HWePS study: evaluation of an integrated community-based health and wellness program for seniors

Submission date	Recruitment status	[X] Prospectively registered
30/08/2021	No longer recruiting	[X] Protocol
Registration date	Overall study status	Statistical analysis plan
02/09/2021	Completed	Results
Last Edited	Condition category	Individual participant data
09/01/2023	Other	[] Record updated in last year

Plain English summary of protocol

Background and study aims

Healthy aging is a critical public health agenda in countries with aging populations, but few studies have addressed unequal individual and community capacities to achieve healthy aging in place. Another gap in the literature is that healthy-aging interventions often focus on changes in health behaviors at the individual level only, in spite of the well-known impacts of social determinants on health. To address such gaps, we developed a theory-based, technology-enhanced integrated health equity intervention that aims to promote the health and wellness of older people in an urban, low-income community in Seoul, South Korea, which is expected to become a super-aged society by 2025. This small-area public-health equity study is being conducted during the COVID-19 pandemic, which has caused most health community and social welfare centers to close and suspend their face-to-face group programs.

Who can participate?

Older adults and community lay health leaders trained as peer-supporters in the community

What does the study involve?

This intervention is a health and wellness program for older people in a low-income community and aims to promote health equity. Older people residing in an urban, low-income community will participate in the study. A three-level health promotion and wellness intervention (Level 1: health-information provision, Level 2: care management, and Level 3: building a healthy community by addressing systemic causes of health inequality) will be sequentially rolled out in the smaller areas (tongs) in the intervention area (dong) over three periods, to which tongs will be assigned in random order. Older adults in matched tongs in the control dong will receive usual care plus the individual-level health-information intervention only.

A three-level intervention will be delivered to the intervention area: the delivery of health information via SNS or postal mail as well as decision-support tools for lay leaders and care teams (Level 1: health-literacy components); tailored nurse-led multidisciplinary care management aiming to improve self-care capabilities, strengthened by support from peers as well as trained community lay health leaders (Level 2: the individual level); and addressing health-related social needs by matching relevant and preferred community programs that have

developed activities to build a healthy aging community (Level 3: the community level). Levels 1 and 3 will be ongoing throughout the entire intervention period, and Level 2 will be sequentially rolled out to tongs as described.

Data will be collected before enrollment and 3 and also 6 months (intervention area only) after enrollment. A community-wide health survey will be conducted at the end of the entire intervention period.

What are the possible benefits and risks of participating?

There may be no direct benefits from study participation, but study participants will contribute to a better understanding of whether this new multilevel health-equity intervention targeting older people in low-income small-area communities can improve quality of life, self-rated health, self-efficacy, and technology acceptance; prevent frailty in older people; and develop/empower community lay health leaders as well as interdisciplinary care teams in urban, low-income communities. There are no known risks associated with participation.

Where is the study run from? Two areas in the Jungnang-gu (district), Seoul, in the Republic of Korea

When is the study starting and how long is it expected to run for? September 2020 to December 2022.

Who is funding the study?
The Korea Disease Control and Prevention Agency (KDCA) and the Seoul Metropolitan Government, Republic of Korea

Who is the main contact? Prof. Dr. Hongsoo Kim hk65@snu.ac.kr

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Effectiveness of a technology-enhanced integrated health and wellness program for seniors in urban, low-income communities: a non-randomized controlled cluster trial

Acronym

HWePS

Study objectives

The principal study question is whether an integrated health and wellness program for seniors (HWePS), a theory-guided, technology-enhanced, health equity intervention model, as compared to usual+ care, will improve the health and quality of life of older adults residing in an urban, low-income community.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 06/11/2020, Seoul National University (1 Gwanak-ro, Gwanak-gu, Seoul, 08826, S. Korea; +82 28805153; irb@snu.ac.kr), ref: 2011/002-016

Study design

Interventional non-randomized

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Promotion of health and wellness of relatively healthy and/or pre-frail seniors

Interventions

The HWePS (Health and Wellness Program for Seniors) study is a non-randomized controlled cluster trial to evaluate a community-based, technology-enhanced, multilevel health equity intervention model for seniors in urban, low-income communities in Seoul, South Korea, during the COVID-19 pandemic. As a preventive-oriented, integrated community care model aiming to decrease small-area health disparities, the HWePS is a community-participatory, multidisciplinary health and wellness promotion model enhanced by technology and targeting relatively healthy

and pre-frail older adults residing in a community. The HWePS model is guided by the Bay Area Regional Health Inequalities Initiatives (BARHII) framework, the Expanded Chronic Care Model (ECCM), the health literacy intervention model, and the System for Person-centered Elder Care (SPEC) model. The key elements of the multifaceted HWePS intervention are as follows:

- 1) Individual- and community-needs assessments using multifaceted decision support tools, delivering tailored health information and promoting multilevel health literacy in the community;
- 2) Individualized care management (care planning/coaching) for empowering older people and strengthening their self-care capacity using evidence-based protocols by nurse-led multidisciplinary care teams along with trained community lay health leaders;
- 3) Developing community-wide healthy living (in particular, service) conditions through creating a supportive environment, strengthening community capacity/action, and building community resources/networks;
- 4) An information and communication system supporting and tracking the entire process of the program described above, including provision of tailored resources for older adults, lay supporters, care teams, and managers, and education, training, and structured on- and off-line programs/support.

Arm 1: intervention group

Target number of participants: 240 older adults in 15 'tongs' in the intervention 'dong'

Arm description: A three-level intervention program based in a senior health-wellness center within the region: a multichannel health information delivery service (Level 1), a technology-enhanced care management program (Level 2), and a community- (dong-)wide initiative promoting healthy living conditions aiming to address midstream/upstream causes of health inequality (Level 3). Both the Level 1 and Level 3 interventions will be ongoing throughout the entire intervention period. Level 2 will be rolled out to older participants in the tongs sequentially over three periods in random order. The Level 2 intervention consists of a 12-week self-care skill-building period followed by a 12-week self-care practice/maintenance period. During the first period, older participants will receive multidisciplinary care management along with support from trained community lay health leaders (CLHLs); during the second period, participants will be offered community activities aimed at maintaining and promoting healthy living and supported by peers and CLHLs.

Total duration of treatment: Level 1 and 3 interventions will be delivered to all participants in the intervention group throughout the entire intervention period (48 weeks). Level 2 intervention will be delivered for 24 weeks to the 3 groups in sequential order.

Arm 2: control group

Target number of participants: 240 older adults in 15 'tongs' in the intervention 'dong'

Arm description: Participants will receive usual care plus an individual-level health information intervention only. Health information will be delivered to the participants via SNS or postal mail.

Total duration of treatment: The health information intervention will be delivered throughout the entire intervention period (48 weeks).

Randomization process:

This is a non-randomized controlled cluster trial study. We will do 1 to 1 matching of 15 intervention tongs and 15 control tongs based on residential type and mean age of potential participants. For Level 2 intervention, the tongs will be randomly grouped into three. The

matching allocation will be conducted with SAS software; we will check whether the imbalance rate is over 20%.

Intervention Type

Other

Primary outcome(s)

- 1. Quality of life (EuroQol EQ-5D) [Time frame: at baseline and after 12 weeks of participant enrollment]
- 2. Self-rated health (WHO World Health Survey & Korea Community Health Survey [KCHS]) [Time frame: at baseline and after 12 weeks of participant enrollment]

Key secondary outcome(s))

- 1. Well-being (WHO-5 Well-being Index) [Time frame: at baseline and after 12 weeks of participant enrollment]
- 2. Frailty (Fried's frailty measure) [Time frame: at baseline and after 12 weeks of participant enrollment]
- 3. Self-efficacy (Health Self-Efficacy Measure) [Time frame: at baseline and after 12 weeks of participant enrollment]
- 4. Community Efficacy (Collective Efficacy Scale) [Time frame at baseline and after 12 weeks of participant enrollment]
- 5. Physical activity (International Physical Activity Questionnaire) [Time frame: at baseline and after 12 weeks of participant enrollment]
- 6. Hypertension awareness and diabetes awareness (KCHS) [Time frame: at baseline and after 12 weeks of participant enrollment]
- 7. Nutrition (Nutrition Questionnaire Elderly), exercise (Physical Activity Readiness Questionnaire), mood (PHQ-9 & KCHS), and stress (KCHS) [Time frame: at baseline and after 12 weeks of participant enrollment]
- 8. Satisfaction (Evaluation Ranking Scale) [Time frame: at baseline and after 12 weeks of participant enrollment]
- 9. Functional health (Scales and CAPs in the interRAI Check-Up) [Time frame: at baseline and after 12 weeks of participant enrollment for the intervention group only]
- 10.Technology acceptance (Senior Technology Acceptance Model Questionnaire [STAM]) [Time frame: at baseline and after 12 weeks of participant enrollment for the intervention group only]
- 11. Quality of life (EuroQol EQ-5D) [Time frame: after 24 weeks of participant enrollment for the intervention group only]
- 12. Self-rated health (WHO World Health Survey & KCHS) [Time frame: after 24 weeks of participant enrollment for the intervention group only]
- 13. Frailty (Fried's frailty measure) [Time frame: after 24 weeks of participant enrollment for the intervention group only]
- 14. Self-efficacy (Health Self-Efficacy Measure) [Time frame: after 24 weeks of participant enrollment for the intervention group only]
- 15. Process evaluation (mixed methods) [Time frame: over 48 weeks]

Other measures: community lay health leaders (CLHLs)

- 16. Self-efficacy (New General Self-Efficacy Scale) [Time frame: at baseline and at the end (48 weeks) of the entire intervention period]
- 17. Collective-efficacy (Community's Self-Efficacy Scale) [Time frame: at baseline and at the end (48 weeks) of the entire intervention period]
- 18. FGI [Time frame: at baseline and at the end (48 weeks) of the entire intervention period]

Completion date

31/12/2022

Eligibility

Key inclusion criteria

- 1. Older adults
- 1.1. Adults aged 65 or older residing in the community
- 1.2. Older adults that agree to participate
- 2. Community lay health leaders (CLHLs)
- 2.1. Adults aged 50 or older who reside in the community and complete training programs for CLHLs
- 2.2. CLHLs that agree to participate

Participant type(s)

Mixed

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

Key exclusion criteria

- 1. Older Adults
- 1.1. Participants who are unable to communicate in Korean
- 1.2. Older adults who plan to move away or out of the community within 6 months
- 1.3. Older adults who are frail and/or long-term care beneficiaries
- 2. Community lay health leaders (CLHLs)
- 2.1. Middle-aged and older community residents who plan to move away or out of the community within 3 months

Date of first enrolment

06/09/2021

Date of final enrolment

30/09/2022

Locations

Countries of recruitment

Korea, South

Study participating centre Seoul National University Graduate School of Public Health

Gwanak-ro 1 Gwanak-gu Seoul Korea, South 08826

Sponsor information

Organisation

Seoul National University

ROR

https://ror.org/04h9pn542

Funder(s)

Funder type

Government

Funder Name

The Korea Disease Control and Prevention Agency (KDCA)

Funder Name

The Seoul Metropolitan Government

Funder Name

The Jungnang-gu Public Health Center

Results and Publications

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output typeDetailsDate createdDate addedPeer reviewed?Patient-facing?Protocol article05/01/202309/01/2023YesNoParticipant information sheet11/11/202511/11/2025NoYes