be applied to patients assigned to the HBPC group. Starting in December 2021, all participating HBPC team members were invited to a monthly seminar, conference, or workshop to develop an intervention protocol for the trial. Clinical experts and community leaders willing to share their expertise in HCBS were also invited to the meetings. Through a total of 13 monthly meetings, a series of case conferences was conducted for 40 patients and eight HBPC centers. Finally, we derived a list of the 20 most encountered clinical problems, eight evidence-based intervention components, and several sets of practical strategies. For example, prior to providing effective healthcare services (e.g., CGA, individualized care plan, geriatric syndrome management, caregiver support, transitional care program, urgent house calls), it is important to establish an interprofessional collaborative system at intra- and extra-institutional levels. A creative and challenging approach was needed to find practical solutions to the following issues: How to generate financial revenues? How to keep the influx of homebound patients constant? How to recruit new staff and maintain quality of service? How to facilitate communication among the workforce not in the office? In addition, microsystems for individualized care planning had to be newly designed (e.g., telephone triage, scheduling, interprofessional team meetings, messenger systems, on-call, and 24-h urgent house calls). A practical method to determine major issues of non-physician personnel regarding the 20-problem list (e.g., CGA interpretation toolkit [*WISH Matrix*]) was required. Details of the process to provide interprofessional collaborative services are described in the *HBPC Intervention Guidebook* (Table 2).

HBPC intervention

Each patient is assigned to an interprofessional care team comprising a physician, nurse, and social worker. One

Table 2 Main topics and questions contained in the *WISH Intervention Guidebook*

	Table of Contents	Key Questions
Part 1	Preparing to Implement HBPC Services • Building an interprofessional care team • Building a supervision and training program • Establishing a community network with local partners	• How to generate financial revenue? • How to recruit new staff and maintain quality of service? • How can we keep the influx of homebound patients constant? • How to make agreements and cooperate with local partners?
Part 2	Patient Registration and Initial Assessment • Pre-enrollment home visits and triage phone calls • Steps after making a home visit •24/7 telephone counseling and urgent house calls	• What to say on the first phone call with a patient/family? • How to schedule multiple personnel? • How to prescribe a drug out of the office? • How to provide after-hour support per patient/family request?
Part 3	Patient-Centered Interview Skills • Setting goals for intervention • Interview skills and shared decision-making	• Why are patients admitted to LTC facilities? • What can be done to prevent LTC facility admission? • How to build trust with the patient/family?
Part 4	CGA and Individualized Care Planning • Performing CGA • Holding regular interprofessional care meetings • Prioritizing main issues among the 20 problem lists	• How to perform CGA according to the official guidelines? • How to facilitate communication among those in the workforce not in the office? • How to interpret CGA and design individualized care plans? • How to detect dynamic changes in intrinsic capacity?
Part 5	Geriatric Syndrome and Caregiver Burden • Polypharmacy and deprescribing • Poor oral intake and nutritional supplementation • Frailty management and rehabilitation techniques • Sleep disorders and depression • Behavioral psychological symptoms of dementia • Symptom management: pain, incontinence • Caregiver stress and family counseling • Hospital-at-home: intravenous fluid therapy • Skilled nursing care: pressure sores, tube management • End-of-life stage: palliative care and ethical issues	• How can we reduce the symptom burden experienced by the patient? • How can we reduce the caregiver burden experienced by the family?

WISH Widely Integrated Services in Home, *HBPC* Home-Based Primary Care

person designated as a case manager through an interprofessional care meeting conducts home visits at least once a month to provide healthcare and family counseling services. The care team schedules the initial home visit within one week after study enrollment. During the first, second, and third home visits, the team performs a CGA to generate clinical and psychosocial problem lists and establish individualized care plans. The CGA is reassessed every six months during the trial. The case manager shares the care plans and collaborative intervention strategies at interprofessional team meetings. With the patient's permission, the meetings are open to HCBS workers (e.g., home-helpers, and social workers) who are community partners within the NLTCI system.

Since all study participants are recruited from among NLTCI recipients, the type, intensity, and amount of HCBS are the same as those of the usual care group. However, there are six differences between the intervention and usual care groups:

1) Pilot Project Registration: The intervention group is invited to register as a participant in the *Home-Based Medical Center Demonstration* project. At the time of registration, they are required to pay out-of-pocket for the new bundle.
2) Interventionists: the program is offered by an interprofessional care team consisting of at least three workers (i.e., physician, nurse, and social worker).
3) Total number and duration of home visits: At least 12 home visits are made during the intervention period for this group. However, due to the minimal requirement presented by the Ministry of Health and Welfare (*Home-Based Medical Center Demonstration* project), it is expected that more than 36 home visits per year (at least 12 and 24 home visits per year by a physician and nurse, respectively) are performed for the HBPC group if there are no dropouts. The length of stay at a patient's home ranges between 20–40 min per visit.
4) Individualized care planning using the *WISH Matrix*: The case manager (may not be the physician) performs the CGA to identify major issues to reduce symptoms and caregiver burden from a list of 20 problems (Fig. 2). Figure 3 is a CGA interpretation toolkit developed by the research team to help with this. Using the *WISH Matrix*, the case manager can easily prioritize problems and set discussion topics for interprofessional care meetings.
5) Trained workers provide healthcare services (e.g., medical treatment, nutritional counseling, physiotherapy, drug management, mental health support, wound care, self-management education) and/or social services (e.g., linkage to personal care, adult protective services) for 12 months according to the individualized care plan.
6) Specially designed program to prevent institutionalization (optional): The following interventions are considered to have a more direct effect on the prevention of LTC facility admission but require relatively more resources for practical implementation: (1) interagency care team meetings involving HBPC and HCBS workers; (2) transitional care program involving HBPC and local partner hospitals; and (3) after-hour telephone counseling or urgent house call services. These interventions can be selectively implemented according to the circumstances of the HBPC center.

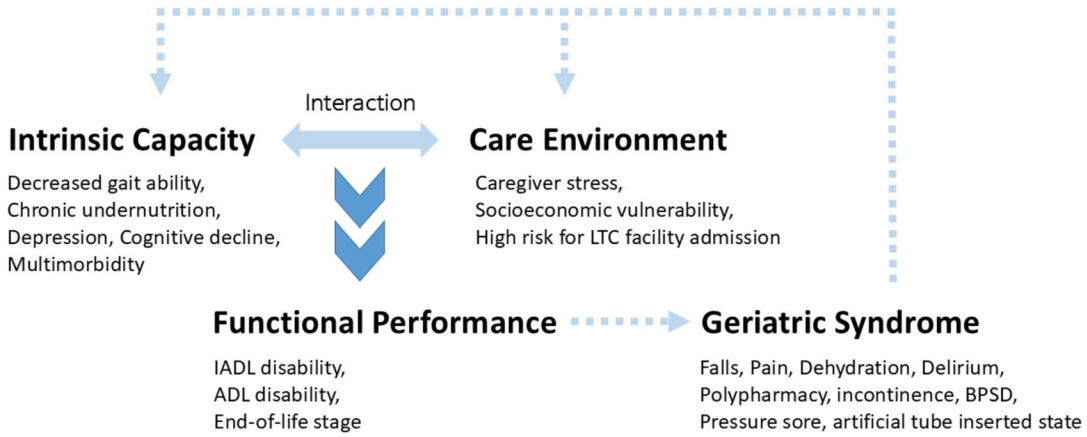

Fig. 2 The list of 20 problems and their interactive relationships. These problems are grouped into four areas: 1) intrinsic capacity; 2) care environment; 3) functional performance; and 4) geriatric syndrome. An individual's functional performance is determined by the interaction between intrinsic capacity and care environment. Accordingly, different types of geriatric syndromes will be identified. Geriatric syndromes can affect intrinsic capacity and care environment, which are then iterated to reform functional performance

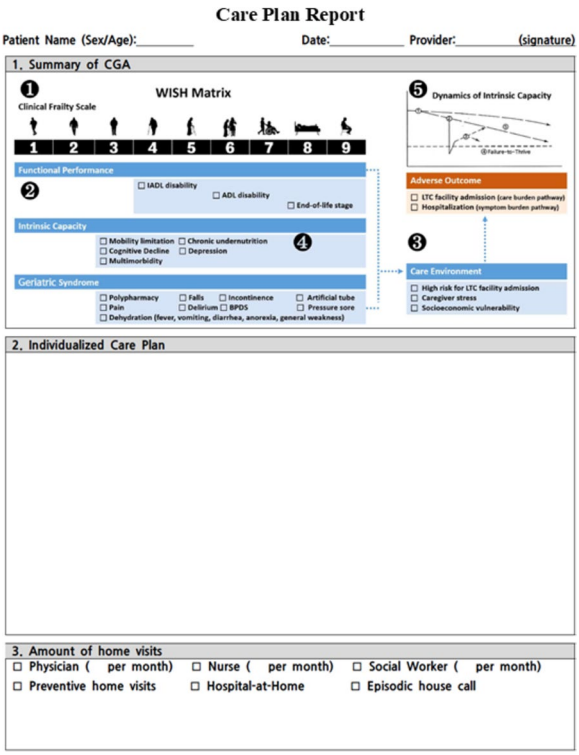

Fig. 3 WISH Matrix: CGA interpretation toolkit. Sequential assessment in the following order will help create individualized care plans for older adults with complex needs: (1) evaluate overall functional status according to the CFS; (2) identify the key items among the list of 20 problems that exacerbate symptomatic burden; (3) identify the key items that exacerbate caregiver burden; (4) hypothesize plausible pathways by which the patient will be admitted to an LTC facility; (5) reconsider the patient's condition based on their intrinsic capacity; (6) derive effective strategies to solve major issues and set the number of home visits. The 'Dynamics of Intrinsic Capacity' diagram is from Buchner and Wagner [34]

Usual care

Participants assigned to the control group receive any type of medical service available in the community along with episodic house call services from the HBPC center as requested. However, they are not informed of or recommended to participate in the *Home-Based Medical Center Demonstration* project although they can request participation. In addition to the usual care, a research coordinator from the research center performs home visits every six months to provide health literacy and basic information related to effective strategies for health promotion and disease prevention.

Outcome measures

Primary outcomes of the trial are 1) between-group community survival days (i.e., time from the date of random allocation to admission to an LTC facility or LTC hospital), 2) between-group potentially avoidable hospitalizations (i.e., inpatient days in an acute care hospital) and 3) between-group dying at home. A Korean version of the ambulatory care-sensitive condition is used to identify potentially avoidable hospitalizations for epilepsy, seizure, severe otitis media, chronic obstructive pulmonary disease, asthma, pneumonia, congestive heart failure, acute pulmonary edema, ischemic heart disease, cellulitis, diabetes mellitus, gastritis, urinary tract infection [35]. Primary outcome variables are collected from a merged data set that links the personally identifiable information of each patient to the National Health Insurance Service database. South Korea operates a unified national health and long-term care insurance system, and all citizen use of outpatient clinics, emergency departments, hospitals, LTC facilities, and death is recorded in this national database. Hospitals in South Korea are largely divided into acute care and LTC hospitals. There are almost no sub-acute care units available. Therefore, it is very common for severely frail older adults who have completed treatment in an acute hospital but who have not sufficiently recovered to go home to be transferred to an LTC hospital for a stay longer than 90 days. LTC facilities are similar to nursing homes or assisted living facilities in the United States, in which the bedridden older person can reside for longer periods of time. Although there are no exact statistics, discharges from LTC facilities home are very rare, and patients often remain in the LTCs until the end of their lives.

Baseline and follow-up assessments for secondary outcomes are conducted by the research coordinator at 0 (baseline), 6, and 12 months. Regardless of adherence to the intervention program, the outcome assessor visits all possible study participants except those that withdraw consent or decline to respond to the assessment. In this study, one researcher (E.Y.), who has no role in the interventions performs baseline and follow-up assessments throughout the study period. This researcher is not offered any information about treatment allocation. Secondary outcomes are as follows: (1) emergency department visit rate; (2) unplanned readmissions within 30 days of discharge; (3) use of outpatient services; (4) annual health and LTC spending (National Health Insurance Service merged database); (5) reductions in symptom burden (Korean version of the Edmonton Symptom Assessment Scale); (6) reductions in primary caregiver burden (Stressful Situation Questionnaire); (7) patient satisfaction and quality of care service (modified version of SERVQUAL); (8) healthcare service provider acceptance index; and (9) changes in functional status and clinical condition (Charlson Comorbidity Index, Activities of Daily Living, Instrumental Activities of Daily Living, Geriatric Depression Scale, Korean Dementia Screening

Questionnaire, Mini-Nutritional Status, Clinical Frailty Scale, Practitioner Assessment of Network Type).

Independent variables

The number of home visits (i.e., the total number of home visits, length of stay at the patient's home, type of interventionist, and after-hour visits) provided by HBPC workers are calculated for both the HBPC group and the usual care group. In this study, which is conducted in a real-world setting, the control group is allowed to receive partial interventions (e.g., episodic house calls, longitudinal home visits per patient's request) from the HBPC interprofessional care team for ethical and practical reasons. In addition, although assigned to the intervention group, some patients are not able to receive longitudinal home visits for various reasons (e.g., affordability, satisfaction with outpatient services, safety concerns). Based on this information, a continuous variable of compliance (i.e., HBPC engagement) is constructed.

Demographic variables of age, gender, LTC grade, marital status, level of education, household income, and health insurance status are collected. Social variables are the number of household members, household composition, primary caregiver's level of education, hours spent with the primary caregiver, hours home alone, current HCBS hours, and type of HCBS (i.e., in-home help, adult day care, in-home bathing, visiting nurse, short-term respite care, or welfare equipment service). Healthcare utilization variables to be collected at 0 (baseline) and the prior 12 months (pre-intervention) are as follows: 1) numbers of acute care hospital admissions and emergency department visits; 2) number and length of stay at LTC institutions; 3) longitudinal medical care by a designated primary care physician; 4) number of primary care physicians and specialists who prescribe medications and provide evaluation and management; 5) number of prescriptions using proxy access; 6) average transportation methods and hours of visits to outpatient clinics; and 8) average duration of time for each patient-doctor encounter.

Sample size and power calculation

The sample size is based on the results of two previous experimental studies conducted in the United States and an interim analysis of our study conducted on May 4, 2023 [11, 36]. In a single-arm before-and-after study (n = 179), 63 patients had received at least one nursing facility stay before enrollment, compared with 33 patients after enrollment (relative change -47.6%). Although both the eligibility criteria and contents of the intervention are different from those of our study, the effect size can be assumed to be 40% (based on the conservative assumption that the LTC facility admission rate does not change over 12 months among the usual care group). However, according to the results of our interim analysis, 13.7% of the initially recruited control group actually received HBPC intervention due to ethical and/or practical reasons. Accordingly, the estimated effect size reflecting the contamination effect is 35% (= 0.40 x [1–0.137]). In addition, the proportion of subjects who refused to participate in our study after randomization was as high as 18% based on our interim analysis. This is not entirely surprising in the HBPC field. In a previous randomized controlled trial (n = 229), 39 patients (of 115 in the HBPC group) never received a home visit even after completing informed consent (33.9%) and the dropout rate at six months was 13.2%. Based on these results, the inflation rate due to attrition is likely to be around 40% (= [1–0.18] x [1–0.34] x [1–0.13 × 2]). The minimum number of participants required per group was calculated to be 300 (80% power, 5% alpha, two-tailed, two-sample t-test, calculated using G*Power software).

Data analyses

Results of the treatment are estimated by both modified intention-to-treat (ITT) and complier average causal effect (CACE) analytic methods. Absolute differences in outcome variables (i.e., after – before) are compared between the HBPC and usual care groups using the Chi-square, independent t-test, or Wilcoxon rank-sum test as appropriate. Kaplan–Meier methods and the log-rank test are used to compare community survival days between the two groups. To avoid the methodological issue of data censoring, we use Weibull regression with robust variance estimated in both the proportional hazards model and the accelerated failure time model to determine the hazard ratio (HR), time ratio (TR), and their 95% confidence intervals. Our interpretation of the HR is as follows: if the HR is less than 1, the intervention is associated with a lower risk of LTC facility admission; if the HR is greater than 1, there is a greater risk of LTC facility admission. We interpret a TR > 1 to indicate that the intervention is associated with a longer time until LTC facility admission and a TR < 1 to indicate the converse. We also address the ancillary parameters of the Weibull models to estimate the hazard function over time.

Although our study is designed to estimate unbiased treatment effects through random assignment, it is difficult to avoid methodological issues related to attrition bias. Theoretically, if one or more dropouts occur for any reason, randomization cannot be assumed. We expect dropout to occur in two situations: (1) when consents are successfully obtained and two or more home visits are performed but there is a failure to follow up (e.g., death, moving out, unable to contact) and (2)

when randomization is completed but the consent is not obtained. As we collect the primary outcome variables of all study participants through linkage to administrative data, we do not anticipate the first situation to not be an issue in our study. We collect variables such as LTC facility admission, hospitalization, dying at home, medical service utilization, and healthcare expenses from all subjects regardless of group assignment or adherence. However, the attrition bias for the second situation is essentially uncontrollable. If such cases occur below 15%, we will apply the modified ITT method and adhere to the 'analyze as assigned' principle. However, since our study is based on a post-randomization consent design, there is a high possibility that a number of the second situations will occur. If there are cases in which older adults are assigned to the control group but refuse to participate in the study because their health is too poor, or if older adults are assigned to the intervention group but refuse to participate in the study because their health is relatively good, selection bias will be present and the treatment effect could be underestimated.

To address this issue, we will use the CACE analytic methods, which is the average impact of an intervention on those who comply with their treatment assignment [37, 38]. In a real-world setting, the number of home visits follow a complex decision-making process among the HBPC team, patient, family caregivers, HCBS workers, and even NLTCI policymakers. Therefore, according to Angrist and his colleagues, study participants can be classified as (1) compliers, (2) always-takers, (3) never-takers, or (4) defiers. Participants assigned to the intervention group will have a greater opportunity to engage with HBPC services than those in the control group. If we find a variable that has an independent effect on the number of home visits and does not affect the outcome variable at all, its unbiased treatment effect can be estimated using the instrumental variable (IV) method. Random sequences generated by a third party would represent a perfect IV. Moreover, according to Zelen's design, study participants are unaware of the existence of a comparison group, so the possibility that randomization itself affects the outcome variable will be lower (exclusion restriction). The use of an IV estimator to estimate CACE parameters in parallel-arm randomized controlled trials has been well described [31, 39–41]. In this study, we will estimate the CACE by applying an IV additive hazard model for censored time-to-event data. Assuming linear structural equation models for the hazard function and the additional assumption of a constant hazard difference, we will use a two-stage estimator for the causal effect in the additive hazard model to obtain a valid estimate of the treatment effect of interest [42, 43]. The IV Poisson model will be used for discrete variables (e.g., inpatient days) with the two-stage least squares estimator. Consideration of ITT and CACE analyses will provide a more complete understanding of the effects of the interventions [41].

Research ethics approval

The study protocol was approved by the Institutional Review Board (IRB) of Chung-Ang University (approval No. 1041078–202206-HR-156) and was registered in the Clinical Research Information System of the Korean Center for Disease Control and Prevention (CRIS registration No. KCT0007921). Subsequent to initial review and approval, the IRB reviews the protocol annually and the researchers provide safety and progress reports to the IRB. Two written informed consent forms are obtained from all participants prior to the baseline assessment. To uphold high standards of research, all researchers, research coordinators, and research assistants completed the research certification for Korean Good Clinical Practice. Additionally, all HBPC team members completed a training workshop regarding the trial procedures. We conducted an interim analysis in May 2023, five months after the initiation of recruitment, and held a statistical advisory meeting to recalculate the sample size.

Discussion

This study protocol evaluates whether the risk of LTC facility admission and acute hospitalization can be reduced by providing HBPC services to homebound older adults who receive HCBS. Although current research evidence suggests that HBPC services are effective, there are many unanswered questions: (1) For which outcome indicators are HBPC interventions effective? (2) Are there patient or organizational characteristics for which HBPC interventions are more effective?, and (3) Through which mechanism(s) does HBPC produce beneficial effects? Regarding the first of these questions, a number of studies have reported that HBPC reduces a number of acute hospitalizations and emergency department visits as well as healthcare costs. However, few high-quality prospectively designed studies have been performed. To our knowledge, only three randomized controlled trials have evaluated the effectiveness of HBPC interventions, and the most recently published randomized controlled trial was prematurely discontinued due to ethical concerns regarding patient safety. This suggests major difficulties in generating high-quality evidence in a community-oriented geriatric research setting [19].

Preventing LTC facility admission is an important outcome indicator to realize the policy goal of Aging-in-Place but has been relatively neglected in HBPC studies. However, some authors have emphasized the importance of integrating medical and social care through the introduction of HBPC services [44]. Valluru and his colleagues

conducted a case-cohort study at three Independence at Home Demonstration sites in the United States (Philadelphia, Richmond, Washington, D.C.), where HBPC and HCBS have long been used in collaboration to help homebound older adults. In these regions, HBPC centers integrate HBPC and HCBS through interagency interdisciplinary team meetings or assigning social workers at HBPC centers more active roles as case managers. Despite the methodological limitation of a retrospectively designed study, the HBPC interventions at the three centers extended the average community residence period by 12.8 months. Integration of medical and social care in homebound older adults could optimize results by offering the appropriate mix of services to the right target population to achieve the desired outcome [18].

In this study, we adapted an HBPC model initiated in the United States to the policy environment of South Korea. To this end, we developed a WISH intervention protocol as a practical diffusion strategy. All eight intervention components are included here, reflecting the latest research trends in HBPC; however, some components were classified as non-essential due to resource constraints. Nevertheless, we made success in including most of the contents (i.e., intervention components 1 to 5) in the official guidelines of *the Home-Based Medical Center Demonstration* project announced by the Ministry of Health and Welfare in South Korea. Primary care clinics and public hospitals that have provided a certain number of home visits over the previous year can participate in the demonstration project if they have submitted a plan to create a new interprofessional team (at least one physician, nurse, and social worker). Then, they can receive additional bundle benefits from the NLTCI by providing longitudinal home visits to Grade 1–4 LTC recipients.

Here, "widely integrated" emphasizes integration at the macro-, meso-, and micro-levels. First, integration at the macro-level implies financial integration between the National Health Insurance and NLTCI system. Since only LTC recipients can benefit from the program, a new bundle payment was designed to be paid from NLTCI funds. In other words, HBPC centers can claim a certain allocation from both the National Health Insurance and NLTCI. Integration at the meso-level implies service integration of HBPC and HCBS. Social workers that belong to HBPC centers should communicate closely with HCBS staff, and mutual referrals must be made according to the needs of homebound older adults and their families. In addition, during patient recruitment, certain agreements must be made between the NLTCI corporation and HBPC centers. For example, it is desirable to set up a screening procedure to recruit HBPC patients during the official process of entering the NLTCI system, where certification grades are determined to receive LTC services. Integration at the micro-level implies interprofessional collaboration among HBPC physicians, nurses, and social workers. In HBPC settings, certain diagnostic and prescribing authorities of physicians should be delegated to other professionals. This can be successfully achieved by visiting the patient's home altogether or holding periodic interprofessional team meetings. Furthermore, knowledge and skills regarding caring for patients must be shared through appropriate supervision or training programs. In this way, 'WISH for homebound older adults' can contribute to the policy goal of Aging-in-Place through 'the right service to the right people in the right way.'

This study may have limitations in terms of acceptability. Although physicians, nurses, and social workers employed by the five HBPC centers participated in the protocol development process along with researchers, it is difficult to predict how well this protocol will function in real-world settings. Field experience with HBPC in South Korea is limited, and HBPC staff may be overloaded or uncertain at the beginning of the demonstration project. There are also methodological issues. In the process of sample size calculation, we could not find any local data to reference. The number of study subjects may be too small to verify the effectiveness of the interventions. In addition, it will be hard to confirm external and internal validity. Despite these limitations, we describe a community-based, multicenter, pragmatic, randomized encouragement trial protocol to verify the effectiveness of HBPC. In terms of originality, robustness, and practicality, this study has both academic and political implications. All difficulties that arise during the research period will be documented for consideration in future research. In addition, if HBPC is effective, this finding can be used as important policy leverage to expand home-based medical centers in South Korea.

Abbreviations

HBPC	Home-Based Primary Care
LTC	Long-term Care
HCBS	Home and Community-Based Service
CGA	Comprehensive Geriatric Assessment
NLTCI	National Long-Term Care Insurance
WISH	Widely Integrated Services in Home
RCT	Randomized Clinical Trial
CFS	Clinical Frailty Scale
ITT	Intention-to-treat
HR	Hazard Ratio
TR	Time Ratio
CACE	Complier Average Causal Effect
IV	Instrumental Variable
IRB	Institutional Review Board

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Authors' contributions
C.K.: study concept, design, protocol development, statistical design, interpretation of data, and preparation of manuscript. T.L.: study design and preparation of manuscript. A.C.: protocol development, data collection, data analysis, and project management. E.C.: protocol development, data collection, data analysis, and project management. H.K.: protocol development, data collection, data analysis, and project management. J.L.: study design and preparation of manuscript. J.H.: protocol development and directing an intervention. D.S.: protocol development and directing an intervention. H.J.: protocol development and directing an intervention. J.P: protocol development and directing an intervention. J.K.: protocol development and directing an intervention. H.L.: protocol development and revising of the manuscript. S.J.: interpretation of data and revising of the manuscript.

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Data availability
The survey and dataset analyzed in the current study are not publicly available. Please contact the corresponding author for specific requests.

Declarations

Ethics approval and consent to participate
This study was approved by the IRB for human subjects at Chung-Ang University, Seoul, South Korea (approval No. 1041078–202206-HR-156). Informed consent has been obtained from all study participants.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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