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Comparison of the effects of various functionalities of the integrated digital self-management system on the improvement of motor health among older adults

Submission date
20/05/2025

Recruitment status
No longer recruiting

Registration date
28/05/2025

Overall study status
Ongoing

Last Edited
28/05/2025

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
With aging, individuals commonly experience a decline in motor function due to natural physiological and physical degradation, leading to reduced independence and quality of life during twilight. In this aging era, traditional healthcare professional-based elderly care resources are no longer sufficient for the increasing elderly population.
Recently, advanced technologies such as sensor technology, the Internet of Things, and artificial intelligence have boosted the development of diverse digital healthcare systems, potentially empowering older adults to self-manage their motor health. Although numerous studies have investigated the effects and usability of such digital self-management systems with unique functionality like assessment and sensor-based physical exercises, few systems have integrated diverse self-management functionalities and identified the optimal functionality design of digital self-management systems to improve older adults' motor health and self-management confidence.
In this context, to improve the effectiveness and efficacy of digital self-management systems on improving older adults' motor health and quality of life, researchers have developed a series of digital self-management systems with diverse functionalities and conducted a 12-week study.

Who can participate?
Older adults aged 60 years or above with movement ability for daily activities and communication, without serious diseases or dementia.

What does the study involve?
Participants are randomly allocated to eight groups as below:
1. Digital self-management system with education functionality.
2. Digital self-management system with motor assessment functionality.
3. Digital self-management system with physical exercise functionality.
4. Digital self-management system with education and motor assessment functionalities.
5. Digital self-management system with education and physical exercise functionalities.

6. Digital self-management system with motor assessment and physical exercise functionalities.
7. Digital self-management system with education, motor assessment and physical exercise functionalities.
8. Control group: no treatment
All participants will come to the laboratory once a week and wear a pedometer every day to record their walking steps. Participants in the intervention groups will receive 12 sessions, one per week, and around 40 minutes per session. Participants in the control group will receive no treatment.

What are the possible benefits and risks of participating?
All programs are expected to improve older adults' motor health and support them with better self-management skills, prevent falls and motor impairments. All procedures will follow ethical guidelines to ensure participant safety.

Where is the study run from?
The Hong Kong Polytechnic University

When is the study starting and how long is it expected to run for?
May 2024 to August 2025

Who is funding the study?
The Hong Kong Polytechnic University

Who is the main contact?
1. Prof. Hailiang Wang, hailiang.wang@polyu.edu.hk
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Comparison of the effects of various functionalities of the integrated digital self-management system on the improvement of motor health among older adults: a pilot randomized controlled trial

Study objectives
1. The digital self-management system positively improves older adults' motor function and self-management ability.
2. Digital self-management systems with comprehensive functionalities are more effective in improving older adults' motor function and self-management ability compared with those with single functionality.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 14/05/2024, PolyU Institutional Review Board (Hong Kong, Hong Kong, 0, China; +852 (0)3400 8541; beckymw.kong@polyu.edu.hk), ref: HSEARS20240502001

Study design
Single-center interventional multi-arm randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual, Laboratory, University/medical school/dental school

Study type(s)
Diagnostic, Prevention, Quality of life, Treatment, Efficacy

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Prevention of motor impairments and falls in community-dwelling older adults

Interventions
The study is a 12-week single-center interventional multi-arm randomized controlled trial aimed at investigating the effect of digital self-management systems with different functionalities on improving community-dwelling older adults' motor health and self-management ability.

All participants' data were collected at baseline with blinded assessors. A computer-based number randomizer (https://www.randomizer.org/) was used for the randomisation of the participants. An independent researcher, not involved in participant recruitment or intervention delivery, was responsible for generating the allocation sequence and sealing it into anonymous envelopes to ensure allocation concealment. The eligible participants were randomly assigned into eight arms as below:
1. Digital self-management system with education functionality
2. Digital self-management system with motor assessment functionality
3. Digital self-management system with physical exercise functionality
4. Digital self-management system with education and motor assessment functionalities
5. Digital self-management system with education and physical exercise functionalities
6. Digital self-management system with motor assessment and physical exercise functionalities
7. Digital self-management system with education, motor assessment and physical exercise functionalities.
8. Control group: no treatment

All participants will come to the laboratory once a week and wear a pedometer every day to record their walking steps. Participants in the intervention group will receive 12 sessions, one per week, and around 40 minutes per session. Participants in the control group will receive no treatment.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Phase I

Drug/device/biological/vaccine name(s)
Digital self-management systems

Primary outcome measure
Motor function is measured at baseline and 12 weeks using the:
1. Timed-Up-and-Go test (3TUG)
2. 6-Metre Walk Test
3. Five Times Sit to Stand Test (5STS)
4. Short Physical Performance Battery (SPPB)
5. Physical Activity Scale for the Elderly (PASE)
6. Falls Efficacy Scale-International (FES-I)
7. SARC-F Screen for Sarcopenia
8. Integrated Care for Old People (ICOPE)
9. Hand strength (left and right)

Secondary outcome measures
Measured at baseline and 12 weeks:
1. Cognitive status measured using the Montreal Cognitive Assessment (MoCA) and the Subjective Cognitive Decline Questionnaire-9
2. Chronic pain measured using the Chronic Pain Grade questionnaire
3. Frail status measured using the FRAIL scale
4. Nutritional screening using the Simplified Nutritional Assessment Questionnaire
5. Quality of life measured using the EuroQol 5-Dimension 5-Level Questionnaire (EQ5D-5L)
6. Self-efficacy measured using the General Self-efficacy Scale (GSE)
7. Perceived usefulness, attitudes and willingness to use, measured using the Technology Acceptance Model

Overall study start date
14/05/2024

Completion date
31/08/2025

Eligibility

Key inclusion criteria
1. Older than 60 years
2. No serious diseases or dementia
3. Have the ability to move by themselves
4. Have the ability to perform daily activities
5. Without communication difficulties

Participant type(s)
Resident

Age group
Senior

Lower age limit
60 Years

Sex
Both

Target number of participants
120

Key exclusion criteria
1. Aged under 60 years
2. Unstable mental conditions
3. Without movement ability
4. With severe hearing problems or others affecting communication

Date of first enrolment
01/04/2025

Date of final enrolment
03/05/2025

Locations

Countries of recruitment
China

Hong Kong

Study participating centre
The Hong Kong Polytechnic University
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University/education

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ROR
https://ror.org/0030zas98

Funder(s)

Funder type
Government

Funder Name
Hong Kong Polytechnic University

Alternative Name(s)
The Hong Kong Polytechnic University, , Hong Kong PolyU, Government Trade School, Hong Kong Technical College, Hong Kong Polytechnic, PolyU, HKPU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Hong Kong

Results and Publications

Publication and dissemination plan
Planned publication in peer-reviewed journals and international conferences

Intention to publish date
01/10/2026

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be available on request from Prof. Hailiang Wang (hailiang.wang@polyu.edu.hk)

IPD sharing plan summary

Available on request