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Effects of a visiting nursing care program for improving the frailty of vulnerable older populations

Submission date 23/12/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 06/01/2025	**Overall study status** Ongoing	
Last Edited 07/07/2025	**Condition category** Other	

Plain English summary of protocol

Background and study aims

The aging population, particularly vulnerable elderly individuals, is growing rapidly, with this group facing higher rates of physical disability and multimorbidity. Frailty, which affects over half of the elderly population (including pre-frail individuals), leads to adverse health outcomes such as functional decline, falls, institutionalization, and increased mortality. However, frailty is preventable and potentially reversible, highlighting the need for effective community-based preventive strategies.

While initiatives like the visiting health management program have attempted to address frailty through case management, resource limitations and a lack of standardized interventions have restricted its impact. Furthermore, evidence from randomized controlled trials (RCTs) on its effectiveness is lacking. To address these gaps, this study aims to evaluate the effectiveness of the NurVisitCare Program, a tailored case management intervention for frail older adults, through a rigorous RCT design.

Who can participate?

1. Phase 1: the development of NurVisitCare

The number of research subjects is 16 visiting nurses and 18 frail elderly people in the first stage.

- Visiting nurses: study participants will include 16 visiting nurses who are currently working as visiting nurses.
- Frail elderly: study participants will include 18 community-dwelling elderly individuals aged 65 to 84 years who are living alone and participating in public health center programs. Eligible participants will be those classified as at-risk frail elderly (pre-frail, scoring 4–12 points) based on the Frailty Screening Questionnaire for Older Adults at Public health centers.

2. Phase 2: the effectiveness evaluation of NurVisitCare

- Study participants will include 50 community-dwelling elderly individuals aged 65 to 84 years who are participating in public health center programs. Eligible participants will be those classified as at-risk frail elderly (pre-frail, scoring 4–12 points) based on the Frailty Screening Questionnaire for Older Adults at Public health centers.

What does the study involve?
The study will be conducted in two phases. In Phase 1, the NurVisitCare program will be developed through FGI, and in Phase 2, the effectiveness of the NurVisitCare program will be evaluated. Study participants in the NurVisitCare program will be randomly assigned to either a control or intervention group. The NurVisitCare program, a 12-week intervention for at-risk frail elderly, includes eight 60-90 minute home visits (or 30 minute telephone consultation) focused on health education (e.g., chronic disease prevention, nutritional guidance) and tailored physical activity (e.g., stretching, strength training). The intervention group receives the program, while the control group receives standard home health care services. Both groups complete pre- and post-surveys via face-to-face visits, including questionnaires and physical measurements to assess outcomes.

What are the possible benefits and risks of participating?
Participants in both the intervention and control groups will benefit from gaining insight into their overall health status and frailty levels through self-reported questionnaires and physical measurements. The intervention group will also participate in the “NurVisitCare Program” for three months, a specialized program designed to prevent frailty by focusing on case management for frail older adults, offering a more tailored approach than standard visiting healthcare programs. All participants will receive incentives based on their level of participation. While participants may experience some physical or psychological discomfort during questionnaires and body measurements, they will be fully informed of any potential inconveniences beforehand. Flexibility in scheduling and assurance of voluntary participation will be emphasized to minimize discomfort or pressure.

Where is the study run from?
College of Nursing, Korea University

When is the study starting and how long is it expected to run for?
The study is scheduled to run from May 2024 to December 2025.

1. Phase 1: May 2024 to March 2025 (Recruitment in January 2025)
2. Phase 2: June 2025 to December 2025 (Recruitment in July 2025)

Who is funding the study?
National Research Foundation of Korea (NRF) grant from the Ministry of Science and ICT, Korean Government (No. RS-2024-00336847).

Who is the main contact?
Jina Choo, PhD, DrPH, RN, jinachoo@korea.ac.kr

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
RS-2024-00336847, IRB-2024-0307

Study information

Scientific Title
Effects of a visiting nursing care program for improving the frailty of vulnerable older populations

Acronym
NurVisitCare study

Study objectives
Current study objectives as of 07/07/2025:
1. The intervention group would have greater improvement in frailty indicators than the control group among the elderly population with frailty risk.
2. The intervention group would have greater improvement in frailty-related outcomes (i.e., physical performance, nutritional status, psychological distress, loneliness, social support, self-care for frailty, and quality of life) than the control group among the elderly population with frailty risk.

Previous study objectives:
1. The intervention group would have greater improvement in frailty indicators than the control group among the elderly population with frailty risk.
2. The intervention group would have greater improvement in frailty-related outcomes (i.e., disease self-management, depression, social support, quality of life, and loneliness) than the control group among the elderly population with frailty risk.

Ethics approval required
Ethics approval required

Ethics approval(s)
Submitted 23/12/2024, Korea University Institutional Review Board (Korea University Research Center, Anam-dong, Seongbuk-gu, Seoul, 02841, Korea, South; +82-02-3290-1137; kuirb@korea.ac.kr), ref: KUIRB-2024-0501-01

Study design
Phase 1: Focus group interview
Phase 2: Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Frailty prevention among community-dwelling elderly population with frailty risk

Interventions
Current interventions as of 07/07/2025:
The intervention period is 12 weeks. The procedure consists of a pre-test, an intervention, and a post-test.
1. Pre-testing is conducted on frail elderly participants. Pre-testing is administered face-to-face to both the control and intervention groups. Pre-testing includes measurements of weight, height, and grip strength.
2. The NurVisitCare intervention will last 12 weeks. The control group will receive regular home health care as usual. The intervention group will receive a total of 8 'NurVisitCare programs' for frail elderly people over 12 weeks. Four sessions will be 60-90 minutes of home visits and four sessions will be 30 minutes of telephone consultations, and the number of visits will be flexibly adjusted up to 8 sessions depending on the condition of the participants. The contents of the "NurVisitCare program" are as follows. Each home visiting session is 60-90 minutes long and is divided into customized health education (30-60 minutes) and physical activity sessions (30 minutes). Customized health education provides an integrated educational program that includes education and practice to prevent the physical, psychological and social aspects of frailty. Physical activity session consists of stretching, simple strength training, and functional walking exercises that frail elderly people can practice indoors and minimize physical burden and risk. All exercises are individually tailored after a preliminary assessment of the participant's physical condition.
3. The post-test is conducted in the same manner as the pre-test, and includes a face-to-face survey and measurements of weight, height, and grip strength.

For the Phase 2 intervention involving 50 participants, the randomization procedure in SPSS software will be used to allocate participants into the intervention group and control group in a 1:1 ratio. Randomization will be stratified by the severity of health status according to the criteria of visiting nurses at public health centers in Korea.
Phase 1, as it involves only Focus Group Interviews (FGI), randomization of participants will not be conducted.

Previous interventions:
The intervention period is 12 weeks. The procedure consists of a pre-test, an intervention, and a post-test.
1. Pre-testing is conducted on frail elderly participants. Pre-testing is applied to both control and intervention groups and is conducted through face-to-face home visits. Pre-testing includes weight measurements.
2. The NurVisitCare intervention will last 12 weeks. The control group will receive regular home health care as usual. The intervention group will receive a total of 8 'NurVisitCare programs' for frail elderly people over 12 weeks. The contents of the "NurVisitCare program" are as follows. Each session is 60 minutes long and is divided into customized health management education (30 minutes) and physical activity sessions (30 minutes). Customized health management education provides an integrated education program that includes chronic disease prevention methods, health management, and nutritional management to prevent frailty. Physical activity consists of stretching, simple strength training, and functional walking exercises that frail elderly people can practice indoors and minimize physical burden and risk. All exercises are individually tailored after a preliminary assessment of the subject's physical condition.
3. The post-test is conducted in the same way as the pre-test and involves a face-to-face visit to conduct a questionnaire and weight measurements.

For the Phase 2 intervention involving 50 participants, the randomization procedure in SPSS software will be used to allocate participants into the intervention group and control group in a 1:1 ratio. Randomization will be stratified by gender and age group (young-old: 65–74 years, middle-old: 75–84 years).
Phase 1, as it involves only Focus Group Interviews (FGI), randomization of participants will not be conducted.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measure as of 07/07/2025:
Frailty indicators, as measured by the Tilburg Frailty Indicator, at pre- and post-intervention (baseline and 12 weeks)

Previous primary outcome measure:
Frailty indicators, as measured by the Kihon Checklist and Tilburg Frailty Indicator, at pre- and post-intervention (baseline and 12 weeks)

Secondary outcome measures
Current secondary outcome measure as of 07/07/2025:
Pre- and post-intervention (baseline and 12 weeks) measurements:
1. Physical performance, nutritional status, psychological distress, loneliness, social support, self-care for frailty, and quality of life (assessed via self-report questionnaire)
2. Body mass index, grip strength (assessed via physical assessment)

Previous secondary outcome measure:
Pre- and post-intervention (baseline and 12 weeks) measurements:
1. Self-management of chronic diseases, depression, social support, quality of life, loneliness (assessed via self-report questionnaire)
2. Nutritional status assessed through body mass index measurement

Overall study start date
01/05/2024

Completion date
31/12/2025

Eligibility

Key inclusion criteria
Phase 1: the development of NurVisitCare
1. Visiting nurse:
1.1. A nurse currently working as a visiting nurse
2. Frail elderly:
2.1. Elderly living alone aged 65 or older and under 84 years old
2.2. Elderly participating in public health center programs
2.3. Elderly classified as at-risk frail elderly (pre-frail, 4-7 points) in the Kihon Checklist

Phase 2: the effectiveness evaluation of NurVisitCare
1. Elderly living alone aged 65 or older and under 84 years old
2. Elderly participating in public health center programs
3. Elderly classified as at-risk frail elderly (pre-frail, 4-7 points) in the Kihon Checklist

Participant type(s)
Health professional, Resident

Age group
Senior

Lower age limit
65 Years

Upper age limit
84 Years

Sex
Both

Target number of participants
84

Key exclusion criteria
Phase 1: the development of NurVisitCare
1. Visiting nurse
1.1. A nurse who has not worked as a visiting nurse for more than one year

2. Frail elderly
2.1. Elderly with severe cognitive impairment
2.2. Elderly with diseases that make it difficult to understand information and participate in education (including visual and hearing impairments)
2.3. Elderly diagnosed with osteoporosis or osteoarthritis by a doctor
2.4. Elderly who experienced a fall in the past year

Phase 2: the effectiveness evaluation of NurVisitCare
1. Elderly with severe cognitive impairment
2. Elderly with diseases that make it difficult to understand information and participate in education (including visual and hearing impairments)
3. Elderly diagnosed with osteoporosis or osteoarthritis by a doctor
4. Elderly who experienced a fall in the past year

Date of first enrolment
08/01/2025

Date of final enrolment
31/07/2025

Locations

Countries of recruitment
Korea, South

Study participating centre
College of Nursing, Korea University
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Sponsor information

Organisation
Korea University

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Sponsor type
University/education

Website
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ROR
https://ror.org/047dqcg40

Funder(s)

Funder type
Government

Funder Name
National Research Foundation of Korea

Alternative Name(s)
, National Research Foundation (South Korea), NRF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Korea, South

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
01/02/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the principal investigator (PI), Jina Choo, PhD, DrPH, RN (jinachoo@korea.ac.kr) when the PI decides to publicize the data. As of now, it is not possible to specify a specific time.

IPD sharing plan summary
Available on request