Innovations in older adult care and health service management: A focus on the Asia-Pacific region

Edited by

Madhan Balasubramanian, Angie Shafei and Zhanming Liang

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Innovations in older adult care and health service management: A focus on the Asia-Pacific region

Topic editors

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Editorial: Innovations in older adult care and health service management: a focus on the Asia-Pacific region

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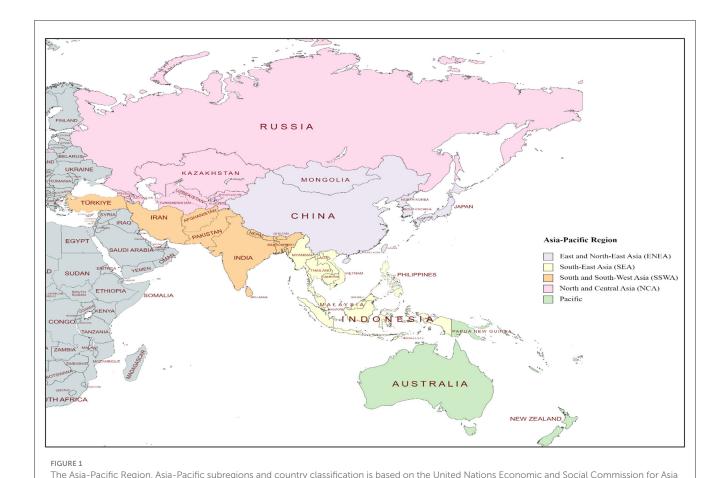
Editorial on the Research Topic

Innovations in older adult care and health service management: a focus on the Asia-Pacific region

Introduction

Population aging in the Asia-Pacific Region is a significant challenge for the 21st century. With countries in the Asia-Pacific aging faster than any region in the world, demographic transition and challenges associated with it have grown to utmost social, political, healthcare, and economic significance. Nearly 60 percent of the world's population over 60 years of age reside in the Asia-Pacific region, which amounts to 630 million people (1). This population is projected to reach 1.3 billion by 2050 (1). In general, older adults exhibit higher prevalence of chronic conditions, comorbidities, and hospital admissions, which in turn elevate health care costs. Women comprise of over 60% of the older adult population in the Asia Pacific (2). Gender imbalance has implications for social support and health care systems, given that women typically have greater life expectancy and can face more years of potential disability. Given the traditional role of women as family caregivers in many societies in the region, older women could face greater pressure potentially impacting their health and wellbeing. Traditional models of health workforce development and service delivery are less likely to be effective in addressing the growing concerns if the focus remains centered on specialized and tertiary care. It is essential to strengthen primary and community-based models of care that caters to the growing needs of and are sensitive to cultural contexts, local challenges, and specific requirements of older adults.

Based on the United Nations Economic and Social Commission of Asia and the Pacific, the region is divided into five divisions (1): (i) East and Northeast Asia, (ii) South-East Asia, (iii) South and South-West Asia, (iv) North and Central Asia, and (v) Pacific (see



and the Pacific categorization. This map has been generated utilizing mapping tools available at mapchart.net, licensed under CC BY-SA 4.0.

Figure 1). The 56 countries in this region come with varying levels of social and economic progress. The World Bank identifies two of these countries as low-income economies, 26 as lower middleincome economies, 17 as upper middle-income economies and 11 as high-income economies (see Supplementary Table 1). Over the last two decades, China, India, Indonesia, Philippines, Thailand, and Vietnam consistently outperformed other emerging markets in the world economically. In addition to the fast-paced economic growth in the region, Asia-Pacific countries share a rich and diverse cultural history. In many cultures, particularly those in the Indian subcontinent, China and Southeast Asia, there is a deeply ingrained tradition of venerating older adults, with the care for aged parents being viewed as a sacred duty bestowed by the divine. Nevertheless, these societies are facing increasing pressure of globalization and westernization of care, reshaping conventional approaches to older adult care.

To steer the global response to aging, the WHO released the first World report on aging and health reviewing knowledge gaps and instigating a public health framework that identified four key areas: integrated care provision, long term care, age friendly environments and improved measurement and monitoring (3). Healthy aging was built on the notion of functional ability, seen as a combination of intrinsic capacity of individual, environmental characteristics, and interactions between individual and the environment. For the first time, a population aging metric reflecting both on longevity and health status was developed by the global

burden of disease study conducted by Chang et al. (4). By incorporating 92 age related diseases, they extended our thinking beyond chronological age to account for both health status and disease severity, allowing cross country comparisons to inform policy decisions. Utilizing this metric, the top five countries globally with the highest aged-standardized disease burden rates are all in the Asia-Pacific region (Papua New Guinea, Marshall Islands, Vanuatu, Afghanistan, and Solomon Islands). Meanwhile Singapore, South Korea and Japan have some of the lowest age standardized disease burden. Comparing across countries, the equivalent age for the reference population (65 years) varied widely ranging from 76.1 years in Japan to 45.6 years in Papua New Guinea; meaning that a 76-year-old in Japan has the same agerelated disease burden as a 65-year-old globally (4). The onus falls on the countries, and as mentioned in the WHO Global Strategy and Action Plan on Aging and Health (5), to accelerate action to ensure older adults can live a long and healthy life.

Unique nature of Research Topic/issue and performance statistics

Our Research Topic was one of the first attempts to explore innovations in aged care and health service management across Asia and the Pacific, especially with a country- or region-specific approach. We adopted a co-design process of by working

TABLE 1 Summary of studies in the Research Topic.

References	Title of article	Country	Type of article	Methods	Author keywords
Boo and Oh	Perceptions of registered nurses on facilitators and barriers of implementing the AI-IoT-based healthcare pilot project for older adults during the COVID-19 pandemic in South Korea	Republic of Korea	Original Research	Qualitative	AI-IOT based healthcare; older adults; facilitators; barriers; digital literacy; public health
Dix et al.	Practical infection control training for Victoria's aged care workforce at the time of COVID-19 pandemic: a community case study	Australia	Original Research	Mixed methods	COVID19; education; health care professionals; infection control; personal protective equipment; program delivery long term care; workplace safety
Hu et al.	Caring load and family caregivers' burden in China: the mediating effects of social support and social exclusion	China	Original Research	Quantitative	Psychological stress; family caregivers burden; older adults; social support; social exclusion; China
Katayama et al.	Relationship between tinnitus and olfactory dysfunction: audiovisual, olfactory and medical examinations	Japan	Original Research	Quantitative	Health checkup; sensory dysfunctions; olfactory test; dietary habits; smoking; alcohol
Kotani et al.*	The research environment of critical care in three Asian countries: A cross-sectional questionnaire survey	Japan, Republic of Korea, Singapore	Original Research	Quantitative	Research activities; cross-sectional studies; community hospital; Asia; critical care
Lim et al.	Hospitalization and emergency department visits associated with potentially inappropriate medication in older adults: self-controlled case series analysis	Republic of Korea	Original Research	Quantitative	Potentially inappropriate medication; self-controlled case series; Poisson regression; older adult; pain medication; gastrointestinal medication; anticholinergics
Mackenzie et al.	The Vietnamese version of the Home Falls and Accidents Screening Tool (HOME FAST) - A preliminary study of validity and inter-rater reliability	Vietnam	Research Report	Mixed methods	Accidental falls; home hazards; assessment; cultural translation; validity expert panel
Mistry et al.*	Stigma toward people with COVID-19 among Bangladeshi older adults	Bangladesh	Original Research	Quantitative	Dynamic ensemble selection machine learning; middle aged patient; older patient; traumatic injury
Nhu et al.	Prediction of posttraumatic functional recovery in middle-aged and older patients through dynamic ensemble selection modeling	Taiwan, China	Original Research	Quantitative	Dynamic ensemble selection machine learning; middle-aged patient; older patient; traumatic injury
Pardoel et al.	The implementation of community-based programs in Vietnam is promising in promoting health	Vietnam	Original Research	Mixed methods	Community based programs community based health promotion; evaluation
Pengpid et al.	Bidirectional association between functional disability and multimorbidity among middle-aged and older adults in Thailand.	Thailand	Original Research	Quantitative	Multimorbidity; functional disability; longitudinal study Thailand; bidirectional
Reddy et al.*	Prevalence, Associated Factors, and Health Expenditures of Noncommunicable Disease Multimorbidity—Findings From Gorakhpur Health and Demographic Surveillance System	India	Original Research	Quantitative	Health and Demographic Surveillance; Health expenditure; India; multimorbidity; non communicable diseases

(Continued)

TABLE 1 (Continued)

References	Title of article	Country	Type of article	Methods	Author keywords
Sastry et al.	Toward Adapting the UN's Healthy Aging Agenda for India: Tailoring to Unique Historical Context and Traditions	India	Perspective	Not applicable	Older adult; healthy aging; healthcare; national health programs; digital health mission; India
Yi et al.	Does home and community-based services use reduce hospital utilization and hospital expenditure among disabled elders? Evidence from China	China	Original Research	Quantitative	Home and community based services; hospital utilization; hospital expenditure; substitution effect; health effect

^{*}Kotani et al. was via Frontiers in Medicine submission; Mistry et al. and Reddy et al. was via General Section, Frontiers in Public Health submission.

collaboratively with key country-level experts well-positioned to reach out to policymakers, academics, and researchers working in aged care and aged care management in different healthcare contexts in the region. The country co-leads or experts were well positioned to promote and disseminate findings to academic and policy networks. The issue and articles were widely marketed in the Asia-Pacific Region through networks, organizations, and media channels.

Since the launch of the Research Topic in July 2022, the issue has garnered significant interest among academics, researchers, and community, amassing close to 15,000 views. The published articles included in the issue have been viewed 12,663 times and downloaded 3,850 times. The level of engagement is also underscored by the 2,250 views on the topic itself. Moreover, the year 2023 has seen a continued upward trend in both views and downloads, indicating a rising interest on the subject matter and the research published therein (see Supplementary Figures 1, 2).

Insights and advances from articles in the Research Topic

The Research Topic offers a rich and diverse collection of scholarly work on innovations in aged care and health service management across the Asia-Pacific region. We include a total of 14 articles, comprising 12 original research articles, one research report, and one perspective article. The research presented comes from nine countries, including Australia, Bangladesh, China, India, Japan, the Republic of Korea, Singapore, Thailand, and Vietnam. Table 1 presents a summary of studies included in the Research Topic, which are further described below.

Dix et al. present a case study on infection prevention and control (IPC) and the use of personal protective equipment (PPE) training for Australia's aged care workforce, set against the backdrop of the COVID-19 pandemic and involving residential aged care facilities (RACF) in the state of Victoria. Utilizing mixed methods techniques, the authors argue that the government, working in partnership with Monash University, an academic institution, had improved the design, development, and implementation of the program. This initiative is argued to be the largest state-funded program delivered to residential aged care workers and addresses the urgent need for rapid training of RACH staff in IPC and PPE. Over 4,200 RACF staff, including 1,207

facility champions, completed this program. This research sheds light on how collaborative efforts that integrate academic expertise can lead to swift and well-founded implementation, a strategy that was especially effective in the initial phase of the COVID-19 crisis in Australia.

A study from Bangladesh by Mistry et al. explored the COVID-19 related stigma among older adults in Bangladesh. Utilizing a cross-sectional design, over 1,000 older adults were surveyed through telephone interviews. The study identified that the prevalence of stigma related to COVID-19 was high among older adults, providing several implications to policymakers and public health personnel, and toward the design of mass media campaigns to inform and educate people on the stigma associated with COVID19. The authors also indicate that failure to understand the role of stigma might result in suboptimal reach of public health programs aimed at COVID19 prevention and management. Reflecting on this fascinating study, one could see similar pivots across the Asia-Pacific region, and relevance to many rural, remote, and disadvantaged communities.

Studies from China focused on community-based services, the role of informal carers, and long-term functional outcomes. Through a study utilizing China Health and Retirement Longitudinal Survey, Yi et al. conclude that the use of homeand community-based services can both reduce hospital utilization and expenditures among disabled older adults that contribute to their physical and psychological health. Hu et al. looked at informal care and examined the association between caring load and family caregivers' burden. The paper concludes that there is a significant positive association between caring load and caregiver burden and recommends more guidance services and support for family caregivers. Nhu et al. used a dynamic ensemble selection modeling approach in the prediction of posttraumatic functional recovery in middle-aged and older patients. They conclude that preexisting conditions can predict long-term functional outcomes, and thereby influence prognosis and clinical decision-making for older adult care.

Sastry et al. provided insights into the rich cultural heritage of India, and how the country is adapting the UN Health Aging Framework to the country's unique historical context and traditions. The paper highlights some interesting innovations by the Indian government such as "Savera Yojana" where older people can utilize digital technologies to reach friendly cops for personal security issues. Newer models of care such as 'adopting

a granny' by school children, when a nursing home and school for orphans are cohabitated, are emerging in India, and seen as an avenue to improve intergenerational bonding. In another article by Reddy et al. the study examined the prevalence, associated factors and health expenditures of non-communicable disease multimorbidity from a health district in India. They identified that a significant proportion of the people had NCDs and argued that those with multimorbidity spent almost four times higher out of pocket expenditure than those without NCDs. The study suggests that national programs (such as Ayushman Bharat Scheme) can improve access to care and address the financial burden for care among older adults.

Japan, a pioneer in aged care solutions, presents valuable opportunities for international learning in this sector. The study by Katayama et al. examined the relationship between vision and hearing conditions among older adults. The study, which employs a mix of audiovisual, olfactory, and medical assessments, explores the connection between tinnitus and olfactory dysfunction. It determines that understanding the interplay between different sensory organs is crucial in assessing how sensory impairments affect cognitive function. The study provides some insights into the interconnectedness of sensory diseases and offers arguments into how and why integrated service provision needs to emerge in primary care.

A strong research environment is the backbone for evidence-informed policy and practice decision-making. In a cross-country study, Kotani et al. examined the critical care research environment in three Asian countries: Japan, South Korea, and Singapore. The study identified that having secured time for research activities, practicing at a university-affiliated hospital, and having clinical experience of 10 years or longer for whom? Were significantly associated with higher research productivity. The authors also argue the importance of building a collaborative environment between academia and non-academia (clinicians, public health professionals, community personnel etc.) as it contributes to the development of an evidence-based culture for care provision.

Boo and Oh, in their research on the use of Artificial Intelligence for a health care pilot project in South Korea, examined the perception of registered nurses on implementing smart technologies for older adults in primary care. The authors confirmed the need for future healthcare policies and strategies for the implementation of digital health technologies, particularly in the context of home visiting technologies. Also from South Korea, Lim et al. examined the risk of hospitalization and emergency department visits due to potentially inappropriate medication use among older adults. The study recommended the development of deprescribing strategies to control potentially inappropriate medication (PIM) and polypharmacy collectively.

A study conducted in Thailand by Pengpid et al. examined the bidirectional association between functional disability and multimorbidity among middle-aged and older adults. Using longitudinal data from the Thailand Health, Aging and Retirement Survey, the study identified that baseline multimorbidity increased the risk of functional disability, and further baseline functional disability increased the risk of incident multimorbidity. The authors argued that health services in Thailand should

be reoriented to tailor the intervention to individuals with multimorbidity to prefer future functional disabilities.

The final two included studies from Vietnam by Pardoel et al. and Mackenzie et al. looked at the implementation of the intergenerational self-help clubs (ISHCs) and fall prevention tools respectively. Pardoel et al. conducted assessed the benefits of 97 ISHCs in nine provinces in Vietnam. The authors reported a high reach and uptake of services by ISHC, and a satisfaction rate of almost 75% among participants using them. Mackenzie et al. evaluated the validity and reliability of a home falls and accidents screening tool. Considering the relevance of home and informal care in Vietnam, the use of early screening and prevention tools cannot be underestimated.

Future implications

A highly cited article published in Frontiers in Medicine by Franceschi et al. (6) argue that aging and age-related diseases share similar molecular and cellular mechanisms, and thus the primary focus of medicine should be on combating aging. The authors also venture to discuss on aging and rejuvenation (or feasible age extension) research and call for the importance of identifying biomarkers able to distinguish individuals with higher risk of developing age related diseases. From a public health perspective, this approach might seem unorthodox, but despite the progress achieved, it calls for wider engagement with a multidisciplinary audience. Our Research Topic, mainly from a public health and health management standpoint, shed light on a number of innovations on aged care in the Asia Pacific region. Although we don't argue that the challenges brought forth in this issue as comprehensive or even methodically organized, we recognize the importance to combat aging through innovative strategies that demand creative and unconventional thinking.

Our issue mainly makes the case for three arguments. First, aging is widely affecting the Asia-Pacific region, and countries are adopting innovative approaches and strategies to deal with aging. Second, Asia-Pacific countries bring rich cultural history and connotations to aged care, and its vital that traditional learnings and practices are nurtured to develop culturally sensitive and locally responsive models for aged care. Finally, the disease disparity and aged care practices across the region, provides an opportunity for cross-cultural and cross-country learnings, which can benefit both the developed and developing economics in the region and beyond.

On reflection: summary of contributions

This Research Topic has featured original research articles (n=12), short reports (n=1) and perspectives (n=1) from nine countries in the region (Australia, Bangladesh, China, India, Japan, Republic of Korea, Singapore, Thailand, and Vietnam). Commissioned in July 2022, we began with a unique process of involving country leads across the region in the promotion of the Research Topic and aimed at improving

social impact through the rapid dissemination of research findings. Over the last 18 months, the Research Topic has generated 14,913 views and 3,850 article downloads. We included research on innovative models such as the intergenerational self-help clubs (Vietnam), artificial intelligence based smart care (Republic of Korea) and infection control training programs during COVID19 (Australia). The Research Topic also included studies that examined role of stigma toward older adults with COVID-19 (Bangladesh), cost benefits of home-based models (China) and the role of United Nations Healthy Aging agenda (India). The dominant themes emerging from the Research Topic mainly included: (i) service redesign, (ii) training for providers, (iii) shift to community/home-based care, and (iv) adapting successful global frameworks/instruments. Overall, it was particularly noteworthy to observe that several countries are thoughtfully assessing and evolving their unique and culturally rich traditional systems of older adult care to addressing contemporary needs and expectations.

Author contributions

MB: Conceptualization, Writing – original draft, Writing – review & editing. AS: Conceptualization, Writing – review & editing. ZL: Conceptualization, Writing – review & editing.

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Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpubh.2024. 1369827/full#supplementary-material

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Practical infection control training for Victoria's aged care workforce at the time of COVID-19 pandemic: a community case study

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The need to improve career development and training for residential aged care workers in Australia to achieve required essential competencies, including infection prevention and control competencies, has been repeatedly highlighted. In Australia long-term care settings for older adults are known as residential aged care facilities (RACFs). The COVID-19 pandemic has brought to light the lack of preparedness of the aged care sector to respond to emergencies, and the urgent need to improve the infection prevention and control training in residential aged care facilities. The government in the Australian State of Victoria allocated funds to support older Australians in RACFs, including funds toward infection prevention and control training of RACF staff. The School of Nursing and Midwifery at Monash University addressed some of these challenges in delivering an education program on effective infection prevention and control practices to the RACF workforce in Victoria, Australia. This was the largest state-funded program delivered to RACF workers to date in the State of Victoria. The aim of this paper is to provide a community case study, where we share our experience of program planning and implementation during early stages of the COVID-19 pandemic and lessons learned.

KEYWORDS

COVID-19, education, health care professionals (HCP), infection control, personal protective equipment (PPE) compliance, program delivery, long-term care, workplace safety

Introduction

In Australia long-term care settings for older adults are known as residential aged care facilities (RACFs). Globally, studies indicate that even before the coronavirus (COVID-19) pandemic, RACFs were the most vulnerable institutions in terms of high incidence of infectious disease and suboptimal infection prevention and control (IPC) procedures (1). Since the beginning of the COVID-19 pandemic, researchers reported numerous coronavirus (SARS-CoV-2) infection outbreaks occurring in RACFs worldwide that affected both residents and staff (2, 3). SARS-CoV-2 can spread rapidly through RACFs if not managed appropriately (4, 5). The underlying factors for this transmission include: (1) the characteristics of the coronavirus pathogen (transmissibility, high replication and mutation rates), (2) the condition of hosts

(residents' older age, frailty and co-morbid conditions), and (3) transmission factors, including the ability to practice preventive behaviors (suboptimal IPC training of the RACF workforce, cognitive impairment of some RACF residents, personal protective equipment (PPE) availability, close-contact personal care) and built environment (close-contact living, shared communal areas and equipment) (4, 6–8). In addition, evidence from a rapid systematic review indicated that a larger facility size (number of beds), greater number of employees, staff availability, RACF staff operating between multiple facilities, and for-profit status of RACFs also contribute to the number and size of COVID-19 outbreaks in this setting (9). A systematic review of the causes of transmission and control measures of any pathogen outbreaks in RACFs indicated that the violation of basic IPC could play a major role in introducing and facilitating the spread of infectious diseases in RACFs (10).

IPC expertise in Australian RACFs is limited; and the COVID-19 pandemic highlighted significant gaps in IPC practices in facilities (7). A recent review reported that out of 134 RACFs, 44% of staff responsible for IPC had no specific IPC qualifications (11). Two independent reports into COVID-19 outbreaks in New South Wales and Victoria, Australia recommended improved continuing IPC training for staff in RACFs outside of outbreak situations, to be overseen by an appropriately trained member of the nursing staff (12, 13).

In Australia, The Royal Commission into Aged Care Quality and Safety (The Royal Commission) special report into COVID-19 in aged care (14) highlighted that the aged care workforce must be provided with regular IPC training, with the responsibility for this training resting with aged care providers. The Royal Commission called on the federal government to establish a national aged care plan for COVID-19 and deployment of infection control experts into RACFs as a condition of accreditation (15). In December 2020, the Australian Commonwealth Department of Health instructed all RACFs to appoint a nurse with appropriate accredited IPC training to lead IPC in their facility (16).

Staff training is important for effective IPC practices in RACFs (17). Infection prevention and control guidelines and training programs are often based on evidence collected in acute healthcare settings and not always relevant for the RACF context (18). Although IPC is the most commonly reported specialist skill among direct care workers in RACFs (19), little is known about the quality, relevance and frequency of training, or the undertaking of competency assessments (20). There are challenges implementing education programs in RACFs due to the diverse workforce with varied knowledge and educational experience, time to participate in education, and relevance, accessibility and sustainability of education programs (19, 21). Factors that may increase the efficacy of staff education in RACFs include a high-quality program using an interactive experiential learning format, that is relevant for staff and includes positive reinforcement and promoting sustainability (22).

The COVID-19 pandemic highlighted the lack of preparedness of the aged care sector in Australia to respond to emergencies and the urgent need to improve IPC training in RACFs among other challenges (23). The Victorian Government allocated funds to support people living in RACFs, including support for training the workforce in IPC practices (24). The School of Nursing and Midwifery at Monash University addressed some of these challenges through design and delivery of an education program on effective IPC practices to the

RACF workforce in Victoria, Australia. This program was co-designed with nurses and direct care workers specifically for the RACF workforce and implemented an innovative education strategy, and evaluated its effectiveness to optimize IPC practice and protect people from healthcare-associated infections in RACFs. To date, this was the largest state-funded program delivered to the residential aged care workforce in the State of Victoria. The aim of this paper is to provide a community case study, where we share our experience of the program planning and implementation from the early emergency stages of the COVID-19 pandemic in Australia and the lessons learned.

Context

Setting and population

Since the beginning of the COVID-19 outbreak in Australia, residents in RACFs were considered at a high risk of COVID-19, leading to illness and loss of life (4, 5, 7). During the 'second wave' of COVID-19 from July to September 2020, there were over 2000 COVID-19 cases occurred within RACFs in the state of Victoria, which lead to almost 700 deaths (25). Older people in general (26, 27), and particularly those with co-existing illnesses, are at increased risk of severe infection, serious complications and increased case-mortality rates if they contract COVID-19 (28–33).

Based on the 2020 National Aged Care Workforce Census (19), 70% of the aged care workforce are Personal Care Attendants (PCAs), 23% are nurses and 7% are allied health professionals. The proportion of PCAs from culturally and linguistically diverse backgrounds (CALD) comprised over 62% (19). The majority (70%) of the PCA workforce were both migrant and spoke a language other than English; and almost three quarters (71%) of PCAs hold a Certificate III or higher qualification in a direct care field (19). The broad and diverse aged care workforce also includes auxiliary workers who may not have substantial infection control training; and as the outbreak progressed, there were surge workforce staff who may have been new to aged care. The delivery of care in RACFs is 24h, 7 days a week and many workers concurrently worked in two or more RACFs (34).

Program funders

The Victorian Government is committed to providing infection control training for the aged care workforce to help them adapt to the risky and changing environment posed by COVID-19. *The Coronavirus (COVID-19) Plan for the Victorian Aged Care Sector for Victoria* developed by the Department of Health and Human Services Victoria (DHHS) (23) provides guidelines to assist RACFs to support their workers, residents, families and visitors to prepare for prevention and management of COVID-19 individual cases and facility outbreaks. This project was funded by the Victorian Government through the DHHS.

Program owners

Monash University, the owner of the program, is Australia's largest university; and the School of Nursing and Midwifery is ranked 5th in

the Academic Ranking of World Universities by Shanghai Ranking in 2022¹. Monash Nursing and Midwifery is one of the largest educators of nurses and midwives in Australia, and has delivered nursing and midwifery educational courses for over 30 years, and graduated over 13,000 students.

Key programmatic elements

Program goal and objectives

The overall aim of this practical education program was to improve RACF staff IPC knowledge and practice, specifically related to appropriate donning and doffing of PPE to prevent transmission of COVID-19.

Program components

This program incorporates three components: (1) practical face-to-face education on IPC knowledge and practices, including the application of PPE; (2) a train-the trainer model to facilitate sustainability of the program via facility champions; (3) and a virtual reality simulation, designed specifically for the aged care sector and used to consolidate knowledge.

Due to the nature of the evolving coronavirus pandemic, the education program was iteratively reviewed and updated to ensure alignment with both Australian and Victorian State Government guidelines and advice.

Practical face-to-face education session

With a focus on practical application of PPE, the face-to-face component of the program addressed the following key concepts related to infection prevention: COVID-19 transmission routes, current COVID-19 pandemic concerns specific to the aged care sector, and the role of health workers in prevention of COVID-19 transmission. The use of standard infection prevention precautions, including hand hygiene, face masks and physical distancing, and their effectiveness in preventing COVID-19 transmission were also covered. Further to this, the use of transmission-based infection prevention precautions, including different levels of PPE required and situations when it is used were a focus. Finally, the correct sequencing for donning and doffing PPE to avoid contamination of self, residents, or the RACF environment were also included in this program component.

This practical education session was conducted using contemporary education practices, including guided group discussion, active learning activities, and role play simulation. Pre- and post-session knowledge quizzes and observation of donning and doffing PPE using a structured checklist to assess each participant's PPE application were used as assessments for learning. The education session was underpinned by a detailed lesson plan, which was used by all educators to promote quality and consistency in program delivery.

Train-the trainer model – Facility Champions

Following the practical component of the education program, additional education was provided to key RACF staff, nominated as IPC Facility Champions. This train-the trainer model was adopted as an effective strategy to equip the appointed Facility Champions with the ability to educate others in their organization. The core advantage of a train-the-trainer model is its cost and time effectiveness when providing education to large numbers, and a greater acceptance of content delivered by internal trainers enabling the facility to have an up to date content expert to assist with day to day challenges.

The train-the-trainer education session focused on the organization of the training sessions in RACFs, education practices during the training session, and accessing follow up support. Facility Champions were also able to further clarify IPC knowledge and practice if required. All education resources used during the face-to-face session, such as lesson plan, PowerPoint presentation, and handout materia were provided to the Facility Champions. Facility Champions were asked to upload a list of RACF staff they conducted training with to Monash University at the end of each session.

The Monash University education program coordinator contacted Facility Champions following their face-to-face session to provide support with ongoing training for their RACF staff. Facility Champions were able to contact the University training team *via* email for ongoing support as required; and all requests were attended within two business days.

Virtual reality simulation

To consolidate knowledge and build on sustainability of the education program, an online competency-based virtual reality simulation (VRS) was developed. The Monash University team worked closely with a commercial company with expertise in immersive technology and together a custom-built program of practice simulations was created. The VRS leveraged an advanced conversation engine allowing learners to have conversations with characters using artificial intelligence (AI). Mimicking real scenarios that aged care workers would face during healthcare delivery, the VRS facilitated consolidation of learning and complemented the face-toface education. Designed purposefully and specifically for the aged care workforce, the VRS was accessible through a Windows-based personal computer PC or MAC. Enabling unscripted conversations between participants and AI characters that speak, listen, interact and are designed to replicate aged care staff, the VRS aimed to further support competency development and continued learning. On entering the VRS, participants were introduced to a simulated RACF environment and presented with a series of realistic clinical scenarios along with three different AI characters, a registered nurse, a PCA and an auxiliary staff member. The scenarios posed cases that required participants to make decisions related to prevention of infection, e.g., which level of PPE is required and the sequence of their use. Each AI character required instruction in the selection of appropriate PPE (transmission-based or standard precautions), and in the safe donning and doffing of PPE.

The VRS provided RACF staff with unlimited opportunities to practice instructions in donning and doffing of PPE, in a safe, low-risk setting, and to receive real-time feedback on the accuracy of their instruction, confirming information when it was provided correctly, and correcting inaccuracies. The VRS continues to be a sustainable source of relevant information, requiring fewer human resources

¹ https://www.shanghairanking.com/rankings/gras/2021/RS0404

while ensuring the quality of training delivery and enabling a depth of understanding. Staff are able to access the platform at any time of the day or night, including weekends. The VRS has been purposefully designed to be engaging for people of all language backgrounds and literacy levels, with cases tailored to ensure they reflect the diversity of the RACFs workforce. As such, the platform provided an inclusive and sustainable risk management strategy.

This education paradigm was chosen by the project team because it is engaging for users, consolidates learning, and assesses decision-making. This paradigm also has the added advantage of creating the basis for potential transformation of ongoing professional development for the aged care workforce, including *via* potential rapid delivery of new modules during times of crisis.

Program planning, design and evaluation strategies

Needs assessment

The education program was developed in response to discussions with the Victorian Government to help support Victoria's RACFs during the second wave of COVID-19. A targeted IPC program that specifically focused on application of PPE in the setting of an ever changing COVID-19 infection landscape. The DHHS had already identified the need for this education in RACFs.

Pilot

Prior to implementation of the education program, a pilot of the face-to-face education session was held with staff at a RACF in Melbourne, Victoria. Eight RACF staff attended: a mix of the facility care manager (a registered nurse), registered nurses (RNs), enrolled nurses (ENs) and PCAs. The aim of the pilot was to ensure the content of the education session was appropriate, engaging and useful for RACF staff, as well ensuring timing and sequencing was appropriate for the setting and intended audience. Participants most highly valued the opportunity to practice donning and doffing PPE. They also highly valued the ability to discuss IPC and PPE, and the challenges faced in the aged care sector, raising potential and actual challenges in relation to the prevention of COVID-19, with discussion related to what they would do if they had a confirmed case. The feedback provided from the pilot session was very positive. The participants valued the opportunity to identify the difficulties and develop possible solutions if a positive case of COVID-19 was detected in their RACF. Following the pilot, the face-to-face education session was refined and reduced to 90 min, with an additional 30 min allocated to the train-the-trainer session.

Program evaluation strategies

The program operated under an education research design to ensure program quality and demonstrate outcomes. Data were collected concurrently with program delivery to inform iterative changes required to program delivery. We used a concurrent triangulation mixed methods design (35), and employed the following

methods of data collection: course engagement, knowledge acquisition and application and translation to practice (Table 1).

Risk mitigation plan

The COVID-19 pandemic has impacted the conduct of education provision, research and evidence synthesis of pandemic-related research projects that were launched at high speed in large numbers (36). Risk management at a University and project level became a key aspect of the project team's approach to quality assurance (37). Monash University has a specialized Risk and Compliance Unit which facilitates risk management programs across the University. The University actions its risk management programs through a number of guidelines, policies and procedures including, risk assessment guidelines for major ventures and projects, fiscal misconduct policy, legal compliance policy and the risk management policy and procedures. Monash University recognized the significant safety and reputation risks associated with the delivery of the program. Five key risks were identified: (1) COVID-19 infection transmission during training; (2) difficulty or delays with educator recruitment; (3) failure to engage and improve understanding of the diverse residential aged care workforce; (4) insufficient reach across the sector to prevent outbreaks; and (5) inconsistency in education provided by Facility Champions. A risk mitigation plan was developed for all risks identified (Table 2).

Results

Implementation of the face-to face and train-the-trainer components

To facilitate smooth implementation of the education program, the following framework guided the approach: (1) provide a rapid response; (2) be safe; (3) be preventive; (4) deliver in person; (5) be inclusive; (6) be flexible; (7) create resilient RACFs; and (8) provide successful and sustainable outcomes (Table 3).

A team of nurse academics from Monash University, with expertise and leadership in IPC, aged care, education evaluation research, clinical training development, and delivery, operations and logistics, worked together to rapidly co-design and implement this large-scale education program designed specifically for RACF staff across Victoria. The importance and urgency of rapid training of RACF staff in IPC and the evidence-based PPE use became heightened with the second wave of COVID-19 pandemic in Australia (7, 17). Prior to this, all available education and training in PPE application for the residential aged care workforce were primarily available online, based on evidence from acute healthcare and not fully adapted to the RACF setting and had low uptake and completion rates by workers.

The program was offered to all Victorian RACFs via an opt-in model and was promoted by the DHHS via newsletters and direct correspondence. A dedicated Monash University website² was launched, enabling RACFs to directly register for the education program.

² https://www.monash.edu/medicine/enterprise/ppe-project

TABLE 1 Program evaluation strategies.

Program evaluation strategy	Description
Course engagement	We recorded the number of participants who registered for, and completed, the face to face training, including basic demographic data, such as employing RACF and role in the RACF. Additionally, data was collected via follow-up at each RACF, to identify the number of staff members who subsequently received training from the Facility Champions. These data reflected the scale of the project, and informed areas to be targeted when engagement from RACFs reduced.
Knowledge acquisition/application	Each participant in the face-to-face training completed a short knowledge quiz at the beginning of the training, and again upon completion. We will compare knowledge scores pre- and post-training. Each participant was observed donning and doffing PPE. A structured checklist was used to assess participant application of PPE using the correct sequence. This approach enabled real-time feedback to be provided to each participant in the face-to-face training. Data from the VRS platform was collected, and aggregated to measure knowledge translation. Data collected included: number of times the platform was accessed, length of time spent on the platform, accuracy of instruction provided by participants, questions asked by participants of the human character. This enabled iterative changes to be made to the program, when common knowledge deficits were identified.
Translation into practice and follow up of compliance following the face-to-face session	Data were collected from a range of stakeholders related to translation of IPC principles into practice as follows: • Education participants from the RACFs of Victoria • Demographic data • Post-education evaluation survey • Education Facility Champions • Post-education evaluation survey • Residential aged care facility managers • Post-education evaluation survey • Monash University education team • Field notes

A team of educators worked in pairs to co-deliver each education session to a maximum of 20 participants per session. Within 3 months of commencement 309 face-to-face education sessions and train the trainer sessions were provided across 226 individual RACFs, including 159 RACFs located in Melbourne metropolitan area and 67 in regional Victoria. In total, 377 face-to-face education sessions were provided across 277 individual RACFs, including 170 RACFs located in Melbourne Metropolitan area and 107 in Regional Victoria. As part of this program, 4,219 RACF staff, including 1,207 Facility Champions completed the education (Table 4).

To evaluate the education program, participants were asked to complete a feedback survey 1–5 weeks after completion of their education session. Questions asked related to the usefulness of the session, changes made to IPC practice following the session and general feedback. Overwhelmingly, the feedback was positive with RACF workers reporting more understanding of IPC practices and their application within the facility. A snapshot of the participants' responses to the process evaluation survey is presented in Table 5. Participants' questions and educators' concerns were regularly assessed by the project team; and the session content modified according with the raised needs (Table 5). Outcomes and impact evaluation of this program be presented in a subsequent publication.

Implementation of the VRS component

Monash University commenced a targeted and intensive roll out of the VRS component in November 2020 to all RACF workers that had attended the face-to-face education session. Access to the VRS was *via* an individual coded license which gave workers unlimited access to the VRS software program.

A longer than anticipated time for testing and updating the VRS to align with emerging IPC knowledge and practice related to COVID-19 precautions meant there were some delays with the roll out of the VR component to RACF's. In an effort to overcome these delays, the education team worked closely with RACF IPC leads and management in the roll out phase to facilitate license provision and VRS access for individual RACF's. A staggered approach to RACF access allowed for follow up phone and video calls and face-to-face VR support sessions with RACF IPC leads and management. To incentivize RACF workers to engage with the VRS a \$500 gift voucher was offered to the top four facilities with the most VR license activations.

Discussion and conclusion

Lessons learned

There have been a few lessons learned from this program design and implementation, which are important to document, analyze and share to improve further educational projects delivered to RACF staff. In the field of health program implementation, the discussion of the lessons learned traditionally consists of reflection on the three key questions what went right, what went wrong, and how it could be improved (38).

Acknowledging the contextual factors, this program was designed to address new reality of IPC and the use of PPE which COVID-19

TABLE 2 Risk mitigation plan.

Key risks	Proposed mitigation strategies	Roles
COVID-19 infections transmission during program implementation New outbreaks Loss of key educators Loss of key RACF workforce Risk for RACF staff and residents Reputation risk	A risk assessment to be put in place for all activities All practice to be aligned to Government guidelines including OHS controls on space requirements Educators to have and provide evidence of Influenza and COVID-19 Vaccination Screening of educators and participants for COVID-19 symptoms prior to each education session and any with symptoms to be asked to get tested and stay home Educators to receive training with academic oversight Preventive program (no overlap with crisis response)	Monash University primarily responsible DHHS to supply PPE that meets specifications in their policies and guidelines
Difficulty or delays with recruitment Delays to program implementation New outbreaks	Swiftly recruit core team of qualified educators Leverage networks to recruit Flexible recruitment responsive to flexible workforce (e.g., fractional and/or regional appointments) Set up logistics working group with HR representation Provide attractive salaries	Monash University primarily responsible DHHS to assist with communication
Failure to engage and improve understanding of diverse RACF workforce Risk for RACF staff and residents Breach of values (Monash University is inclusive) Reputation risk	Design and deliver a face to face education package tailorable to the experience and education level of attendees Develop inclusive and engaging VR/AI platform to support RACF staff in knowledge upkeep and dissemination (platform responsive to language backgrounds and accents)	Monash University primarily responsible
Insufficient reach across the sector to prevent outbreaks • Safety risk for RACFs and residents • Reputation risk	Employ dedicated personnel to manage relationships and booking with RACFs Target RACFs all over Victoria Hold 300 sessions at minimum	Monash University primarily responsible
Inconsistency in education provided by Facility Champions Misinformation New outbreaks Reputation risk	VR platform provides unlimited reinforcement of understanding of Facility Champions so they provide quality translation across other RACF staff	Monash University primarily responsible

brought to RACFs. This reality was evolving and changing in line with the SARS-CoV-2 adaptation, the stage of the pandemic, and new rapidly-attained evidence on COVID-19 infection control and prevention (39). These contextual factors impacted project planning and implementation. The importance of rapid training of RACF staff in IPC and the accurate use of PPE became heightened with the second wave of COVID-19 pandemic in Australia (7, 17); and the project team had limited time for planning the project. Nevertheless, effective leadership and the project team's previous experience in delivering healthcare related education, including state-level projects allowed for successful planning, including the design of the multicomponent training program, the development of the risk-mitigation plan, and adoption of the practical implementation approaches. A KPMG report (40) on program management in COVID-19 reality emphasized the importance of clarity of the project scope and delivery structures and the role of the project leadership. Other key lessons emphasized in this report (40), and also observed by us during the

implementation process, were the need for stakeholder engagement, effective use of resources and successful management of the project phases, ensuring flexibility in altering schedules to accommodate changing needs. Well established research-RACF community collaborations between Monash University and RACF management and stakeholders' direct interest in improved IPC skills of RACF staff were the main factors that facilitated successful implementation of the Program. The direct responsibility of the RACF management for IPC training of their staff (14) enabled the project team to run training sessions during the most challenging time when many staff were either sick or quarantined and the need for direct care was prioritized over training as the remaining staff were overworked (17).

The program design, specifically intended for the RACF setting, and particularly the multi-component program structure, contributed to successful program implementation despite the fact that some components were not engaged with as much as others by the RACF management and staff. The face-to-face training component, and

TABLE 3 Program implementation framework.

Practical approach	Description
Provide a rapid response	We will launch immediately with targeted invited RACFs (in collaboration with the Department to identify priority areas) and subsequently roll out a coordinated process for RACFs to opt-in, to book up to two education sessions for their staff in the first instance. The program applies to staff working in RACFs and this would include agency working therein. We will start with 2 teams of trainers (up to 10 sessions per week) and scale up to as many as 30 trainers (15 flexible, fractional teams, 60 or more sessions a week) as soon as possible as required to be responsive to RACF availability and flexible to the sessional nature of the workforce.
Be safe	Safety is our first priority. The program will align to the Coronavirus (COVID-19) Residential Aged Care Facilities Plan for Victoria, the Australian Government Department Coronavirus (COVID-19) guidelines for infection prevention and control in residential care facilities and the Communicable Diseases Network Australia (CDNA) National Guidelines for the Prevention, Control and Public Health Management of COVID-19 Outbreaks in Residential Care Facilities in Australia version 3.0 and applicable government restrictions. e.g., deliver training in environments with 4m² per person, physically distanced to ≥1.5 m wherever possible, screening of trainers and participants. All educators will be required to have had the current influenza vaccination, will be screened for symptoms prior to conducting all education sessions, and will work in dedicated teams to avoid cross-contamination. Participants will be screened for symptoms at the beginning of each education session and no one with symptoms will be involved in the session; we will educate groups from one RACF at a time to reduce risk of cross-contamination and only hold sessions <i>in-situ</i> where it is safe to do so and adjust maximum group size accordingly; we will consider risk management and outbreak plan of the RACF and our internal risk assessment in determining the location (with assessment of room suitability including size).
Be preventive	We will work with RACFs without current or suspected COVID-19 cases; we will not overlap with the outbreak teams providing first response and crisis training. This will be considered at the time of booking and between booking and delivery of the session.
Deliver in person	We will deliver education face-to-face in person where we can build trust, any question asked can be addressed, and the use of Personal Protective Equipment (PPE) can be demonstrated, practiced and corrected.
Be inclusive	Any RACF (with the exception of those with a positive case of COVID-19) will be able to register with us for education; staff from any and all roles in aged care delivery and support are welcome to attend non-exclusively including Registered and Enrolled Nurses, Personal Care Attendants, clinical staff, lifestyle coordinators, laundry and kitchen staff, agency staff. The program will be accessible for a range of education and language backgrounds and literacy levels, to support workers at every level across RACFs. Users of the VR platform will have the ability to engage in the virtual environment in their level of English language proficiency – and in a high English language proficiency environment – this allows users to gain the ability to communicate about the course content with high English language proficiency, as is required in a crisis.
Be flexible	The COVID-19 situation is rapidly changing, the program will be regularly reviewed for scope to respond to education demands; we will work with RACFs to book appropriate times and training locations (<i>in-situ</i> where possible within physical distancing and local risk assessments and if required at Monash University campuses, or community centres/hospital education spaces with safety being the first priority in these decisions).
Create resilient RACFs	We will ask RACFs to nominate up to two Facility Champions (per session) which we will work with closely during the education session and empower with education materials to enable them to upskill staff at their facility; we will provide up to 300 RACFs with a VR platform and license for up to 20 staff to demonstrate an accessible, tailorable and swift education solution to support an agile workforce.
Provide successful and sustainable outcomes	Provide successful and sustainable outcomes: the program will be delivered through education research. The program is evidence-based, and the team will utilize a continuous evaluation process, enabling iterative development of the program based on outcomes from each course. Data to inform program evaluation will be collected <i>via</i> knowledge quizzes at the beginning and end of the program, a structured checklist assessing proficiency of donning and doffing PPE, and assessment of infection control decision-making using an VR platform.

particularly physical practice donning and doffing PPE, were acknowledged by the participants as the most useful parts of the program. The train-the trainer component was adopted as an effective strategy to equip the RACF Facility Champions with the ability to educate others in their organization and ensure program sustainability. The core advantage of a train-the trainer model is its cost and time effectiveness when providing education to large numbers, a greater acceptance of content delivered by internal trainers; and certainty the facility has an up to date content expert to assist with day to day challenges (41–43). Despite effective implementation of face-to-face, and train-the-trainer components, the VRS component was not well accepted. As already discussed, the unanticipated challenges included the lower than expected level of computer literacy among participants

and issues with access to computers. Although the project team decided to incentivize the use of the VR component, this approach did not work given that the barriers to its implementation were not financial.

VR is an effective teaching/learning strategy, which is well established and is increasingly used in health professions education to improve procedural skills, technical knowledge and proficiency, and psychomotor skills (44–48). Acceptability and perceived usefulness of VR programs may vary and depend on the ability of the VR program to meet the users' needs and complexity of the VR platform. In Australia, VR-based education on empathy and understanding of the physical environment for dementia care workers reported that VR may differentially assist the participants of different age and English-speaking background (49).

TABLE 4 Program implementation data.

Face-to-face training sessions delivered from August 2020 to October 2021	
Sessions commissioned and provided (total number)	
Sessions commissioned by the Department of Health and Human Services	370
Sessions provided	367
Sessions commissioned by Infection Prevention Control advice and response (IPCAR)	15
Sessions provided	382
Number of residential aged care facilities visited - geographic location	
Residential aged care facilities in Melbourne Metropolitan area	170
Residential aged care facilities in Regional Victoria	107
Total number of residential aged care facilities	277
Number of residential aged care facilities and other agencies visited - facility type	
Residential facilities	224
Public residential facilities	46
Supported Residential Service facilities	4
National Aboriginal and Torres Strait Islander Aged Care Program facilities	1
Community Housing facilities	1
Mental Health Hospital facilities	1
Torrens Agency	1
Aged Care Quality and Safety Commission (ACQSC)	1
Number of residential aged care facilities and other agencies visited – care type	
Facilities with high care beds	258
Total number of high care beds	16,652
Facilities with low care beds	134
Total number of low care beds	888
Program participants	
Total number of the program participants	4,175
Total number of Facility Champions participated in the program	1,207
Virtual Reality component	
Total number of facilities provided with Virtual Reality licences	301
Number of facilities (out of 301) have had a staff member activate at least one license	100
Total number of Virtual Reality licences provided to these 301 facilities	4,644
Number of Virtual Reality licences have been activated (out of 4,644 licences provided)	231

Program limitations

This education program was designed and implemented as an emergency response to the evolving impact of COVID 19 in RACFs rather than regular planned professional development. An education program that is purposefully planned for specific learners allows for development of deeper understanding and knowledge that can be applied in the workplace to improve patient care (50). The rapid nature of the development and implementation of this education program limited the impact of the use of the VRS as a sustainable education strategy, with implications for future program implementation.

During the roll-out of the VRS, a number of unanticipated challenges were encountered in engaging RACF staff; and current activation sits at 19% of RACFs. These challenges included lower

than expected level of computer literacy among RACF workers and reported limited access to computers both during work time and outside of work. Compounding this, is the lack of dedicated professional development time for RACF workers, an issue highlighted in The Royal Commission (14). Large changes in staffing in RACFs during and following the COVID-19 pandemic has seen many RACF workers that completed the face-to-face education, no longer working in the sector. Finally, the introduction of a trained IPC lead nurse at all RACFs within the aged care sector [following the impact of COVID 19 in some RACFs and the COVID-19 Special report by The Royal Commission (14)], who have been focusing more on the requirements for their new roles and responsibilities including ensuring their IPC education qualifications are met and have not yet established program implementation/staff training in their RACF.

TABLE 5 A snapshot from the process evaluation survey and feedback from the participants and educators.

Evaluation questions from post-education surveys	Summary of the participants' responses	Examples of quotes
What changes (if any) have you seen in your practice of infection prevention following the education?	Participants reported that staff were more stringent in correctly donning and doffing PPE; they understood the use of PPE better; and there were changes in availability of PPE, such as P2/N95 masks.	"Donning and doffing with more understanding." "More concentrated effort to get it right." "We purchased nitrile gloves and changed the type of N95 masks and gowns we had. There is also more emphasis on 'fit check' when using N95 masks."
	Participants reported changes in understanding of infection prevention principles, which may assist them in the future application of PPE across different clinical situations.	"Better understanding of why and how we do infection control." "Continue infection prevention by being more aware of use of PPE."
	Participants reported higher confidence in their practice when using PPE, along with more awareness of correct practices.	"Being more aware of my actions in regards to PPE and how to correctly follow the sequence." "More confidence in ability to do things right." "Definitely more confident and not as daunted."
2. What was the most useful part of the education?	Participants overwhelmingly reported that the practical nature of the face to face sessions, especially being able to physically practice donning and doffing PPE was by far the most useful part of the session.	"Actively donning and doffing." "The hands-on approach to learner made the session more beneficial and tailored to my learning style." "The practical exercise of donning/doffing."
	Participants reported it was useful to understand different elements of infection prevention and use of PPE, such as better understanding of hand hygiene practices, zoning and donning and doffing sequences.	"Use of alcohol-based hand rub." "The understanding of clean and dirty areas." "Correct sequence of donning and doffing of PPE."
3. What was the least useful aspect of the training?	Most participants reported that all aspects were considered "very useful," "effective" and "important."	None provided in the participants' replies
4. Do you have any other feedback for us?	Many participants stated that this program was a good refresher course in infection prevention principles related to the use of PPE; and they felt it was essential to keep up to date. They recognized the need to keep updating themselves with changes related to PPE use. They also reported the sessions were interesting, engaging and interactive and educators knowledgeable and approachable. Some would have liked further information related to specific issues faced in the aged care sector in relation to ICP.	"Good refresher of the course was well worth the time." "Brilliant - could do refresher course once every 2–3 months – practice makes all difference." "It's good to keep updated to help keep people aware."
Questions and concerns raised by participants during education sessions	Specific questions during the education session	Response to the feedback
Relevance and correct use of PPE within the RACF	 The different levels of PPE use in different situations. The use of face masks and eye protection within the aged care facility. The availability of different types/levels of face masks. Correct application of P2/N95 masks. The use of eye protection – types and situations when it was required Wearing additional PPE, such as hairnets and booties. RACF staff often reported this as common practice at their facility. At times they were unsure about why they use this and how to don and doff safely when it is not included in the current sequence posters. 	The requested information was incorporated in the future sessions and followed by a discussion with the participants.
Zoning and cohorting	RACF staff reported ongoing confusion about and asked questions related to how to zone and/or cohort residents in the setting of an outbreak.	Discussion related to application of ICP principles and challenges in an aged care environment to reflect these concepts.

(Continued)

TABLE 5 (Continued)

Evaluation questions from post-education surveys	Summary of the participants' responses	Examples of quotes
Waste disposal and linen cleaning	Monash educators were often asked about correct practices related to waste disposal and linen cleaning	Discussion related to waste disposal and linen cleaning incorporated in future sessions.
Questions and concerns raised by educators during education sessions	Specific concerns	Response to the feedback
Ongoing inconsistencies in PPE practices	Eye protection – Variability in the use of and type of eye protection used in RACFs, including face shields and/or goggles, was observed	Discussion with participants during education sessions aimed to address these observations. Follow up discussion by the education team with RACF managers were also held.
	Face masks – Variability in the use a mask, including some RACFs limiting staff to two surgical masks per day and some RACFs allowing the use of cloth masks. In addition to this, there was ongoing confusion related to the use of P2/ N95 masks including of the correct practice completing a 'fit check'.	
	Hand hygiene – Continued variability in hand hygiene practice, including understanding situations when hand hygiene should occur.	

Practical implications

The need to improve career development and training the RACF workforce in Australia to improve the required essential competencies has been repeatedly highlighted (51), including their IPC competencies (7, 17). Effective IPC training is essential for protection of residents and staff in RACFs not only during a pandemic, but also for routine care; however, it is often neglected (52). Improved IPC practices will help to reduce RACF financial costs related to the need to replace quarantined staff with agency staff, and employ additional staff to address the extra workload due to the increased acuity of care (52).

Education and training in the aged care sector are often based on evidence collected in acute healthcare settings and adapted for their use in RACFs, where the needs of patients and educational level of staff are significantly different to that of RACFs. These programs are not always relevant for the RACF context (18), making it difficult for staff to translate knowledge and understanding gained from the education to care of residents in RACFs. Therefore, well planned education programs specifically designed for RACF workers would be meaningful and beneficial for future education practice.

Adding to this, the RACF workforce development in Australia is a complex issue, as RACF staff do not have time away from care tasks to attend training and access educational resources (53). Previous studies also discussed the RACF staff diversity and highlighted the need for equitable access to educational resources for staff from non-English speaking backgrounds (53). The lack of clear pathways for RACF workers to develop their knowledge and skills and advance within the sector has also been acknowledged (54). In addition to attracting and retaining, RACF staff, education and training in Australia becomes an increasingly important area of concern (54).

This program was implemented in the beginning of COVID-19 outbreak when a State of Emergency was declared in Victoria. At that time, knowledge of the impact of the pathogen and its transmission routes were limited. It is important to note that, in addition to

common worries about their own and their family's health and life, RACF workers were anxious about transmitting COVID-19 infection to residents (14). This situation was the main driver of the program uptake by RACFs, potentially reducing motivation for ongoing education related to IPC practices after the State of Emergency was lifted.

We shared this community case study to demonstrate that educational sector-aged care sector partnership enhanced the collaborative capacity of our project for the design, development and implementation of an education program specifically for the IPC training of RACF workers. Careful project planning and program co-design, strong leadership, effective communication with the project stakeholders and their engagement in the project, as well as process evaluation and program adaptation to reflect the participants' needs and address the educators' concerns, were the critical success factors that facilitated smooth implementation. The program provided direct feedback and support to industry partners, and optimized potentially life-saving procedures during a traumatizing time for the sector.

In regards to the programmatic elements, we aimed to highlight the RACF workers' and managers' preference for the traditional face-to-face and the train-the trainer components of the IPC training rather than VR component. In emergency situations, such as the COVID-19 outbreak, we suggest that developers of educational projects intended to upskill RACF staff use these traditional educational methods. However, the use of technology, such as VR, for education purposes in RACFs warrants further exploration.

Ethical issues

An online survey using a secure web-based platform was used to collect pre-and post-quiz knowledge data. Completion of the quiz was anonymous and contained no identifying features. Participants used a QR code at the face-to-face session to access and complete the pre-quiz and were emailed the link to the

post-quiz 3-6 weeks following completion of face-to-face education. Participant email addresses were provided to the Monash University PPE Project Administrator upon registration in the program.

VRS data was collected when participants accessed and interacted with the virtual reality platform using an individual access code emailed to each participant with the link to the post-quiz survey. Prior to entering the VRS, participants were required to complete a privacy statement regarding the collection and use of data for this activity. Data collected were de-identified, aggregated and analyzed to evaluate the PPE education program outcomes.

All survey and VRS data were stored securely in LabArchives, and were accessible only to the research team.

Data availability statement

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author.

Ethics statement

The studies involving human participants were reviewed and approved by the Monash University Human Research Ethics Committee (Project ID: 26516). Written informed consent for participation was not required for this study in accordance with the national legislation and the institutional requirements.

Author contributions

SD, JM, HR, PR, and DG secured the grant. SD and VT conducted the literature search and drafted the manuscript with support and guidance from JM, HR, PR, and DG. All the authors critically reviewed and contributed to the individual parts of the manuscript,

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approved the final version, and agreed to be accountable for the content of this work.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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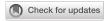
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Stigma toward people with COVID-19 among Bangladeshi older adults

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The onset of the coronavirus disease (COVID-19) pandemic and its overwhelming physical and mental health burden can result in stigmatization toward the disease and those affected. This study aimed to measure the prevalence of COVID-19-related stigma and its associated factors among older people in Bangladesh. This cross-sectional study was conducted among 1,045 Bangladeshi older adults aged 60 years and above through telephone interviews in September 2021. The outcome was measured using an eight-point Stigma Scale, adapted to the Bengali language. Level of stigma was indicated by the cumulative score of the eight-items, ranging from 0 to 8, with a higher score indicating a higher level of stigma. On average, participants had stigmas on three of the eight items, and 62.6% had a high stigma score. The most prevalent stigmas were as follows: COVID-19 is a punishment from God (79.3%), patients with previous COVID-19 must be isolated (67.3%), and people infected with COVID-19 did not meet hygiene standards (63.9%). Participants who lived in rural areas (β: 0.67, 95% CI: 0.39 to 0.95) and who perceived needing additional care during the pandemic (B: 0.35, 95% CI: 0.09 to 0.60) had a higher average stigma score, whereas stigma scores were lower among unemployed/retired participants (β : -0.22, 95% CI: -0.45 to 0.00). The study findings suggest implementing interventions to raise awareness through appropriate health literacy interventions and mass media campaigns.

KEYWORDS

stigma, COVID-19, older adults, aged, Bangladesh

Introduction

The novel coronavirus disease (COVID-19) pandemic is recognized as one of the biggest global public health challenges of the century. According to the Director-General of the World Health Organization, "Our greatest enemy right now is not the virus itself. It's fear, rumors, and stigma" (1). Stigma is an important public health issue because of its direct correlation with adverse physical and mental health (2). Furthermore, stigma creates constraints to access to health and social services, disrupts health-seeking behavior, and creates social discrimination, exclusion, mental distress, and violence (3). Stigma may lead to distress and can affect early detection and timely treatment (4). Delayed diagnosis is linked with prognostic deterioration of the disease among vulnerable groups such as the older population, facilitating the quick spread of the infection, and increasing disease severity and complications (5). Stigma is also closely related to discrimination and injustice (6).

Despite its strong relationship with adverse health consequences, historically, stigma has been prevalent during the peak of many infectious diseases, including HIV/AIDS, tuberculosis and COVID-19 (7). Several factors facilitate stigma, including the lack of awareness, misinformation, fake news, extreme fears, and anxiety about the diseases, which are widespread during the COVID-19 pandemic (8). Misconceptions about various aspects of the pandemics as well as fear of the disease further reinforce the stigma in societies (9, 10). In line with these, evidence suggests that facilitators of stigma are widespread. Studies from Jordan (11), Uganda (12), and Lebanon (13) found COVID-19-related stigma to be prevalent among the general population. Notably, these studies include younger adults, and there is scarce COVID-19related stigma research among the older population. In a study from Ghana, patients with COVID-19 reported experiencing various forms of stigma, e.g., stereotyping, social exclusion, mockery, finger-pointing, and insults (14). In another study from Ghana, nearly half of the participants exhibited stigma and discriminatory tendencies toward COVID-19 survivors (15). In the study from Malaysia, COVID-19-recovered participants expressed experiencing being labeled and blamed by the people around them (16). For several reasons, mentioned in the following paragraph, we believe that the level of COVID-19 stigma would be higher among older adults, in general, and more especially among Bangladeshi older adults, which warrants a separate study. In resource-constraint countries, such as Bangladesh, some critical social factors, including poverty, poor living conditions, low illiteracy rates, ethnic disparity, age, and gender disparities, can make COVID-19related stigma conditions more complicated than in other resource-rich countries (4, 17). In line with the international studies, stigma against specific groups, such as healthcare professional, returning migrant workers, and persons with a travel history from COVID-19 hotspot countries (18–21), was also observed in Bangladesh (22–24).

The population groups most vulnerable to stigma are those directly and indirectly affected by the disease or those highly susceptible to the infections (6). Evidence has already proved that older adults (the age group of 65 and above) are one of the most vulnerable groups impacted by the COVID-19 disease globally. Compared to other age groups, older adults are at increased risk of developing severe disease, requiring hospitalization, and dying from COVID-19. According to Kaiser Family Foundation (KFF) data, as of 19 September 2021, about 80% of COVID-19 deaths were among those aged 65 and above (25). Recent studies conducted among older Bangladeshi adults aged 60 years and above revealed significant misconceptions and an overwhelming fear of COVID-19 (9, 10). Bangladeshi older adults also faced difficulty in getting medicine and receiving COVID-19-related information during this pandemic (26). The literacy rate and access to health information, two important determinants of stigma, are low among Bangladeshi older adults (27). While all these characteristics suggest that stigmas can be higher among Bangladeshi older adults, there is no evidence from Bangladesh regarding the extent to which COVID-19-related stigmas are present among them. In this context, using an analytical approach, our paper investigates the level of stigma toward people with COVID-19 and its associated factors among older adults in Bangladesh.

Materials and methods

Study design and participants

This cross-sectional study was conducted remotely through telephone interviews in September 2021 by the Aureolin Research, Consultancy and Expertise Development (ARCED) Foundation. The primary challenge for this study was to develop a sampling frame to select the participants during the COVID-19 pandemic, and thus, we utilized a pre-established registry, developed through merging the contact information of households from 10 different community-based studies accomplished by Aureolin Research, Consultancy, and Expertise Development (ARCED) Foundation during 2016-2020, which included households from all eight administrative divisions of Bangladesh, as a sampling frame. Based on the population distribution of older adults by geography in Bangladesh, we adopted a probability proportionate to size (of the eightdivision) approach to select older adults in each division (28). The inclusion criterion was the minimum age of 60 years. Considering 50% prevalence with a 5% margin of error, at

the 95% level of confidence, 90% power of the test, and 95% response rate, a sample size of 1,096 was required. However, of the 1,096 eligible participants approached, 1,045 responded to the study with an overall response rate of approximately 95%.

Measures

Outcome measure

Level of stigma was measured using the eight-item Stigma Scale, which was previously translated and validated in the Bengali language (11). Each item was nominally coded as a yes/no statement where a correct response scored 0 and each stigma scored 1. The cumulative of the eight items generated a stigma score for each participant. The cumulative score of the eight-items ranged from 0 to 8, with a higher score indicating a higher level of stigma. We further classified COVID-19-related stigma into low (if the stigma score was below the mean of the scale value, i.e., <4) or high (if the stigma score was equal to or higher than the mean of the scale value, i.e., ≥ 4). The scale is reliable among the study participants, as indicated by the high internal consistency (Cronbach's alpha 0.74).

Explanatory variables

Explanatory variables considered in this study were age (categorized as 60-69 and ≥70), sex (male/female), marital status (married/without partner), formal education (no/yes), family size (≤4 or >4), family income in Bangladeshi Taka (BDT) (<5,000, 5,000-10,000, >10,000), residence (urban/rural), current work arrangements (employed and unemployed/retired), living arrangements (living alone or with family), walking distance to the nearest health center (<30 /≥30 min), memory or concentration problems (no problem/low memory or concentration), the presence of prevalent non-communicable chronic conditions (yes/no), concerned about COVID-19 (not concerned/somewhat to very concern), overwhelmed by COVID-19 (hardly, sometimes/often), perceived to be at risk of COVID-19 (low risk/high), difficulty in obtaining food, medicine, routine medical care, and earning during COVID-19 (no/yes), perceived isolation (hardly, sometimes/often), frequency of communication with friends and family during COVID-19 (less than previous/same as previous), perceived that family members are non-responsive (yes/no), and that they required additional care during COVID-19 (yes/no). Self-reported information on pre-existing medical conditions, such as arthritis, hypertension, heart diseases, stroke, hypercholesterolemia, diabetes, chronic respiratory diseases, chronic kidney disease, and cancer, was collected.

Data collection tools and techniques

A pre-tested semi-structured questionnaire was used to collect the information through a telephone interview. Data collection was accomplished electronically using SurveyCTO mobile app (https://www.surveycto.com/) by trained research assistants, who were recruited based on previous experience administering health surveys using the same electronic platform. The research assistants were trained extensively before the data collection through Zoom meetings.

The English version of the questionnaire was first translated into Bengali language and then back-translated to English by two researchers to ensure the contents' consistency. The questionnaire was then piloted among a small sample (n=10) of older adults to refine the language in the final version. The tool used in the pilot study did not receive any corrections/suggestions from the participants in relation to the contents developed in the Bengali language.

Statistical analysis

The distribution of the variables was assessed through descriptive analysis. We used linear regression models to explore the factors associated with stigma. The initial model was run with all potential covariates, and then, using the backward elimination criteria with the Akaike information criterion (AIC), the variables for the final model were selected and executed. Adjusted beta-coefficient and associated 95% confidence interval (95% CI) were reported. We also performed the model diagnostics, such as normality of the residuals and multicollinearity using variance inflation factor (VIF). All analyses were performed using the statistical software package Stata (version 14.0).

Results

Characteristics of the participants

Table 1 describes the sociodemographic and lifestyle characteristics of participants. A higher proportion of participants were aged 60–69 years (75.6%), male (59.3%), married (76.5%), without formal schooling (51.7%), from a family with more than four members (66.8%), with monthly family income between 5,000 and 10,000 BDT (44.9%), from rural areas (82.6%), unemployed/retired (61.1%), living with family members (94.9%), and residing <30 min of walking distance to the nearest health center (55.6%). Many participants also reported pre-existing non-communicable chronic conditions (57.2%). The majority of participants reported that they were concerned about (66.7%) and overwhelmed by (67.9%) COVID-19 but perceived themselves

TABLE 1 Characteristics of the participants (N = 1,045).

TABLE 1 (Continued)

Characteristics	n	%	Characteristics	n	%
Administrative division			Feeling concerned about COVID-19		
Barishal	146	14	Not concerned	348	33.3
Chattogram	98	9.4	Somewhat to very concern	697	66.7
Dhaka	172	16.5	Feeling overwhelmed by COVID-19		
Mymensingh	69	6.6	Hardly	334	32.1
Khulna	198	19	Sometimes/Often	706	67.9
Rajshahi	145	13.9	Self-perceived risk of COVID-19		
Rangpur	161	15.4	Low risk	760	72.7
Sylhet	56	5.4	High	285	27.3
Age (year)			Difficulty getting food during COVID-19		
60-69	790	75.6	No difficulty	514	49.7
≥70	255	24.4	Some difficulty	521	50.3
Sex			Difficulty getting medicine during COVID-19		
Male	620	59.3	No difficulty	764	74.8
Female	425	40.7	Some difficulty	258	25.2
Marital status			Difficulty earning during COVID-19		
Married	799	76.5	No difficulty	274	27.7
Without partner ^a	246	23.5	Some difficulty	714	72.3
Formal schooling			Difficulty receiving routine medical care during		
No	540	51.7	COVID-19		
Yes	505	48.3	No difficulty	709	71
Family size			Somewhat difficulty	290	29
≤4	347	33.2	Frequency of communication during COVID-19		
_ >4	698	66.8	Same as previous	656	62.8
Family monthly income (BDT) ^b			Less than previous	389	37.2
<5,000	121	11.6	Perceived isolation during COVID-19		
5,000-10,000	469	44.9	Hardly	718	68.7
>10,000	455	43.5	Sometimes/Often	327	31.3
Residence			Perceived family members to be non-responsive		
Urban	182	17.4	No	738	70.6
Rural	863	82.6	Yes	307	29.4
Current work arrangements			Feeling that they required additional care during the		
Employed	407	39	pandemic		
Unemployed/retired	638	61.1	No	770	73.7
Living arrangement	030	01.1	Yes	275	26.3
Living with family	992	94.9		2,3	2010
Living alone	53	5.1	^a Includes widowed, separated, and never married.		
Walking distance to the nearest health center	33	5.1	^b BDT ~0.012 USD.		
<30 min	581	55.6			
>30 min	464	44.4			
Problem in memory or concentration	101	11,7	as at low risk of developing COVID-19 (7	2.7%) In to	otal, 37 29
No problem	676	64.7	of the participants reported reduced co		
Low memory or concentration	369	35.3	the pandemic, and many reported exp		
Prevalent non-communicable chronic conditions	309	55.5	in obtaining food (50.3%) and earning r		
No	447	42.8	than a quarter of the participants repo	-	
Yes	598	57.2	(31.3%) and perceived that they requ		-
160	370	J1.4	during the pandemic (26.3%), but their f		
		(Continued)	non-responsive (29.4%).	111011	13015 WCI

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Prevalence of stigma

Table 2 shows the prevalence of stigma related to COVID-19 among the participants. On average, participants had stigma on three items (mean stigma score = 2.97 and range 0-8). We found that 62.6% of the participants had a high level of stigma. The most prevalent stigmas were as follows: infection with COVID-19 is a punishment from God (79.3%), previous

TABLE 2 Prevalence of stigma among the participants (N = 1,045).

Items of Stigma Scale	n	%
Infection with COVID-19 is a punishment from God	829	79.3
(yes)		
Previous COVID-19 patients have to be isolated (yes)	703	67.3
People infected with COVID-19 did not meet the	668	63.9
standards for hygiene (yes)		
It is unsafe to deal with people who have been infected	652	62.4
with COVID-19 (yes)		
People who have been infected with COVID-19 should	623	59.6
expect some restrictions on their freedom (yes)		
It should not be allowed to work for those who have	353	33.8
been infected with COVID-19 (yes)		
You do not want to be a friend of someone who has	285	27.3
been infected with COVID-19 (yes)		
Those infected with COVID-19 should be ashamed of	192	18.4
themselves?		

patients with COVID-19 have to be isolated (67.3%), people who were infected with COVID-19 did not meet the standards for hygiene (63.9%), it is unsafe to deal with people who have been infected with COVID-19 (62.4%), and people who have been infected with COVID-19 should expect some restrictions on their freedom (59.6%). Other less prevalent yet notable stigmas related to COVID-19 included: it should not be allowed to work for those who have been infected with COVID-19 (33.8%), to be friends with someone who has been infected with COVID-19 (27.3%), and those infected with COVID-19 should be ashamed of themselves (18.4%).

Factors associated with stigma

An initial regression model was run with all the variables presented in Table 1, and a final model was executed with variables retained from the initial model based on the lowest AIC values. The result of the final model is presented in Table 3. The Q-Q plot of the residuals of the model shows that the data are normally distributed, whereas VIF values of <10 for each variable (Supplementary Tables S1, S2) suggest the absence of multicollinearity. In both adjusted and unadjusted analyses, residence and perception that they need additional care during the pandemic was associated with higher stigma score. In the adjusted analysis, participants who lived in rural areas had 0.67 units (β : 0.67, 95% CI: 0.39 to 0.95) higher stigma than those living in urban areas. Likewise, participants who felt that they required additional care during the pandemic had 0.35 unit

TABLE 3 Factors associated with stigma among the participants (N = 1,045).

Characteristics	Unadjusted			Adjusted		
	β	P	95% CI	β	P	95% CI
Residence						
Urban	Ref			Ref		
Rural	0.68	< 0.001	0.41, 0.96	0.67	< 0.001	0.39, 0.95
Current occupation						
Employed	Ref			Ref		
Unemployed/retired	-0.21	0.072	-0.43, 0.02	-0.22	0.048	-0.45, -0.002
Frequency of communication during COVID-19						
Same as previous	Ref			Ref		
Less than previous	0.11	0.321	-0.11, 0.34	0.18	0.137	-0.06, 0.41
Perceived isolation during COVID-19						
Hardly	Ref			Ref		
Sometimes/often	0.21	0.071	-0.02, 0.44	0.15	0.223	-0.09, 0.38
Feeling that they required additional care during the pandemic						
No	Ref			Ref		
Yes	0.36	0.005	0.02, 0.60	0.35	0.008	0.09, 0.60

higher stigma score (β : 0.35, 95% CI: 0.09 to 0.60) than those who did not feel so. On the other hand, stigma scores were 078 unit lower among unemployed/retired participants than those employed (β : -0.22, 95% CI: -0.45 to 0.00).

Discussion

This study assessed the COVID-19-related stigma and its associated factors among Bangladeshi older people. Overall, our study found a high prevalence of stigma among participants. Although we did not find any studies exploring COVID-19related stigma among older adults in Bangladesh and worldwide, our findings are consistent with similar literature among younger people. Our findings are similar to studies among COVID-19 survivors (24-59 years) in Uganda (12), COVID-19infected Jordanian people (18-65 years) (11), Lebanese adults (>18 years) (13), and Chinese adults (aged ≥18) living in the United States (8). These studies reported highly prevalent COVID-19-related stigma, ranging from 62 to 65%. Likewise, in two studies from Ghana, patients with COVID-19 reported experiencing stigma and discrimination (14, 15). In the study from Malaysia, COVID-19-recovered participants expressed experiencing being labeled and blamed by the people around them (16). While being novel among the older population, our study extends and supplements previous research among younger adults (8, 11-13) to enrich our understanding of COVID-19 stigma. Our study's finding may not be surprising and could be attributable to various factors. One potential reason for a high COVID-19-related stigma in older people in our study can be their limited literacy and inadequate understanding of the disease and how the SARS-CoV-2 virus is transmitted (11). Specifically, in Bangladesh, literacy rate is only 39.4% among older adults aged 65 years or above (29). Furthermore, given that the second wave of the COVID-19 pandemic was ongoing in Bangladesh during the data collection period, and COVID-19-related misinformation, fear, and panic may be other reasons for the observed stigma (30). As COVID-19-related mortality instigates fear and panic among individuals (8, 31), having family members, relatives, friends, colleagues, and neighbors die from the SARS-CoV-2 virus may be another reason for increasing COVID-19-related stigma (30). Irrespective of the reasons, prevalent stigma during the pandemic could threaten public health preventive measures. High COVID-19-related stigma may increase the risk of spreading the SARS-CoV-2 virus by delaying the early testing and detection of COVID-19, hampering individuals' health-seeking behaviors (32), and utilization of healthcare services (30). Furthermore, COVID-19related stigma may increase individuals' psychological distress (12). Our findings suggest that it is vital to tailor interventions to this specific group of older people to reduce COVID-19-related prejudices and stigmas.

In our study, compared to urban residents, those living in rural areas in Bangladesh had a higher COVID-19-related stigma. Given that stigma is highly correlated with literacy and can be reduced with appropriate educational interventions (33), the wide gap in literacy rate between urban and rural Bangladesh (34) may explain this finding. Rural Bangladesh has a low literacy rate and limited access to health information (34). Studies have already shown that people with limited knowledge or education are more stigmatized than others (35). As such individuals with limited knowledge about COVID-19 transmission and prevention may have increased stereotypes and stigma related to the disease (36), additionally, they have limited awareness about the pandemic and increased fear of SARS-CoV-2 virus infection, which may further increase the likelihood of COVID-19-related stigma (37). Our finding highlighted the importance of providing older residents in rural areas of Bangladesh with appropriate knowledge about the prevention and transmission of COVID-19, which can potentially reduce COVID-19-related stigma among in the community.

In our study, stigma scores were also higher in the older adults who felt that they required additional care during the COVID-19 pandemic. No previously documented studies are available for cross-comparisons. The potential explanations for the finding could be attributed to personal insecurities amidst the pandemic. When a person is highly concerned about their inadequate medical support and care during COVID-19 and its consequence (e.g., possible deterioration of existing comorbidities, illness, death, etc.), mental trauma is likely to be high (38). Further, in the context of Bangladesh, where financial support from governmental and non-governmental organizations are limited (39) and financial and food insecurities are high, the COVID-19 pandemic has negatively impacted livelihood directly or indirectly (39). This disruption in household food supply and livelihood strategies may have exacerbated their fear and mental trauma (40). In addition, health facilities were disrupted, and routine medical care and medications were inaccessible in Bangladesh during the pandemic (26). Such concerns may have produced negative thoughts about COVID-19, leading to COVID-19-related stigma (30).

We also found that unemployed/retired participants had lower COVID-19-related stigma than those employed. We did not find any study in the literature to compare this finding with. The probable reason is that unemployed/retired older people mostly stay at home and get adequate time to read newspapers, watch live television news, and engage in interactions and communications with families, which can be a vital source of COVID-19 information (10). Furthermore, they are less fearful about the infection of COVID-19, given that their limited exposure at the workplace or outside of the home. Thus, they may be less fearful and less stigmatized against COVID-19 (30).

Strengths and limitations of the study

To the best of our knowledge, this is the first study that explored the level of COVID-19-related stigma and associated factors among older people in Bangladesh. However, the study has specific limitations. First, our research was cross-sectional in nature. Therefore, causality cannot be established. Second, our study is limited to quantitative analysis, as we did not explore the qualitative aspects of older people's COVID-19-related stigma.

Conclusion

Overall, we found that the prevalence of stigmas related to COVID-19 is high among the older population in Bangladesh, which has an implication for policy and practice in COVID-19 management and moving beyond the WHO's world goal of 70% fully vaccinated by mid-2022. It is important that policymakers and public health practitioners working in this space are cognizant of the prevalent stigma while designing and planning for mass media campaigns to inform, educate, and counter the stigma associated with COVID-19. Failure to consider the context for stigma may result in suboptimal reach and social exclusion of the people affected with COVID-19 in Bangladesh. Given the high level of COVID-19 stigma in rural areas of Bangladesh, initiatives should be directed toward this targeted population.

Data availability statement

The original contributions presented in the study are included in the article/Supplementary material, further inquiries can be directed to the corresponding author/s.

Ethics statement

The Institutional Review Board of the Institute of Health Economics, University of Dhaka, Bangladesh approved the study

protocol (Ref: IHE/2020/1037). All participants enrolled in the study provided voluntary verbal informed consents.

Author contributions

SKM conceived and designed the study. MMR and SKM carried out the data analysis and interpretation of the result. SKM, AMA, UNY, MNH, MMR, MS, MAR, and DL contributed to the first draft of the manuscript. SG, UNY, DL, and MNH extensively edited the first draft to finalize. All authors approved the final version of the manuscript.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpubh. 2022.982095/full#supplementary-material

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Does home and community-based services use reduce hospital utilization and hospital expenditure among disabled elders? Evidence from China

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Introduction: In the background of aging in place, home and community-based services (HCBS) have been playing an increasingly important role in long-term care (LTC) security systems. However, it is still uncertain whether and how HCBS use affects hospital utilization and the corresponding expenditures.

Methods: Using data from the China Health and Retirement Longitudinal Survey (CHARLS) and the China City Statistical Yearbook, the instrumental variable (IV) approach is applied to identify the causal effects of HCBS use on hospital utilization and hospital expenditure among disabled elders.

Results: We find that HCBS use significantly reduces the probability of being hospitalized, the times of hospitalization, and the length of inpatient stay, as well as the total, out-of-pocket and reimbursement inpatient expenditures, demonstrating not only the substitution impact of HCBS for hospital care but also the effectiveness of medical expenditure control in LTC security systems. Heterogeneity analysis shows that the impacts of HCBS use on hospital utilization and hospital expenditure concentrate on disabled elders who are younger, male, living in urban areas, or from higher-income households; both healthcare and spiritual consolation services have significant negative effects, while the anticipated effects of daily care service use are not supported. The possible mechanisms are the substitution of HCBS for hospital care and the improvements in both the physical and psychological health of disabled elders. However, the mechanism of adverse events decrease is not verified, which needs to be investigated further with more proxy variables.

Conclusion: This study provides empirical evidence that HCBS use can not only reduce hospital utilization and hospital expenditure among disabled elders but also improve their physical and psychological health. Policy designs should emphasize the orientation of HCBS, ensure the fundamental and central position of HCBS in the formal care service system, pay more attention to the accessibility and affordability of HCBS for fragile groups, and diversify and optimize the development of the health service and the spiritual consolation service.

KEYWORDS

home and community-based services, hospital utilization, hospital expenditure, substitution effect, health effect

Introduction

With the ever-increasing aging population, elders with disabilities are growing and their long-term care (LTC) needs have been bringing substantial financial and caregiving burdens to households and governments (1, 2). In OECD countries, LTC expenses were 0.5 to 5 times the median disposable income of older adults aged 65 and over in 2020 (3). Public LTC expenditure was expected to increase from 1.6% of GDP in 2016 to 2.2% in 2040 in the European Union (4). When family caregivers cannot fully meet LTC needs, households will shift to formal care services to supplement and even replace informal care. Home and community-based services (HCBS), as a category of more preferable and less costly services, have been playing an increasingly important role in LTC security systems. On the one hand, HCBS can satisfy the needs of elders better because the majority of them prefer to live in their own homes and have a greater mastery of their daily lives. On the other hand, services supplied in home and community-based settings are much cheaper than in institutions, so HCBS becomes an alternative for governments to control LTC costs more effectively (5). Meanwhile, HCBS can also substitute for hospital care because it can enable hospital inpatients to be discharged sooner (6). A growing body of research has evaluated the impacts of HCBS on hospital utilization and the corresponding expenditures, but no unanimous conclusion has been reached.

Early studies usually apply a comparison-group strategy or a randomized design to evaluate the effects of HCBS (7). However, most find no significant impacts on medical service utilization or expenditures (6). Recently, some studies have supported the effectiveness of HCBS use in reducing hospital utilization. HCBS use is found to be related to a lower probability of hospitalization (8), and the more volume of HCBS use, the less likely it is to be hospitalized, though the effect may fade over time (9). Studies using macro data at the district level also provide encouraging evidence. Forder (10) reported that every additional £1 expended on care home services can reduce hospital costs by approximately £0.35 and vice versa, implying that care home services and hospital services can partially substitute for each other. Gaughan et al. (11) found that an increase in care home beds can reduce delayed discharges significantly. Still, there are doubts about the negative effects of HCBS use on hospital utilization. Hermiz et al. (12) found that although home visits by community nurses and preventive care by general practitioners improve the health knowledge and life quality of patients discharged after acute care, these services have no effect on readmission to the hospital or visits to general practitioners. Even more, Deraas et al. (13) reported that LTC rates (total number of LTC recipients per 1,000 inhabitants) have a weak positive adjusted relation to HD rates (hospital days per 1,000 inhabitants). These inconsistent conclusions may arise from various types of HCBS, diverse target populations, different research designs, etc., making the effects of HCBS on hospital utilization and expenditure unclear, and many of the studies are also limited to small sample sizes and lack of concern for endogeneity. The two studies of Forder (10) and Gaughan et al. (11) selected the instrumental variable (IV) approach to address endogeneity, but both use macro data at the district level, not representative individual data. Therefore, combining nationally representative individual data from the China Health and Retirement Longitudinal Survey (CHARLS) and city-level macro data from the China City Statistical Yearbook, this study investigates the impacts of HCBS use on hospital utilization and expenditure among disabled elders.

HCBS use can affect hospital utilization directly and indirectly. First, as a substitute for hospital care, HCBS can be used to replace hospital care directly. If HCBS is available and cheaper, patients will transfer from hospitals to homes or community centers when ready to be discharged medically, which will attenuate hospital bed-blocking. Second, HCBS use can indirectly reduce hospital admissions and readmissions by better meeting LTC needs and reducing adverse events. Disabled elders are more likely to be hospitalized with unmet needs, but this situation disappears 6 weeks after enrolling All-inclusive Care program (14). Older patients are vulnerable (15), of whom 20% experience adverse events during the early several weeks after discharge (16), which can lead to readmissions. Adequate care can be very helpful for them to manage well (17). Third, through its effects on health, HCBS use can indirectly influence hospital utilization. The supply and utilization of HCBS can increase the physical and psychological health of the older adults (18), which can decrease hospital utilization.

The IV approach is applied to identify the causal effects of HCBS use on hospital utilization and hospital expenditure. We first demonstrate that HCBS use significantly reduces the probability of being hospitalized, the times of hospitalization and length of inpatient stay, and the total, out-of-pocket (OOP), and reimbursement inpatient expenditures. Then, we compare heterogeneous effects of HCBS use across individual characteristics and service categories and find that the effects concentrate on the disabled elders who are younger, male, living in urban areas, or from higher-income households, and both health services and spiritual consolation services have significant negative impacts on hospital utilization and hospital expenditure, while the anticipated effects of daily care service use are not supported. Finally, we demonstrate that the HCBS use by disabled elders is beneficial to their physical and psychological health, which can further reduce their hospital utilization and hospital expenditure.

This study makes several contributions to the literature as follows. First, using nationally representative individual data from the recent wave of CHARLS, this study provides empirical evidence from the individual level to support the substitution of LTC services for medical care and the medical cost control effect of HCBS. Compared to macro data, there is abundant information on demographic and socioeconomic factors, which are controlled for when they are potential confounders, helping us to estimate the effects more precisely. Second, by applying the IV method and controlling for city-level confounders from the China City Statistical Yearbook, this study addresses the potential endogeneity of HCBS use more carefully. Third, in addition to previous studies, this study investigates the heterogeneous effects of HCBS use on different groups with individual characteristics and the heterogeneous impacts of three different types of HCBS use, which provide empirical evidence for the further optimization of service items. Fourth, this study argues that the possible mechanisms are the substitution of HCBS for hospital care and the improvement of both the physical and psychological health of disabled elders.

Materials and methods

Data source

Individual data used in this study are from the CHARLS, while city-level data are from the China City Statistical Yearbook. CHARLS is an interdisciplinary longitudinal survey conducted by the National School of Development at Peking University, and CHARLS has been collecting abundant information from a nationally representative sample of Chinese residents aged 45 years and above on their demographic characteristics, family structure, physical and psychological health, medical services utilization and expenditures, household income, and consumption. The baseline survey was conducted in 2011, and three follow-up surveys were implemented in 2013, 2015, and 2018, with a final sample of 19,000 respondents from 12,400 households. We only use the recent wave of data in 2018 because only in this wave there was information on HCBS use, the key independent variable in this study. The China City Statistical Yearbook contains primary statistical data on the social and economic development of more than 650 cities in China, and we use city-level information in 2018 on population, economy, and public health conditions.

Study sample

The study sample consists of disabled elders who are 60 years or older. Respondents were inquired about their difficulties in ADLs, including dressing, bathing, eating, getting into or out of bed, using the toilet, and controlling urination, and in instrumental ADLs, such as doing household chores, preparing hot meals, shopping for groceries, making phone calls, taking medications, and managing money. Individuals who reported having difficulties in any of those activities are defined as disabled in this study. We first identify 6,734 disabled people and then drop those under the age of 60 years and those with missing information on independent variables. Finally, 4,544 valid samples remain.

Variables

Outcome variables in this study are selected from two aspects: hospital utilization and hospital expenditure. Following previous studies (19-21), we measure hospital utilization by three variables: hospital admission, hospitalizations, and length of inpatient stay, and select multiple variables of hospital expenditure: total inpatient expenditure, OOP inpatient expenditure, and reimbursement inpatient expenditure. Hospital admission is assessed with the question "Have you received inpatient care in the past year?" and takes the value 1 if the answer is "yes" and the value 0 if the answer is "no." The variable hospitalizations is a count variable that measures the number of times a disabled older adult had been hospitalized during the past year. Length of inpatient stay is also a count variable representing the number of nights a disabled older adult had spent for the last hospitalization in the past year. For variables of hospital expenditure, the respondents were required to report the total medical cost for all the inpatient care they had received during the past year and the OOP part of it, so the reimbursement inpatient expenditure is the difference between the two.

The key independent variable is HCBS use, constructed according to the question, "Have you ever received the following home and community care services?" The answers include daycare centers, nursing homes, senior dining tables, regular physical examinations, onsite visits, family beds, community nursing, health management, entertainment, and the option of "other." HCBS use is coded as 1 if a respondent reported having used any of the above services and 0 if the respondent had not.

Covariates are chosen from two aspects: individual level and city level, to account for possible confounding factors. While demographic and socioeconomic variables at the individual level include age, female, marital status (married and living with one's spouse = 1, other = 0), education level (primary school and below = 0, junior high school and above = 1), residence (urban = 1, rural = 0), number of living children, UEBMI (having urban employee basic medical insurance = 1, otherwise = 0), URRBMI (having urban and rural residents basic medical insurance = 1, otherwise = 0), and household income per capita, city-level covariates contain natural growth rate of population, GDP per capita, fiscal expenditure per capita, number of hospital beds per 1,000 inhabitants, and number of doctors per 1,000 inhabitants.

The ordinary least squares model

We use the ordinary least squares (OLS) model to estimate the association between HCBS use and hospital utilization. The equation is as follows:

$$Y_i = \alpha_0 + \alpha_1 HCBS_i + \alpha_2 X_i + \alpha_3 W_c + u_i \tag{1}$$

 Y_i represents the potential outcomes of hospital utilization or hospital expenditure for the disabled elder i, including six indicators: hospital admission, hospitalizations, length of inpatient stay, total inpatient expenditure, OOP inpatient expenditure, and reimbursement inpatient expenditure. $HCBS_i$ is a dummy variable indicating whether the disabled elder i had used HCBS in the past year. While X_i is a set of individual covariates including age, age's square, female, marital status, education level, urban residence, number of living children, UEBMI, URRBMI, and household income per capita, W_c contains city-level variables such as natural growth rate of population, GDP per capita, fiscal expenditure per capita, number of hospital beds per 1,000 inhabitants, and number of doctors per 1,000 inhabitants.

Instrumental variable approach

The endogeneity of HCBS use should be considered when estimating the impacts of HCBS use on hospital utilization and hospital expenditure. The endogeneity may stem from the two following sources: first, there may be bias from omitted variables. Factors such as the quality of LTC, the quality of medical care services, individual preference, and so on may simultaneously affect the decision between HCBS and hospital care, which are

unobservable or unavailable. Second, there may be bias from self-selection. Whether a disabled elder used HCBS is decided by oneself or one's family, which may lead to systematic differences between the sample who had used HCBS and the one who had not. In the following section of Descriptive Statistics, we find significant differences in age, marital status, educational level, and GDP per capita between the used and unused samples, indicating that there may be endogeneity caused by self-selection.

We apply the IV approach to address the potential endogeneity of HCBS use. Following previous studies (22-24), we use Ratecity, which represents the average utilization rate of HCBS in the city where the disabled elder i lived, as the IV of HCBS use. First, Ratecity is strongly related to the HCBS use by a disabled elder. Traditionally, most of the disabled elders in China depend on informal care, especially the care provided by spouses and children, to meet their LTC needs, and both the supply and utilization of HCBS are limited. The increase in HCBS use in recent years is mainly driven by the pilot reform of community and home-based care services for older adults, which is declared to start officially in 2016, aiming to build a multi-level care service system that is based on home care, supported by community care, and supplemented by institution care. The HCBS use by a disabled elder is affected by the supply of those services in the city and the demonstration effect of other people; therefore, Ratecity is closely associated with one's HCBS use. Second, Ratecity does not directly influence the hospital utilization and hospital expenditure of a disabled elder. As discussed just now, the variation in Ratecity among various cities is mainly affected by exogenous institutional reform, making Ratecity independent of other factors that influence the hospital utilization and hospital expenditure of a disabled elder. Moreover, by controlling for city-level covariables and carefully excluding the individual self when calculating Ratecity, the independence of *Ratecity* is further guaranteed.

Specifically, we select two-stage least squares (2SLS) for IV estimation. The equations are as follows:

$$HCBS_i = \beta_0 + \beta_1 Rate_{city} + \beta_2 X_i + \beta_3 W_c + v_i$$
 (2)

$$Y_i = \gamma_0 + \gamma_1 \widehat{HCBS_i} + \gamma_2 X_i + \gamma_3 W_c + \varepsilon_i \tag{3}$$

While equation (2) is the first stage regression of 2SLS, equation (3) represents the second stage. Our primary interest is γ_1 , which estimates the causal effects of HCBS use on hospital utilization or hospital expenditure.

Results

Descriptive statistics

Table 1 shows descriptive statistics for the full sample, the used subsample, and the unused subsample. For the dependent variables, 27% of the disabled elders reported having been hospitalized during the past year, and the average hospitalizations and length of inpatient stay in the past year are 0.445 and 3.033, while the means of total, OOP, and reimbursement inpatient expenditures are RMB 3,618, 1,724, and 1,714 yuan, respectively. Except for hospital admission, the average hospitalizations, length of inpatient stay, and each inpatient expenditure of the used sample are slightly

lower than those of the unused subsample. However, there are no significant differences in all the outcome variables between the two subsamples, according to the results of the t-test.

For the key independent variables and IVs, 18.1% of the disabled elders reported having used HCBS in the past year, and *Ratecity* and *Ratecomty* are 18.0% and 17.9%, respectively. The *Ratecity* and *Ratecomty* of the used sample are much higher than those of the unused sample, i.e., 9 and 11.1 percentage points higher, respectively, indicating that whether a disabled elder chooses to use HCBS is strongly related to the HCBS use by other people in the same community and the development of HCBS reform in the city.

For covariates, the disabled elders have an average age of 71.39, of which 61.3% are women, 71.3% are married and living with their spouse, and 15.5% live in urban areas. The average means or proportions of the used subsample on most of the variables are slightly higher than the unused subsample except for three, namely marital status, education level, and urban residence, while the results of the t-test show that there are significant differences between the two subsamples in age, marital status, education level, and GDP per capita, suggesting that the used subsample is much different from the unused subsample and there is endogeneity from self-selection.

OLS estimates

Table 2 represents the OLS estimates of the effects of HCBS use on hospital utilization and hospital expenditure. Although HCBS use is negatively associated with all the outcome variables of hospital utilization and hospital expenditure, the estimated coefficients of HCBS use are not statistically significant except for one, namely the coefficient of HCBS use on length of inpatient stay. In particular, HCBS use by disabled elders is related to a drop of 0.41 nights in the inpatient stay, and the coefficient is significant at the confidence level of 10%. Overall, the results of OLS show that HCBS use can significantly reduce the length of inpatient stays for disabled elders but has no impact on the other two variables of hospital utilization or all three outcomes of hospital expenditure. However, the OLS estimates may be biased because HCBS use might be endogenous according to the previous analysis, and further tests are required.

IV estimates

Table 3 shows the estimates of IV regressions. We first pay attention to the results of validity tests on IV. The P-values of the Durbin-Wu-Hausman test range from 0.023 to 0.078, rejecting the assumption that HCBS use is an exogenous variable in all IV regressions at the confidence levels of 5% or 10%. In the first-stage regressions, the coefficients of HCBS are all positive at the confidence level of 1%, illustrating that our IV $Rate_{city}$ is strongly associated with the endogenous key independent variable of HCBS use. Besides, the F-statistics in all the first-stage regressions are far >10, also rejecting the assumption of weak IV. Therefore, the selection of $Rate_{city}$ as IV is necessary and appropriate.

TABLE 1 Descriptive statistics.

Variables		Full		Used	Unused
	Observations	Mean/%	Standard deviation	Mean/%	Mean/%
Dependent variables					
Hospital admission	4,544	0.270	0.444	0.270	0.270
Hospitalizations	4,544	0.445	0.877	0.440	0.446
Length of inpatient stay	4,544	3.033	6.264	2.778	3.089
Total inpatient expenditure	4,443	3,648	10,615	3,365	3,710
OOP inpatient expenditure	4,443	1,724	5,276	1,632	1,743
Reimbursement inpatient expenditure	4,443	1,714	5,276	1,577	1,743
The key independent variable and IVs					
HCBS	4,544	0.181	0.385	1.000	0.000
Rate _{city}	4,544	0.180	0.129	0.253***	0.164
$Rate_{comty}$	4,532	0.179	0.170	0.270***	0.160
Covariates					
Age	4,544	71.39	7.641	72.54***	71.14
Female	4,544	0.613	0.487	0.618	0.612
Marital status	4,544	0.713	0.452	0.688*	0.719
Education level	4,544	0.127	0.333	0.107*	0.132
Urban residence	4,544	0.155	0.362	0.146	0.157
Number of living children	4,544	3.404	1.497	3.458	3.392
UEBMI	4,544	0.094	0.291	0.096	0.093
URRBMI	4,544	0.862	0.345	0.872	0.859
Household income per capita	4,544	9,617	13,125	9,945	9,545
GDP per capita	4,544	52,515	30,575	54,965**	51,975
Fiscal expenditure per capita	4,544	9,982	5,788	10,177	9,938
Number of hospital beds per 1,000 inhabitants	4,544	4.431	1.636	4.488	4.419
Number of doctors per 1,000 inhabitants	4,544	2.373	0.993	2.405	2.366
Natural growth rate of population	4,544	6.345	4.175	6.443	6.323

The t-test is applied for pairwise comparisons between the HCBS used sample and unused sample respectively. ***, **, and * mean the significance levels of 1%, 5%, and 10%, respectively.

TABLE 2 OLS estimates of the effects of HCBS use on hospital utilization and hospital expenditure.

Variables	(1)	(2)	(3)	(4)	(5)	(6)
	Hospital admission	Hospitalizations	Length of inpatient stay	Total inpatient expenditure	OOP inpatient expenditure	Rei. inpatient expenditure
HCBS	-0.0092	-0.0196	-0.413*	-0.152	-0.110	-0.0364
	(0.0171)	(0.0330)	(0.224)	(0.152)	(0.137)	(0.136)
Individual covariates	Yes	Yes	Yes	Yes	Yes	Yes
City-level covariates	Yes	Yes	Yes	Yes	Yes	Yes
Observations	4,544	4,544	4,544	4,443	4,443	4,443
R-squared	0.028	0.025	0.024	0.029	0.025	0.033

Robust standard errors are reported in parentheses. ***, ***, and * mean the significance levels of 1%, 5%, and 10%, respectively. Individual covariates include age, age's square, female, marital status, education level, urban residence, number of living children, UEBMI, URRBMI and household income per capita. City-level covariates contain natural growth rate of population, GDP per capita, fiscal expenditure per capita, number of hospital beds per 1,000 inhabitants, and number of doctors per 1,000 inhabitants.

TABLE 3 IV estimates of the effects of HCBS use on hospital utilization and hospital expenditure.

Variables	(1)	(2)	(3)	(4)	(5)	(6)
	Hospital admission	Hospitalizations	Length of inpatient stay	Total inpatient expenditure	OOP inpatient expenditure	Rei. inpatient expenditure
Panel A: the second stage						
HCBS	-0.144**	-0.243**	-2.146**	-1.475***	-1.239**	-1.141**
	(0.063)	(0.122)	(0.853)	(0.567)	(0.511)	(0.505)
Individual covariates	Yes	Yes	Yes	Yes	Yes	Yes
City-level covariates	Yes	Yes	Yes Yes		Yes	Yes
Panel B: the first stage						
Rate _{city}	0.768***	0.768***	0.768***	0.763***	0.763***	0.763***
	(0.0516)	(0.0516)	(0.0516)	(0.0522)	(0.0522)	(0.0522)
Individual covariates	Yes	Yes	Yes	Yes	Yes	Yes
City-level covariates	Yes	Yes	Yes	Yes	Yes	Yes
First-stage F-statistics (P-value)	221.43 (0.000)	221.43 (0.000)	221.43 (0.000)	212.98 (0.000)	212.98 (0.000)	212.98 (0.000)
Durbin-Wu-Hausman (P-value)	4.431 (0.035)	3.101 (0.078)	3.666 (0.056)	5.205 (0.023)	4.624 (0.032)	4.587 (0.032)
Observations	4,544	4,544	4,544	4,443	4,443	4,443
R-squared	0.014	0.015	0.013	0.013	0.010	0.019

Notes are the same as specified in Table 2.

In particular, the results of the second stage of IV regressions show that for hospital utilization, HCBS use is associated with a decrease of 14.4 percentage points in the proportion of hospital admissions, a reduction of 0.243 times in hospitalizations, and a drop of 2.146 days in the length of inpatient stay, implying that HCBS use by disabled elders significantly reduces their hospital utilization and that HCBS are substitutes for hospital services; for hospital expenditure, HCBS use reduces total, OOP, and reimbursement inpatient expenditures by 148%, 124%, and 114%, respectively. In summary, HCBS use can not only reduce hospital utilization of disabled elders and relieve hospital bed-blocking but also can be very helpful in controlling medical expenses effectively and reducing the burden of medical insurance funds.

Comparing the results in Tables 2, 3, we can see that while five in six estimates of OLS regressions are insignificant and one is significant at the confidence level of 10%, all IV estimates become statistically significant at the confidence level of 5% or 1%. Furthermore, all the coefficients of HCBS use of IV regressions are far greater than those of OLS regressions, suggesting that ignoring the endogeneity of HCBS use will lead to an underestimation.

Robustness

Following the strategy of Feng (24), we further test the robustness of our baseline IV estimates and the exogeneity of IVs by adding another IV $Rate_{comty}$ and changing 2SLS to GMM (generalized method of moments), of which the results are revealed in Table 4. The results show that HCBS use is related to a decrease of 12.8 percentage points in the proportion of hospital admissions, a reduction of 0.203 in hospitalizations, and a drop of 1.956 days

in the length of inpatient stay. HCBS use also significantly reduces total, OOP, and reimbursement expenditures by 132.7%, 113.8%, and 100.7%, respectively. With the added IV *Ratecomty*, the results are very similar to those with one IV, both in significance and magnitude, implying that our baseline IV estimates are reliable. Besides, the statistics of Hansen J range from 0.294 to 2.300 and are all not significant, suggesting that both the two IVs are exogenous variables.

Heterogeneity

The effects of HCBS use on hospital utilization and hospital expenditure may differ across different individual characteristics, and different types of HCBS may also have heterogeneous performances. Therefore, again using <code>Ratecity</code> as IV, we estimate the heterogeneous effects of HCBS use. Figure 1 shows the heterogeneous effects of HCBS use on different groups of disabled elders, divided by some variables of individual characteristics, while Table 5 represents the heterogeneous effects of three different types of HCBS use on hospital utilization and hospital expenditure.

Figure 1A shows the heterogeneous effects of HCBS use on hospital utilization and hospital expenditure between younger and older disabled elders. We classify disabled elders under 70 years old into the younger group, making those aged 70 years and above fall into the older group. For the younger group, HCBS use has significant negative impacts on all the outcome variables of hospital utilization and hospital expenditure except hospitalizations, while for the older group, there are no significant expected effects. The effects of HCBS use on hospital utilization and hospital expenditure concentrate on the younger disabled elders.

TABLE 4 Robustness: estimates with two IVs.

Variables	(1)	(2)	(3)	(4)	(5)	(6)
	Hospital admission	Hospitalizations	Length of inpatient stay	Total inpatient expenditure	OOP inpatient expenditure	Rei. inpatient expenditure
Panel A: the second stage						
HCBS	-0.128**	-0.203*	-1.956**	-1.327**	-1.138**	-1.007**
	(0.0599)	(0.118)	(0.827)	(0.545)	(0.492)	(0.487)
Individual covariates	Yes	Yes	Yes	Yes	Yes	Yes
City-level covariates	Yes	Yes	Yes	Yes	Yes	Yes
Panel B: the first stage						
Rate _{city}	0.552***	0.552***	0.552***	0.560***	0.560***	0.560***
	(0.077)	(0.077)	(0.077)	(0.077)	(0.077)	(0.077)
Rate _{comty}	0.232***	0.232***	0.232***	0.218***	0.218***	0.218***
	(0.057)	(0.057)	(0.057)	(0.057)	(0.057)	(0.057)
Individual covariates	Yes	Yes	Yes	Yes	Yes	Yes
City-level covariates	Yes	Yes	Yes	Yes	Yes	Yes
First-stage F-statistic(P-value)	125.01 (0.000)	125.01 (0.000)	125.01 (0.000)	119.35 (0.000)	119.35 (0.000)	119.35 (0.000)
Durbin-Wu-Hausman (P-value)	3.728 (0.054)	1.902 (0.168)	2.960 (0.085)	4.404 (0.036)	4.141 (0.042)	3.760 (0.053)
Hansen J statistic(P-value)	0.482 (0.487)	2.300 (0.129)	0.720 (0.396)	0.656 (0.418)	0.294 (0.588)	0.791 (0.374)
Observations	4,532	4,532	4,532	4,432	4,432	4,432
R-squared	0.017	0.019	0.015	0.016	0.013	0.022

Notes are the same as specified in Table 2.

Figure 1B demonstrates that for both female and male disabled elders, HCBS use can reduce their hospital utilization and hospital expenditure. However, while five in six coefficients of HCBS use for the male sample are significant, only two for the female sample. Furthermore, all the coefficients of HCBS use for men appear to be greater than those for women, indicating that the effects of HCBS use on hospital utilization and hospital expenditure are stronger among male disabled elders.

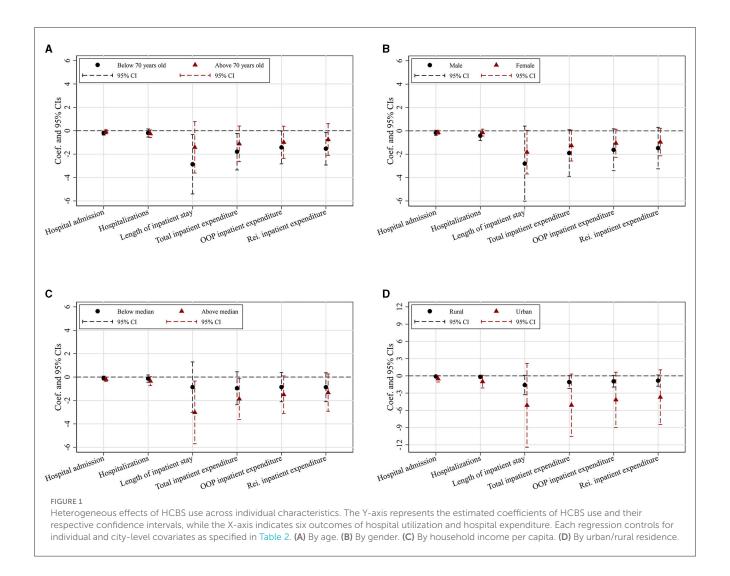
Figure 1C represents the heterogeneous effects between the lower- and higher-income groups. The full sample is divided by household income per capita. For the higher-income group (above the 50th percentile), the impacts of HCBS on various outcome variables are all significant, but not for the lower-income group (less than or equal to the 50th percentile). Furthermore, the estimates for the higher-income group seem to be larger than those for the lower-income group, implying that HCBS use is more effective for the higher-income group in reducing hospital utilization and controlling hospital expenditure.

Figure 1D shows the heterogeneous effects across urban and rural residences. Disabled elders in urban and rural areas have reduced hospital utilization and hospital expenditure because of HCBS use. Specifically, HCBS use significantly reduces the probability of hospital admission, hospitalizations, total inpatient expenditure, and OOP inpatient expenditure among urban disabled elders, while among rural ones, HCBS use has significant negative effects on the length of inpatient stay, total inpatient expenditure, and OOP inpatient expenditure. However, all the coefficients of

HCBS use for the urban group seem to be greater than those for the rural group, whether significant or not, implying that the effects of HCBS use on hospital utilization and hospital expenditure are stronger for the urban disabled elders.

Panels A–C in Table 5 represent, respectively, the effects of the use of three different types of HCBS, namely daily care service use, health service use, and spiritual consolation service use, on hospital utilization and hospital expenditures. The questionnaire of CHARLS enquired the respondents about the HCBS they had received in the last year, and the variable daily care service use is coded as 1 if respondents reported that they had used any service of daycare centers, nursing homes, senior dining tables, etc.; the variable health service use takes the value 1 if they reported using any of regular physical examination, onsite visits, community nursing, and health management; and the variable spiritual consolation service use is equal to 1 if they reported participating in community entertainments. For those who did not report using the specific kind of HCBS, the corresponding variable takes the value 0.

The results in Table 5 show that both health service use and spiritual consolation service use have significant negative effects on all six outcomes of hospital utilization and hospital expenditure, and all the estimated coefficients of spiritual consolation service use are greater than those of health service use, implying that mental health is of particular importance to the disabled elders. However, no significant evidence supports the anticipated impacts of daily care service use. The IV $Rate_{city}$, which is always significantly



related to the endogenous key independent variable in other IV regressions, is a weak IV here, and this problem remains even when we use the two IVs and change 2SLS to LIML (limited-information maximum likelihood), as shown in panel A. There may be two reasons. First, daily care services require a relatively lower level of technical ability, so they are not substitutes for hospital inpatient care with high-level professional knowledge and skills. Second, very few respondents reported using daily care services, i.e., only 0.5% of the full sample, resulting in too few variations in the key independent variable to influence the dependent variables. Whatever the causes are, they need to be examined further.

Mechanisms

As discussed in the "Introduction" section, the HCBS use by disabled elders can influence hospital utilization and hospital expenditure, both directly and indirectly. Without information on LTC care delayed discharges, we cannot directly test the direct substitution effect. However, consistent with the study of Wang and Feng (27), the results of age and gender heterogeneity provide evidence for the direct substitution impact because the effects are stronger among younger and male disabled elders, who have average lower disability levels. Limited by the availability of data, we only test the impacts of HCBS use on self-reported health, depression, and fall here, and the results are revealed in Table 6. The results show that HCBS use is related to a reduction of 13.7 percentage points in self-reporting fair/poor health and a drop of 22.1 percentage points in depression, indicating that HCBS use improves both the physical and psychological health of disabled elders, but there is no evidence to support the expected effects on fall, so the mechanism of adverse event decrease is not illustrated, which needs to be investigated further with more proxy variables.

Discussion

Using data from the 2018 wave of CHARLS and the China City Statistical Yearbook published in 2019, this study examines the causal effects of HCBS use on hospital utilization and hospital expenditure by IV approach.

We demonstrate that the HCBS use by disabled elders in China reduces both their hospital utilization and hospital expenditure, indicating that HCBS are substitutes for hospital inpatient care and that HCBS use can be very helpful in alleviating the care burden

TABLE 5 The heterogeneous effects of three different types of HCBS use.

Variables	(1)	(2)	(3)	(4)	(5)	(6)
	Hospital admission	Hospitalizations	Length of inpatient stay	Total inpatient expenditure	OOP inpatient expenditure	Rei. inpatient expenditure
Panel A						
Daily care service use	-0.489	1.669	2.640	-4.114	-2.968	-3.096
	(1.052)	(2.218)	(14.61)	(9.358)	(8.812)	(8.290)
First-stage F-statistics	2.27	2.27	2.27	2.06	2.06	2.06
(P-value)	(0.104)	(0.104)	(0.104)	(0.128)	(0.128)	(0.128)
Observations	4,532	4,532	4,532	4,432	4,432	4,432
R-squared	0.021	0.003	0.022	0.026	0.023	0.031
Panel B						
Health service use	-0.146**	-0.246**	-2.175**	-1.483***	-1.246**	-1.147**
	(0.0635)	(0.124)	(0.864)	(0.570)	(0.514)	(0.508)
First-stage F-statistics	219.09	219.09	219.09	213.52	213.52	213.52
(P-value)	(0.000)	(0.000)	(0.000)	(0.000)	(0.000)	(0.000)
Observations	4,544	4,544	4,544	4,443	4,443	4,443
R-squared	0.016	0.016	0.015	0.013	0.011	0.019
Panel C						
Spiritual comfort service use	-0.847**	-1.427*	-12.62**	-8.987**	-7.554**	-6.955**
	(0.399)	(0.761)	(5.546)	(3.839)	(3.423)	(3.340)
First-stage F-statistics	26.04	26.04	26.04	23.74	23.74	23.74
(P-value)	(0.000)	(0.000)	(0.000)	(0.000)	(0.000)	(0.000)
Observations	4,544	4,544	4,544	4,443	4,443	4,443
R-squared	-0.023	-0.009	-0.039	-0.036	-0.032	-0.016

Robust standard errors are reported in parentheses. ***, **, and * mean the significance levels of 1%, 5%, and 10%, respectively. Each regression controls for individual and city-level covariates as specified in Table 2.

TABLE 6 Mechanisms.

Variables	(1)	(2)	(3)	
	Health	Depression	Fall	
HCBS	-0.137**	-0.221***	-0.000276	
	(0.0611)	(0.0782)	(0.0674)	
First-stage F-statistics(P-value)	198.07	197.70	220.69	
	(0.000)	(0.000)	(0.000)	
Observations	3,925	3,804	4,540	
R-squared	-0.009	0.018	0.012	

Notes are the same as specified in Table 5.

of hospitals and controlling the ever-increasing medical expenses. Our findings are consistent with previous studies assessing the negative impacts of formal LTC on hospital utilization and hospital expenditure (10, 11), which use macro data at the district level. However, some other studies find less effect of community-based health services on medical services (6, 12) and even a positive relationship between the two (13). This study adds new evidence

from the individual level to the literature to support the significant negative effects of LTC on reducing the utilization of medical services and the corresponding expenses.

We find that the impacts of HCBS use on hospital utilization and hospital expenditure concentrate on disabled elders who are younger or male. Previous studies illustrate that the disability degree of the elders will increase with age (25-28), women have poorer health than men (29, 30), and the disability status is more severe among women elders than men (31). The higher the level of disability an elder has, the more professional medical care one needs. For the lower-level disabled elders, their requirements for high-level professional care services are much fewer, which can be met better by HCBS. On the contrary, the higherlevel disabled elders may need more high-level professional medical care services, which usually cannot be supplied well by community centers. Besides, we also found more pronounced impacts among disabled elders from higher-income households or living in urban areas, which may be related to their higher capacity to pay, the relatively fewer medical and formal care resources in rural areas, and even the stronger concept of relying on family members, especially children, for LTC care of rural elders. These findings call our attention to fragile

groups. More precise measures should be developed to help them access and afford HCBS, enabling them to live in their own homes longer.

Furthermore, there are kind-specific heterogeneous effects of HCBS use on hospital utilization and hospital expenditure. Specifically, the significant influences of spiritual consolation service use seem to be greater than those of health service use, while there is no significant evidence to support the anticipated effects of daily care service use. These findings provide evidence to emphasize the psychological well-being of disabled elders and the necessity of diversifying and optimizing various service items of HCBS to satisfy the various needs of disabled elders, especially their spiritual needs.

The possible mechanisms are the direct substitution of HCBS on hospital care and health improvement, which are in line with that of Wang and Feng (25), who argued that the substitution of LTCI on inpatient care utilization and impatient expenditure concentrate more on elders with lower disability levels, and that of Lv and Zhang (18), who illustrated that HCBS use is beneficial to the health of old adults. However, we find no evidence to support the mechanism of adverse events decreasing, which is not consistent with previous studies by Sands et al. (14) and Bragstad et al. (17). It is necessary to investigate further with more proxy variables as there is only one in our study.

This study has several limitations. First, we use hospital admission, hospitalizations, and length of inpatient stay instead of hospital readmissions, avoidable hospital utilization, or social care delayed discharges because there is no information on these variables in our data. Second, it should be interpreted with caution that the estimated effects of HCBS use on the length of inpatient stay for the variable here refer to only the nights of the last time spent in the hospital rather than the past year a respondent had spent in the hospital. Third, there may still be violations of the assumptions of the IV method even if we have illustrated the exogeneity of our IV Ratecity conceptually and empirically. Moreover, there is a problem of weak IV when we estimate the effects of daily care service use on hospital utilization and hospital expenditure, which calls for a more comprehensive investigation in the future.

Conclusion

This study provides empirical evidence that HCBS use can not only reduce hospital utilization and hospital expenditure of disabled elders but also improve their physical and psychological health, implying that HCBS can help achieve the healthcare goal of ensuring healthy lives for all by 2030, which was adopted as the United Nations Post-2015 Sustainable Development Goals (32), with fewer costs. Furthermore, HCBS use can satisfy the needs of elders much better by maintaining a virtuous cycle, i.e., HCBS use, which can promote the health status of disabled elders, enables them to live in their own homes and maintain some control of their daily lives, and with improved health status, disabled elders can participate more in the household's decision-making activities (33) and therefore maintain more control of their daily lives and live

in their own home much longer. Policy designs should emphasize the orientation of HCBS and ensure the fundamental and central position of HCBS in the formal care service system. In addition, more attention should be paid to the accessibility and affordability of HCBS for fragile groups and the diversification and optimization of the development of various service items, especially the health service and the spiritual consolation service, in order to fully utilize its role in improving the wellbeing of elders and controlling medical expenses.

Data availability statement

Publicly available datasets were analyzed in this study. This data can be found here: https://charls.pku.edu.cn/en.

Ethics statement

Ethical approval for all the CHARLS waves was granted from the Institutional Review Board at Peking University. The IRB approval numbers are IRB00001052-11015 and IRB00001052-11014. The studies were conducted in accordance with the local legislation and institutional requirements. Written informed consent for participation was not required from the participants or the participants' legal guardians/next of kin because as the datasets of CHARLS are publicly available, ethical approval was not needed for this study.

Author contributions

YY: Data curation, Conceptualization, Formal analysis, Writing—original draft. JL: Supervision, Writing—review and editing. LJ: Data curation, Writing—review and editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Caring load and family caregivers' burden in China: the mediating effects of social support and social exclusion

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Objective: Caring for older adults with disabilities is a source of stress for family caregivers, and the lack of social support and the pressure of social exclusion might aggravate family caregiver burden. This study aimed to examine the association between caring load and family caregivers' burden, as well as the mediating effects of social support and social exclusion.

Methods: Data used in this study was derived from the nationally representative database of the aged population in China, and 3,125 households with disabled old adults and their home-bound caregivers were eventually selected for this analysis. Regression methods and mediation analysis methods were employed in this study.

Results: The results indicated that there was a significant positive association between caring load and the caregiver burden, and specifically, social support intensity (rather than social support breadth) and passive social exclusion (rather than active social exclusion) played partial mediating effects. Furthermore, the contributions of mediating effects of social support intensity and passive social exclusion were 13–15 and 27–29%, respectively, and the total contribution of mediating effects was about 35–38%.

Conclusion: Family caregivers' burden should be paid more attention to in the large population with rapidly aging speed like China, and more guidance services as well as support should be provided to family caregivers. In addition, it is crucial to focus on the community's social support and social exclusion in public policy innovation.

KEYWORDS

psychological stress, family caregivers' burden, older adults, social support, social exclusion, China

1. Introduction

With the improvement of life quality and the extension of life expectancy, population aging has become a worldwide tendency. China's aging population is large in scale and fast in growth, and the number of older adults with disabilities is enormous. By the end of 2020, there were 249 million people aged over 60 and 167 million people aged over 65. Meanwhile, more than 180 million older adults have chronic diseases, and the disabled or partially disabled older population is as high as 42 million, accounting for 11.8% of the total older population, according to the

statistics of the National Health Commission of the People's Republic of China. World Health Organization defines disability as the loss or limitation of a person's ability to perform major activities or activities in daily life, which is an important indicator of health (1). In China, according to the Law of the People's Republic of China on the Protection of Persons with Disabilities, disability is "a person who is mentally, physically, or structurally deprived of a certain kind of tissue or function or is not normal, completely or partially unable to perform a certain activity in a normal manner." Older adults have become the main component of the disabled population in China, and the quality of life of older adults with disabilities is deficient, and daily life needs care from others.

Family caregivers are responsible for most of the caring service load of older adults with disabilities in most households, especially in China, with a long history of the cultural tradition of filial piety and an imperfect social security system. The burden on family caregivers is severe (2). However, caring for older adults with disabilities is a challenging and complex task, exerting a huge and long-term negative impact on family caregivers. The scores of physiological function, social function and mental health of family caregivers were lower than those of the general population (3). Mental health disorders including insomnia, psychological discomfort, despair, stress, physiological problems, and emotional confusion (anxiety, depression) could be frequently and long-term observed among family caregivers, due to the suffocating workload (including limited social activities, difficulties in work and occupation and less leisure time), which eventually greatly reduced the quality of life of caregivers. In severe cases, family caregivers would withdraw from the care state because of the long-run overload (4).

The research focused on the family caregivers' burden began in the 1960s, and family caregivers' burden was regarded as the cost of taking care of patients at that time (5). Caregiver burden was challenging in psychological, physical, social and economic aspects, while caring for family members suffering from disease and disability (6). Caregiver burden is a Negative Care Experience, family caregivers were vulnerable to adverse results from physics, psychologic, economy, society and other aspects, when lacking the support of emotion, information, finance, facilities and others in the process of care, and this would bring about the caregiver burden (7). Caregiver burden could be divided into four aspects, including physical fatigue (including physical pain, disease occurrence), psychological and emotional guilt (depression and anxiety, etc.), economic strain (such as increasing medical expenditure and decreasing occupational competitiveness), and social isolation or helplessness. The patients' diseases can also disrupt family life and cause adverse events, including family caregivers' health decline, dysfunction in the family, and an increase in family economic burden (8).

Stress Coping Model Theory was proposed by American psychologist Richard S. Lazarus in the 1960s, and has been widely used in the study of family caregivers' burden by many scholars in the past decades. Stress research began in the field of physiology and later also focused on the relationship between "life events" and physical and mental diseases. One quantitative research took the lead in studying stress and introducing the concept of "life events," which were defined as events that affect people's spirit in life change, as well as the operational definition of stressors (9). There was a very close correlation between an individual's subjective evaluation of life events and their health. Some research also showed that in real life, it was not

those major life events but life disturbances caused by life events that occur all the time around us that affect people's physical and mental health and bring about undesirable consequences (10). Consequently, caring for older adults with disabilities could be regarded as a "life event" that causes stress to the family caregivers, negatively affecting their physical and mental health.

The Stress Coping Model applied to family caregivers exists in the typical Chinese cultural background-Chinese filial piety, and the introduction of this environmental constraint element of Chinese filial piety strengthens the analytical framework in terms of the inevitability of caregivers' pressures, as well as the inevitable choice that social network play as the important coping mechanism for stress event. However, family caregivers seem unavoidable in caring for older adults with disabilities in Chinese society with a profound cultural tradition of filial piety. The filial piety culture weakens the possibility of family caregivers "evading" caring for older adults with disabilities. Caring for older adults is because of the tradition of the family care system for older adults, and the family care system for older adults from the filial piety cultural circumstance. China had a tradition of filial piety for thousands of years, for a long-time, family care for older adults has always been in a dominant position in the urban and rural care-system for older adults (11). Therefore, family caregivers are given a typical cultural background in caring for older adults with disabilities. Chinese traditional society is an "Acquaintance society," which is characterized by a private relationship between people; people interact through this relationship and form a network of relationships. Inconsistent with the traditional Stress Coping Model, we believe that the coping mechanism of social interaction in China maybe has two sides, both positive (social support) and negative (Social exclusion). Coping mechanisms reflect family caregivers' best efforts to deal with the caring load and their internal needs, and resolve the conflict between them, including evaluating the meaning of care tasks, controlling or changing the care environment, solving or eliminating problems, and alleviating emotional reactions due to care tasks. The outcome of coping mechanisms can affect the life attitudes and concepts, social abilities, and physical and mental health of family caregivers.

Social support refers to the care and support from others (12). It is a general or specific supportive behavior from others, which can improve the individual's social adaptability and protect them from the adverse environment. Social support plays as a buffer for caregiver burden, and the higher the level of social support is, the lighter the caregiver burden would be (13). One research pointed out that effective social support can enhance the ability to tolerate, cope with and get rid of stressful situations (14). That is, serving as a buffer, social support could alleviate the negative effects of stressors on physical and mental health to maintain and even improve the individuals' physical and mental health.

Social exclusion was defined as the break between the individual and the whole society (15). Social exclusion was regarded as when individuals or groups were totally or partly excluded from full social participation, according to the participatory nature of social exclusion (16). As family caregivers usually do not have enough time for social interaction and personal development, they not only suffer from the stress in the care process, but also the pressure brought by social exclusion. Social exclusion is the effect of family caregivers on cognition, thus affecting the cognitive evaluation of the excluded on themselves or others. Social exclusion will damage the individual's

self-regulation ability; it will not only damage the health of the excluded, but also lead to bad emotions such as loneliness, jealousy, depression, and anxiety. Therefore, social exclusion will increase the care burden on family caregivers (17).

Based on the Stress Coping Model Theory, "life events" are seen as "stress source." Whether "life events" can generate stress after acting on individuals mainly depends on two important psychological processes: cognitive evaluation and coping. Coping is the use of behavioral or cognitive approaches to address the needs between the environment and people, and to address the conflict between "life events" and stress. In our study, the life event of caring for older adults with disabilities is a source of stress for family caregivers, which would bring negative impacts on their physical and mental health. Social support and social exclusion are the coping ways of the family caregivers to "life event" or "stress source." The impacts on the family caregivers' physical and mental health (caregiver burden) were coping-consequences of "life event" or "stress source."

Based on the above Stress Coping Model Theory and previous literature, this study proposed the relationship model between caring load and caregiver burden, which included the mediating effects of social support and social exclusion (Figure 1). Furthermore, this study would test the integrated relationship model with a nationally representative database on family caregivers for older adults with disabilities, especially investigating the mediating effects of social support and social exclusion.

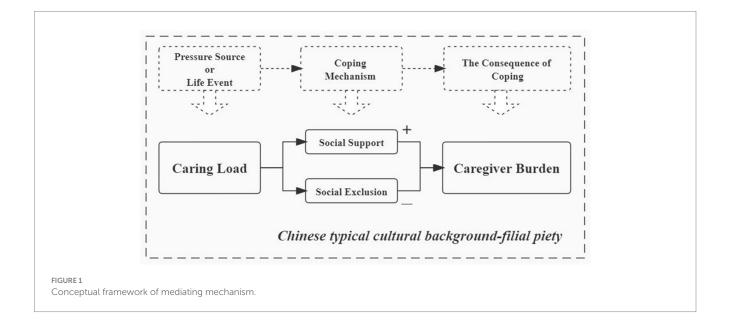
This study took the family caregivers of older adults with disabilities as the study population, and made a more comprehensive study on the situation of caregivers' care burden. On the one hand, it provides a unique experience for reference for the international community to study the care burden of caregivers. Compared with the international community, the research on the care burden of caregivers in Chinese society is insufficient and the research progress is relatively slow. Under the background of the rapid development of aging and the unique long-established filial piety culture in Chinese society, the research on the care burden of family caregivers is more unique and novel, which enriches international literature. On the other hand, problems are identified and policy

recommendations are made, thus providing a scientific basis for the government to formulate corresponding policies. Starting with family caregivers, this study explored the influencing mechanism and effective path of caregivers' care stress, to provide reference and enlightenment for the formulation of related policies to alleviate care stress and improve the quality of care, to improve the quality of life of older adults with disabilities. In addition, the study on the care status of family caregivers is also of great significance for the construction and improvement of China's long-term care service system.

2. Materials and methods

2.1. Data

The data used in this study were drawn from Survey on Aged Population in Urban/Rural China (2018), which was conducted from July to September 2018. The survey was approved and sponsored by the Ministry of Civil Affairs of the People's Republic of China, and carried out by the Institute of Social Science Survey, Peking University. This survey employed a multistage, stratified and random-cluster sampling method, which covered 155 counties (districts) and 1,800 communities (villages) in 28 provinces, autonomous regions, and municipalities in China. Trained investigators conducted home visits. All participants consented to participate in the survey, and the initial sample consisted of 10,273 households. According to the purposes of the study, the study population is caregivers of older adults with disabilities, so we set households screening criteria. Screening households based on two criteria: older adults with disabilities in the household, and older adults with disabilities received care in the household. For households with older adults with disabilities and caregivers, the primary caregivers of older adults with disabilities in the household were asked to complete the survey. After screening, 3,203 households met the above two criteria, of which 78 households had missing values in the corresponding variables and were eliminated from the analyses in this study. Finally, 3,125 households with older



adults with disabilities cared by family caregivers were selected and used in this study.

2.2. Variables

2.2.1. Dependent variables

Caregiver Burden was measured by the Zarit Burden Interview (ZBI), developed by Zarit et al. The Chinese version of the Zarit Burden Interview has a high level of reliability and validity, with a total Cronbach coefficient of 0.870 (18). It consists of 22 items evaluating five aspects, including caregivers' health, mental state, economic status, social life and total evaluation. The score of each question ranges from 0 to 4 points, and the total score is from 0 to 88 points. The higher score indicates the heavier caregiver burden.

In the data analysis process, caregiver burden was operated into three variables: burden score, burden grade, self-assessed burden. The burden score is the sum of the scores of 22 items, with a higher score indicating the heavier caregiver burden. According to these references which used the Chinese version of Zarit Burden Interview to measure caregivers' burden, burden grades consist of little to no burden, light burden, moderate burden and heavy burden, with the range of 0–19, 20–39, 40–59, and 60–88, respectively (19–21). The self-assessed burden was measured by responding to the last question of the scale, "In general, how do you evaluate your caregiver burden?" Self-assessed burden ranges from 0 to 4 points, with 4 indicating severity.

2.2.2. Independent variables

The number of home-bound older adults with disabilities who need care affects the load of family caregivers. In this study, the caring load was measured by the number of older adults with disabilities who need care in households, which is based on the question, "How many disabled older adults were in need of care in your family?"

2.2.3. Control variables

Based on previous studies, three dimensions of factors including individual, family and surrounding characteristics were primary indicators being proved to be associated with Caregiver Burden (22). Individual characteristics included gender, age, marital status and education status. Family characteristics included family size and household income. Surrounding characteristics were measured by the number of social service supplies in the community, including meal services, bath services, housekeeping services, daycare services, rehabilitation care services, health education services, psychological counseling services, home medical services, medical care services, social work services and respite services.

2.2.4. Mediating variables

Social support is the state that a person obtains through social contact, which could reduce psychological stress, relieve tension, and improve social adaptability. The more powerful a person's social support network is, the better he or she can cope with various challenges. In this study, social support was measured by social support breadth and social support intensity, referring to the widely used Social Support Rating Scale and previous studies (23), which possessed a high universality and credibility. Specifically, social support breadth was defined as the breadth of the relationship network of individual, and was measured by the number of people who contact

and communicate with each other normally. These people are relatives, friends, neighbors, etc., other than family members. Social support intensity was defined as the degree and strength of an individual social network, and was measured by the frequency of interaction with others, with the coding ranging from 1 (very infrequently) to 3 (very frequently).

Social exclusion was operated into active social exclusion and passive social exclusion, according to the measurements in the previous studies (24, 25). Active social exclusion was defined as the social break caused by their behavior and attitude against social participation, which was the result of self-active choice. Active social exclusion, in this study, was based on the question, "Are you willing to interact or contact with neighbors or other people?" The coding range was from 1 (very willing) to 5 (very unwilling). Passive social exclusion was defined as the social break that came from the outside world (15), which was not caused by their own subjective will, but by the non-subjective factors outside the individual. Passive social exclusion was based on the question "Do you feel excluded or discriminated against by others when interacting or contacting with others?" The coding range was from 1 (not at all) to 5 (severe).

2.3. Analysis strategy

Descriptive analyses were conducted to describe caregiver burden and other characteristics of the respondents. After adjusting for all the confounding variables, the Ordinary Least Square (OLS) methods as well as Ordered Logistic Regression methods were also employed to examine the relationship between caring load and family caregivers' burden. Especially, the KHB method (26) was employed to examine the mediating effects of social support and social exclusion. Data analysis was implemented in Stata 15 in this study.

3. Results

3.1. Descriptive statistics

Descriptive analyses for all variables were presented in Table 1. The average burden score of family caregivers was 32.98, and caregivers in the light burden group accounted for 36.83%, followed by the little to no burden group (28.38%), moderate burden (23.74%), and heavy burden group (11.04%). Besides, the average self-assessed burden of family caregivers was 1.54. The average caring load was 1.54, and family caregivers, in extreme cases, may care for even up to 6 home-bound older adults with disabilities. As for social support, more than half of the participants were very infrequent to contact with others (59.04%), but the average scores of social support breadth were 10.92, which showed that respondents were with high levels of social support breadth, but low levels of social support intensity. In the aspect of active social exclusion, the largest proportion of the respondents was willing (42.27%) to interact with others, followed by a very willing group (31.14%). Moreover, nearly half of respondents did not feel discrimination from others in their communication (46.34%), revealing that respondents were in low levels of passive social exclusion.

More than half of the participants were males (57.63%) and nearly three-quarters lived without a spouse (71.36%). The

TABLE 1 Descriptive statistics for all variables of the study in China, 2018 (N = 3,125).

Variables	Variables definition and values	Mean (S.D.)/percentage
Dependent variables		
Burden score [0–88]		32.98 (19.64)
Burden grade [1–4]	1 = Little to no burden	28.38%
	2 = Light burden	36.83%
	3 = Moderate burden	23.74%
	4 = Heavy burden	11.04%
Self-assessed burden [0-4]	·	2.67 (1.42)
Independent variable		
Caring load [1–6]		1.54 (0.75)
Mediating variables		
Social support intensity [1–3]	1 = Very infrequently	59.04%
	2 = Frequently	29.47%
	3 = Very frequently	11.49%
Social support breadth [0–30]	, , ,	10.92 (9.59)
Active social exclusion [1-5]	1 = Very unwilling	2.66%
	2 = Unwilling	5.70%
	3 = General	18.24%
	4 = Willing	42.27%
	5 = Very willing	31.14%
Passive social exclusion [1–5]	1 = Not at all	46.34%
Tussive social exclusion [1 3]	2 = A little	19.10%
	3 = General	28.54%
	4=Serious	2.75%
	5 = Severe	3.26%
Control variables	3 – severe	3.2070
	1 Mil.	F7 (20)
Gender [0-1]	1 = Male	57.63%
4 [40 00]	0 = Female	
Age [18–82]		53.49 (13.64)
Marital Status [0–1]	1 = With a spouse	71.36%
	0 = Without a spouse	
Education [1–4]	1 = Illiteracy	14.88%
	2 = Primary school	27.49%
	3 = Junior Middle school	35.33%
	4=High school	22.30%
Family size [2–8]		3.87 (1.63)
Household income [1–5]	1 = Low income	20.67%
	2 = Middle lower income	19.04%
	3=Middle income	21.34%
	4 = Upper income	19.04%
	5 = High income	19.90%
Community service [0–11]		1.04 (2.17)

average age of respondents was about 53.49. More than half of respondents (57.63%) had completed at least junior middle school education. About 40% of respondents were below middle household income status. The average number of community services was 1.04.

3.2. Regression results

In order to further examine the association between caring load and caregiver burden, this study used burden score to measure caregiver burden (the dependent variable), and used burden grade as

well as self-assessed burden to verify the robustness of the results. Meanwhile, Ordinary Least Square (OLS) methods as well as Logistic Regression methods were used in this study, and the regression coefficients were presented in the Tables 2, 3.

The regression results in the front three columns in Table 2 showed that caring load ($\beta = 0.058$, p < 0.01; $\beta = 0.049$, p < 0.01; β = 0.035, p < 0.05) was significantly positively related to caregiver burden when controlling for covariates. Family caregivers with a more caring load had a higher risk of caregiver burden. In addition, with the four mediating variables gradually added into the regression model, the coefficient values of the independent variable showed a downward trend, indicating that the mediating effects might exist in the equations. Meanwhile in the control variables, male caregivers had lower burden scores compared to female caregivers. This is consistent with existing findings (27). Female caregivers tended to experience higher levels of physical and mental stressors and generally provide care for longer periods of time compared to male caregivers; Also male caregivers tended to view caregiving tasks less emotionally than female caregivers, which may help reduce caregiver stress (28, 29). Caregivers with a spouse had higher burden scores compared to caregivers without a spouse. This finding is also consistent with other studies (30). When a caregiver had a spouse, he/she had multiple roles to play as a caregiver, a spouse, and as a parent of a child, which created conflict between the roles, and increased stress in turn (31).

The regression results in the last four columns in Table 2 showed the regression results with the mediating variables as the dependent variables, indicating that the mediating effects of social support breadth and active social exclusion were not significant while the mediating effects of social support intensity and passive social exclusion were significant. Specifically, caring load (β = -0.042, p<0.05) was significantly negatively related to social support intensity, caring load (β =0.064, p<0.01) was significantly positively related to passive social exclusion, when controlling for covariates. The heavier the caring load, the less the intensity of social support, and the higher passive social exclusion.

Furthermore, a robustness test was conducted to test the association between social support intensity and caregiver burden, as well as the association between passive social exclusion and caregiver burden, with the variables burden grade and self-assessed burden as the dependent variable. In addition, the regression coefficients are presented in Table 3.

The logistic regression results in the front three columns in Table 3 showed that caring load (β =0.0055, p<0.01; β =0.0048, p<0.01; β =0.0036, p<0.05) was significantly positively related to caregivers' burden grade, indicating that the associations were also steadily significant when controlling for covariates gradually. In addition, social support intensity (β =-0.017, p<0.01; β =-0.014, p<0.01) was significantly negatively related to caregivers' burden grade, passive social exclusion (β =0.022, p<0.01) was significantly positively related to caregivers' burden grade, and the conclusion that social support intensity and passive social exclusion had partial mediating effects in the association was robust.

The regression results in the last three columns in Table 3 showed that caring load was (β =0.046, p<0.01; β =0.040, p<0.05; β =0.029, p<0.10) significantly positively related to caregivers' self-assessed burden, indicating that the associations were also steadily significant when controlling for covariates gradually. Specifically, social support

intensity (β = -0.154, p<0.01; β = -0.123, p<0.01) was significantly negatively related to caregivers' self-assessed burden, passive social exclusion (β =0.192, p<0.01) was significantly positively related to caregivers' self-assessed burden, and the conclusion that social support intensity and passive social exclusion had partial mediating effects in the association was robust.

3.3. Mediating effects

This study focuses on the mediating role of social support and social exclusion in the relationship between caring load and family caregiver burden. The contributions of the mediating effects are shown in Table 4.

The contributions of mediating effects of social support intensity were robust, probably between 13 and 15%. The contribution of social support intensity in the models with burden score as a dependent variable was14.11%; meanwhile, in the models with burden grade or self-assessed burden as dependent variables, the contribution ratios were 13.16% or 13.73%, respectively. The contributions of mediating effects of passive social exclusion were robust, probably between 27 and 29%. The contribution of passive social exclusion in the models with burden score as a dependent variable was 28.85%; meanwhile, in the models with burden grade or self-assessed burden as dependent variables, the contribution ratios were 27.12% or 28.49%, respectively. Table 4 showed the total mediating effects of social support and social exclusion were robust. In the model with burden score as a dependent variable, the total mediating effects of social support and social exclusion were 37.52%; in addition, in the models with burden grade or self-assessed burden as dependent variables, the total contribution ratios were 35.34% or 36.89%, respectively.

4. Discussion

In this study, the stress coping model is applied to investigate the burden of caregivers of disabled families in China, and the coping mechanism is expanded in combination with the specific cultural context of China, and social network (especially social support and social exclusion). The study found a significant positive association between the caring load and the caregiver burden, indicating that the greater the caring load is, the more serious the caregiver burden would be, consistent with previous studies (32). In the care process, the family caregiver would bear a greater burden due to the heavy and complicated caring load, as well as the potential social isolation and exhaustion (33).

It should also be noted that the role of family caregivers in caring for older adults comes from a specific Chinese cultural background——Filial Piety. China's filial piety culture provides a cultural constraint that the adult children should provide various care services for older adults, including caring services for older adults with disabilities. Different from the concept of rights and obligations in western society, the link to maintaining the operation of the family care system for older adults in Chinese society is emotional exposure and kinship (11). Because of this inescapable duty in providing care for older adults with disabilities under Chinese traditional culture, the burden of caregivers is becoming an increasingly serious social concern in China who is experiencing a rapid population aging.

TABLE 2 Results of the ordinary least square (OLS) regression in China, 2018 (N = 3,125).

	Burden score	Burden score	Burden score	Social support intensity	Social support breadth	Active social exclusion	Passive social exclusion
Caring load	0.058***	0.049***	0.035**	-0.042**	-0.019	-0.017	0.064***
Social support intensity		-0.161***	-0.133***				
Social support breadth		-0.073***	-0.063***				
Active social exclusion			0.022				
Passive social exclusion			0.237***				
Gender (Refer to Female)							
Male	-0.122***	-0.100***	-0.106***	0.082***	0.115***	0.058***	0.006
Age	0.088***	0.101***	0.116***	0.057***	0.051***	0.001	-0.073***
Marital status		1					
(Refer to: without a	spouse)						
With a spouse	0.045**	0.049***	0.050***	0.008	0.044**	0.071***	-0.013
Education (Refer to:	Illiteracy)	,	'				
Primary school	0.001	0.003	0.008	-0.001	0.035	0.009	-0.025
Junior Middle school	0.053*	0.058**	0.064**	0.021	0.025	0.000	-0.031
High school and above	0.087***	0.086***	0.104***	-0.002	-0.001	-0.052*	-0.071***
Family size	-0.041**	-0.004	-0.004	0.171***	0.128***	0.078***	-0.033
Household income			·				
(Refer to: Low incom	e)						
Middle lower income	-0.060***	-0.053**	-0.051**	0.010	0.054**	0.018	-0.014
Middle income	0.009	0.008	0.005	-0.014	0.021	0.027	0.009
Upper income	-0.024	-0.021	-0.013	-0.006	0.056**	0.034	-0.036
High income	-0.051**	-0.044*	-0.038	0.015	0.060**	0.023	-0.032
Community service	-0.038**	-0.028	-0.021	0.041**	0.037**	0.039**	-0.039**
R-squared	0.036	0.076	0.129	0.041	0.048	0.026	0.017

Standard errors in parentheses; ***p < 0.01, **p < 0.05, *p < 0.1.

TABLE 3 Results of the ordinary least square (OLS) regression and logistic regression in China, 2018 (N = 3,125).

	Burden grade	Burden grade	Burden grade	Self-assessed burden	Self-assessed burden	Self-assessed burden
Caring load	0.0055***	0.0048***	0.0036**	0.046***	0.040**	0.029*
Social support intensity		-0.017***	-0.014***		-0.154***	-0.123***
Passive social exclusion			0.022***			0.192***
Control variables	Control	Control	Control	Control	Control	Control
Pseudo R2/R2	0.013	0.026	0.046	0.025	0.048	0.084

Standard errors in parentheses; *** p < 0.01, ** p < 0.05, * p < 0.1.

TABLE 4 Results of mediating effects with the KHB method in China, 2018 (N = 3,125).

	Mediating effect of Social support intensity	Mediating effect of Passive social exclusion	Total Mediating effects
Burden score	14.11%	28.85%	37.52%
Burden grade	13.16%	27.12%	35.34%
Self-assessed burden	13.73%	28.49%	36.89%
Control variables	Control	Control	Control

This study proved that social support (social support intensity rather than social support breadth) could significantly mediate the association between caring load and family caregiver burden, and the corresponding contribution was stable, probably between 13 and 15%. Compared with the previous literature, this study further deepened the conclusion that social support played a mediating role, and found that social support intensity rather than social support breadth played the mediating effect (34). Social support alleviates the family caregiver burden, maybe because of the power of social relations. Chinese traditional society is an "Acquaintance society," which is characterized by a private relationship between people, people are connected through this relationship and form a network of relationships. Therefore, "Guanxi" is one of the typical words for "Acquaintance society." Solid and sound social relations will strengthen caregivers' social support, thereby alleviating the pressure burden of physical fatigue, psychological and emotional guilt, economic strain and social isolation or helplessness. However, the family caregivers with heavier caring loads have no time to participate in social interaction, which is the main component of social support intensity, and the decline of social support intensity would eventually lead to an increase in caregiver burden. The heavy caring load affects the ultimate caregiver burden, not by reducing the number of caregiver's nodding acquaintances (e.g., ordinary friends or acquaintances), but by reducing the caregiver's social contact strength (e.g., contact intensity with closer relatives and friends) (35).

This study also proved that social exclusion (passive social exclusion rather than active social exclusion) could significantly mediate the association between caring load and family caregiver burden, and the corresponding contribution was stable, probably between 27 and 29%. Social exclusion aggravates the burden of family caregivers, maybe because of social relations' alienation, which is different from the power of social support. Family caregivers of older adults with disabilities suffer from "social exclusion caused by alienation," including their becoming marginalized groups due to social contact, social relations, and group identity restrictions and restrictions. As a marginal group, family caregivers may be excluded from many aspects of social life. Social exclusion is defined as "social relation exclusion" when it is emphasized as the concept of "relation" (36). People being excluded from social relations could lead to "deprivation" and further limit people's life opportunities. Those who are excluded from social relations will be socially, psychologically and even economically disadvantaged (37). To some extent, these findings have deepened the existing literature on this issue. Family caregivers who are responsible for caring for older adults with disabilities face the break and exclusion from others, which will further aggravate family caregivers' burden (38). Meanwhile, social exclusion may not be the result of family caregivers' willing choice but the result of passive acceptance (24).

This study further proved that social support and social exclusion contributed more than 30% to the mechanism of how the caring load affected the family caregivers' burden, and these findings require policymakers to pay more attention to the mediation effects of social support and social exclusion, especially in the innovation of public policy on reducing family caregivers' burden. In order to provide better care services for older adults with disabilities at home, social support and social integration should be paid more attention to, and it requires the informal social network to provide substantial, inclusive and stable support rather than exclusion or quarantine. Public policies should provide various support and assistance to these family caregivers, such as respite service, specific care skills training and support, etc., to optimize the well-being of caregivers. In addition, it is also important to develop community social organizations, carry out community activities, and cultivate community workers, so as to provide emotional assessment, spiritual and psychological support and other services for family caregivers.

There are some limitations to this study. First, although the data used in this study was based on a standardized questionnaire covering a wide range of characteristics of family caregivers, due to the vulnerability and sensitivity of family caregivers, the data collection referring to indicators of social support and social exclusion may be still not rich enough. Additionally, due to the limitations of the survey design, some relevant information about older adults with disabilities, caregivers and family is incomplete. There was a lack of survey information on the types and severity of disability of older adults with disabilities, the status of activities of daily living in the older adults with disabilities, number of family caregivers and particular roles of family caregivers, family composition and relationship quality of family members, etc. Actually, the data used in this study was cross-sectional data. Due to the crosssectional design, it is a challenge for this study to make causal inferences. Fortunately, due to the different questions in the questionnaire point to different time points/periods, this makes the variables in this study have their own chronological orders. Thus, endogeneity could be dispelled to a certain extent. In the survey questionnaire, the caregiver burden is the current state of the respondents, however, social support (include social support breadth and social support intensity) and social exclusion (include active social exclusion and passive social exclusion) is asked about the situation of the respondents in the past year. There is a chronological relationship, for respondents, the state of social support and social exclusion in the front, the caregiver burden in the back. The chronological order of these variables strongly supported the mediation analyses and the causal inference in this study.

Despite the above potential research design challenge, this study still has its strengths and advantages, which enhance the necessity and value of this study. First, it is helpful for the readers to

understand the unique pressure faced by Chinese caregivers in China, with the largest aging population on the earth. With the rapid aging of the population, the increase of care demand for older adults with disabilities in China has become increasingly prominent, and due to the traditional filial piety culture in China, the growing care burden of caregivers becomes an extremely urgent and severe concern. Meanwhile, due to the unique way of social network in China, which was deeply influenced by traditional culture (including filial piety and traditional clan networks), both social support and social exclusion under the specific cultural context may play an important mediating role between caring load and caregiver's burden, which may be different from that under the cultural background of Western society. This study contributes significantly to the literature related to this topic. Second, this study used nationally representative data to investigate the relationship between caring load and caregiver's burden, as well as the mediating role of social support and social exclusion, and this makes this study significantly different from previous studies using small-scale or regional data (33, 39, 40). The data (showing caregivers' burden in China), used in this study, have the advantages of large-scale and representativeness, which could make up for the limitations of the cross-sectional nature of the data, to a certain extent. Third, to present more rigorously, this study used more cautious wording in interpreting the results, including trying to use association rather than causality to explain the relationship between some variables in this study. In the future, it is expected that longitudinal data could be used to provide support for better revealing the causal relationship between the above variables.

5. Conclusion

Based on nationally representative data, this study investigated the association between caring load and family caregivers' burden in China, especially exploring the mediating effects of social support and social exclusion. The results showed that there was a significant positive association between the caring load and caregiver burden, and there were significant steady mediating effects of social support intensity and passive social exclusion on the association between caring load and family caregivers' burden (the total contribution ratios of mediating effects was over 30%). Specifically, social support intensity and passive social exclusion played partial mediating roles, while social support breadth and active social exclusion did not, furthermore, the total mediating effects were about 35%, and the results were robust. In order to better cope with the rapidly rising aging and the corresponding rapidly expanding demand for potential care for older adults with disabilities, China's public policy should pay more attention to the support of family caregivers, especially including the reinforcement of social support and social integration for these caregivers in communities.

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Data availability statement

The data analyzed in this study is subject to the following licenses/ restrictions: the data that support the findings of this study are available from the Institute of Social Science Survey, Peking University, but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Researchers interested in these data can contact the corresponding author to process the data request.

Ethics statement

The studies involving humans were approved by the Ministry of Civil Affairs of the People's Republic of China. The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

HH participated in the design, review, revision and editing of the manuscript. XH participated in the discussion, revision, and editing of the manuscript. YX participated in the drafting and revision of the manuscript, and conducted data processing, and analysis. All authors have read and approved the manuscript.

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Conflict of interest

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Prediction of posttraumatic functional recovery in middle-aged and older patients through dynamic ensemble selection modeling

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Introduction: Age-specific risk factors may delay posttraumatic functional recovery; complex interactions exist between these factors. In this study, we investigated the prediction ability of machine learning models for posttraumatic (6months) functional recovery in middle-aged and older patients on the basis of their preexisting health conditions.

Methods: Data obtained from injured patients aged ≥45 years were divided into training-validation (n=368) and test (n=159) data sets. The input features were the sociodemographic characteristics and baseline health conditions of the patients. The output feature was functional status 6 months after injury; this was assessed using the Barthel Index (BI). On the basis of their BI scores, the patients were categorized into functionally independent (BI >60) and functionally dependent (BI ≤60) groups. The permutation feature importance method was used for feature selection. Six algorithms were validated through cross-validation with hyperparameter optimization. The algorithms exhibiting satisfactory performance were subjected to bagging to construct stacking, voting, and dynamic ensemble selection models. The best model was evaluated on the test data set. Partial dependence (PD) and individual conditional expectation (ICE) plots were created.

Results: In total, nineteen of twenty-seven features were selected. Logistic regression, linear discrimination analysis, and Gaussian Naive Bayes algorithms exhibited satisfactory performances and were, therefore, used to construct ensemble models. The k-Nearest Oracle Elimination model outperformed the other models when evaluated on the training-validation data set (sensitivity:

0.732, 95% CI: 0.702–0.761; specificity: 0.813, 95% CI: 0.805–0.822); it exhibited compatible performance on the test data set (sensitivity: 0.779, 95% CI: 0.559–0.950; specificity: 0.859, 95% CI: 0.799–0.912). The PD and ICE plots showed consistent patterns with practical tendencies.

Conclusion: Preexisting health conditions can predict long-term functional outcomes in injured middle-aged and older patients, thus predicting prognosis and facilitating clinical decision-making.

KEYWORDS

dynamic ensemble selection, machine learning, middle-aged patient, older patient, traumatic injury

1. Introduction

Traumatic injuries are a leading cause of morbidity and mortality in middle-aged and older individuals (1, 2). Due to various sociodemographic factors and frailty, these patients have posttraumatic complications, prolonged hospitalization, and a poor quality of life, which, in turn, increase the risk of functional disability (3–7). Although prognosis and clinical decision-making are highly complicated in injured middle-aged and older patients, these factors are crucial for ensuring optimal care and rehabilitation, which may minimize mortality rates and improve functional independence in these patients (8, 9).

Approximately 50% of injured older patients have comorbidities, which result in functional limitations and poor physical health (10). Severe complications are associated with certain demographic characteristics and preexisting diseases (e.g., diabetes, cardiovascular disease, liver disease, and psychological conditions) (11); these factors may delay functional recovery. In patients with hip bone fractures, neurological and renal disorders are associated with reduced performance of activities of daily living (ADL), as assessed using the Barthel Index (BI) (6). These findings imply that demographics and baseline health conditions are associated with the risk of functional dependence in injured middle-aged and older patients. Therefore, those features might be used to build the predictive model for predicting long-term functional outcomes in this clinical population, which could support physicians in clinical practice.

In medicine, machine learning (ML) is an effective approach for making diagnoses and predicting prognoses; ML models exhibit satisfactory performance on clinical data sets, which are generally highly dimensional and imbalanced (12). An ML model was successfully used to predict knee pain in middle-aged and older individuals by using demographic, body measurement, and blood test data; the sensitivity and specificity of the prediction were 0.72 and 0.71, respectively (13). Furthermore, the CatBoost algorithm was used to identify depression in this population (sensitivity: 0.71; specificity: 0.89) (14). A study using an ML model demonstrated that physiological biomarkers are associated with mortality, extremity mobility, and ADL in middle-aged and older individuals (15). In addition, previous studies also evaluated the predictions of ML models on poststroke functional recovery, supporting rehabilitation practice (16, 17). These findings suggest that ML explores complicated patterns in clinical data to predict functional outcomes in middle-aged and older individuals in different clinical conditions. However, to the best of our knowledge, no predictive ML model has been constructed to predict the risk of long-term functional dependence in this population on the basis of preexisting health conditions. Therefore, by adopting an ML approach, we investigated the prediction ability of ML models for the risk of functional dependence in middle-aged and older patients 6 months after injury on the basis of their demographic characteristics and preexisting health conditions. We hypothesized that baseline features can be used to classify patients with and without functional dependency 6 months after injury and to predict functional prognosis in clinical practice.

2. Patients and methods

2.1. Study design

The protocol of this prospective observational study was approved by the Institution Research Board of Taipei Medical University, Taiwan (approval number: N202002099). All participants provided informed consent. This study was conducted and reported following the STROBE checklist. The funders had no roles in analyzing the data, interpreting the data, or drawing study conclusions.

2.2. Participants and data sets

We included 670 middle-aged and older patients with primary injury who were admitted to the Emergency Department of Wan Fang Hospital, Taipei Medical University, Taiwan, between August 2020 and March 2022. The inclusion criteria were an age of \geq 45 years and the ability to provide informed consent. After the completion of treatment, the researchers contacted eligible patients and explained the study to them. After informed consent was obtained, the patients were interviewed and under physical examination. Data regarding the patients' sociodemographic characteristics, preexisting diseases, and baseline clinical characteristics were collected. For patients with severe injury, the interviews and assessments were conducted after their conditions had stabilized. Clinical events during hospitalization (e.g., intensive care unit [ICU] admission) were also recorded. After 6 months, a follow-up assessment was performed through telephonic interviews. All assessments were performed by experienced physicians and nurses. After excluding 9 patients who died in the hospital, 134 patients who were lost to

follow-up, and 26 patients who died during follow-up, 527 patients were included in this study (Supplementary Figure S1).

Clinical characteristics were assessed using a standardized format. The BI, a 10-item scale that assesses ADL, was used to evaluate the patients' baseline (preinjury) levels of functional dependence (18). The total BI score ranges from 0 to 100, and a BI score of ≤60 indicates severe or complete functional dependence (19). The Clinical Frailty Scale (CFS), a 9-point scale that assesses physical frailty and cognitive impairment, was used to evaluate overall frailty (20). The CFS score from one to three indicates that an individual is healthy or has wellcontrolled medical problems, whereas the CFS score from four to nine indicates that an individual has "very mild frailty" to "terminally ill" (20). The Charlson comorbidity index (CCI), a 17-item tool with high validity and reliability, was used to assess the risk of 1-year mortality in the patients (21). The death rate is smaller than 0.5% when the CCI score is equal to zero, whereas this rate is approximately 20-25% when the CCI score is higher than six (21). Furthermore, the revised trauma score (RTS) was used to assess functional outcomes after injury (22, 23). The injury severity score, which is used to assess the severity of injury in six body systems, was calculated for the patients upon admission to the emergency department (ED-ISS), during hospitalization (HOSP-ISS), and before discharge (ISS) (24). The RTS score smaller than seven might suggest the high rates of survival and the low rate of complication in an individual (22, 23).

2.3. Independent input and output features

We used the patients' baseline health conditions to predict their functional recovery 6 months after injury. The initial input features were sociodemographic characteristics (e.g., age, sex, marital status, employment status, education level, and body mass index), causes of trauma, preexisting diseases (e.g., diabetes, hypertension, heart failure, chronic kidney disease, liver diseases, chronic obstructive pulmonary disorder, stroke, anemia, hip fracture, Parkinson's disease, and dementia), clinical events (e.g., ICU admission and hospital rehabilitation), and baseline assessment scores (e.g., BI score, CCI score, CFS score, RTS, ED_ISS, HOSP_ISS, and ISS). The outcome feature was functional status determined using the patients' BI scores calculated 6 months after injury; on the basis of their BI scores, the patients were categorized into two groups: functionally independent (BI \leq 60) and functionally dependent (BI \leq 60) groups (16, 25).

2.4. Descriptive statistical analysis

Data are presented as mean \pm standard deviation values for continuous variables and number and percentage values for categorical variables. The functionally independent and dependent groups were compared in terms of demographic and clinical characteristics by using the independent samples t test (for continuous variables) or chi-square test (for categorical variables). The BI scores and the number of patients with functional dependency were compared between baseline and 6 months after injury by using paired t and McNemar tests, respectively. In addition, the validation and independent data sets were compared in terms of patient characteristics. A p value of <0.05 indicated statistical significance. R (version 4.1.2; R Foundation for Statistical Computing, Vienna,

Austria) and Jeffrey's Amazing Statistics Program (version 0.16.3; The JASP Team, 2020) were used for statistical analyses.

2.5. ML process

Figure 1 illustrates the ML process, which included data preprocessing, feature selection, model construction, model validation and testing, and model interpretation. All process steps were performed using Python 3.7 with Scikit-learn 1.1.3 (26) and DESlib library 0.3.5 (27).

2.5.1. Data preprocessing

The data set was first analyzed for missing values and outliers and then randomly divided into training–validation and test data sets by the ratio 70:30 that is commonly used in ML (28, 29). The training–validation data set (n=368) was used to train and construct ML models, whereas the independent test data set (n=159) was used for evaluate the constructed models.

2.5.2. Feature selection

The imputation feature importance method was used to select important features and exclude noise. The logistic regression (LR) algorithm was used as an estimator with 1,000 repeats. The features with negative or 0 important scores were eliminated. The remaining features were used to construct the ML model.

2.5.3. Model construction

We first evaluated the classification performance of individual algorithms. The following six algorithms were selected: support vector machine (SVM), LR, k-nearest neighbor (KNN), Gaussian Naive Bayes (GNB), linear discrimination analysis (LDA), and decision tree (DT); these algorithms are commonly used for classification based on highly dimensional clinical data (13, 15, 16). Hyperparameter optimization was performed using GridSearchCV (Supplementary Table S1). The algorithms exhibiting poor performance were excluded.

For classification, an ensemble of classifiers is generally considered to be superior to a single classifier and could reduce the risk of overfitting (30). Therefore, the algorithms exhibiting satisfactory performance were subjected to bagging (a number of estimators were searched using GridSearchCV); then, these were used as base learners to construct stacking, voting, and dynamic ensemble selection (DES) models, including k-nearest oracle union (KNORA-U), k-nearest oracle elimination (KNORA-E), DES performance (DES-P), and meta learning for DES (META-DES).

2.5.4. Cross-validation and internal validation on the test data set

The models were trained on the training–validation data set through stratified five-fold cross-validation, repeated twenty times. Because our data were imbalanced, random oversampling was separately applied on each training fold (but not the testing folds) during cross-validation. The DES and single-algorithm models were compared in terms of performance. The best model was evaluated on the independent test data set for assessing its performance on unseen data. In the cross-validation process, we estimated a 95% confidence interval for each performance indicator of all algorithms, defined by a mean score $\pm\,1.96^*$ validated

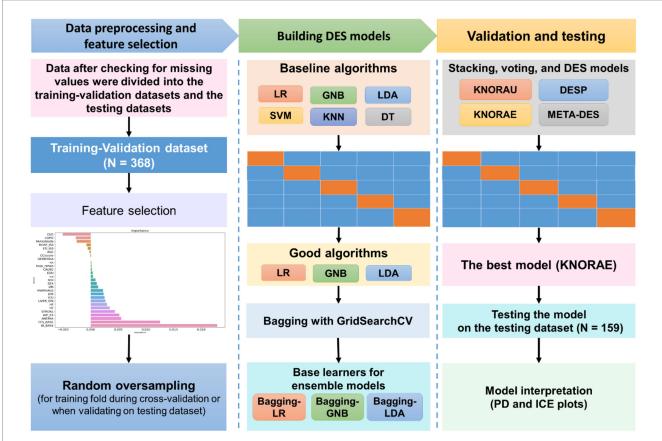


FIGURE 1

Machine learning process. Data obtained from the patients were first checked for missing values and outliners and then divided into training-validation data set (for model construction) and independent test (for model evaluation) data sets. The permutation feature importance method was used for feature selection. Because our data were imbalanced, random oversampling was applied on each training fold during cross-validation. Six algorithms, including support vector machine (SVM), logistic regression (LR), k-nearest neighbor (KNN), Gaussian Naive Bayes (GNB), linear discrimination analysis (LDA), and decision tree (DT), were validated through five-fold cross-validation. The algorithms exhibiting satisfactory performance (LR, GNB, and LDA) were subjected to bagging; afterward, they were used as the pool of classifiers for ensemble models (i.e., stacking, voting, and dynamic ensemble selection [DES] models). The ensemble models were compared in terms of performance, and the best model (k-nearest oracle elimination [KNORA-E]) was evaluated on the independent test data set. Partial dependence (PD) and individual conditional expectation (ICE) plots were constructed to investigate the interpretability of the model.

standard error. When testing the final model on the independent test data set, the 95% CIs for performance indicators were calculated by conducting the bootstrap method (1,000 repeats) on the independent test data set.

2.5.5. Performance matrix

The performance matrix included accuracy, sensitivity, specificity, F1 score, and area under the receiver operating characteristic curve (ROC-AUC). Because our aim was to investigate the prediction ability of the models for the risk of functional dependence, minimizing false negative rates was important. Therefore, we preferred sensitivity over specificity for model evaluation. In addition, because our data sets were imbalanced, a dummy classifier (uniform strategy) was used to construct a no-skill model, whose performance matrix was used as the baseline cutoff score for comparisons.

2.5.6. Model interpretability analysis

Regarding the intuitive interpretation of the models, partial dependence (PD) and individual conditional expectation (ICE)

plots were constructed to compare the effects of features on the outcomes predicted by the ML models with clinical tendencies. Given that the assessment scores indicated the effects of preexisting diseases on the model outcome, we constructed PD and ICE plots only for the assessment scores to evaluate the effects of changes in these scores on the risk of functional dependence 6 months after injury.

3. Results

3.1. Patient characteristics

Tables 1, 2 summarize the patient's sociodemographic characteristics, injury severity levels, and functional outcomes. The most common cause of trauma was falling (69.1%; Table 1). Of the patients, >50% had at least one chronic disease. As shown in Table 2, the most common comorbidities were hypertension (53.7%), diabetes (29.2%), and heart failure (24.7%). The proportion of patients with functional dependency significantly

TABLE 1 Sociodemographic characteristics of the patients and causes of trauma.

Patient characteristics	Total (<i>N</i> =527)	Training– validation data set (N=368)	Independent test data set (N=159)
Age (years), mean ± standard deviation	72.1 ± 12.8	72.4±12.6	71.4±13.1
Sex (women), n (%)	318 (60.3)	218 (59.2%)	100 (62.9)
Marital status, n (%)			
Single	32 (6.1)	25 (6.8)	7 (4.3)
Married	301 (57.1)	209 (56.8)	92 (57.9)
Divorced	34 (6.5)	23 (6.3)	11 (6.9)
Other	160 (30.3)	111 (30.1)	49 (30.9)
Job, n (%)			
Working	147 (27.9)	101 (27.5)	46 (28.9)
Housekeeping	27 (7.0)	28 (7.6)	9 (5.7)
Retired	329 (62.4)	230 (62.5)	99 (62.3)
Unemployed	14 (2.7)	9 (2.4)	5 (3.1)
Education level, n (%)			
None	51 (9.7)	35 (9.5)	16 (10.1)
Elementary	157 (29.8)	112 (30.4)	45 (28.3)
Secondary	59 (11.2)	47 (12.8)	12 (7.6)
High school	116 (22.0)	79 (21.5)	37 (23.3)
Undergraduate	125 (23.7)	82 (22.3)	43 (27.0)
Postgraduate	19 (3.6)	13 (3.5)	6 (3.7)
Cause, n (%)			
Fall	364 (69.1)	256 (69.6)	108 (67.9)
Traffic accident	133 (25.2)	90 (24.5)	43 (27.0)
Other	30 (5.7)	22 (5.9)	8 (5.1)

Patient characteristics did not vary significantly between the training-validation and independent test data sets (independent samples *t*-test or chi-square test).

increased 6 months after injury (from 5.6 to 11.4% in total; p < 0.01; Table 2). The patients' demographic and clinical characteristics did not vary significantly between the training–validation and independent test data sets (p > 0.05; Tables 1, 2), which indicates that the independent test data set can be used for validation.

3.2. Selection of informative features for classification

To reduce noise and select the most efficient features for predicting the risk of functional dependence 6 months after injury, feature selection was performed using the permutation feature importance method. Of the total 27 features, 8 had 0 or negative important scores and thus were removed (Figure 2). The remaining 19 features were used as input features to construct the classification models.

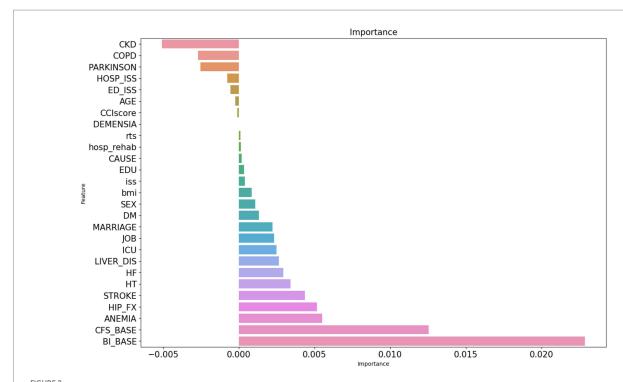
TABLE 2 Clinical characteristics of the patients.

Preexisting health conditions	Total (<i>N</i> =527)	Training – validation data set (N=368)	Independent test data set (N=159)				
Health conditions, n (%)							
Hypertension	283 (53.7)	200 (54.4)	83 (52.2)				
Diabetes	154 (29.2)	111 (30.2)	43 (27.4)				
Heart failure	130 (24.7)	88 (23.9)	42 (26.4)				
Anemia	84 (15.9)	64 (17.4)	20 (12.6)				
Chronic kidney disease	66 (12.5)	48 (13.4)	18 (11.3)				
Dementia	55 (10.4)	38 (10.3)	17 (10.7)				
Stroke	49 (9.3%)	36 (9.8)	13 (8.2)				
Hip bone fracture	31 (5.9)	25 (6.8)	6 (3.8)				
Chronic obstructive pulmonary disorder	23 (4.4)	16 (4.4)	7 (4.4)				
Parkinson's disease	23 (4.4)	12 (3.3)	11 (6.9)				
Liver diseases	20 (3.8)	13 (3.5)	7 (4.4)				
Scores, mean ± standare	d deviation						
Baseline CFS	3.3 ± 1.5	3.3 ± 1.5	3.3 ± 1.5				
Baseline ISS	7.1 ± 5.9	7.1 ± 5.9	7.2 ± 6.0				
Baseline RTS	7.8 ± 0.2	7.8 ± 0.1	7.8 ± 0.2				
BI							
Baseline	93.7 ± 15.16	93.9 ± 14.9	93.2 ± 15.7				
After 6 months	86.8 ± 20.4***	86.6 ± 19.8***	87.2 ± 21.6***				
Number of patients with functional dependency, <i>n</i> (%)							
Baseline	31 (5.9)	22 (6.0)	9 (5.6)				
After 6 months	60 (11.4)**	42 (11.4)**	18 (11.3)**				

Patient characteristics did not vary significantly between the training–validation and independent test data sets (using independent samples t-test or chi-square test). The BI scores and number of patients with functional dependency varied significantly between baseline and 6 months after injury when analyses were performed using the total, training–validation, and independent test data sets (paired t and McNemar tests, respectively). BI, Barthel Index; CFS, Clinical Frailty Scale; ISS, injury severity score; and RTS, revised traumatic score. **p < 0.01 and ***p < 0.001 compared with baseline.

3.3. Performance of single-algorithm models for predicting the risk of functional dependence

Six single-algorithm classification models were constructed through hyperparameter optimization. The LR, LDA, and GNB models exhibited balanced performance. LR exhibited the highest sensitivity (0.789, 95% CI: 0.761–0.817) and specificity (0.789, 95% CI: 0.778–0.799), followed by GNB (sensitivity: 0.719, 95% CI: 0.690–0.745; specificity: 0.761, 95% CI: 0.739–0.783) and LDA (sensitivity: 0.687, 95% CI: 0.656–0.718; specificity: 0.777, 95% CI: 0.766–0.787). The F1 scores of the LR, LDA, and GNB models were higher than the baseline F1 score of the no-skill model, i.e., 0.462 (95% CI: 0.446–0.478), 0.416 (95% CI: 0.397–0.436), and 0.402 (95% CI: 0.386–0.419) vs. 0.181 (95% CI: 0.168–0.193), respectively. By contrast, the SVM, KNN, and DT models exhibited imbalanced performance with high specificity but low sensitivity (Table 3).



Permutation feature importance selection. The figure presents important scores of the features assessed using the permutation importance ranking method (1,000 repeats). CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disorder; HOSP_ISS, injury severity score during hospitalization, ED_ISS, injury severity score upon admission to the emergency department; CCI score, Charlson comorbidity index score; RTS, revised traumatic score; EDU, education level; ISS, injury severity score before discharge; DM, diabetes mellitus; LIVER_DIS, liver diseases; HF, heart failure; HT, hypertension; HIP_FX, hip bone fracture; CFS_BASE, baseline score on the Clinical Frailty Scale; and BI_BASE, baseline score on the Barthel Index.

TABLE 3 Performance of single classifiers on the training-validation data set.

Classifiers	Accuracy	Sensitivity	Specificity	F1 score	ROC-AUC
SVM	0.900 (0.897; 0.903)	0.149 (0.124; 0.175)	0.997 (0.995; 0.998)	0.234 (0.197; 0.270)	0.632 (0.611; 0.652)
LR	0.789 (0.780; 0.798)	0.789 (0.761; 0.817)	0.789 (0.778; 0.799)	0.462 (0.446; 0.478)	0.854 (0.842; 0.866)
KNN	0.853 (0.846; 0.860)	0.381 (0.349; 0.413)	0.914 (0.907; 0.920)	0.367 (0.338; 0.393)	0.647 (0.631; 0.664)
GNB	0.756 (0.737; 0.775)	0.719 (0.690; 0.745)	0.761 (0.739; 0.783)	0.416 (0.397; 0.436)	0.811 (0.797; 0.826)
LDA	0.766 (0.757; 0.775)	0.687 (0.656; 0.718)	0.777 (0.766; 0.787)	0.402 (0.386; 0.419)	0.815 (0.801; 0.829)
DT	0.843 (0.835; 0.851)	0.328 (0.294; 0.362)	0.910 (0.902; 0.918)	0.317 (0.287; 0.347)	0.619 (0.602; 0.636)
No-skill model	0.500 (0.492; 0.507)	0.485 (0.452; 0.518)	0.501 (0.497; 0.505)	0.181 (0.168; 0.193)	0.500 (0.500; 0.500)

A no-skill model was constructed using a dummy classifier; the performance matrix of this model was used as the baseline threshold for comparison. SVM, support vector machine; LR, logistic regression; KNN, k-nearest neighbor; GNB, Gaussian Naive Bayes; LDA, linear discrimination analysis; DT, decision tree; and ROC-AUC, area under the receiver operating characteristic curve.

3.4. Performance of ensemble models for predicting the risk of functional dependence

To investigate whether the ensemble models could improve the prediction ability of the input features, stacking, voting, and DES models were constructed through the bagging of LR, LDA, and GNB as the pool of classifiers (Table 4). The KNORA-E model outperformed the other ensemble models (sensitivity: 0.732, 95% CI: 0.702-0.761; specificity: 0.813, 95% CI: 0.805-0.822; Table 4; Figure 3A). Furthermore, the F1 score of this model (0.460, 95% CI: 0.444-0.477) was higher than the baseline F1 score of the no-skill model 0.181 (95% CI: 0.168-0.193) and the F1 scores of the other models.

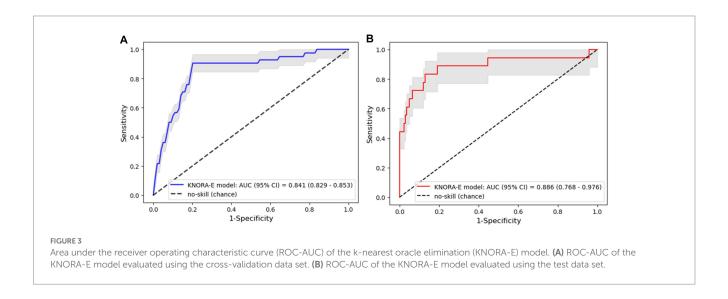
3.5. Validation on the independent test data set

To investigate the performance of the KNORA-E model on unseen data, the model was applied to the independent test data set. The performance matrix on the test data was similar to the performance on the train-validation data set, with accuracy, sensitivity, specificity, F1 score, and ROC-AUC values of 0.850 (95% CI:

TARIF 4	Performance of	f heterogeneous	assemble r	nodels on	the training	-validation data set.

Classifiers	Accuracy	Sensitivity	Specificity	F1 score	ROC-AUC
KNORA-U	0.783 (0.775; 0.791)	0.719 (0.690; 0.748)	0.791 (0.782; 0.801)	0.431 (0.415; 0.446)	0.821 (0.808; 0.834)
KNORA-E	0.804 (0.796; 0.812)	0.732 (0.702; 0.761)	0.813 (0.805; 0.822)	0.460 (0.444; 0.477)	0.841 (0.829; 0.853)
DES-P	0.786 (0.777; 0.795)	0.713 (0.684; 0.741)	0.796 (0.786; 0.806)	0.431 (0.416; 0.451)	0.834 (0.823; 0.846)
META-DES	0.801 (0.793; 0.809)	0.668 (0.638; 0.697)	0.819 (0.810; 0.827)	0.434 (0.417; 0.452)	0.822 (0.809; 0.836)
Stacking	0.761 (0.752; 0.770)	0.707 (0.675; 0.739)	0.768 (0.758; 0.778)	0.404 (0.387; 0.421)	0.818 (0.804; 0.831)
Voting	0.780 (0.770; 0.790)	0.732 (0.702; 0.763)	0.786 (0.774; 0.798)	0.433 (0.417; 0.449)	0.836 (0.824; 0.848)
No-skill model	0.500 (0.492; 0.507)	0.485 (0.452; 0.518)	0.501 (0.497; 0.505)	0.181 (0.168; 0.193)	0.500 (0.500; 0.500)

A no-skill model was constructed using a dummy classifier; the performance matrix of this model was used as the baseline threshold for comparison. KNORA-U, k-nearest oracle union; KNORA-E, k-nearest oracle elimination; DES-P, dynamic ensemble selection performance; META-DES, meta learning for dynamic ensemble selection; and ROC-AUC, area under the receiver operating characteristic curve.



0.792–0.899), 0.779 (95% CI: 0.559–0.950), 0.859 (95% CI: 0.799–0.912), 0.534 (95% CI: 0.359–0.680), and 0.886 (95% CI: 0.768–0.976), respectively (Figure 3B).

3.6. Model interpretability

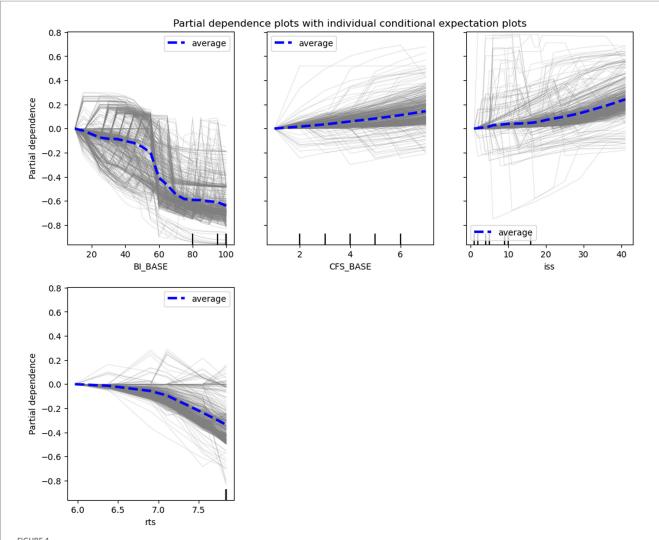
PD and ICE plots were constructed for continuous predictive features (e.g., BI_BASE score, CFS_BASE score, ISS, and RTS) to investigate the effects of changes in the scores on the risk of functional dependence. These plots showed a consistent trend. The effects of predictive features on the model-predicted outcomes were consistent with the practical tendency. The risk of functional dependence decreased with increasing baseline BI scores and RTS, particularly when the scores were 40–60 and > 7, respectively. By contrast, this risk increased with increasing baseline CFS scores (nearly linear increase) and ISS scores, particularly when the score was >4 and > 20, respectively (Figure 4).

4. Discussion

Pathophysiological changes may worsen posttraumatic functional outcomes in middle-aged and older individuals (3–7). The pattern of

functional recovery in these patients may vary from that in younger patients (2). Developing a model to predict long-term functional dependency in middle-aged and older individuals may facilitate treatment and rehabilitation, thus reducing the risk of functional disability. In the present study, using the DES models including selected features, we found that baseline sociodemographic characteristics, functional assessment scores, and preexisting diseases successfully predicted the risk of functional dependence in the study population 6 months after injury. The assessment scores may be non-linearly correlated with functional outcomes, and the correlation may be stronger in some score ranges. Our findings suggest that preexisting health conditions considerably affect functional recovery in injured middle-aged and older individuals; furthermore, ML models constructed using these input features can be used to predict prognosis in this population.

High dimensionality and imbalance are the characteristics of reallife clinical data; these characteristics complicate the analysis of data using ML models and reduce the applicability of these models (12). In the present study, the selection of features through the permutation importance method helped remove noise from the input features and improve model performance. Using the remaining features, several single-algorithm models, such as the LR, LDA, and GNB models, were constructed; these models predicted functional outcomes with acceptable performance. Although these algorithm exhibited



Partial dependence (PD) plots (blue lines) with individual conditional expectation (ICE) plots (grey lines). The plots indicate the overall (for PD) and individual (for ICE) effects of the features, including the baseline Barthel Index (BI_BASE) score, baseline Clinical Frailty Scale (CFS_BASE) score, revised traumatic score (RTS), and injury severity score (ISS).

acceptable classification performance on highly dimensional data after appropriate feature selection, they may exhibit overfitting in several circumstances, particularly in the case of data imbalance (31). Thus, we constructed heterogeneous ensemble models; these models may have a reduced overfitting risk and improved prediction ability (30). In the present study, the KNORA-E model exhibited the highest, balanced performance on both the training-validation and independent test data sets, which indicated that the levels of bias and variance were low for this model. Because of the nature of ML on extremely imbalanced data, the different gap between sensitivity and specificity in the final model in our study might be acceptable, which was similar to a previous study conducted an on extremely imbalanced cancer dataset (32). This finding corroborates that DES models exhibit improved classification performance on imbalanced data (33). Thus, DES modeling with feature selection may be an effective ML approach for prognosis using clinical data.

In this study, baseline BI and CFS scores (indicating functional level and frailty, respectively) were found to be the best features for predicting the risk of functional dependence in middle-aged and older

patients 6 months after injury. The other assessment scores used in this study, such as RTS and ISS, also contributed to the model-based prediction of functional recovery. The BI is a common scale used for evaluating functional independence in patients with various health conditions; this scale has high validity and reliability (19). The CFS score indicates the requirement of additional health care support for injured patients (34). However, the BI and CFS scores are influenced by comorbidities, age, and other sociodemographic factors (18, 35). The use of only assessment scores may not be sufficient for effectively predicting long-term functional outcomes in injured patients; therefore, additional features, such as sociodemographic characteristics and preexisting health conditions, must be included in the models.

Several preexisting diseases, including anemia, hip bone fracture, hypertension, heart failure, stroke, liver disease, and diabetes, helped predict functional recovery in older patients 6 months after injury. Hypertension, stroke, and diabetes markedly reduced the function and quality of life in patients with those diseases, particularly middle-aged and older patients (36). Anemia

reduces physical and cognitive functions, thus worsening functional outcomes in middle-aged and older individuals (37, 38). Hip fractures are common in this population; this reduces their mobility and quality of life (39–41). In a relevant study, approximately 40% of all patients with heart failure experienced moderate to severe difficulties in performing ADL; these challenges were associated with mortality and hospitalization (42). Liver diseases may alter the structure and function of the brain and heart, thus worsening patients' functional outcomes (43, 44). In summary, preexisting diseases may worsen functional outcomes in injured middle-aged and older individuals and may help predict the risk of long-term functional dependence in this population.

Using PD and ICE plots, we found that several assessment scores nonlinearly affected the risk of functional dependence. Higher baseline BI (particularly >40) scores exerted stronger effects on functional outcomes, which is consistent with Sinoff's interpretation that older individuals with BI scores of <40 may exhibit severe or complete functional dependence (45). In patients who experienced an acute stroke, those with BI scores of ≥ 40 exhibited considerable improvements in their ADL compared with those with BI scores of <40 (46). In the present study, CFS scores of >4 markedly increased the risk of functional dependence. According to the CFS guideline, patients with CFS scores of 4 exhibit limited performance of activities, and those with CFS scores of >5 require assistance in performing ADL (47). Prolonged hospitalization in acute medicine units has been reported in patients with CFS scores of >4 (48). In the present study, RTSs of >7 strongly reduced the risk of functional dependence; this is consistent with the findings of other studies indicating that an RTS of 7 serves as the cutoff value for predicting mortality and complication development in injured patients (22, 23). Taken together, the findings support the interpretability of our ML models and their feasibility in clinical practice.

This study has some limitations. First, our data sets were imbalanced; although we validated our models using the independent test data set, the patient sample was regional and may not represent the general population. Thus, external validation is necessary to evaluate the generalizability of the model. Second, we assessed functional outcomes only at baseline and the 6-month follow-up; thus, time-related changes in functional outcomes, which may differ across preexisting health conditions, could not be recorded. Finally, our model did not include preclinical data; thus, the predictive value of preclinical features for long-term functional outcomes could not be estimated.

In conclusion, our model constructed through feature selection and DES modeling exhibited high performance for predicting the risk of functional dependence in injured middle-aged and older patients on the basis of their sociodemographic characteristics and preexisting health conditions. The model showed practical interpretability. This study may facilitate further large-scale studies on the prediction ability of baseline information and its application for the prediction of long-term functional prognosis in injured patients.

Data availability statement

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author.

Ethics statement

The studies involving human participants were reviewed and approved by Taipei Medical University Joint Institution Research Board. The patients/participants provided their written informed consent to participate in this study.

Author contributions

J-HK and CL: study design, manuscript revising, and editing. C-CW and CL: patient enrollment and data collection. NTN, J-HK, T-SY, C-CW, C-YT, KP, and CL: data analysis and interpretation. NTN, J-HK, and CL: manuscript drafting. All authors contributed to the article and approved the submitted version.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

The Supplementary material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpubh.2023.1164820/full#supplementary-material

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Toward adapting the UN's healthy aging agenda for India: tailoring to unique historical context and traditions

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India is known for its rich cultural heritage with different cultures and customs. Indian historical traditions and cultures were molded in a manner that most older adults were cared for at home by their children. However, India is being urbanized and developing swiftly changing its socio-cultural scenarios. With globalization and the increased popularity of social media, the youth is more ambitious than ever and is ready to migrate and explore. Fueled by the rapid aging of the global population, demand is escalating for robust programs, policies, and activities to improve the lives of older adults. However, most of these schemes have not yet been fully implemented nationwide; several state governments have yet to realize their full potential due to the lack of resources and competing priorities. Aligning with the UN's healthy aging agenda, several programs and policies in India are contributing toward ensuring quality aged care services. This paper explores the challenges and opportunities for effective ground-level translation from precepts to practice.

KEYWORDS

older adult, healthy aging, healthcare, healthcare services, National Health Programs, digital health mission, India

Introduction

India is known for its rich cultural heritage with different cultures, religions, customs, traditions, and languages. Thus, the Indian social matrix and the cultural pattern are characterized by "Unity in Diversity" (1). Many mythological stories show that the aged parents were respected and worshipped like Gods, as in the story of Shravan Kumar, known for his filial piety toward his parents (2). *Thaittiriya Upanishad* states "Let your mother be God. Let your father be God" which brings out the importance of caring for older adults which is deeply rooted in the traditions (3). Indian historical traditions and cultures were molded for the care of an older adult at home by their children. Also, older adults have a societal expectation from their children, a tradition that has been long-standing and pervasive (4).

India is rapidly urbanizing and developing swiftly with changing socio-cultural scenarios. With globalization, the youth is ambitious to migrate and explore (5). There is also an increased participation of women in the workforce (6). These factors have caused a

shift from the idea of a joint family to a nuclear family over time leaving the older adults to look after themselves. This is compounded by the system's failure to offer adequate pension and healthcare services for older adults (7).

In this perspective article, we offer our viewpoints on how India is tailoring its unique cultural and historical traditions to conform with the guidelines and expectations of the UN's Healthy Ageing Agenda.

Epidemiology of aged care in India

The population of older adults in India was 104 million (8.6% of the total population) according to the 2011 census, and is projected to increase to 173 million by 2026 (8). According to the World Health Organization (WHO), one in six people in the world will be aged 60 years or older by the year 2030. Alongside the rapid aging of the global population, demand is escalating for robust programs, policies, and activities to improve the lives of older adults. Therefore, today it is essential to increase the focus on providing healthy life expectancy of the population.

Policies and programs

Over the years, India proposed and implemented policies, programs, and legislation for the older adults. The government has formulated policies and legislation to facilitate the care for the older adults within the families, thereby tailoring to the cultural and historical context in India. Since 1992, Government of India has implemented various schemes and programs, through different Ministries and Departments for care and welfare of senior citizens (Table 1). However, most of these schemes have not yet been implemented nationwide; many state-level governments have failed due to lack of resources and competing priorities.

Need for quality care for older adults in India

Beyond expanding and strengthening networks of health care provision for older adults, a need and an opportunity exist to utilize technology to aid people living in remote areas, or for those who have limited mobility. One promising technology application is information and resource 'telehealth' call and monitoring centers that offers health advice and support to older adults (9).

Both low-tech and high-tech innovations are also needed to help maintain older individuals' independence, dignity, and quality of life; low-cost and readily available versions of adaptive devices and aids, such as walkers, hearing aids, reading glasses and magnifiers, and grab bars present another form of technology solution. Additionally, infrastructure in India needs to be more accommodating for older adults and those with disabilities. As India continues to modernize its infrastructure, designing spaces for an aging population will involve building structures, adapting transportation, and implementing services that meet the needs of older adults and address the principles of inclusivity, accessibility, and connectivity (9).

UN healthy aging agenda

In 1994, the World Bank saw population aging as a crisis that needed 'averting' (10). Ensuring the healthy aging of older adults has been at the forefront of the UN agenda since 1982, with the formulation of the Vienna International Plan of Action on Ageing (11, 12). Despite collective achievements in recognizing and advancing the rights of older adults, the pressing need for improving the health and well-being of older persons was not central in the conception of the multilateral 2030 Agenda for Sustainable Development.

To foster healthy aging and improve the lives of the older adults, their families and communities, fundamental shifts will be necessary both in thoughts and actions. The 2021–2030 UN's Healthy ageing addresses four action areas (Figure 1).

Age friendly environment: Some of the prerequisites for age friendly environment are: room in the ground floor with switches close to the bed, commode with rails and antiskid bathroom without pooled lighting, ramp if needed to go upstairs, uncluttered areas for movement. Outside the home, roads should be well asphalted with even surfaces, visual and sound prompts and signals for lane intersection for senior adults with various handicaps. Structures are well-set apart outside and inside, with satisfactory seating and toilets, accessible lifts, slants, railings and stairs, and nonslip floors (13).

Combating aging: or "healthy aging" encompasses regular exercise and physical activity, making smart food choices, relaxing bedtime with 8–9h of sleep, annual health checkup and more frequently, if symptoms develop. Healthy aging also includes being socially connected with friends and relatives, practicing mindfulness and reading books, pursuing hobbies (14).

Integrated Care: WHO has developed Integrated Care for Older People (ICOPE) to meet the demand of the increasing older population. The delivery models could be community-based or home-based interventions at organizational level or at the clinical level (15, 16). The assessment could be personalized, and care plans integrated into it. The decision-making between the older adult and the physician should be shared, goals need to be set and work toward it. The physician can assist in supporting self-management and provide linkages with social support services. At the management level, data should be shared, the community should be involved and support provided for caregivers (17). The ultimate aim is to maximize the intrinsic capacity and functional ability of the older adults, with comprehensive assessments of all dimensions (Physical, Mental and Social Well-being) and not morbidity centric approach alone.

Long Term Care: It is the medical, and psychosocial support for older adults with limited Activities of Daily Living (ADL), Instrumental Activities of Daily Living (IADL), and chronic morbidities including palliative care. They need support from family, caregivers, community, or institutions. Caring for senior adults with mental instability, Parkinson's disease and Alzheimer's is a challenge for family members or paid caregivers. Tata Institute of Social Sciences (TISS) provides professional courses for social work for older adults in India. Social work professionals in the field are however very scarce (18).

Issues, concerns, and solutions

There is pressure on the health system for age-appropriate health care especially long-term care. The services and technologies for

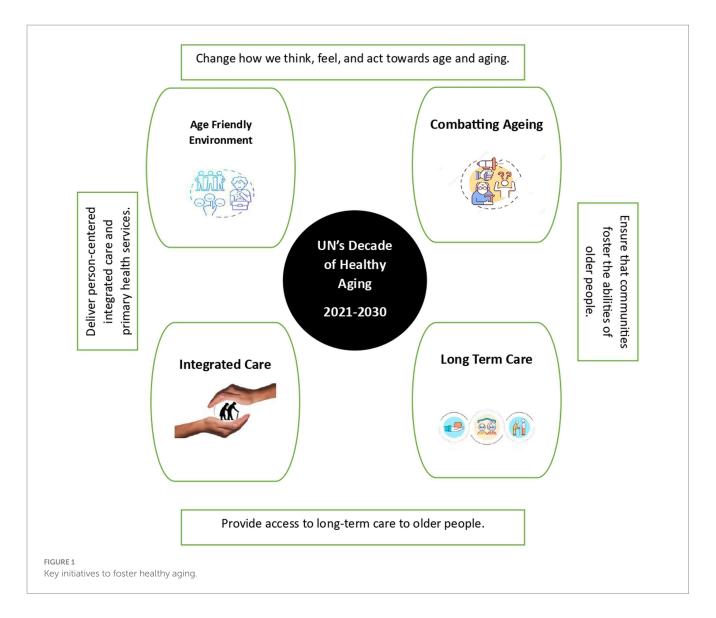
TABLE 1 Policies, agenda, and implementation challenges in India.

Schemes	Agenda	Challenges		
National Policy for Older Persons, 1999	Pensions, travel concessions, income tax relief, medical benefits, extra interest on savings, and security of older persons through an integrated scheme of the Ministry of Social Justice and Empowerment	Absence of savings. Physical decline Increased Destitution		
Indira Gandhi National Old Age Pension Scheme, 1995	Old age pension scheme would cover all senior citizens living below the poverty line. The rate of monthly pension would be raised to Rs.1000 per month per person and revised at intervals to prevent its deflation due to the higher cost of purchasing.	The monthly pension is not proportionate to the rate of inflation. Poor and irregular flow of funds will add to the plight of elders		
The Maintenance and Welfare of Parents and Senior Citizens Act, 2007	Public distribution system under Annapurna scheme to provide free rice up to 10 kgs for destitute	Lack of awareness, supply chain and consumer availability		
National Policy for Senior Citizens, 2011	 The policy seeks to reach out to the bulk of senior citizens living in rural areas who are dependent on family bonds and intergenerational understanding and support. The policy will consider institutional care as the last resort. 	Family migration to urban areas for better job opportunities and resistance of elders to adapt to the new environment.		
National Programme for Healthcare for the Older Adults (NPHCE), 2011	To provide accessible, affordable, and high-quality long-term, comprehensive, and dedicated care services to an aging population	Urgent need for developing specialized health services for older people at primary, secondary and tertiary care levels given their rapidly increasing number with varied health, economic and psychosocial needs. Outreach services for patients discharged for follow-up care. Multidisciplinary team to provide comprehensive services		
Central Sector Scheme of Integrated Programme for Senior Citizens (IPSrC), 1992	Grants in aid are given for running and maintenance of Senior Citizens Homes (Old Age Homes)/Continuous Care Homes, Mobile Medicare Units	Registration of Senior Citizens Homes, poor infrastructure and maintenance, lack of funds, lack of trained caregivers, non-admission of elders with poor ADL, nonfamilial support		
Rashtriya Vayoshri Yojana (RVY), 2017	Aids and assistive living devices are provided to senior citizens belonging to the BPL category or those senior citizens who earn less than 15,000/— per month and suffer from age-related disabilities	Identification of beneficiaries and customized good quality supply of appliances is a challenge. Lack of awareness by older adults adds to the low usage and distribution		
National Helpline for Senior Citizen, 2021 Elder line (14567)	The helpline is to address the grievances of the elders.	Inability, lack of awareness and underreporting of elder abuse, security		
State Action Plan for Senior Citizens (SAPSrC)	Each State/UT is expected to plan and strategize taking into account their local considerations and frame their own State Action Plans for the welfare of their senior citizens. This Plan takes care of the top four needs of the senior citizens viz. financial security, food, health care and human interaction /life of dignity	Challenges in trained manpower, creation of multidisciplinary teams and capacity building will be visible. Funds for Infrastructural facilities may be delayed.		
SAGE, 2021	Innovative start-ups will be identified and encouraged to develop products, processes, and services for the welfare of the older adults under this initiative	It may be difficult for committed youths to work for this initiative.		
Atal Vayo Abhyuday Yojana, 2021	Awareness generation/sensitization programs with school/ college students for strengthening Inter-generational bonding.	There is a disintegration of joint family and the concept of one child norm with both working parents. Physical distance between grandparents and only one grandparent alive is also another challenge.		

prevention, and treatment of diseases has not been forthcoming. With the dwindling joint family system, household care support is becoming more challenging. Further, the insecurity of family income and even if older adults are a pensioner, this source may not be adequate to support for a paid caregiver. It is also observed that there is prejudice and discrimination for ageism. Though not adequately documented,

financial abuse of older women and men due to property dispute among the siblings is observed. Indian elders are overwhelmed by the affection to their children; hence they turn a blind eye to the environment around them.

However, opportunities can be tapped with the available resources for income generation. There is scope for providing and



expanding social protective measures. Jobs can be created for older adults with flexible working schemes with no limitation for working age. They could work online in marketing, communications, designing, voluntary social activities. Need based skills training can be provided. Those in the rural areas can be trained on paper making, food processing, agarbathi making, mushroom cultivation etc. Day care centers can be initiated for elders for social security.

Aging in place: Due to the breakdown of joint families, and the moving away of children for better job opportunities, older adults prefer aging in place because of familiar immediate surroundings and neighborhood. If they are physically independent, medically, and mentally fit, there are no issues. However, challenges emerge when older adults are left alone as the slow withdrawal in daily activities raises the risk of crime.

Older adults can be provided with personal security, contact cards can be displayed and friendly cops can ease the situation, as in the "SAVERA YOJANA" initiative by the Uttar Pradesh Police (19). Digital innovative solutions for older adults in urban areas can be developed by entrepreneurs to ensure safety and security,

providing daily essential activities, home care, hygiene, and innovative health care. Additionally, empowering the family members and informal caregivers with certain skill will help the older adults to stay in residential environment rather than facility-based dwellings.

Age-friendly environment: Rented houses/apartments may not be conducive to modifications. In such instances, need-based temporary alterations may be a necessity. Several apartment builders are providing the option of minor customization to suit the requirements of older adult population within their projects. In India, there are ample opportunities for spiritual well-being through religious activities both within internal (domestic) and external (community) environment.

Combatting aging: In India, it is the psychosocial and financial security that needs to be addressed especially with migration, poor socioeconomic status, and lack of education contributing to the plight of older adults. Therefore, it is imperative to inform older adults about the maintenance and welfare of parents/senior citizens, the net of social safety measures available, and continued employment beyond the retirement age through Mahatma Gandhi

National Rural Employment Guarantee Act (MNREGA). The measures to be undertaken by the policy makers/Government are periodic review of select social welfare schemes, revisiting its retirement and pension policy, removal of administrative bottlenecks and simplification of required documentation, enhancement in the pension amount, and adoption of a transparent disbursal mechanism.

Private health insurance does not cover the chronic morbidities in older adults though it is needed the most at these critical times of life. The premium escalates due to inflation and the coverage is after a waiting period of three to 4 years. If any untoward health event occurs during this period, it could be disastrous.

There are success stories on older adults' self-groups in India which can be studied and implemented among those in the lower socioeconomic status and living in rural areas with community participation.

Food insecurity can be solved via the ICDS (Integrated Child Development Scheme) program in the Anganwadi, public distribution system by extending this to the older adults who are unable to cook. Meals on wheels at subsidized rates could also be encouraged.

Integrated care: This issue can be addressed through Community-based day care centers, NGO's and Panchayat Raj Institutions, mobile medical clinics, and home-based care. The challenge for utilizing day care centers is that the older adult should have good ADL, IADL, accessibility and affordability to reach the day care center. Community based palliative care and dementia care are other explored areas with challenges of restricted trained and compassionate manpower.

Long term care: Practitioners are inadequately prepared to provide comprehensive care to the older adults. The informal caregivers and family caregivers are less prepared for these responsibilities and the burden of caregiving is translated to abuse of older adults (20). Equipping the family members to handle caring and daily decision-making of managing the chronic illness is a Herculean task, which should be addressed.

Newer models of financing and care delivery

- "Adopting a granny" by school children especially when an old age home and school for orphans' is cohabitated. This helps in intergenerational bonding and reduces the psychological stress. It also prevents burnout among the caregivers.
- Capacity building on caregiving, bedside assistance, and methods to improve intergenerational bonding under the aegis of NICE (National Initiative on Care of Elderly)
- Clinicians could utilize digital innovations for predicting falls, ensuring early interventions which in turn supports the healthcare system through reduced ICU (Intensive Care Unit) admissions and medical expenditure.
- Promoting Silver economy by the Government with cash assistance to encourage entrepreneurs to think tank on innovative solutions for older adults.
- Corporate Social Responsibility (CSR) funds by companies for older adults for infrastructure and or care is an approved item yet untapped resource.

Adapting to Indian context

The number of older adults is bound to increase with better health affordability, improved technology, higher life expectancy and feminization, and evolving family structure both in urban and rural areas. It is therefore imperative that we organize our fragmented older adult care ecosystem. A multipronged approach is essential for acute and long-term care of older adults. India needs to evolve a framework with appropriate policies to attract investment in the sector, quality standards should be set for care delivery and appropriate timely regulations should be in place. Co-financing for the health of senior adults can mitigate health expenditure. For the home environment to be safe and secure for older adults, innovative cost effective, feasible digital tech solutions should be developed and nurtured by entrepreneurs.

Case Study

In southern India, Mrs. X, aged 80 years, a widow with three children (two males and one female), went into an institutionalized home due to the absence of a devoted full-time family caregiver. Her husband's pension was the only financial support but could not meet the entire medical expenses. Philanthropic organizations helped her to deal with this (socio-cultural support was provided in the institutional setting). Since she was a resident for a long time, her last few days were spent peacefully in the same place. Finally, she donated her body to the medical college for the student's learning.

Despite the availability of such philanthropic organizations and non-governmental agencies (NGO) many are not aware about them. Owning to the urban concentration of such facilities, the affordability to avail some of these services are beyond the reach of many older adult.

Key Observations:

- Inadequate knowledge about professional caregivers and the organizations providing such services.
- Lack of affordability and absence of pooled human and financial resources.
- Dealing with co-morbidities through an integrated multi-disciplinary approach.

Proposed Direction of Travel:

Ageing in place in the familiar environment of home through trained domiciliary care givers could be a potential solution.

Data availability statement

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author.

Author contributions

NS: Writing – original draft, Conceptualization, Formal analysis, Methodology, Supervision, Validation. MV: Conceptualization, Methodology, Writing – original draft. SS: Writing – review & editing, Conceptualization, Supervision.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Prevalence, Associated Factors, and Health Expenditures of Noncommunicable Disease Multimorbidity—Findings From Gorakhpur Health and Demographic Surveillance System

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Background: Noncommunicable disease (NCD) multimorbidity throws a unique challenge to healthcare systems globally in terms of not only management of disease, but also familial, social, and economic implications associated with it.

Objective: To assess the prevalence of NCD multimorbidity and its associated risk factors along with health expenditures among adults (>18 years) living in a rural area.

Methods: A secondary data analysis of the first-round survey done as part of the Gorakhpur Health and Demographic Surveillance Site (GHDSS) was done. Information related to self-reported morbidity and other variables related to sociodemographics and out-of-pocket expenditure (OOPE) was captured using a pretested questionnaire. Multivariable cluster adjusted binomial regression analysis was done to identify factors associated with multimorbidity.

Results: The overall prevalence of NCD multimorbidity was found to be 1.8% (95% CI: 1.7–1.9%). The prevalence of NCD multimorbidity was highest among elderly (≥60 years) [6.0% (95% CI: 5.5–6.5%)] and among women [2.4% (95% CI: 2.3–2.6%)]. Sociodemographic factors, such as age, gender, occupation, education, marital status, religion, caste, and household wealth, were all found to be independently associated with NCD multimorbidity. The median annual OOPE was found to be significantly higher among those with NCD multimorbidity (INR 20,000) compared with those with no NCD (INR 5,000) or having only one NCD (INR 8,000).

Conclusion: Among the adults in GHDSS, about 13 in every 100 were suffering from at least one NCD and around two in 100 were having NCD multimorbidity. Those with NCD multimorbidity spent almost four times higher annual OOPE compared with those without NCDs.

Keywords: HDSS, health expenditures, India, multimorbidity, noncommunicable diseases

INTRODUCTION

Multimorbidity is simply defined as the "coexistence of two or more chronic conditions in the same individual." These chronic conditions although are usually noncommunicable diseases (NCDs) in nature but are not limited to NCDs. Some chronic communicable diseases, such as hepatitis B infection, hepatitis C infection, and human immunodeficiency virus infections, also form a part of multimorbidity (1).

Tackling multimorbidity is identified as a health system challenge and identified as a huge problem at present and in coming decades in high-income countries (2). The prevalence of multimorbidity varies over a wide range globally to as high as 90% across the varied age groups (3). In South Asia, the prevalence ranges between 4.5 and 83% (4). The variability may largely be attributed to the way multimorbidity was captured in these studies. Studies reporting the prevalence of multimorbidity in India are limited and mostly done in the elderly age group giving only limited estimates (5–8).

Multimorbidity has been shown to have a greater burden on the healthcare system. Because of multiple conditions, there is an increased risk for hospital admissions, increased medications, all making one invest more in healthcare (9). As seen in individual diseases, premature mortality due to NCDs is on the rise in India which forms the majority of multimorbidity (10). Although age is identified as a single risk factor to multimorbidity, others need to be explored in depth.

The burden of NCDs is on the rise in rural areas and also among younger age groups. The recommendations to screen for NCDs in India in populations <30 years are becoming prominent (11). With the increase in life expectancy in India, people may have to spend more years with multimorbidity and, thus, more healthcare expenses (12). Based on the current demographics in India, identifying multimorbidity is more relevant not only in the elderly, but also in all the adult populations. Studying the epidemiology of multimorbidity, especially in rural India, is essential to tackle this ever-increasing problem at various levels of healthcare.

With this background in this study, we tried to assess the prevalence of NCD multimorbidity and its associated risk factors among adults (\geq 18 years) living in a rural area. We also tried to see the association of NCD multimorbidity with perceived health status and also OOPE.

METHODOLOGY

We adopted a cross-sectional analytical study design to determine the prevalence of self-reported NCD multimorbidity and its associated factors wherein secondary data analysis of the first-round survey which was done as part of the Gorakhpur Health and Demographic Surveillance Site (GHDSS) project at Gorakhpur, Eastern Uttar Pradesh was used.

The GHDSS conducted its first-round survey from November 2019 to January 2021. GHDSS included a survey in 28 villages belonging to two blocks of the district of Gorakhpur. Apart from the private clinics, the site is catered to by three public healthcare facilities: one primary health center and two community health

centers. The majority of the population depends on agriculture for employment. A total of 27,064 households were enlisted during primary household mapping in the GHDSS area. We were able to get consent for data collection from 20,965 households therefore out of 27,064 listed households only 20,965 households were enrolled in the survey. A total of 20,965 households consisting of 120,336 individuals were surveyed during the first round of GHDSS. For this study, we included all the adults (≥18 years) surveyed in the study.

In this GHDSS survey, all the households in the 28 villages were included. If the door was found locked in the first visit, then, it was visited once more on a different day and if found locked again then the house was declared to be "locked." Informed oral consent was taken from the head of the household and in a case when he/she was not available, it was taken from the available elder member of the household before starting the interview. Preferably, the head of the household and in cases where the head of the household was not available, any other adult member (aged \geq 18 years) of the household was interviewed using pretested questionnaires to collect data on the health and demography of the household and its members. The data were collected by trained field investigators and was supervised and monitored by trained field supervisors and field scientists. Complete methodology and profile shall be reported as a separate paper.

Information related to self-reported morbidity was captured by asking "Are you suffering from any ailment during the last 15 days?". In case of more than one morbidity, each morbidity was captured separately and details regarding each morbidity, such as treatment, consultation, and expenditure on ailment, were captured. The ailment name was captured as stated by the participant and then were later coded, which ensured capturing of ailment/disease in a better way. Among the ailments recorded to capture NCD multimorbidity, we took into account the various ailments/diseases which included anemia, cataract, goiter/any thyroid gland disorder, bronchial asthma, chronic obstructive pulmonary disease, gastritis/gastric or peptic ulcer, and digestive system diseases, including hemorrhoids, gallbladder disease/liver disease/pancreatic disease, dementia, mental disorders, stroke, hypertension, ischemic heart disease, diabetes mellitus, kidney diseases, namely, renal failure and renal stones, neoplasms, and musculoskeletal disorders. A person reporting more than one of the included NCD diseases was categorized as having NCD multimorbidity.

The other details collected included age, gender, marital status, occupation, education, family type, religion, and caste. Household wealth was used as a proxy to capture the socioeconomic status and was divided into five quintiles (poorest to wealthiest quintile). The list of assets used in calculating household wealth index included electricity, electric fan, chair, cot/bed, table, sofa, watch/clock, pressure cooker, radio/transistor, sewing machine, animal-drawn cart, mobile/telephone/tablet, television, bicycle, audio-video player, air cooler, computer/laptop, internet connection, refrigerator, mixer/grinder, washing machine, camera/video recorder, motorcycle/ scooter, car, water pump, thresher, tractor, solar panel, mattress, and any other material assets. The steps used in

calculating the wealth index were as per the new DHS wealth index calculation (13).

We also determined the coverage of any health insurance and the out-of-pocket health expenditure (OOPE) incurred by the individual. The OOPE was calculated by collecting expenditure status for each ailment, if the expenditure is episodic, it was captured as it is (for example, surgery, outpatient department visits), in case of medications and other monthly recurring expenditures it was captured for monthly and then multiplied by 12 to get annual expenditure; the sum of all expenditures was taken as annual OOPE for that particular ailment. The expenditure was captured as a whole after calculation of OOPE for that particular ailment and then only the total was captured using the ODK tool questionnaire, individual particulars were not captured. The total OOPE per year for an individual was obtained by the total expenditures for all ailments. Similarly, usage of any health facility was also captured for ailments. Thus, we have reported the number who visited any healthcare facility and among them the proportion who incurred OOPE and among those who incurred OOPE the median OOPE [along with interquartile range (IQR)] incurred per year per person in Indian National Rupees (INR). We tried to assess whether there was any difference across the OOPE based on the status of no NCD, one NCD, and NCD multimorbidity (2⁺ NCD).

We also captured their current health status by asking "Currently how do you feel about your health?" with responses captured as either "very good," "good/fair," or "poor." We tried to assess whether the reporting of current health status varied across the NCD and "no NCD" groups.

DATA ENTRY AND ANALYSIS

Data were collected using the Open Data Kit (ODK) software installed in android tablets. Data from the ODK tool were exported into Microsoft Excel format and later coded using STATA version 14.0 for analysis purposes. Continuous variables, such as age, were reported using mean and SD and OOPE was reported using median and IOR. Categorical variables, such as gender, marital status, family type, education status, occupation, religion, caste, and usage of health insurance scheme, were reported as frequency along with percentage. The major outcome of NCD multimorbidity was reported using percentage and its respective 95% CI. NCD multimorbidity along with their 95% CI across different age categories and gender was represented using CI plots and the statistical significance was determined using Pearson's chi-square test. The difference of OOPE across no NCD, one NCD, and 2+ NCD groups were represented using boxplot and the statistical significance was determined using the Kruskal-Wallis test. The difference in reporting of current health status across two groups based on presence or absence of NCD was represented using pie charts and the statistical significance was assessed using the chi-squared test.

The factors associated with NCD multimorbidity were initially assessed using univariate binomial regression analysis. All the associations were reported using prevalence rates

TABLE 1 Details of sociodemographic characteristics of adults residing in HDSS. Gorakhpur (N = 75.037).

Sociodemographic variable	Number, n	(%)
Age in years		
18–29	29,048	(38.7)
30–44	23,551	(31.4)
45–59	12,929	(17.2)
≥60	9,509	(12.7)
Gender		
Male	39,071	(52.0)
Female	35,920	(47.9)
Transgender	46	(0.1)
Education		
No formal schooling	29,382	(39.1)
Primary school or below	9,436	(12.6)
Middle school	10,461	(13.9)
Secondary school	8,386	(11.2)
Higher secondary school/Diploma	9,143	(12.2)
Graduate and above	8,229	(11.0)
Occupation		
Unemployed	3,574	(4.8)
Self-employed	9,869	(13.1)
Salaried employee	2,605	(3.5)
Daily wage laborer	21,033	(28.0)
Homemaker	30,318	(40.4)
Student	7,638	(10.2)
Marital status		
Never married	16,479	(22.0)
Currently married	53,345	(71.1)
Divorced/Separated/Widowed	5,213	(6.9)
Family type		
Nuclear	44,164	(58.9)
Joint/Extended	30,873	(41.1)
Religion		
Hindu	71,122	(94.8)
Others	3,915	(5.2)
Caste		
Scheduled caste	19,670	(26.2)
Scheduled tribe	1,229	(1.7)
Other backward caste	50,377	(67.1)
Others	3,761	(5.0)
Household wealth		,
Poorest quintile	11,693	(15.6)
Second poorest quintile	13,254	(17.7)
Mid quintile	14,641	(19.5)
Second wealthiest quintile	15,909	(21.2)
Wealthiest quintile	19,540	(26.0)
Health insurance/scheme	,	()
Government funded	7,794	(10.4)
Employer funded	615	(0.8)
Self-funded	2,360	(3.2)
No scheme	64,268	(85.6)
Perceived health status	01,200	(00.0)
Very good	17,548	(23.4)
Good / Fair	43,965	(58.6)
GOOG / Tuli	70,300	(00.0)

HDSS, Health and Demographic Surveillance Site.

(PRs) along with their 95% CI. Multivariable cluster adjusted binomial regression models with all the variables used in univariate analysis were built to determine the adjusted PR with 95% CI. Villages were considered as clusters and adjusting for the cluster was done in the multivariable model. Model significance was reported using the Nagelkerke pseudo- R^2 and corresponding p-value for the model which was calculated by using link log under generalized linear model using same variables as used for the multivariable binomial regression model. All the analyses were performed using STATA version 14.0. A p < 0.05 was considered to be statistically significant.

RESULTS

A total of 75,037 individuals aged 18 years and above were included in the final analysis (294 records were excluded as it had missing data for at least one of the variables considered under study). The mean (SD) age of study participants was 37 (15.6) years and 39,071 (52%) were men. Among the participants, 39.1% had no formal schooling and 26% belonged to the wealthiest quintile. The detailed sociodemographic profile is as described in **Table 1**.

Noncommunicable Disease Multimorbidity and Its Associated Factors

Of 75,037 individuals surveyed, 9,885 (13.2%) reported having at least one NCD. The overall prevalence of NCD multimorbidity (2+ NCD) was found to be 1.81% (95% CI: 1.71–1.90%). The NCD multimorbidity prevalence across different age categories and gender is given in **Figures 1**, **2**, respectively. The prevalence of NCD multimorbidity was highest in the age group of \geq 60 years and among women. Sociodemographic factors, such as age, gender, occupation, education, marital status, religion, caste, and household wealth, were all found to be independently associated with NCD multimorbidity. The PRs increased with increasing age and increasing household wealth. The cluster adjusted PRs along with 95% CI of all the independent associations is shown in **Table 2**.

Health Insurance Coverage and OOPE

Overall, 10,769 (14.4%) had coverage under any of the health schemes. Among those with NCD multimorbidity, 226 (16.7%) were covered under any of the health schemes. Of 75,037, 14,599 (19.5%) reported using any healthcare facility for their health-related problems. Of the 14,599 who used any healthcare facility, 14,032 (96.1%) reported having incurred OOPE. Among those who incurred OOPE, the median (IQR) overall annual OOPE

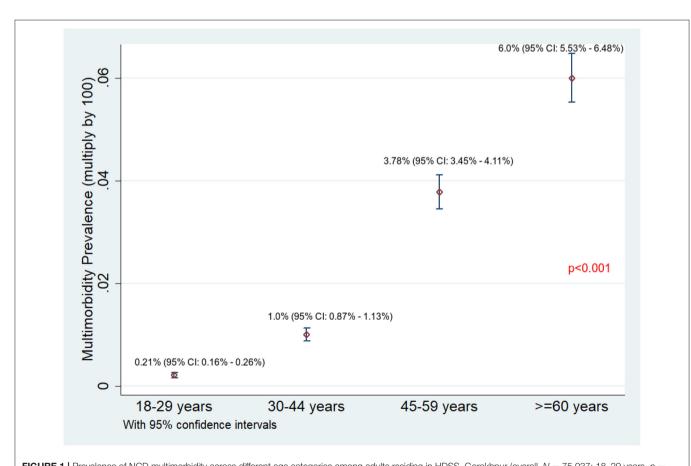


FIGURE 1 | Prevalence of NCD multimorbidity across different age categories among adults residing in HDSS, Gorakhpur (overall, N = 75,037; 18–29 years, n = 29,048; 30–44 years, n = 23,551; 45–59 years, n = 12,929; ≥ 60 years, n = 9,509).

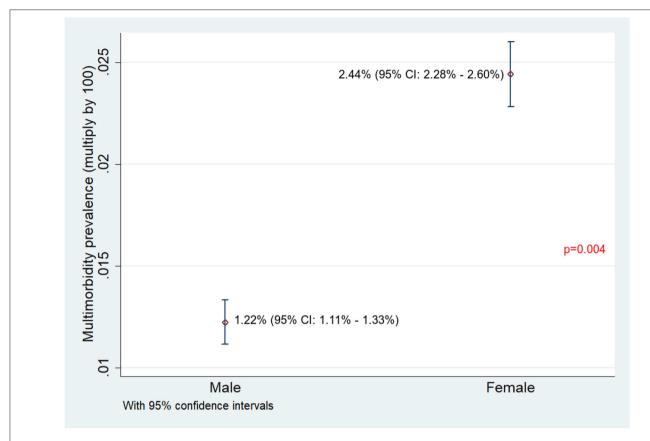


FIGURE 2 | Prevalence of NCD multimorbidity among male and female adults residing in HDSS, Gorakhpur (overall, N = 75,037; male, n = 39,071; female, n = 35,920).

was found to be INR 8,000 (2,300–20,000). The median annual OOPE was found to be significantly higher among those with NCD multimorbidity compared with those having no NCD or having only one NCD (see **Figure 3**).

Noncommunicable Disease and Self-Reported Health Status

Overall, 13,524 (18.0%) felt that their current health status was "poor." This reporting of "poor" health status was significantly higher among those having at least one NCD compared to those without NCD (see **Figure 4**). There was not much difference in reporting of "poor" health status among those with one NCD and NCD multimorbidity groups (83.7 vs. 82.7%).

DISCUSSION

Noncommunicable disease multimorbidity is ever increasing and more so in low- and middle-income countries (LMICs), such as India. Most of the studies on multimorbidity are done in the elderly population and very limited community-based studies are reported from India (5–8). This study covered one of the largest rural populations covering 28 villages of eastern Uttar Pradesh state of India. This study reported that 13% of the adult population have at least one NCD and 1.8% of them have NCD

multimorbidity. NCD multimorbidity was found to be 6% among the elderly population (\geq 60 years).

Studies in India, which included adults more than 18 years, showed the overall prevalence of multimorbidity to be between 9.8 and 34.3% (14-17). Two studies from HDSS in different countries estimated multimorbidity to be 22.8 and 28.7% among 40 years and above population (18, 19). One study done in India in 26 villages in the age group of 20-69 years showed NCD multimorbidity to be 0.7% (20). As there is no standard definition in defining multimorbidity and as also many studies do include other than NCDs in defining multimorbidity the comparisons across studies are difficult. The varied results could also be attributed to reasons, such as studies being conducted across different age groups, the nature of capturing multimorbidity (self-report, measurement, or both), the number of diseases included in capturing multimorbidity, whether it was a community-based survey or facility-based survey and also some regional variations.

With regard to factors associated with NCD multimorbidity, similar to the other studies, we also found NCD multimorbidity to be increasing with age and higher among women and those who were unemployed and those belonging to higher economic status (17–19, 21). Apart from these factors, we found that compared to those who had a graduate level of education

TABLE 2 | Factors associated with NCD multimorbidity among adults residing in HDSS, Gorakhpur (N = 75,037).

Sociodemographic variable	Number, n	NCD Multimorbidity, n (%)	Unadjusted PR (95% CI)	Adjusted PR (95% CI)
Age in years				
18–29	29,048	61 (0.2)	1	1
30–44	23,551	236 (1.0)	4.8 (3.6-6.3)	3.5 (2.5–5.0)
45–59	12,929	489 (3.8)	18.0 (13.8–23.5)	13.2 (8.8–19.8)
≥60	9,509	571 (6.0)	28.6 (22.0–37.2)	19.1 (12.9–28.2)
Gender				
Male	39,071	478 (1.2)	1	1
Female	35,920	877 (2.44)	2.0 (1.8–2.2)	1.6 (1.2–2.2)
Transgender	46	2 (4.3)	3.6 (0.9–13.8)	2.4 (0.8–7.4)
Education				
No formal schooling	29,382	840 (2.9)	4.4 (3.3–5.7)	1.2 (0.9–1.6)
Primary school or below	9,436	152 (1.6)	2.5 (1.8–3.3)	1.5 (1.1–2.2)
Middle school	10,461	124 (1.2)	1.8 (1.3–2.5)	1.5 (1.2–1.9)
Secondary school	8,386	105 (1.3)	1.9 (1.4–2.7)	1.6 (1.2–2.1)
Higher secondary school/Diploma	9,143	82 (0.9)	1.4 (1.0–1.9)	1.4 (1.0–2.0)
Graduate and above	8,229	54 (0.7)	1	1
Occupation				
Unemployed	3,574	157 (4.4)	7.3 (5.8–9.2)	3.4 (2.5–5.6)
Self-employed	9,869	231 (2.3)	3.9 (3.1-4.8)	1.8 (1.4–2.3)
Salaried employee	2,605	52 (2.0)	3.3 (2.4-4.6)	2.1 (1.5–3.0)
Daily wage laborer	21,033	127 (0.6)	1	1
Homemaker	30,318	784 (2.6)	4.3 (3.6–5.2)	2.2 (1.7–2.9)
Student	7,638	6 (0.1)	0.1 (0.1-0.3)	0.8 (0.3–2.3)
Marital status				
Never married	16,479	22 (0.1)	1	1
Currently married	53,345	1,053 (2.0)	14.8 (9.7–22.5)	2.0 (1.2–3.2)
Divorced/Separated/Widowed	5,213	282 (5.4)	40.5 (26.3–62.5)	2.0 (1.2–3.5)
Family type				
Nuclear	44,164	727 (1.7)	1	1
Joint/Extended	30,873	630 (2.0)	1.2 (1.1–1.4)	0.9 (0.8–1.1)
Religion				
Hindu	71,122	1256 (1.8)	1	1
Others	3,915	101 (2.6)	1.5 (1.2–1.8)	1.4 (1.1–1.7)
Caste				
Scheduled caste	19,670	273 (1.4)	1	1
Scheduled tribe	1,229	29 (2.4)	1.7 (1.2–2.5)	1.7 (1.1–2.7)
Other backward caste	50,377	941 (1.9)	1.4 (1.2–1.5)	1.2 (1.0–1.5)
Others	3,761	114 (3.0)	2.2 (1.8–2.7)	1.4 (1.0–1.9)
Household wealth				
Poorest quintile	11,693	165 (1.4)	1	1
Second poorest quintile	13,254	184 (1.4)	1.0 (0.8–1.2)	1.1 (0.9–1.3)
Mid quintile	14,641	190 (1.3)	0.9 (0.8–1.1)	1.0 (0.8–1.2)
Second wealthiest quintile	15,909	298 (1.9)	1.3 (1.1–1.6)	1.4 (1.1–1.6)
Wealthiest quintile	19,540	520 (2.7)	1.9 (1.6-2.2)	1.7 (1.4–2.1)

Cl, confidence interval; HDSS, Health and Demographic Surveillance Site; NCD, noncommunicable disease; PR, prevalence rate. Model statistics: Pseudo $R^2=0.149,\,p<0.001.$

Bold values indicate statistical significance (p < 0.05).

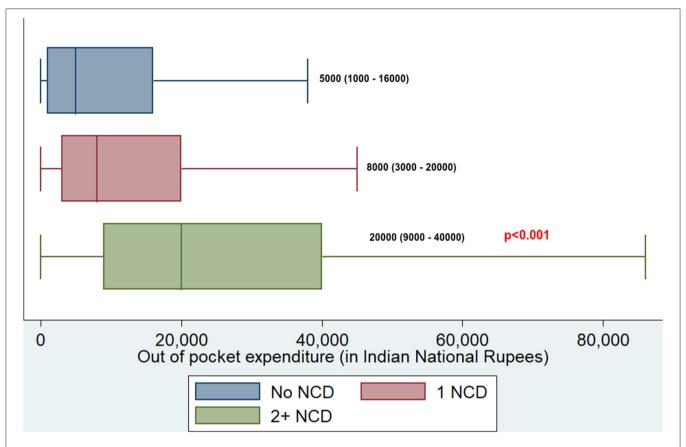


FIGURE 3 | Boxplot depicting median OOPE along with interquartile range among those having no NCD, one NCD, and NCD multimorbidity in adults residing at HDSS, Gorakhpur (overall, N = 14,032; no NCD, n = 5,078; 1 NCD, n = 7,625; 2+ NCD, n = 1,329). NCD, noncommunicable disease.

those who were literate but below the level of graduate had a higher prevalence of multimorbidity. Similarly, not only unemployed but people employed as either self or salaried class and also homemakers had a higher prevalence of multimorbidity compared to daily wage laborers. With respect to marital status, those who were married had a two times higher prevalence of multimorbid status compared to those who were "never married." We also found that compared to SC, people belonging to other castes had a higher prevalence of NCD multimorbidity. One of the reasons for these associations can be related to the health-seeking behavior status and thus increased chance of a diagnosis of NCDs. People who are graduates may be busy with their work-life and may have not got themselves screened for NCDs, similarly, those who are economically better may have more access to healthcare facilities and thus increased chances of diagnosing themselves with NCDs. Married people may get themselves screened more due to their social or familial pressure to seek healthcare when required and thus increasing the chance of detection of NCDs.

The higher prevalence among women would call for further integration of national programs directed toward maternal and women's health with NPCDCS. In India, both the programs for NCD and the elderly work in unison and may further be strengthened. There is a need to

increase the screening among disadvantaged sections (SCs) and also among the daily wage laborers. As with all the national programs, the need of the hour is to increase the awareness with regard to multimorbidity and the effects that it can have on an individual, family, and at the national level needs to be percolated across all the sections of society.

In this study, we found only 14.4% of adults were having health insurance, of them around three-fourths were public health insurance (72.4%). The health insurance coverage has been on the lower side in India, which contributes to higher OOPE. This study showed that compared to those who do not have NCD, those with NCD multimorbidity incurred four times higher median annual OOPE per person. Although we have not captured the costs as in-patient or outpatient costs; few studies have highlighted an increase in costs in those with NCDs, with the majority being contributed toward medications. We have captured the annual expenditure rather than episodic expenditure which gives an average expenditure toward healthcare in India (22, 23). The increase in expenditure could be due to an increase in seeking healthcare for any of the problems which may be NCD-related or aggravated due to multimorbidity status. Introduction of Pradhan Mantri Jan Arogya Yojana under

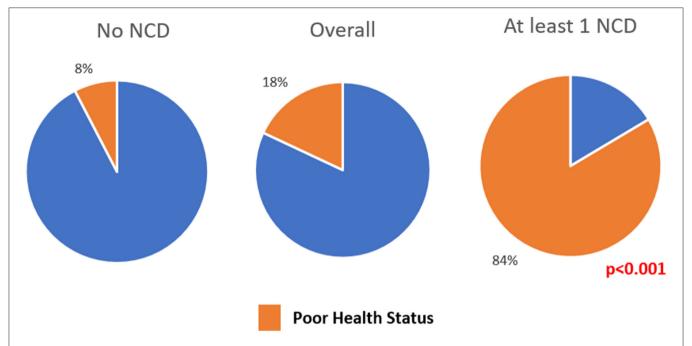


FIGURE 4 Pie chart depicting the proportion of people reporting current health status as "poor" among adults residing in HDSS, Gorakhpur (overall, N = 75,037; no NCD, n = 65,152; at least 1 NCD, n = 9,885).

Ayushman Bharat scheme could address decreasing the OOPE in India (24).

Although multimorbidity itself did not change the perception toward individual health status; having NCD itself, had a significant effect on one's perceived health status with about 84% of those with NCD citing their health status to be "poor" compared to only 8% among those without NCDs. A study centered around the patient satisfaction of the healthcare system toward chronic care in India and Bangladesh showed that 42% were dissatisfied with the health system management toward NCDs (14). Although we have not captured the severity of multimorbidity, this very high number of people with NCDs perceiving their health status to be "poor" needs to be addressed on a high priority. This more so emphasizes the need for counseling among multimorbidity patients to make them aware of their disease status and also its management. There is a hope that this shall be bridged by the Health and Wellness centers which are started across India to strengthen the primary healthcare system as part of the Ayushman Bharath scheme (24).

The increase in the prevalence of NCD multimorbidity in LMICs, such as India, is a cause of public health concern and this needs to be tackled by targeting the root cause of NCD risk factors. A multiprong approach involving crosscutting interventions (chronic care model) to reduce modifiable risk factors, such as diet, physical activity, and behavioral change in reducing the use of tobacco and alcohol needs to be adopted. There is a need for further research in different settings and high-risk populations along with follow-up surveys to monitor the effectiveness of interventions and also trends.

STRENGTHS AND LIMITATIONS

This study has a few strengths. The reporting is from the HDSS which itself accounts for robust data collection and documentation. Instead of listing diseases names and documenting the multimorbidity count, we used a method wherein the individual lists out their ailments in local language which was later coded into diseases, which would have helped in capturing the disease status more accurately. This is one of the largest surveys conducted wherein multimorbidity status was calculated which would have further increased the precision estimates of the outcome measured. We have captured the annual OOPE per person rather than episodic OOPE which would give a new dimension in terms of OOPE incurred in India. We have calculated the household wealth index to determine the economic standards rather than using the income of the family which would have captured the socioeconomic status more accurately. In terms of reporting of association, we have used PRs along with 95% CI which is a more robust measure to report association in the case of cross-sectional studies than using the odds ratio (25). Finally, we have followed the Strengthening the Reporting of Observational studies in Epidemiology (STROBE) guidelines to report this study findings (26).

This study is not without limitations. We have used self-reporting to capture the outcome on multimorbidity which has its inherent bias. Studies in western countries have shown that there is not much difference in capturing multimorbidity via self-reporting compared to actual measurements (27, 28). Although we have captured the annual OOPE we have not captured the episodic OOPE and also not accounted for direct and indirect cost estimation. We have captured the current

health status using a single question rather than any standard assessment tool which may have introduced bias. As with all cross-sectional studies, temporality between factors associated with multimorbidity cannot be established.

CONCLUSION

Among the adults in GHDSS, around 13 out of every 100 are suffering from at least one NCD and around two in 100 are having at least two NCDs. Being women, elderly, married, and belonging to higher economic status were a few factors that were found to be independently associated with NCD multimorbidity. Those with NCD multimorbidity spent almost four times higher annual OOPE compared to those without NCDs. More than four-fifths of those with NCD multimorbidity described their current health status to be "poor." There is a need for further strengthening of NCD screening, counseling, and integration of various national health programs to tackle NCD multimorbidity.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

The study uses secondary data for analysis which do not warrant ethical approval. The primary study involving human participants were reviewed and approved by Institutional Ethical Committee, ICMR-RMRC Gorakhpur.

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AUTHOR CONTRIBUTIONS

MR and KZ conceived and designed the study. RY, PY, and KK were involved in the acquisition of data. MR, KZ, and RY were involved in analysis and interpretation of data. MR and KZ wrote the first draft. RK revised the manuscript and gave critical inputs. All the authors approved the final version submitted for a journal.

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Relationship between tinnitus and olfactory dysfunction: audiovisual, olfactory, and medical examinations

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Introduction: Sensory dysfunctions and cognitive impairments are related to each other. Although a relationship between tinnitus and subjective olfactory dysfunction has been reported, there have been no reports investigating the relationship between tinnitus and olfactory test results.

Methods: To investigate the relationship between tinnitus and olfactory test results, we conducted sensory tests, including hearing and visual examinations. The subjects included 510 community-dwelling individuals (295 women and 215 men) who attended a health checkup in Yakumo, Japan. The age of the subjects ranged from 40 to 91 years (mean \pm standard deviation, 63.8 \pm 9.9 years). The participants completed a self-reported questionnaire on subjective tinnitus, olfactory function, and hearing function, as well as their lifestyle. The health checkup included smell, hearing, vision, and blood examinations.

Results: After adjusting for age and sex, the presence of tinnitus was significantly associated with subjective olfactory dysfunction, poor olfactory test results, hearing deterioration, vertigo, and headache. Additionally, high serum calcium levels and a low albumin/globulin ratio were significantly associated with low physical activity and nutrition. Women scored higher than men in olfactory and hearing examinations, but there was no gender difference in vision examinations.

Conclusion: Subjective smell dysfunction and poor smell test results were significantly associated with tinnitus complaints. Hearing and vision were associated even after adjusting for age and sex. These findings suggest that evaluating the mutual relationships among sensory organs is important when evaluating the influence of sensory dysfunctions on cognitive function.

KEYWORDS

health checkup, sensory dysfunctions, olfactory test, dietary habits, smoking, alcohol

Introduction

Many reports have described age-related sensory dysfunctions regarding vision, hearing, smell, and taste. However, there have been fewer studies investigating the relationships among these senses (1, 2). Oleszkiewicz et al. (3) reported alterations in gustatory sensitivity and taste preferences in individuals with blindness or deafness.

Not only a decrease but also abnormal sensations in smell and taste function are significant complaints in some patients after COVID-19 infection. Parosmia changes the usual perception of odors, such as when the smell of something familiar is distorted or when something that usually smells pleasant starts smelling foul. Phantosmia refers to an olfactory hallucination that is not caused by an actual odor. Parosmia and phantosmia can sometimes be more troublesome than hyposmia or anosmia. Tinnitus, on the other hand, is characterized by hearing sounds that are not present in the external environment. The relationship between phantosmia and smell dysfunction is similar to that between tinnitus and auditory dysfunction. Qualitative smell/taste disorders (such as phantosmia, parosmia, phantogeusia, and parageusia) have not yet been fully characterized, whereas quantitative disturbances (i.e., reduction/loss of smell/taste) have been widely investigated (4).

The coexistence of olfactory dysfunction and tinnitus with or without hearing loss after having COVID-19 has been reported (5–8). Some individuals did not complain of olfactory dysfunction but had abnormal results on smell tests after having a COVID-19 infection (9). Some individuals complained of the symptoms for over 1 year after having a COVID-19 infection (10, 11). The long-term prognosis is a matter that needs to be further examined in the future (12).

Park et al. (13) recently investigated the relationship between olfactory dysfunction and tinnitus in the general population, particularly in middle-aged and older adults. This study was based on a self-reported questionnaire completed by 25,534 people. Both olfactory function and tinnitus are associated with the limbic system, but few studies have clinically investigated the relationship. Moreover, there have been no reports comparing olfactory test results with tinnitus. In the present study, we attempted to investigate whether or not a relationship exists between olfactory test results and tinnitus, including hearing and vision tests.

Methods

Self-report questionnaire

We sent a detailed questionnaire, including questions on health problems and lifestyles, to the participants before the health examination. To the question "Can you smell?", the participants chose one among the following four answers: (1) "sense smell well," (2) "sometimes hard to smell," (3) "slightly," and (4) "not at all." To the question "Do you have tinnitus?" the participants chose one among the three answers: (1) "no," (2) "sometimes," and (3) "always." The difficulty of conversation includes two questions: "Can you hear one-to-one conversations without a hearing aid?" and "Can you hear conversations between four or five people without a hearing aid?" The participants selected one among four

answers: (1) "completely," (2) "mostly," (3) "not much," and (4) "almost nothing." The participants also selected one among three answers, (1) "no," (2) "sometimes," and (3) "always," to the question "Do you have vertigo?" We also asked them about the presence or absence of chronic headaches.

Dietary and lifestyle habits were investigated by the method described previously (14). Briefly, we investigated the frequency of 28 kinds of foods and drinks. (1) potatoes; (2) pumpkins; (3) carrots; (4) broccoli; (5) green leafy vegetables (green and yellow vegetables group A); (6) other green and yellow vegetables, including green peppers and snap beans (green and yellow vegetable group B); (7) cabbages; (8) radishes; (9) light-colored vegetables; (10) mushrooms; (11) seaweeds; (12) oranges and grapefruits; (13) other fruits, including strawberries, kiwis, apples, and watermelons; (14) tofus; (15) eggs; (16) chicken; (17) beef and pork; (18) hams, sausages, and bacons; (19) fish; (20) squid, shrimp, crabs, and octopuses; (21) shellfish; (22) deep-fried foods; (23) stirfried foods; (24) miso soup; (25) milk; (26) yogurt; (27) green tea; and (28) coffee. In addition, we asked questions concerning sports and exercise per week as follows: rare, 1-2 h, 3-4 h, and 5 h or more. The answer "rare" was interpreted as having no exercise habits, while the other options were considered to have exercise habits (14).

We asked the participants about the amount of alcohol consumed with six kinds of beverages: beer, whiskey, wine, Japanese rice wine (Japanese sake), shochu (a traditional Japanese distilled spirit), and chuhai (a cocktail of shochu with fruit or soda). The amount of alcohol (g) per week was obtained from the table as follows: 20 g in 500 ml beer, 9.6 g in 30 ml whiskey single, 19.2g in 30 ml whiskey double, 11.5 g in a 120-ml glass of wine, 21.6 g in 180 ml (1 Gou) of Japanese sake, 36 g (180 ml) in a glass of shochu, and 14 g in 350 ml chuhai.¹

The present status and history of smoking were enquired, including for heat-not-burn tobacco and electronic cigarettes (with or without nicotine). Then, we calculated the Brinkman index by multiplying the number of cigarettes smoked per day with the number of years of smoking while also incorporating the participants' conversion to the consumption of heat-not-burn tobacco. To achieve this, we utilized the questionnaire described in the Yakumo study (14, 15).

Examination

We measured body weight, body mass index (BMI), and body fat percentage during the health checkup. We also conducted a blood test to assess the number of red and white blood cells, platelets, hemoglobin, hematocrit, mean corpuscular hemoglobin concentration (MCHC), total protein, albumin/globulin (A/G) ratio, globulin, triglyceride, high-density lipoprotein cholesterol, low-density lipoprotein cholesterol, hemoglobin A1c, creatinine, blood urea nitrogen, uric acid, serum calcium, aspartate aminotransferase: AST (GOT), alanine aminotransferase: ALT (GPT), alkaline phosphatase: ALP, C-reactive protein: CRP, and γ -glutamyl transpeptidase (γ GTP).

¹ https://www.kirin.co.jp/csv/arp/proper/check_list.html

Hearing test

Of the 510 participants, 369 of them underwent the hearing test. An otolaryngologist examined the ears, nose, and throat before the hearing test. In a quiet room, we evaluated hearing levels using an audiometer (Model AA-79S; Rion, Tokyo, Japan). The noise level in the examination room was measured every hour using a sound level meter (Rion NL-20; Rion) to confirm the room's suitability for the hearing test. The equivalent continuous sound level ranged from 41.1 to 53.9 dB, with an average of 45.0 dB. We measured the hearing level bilaterally at 1 kHz and 4 kHz. When the participants could respond to 30 dB at 1 kHz and 4 kHz, we determined the hearing test to be acceptable, either unilateral or bilateral.

Olfactory test

Of the 369 people who underwent the hearing test, 298 hoped for the olfactory test. The Odor Stick Identification Test for Japanese (OSIT-J, Daiichi Yakuhin Sangyo, Tokyo, Japan) was developed as a simplified olfactory function test (16), which consists of 12 odors that are likely to be recognizable to Japanese individuals: Indian ink, wood, perfume, menthol, Japanese orange, curry, household gas, rose, Japanese cypress, sweaty socks, condensed milk, and roasted garlic. The participants were asked to identify the odor by choosing one of the six answers (one "correct," three "incorrect," and the other two were "unknown" and "not detected"). In this study, participants that recognized correctly six or more kinds of odors among the 12 kinds of odors were added to the good smell test group.

Vision test

The best-corrected visual acuity (BCVA) was measured using an automatic vision tester (Nidek, NV-350, Gamagori, Japan) after the measurement of refractive errors (TONOREF III, Gamagori, Japan). The present study used visual acuities of 1.0 (20/20) and 0.8 (20/25) on either side or both sides to classify good or bad visual acuity.

Statistical analysis

The Chi-square tests, Mann–Whitney tests, and generalized linear model analyses were performed. A logistic regression model estimated the odds ratio (OR) and 95% confidence intervals (CIs). The calculations were conducted using Stata 15 and SPSS 26.0, and statistical significance was set at a p-value of < 0.05.

Ethics and consent

The Ethics Committee of Nagoya University School of Medicine approved this study (Approval number 2014–0207). All the participants approved the publication of anonymized data and provided informed consent to the participation.

Results

Participants in the health checkups

The participants were volunteers who attended an annual health examination in Yakumo, Hokkaido, Japan. These examinations were supported by the local government (the Yakumo study). In addition, a cross-sectional study was performed on 510 people (215 men and 295 women, average age: 63.8 years, age range 40–91 years) who attended a health checkup in 2019.

Table 1 shows the age distribution, subjective olfaction, smell test result, tinnitus, subjective hearing, hearing test result, and vision test result for women and men. In the age group of 80 or more people, two men were in their 90's. The age of men was significantly greater than that of women (Mann-Whitney test, p < 0.001). The questionnaire revealed that 25.4% and 8.8% of the participants reported experiencing tinnitus occasionally or constantly. The participants responded that subjective hearing in one-to-one conversations was much better than in conversations between four or five people. Two women and seven men used a hearing aid, and the answers were under status without a hearing aid.

Influence of age and sex on smell, hearing, and vision

Table 2 shows the OR and 95% CI of age and sex when logistic regression analysis was performed. The explanatory variables were age and sex, and each objective variable is shown in Table 2. Both older age and male sex worsened the results in the smell and hearing tests. However, in the subjective evaluation of their olfactory and hearing functions, older age but not sex worsened the subjective evaluation. Men evaluated their smell and hearing functions as relatively good compared to women's evaluations.

The visual acuity test result was worse in older age, but no significant sex difference was observed. In addition, the presence of tinnitus was not associated with age or sex.

Factors associated with the smell test results

The influence of various factors on the smell test (correct answer: six or more) is shown in Table 3 before and after adjusting for age and sex. The subjective perception of good smell was significantly associated with good smell test scores. In addition, our analysis revealed a significant negative relationship between the presence of tinnitus and olfactory function. Specifically, participants with tinnitus had a significantly lower sense of smell, as evidenced by the results of the smell tests. However, vertigo, headache, subjective hearing, and hearing test results had no significant relationship with the smell test after we adjusted for age and sex. However, we found that the hearing test results for audibility at $4\,\mathrm{kHz}$ at 30 dB on either side were marginally close to reaching a significant level (p=0.0664). Additionally, after adjusting for age and sex, the participants with a visual acuity of

TABLE 1 Results of questionnaire and tests associated with olfaction, tinnitus, hearing and vision.

40's 50's 60's 70's 80 or more Sense smell well netimes hard to smell Slightly	34 (12) 67 (23) 119 (40) 69 (23) 6 (2) 65 [55, 69] 227 (77) 53 (18)	12 (6) 40 (19) 80 (37) 70 (33) 13 (6) 68 [60, 71] 147 (68)	46 (9) 107 (21) 199 (39) 139 (27) 19 (4) 65 [57, 71] 374 (73)
60's 70's 80 or more Sense smell well metimes hard to smell	119 (40) 69 (23) 6 (2) 65 [55, 69] 227 (77) 53 (18)	80 (37) 70 (33) 13 (6) 68 [60, 71] 147 (68)	199 (39) 139 (27) 19 (4) 65 [57,71]
70's 80 or more Sense smell well metimes hard to smell	69 (23) 6 (2) 65 [55, 69] 227 (77) 53 (18)	70 (33) 13 (6) 68 [60, 71] 147 (68)	139 (27) 19 (4) 65 [57,71]
80 or more Sense smell well metimes hard to smell	6 (2) 65 [55, 69] 227 (77) 53 (18)	13 (6) 68 [60, 71] 147 (68)	19 (4) 65 [57, 71]
Sense smell well	65 [55, 69] 227 (77) 53 (18)	68 [60, 71] 147 (68)	65 [57, 71]
metimes hard to smell	227 (77) 53 (18)	147 (68)	
metimes hard to smell	53 (18)	` '	374 (73)
		10 ()	3/1(/3)
Slightly	, ,	48 (22)	101 (20)
	7 (2)	11 (5)	18 (4)
Not at all	8 (3)	9 (4)	17 (3)
Six or more	151 (89)	86 (67)	237 (80)
From three to five	16 (9)	31 (24)	47 (16)
Two or less	2 (1)	12 (9)	14 (5)
No	189 (64)	146 (68)	335 (66)
Sometimes	86 (29)	44 (20)	130 (25)
Always	20 (7)	25 (12)	45 (9)
Completely	206 (70)	131 (61)	337 (66)
Mostly	81 (28)	76 (35)	157 (31)
Not much	6 (2)	7 (3)	13 (3)
Almost nothing	1 (0.3)	1 (0.5)	2 (0.4)
Completely	159 (54)	100 (47)	259 (51)
Mostly	122 (42)	94 (44)	216 (43)
Not much	11 (4)	18 (8)	29 (6)
Almost nothing	1 (0.3)	2 (1)	3 (0.6)
Either side	205/230 (89)	85/166 (51)	290/396 (73)
Bilateral	171/230 (74)	52/166 (31)	223/396 (56)
Either side	188/292 (64)	131/211 (62)	319/503 (63)
Bilateral	94/292 (32)	75/211 (36)	169/503 (34)
Either side	241/292 (83)	164/211 (78)	405/503 (81)
Bilateral	169/292 (58)	123/212 (58)	292/503 (58)
	Six or more From three to five Two or less No Sometimes Always Completely Mostly Not much Almost nothing Completely Mostly Signature Either side Bilateral Either side Either side	Six or more 151 (89) From three to five 16 (9) Two or less 2 (1) No 189 (64) Sometimes 86 (29) Always 20 (7) Completely 206 (70) Mostly 81 (28) Not much 6 (2) Almost nothing 1 (0.3) Completely 159 (54) Mostly 122 (42) Not much 11 (4) Almost nothing 1 (0.3) Either side 205/230 (89) Bilateral 171/230 (74) Either side 188/292 (64) Bilateral 94/292 (32) Either side 241/292 (83)	Six or more 151 (89) 86 (67) From three to five 16 (9) 31 (24) Two or less 2 (1) 12 (9) No 189 (64) 146 (68) Sometimes 86 (29) 44 (20) Always 20 (7) 25 (12) Completely 206 (70) 131 (61) Mostly 81 (28) 76 (35) Not much 6 (2) 7 (3) Almost nothing 1 (0.3) 1 (0.5) Completely 159 (54) 100 (47) Mostly 122 (42) 94 (44) Not much 11 (4) 18 (8) Almost nothing 1 (0.3) 2 (1) Either side 205/230 (89) 85/166 (51) Bilateral 171/230 (74) 52/166 (31) Either side 188/292 (64) 131/211 (62) Bilateral 94/292 (32) 75/211 (36) Either side 241/292 (83) 164/211 (78)

In the age group, there were two males in his 90's. *Two women and seven men were using a hearing aid. The answers was under status without the hearing aid. Hearing test 30 dB was the smallest sound in the examination room. The values in parentheses are percentages.

0.8 or higher in both eyes had significantly higher scores on the smell test.

Factors associated with tinnitus

Table 4 shows the influence of various factors on the presence of tinnitus evaluated by logistic regression analysis before and after adjusting for age and sex. We observed a significant correlation between subjective good smell, performance on the smell test, and the absence of tinnitus complaints.

Good subjective hearing and positive results of hearing tests were also associated with no tinnitus complaints. An elevated hearing threshold due to hearing loss at 1 kHz and 4 kHz was related to tinnitus. Visual acuity had no association with tinnitus, but vertigo and headache were significantly associated with tinnitus. Of the 43 people with chronic headaches, 22 reported having migraine-type headaches on one side, while 21 reported having non-migraine-type headaches. A logistic regression analysis revealed that migraine-type and non-migraine-type headaches were significantly associated with tinnitus. Table 4 depicts the blood examination results related to tinnitus. High

TABLE 2 Influence of age and sex on subjective smell, smell test, subjective hearing, hearing test, visual acuity and tinnitus (logistic regression analysis).

Objective variable	Explanatory variables						
		Age (years)		Sex (M $=$ 0, F $=$ 1)			
	Odds ratio	р	CI	Odds ratio	р	CI	
Subjective smell: sense smell well	0.954	< 0.0001	0.933-0.976	1.342	0.278	0.893-2.014	
Smell test good (correct answer 6 or more)	0.928	< 0.0001	0.896-0.962	3.682	0.0001	1.969-6.920	
One-to-one conversation subjective hearing complete	0.958	<0.0001	0.939-0.978	1.315	0.1594	0.898-1.925	
Between 4 or 5 persons subjective hearing complete	0.968	0.0006	0.950-0.986	1.219	0.2826	0.849-1.715	
Hearing test 1 kHz and 4 kHz either side audible	0.901	<0.0001	0.871-0.933	7.770	<0.0001	4.481-13.475	
Hearing test 1 kHz and 4 kHz both sides audible	0.907	<0.0001	0.881-0.934	6.546	<0.0001	4.034-10.620	
Visual acuity 1.0 or more either side	0.934	< 0.0001	0.914-0.955	0.890	0.557	0.604-1.312	
Visual acuity 1.0 or more both sides	0.940	< 0.0001	0.920-0.959	0.685	0.0614	0.460-1.018	
Visual acuity 0.8 or more either side	0.925	< 0.0001	0.900-0.951	1.079	0.747	0.678-1.718	
Visual acuity 0.8 or more both sides	0.949	< 0.0001	0.930-0.968	0.823	0.309	0.566-1.198	
Tinnitus (+)	1.003	0.780	0.984-1.022	1.198	0.349	0.821-1.748	

TABLE 3 Influence of various factors on smell test good.

Factors		Unadjusted		Ac	djusted for age ar	nd sex
	Odds ratio	р	95% CI	Odds ratio	р	95% CI
Subjective smell: sense well	4.409	< 0.0001	2.425-8.016	3.588	0.0001	1.880-6.846
Tinnitus presence	0.521	0.0254	0.294-0.923	0.465	0.0168	0.248-0.871
Vertigo presence	1.329	0.4395	0.646-2.733	1.133	0.7559	0.515-2.497
Headache presence	1.880	0.3201	0.542-6.521	0.642	0.5376	0.157-2.630
One-to-one conversation subjective hearing complete	1.692	0.0746	0.949-3.017	1.312	0.3989	0.698-2.465
Between 4 or 5 people subjective hearing complete	1.441	0.2078	0.816-2.542	1.147	0.6635	0.619-2.126
Hearing test 1 kHz and 4 kHz 30 dB either side audible	3.865	<0.0001	2.140-6.979	1.639	0.1571	0.827-3.251
Hearing test 1 kHz and 4 kHz 30 dB both sides audible	3.344	0.0001	1.852-6.038	1.353	0.3932	0.676-2.706
Hearing 4 kHz 30 dB either side audible	4.409	<0.0001	2.425-8.016	1.909	0.0664	0.957-3.809
Hearing 4 kHz 30 dB both sides audible	3.351	0.0001	1.863-6.028	1.301	0.4615	0.646-2.623
Visual acuity 1.0 or more either side	2.248	0.0055	1.268-3.985	1.604	0.1520	0.840-3.064
Visual acuity 1.0 or more both sides	2.012	0.0288	1.075-3.765	1.610	0.1793	0.803-3.226
Visual acuity 0.8 or more either side	2.284	0.0153	1.172-4.452	1.347	0.4349	0.637-2.848
Visual acuity 0.8 or more both sides	2.898	0.0003	1.626-5.166	2.488	0.0060	1.299-4.766

serum calcium, globulin, and a low A/G ratio were associated with tinnitus.

Table 5 shows the relationship between tinnitus and exercise habits, including sports, in both women and men. Out of the 113

TABLE 4 Influence of various factors on tinnitus presence.

Factors	Unadjusted			Adjusted for age and sex			
	Odds ratio	р	95% CI	Odds ratio	р	95% CI	
Subjective smell: sense well	0.495	0.0006	0.331-0.741	0.474	0.0004	0.313-0.718	
Smell test good	0.521	0.0254	0.294-0.923	0.461	0.0151	0.247-0.861	
One-to-one conversation subjective hearing complete	0.469	0.0001	0.320-0.687	0.448	0.0001	0.303-0.664	
Between 4 or 5 persons subjective hearing complete	0.362	<0.0001	0.248-0.530	0.349	<0.0001	0.237-0.514	
Hearing level 1 kHz and 4 kHz 30dB either side audible	0.626	0.0438	0.396-0.987	0.504	0.0135	0.292-0.868	
Hearing level 1 kHz and 4 kHz 30 dB both sides audible	0.704	0.0972	0.465-1.066	0.588	0.0362	0.357-0.966	
Visual acuity 1.0 or more (both sides)	0.681	0.0603	0.455-1.017	0.676	0.0658	0.445-1.026	
Visual acuity 1.0 or more (either side)	0.813	0.287	0.556-1.190	0.807	0.2916	0.543-1.202	
Visual acuity 0.8 or more (both sides)	0.715	0.0780	0.493-1.038	0.711	0.0810	0.484-1.043	
Visual acuity 0.8 or more (either side)	0.731	0.1780	0.464-1.153	0.715	0.1639	0.445-1.147	
Vertigo presence	3.053	< 0.0001	1.992-4.680	3.045	< 0.0001	1.979-4.685	
Headache presence	2.643	0.0026	1.405-4.975	2.717	0.0032	1.399-5.278	
Current smoking	1.018	0.9444	0.608-1.705	1.090	0.754	0.637-1.863	
Brinkman index	1.00016	0.4744	0.9997-1.0006	1.00037	0.1706	0.9998-1.0009	
Alcohol intake (gram per week)	1.0007	0.238	0.9995-1.002	1.0008	0.234	0.9995-1.002	
Having sports or exercise habits	0.711	0.078	0.487-1.039	0.703	0.0768	0.475-1.039	
Serum calcium	1.924	0.0194	1.111-3.330	1.886	0.0242	1.086-3.274	
Total protein	1.776	0.0160	1.113-2.835	1.748	0.0199	1.092-2.797	
Globulin	1.842	0.0149	1.127-3.013	1.812	0.0201	1.098-2.991	
Albumin/globulin (A/G) ratio	0.434	0.0347	0.200-0.942	0.444	0.0446	0.201- 0.981	
Body mass index (BMI)	0.974	0.3147	0.925-1.025	0.977	0.388	0.928-1.030	

men who reported no exercise habits, 42 had tinnitus, while 27 out of 102 men who exercised regularly reported experiencing tinnitus. Although the proportion of tinnitus (+) was observed to be higher among those without exercise habits than in those with exercise habits, particularly in men, the difference was not statistically significant based on the chi-squared test (0.05< p < 0.1). These findings are consistent with the trend observed in Table 4, which suggests that there is a potential relationship between having exercise habits and the absence of tinnitus (p = 0.0768).

Hearing, visual, and olfactory dysfunctions: relationships, and the background

The relationship between the hearing test and the visual and olfactory tests is shown in Table 6. The good hearing result was associated with a good vision test after adjusting for age and sex,

TABLE 5 Relationship between tinnitus and exercise habits.

	Exercise	habits (–)	Exercise habits (+)			
	Female	Male	Female	Male	Total	
Tinnitus (-)	119	71	68	75	333	
Tinnitus (+)	72	42	34	27	175	
Total	191	113	102	102	508	

especially at 4 kHz rather than 1 kHz. Thus, impaired hearing and bad vision have some relationship with each other after adjusting for age and sex. In addition, we investigated factors associated with poor sensations. However, neither the hearing test result nor the vision test result had a significant relationship with BMI, hemoglobin A1c, triglycerides, cholesterol, the Brinkman index, the amount of alcohol intake, or the intake frequency of 28 kinds of food in this study.

TABLE 6 Relationship between hearing test and olfactory and vision tests (logistic regression analysis).

Objective vari	iables				Explar	natory va	riables				
			Factors			Д	ge (years	s)	Sex	M = 0, F	= 1)
		Vision and smell	Odds ratio	р	CI	Odds ratio	р	CI	Odds ratio	р	CI
Hearing 1 kHz and 4 kHz both sides audible	A	Visual acuity 1.0 or more both sides	1.760	0.0365	1.036- 2.991	0.913	<0.0001	0.886- 0.940	7.024	<0.0001	4.263– 11.573
		Visual acuity 1.0 or more either side	1.816	0.0221	1.089- 3.027	0.914	<0.0001	0.887- 0.941	6.795	<0.0001	4.147- 11.132
		Visual acuity 0.8 or more both sides	1.222	0.4299	0.742- 2.014	0.909	<0.0001	0.882- 0.936	6.571	<0.0001	4.033- 10.707
		Visual acuity 0.8 or more either side	1.237	0.5015	0.665- 2.302	0.908	<0.0001	0.882- 0.936	6.474	<0.0001	3.985– 10.519
		Smell test good	1.295	0.4682	0.644- 2.602	0.908	<0.0001	0.878- 0.939	5.903	<0.0001	3.331- 10.464
Hearing 1 kHz and 4 kHz either side audible	В	Visual acuity 1.0 or more both sides	1.477	0.1992	0.814- 2.679	0.906	<0.0001	0.875- 0.939	7.949	<0.0001	4.555– 13.874
		Visual acuity 1.0 or more either side	2.150	0.0074	1.227- 3.767	0.912	<0.0001	0.880- 0.945	8.182	<0.0001	4.653- 14.387
		Visual acuity 0.8 or more both sides	1.714	0.0556	0.987- 2.974	0.908	<0.0001	0.876- 0.940	8.078	<0.0001	4.613- 14.144
		Visual acuity 0.8 or more either side	1.823	0.0703	0.951- 3.492	0.908	<0.0001	0.877- 0.940	7.772	<0.0001	4.457– 13.551
		Smell test good	1.643	0.1554	0.828- 3.259	0.910	<0.0001	0.876- 0.945	5.891	<0.0001	3.127- 11.097
Hearing 1 kHz both sides audible	С	Visual acuity 1.0 or more both sides	1.499	0.2263	0.778- 2.887	0.924	<0.0001	0.892- 0.958	1.762	0.0469	1.008- 3.079
		Visual acuity 1.0 or more either side	0.994	0.9840	0.557- 1.773	0.919	<0.0001	0.887- 0.953	1.708	0.0586	0.981- 2.973
		Visual acuity 0.8 or more both sides	1.125	0.6844	0.638- 1.984	0.921	<0.0001	0.889- 0.954	1.718	0.0562	0.986- 2.995
		Visual acuity 0.8 or more either side	0.899	0.7578	0.456- 1.772	0.918	<0.0001	0.886- 0.951	1.712	0.0575	0.983- 2.981
		Smell test good	0.966	0.9303	0.446- 2.095	0.912	<0.0001	0.874- 0.950	2.086	0.0360	1.049- 4.149
Hearing 1 kHz either side audible	D	Visual acuity 1.0 or more both sides	2.500	0.2439	0.535- 11.672	0.870	0.0002	0.809- 0.937	2.818	0.0647	0.939- 8.456
		Visual acuity1.0 or more either side	3.910	0.0241	1.195- 12.787	0.878	0.006	0.815- 0.945	2.836	0.0650	0.937- 8.583
		Visual acuity 0.8 or more both sides	2.549	0.0989	0.839- 7.743	0.872	0.0003	0.810- 0.940	2.816	0.0656	0.936- 8.474
		Visual acuity 0.8 or more either side	2.007	0.1906	0.707- 5.700	0.869	0.0002	0.807- 0.935	2.667	0.0800	0.889- 8.001
		Smell test good	1.248	0.708	0.391- 3.985	0.873	0.0003	0.811- 0.940	2.867	0.0932	0.838- 9.801
Hearing 4 kHz both sides audible	Е	Visual acuity 1.0 or more both sides	1.749	0.0434	1.017- 3.007	0.912	<0.0001	0.885- 0.940	8.221	<0.0001	4.941– 13.677
		Visual acuity 1.0 or more either side	2.325	0.0017	1.372- 3.940	0.916	<0.0001	0.888- 0.944	8.329	<0.0001	4.990- 13.902
		Visual acuity 0.8 or more both sides	1.363	0.2333	0.819- 2.270	0.909	<0.0001	0.882- 0.937	7.8011	<0.0001	4.733- 12.858

(Continued)

TABLE 6 (Continued)

Objective vari hearing	iables	Explanatory varia						ables			
			Factors			Д	ge (year:	s)	Sex	Sex (M = 0, F = 1)	
		Vision and smell	Odds ratio	р	CI	Odds ratio	р	CI	Odds ratio	p	CI
		Visual acuity 0.8 or more either side	1.465	0.2355	0.780- 2.752	0.909	<0.0001	0.882- 0.937	7.635	<0.0001	4.648- 12.542
		Smell test good	1.252	0.5296	0.620- 2.532	0.909	<0.0001	0.878- 0.940	7.176	<0.0001	3.997- 12.883
Hearing 4 kHz either side audible	F	Visual acuity 1.0 or more both sides	1.262	0.4484	0.692- 2.302	0.906	< 0.0001	0.874- 0.939	8.302	<0.0001	4.684- 14.714
		Visual acuity 1.0 or more either side	1.796	0.0432	1.018- 3.167	0.911	<0.0001	0.879- 0.944	8.477	<0.0001	4.763- 15.088
		Visual acuity 0.8 or more both sides	1.569	0.1147	0.896- 2.747	0.908	<0.0001	0.876- 0.941	8.483	<0.0001	4.771- 15.083
		Visual acuity 0.8 or more either side	1.931	0.0501	1.000- 3.731	0.91	<0.0001	0.878- 0.943	8.312	<0.0001	4.678- 14.770
		Smell test good	1.922	0.0639	0.963- 3.835	0.911	<0.0001	0.876- 0.947	6.502	<0.0001	3.359- 12.585

Objective variable A; hearing 1&4 kHz both sides OK, B; hearing 1&4 kHz either side OK, C; hearing 1 kHz both sides OK, D; hearing 1 kHz either side OK, E; hearing 4 kHz both sides OK, F; hearing 4 kHz either side OK.

TABLE 7 Smoking situation in participants.

	ı	emale (<i>n</i> = 295	5)	Male (n = 213)			
	Never	Quit	Current smoker	Never	Quit	Current smoker	
Number of persons	203 (68.8%)	66 (22.4%)	26 (8.8%)	48 (22.5%)	116 (54.5%)	49 (23.0%)	
Age	65 [58, 71]	61.5 [47, 67]	58 [52, 67]	70 [60.5, 76.5]	69 [62, 71]	62 [55, 68]	
Brinkman Index	0	153 [60, 395]	512.5 [280, 760]	0	540 [300, 800]	760 [560, 1000]	
Age at smoking initiation		20 [20, 23]	20 [20, 25]		20 [20, 20]	20 [20, 20]	
Age at quitting smoking		40 [30, 50]			45 [40, 56]		
Body Mass Index (BMI)	22.8 [20.6, 25.4]	22.8 [20.2, 26.5]	22.15 [20.9, 23.5]	24.4 [22.15, 26.9]	24.6 [22.3, 26.4]	24.3 [21.5, 25.7]	

Figures are median [25th percentile, 75th percentile].

We investigated the influence of diabetes mellitus (DM), hypertension, and dyslipidemia on visual, olfactory, and auditory dysfunctions from the medical history, the drug intake, and the blood examination results, including hemoglobin A1c, triglyceride, total cholesterol, HDL, and LDL cholesterol. The logistic regression analysis revealed that medical history of DM (OR = 1.97, 95% CI, 1.05-3.68) and anti-DM drug intake (OR = 2.08, 95% CI, 1.036-4.170) but not hemoglobin A1c had a significant relationship with visual acuity <1.0 on both sides after adjusting for age and sex. However, we could not find the influence of DM on olfactory and hearing test results. We could not find the influence of hypertension and dyslipidemia on the results of the visual, olfactory, and hearing tests. Table 6 shows significant associations between hearing and visual acuity test results, even after controlling for other explanatory variables such as medical history and drug intake for DM, hypertension, and dyslipidemia.

We investigated the effects of smoking on olfactory, hearing, and vision tests. Table 7 reveals the smoking situation. Of the current smokers, 13 consumed heat-not-burn tobacco, and three consumed electronic cigarettes with nicotine. After adjusting for age and sex, a logistic regression analysis was conducted to evaluate the association between smoking status (never, quit, and current smoker) or the Brinkman index and test results. The results showed that only the vision test was significantly associated with a Brinkman index of 100 or higher, with a visual acuity <1.0 on both sides (p=0.0469) and of <0.8 on both sides (p=0.0230). However, we found no significant relationship between alcohol consumption and test results for visual, olfactory, and auditory perception after adjusting for age and sex.

Figure 1 shows the difference in eating and drinking habits between non-smokers and current smokers. The Mann–Whitney test revealed that the current smoking status was significantly associated with a low intake frequency of vegetables (carrots, p < 0.0001, broccoli, p = 0.0011), dairy products (yogurt and milk,

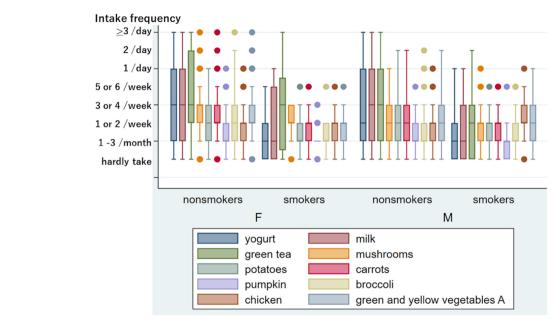


FIGURE 1

Frequency of eating and drinking in non-smokers and current smoker among women and men. Ten kinds of food and drink with a significant difference between non-smokers and current smokers after adjusting for age in women and/or men. The y-axis shows the intake frequency divided into 8. If the median intake frequency is within the lower quartile, the box's bottom line is thicker than its top line. Similarly, the box's top line is thicker than its bottom line if the median intake frequency is within the upper quartile. Outliers indicated by dots include multiple individuals. The intake frequency and the number of persons indicated by words are as follows: in 269 female nonsmokers, mushrooms "hardly take": five, "1/day": 26, "2/day": one; carrots "hardly take": seven, "1/day": 13, "2/day": one, " \geq 3/day": one; pumpkin "5 or 6/week": five, "1/day": one, in 269 female smokers, mushrooms "hardly take": two; green and yellow vegetables A "hardly take": two, "1/day": 19, "2/day" five, " \geq 3/day": one, in 269 female smokers, mushrooms "hardly take": two; potatoes "5 or 6/week": one; carrots "5 or 6/week": one; pumpkin "hardly take": six, "1 or 2/week": four, "3 or 4/week": one; broccoli "5 or 6/week": one; chicken "5 or 6/week": one, '1/day": three, "2/day": one; chicken "5 or 6/week": one, '1/day": three, "1/day": one; broccoli "5 or 6/week": one; broccoli "5 or 6/week": two, "1/day": three, "2/day": one; carrots "5 or 6/week": four; pumpkin "5 or 6/week": one; broccoli "5 or 6/week": three, "1/day": three, "2/day": one; carrots "5 or 6/week": four; pumpkin "5 or 6/week": one; broccoli "5 or 6/week": three, "1/day": one; carrots "5 or 6/week": four; chicken "hardly take": one, "1/day": one.

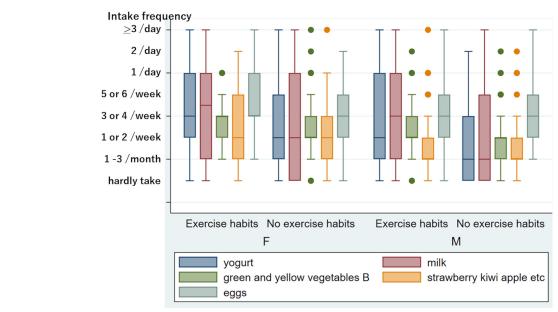
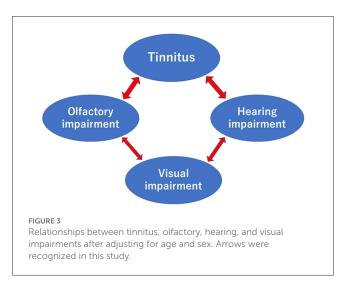


FIGURE 2

Frequency of eating and drinking in people with and without exercise habits in women and men. Five kinds of food and drink with a significant difference between persons with and without exercise habits after adjusting for age in women and/or men. The y-axis is the same as in Figure 1. The number of people belonging to outliers is as follows: In 102 women with exercise habits, green and yellow vegetables B "1/day": five. In 192 women without exercise habits, green and yellow vegetables B "hardly take": three, "1/day": 13, "2/day": one, " \ge 3/day": one; strawberry, kiwi, apple, etc. " \ge 3/day": one. In 102 males with exercise habits, green and yellow vegetables B "hardly take": two, "1/day": four, "2/day": one; strawberries, kiwis, apples, etc. "5 or 6/week": five, "1/day": five, " \ge 3/day": one. In 113 men without exercise habits, green and yellow vegetables B "5 or 6/week": six, "1/day": two, "2/day": one; strawberries, kiwis, apples, etc. "5 or 6/week": two, "1/day": six, "2/day": one.



p < 0.0001), and green tea, p = 0.0002) in total. Thus, smoking habits reduced healthy eating and drinking patterns significantly. No exercise habits were also significantly associated with a low intake of dairy products (yogurt p < 0.0001, milk p = 0.0001), vegetables (green and yellow vegetable group B, p = 0.0051), and fruits (strawberries, kiwis, apples, etc., p = 0.0005) (Figure 2). However, we could not find a significant influence of food and drink intake frequency on tinnitus and sensory dysfunctions after adjusting for age and sex.

Discussion

We found a relationship between tinnitus and poor olfactory test results after adjusting for age and sex. The findings are consistent with those of a previous report based on questionnaire responses (13). Because the subjective evaluation of sensory functions differed from the sensory test results (17-20), we compared the presence of tinnitus and olfactory test results. The relationship between tinnitus and the limbic system has been studied using neuroimaging techniques, including positron emission tomography (PET), functional MRI, and voxel-based morphometry (21-23). The olfactory function connects with the limbic system, including the hippocampus (24-26). Therefore, tinnitus and olfactory dysfunction may have a strong association with the limbic system and are also associated with depression (27, 28). Sound therapy for tinnitus may work by altering limbic and auditory networks (29). Olfactory training to restore the olfactory function was associated with increased gray matter volume of the hippocampus and the thalamus (30). Thus, rehabilitation aimed at improving both tinnitus and olfactory dysfunction can stimulate the senses.

Research has shown that individuals can experience auditory, vestibular, olfactory, and gustatory dysfunctions for an extended time following a COVID-19 infection (31). Additionally, numerous literature reviews have demonstrated that long-term COVID is frequently associated with tinnitus and olfactory and gustatory dysfunction (32). These findings are consistent with the results of our report.

However, the present study did not reveal a relationship between hearing and olfaction after adjusting for age and sex. However, tinnitus and auditory dysfunction were significantly associated after adjusting for age and sex. The connection between hearing loss and tinnitus is widely known. For example, vertigo, hearing loss, and tinnitus are significant symptoms of Meniere's disease (33), and tinnitus accompanying idiopathic sudden sensorineural hearing loss is an important symptom for the treatment (34, 35). In addition, we recognized a relationship between visual acuity and hearing or smell after adjusting for age and sex. Figure 3 demonstrates these mutual relationships. The entorhinal cortex, the primary interface between the hippocampus and neocortex, may be related to the mutual relationships because it relates to audiovisual information processing and tinnitus (36).

High serum calcium and a low A/G ratio were identified as risks for tinnitus in this study. The risk may be related to physical activity and nutrition. We could not observe a statistically beneficial effect of exercise on tinnitus (0.05 ; however, several reports have revealed that physical activity significantly reduced the risk of tinnitus <math>(37, 38). Because exercise can cause a decrease in serum calcium (39, 40), exercise habits that lower the serum calcium level may be better for reducing tinnitus. Dawes et al. (41) reported that higher calcium intake was associated with an increased risk of tinnitus. As smoking and exercise habits significantly influence dietary habits (42), as shown in Figures 1, 2, the influence of lifestyle habits should be investigated comprehensively. In addition, olfactory dysfunction may be related to food choices and eating enjoyment.

We did not observe a relationship between hearing loss and diabetes mellitus after adjusting for age and sex. Previous studies have reported a significant association between hearing loss and diabetes mellitus (43–46), but some did not (47, 48). Similarly, we did not observe a relationship between olfactory dysfunction and diabetes mellitus. Numerous studies have reported a relationship between olfactory dysfunction and diabetes mellitus; however, some of them did not find such a relationship (49). Naka et al. (50) found no significant difference in smell function between healthy subjects and patients with uncomplicated diabetes mellitus.

The history of hypertension was independently associated with a modestly higher risk of hearing loss (multivariable-adjusted relative risk, 1.04 [1.01–1.07]) (51). Higher systolic blood pressure was associated with the incidence of retinopathy (hazard ratio per 10 mmHg, 1.15 [1.07–1.20]) in multivariate analysis (52). Some signs of hypertensive retinopathy, specifically generalized and focal retinal arteriolar narrowing, may be subclinical indicators of hypertension and may be detected even before the clinical diagnosis (53). Considering the risk ratio and the relationship between hypertensive retinopathy and the clinical diagnosis of hypertension, at least the number of participants should have been greater to reveal a significant difference in the hearing and vision tests between participants with and without hypertension after adjusting for age and sex.

Many reports have described the influence of smoking on sensory functions, including olfactory (17), visual (54, 55), and hearing impairments (56, 57). While the present study found an association between smoking and visual impairments, no significant relationship was observed between smoking and olfactory or auditory dysfunctions. Although Nomura et al. (58)

reported that a Brinkman index of 750 or higher was related to hearing loss in a Japanese operating company, there was no significant relationship between a Brinkman index of 750 or higher and hearing after adjusting for age and sex in the present study. Smoking has also been reported to be associated with tinnitus (59, 60). However, we could not find a relationship between tinnitus and current smoking or the Brinkman index. The negative results may depend on a characteristic of our study group, in which 36% of participants quit smoking. Typically, cigarette smokers have a lower BMI than non-smokers after controlling for age in men and women (61), but there was no significant difference in BMI observed between smokers and non-smokers in this study.

Hearing aids are helpful to compensate for hearing loss, but the percentage of hearing aid users (9/510) was low during this health checkup. The low percentage may be related to the fact that the nearest hearing aid store is ~100 km away. Many reports have described the effects of sensory dysfunctions on cognitive impairment or dementia. For example, the effects of olfactory, hearing, and visual impairment have been investigated (62). In addition, dual or multiple sensory impairments may synergistically influence cognitive impairment (63, 64). A few studies have reported a background of dual or multiple sensory impairments (65, 66). The present study revealed the results of the visual acuity test, but neither the olfactory nor the hearing tests were related to smoking habits after adjusting for age and sex. Further studies should investigate the mutual relationships among sensory dysfunctions.

The limitation of this study was the relatively small sample size, and not all participants underwent sensory testing, as their participation in the health checkup was voluntary. Additionally, the participants in this study may have had higher health consciousness compared to the general population of Japan, as evidenced by the high proportion of individuals who had quit smoking (more than 70%) (67).

Conclusion

To date, the relationship between tinnitus and olfactory test results has not been investigated, but a significant association between tinnitus and subjective olfactory dysfunction has been reported. We found a significant relationship between tinnitus and olfactory test results after adjusting for age and sex. In the present study, hearing and olfactory impairments were associated with visual impairment after adjusting for age, sex, and other confounding factors. Various studies have reported the persistence of tinnitus and olfactory and gustatory dysfunctions in people with long-term COVID-19. Mutual relationships among sensory dysfunctions need to be studied in future studies.

Data availability statement

The original contributions presented in the study are included in the article/Supplementary material, further inquiries can be directed to the corresponding author.

Ethics statement

The studies involving human participants were reviewed and approved by the Ethics Committee of Nagoya University School of Medicine (approval number 2014–0207). The patients/participants provided their written informed consent to participate in this study.

Author contributions

NK, TY, TsN, and MiS designed this study. NK, TY, and TaN performed olfactory tests and evaluations. TY, TaN, AK, and ES performed hearing tests and evaluations. YI, TI, KG, YT, AT, and YN performed vision tests and evaluations. TY, TsN, MT, SS, YU, HS, MaS, and NS evaluated multiple sensory dysfunctions and related factors. TY, TsN, and NH performed the statistical analysis. The manuscript was written by NK, TY, TsN, YI, MT, and NH. All authors contributed to the article and approved the submitted version.

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Conflict of interest

Nidek Co., Ltd. provided survey instruments for the vision test during the health checkup.

The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpubh.2023. 1124404/full#supplementary-material

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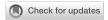
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The research environment of critical care in three Asian countries: A cross-sectional questionnaire survey

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Although inadequate research support for intensivists can be one major reason of the poor research productivity, no study has investigated the current research environment in critical care medicine in Asia. The objective of this study was to describe Asian academia in critical care from the research environment perspective. We conducted a cross-sectional questionnaire survey targeting all physician members of the Societies of Intensive/Critical Care Medicine in Japan, South Korea, and Singapore. We collected the characteristics of the participants and their affiliated institutions and the research environment. The outcome was the number of peer-reviewed publications. Multivariable logistic regression analyses examined the association between the outcome and the following five research environmental factors (i.e., country of the respondents, availability of secured time for research activities or research supporting staff for the hospital, practice at a university-affiliated hospital, and years of clinical practice of 10 years or longer). Four hundred ninety responded (overall response rate: 5.6%) to the survey between June 2019 and January 2020. Fifty-five percent worked for a university-affiliated hospital, while 35% worked for a community hospital. Twenty-four percent had secured time for research within their full-time work hours. The multivariable logistic model found that a secured time for the research activities [odds ratio (OR): 2.77; 95% confidence interval (CI), 1.46-5.24], practicing at a university-affiliated hospital (OR: 2.61; 95% CI, 1.19-5.74), having clinical experience of 10 years or longer (OR:11.2; 95%CI, 1.41-88.5), and working in South Korea (OR: 2.18; 95% CI, 1.09-4.34, Reference: Japan) were significantly associated with higher research productivity. Intensivists in the three countries had limited support for their

research work. Dedicated time for research was positively associated with the number of research publications.

KEYWORDS

research activities, cross-sectional studies (MeSH), community hospital, Asia, critical care

Introduction

The advancement of clinical medicine in Asian countries has led to an improvement in mortality among patients requiring intensive care (1–4). However, recognition in academia of critical care medicine lags behind that of North American or European countries. The growth in the number of peer-reviewed research papers from Asian countries has been sluggish except for some countries like China (5–7). Specifically, the number of accepted papers per year in high-impact critical care journals in high-income Asian countries such as Japan, South Korea, and Singapore has even remained low (Supplementary Figure 1).

There are many potential challenges to conducting highquality studies and trials in critical care medicine due to high disease acuity and severity and heterogeneity of disease etiology of the patients, and poor resource availability, particularly in intensive care units (ICUs) in community hospitals (8-12). It has been suggested that the development of support and its system for research is central to overcome those difficulties. Trial groups such as the Canadian Critical Care Trials Group (CCCTG), for example, have established their research supporting environments such as meetings, ethics committee, a mentoring system, funding system, and research coordinators, which enabled them to conduct numerous high-quality clinical trials (13). In contrast, financial and personal support for research activities are major barriers for critical care research in lower-middle income countries (14). In addition, a survey targeting Japanese and Korean physicians identified a lack of personnel support and time for research as the main hindrance to conducting clinical trials (15).

To our knowledge, there is no study about the current research environment in critical care medicine in Asia. We conducted a cross-sectional survey targeting intensivists in Japan, South Korea, and Singapore. The objectives of this survey were to describe the current status of the research environment in the three countries and explore the differences between the countries, which can be applied for future building or improvement of the research program.

Materials and methods

This study was a cross-sectional questionnaire survey in Japan, South Korea, and Singapore between July 2019 and January 2020.

Eligibility criteria

We included all the physician members of the Japanese Society of Intensive Care Medicine (JSICM), the Korean Society of Critical Care Medicine (KSCCM) as of June 2019, and the Society of Intensive Care Medicine (SICM) in Singapore as of November 2019.

Measurements

The questionnaire included four domains:

- 1) Characteristics of intensivists including their subspecialty, experience of the research activity, and postdoctoral education(s).
- 2) Details of the work environment to conduct research.
- 3) Financial support environment such as gran funding opportunity.
- 4) Ethics committees and their activity.

Validation of the questionnaire

We first performed face validation and content validation when creating the original questionnaire in Japanese. In the face validation, we asked all the co-investigators as content experts to evaluate whether the questionnaire measured what we intended to measure. In the content validity, we invited three critical care content experts (other than the co-investigators) from the pediatric and adult field, who individually assessed whether the questionnaire content accurately assessed all fundamental aspects of the topic. We asked them to fill out a sensibility-testing tool (Appendix 1) and a table of specifications (Appendix 2) to measure the survey's sensibility and specificity. We then modified the survey content according to the testing and the sensibility testing results.

We then translated the original Japanese version to Korean, in which the principal investigators (YK and AK) used a computer-based translation tool to prepare a draft version of the translated questionnaire and a co-investigator (SN) added grammatical corrections to it; then, a co-investigator (JHJ), who was fluent in both Japanese and Korean languages, validated it accordingly. We also translated the original

Japanese version to English (AK and YK), in which JP performed final validation independently. We did not use backward translations for both languages considering that the questionnaire consisted only of closed questions without any open-ended or qualitative questions.

Survey distribution

We collected responses using REDCap electronic data capture tools hosted at the University of Alberta (16, 17). We distributed the final survey link to the Japanese cohort's eligible physicians, obtaining individual email addresses of JSICM physician members. The JSICM physician members' email addresses were entered into the REDCap® system by an independent administrator from the JSICM office. For the Korean cohort, we distributed the final survey link in the same way as the Japanese cohort, except that the person who entered the physicians' email addresses into the REDCap system was a principal investigator (YK). The email addresses were provided and used only for the distribution to assure anonymity and privacy. For the Japanese and Korean cohorts, we sent three reminders at least 2 weeks apart (i.e., four times in total). In Singapore, we could reach all the intensivists directly by sending emails attached with URLs of the survey distributed by ICU directors in each unit. We did not send a reminder due to the time-sensitivity and the good response rate after the first invitation in Singapore.

Statistical analyses

Descriptive data were expressed with frequencies (%). The denominator of each variable was the number of respondents answering each question. Each continuous variable's distribution is described by medians and interquartile ranges (IQRs). Mann-Whitney U test, Chi-Square test, and Fisher's exact test were used to compare the continuous and nominal variables, respectively. The Kruskal-Wallis test was used to compare continuous variables among more than two groups. We did not impute the missing data. We compared the findings of physician and ICU demographics by countries of the respondents and types of hospitals they work for, i.e., university-affiliated hospitals vs. community hospitals. We also explored the factors which could be associated with the number of peer-review papers in English by applying multivariable logistic regressions adjusted with the following five research environmental factors (i.e., country of the respondents, availability of secured time for research activities, availability of research supporting staff for the hospital, practicing at a university-affiliated hospital, and years of clinical practice of 10 years or longer). Since we could assume that the intensivists working for a university-affiliated hospital were more likely to have secured time for research activities and

availability of research supporting staff, we examined the models with interaction terms for the following two factors (working for a university-affiliated hospital for secured research time and availability of research supporting personnel). A two-sided *p*-value of <0.05 was considered statistically significant. All statistical analyses will be conducted with EZR (Saitama Medical Center, Jichi Medical University, ver. 1.36), a graphical user interface for R (The R Foundation for Statistical Computing, Vienna, Austria). The ethics committee of Kameda Medical Center and the Clinical Trial Group committee of JSICM approved this study (No. 18-021 and No. 2018004, respectively).

Results

Baseline characteristics of the respondents

Table 1 shows the demographic characteristics of the respondents. Among 8,824 physician members approached in each cohort, 490 responded (response rate: 5.6%) to the survey, and all the responses were included in the analyses. The specific response rate was 4.5% (323/7,106) in Japan, 7.0% (111/1,579) in South Korea, and 40.2% (56/139) in Singapore, respectively. Fifty-five percent of respondents worked for a university-affiliated hospital and 35% for a community hospital, in which the proportion of the respondents from community hospitals was higher in Japan (44%) than in the other two countries. On top of the ICU practice, nearly half of respondents practiced in the non-intensive care field by >50% such as outpatient clinics, particularly for the cohorts in Japan and South Korea. Over 80% of respondents had their clinical career of 10 years or longer. The number of ICU beds was 11 or more in 89% in South Korea, 76% in Singapore, and 53% in Japan. The number of full-time intensivists was ≤ 5 in 68%.

Factors related to research environment and the comparisons between the countries and the types of hospitals

Table 2 describes factors potentially representing the quality of the research environment for intensivists. The Singapore respondents had better full-text accessibilities to the major peerreview scientific journals than those in Japan or South Korea. Forty percent of the respondents in South Korea had secured time for research activities in which more than 50% had 5h or more hours. A higher proportion of Korean respondents received competitive research funding (34.7% in South Korea vs. 29.1% in Japan or 16.7% in Singapore, respectively). More than half of the respondents in South Korea and Singapore had research supporting personnel in their hospital compared with 21% in Japan. Concerning the way to submit to the research

TABLE 1 Demographic characteristics of the respondents and their hospitals.

Variables	All	Japan	South Korea	Singapore
	(N = 490)	(N=323)	(N=111)	(N = 56)
University faculty position	46.1 (205/445)	43.4 (121/279)	60.9 (67/110)	30.4 (17/39)
(%)				
Location for clinical practice (%)				
University-affiliated hospital	55.3 (271/490)	42.1 (136/323)	85.6 (95/111)	71.4 (40/56)
Community hospital	35.3 (173/490)	44.0 (142/323)	13.5 (15/111)	28.6 (16/56)
No clinical practice	9.4 (46/490)	13.9 (45/323)	0.9 (1/111)	0
Graduate student (%)	13.3 (32/240)	13.3 (21/158)	20.9 (9/43)	5.1 (2/39)
Proportion of time for intensive care	to the time of the overall clinical	practice (%)		
≥90%	21.2 (94/444)	21.9 (61/278)	26.4 (29/110)	7.1 (4/56)
50< and <90%	30.0 (133/444)	30.6 (85/278)	30.0 (33/110)	26.8 (15/56)
0%< and <50%	38.7 (172/444)	34.5 (96/278)	35.5 (39/110)	66.1 (37/56)
None	10.1 (45/444)	12.9 (36/278)	8.2 (9/110)	0
Proportion of the number of pediatri	c patients under 15 years of age a	mong the total number of ICU pa	tients (%)	
100%	3.8 (15/396)	5.0 (12/240)	3.0 (3/101)	0
50=< and <100%	3.5 (14/396)	3.3 (8/240)	5.9 (6/101)	0
0%< and <50%	46.5 (184/396)	62.5 (150/240)	26.7 (27/101)	12.7 (7/55)
None	46.2 (183/396)	29.2 (70/240)	64.4 (65/101)	87.3 (48/55)
Specialty other than intensive care (%)			
Anesthesia	34.1 (104/305)	37.6 (69/181)	11.1 (8/72)	53.8 (28/52)
Emergency medicine	30.8 (94/305)	45.3 (82/181)	13.9 (10/72)	3.8 (2/52)
Respiratory medicine	21.3 (65/305)	9.9 (18/181)	43.1 (31/72)	30.8 (16/52)
General medicine	4.3 (13/305)	0.6 (1/181)	8.3 (6/72)	11.5 (6/52)
Surgery (excluding cardiac	3.6 (11/305)	3.3 (6/181)	6.9 (5/72)	0
surgery)				
Cardiac surgery	2.6 (8/305)	2.2 (4/181)	5.6 (4/72)	0
General pediatrics (excluding	3.3 (10/305)	1.1 (2/181)	11.1 (8/72)	0
pediatric intensive				
care/emergency medicine)				
Other	0	0	0	0
Years of clinical practice (%)				
≥20	41.0 (182/444)	42.2 (118/278)	40.0 (44/110)	35.7 (20/56)
10-19	41.9 (186/444)	37.8 (105/278)	45.5 (50/110)	55.4 (31/56)
6–9	14.4 (64/444)	15.5 (43/278)	14.5 (16/110)	8.9 (5/56)
2–5	2.7 (12/444)	4.3 (12/278)	0	0
<2	0	0	0	0
Board-certified intensivist (%)	71.6 (318/444)	57.6 (160/278)	97.3 (107/110)	91.1 (51/56)
Number of funded beds in ICU (%)				
≥21	20.1 (77/384)	12.4 (29/233)	39.2 (38/97)	18.5 (10/54)
11-20	45.3 (174/384)	40.8 (95/233)	49.5 (48/97)	57.4 (31/54)
6–10	30.2 (116/384)	41.6 (97/233)	9.3 (9/97)	18.5 (10/54)
1–5	4.4 (17/384)	5.2 (12/233)	2.1 (2/97)	5.6 (3/54)
Number of intensivists with	13.3 (51/383)	16.4 (38/232)	0	24.1 (13/54)
full time employment (%)				
≥11				
6–10	18.8 (72/383)	25.0 (58/232)	4.1 (4/97)	18.5 (10/54)
1–5	56.7 (217/383)	51.3 (119/232)	87.6 (85/97)	24.1 (13/54)
None	11.2 (43/383)	7.3 (17/232)	8.2 (8/97)	33.3 (18/54)

TABLE 2 Factors related to research environment of the respondents.

Variables	All (N = 490)	Japan $ (N = 323)$	South Korea (<i>N</i> = 111)	Singapore $(N = 56)$
		(14 — 323)	(14 = 111)	(14 = 30)
Full-text availability in the library of	- '			
New England Journal of	67.3 (330/490)	60.1 (194/323)	76.6 (85/111)	91.1 (51/56)
Medicine		(()	/ /	
Lancet	61.6 (302/490)	55.4 (179/323)	69.4 (77/111)	82.1 (46/56)
JAMA	61.8 (303/490)	55.4 (179/323)	70.3 (78/111)	82.1 (46/56)
Intensive Care Medicine	53.3 (261/490)	45.5 (147/323)	63.1 (70/111)	78.6 (44/56)
Critical Care Medicine	56.9 (279/490)	49.5 (160/323)	70.3 (78/111)	73.2 (41/56)
American Journal of	42.7 (209/490)	32.2 (104/323)	59.5 (66/111)	69.6 (39/56)
Respiratory and Critical Care				
Medicine				
Secured time for research activities po	-			
Yes	24.3 (90/371)	20.7 (46/222)	40.0 (38/95)	11.1 (6/54)
≥20 h	2.2 (8/371)	1.4 (3/222)	4.2 (4/95)	1.8 (1/56)
10 h = < and < 20 h	6.7 (25/371)	5.9 (13/222)	9.1 (10/110)	3.6 (2/56)
5 h = < and < 10 h	12.4 (46/371)	10.8 (24/222)	18.2 (20/110)	3.6 (2/56)
0< and <5 h	3.0 (11/371)	2.7 (6/222)	3.6 (4/110)	1.8 (1/56)
No	75.7 (281/371)	79.3 (176/222)	60.0 (57/95)	88.9 (48/54)
Competitive research funding	28.7 (106/369)	29.1 (64/220)	34.7 (33/95)	16.7 (9/54)
as a principal investigator				
over the past 5 years (%)				
Non-competitive research	14.8 (55/371)	19.4 (43/222)	7.4 (7/95)	9.3 (5/54)
funding for the ICU (%)				
Research supporting	34.3 (127/370)	21.6 (48/222)	52.1 (49/94)	55.6 (30/54)
personnel for the hospital				
(%)				
Epidemiologist	13.8 (51/370)	8.6 (19/222)	27.7 (26/94)	11.1 (6/54)
Biostatistician	21.6 (80/370)	13.5 (30/222)	35.1 (33/94)	31.5 (17/54)
Native English proofreader	5.7 (21/370)	2.7 (6/222)	12.8 (12/94)	5.6 (3/54)
Research assistant	11.4 (42/370)	5.9 (13/222)	18.1 (17/94)	22.2 (12/54)
Research coordinator	12.2 (45/370)	5.9 (13/222)	18.1 (17/94)	27.8 (15/54)
Other	0.5 (2/370)	0	1.1 (1/94)	1.9 (1/54)
Research supporting	2.2 (8/370)	2.3 (5/222)	1.1 (1/94)	3.7 (2/54)
personnel dedicated for the				
(CU (%)				
Access to a research ethics	95.9 (354/369)	97.7 (216/221)	92.6 (87/94)	94.4 (51/54)
committee/institutional				
review board (IRB) at the				
nospital (%)				
Frequency of research ethics committ	ee/IRB (%)			
Regularly > once in a week	4.2 (15/354)	1.4 (3/216)	11.5 (10/87)	3.9 (2/51)
Regularly once in a month	45.5 (161/354)	52.8 (114/216)	36.8 (32/87)	29.4 (15/51)
=< and <once a="" in="" td="" week<=""><td></td><td></td><td></td><td></td></once>				
Regularly <once a="" in="" month<="" td=""><td>18.6 (66/354)</td><td>19.0 (41/216)</td><td>17.2 (15/87)</td><td>19.6 (10/51)</td></once>	18.6 (66/354)	19.0 (41/216)	17.2 (15/87)	19.6 (10/51)
Held only when requested	11.9 (42/354)	12.0 (26/216)	18.4 (16/87)	0
Oon't know	19.8 (70/354)	14.8 (32/216)	16.1 (14/87)	47.1 (24/51)
How to submit for the research ethics	committee/IRB in the hospital (9	6)		
Online	51.7 (183/354)	36.5 (79/216)	66.7 (58/87)	90.2 (46/51)
Not online (in any media)	35.9 (127/354)	51.4 (11/216)	18.4 (16/87)	0
Don't know	12.4 (44/354)	12.0 (26/216)	14.9 (13/87)	9.8 (5/51)

ethics committee or institutional review board, a significantly lower proportion of the respondents reported the availability of online submission in Japan (36.5%) compared to the other two countries (66.7% in South Korea and 90.2% in Singapore).

Compared with the respondents working for university-affiliated hospitals, the respondents working for community hospitals had less secured time for research activities (14.2 vs. 30.4%), less competitive and non-competitive research funds (12.1 vs. 39.0% and 4.3 vs. 21.3%, respectively), less research support personnel (21.3 vs. 42.4%), and less frequency of research ethics committee (Supplementary Table 1).

Research productivity and the associated factors

Almost all the respondents in South Korea had at least one original publication in any language. A higher proportion of South Korean respondents had more than 20 or more than ten original English language publications than the respondents in Japan or Singapore (Table 3).

Table 4 shows the multivariable logistic regression analysis result to examine the potential factors associated with the number of peer-review publications. The adjusted odds ratio (OR) to have more than ten original peer-reviewed publications in English for those with a secured time for the research activities was 2.77 (95% confidence interval (CI), 1.46-5.24, p = 0.002) compared to the respondents without. The adjusted OR was 2.61 in the respondents practicing at a university-affiliated hospital (95%CI, 1.19–5.74, p = 0.017) compared to the others. The adjusted OR was 11.2 when having clinical experience of 10 years or longer (95%CI, 1.41-88.5, p = 0.022), compared to those with clinical experience of <10 years. When comparing the cohorts by countries, the odds ratio was significantly higher for the Korean cohort (OR: 2.2; 95%CI, 1.1-4.3) compared to it in Japan. The models including an interaction term did not present significant evidence of interactions. When we looked at the respondents who worked for a university-affiliated hospital with secured time for research activities and the research supporting staff in their hospital, the odds to have more than ten English publications was 2.4 (95%CI, 1.1-5.2) compared to those without all the three factors.

Discussion

This study is the first report describing the current status of the research environment for intensivists in the three Asian countries. There were some differences in the baseline characteristics of the respondents between the three countries, such as type of hospital/ICU they worked for and years of clinical experience. However, we found a commonality such that a large proportion of the intensivists lacked secured time for the

research activities, research supporting personnel, and research funding in their hospital. Also, there were substantial differences in the secured time for the research and research supporting staff in the hospital among the three countries.

Our results were consistent with previous studies evaluating challenges for critical care research. A scoping review in lower-middle income settings identified limited funding/investment, inadequate access to mentors/training, and limited research/statistical support staff as barriers in critical care research in lower-middle income countries (14). An international survey on barriers and facilitators of conducting randomized controlled trials in pediatric critical care reported that lack of funding was the major barrier and that protected time for research, a stable recruit system, collaboration with a research network, government funding, and academic department support were the facilitators (18). Recently, international critical care randomized trials have overcome these challenges through sharing the resources and published important papers incorporating areas with inadequate research infrastructure in the context of the pandemic of coronavirus disease 2019 (19, 20).

Based on our results, one way to overcome the barriers can be to build a collaborative environment between academics and non-academics such as mentoring or sharing research resources. Our study suggests that this is particularly important for the intensivists working for a community hospital supposed to have limited research support or resources, shown in prior literature (12, 15, 21). These collaborations would help build a robust and sustainable clinical research program in community hospitals (11). We should also acknowledge the potential benefits for the researchers in academic sites in constructing these collaborations by increasing the number and representativeness of the patients enrolled, which is crucial given the heterogeneity in patients' characteristics (8, 22). Given the complexity of the contemporary study methodologies, supports from experienced personnel such as epidemiological, statistical analysis, and data management are also essential for all intensive care researchers to perform high-quality clinical research.

Building a financial support system for the researchers in community hospitals should be another essential aspect of promoting research. For example, in Japan and South Korea, competitive government-based research funds ask applicants to belong to an academic institution, which has been a significant challenge for the researchers working in non-academic institutions (23). Besides, out-of-hours work related to research activities is often done without extra remunerations, which may lead to a great shackle about the continuity of researchers' motivation (21).

The limited resources of critical care practice in Asia could also contribute to its poor research productivity. A lack of organizational and human resources for ICUs is a major problem worldwide (24). Of note, according to a global survey concerning ICU structure, the ICUs in Asia were

TABLE 3 Research productivity.

Variables	All	Japan	South Korea	Singapore	
	(N = 490)	(N=323)	(N=111)	(N = 56)	
Original article* in any language as the	77.0 (341/443)	72.6 (201/277)	95.6 (105/110)	62.5 (35/56)	
first or corresponding author (%)					
Number of original articles* published in Eng	lish as the first or corresponding	ng author (%)			
≥21	11.5 (39/339)	8.5 (17/200)	20.2 (21/104)	2.9 (1/35)	
11–20	11.5 (39/339)	9.0 (18/200)	17.3 (18/104)	8.6 (3/35)	
6–10	14.5 (49/339)	11.0 (22/200)	21.2 (22/104)	14.3 (5/35)	
1–5	53.4 (181/339)	56.5 (113/200)	40.4 (42/104)	74.3 (26/35)	
0	9.1 (31/339)	15.0 (30/216)	1.0 (1/104)	0	

^{*}Case reports or letters to editors are excluded.

TABLE 4 Associated factors with the number of publications.

Independent variables	The r	number of publicatio	ons	Adjusted			
	≧11	10≦	p-value	Odds Ratios	95% CIs	p-value	
Country			< 0.001				
Japan	44.9% (35/78)	63.2% (165/261)		Reference			
South Korea	50.0% (39/78)	24.9% (65/261)		2.18	1.09-4.34	0.027	
Singapore	5.1% (4/78)	11.9% (31/261)		0.50	0.15-1.64	0.25	
Secured time for research	51.5% (35/68)	22.7% (50/220)	< 0.001	2.77	1.46-5.24	0.002	
activities (Yes/No)							
Research supporting	45.3% (29/64)	37.5% (78/208)	0.31	0.80	0.41-1.55	0.50	
personnel for the hospital							
(Yes/No)							
Practice at a	80.8% (63/78)	63.2% (165/261)	0.004	2.61	1.19-5.74	0.017	
university-affiliated hospital							
(Yes/No)							
Years of clinical practice ≥ 10	97.4% (76/78)	87.7% (229/261)	0.010	11.2	1.41-88.5	0.022	
years (Yes/No)							

95% CI, 95% confidence interval.

managed in open formats more frequently than those in Europe or Oceania. In addition, the Asian ICU had fewer admissions per year compared with those in North America or Oceania (25). Open ICUs might limit consistent, intensive care delivery or systematic data collection, and fewer ICU admissions would prevent timely patient recruitment. Since previous meta-analyses showed that closed ICUs have better patient outcomes (26) than open ones and that critically ill patients were more likely to benefit from high-volume centers than low-volume ones (27), aggregating small ICUs into a larger one could improve both critical care practice and research in Asia (23).

In this study, we found that the intensivists in Korea had more peer-reviewed publications and better research supporting infrastructure than those in the other two countries. This result may be because a higher proportion of Korean respondents worked for academia. Although this survey was emailed to all the KSCCM members, most Korean respondents worked for university-affiliated hospitals. It may come from a selection bias, which means those who are not interested in research activities did not respond to the survey. This trend was a little stronger in South Korea because responding to the survey was promoted to the board of committee members of the KSCCM.

Ethical issues can be a challenge for critical care research given the urgency of patient condition and the difficulty of obtaining informed consent from the patient (8). Applying an alternative method of informed consent, such as deferred consent, could help us enroll patients; however, institutions and institutional review boards (IRBs) that can understand and practice those methods are still limited. It will be necessary to share the know-how among the institutions

and promote such as central IRBs to break down the barriers (13).

Lastly, to further boost critical care science, it is essential to train new intensivists to pursue research. Providing a roadmap in the research career will attract them and alleviate worries for their future job security. A survey conducted in the United States reported that most clinical trainees felt that spending time and research activity efforts would not necessarily lead to their job security or even a better job (28, 29). It should be necessary to build a program to nurture new researchers in Asia across countries and societies.

There are limitations to this study:

- 1. Due to the nature of cross-sectional research, a thorough causal inference could not be made in this study's findings.
- 2. A selection bias could have occurred. For instance, intensivists interested in research activities might have responded more to this survey. Besides, because most KSCCM members worked for university-affiliated hospitals, working for South Korea and working for a university-affiliated hospital can be confounding.
- 3. The overall response rate was low. The denominators used for the rate calculation in the Japanese cohort included specific proportions of physicians who were not actively practicing in intensive care such as anesthesiology or emergency medicine. We applied a rigorous methodology in the development and administration stage of this survey to minimize the biases.

In conclusion, intensivists in the three high-income Asian countries had limited research supporting environment and infrastructure with some variations among the countries. It is necessary to build a collaborative environment between academia and non-academia and across countries to share the experience and resources, and to present various roadmaps to new intensive care researchers.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving human participants were reviewed and approved by the Ethics Committee of Kameda Medical Center. Written informed consent for participation was not required for

this study in accordance with the national legislation and the institutional requirements.

Author contributions

YK conceptualized and designed the study, built a survey database, conducted data collection and cleaned the data, carried out analyses, drafted the initial article, revised the initial article, and approved the final article as submitted. AK conceptualized and designed the study, drafted the initial article, revised the initial article, and approved the final article as submitted. NS, TK, and HY conducted a pre-testing, contributed in designing the survey, revised the initial article, and approved the final article as submitted. NS, JP, and JJ played a role in leading and organizing survey distribution in each country, contributed in designing the survey, revised the initial article, and approved the final article as submitted. All authors approved the final article as submitted and agree to be accountable for all aspects of the work.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fmed.2022.975750/full#supplementary-material

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Perceptions of registered nurses on facilitators and barriers of implementing the AI-IoT-based healthcare pilot project for older adults during the COVID-19 pandemic in South Korea

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Objective: This study explored the perceptions of registered nurses on the facilitators and barriers to implementing an AI/IoT (Artificial Intelligence/Internet of Things)-based healthcare pilot project, designed to prevent frailty and improve health behaviors by providing Bluetooth-enabled smart devices (including blood pressure and blood glucose meters) for the older adults aged over 65years and above in South Korea.

Methods: Using a qualitative descriptive methodology, interviews and qualitative surveys were conducted with 15 registered nurses from 11 public health centers. Data were analyzed using qualitative content analysis.

Results: The study found that the Al·loT-based healthcare pilot project was well received by participants, leading to increased client satisfaction and improved health behaviors. Government support and funding were crucial facilitators of project implementation. However, technical challenges and disparities in digital literacy among older adults pose significant barriers.

Conclusion: The findings highlight the potential of Al·IoT technologies in improving the healthcare of older adults. Efforts to address technological challenges and enhance digital literacy among vulnerable populations are necessary for successfully implementing such interventions. Government support and ongoing training for healthcare professionals can help optimize the Al·IoT-based healthcare services for older adults.

KEYWORDS

Al·loT-based healthcare, older adults, facilitators, barriers, digital literacy, public health

1. Introduction

South Korea's rapidly aging population and the ongoing COVID-19 pandemic have highlighted the need for innovative healthcare delivery methods (1). Among the approaches explored, the Artificial Intelligence/Internet of Things-based healthcare Pilot Project (AI-IoT-PP) launched by the Korean government in the latter half of 2020 stands out (1, 2). The AI-IoT-PP, designed to prevent frailty and improve health behaviors, provides Bluetooth-enabled smart devices such as blood pressure meters, blood glucose meters, smart scales, activity-tracking Bluetooth pedometers, and AI speakers to older adults aged 65 years and above (1). These

devices are incorporated into the country's home-visiting healthcare service, operated by registered nurses from public health centers (RN-PHC), to offer contactless public health services through a mobile health application (mHealth app).

The AI-IoT-PP initiative offers an integrated approach to remote healthcare consultations for older adults. In this method, participants undergo an initial health screening, after which they are categorized into different groups: healthy, high-risk frail, and frail. These categories determine the level and frequency of non-face-to-face health consultations. Each participant, based on their health conditions, is assigned specific health goals, fostering a proactive approach towards health maintenance. The Today's Health app, pivotal to the AI-IoT-PP, allows for efficient data sharing between the AI-IoT devices and RN-PHCs, streamlining communication and collaboration.

The implementation of AI·IoT-PP is crucial in an era where face-to-face services have become limited due to the pandemic, particularly for vulnerable groups, including older adults, those from low-income families, and individuals with health problems (1, 3, 4). These challenges in providing public health services to vulnerable community members have underlined the importance of advancements in mHealth technologies (5). Notably, mHealth technologies can facilitate improved self-management, efficient home healthcare services, and enhanced communication and collaboration among older adults with chronic diseases (6).

The current proliferation of digital health initiatives, including AI-IoT-PP, presents new opportunities but also significant challenges, particularly in the context of an aging society and amidst public health emergencies like the COVID-19 pandemic (3, 6). While several studies have focused on the potential of digital health technologies, comprehensive research that specifically addresses the facilitators and barriers experienced by healthcare professionals in implementing these technologies remains scarce. Particularly in the context of home-visiting healthcare services, understanding these challenges is critical to the successful integration of AI-IoT technologies. Therefore, this study contributes to the existing body of knowledge by providing an in-depth analysis of RN-PHC's experiences and identifies strategies for overcoming barriers and leveraging facilitators. The findings of this study have the potential to guide future healthcare policies and strategies for the implementation of digital health technologies, ultimately benefiting vulnerable groups and enhancing the overall quality of healthcare services.

In light of these considerations, this study aims to investigate the facilitators and barriers encountered by RN-PHC during the implementation of AI-IoT-PP in 2021. The primary focus is on understanding the implications of incorporating this new technology into home-visiting healthcare services. This study seeks to identify key facilitator and barrier domains and provide recommendations for improving the delivery and dissemination of AI-IoT healthcare services to older adults in public health. The study's implementation-focused research question is: What are the facilitators and barriers related to AI-IoT-PP, as experienced by RN-PHC?

2. Materials and methods

2.1. Design

This study adopted a qualitative descriptive method (7, 8) to explore the perceptions of RN-PHC on their experience of facilitators

and barriers while implementing AI-IoT-PP during the initial phase of the COVID-19 pandemic. The research employed a qualitative descriptive approach, as suggested by Sandelowski (7, 8), to gather and document narratives from managers. This method prioritizes proximity to the original data by employing straightforward sorting and coding techniques.

2.2. Participants and setting

The AI-IoT-PP, is a pilot initiative funded by the government of South Korea. This program involved 24 out of 256 public health centers across eight out of 17 cities and provinces, nationwide. The selection of participating public health centers for this government-run pilot health project was made after considering the project's requisites and appropriateness within the predetermined budget constraints. The study focused on RN-PHC with a minimum of 2 years of experience in home-visiting healthcare services, and who had also engaged in the AI-IoT-PP for over 3 months. The study utilized a sample of 15 participants from 11 public health centers, with one to three participants per center (Table 1). To qualify for inclusion in the study, participants had to satisfy two criteria: (1) active involvement as a service provider in the AI-IoT-PP within the participating public health centers for over 3 months and (2) consented to permit the use of their data for the research objectives. The study did not define any specific exclusion criteria. Ethical approval was obtained from Ajou University medical center (AJOUIRB-SUR-2021-330).

2.3. Procedures and data collection

Data was gathered through a combination of individual interviews and qualitative surveys. Participants were given the option to select

TABLE 1 Demographic information (n = 15).

Participants	Sex	Region	Career (year)	Age	Interview
P1	F	Rural	14.6	56	Qualitative Survey
P 2	F	Rural	6.8	49	Qualitative Survey
Р3	F	Urban	1.0	27	Qualitative Survey
P4	F	Urban	13.0	42	Qualitative Survey
P5	F	Urban	13.0	37	Qualitative Survey
P6	F	Rural	9.0	35	Qualitative Survey
P7	F	Urban	13.0	41	Qualitative Survey
P8	F	Rural	8.0	50	Qualitative Interview
P9	F	Rural	14.0	48	Qualitative Interview
P10	F	Rural	22.0	64	Qualitative Interview
P11	F	Rural	5.9	55	Qualitative Interview
P12	F	Urban	17.0	51	Qualitative Survey
P13	F	Rural	7.0	59	Qualitative Survey
P14	F	Rural	10.0	38	Qualitative Interview
P15	F	Rural	6.0	37	Qualitative Interview

either a qualitative interview or a qualitative survey, taking into consideration their personal circumstances. The interview guide was developed through an extensive literature review on the adaptability of online-based public health projects (3, 9, 10). We used open-ended questions to encourage rich, detailed responses from the participants. Each interview lasted between 60–90 min. The interviews were carried out by the authors in the fall of 2021, either in a location chosen by the participant or online through the Zoom platform. All interviews were audio-recorded with the permission of the participants and later transcribed verbatim for analysis.

Table 2 included examples of interview questions: "Can you describe your experience with the AI-IoT-PP?," "What are the advantages of contactless programs compared to face-to-face home healthcare services (in terms of health promotion for recipients, nursing practice for nurses, health center budgets, workforce, etc.)?," "What do you consider as the barriers of AI-IoT-PP programs?" and "What do you consider as the facilitators of AI-IoT-PP programs?"

In addition to the interviews, we employed a qualitative survey method that involved the distribution of open-ended questions via email (11). This approach was designed to give participants ample time and flexibility to provide thorough and in-depth responses, thereby reflecting their unique perspectives and experiences related to the research subject (11). The aim of this qualitative survey was to acquire a comprehensive and deep understanding of the phenomena being investigated.

2.4. Program

The goal of this initiative is to use AI-IoT technologies to deliver non-face-to-face healthcare consultations to older adults aged 65 years or older who experience difficulty in managing their own health, which not only improves the efficacy of home-visiting healthcare services but also assists in the provision of healthcare for the older adults in vulnerable groups, even during the COVID-19 pandemic. The program included initial health screening, tailored goal setting with the old adults, self-check of health using the Bluetooth device for 6 months, non-face-to-face health consulting using *Today's Health app*, and health reevaluation at 6 months of enrollment. The *Today's Health app* has been developed to automatically update the content of AI-IoT

TABLE 2 Interview guides.

What are the advantages of contactless programs compared to face-to-face home healthcare services (in terms of health promotion for recipients, nursing practice for nurses, health center budgets, workforce, etc.)?

What do you consider as the barriers of AI-IoT-PP programs?

What do you consider as the facilitators of AI-IoT-PP programs?

Considerations and Improvements for Program Expansion

Do you think the "AI-IoT-PP" can be applied to other public health centers with different conditions (population demographics, regional characteristics, etc.)?

What aspects of the "AI-IoT-PP" need modification for program expansion, and how do you propose to make those modifications?

What potential issues may arise when applying the program in other public health centers?

How do you perceive the Today's health app and smart devices used in the "AI-IoT-PP"?

AI-IoT-PP, artificial intelligence/internet of things-based healthcare pilot project.

devices owned by older adults and share that information with RN-PHCs in an effort to enhance communication and collaboration.

Based on the initial health screening results, the older adults were divided into three groups: healthy, high-risk frailty, and frail. Every day, the participants measured their own blood pressure, blood sugar, and weight, using the provided health-measuring Bluetooth device and send the data to the *Today Health* app. Nurses in public health centers monitor the health status of participants in real-time via the Today Health app and provide health education and non-face-to-face health consultations to motivate participants to engage in healthy behaviors. The frequency and intensity of non-face-to-face health consultations vary among the groups. The frail group receives non-face-to-face health consultation and education twice a month, whereas the high-risk frail and healthy groups receive it once a month. All groups were assigned health related goals based on their health conditions, such as taking their medications on time every day, measuring their blood pressure daily, and walking for 30 min every day. The participants completed the missions and reported them on the app, while nurses checked whether they were completed. Incentives were provided according to how well the mission was accomplished.

2.5. Data analysis and rigor

We implemented both qualitative surveys and interviews in our data collection process, both adhering to the same interview protocols. The structured nature of the surveys ensured consistency across participants, while the open-ended interviews enabled the elicitation of deeper and more nuanced responses. This approach facilitated a comprehensive collection of data.

We utilized the qualitative data analysis method proposed by Hsieh and Shannon (12) for our research. The execution of this process was primarily carried out by one author (Oh) using ATLAS.ti 8 Windows software, resulting in a robust coding structure. The process began with discussing the definitions of codes and examining their similarities and differences until consensus was achieved by authors. These related codes were then categorized based on similar experiences. Subsequently, the interrelationships among the categories were analyzed, and initial themes were identified. The following step entailed group deliberations on the identified subthemes, paying special attention to ensure no crucial detail was missed, thereby bolstering the validity of the themes. After these collective discussions, the themes were refined and finalized, then defined and categorized, resulting in precise and substantial findings (Table 3).

To enhance the credibility of our study, we initiated the analysis concurrently with data collection, which provided an immediate and continuous reflection on the data. We augmented the robustness of our findings through a cross-checking process with two other RN-PHCs. In addition, we adopted reflexivity and peer debriefing strategies. Reflexivity allowed us to continually assess our biases throughout the research process, while peer debriefing offered a platform for discussion with impartial peers, helping identify and correct potential biases. These strategies collectively fortified the credibility of our research. Regular meetings were held by the authors during the analysis phase to review the data, reflect on it, and discuss the results, further assuring the credibility and grounding of our findings (12, 13).

TABLE 3 Data analysis.

Quotations	Primary codes	Subthemes	Themes
"The effect is greatly shown by improving interest in healthcare methods according to the use of smartphones and devices. Expectations for possible changes in health [-related] habits due to voluntary participation." (1:14)	Use of Technology/Divices	Tech-empowered Health Autonomy	Facilitators: Digital Health Empowerment and
"People checked their blood pressure, blood sugar, steps, and weight, and could see how they compared to their old info. It was easy to manage their own health, and they could get into good habits with the daily missions. They looked at the numbers with the nurses, who could give advice without seeing them in person." (5:9)	Self-management		Transformation
"Once the older adults get used to it, being able to manage their health with their smartphones gives them a sense of accomplishment. A notable	Health Monitoring		
advantage is that they can see the results of their efforts. The pedometer was especially popular, although it had limited functionality, only measuring	Real-time Health Advice		
steps and pulse." (10:16)	Sense of accomplishment		
	Voluntary Participation		
"The best part for the people doing the program was that doing the missions every day, kind of like homework, made their lives better by helping them exercise and manage their health." (8:12)	Health management/Improvement	Comprehensive Health Advancement through	
"People were happy to take part because it was about their own health. The program included counseling about health and updates on their health	Participant Engagement	Structured Engagement	
indicators, and helped them learn how to take care of themselves. When they were given health info and rewards, they were more likely to keep participating in the program." (2:19)	Program Structure		
"During the COVID-19 pandemic, it was better to have fewer face-to-face visits and instead offer more remote services like phone counseling. This helped keep everyone safe." (4:10)	Remote Health Services	Digitally Facilitated Personalized Health	Facilitators: Government Support for Digital Health
"Because of the pandemic, managing your health became harder. But some people found it helpful that they could use technology to manage their health at home. For example, they could easily check their blood pressure and blood sugar levels and see how they were doing over time. (5:2)"	Use of Technology for Health monitoring	Management and Support	Management
"This program has enough budget to promote healthy behaviors and provide incentives for individualized health-related missions." (5:19)	Financial Incentives		
	Support Beyond Material Provisions		
Users encountered situations where they couldn't fix issues with their device while trying to measure their health, so they had to ask for help. They felt let down when the step count disappeared due to machine errors after putting in effort to walk more. Moreover, they faced difficulty when their device did not connect well with their phone due to differences in phone model, which required them to manually input data, and that was quite annoying. (4:4)	Technical difficulties	Challenges in Digital Health Implementation and Participant Retention	Barriers: Tech Challenges in Digital Health for the older adults
Some participants dropped out of the project due to low participation, loss of contact, and other reasons, and there were difficulties because they did	Participant Engagement		
not return the devices. Despite my attempts to encourage them to complete the mission and stay in contact, I was unable to reach them, and their level of participation in the project was very low. Furthermore, there are no clear guidelines for withdrawing from the project. (5:12)	Program management Challenges		
"Some participants wanted to join the project, but they had little experience with the device, especially older and less tech-savvy individuals." (1:23)			
"Based on the participants' characteristics, it seemed like there was a correlation between their economic status, education level, and ability to use mobile phones. Those who found it easy to use the device participated more actively and even took on additional missions. However, some participants found even the basic mission of wearing the activity tracker every morning challenging and dropped out of the project." (6:12)			
It's taking a while for our participants to adapt to the devices. We found that there were only a few people who were suitable for the IOT project among the home visiting project participants. (9:2)			

TABLE 3 (Continued)				
Quotations	Primary codes	Subthemes	Themes	
In my opinion, we should aid vulnerable individuals. With solutions for mobile phone compatibility issues and adequate education, I think the IOT Technological inexperience	Technological inexperience	Addressing barriers to	Barriers: The digital	
project can work for older adults and vulnerable participants (with help from their children if needed). (7:34)	Socioeconomic and Educational	technological adoption	alienation of vulnerable	
	Factors	and adaptation among	older adults	
	Adaptation Challenges	diverse populations		
	Need for Assistance			

In order to meet our research goals and maintain a rigorous process, we adopted a clear methodological framework. This facilitated the capturing and recording of participants' expressions using straightforward descriptive data (7, 8). We employed a comprehensive sampling strategy, enlisting participants from 11 out of 24 participating public health centers, which enabled us to encapsulate a spectrum of managerial perceptions regarding RN-PHCs.

3. Results

The RN-PHC expressed excitement about the potential benefits and possibilities of AI-IoT-PP. Despite identifying critical areas for improvement in the intervention and its implementation over the period of 6–9 months, they still gave the pilot program high evaluations. These insights are delineated below as key facilitators and barriers in the execution of the AI-IoT-PP. Furthermore, the AI-IOT initiative was viewed as an innovative healthcare approach and an expansion of public health services. Although remote public health services have been identified as a national priority, there are potential challenges concerning real-time interventions for the older adults who may be unfamiliar with digital devices. Consequently, these challenges need to be addressed, and the project has expanded.

3.1. Facilitators

The RN-PHC viewed the implementation of AI-IoT-PP as highly beneficial and pragmatic owing to several significant aspects.

3.1.1. Digital health empowerment and transformation

Digital health technology has been transformative for older adults, encouraging proactive healthcare management through personal devices. Although these individuals initially faced challenges in using the technology, consistent training and support led to their proficiency, heightened satisfaction, and self-assuredness. They embraced the immediate feedback and self-monitoring capabilities offered by these tools, appreciating the accessibility and personalization. The introduction of mobile devices particularly saw high levels of satisfaction, illustrating the power of digital health empowerment and transformation in fostering health autonomy and advancing comprehensive health.

The effect is greatly shown by improving interest in healthcare methods according to the use of smartphones and devices. Expectations for possible changes in health [-related] habits due to voluntary participation. (P1:14).

People checked their blood pressure, blood sugar, steps, and weight, and could see how they compared to their old info. It was easy to manage their own health, and they could get into good habits with the daily missions. They looked at the numbers with the nurses, who could give advice without seeing them in person. (P5:9).

Once the older adults get used to it, being able to manage their health with their smartphones gives them a sense of accomplishment.

A notable advantage is that they can see the results of their efforts. The pedometer was especially popular, although it had limited functionality, only measuring steps and pulse. (P10:16).

RN-PHCs underscore the effectiveness of a daily digital health program that fosters health autonomy and facilitates proactive self-care among participants. Central to this approach was a goal-setting functionality, viewed as indispensable for older adults to define and reach personal health objectives. Older adults were supported by diverse devices, incentives, and personalized health missions, all of which were integral to the sustained progress and success of the program. The ability to autonomously tailor and administer missions and rewards further underscored the program's commitment to personalized care and highlighted the transformative potential of combining AI-IoT-PP in public health care.

The best part for the people doing the program was that doing the missions every day, kind of like homework, made their lives better by helping them exercise and manage their health. (P8:12).

People were happy to take part because it was about their own health. The program included counseling about health and updates on their health indicators, and helped them learn how to take care of themselves. When they were given health info and rewards, they were more likely to keep participating in the program. (P2:19).

3.1.2. Government support for digital health management

During the COVID-19 pandemic, government support played a critical role in expanding digital health services to vulnerable groups, such as older adults. These efforts were made feasible through sufficient funding and capitalizing on South Korea's widespread mobile technology use. Digital health tools provided valuable data, allowing healthcare professionals to enhance their counseling services and improve the precision and individuality of their interventions. Through the allocation of funds, the government effectively promoted healthy behaviors, provided incentives for health-related missions, and enabled access to crucial health devices, demonstrating its commitment to enhancing health outcomes in challenging times. This comprehensive approach to digital health management has led to high levels of participant satisfaction and the overall success of the program.

During the COVID-19 pandemic, it was better to have fewer face-to-face visits and instead offer more remote services like phone counseling. This helped keep everyone safe. (P4:10).

Because of the pandemic, managing your health became harder. But some people found it helpful that they could use technology to manage their health at home. For example, they could easily check their blood pressure and blood sugar levels and see how they were doing over time. (P5:2).

This program has enough budget to promote healthy behaviors and provide incentives for individualized health-related missions. (P5:19).

3.2. Barriers

The implementation of the project encountered notable challenges, which were primarily attributed to technical issues and substantial disparities in digital literacy skills among older adults. This disparity was particularly pronounced among economically and educationally vulnerable seniors who exhibited lower levels of digital literacy and were at a higher risk of facing digital exclusion.

3.2.1. Tech challenges in digital health for the older adults

The adoption of digital health technologies by older adults has been marked by numerous technical challenges, spanning device malfunctions, software usability issues, and connectivity difficulties. A common problem is that devices like pedometers frequently disconnect or malfunction, which is particularly challenging given the older participants' limited familiarity with technologies like Bluetooth. Additionally, delays in notification about these issues further complicate the user experience and pose obstacles during phone consultations. Therefore, it's clear that additional tech support and resources are essential to address these challenges and ensure the successful integration of digital health technologies among the older population.

Users encountered situations where they could not fix issues with their device while trying to measure their health, so they had to ask for help. They felt let down when the step count disappeared due to machine errors after putting in effort to walk more. Moreover, they faced difficulty when their device did not connect well with their phone due to differences in phone model, which required them to manually input data, and that was quite annoying. (P4:4).

RN-PHC faced challenges in sustaining older adults' participation in the digital health program due to varied interest and skill levels. Complications arose from dropouts not returning devices and the absence of clear withdrawal guidelines. These issues underscore the need for additional resources and strategic planning for effective implementation of digital health initiatives for the older population.

Some participants dropped out of the project due to low participation, loss of contact, and other reasons, and there were difficulties because they did not return the devices. Despite my attempts to encourage them to complete the mission and stay in contact, I was unable to reach them, and their level of participation in the project was very low. Furthermore, there are no clear guidelines for withdrawing from the project. (P5:12).

3.2.2. The digital alienation of vulnerable older adults

Among older adults and vulnerable populations, such as those residing alone, certain individuals faced obstacles in participating because of the limited functionality of their mobile phones. Older adults or diminished cognitive abilities also encounter difficulties with device connectivity and other technical complications. Furthermore, a considerable number of individuals did not possess smartphones, which complicates their involvement. Particularly, the older adults required extensive education, encouragement, and assistance to actively engage in the project.

Some participants wanted to join the project, but they had little experience with the device, especially older and less tech-savvy individuals. (P1:23).

Based on the participants' characteristics, it seemed like there was a correlation between their economic status, education level, and ability to use mobile phones. Those who found it easy to use the device participated more actively and even took on additional missions. However, some participants found even the basic mission of wearing the activity tracker every morning challenging and dropped out of the project. (P6:12).

The RN-PHC highlighted that certain older adults required more time to acclimate to the devices and faced challenges in adapting to AI-IoT projects. However, they emphasized the significance of delivering services to vulnerable older adults and expressed confidence that addressing technical issues would enable effective service provision. In essence, they believed that with adequate education, vulnerable older adults would be able to access the services they require.

It's taking a while for our participants to adapt to the devices. We found that there were only a few people who were suitable for the IOT project among the home visiting project participants. (P9:2).

In my opinion, we should provide assistance to vulnerable individuals. With solutions for mobile phone compatibility issues and adequate education, I think the IOT project can work for older adults and vulnerable participants (with help from their children if needed). (7,34).

4. Discussion

This study aims to explore the facilitators and barriers experienced by RN-PHCs during the implementation of AI-IoT-PP in 2021, with a primary focus on understanding the implications of integrating this emerging technology into home-visiting healthcare services. This study emphasizes the effective use of AI-IoT-PP in enhancing public health care for older adults, thanks to goal-setting functionalities and government support.

Our study highlights the transformative potential of digital health technologies, especially AI-IoT-PP interventions, in enabling older adults to actively manage their health. The pilot phase of the AI-IoT-PP intervention proved feasible and was positively received, demonstrating the effectiveness of mobile technology in enhancing communication and goal setting between RN-PHCs and clients. These findings echo community-based studies that underscored the critical role of health worker involvement and efficient clinician workflows in the successful adoption of mobile apps among low-income populations and vulnerable families (9, 14). This aligns with the literature (14, 15), which advocated for mHealth applications as significant facilitators in health management. Mohammed's study showcased how mHealth apps can assist individuals with chronic conditions in effectively tracking their health-related goals, indicating a potential for these apps to boost health-promoting behaviors. Our findings further reaffirm the necessity of health worker participation in ensuring successful mobile app adoption within disadvantaged populations. The RN-PHCs were instrumental in implementing a daily digital health program that delivered high client satisfaction, leveraging AI·IoT-PP interventions to improve communication, goal setting, and provide user-friendly access to health features. In particular, the goal-setting functionality emerged as critical for helping older adults set and attain personal health objectives, demonstrating how technology can encourage self-care and consistent progress in health management. Moreover, RN-PHCs reported that AI-IoT-PP interventions enabled timely interventions, leading to positive health behavior changes, with optimism regarding the program's long-term outcomes. Second theme was Government Support for Digital Health Management. Given the nature of community-based health nursing, a limited number of RN-PHC are responsible for a large number of community-dwelling clients. Consequently, existing services have primarily focused on one-way interventions, including health screening, health and lifestyle counseling, referrals, and documentation (16). As part of the AI-IoT-PP, participants were equipped with health-related devices such as blood pressure monitors, blood glucose meters, pedometers, and smart scales. RN-PHCs reported that clients' heightened satisfaction stemmed from receiving these devices free of charge and monetary incentives, which was made possible, in part, by government-funded support. Almost all RN-PHCs emphasized the indispensability of government support for the continued provision of services. This support is crucial not only for enrolling more clients and delivering services, as previously suggested (10), but also because of concerns regarding the program's sustainability resulting from insufficient funding transparency. If the feasibility and effectiveness of the pilot project are confirmed, further analysis of the cost-effectiveness and suitability of government support should be conducted. Additional deliberation is necessary regarding the process of selecting appropriate candidates for AI-IoT projects among the recipients of home healthcare services.

The third theme identified in this study was the Tech Challenges, which served as barriers to Digital Health adoption among older adults. These difficulties encompassed technical glitches, usability issues with software, and connectivity problems, all of which obstructed the successful integration of these technologies, despite their immense potential. Existing literature echoes these challenges, indicating the widespread nature of these technical hurdles when older adults interact with digital health technologies (14, 17). Further complicating this issue, not all available telehealth technologies are suitable for older adults due to age-related changes like diminished vision, impaired hearing, and reduced dexterity, potentially restricting their ability to efficiently use various telehealth devices (18, 19). This study was unable to conclusively establish a direct correlation between the physical changes associated with aging in older adults, advanced age itself, and the technology challenges encountered. Further research is warranted to elucidate this relationship more precisely.

Moreover, these issues were further complicated by participant attrition and a lack of clear protocols for withdrawal, thereby underlining the pressing need for increased technical assistance, resources, and strategic planning for successful and sustainable adoption within this demographic (10). In response to these challenges, some studies have proposed potential solutions, such as the design of more user-friendly interfaces and the establishment of

dedicated support hotlines to assist older adults in navigating these technologies (20).

Initially perceived as minor, these technical difficulties morph into intricate and disruptive obstacles during the implementation of interventions, requiring the addressing of additional barriers, including the capacity and integration of workflows for RN-PHC. As part of their role, RN-PHCs are tasked with providing technical support to clients, which necessitates possessing the necessary skills and familiarity with the application while promptly resolving client concerns.

Despite the profound influence of information technology in driving digitization in daily life, a persistent disparity between those who have access to information and those who do not remains. Consequently, addressing this information gap among vulnerable populations has emerged as a pressing concern (21). Given this context, the incorporation of previous literature on similar technical challenges and their potential solutions provides a more holistic understanding of the complexities involved in adopting digital health technologies, especially among older adults. The digital alienation of vulnerable older adults, particularly those living alone or with diminished cognitive abilities, is exemplified by their challenges in using mobile phones, facing connectivity issues, and even lack of smartphone ownership, necessitating comprehensive education and support. However, RN-PHC highlighted that with time and adequate education, these vulnerable groups could successfully adapt to AI-IoT projects and gain access to essential services.

South Korea has the highest smartphone distribution rate globally. However, the level of digital health literacy varies significantly depending on age and income levels. Almost all individuals in their 20s and 40s own smartphones, while the ownership rate decreases to 80% for those in their 60s and is as low as 38% for individuals aged 70 and above (22). In the context of a globally aging population, it is crucial to engage older adults in digital technology, including mHealth, to promote their health and functioning (23). The literature suggests that telehealth and mHealth offer valuable solutions for remote support to frail older adults (24, 25).

However, the older adult population in particular, frequently face exclusion and a sense of alienation from utilizing information technology. This phenomenon, known as digital alienation, often leads to feelings of unfamiliarity and helplessness due to a widening technology gap (26-28). Previous research demonstrated that individuals with higher income and educational levels are more inclined to adopt and express satisfaction with technology, whereas those with lower income and educational levels experience greater digital alienation (28). Considering that recipients of communitybased home healthcare services often belong to low-income groups with limited educational backgrounds, it is crucial to enhance their confidence and competence in using technology. Interventions incorporating video technologies and telephone support have shown promise in reducing isolation and improving health outcomes (4, 21). As frontline service providers, RN-PHCs play vital roles in endorsing and adopting technological solutions. Their adoption of technology enhances client engagement, satisfaction, and overall outcomes (9, 29). Therefore, for participants experiencing exclusion and a sense of alienation, a variety of approaches including video technologies, telephone support, or a combination of online and offline visits could potentially be beneficial.

In the era of the digitalization and smartification of nursing practice, nurses are required to act as catalysts for change and possess the ability to seamlessly deliver advanced nursing services. As society increasingly embraces contactless practices, there will be a growing demand for various forms of nursing services. Hence, it is essential to develop and provide patient-centered, tailored nursing education, counseling, and care management programs. These programs should utilize blended approaches that combine online services with traditional face-to-face consultation and education. Amidst these transformative changes, it is of utmost importance for RN-PHC to recognize the unique needs of vulnerable populations and assume an even more significant role in ensuring that their health is effectively managed without facing marginalization.

4.1. Limitation

This study acknowledges a few limitations. Initially, as it was a pilot study, the AI-IoT-PP was deployed in a restricted number of health centers, potentially limiting the wide-ranging applicability of our results. Despite the lingering potential for either over- or underestimation, we believe the preservation of an open and non-judgmental interview is key to accurately depicting participants' experiences and viewpoints. While we do not foresee major issues regarding the authenticity of their responses, the possibility of overestimation or underestimation, given the RN-PHCs' role in implementing the pilot program, is a consideration that we have recognized. Despite efforts, the complete eradication of these biases remains a challenge due to sample size restrictions. An additional limitation lies in the relatively low adoption rate of AI-IoT-PP among enrollees of the home-visiting healthcare service, even with explicit registration suggestions. This pattern underscores potential hurdles in promoting the wider adoption of AI-IoT-PP within this demographic. To address these limitations, we understand the imperative for more extensive research, particularly emphasizing the verification of the authenticity and accuracy of data obtained from RN-PHCs.

5. Conclusion

This study underlines the transformative potential of the AI-IoT-PP in older adults' healthcare in the public health sector. Key facilitators include technology-assisted behavioral adoption, real-time interventions, and government support, which are particularly relevant during the COVID-19 pandemic. However, technological hurdles and disparities in digital literacy skills among the older adults, especially those who are economically and educationally disadvantaged, have emerged as significant barriers. Therefore, strategies aimed at enhancing digital literacy and addressing technological challenges are critical for ensuring a more inclusive and effective healthcare system.

While these challenges persist, this study also reveals that with continued support and training, the older adult population can adapt to healthcare technology. These findings reinforce the necessity for persistent efforts to support this demographic in an evolving digital healthcare landscape. Hence, this research underscores the significance of technological interventions, such as AI·IoT-PP, especially for vulnerable demographics in the public health sector. This further highlights the necessity for all-encompassing strategies to optimize their effectiveness while maintaining an inclusive approach.

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Data availability statement

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author.

Ethics statement

The studies involving human participants were reviewed and approved by Ajou University IRB. The patients/participants provided their written informed consent to participate in this study.

Author contributions

HO conceived and designed the study, conducted data collection (interviews) performed data analysis, and contributed to the interpretation of the findings. SB conceived and designed the study, participated in data collection (interviews, member checks), contributed to the data analysis process, and played a role in the interpretation of the findings. SB and HO contributed to the writing and revision of the manuscript. All authors contributed to the article and approved the submitted version.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Hospitalization and emergency department visits associated with potentially inappropriate medication in older adults: self-controlled case series analysis

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Introduction: Potentially inappropriate medications (PIM) and resulting adverse health outcomes in older adults are a common occurrence. However, PIM prescriptions are still frequent for vulnerable older adults. Here, we sought to estimate the risk of hospitalization and emergency department (ED) visits associated with PIM prescriptions over different exposure periods and PIM drug categories.

Methods: We used the National Health Insurance Service-Elderly Cohort Database (NHIS-ECDB) to construct the cohort and implemented a Self-Controlled Case Series (SCCS) method. Hospitalization or ED visits during the exposure and post-exposure periods were compared to those during the non-exposure period, and six PIM drug categories were evaluated. A conditional Poisson regression model was applied, and the risk of outcomes was presented as the incidence rate ratio (IRR). All potential time-varying covariates were adjusted by year. A total of 43,942 older adults aged ≥65y who had at least one PIM prescription and the events of either hospitalization or ED visits between Jan 2016 and Dec 2019 were selected.

Results: Mean days of each exposure period was 46d (±123); risk was highest in exposure1 (1-7d, 37.8%), whereas it was similar during exposure2 (15-28d), and exposure3 (29-56d) (16.6%). The mean number of total PIM drugs administered during the study period was 7.34 (\pm 4.60). Both hospitalization and ED visits were significantly higher in both exposure (adjusted IRR 2.14, 95% Confidence Interval (CI):2.11-2.17) and post-exposure periods (adjusted IRR 1.41, 95% CI:1.38-1.44) in comparison to non-exposure period. The risk of adverse health outcomes was highest during the first exposure period (1-14d), but decreased gradually over time. Among the PIM categories, pain medication was used the most, followed by anticholinergics. All PIM categories significantly increased the risk of hospitalization and ED visits, ranging from 1.18 (other PIM) to 2.85 (pain medication). Sensitivity analyses using the first incidence of PIM exposure demonstrated similar results. All PIM categories significantly increased the risk of hospitalization and ED visits, with the initial period of PIM prescriptions showing the highest risk. In subgroup analysis stratified by the number of medications, PIM effects on the risk of hospitalization and ED visits remained significant but gradually attenuated by the increased number of medications.

Discussion: Therefore, the development of deprescribing strategies to control PIM and polypharmacy collectively is urgent and essential.

KEYWORDS

potentially inappropriate medication, self-controlled case series, Poisson regression, older adult, pain medication, gastrointestinal medication, anticholinergics

1. Introduction

Worldwide, the proportion of adults aged ≥60 y is increasing dramatically. One in six people in the world will be aged 60 y or older by 2030, and their population will double by 2050 (2.1 billion) (1). Older adults have an increased risk of adverse drug reactions due to age-dependent changes in pharmacokinetics and pharmacodynamics as well as polypharmacy and complex drug regimens based on increased susceptibility to chronic complex diseases (2). As a result, drug-related problems are an important health care safety concern for older people. Potentially inappropriate medications (PIMs) are defined as those with a greater risk of harm than benefit, particularly in patients older than 65 y (3). The prevalence of PIMs in older adults ranges from 20 to 60% based on the healthcare settings or criteria used to define PIM (Beers Criteria® or STOPP criteria) (4). Potentially inappropriate medication prescriptions are associated with 10 to 30% increased risk of hospitalization (5-9), increased risk of adverse drug events (ADEs) (10-12), emergency department (ED) visits (13, 14), and a poor health status (15). In addition, PIMs directly or indirectly increase healthcare use and costs (16). However, a Japanese study using the 2012 Beers criteria found no relationship between PIM exposure and adverse outcomes (17). Adverse health outcomes associated with PIM use should be associated with the number and types of comorbidities in older adults (18, 19), which is usually accounted for as a covariate adjustment, but not taken into full consideration in most studies.

In Korea, over 80% of older adults have experience of PIM consumption, defined by 2012 Beers criteria, according to a 2009–2011 study using Health Insurance Review and Assessment (HIRA) database (20) and their use is recurrent and consistent in many cases. Therefore, finding a control group and assessing the precise outcomes accordingly is difficult, as determining prescription days is complicated.

In this context, we implemented a Self-Controlled Case Series (SCCS) model to fit the characteristics of PIM use in older adults in Korea and fully implement the meticulous analysis method.

The SCCS method provides an alternative epidemiological study design for investigating the association between transient exposure and outcome events. The SCCS method is a case-only method; it has the advantages that no separate controls are required and any time-invariant confounders, such as comorbidity, are automatically controlled. It also requires precise timings; therefore, the SCCS method is best suited to acute events and transient exposures for which periods of exposure risk can be clearly defined (21).

This study had two main aims: (1) to estimate the risk of adverse health outcomes due to PIM use: hospitalization and ED visits, as well as risk stratification based on different risk (exposure) periods (prescription days), and (2) PIM categorization according to the differential risk toward hospitalization and ED visits.

2. Materials and methods

2.1. Data sources

We used the National Health Insurance Service-Elderly Cohort Database (NHIS-ECDB), a sample research database providing insurance claim information on individuals over the age of 60, starting in 2012, which currently comprises approximately 1,000,000 cases. The NHIS-ECDB provides multiple variables regarding basic demographic information, disability, death, social and economic status, medical service utilization, and long-term nursing home services; details of medical and dental treatment; and prescription information (National Health Insurance Sharing Service, Sample Research DB, https://nhiss.nhis.or.kr/bd/ab/bdaba022Oeng.do#). This study protocol was exempt from review by the Institutional Review Board of Gachon University (IRB number: 1044396-202,005-HR-100-01).

2.2. Study design and outcomes

We implemented a SCCS method where study participants act as their own controls, therefore this study included participants who had the exposure (PIM use), non-exposure (PIM non-use) periods and outcome (hospitalization/ED visits) events from Jan 2016 to Dec2019. All exposures occurring within the observation period, both before and after individuals have experienced the event, are included in the analysis. The outcomes of this study were to assess the overall risk of hospitalization or ED visits associated with PIM use stratified by exposure period and the differential risk of each PIM drug category with regard to outcome events.

2.2.1. Study population

The inclusion criteria were as follows: (1) age \geq 65 y who experienced outcomes of interest, and had at least one prescription of PIM during the study period (Jan 2016–Dec to 2019), (2) no PIM prescriptions 6 months before cohort enrollment (Jul 2015–Dec 2015), and (3) no cancer history during the entire study period. To account for new user qualifications, we defined older adults who had no PIM prescription for 6 months (wash-out period) before cohort enrollment as new PIM users. This criterion was to make sure the outcome events were from incidental PIM use not from carry-over effects from the previous PIM use. Due to the complex disease characteristics and complicated treatment regimens, we excluded older adults who had any cancer history during the study period (removed individuals with ICD-10 codes C00-C97).

2.2.2. Outcome events, exposure, and non-exposure periods

PIM was defined based on the 2019 updated Beers criteria (22). The Beers Criteria are one of the most widely used explicit lists of PIMs for the older adults, originally developed by Beers and colleagues in 1991 through an evidence-based comprehensive literature review and expert panel consensus using the Delphi method (23). We only used PIM categories in Beers criteria 2019 as exposures (Supplementary Table S1), due to the fact that others in Beers criteria 2019 are regarding older adults with specific conditions and specific PIM properties, and aimed to represent the more general PIM use outcomes in older adults. The PIM drugs and categories used in this study, are presented in Supplementary Table S1 (22). The outcomes of interest were combined events of hospitalization and ED visits, and hospitalization and ED visit alone.

We stratified the exposure periods into exposure1 ($day_0 \sim day_{14}$), 2 ($day_{15} \sim day_{28}$), 3 ($day_{29} \sim day_{56}$), and 4 ($day_{57} \sim day_{end}$), considering

the duration of PIM prescription after its initiation. We also defined the post-exposure period as post1 (day_{end+1}-day_{end+14}) and post2 (day_{end+15}-day_{end+28}) to account for the residual effects of the PIM. The period when there was no PIM prescription, before or after the exposure, was defined as the non-exposure period after excluding exposure and post-exposure periods. The follow-up period continued until December 2019, but older adults who died before the study end date were observed until the death event. The overall study design is depicted in Figure 1.

2.3. Statistical analysis and covariates definition

The baseline characteristics of the included older adults were represented by descriptive statistics by numbers and percentages in discrete variables or mean and standard deviation in continuous variables (Table 1). In our SCCS study design, study participants acted as their own controls, thus all time-invariant covariates within individuals were controlled. We estimated the risk of hospitalization and ED visits by comparing the incidence rates of the outcome between the exposure/postexposure and non-exposure periods within the same individuals using a conditional Poisson regression model and presented the crude incidence rate ratio (IRR). The IRR was calculated by dividing number of events by the sum of person-years multiplied in each period, and the 95% confidence intervals (CIs) were calculated using a Poisson distribution. Since the study period was 3 y, we used time-variant covariate information that could potentially affect the outcome events by year into adjusted models, such as age group, insurance type, long-term care eligibility, disability, Charlson Comorbidity Index (CCI), comorbidity, and comedication (antithrombotics and systemic steroids), and presented the adjusted IRR (aIRR). Comorbidity information was retrieved and confirmed with a previous 1y history of ICD-10 codes (Supplementary Table S2) or two or more prescriptions specific to those comorbidities. For psychiatric diseases, which are assumed to be highly confidential in Korea, the data were not available to the researchers, so we used medication history to detect psychiatric diseases as comorbidities. For co-medications, we used the previous 1-month history as a definition period, which is reasonably assumed period to affect the outcomes of interest. The number of co-medications was also assessed 1 month before cohort enrollment. After excluding all PIM drugs used in the study as exposures, the remaining antithrombotics and systemic corticosteroids were selected as potential medications that might affect outcomes. All analyses were performed using SAS version 9.4 and significance was determined with two-sided 95% CI and a p value <0.05.

2.3.1. Sensitivity analysis

Given that older adults in Korea tend to have PIM recurrently and consistently, we performed a sensitivity analysis to assess the robustness of the main outcome of this study by comparing the association of first incidental use of PIM (exposure) and outcome events with the association of overall PIM use, including recurrent or consistent prescriptions and outcome events.

3. Results

3.1. Baseline characteristics

Of the total older adults aged 65 y and older from 2016 to 2019 (n = 541,044), 43,942 individuals with PIM exposure and outcomes of hospitalization or ED visits were selected (Figure 2). The number of females was slightly higher (51.62%) than males (48.36%), and 64-74 age group was dominant (58.55%), with a mean age of 73.71 (\pm 6.36). Income status based on medical care (4.62%, categorized as low income) and insurance premium (0-4: no to low income, 31.5%) was observed to be within average. The CCI score showed that the average health status was in good condition (score 0, 73.12%). Long-term care insurance eligible (frail) older adults, and the proportion of disability and death events comprised of 8.12, 14.74, and 8.9%, of individuals, respectively. The predominant comorbidities were hypertension (31.75%), hyperlipidemia (24.91%), and arthritis (both rheumatoid arthritis and osteoarthritis, 9.51%). The proportion of older adults who had polypharmacy (number of co-medications ≥5) was 27.0% (Table 1).

3.2. Outcome: overall exposure and outcome events and risk estimation

The mean total number of observation days per individual was 1,352 d, and that of non-exposure days per individual was three times

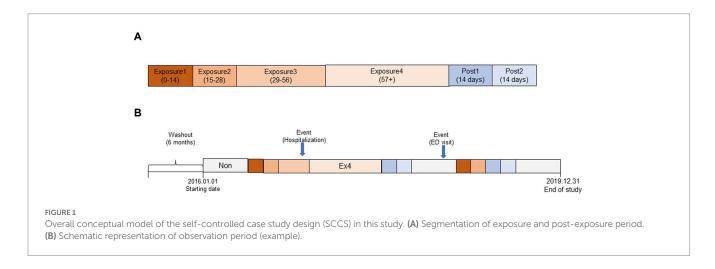
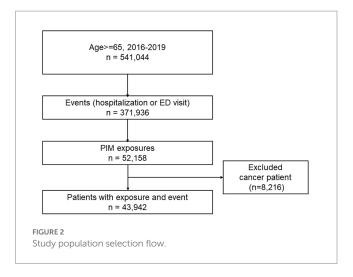


TABLE 1 Baseline characteristics of study population (N=43,942).

Variable	Category	
Sex (n, %)	Female	22,692 (51.64)
	Male	21,250 (48.36)
Age (mean, sd)		73.71 (6.36)
Age group (n, %)	65-74	25,728 (58.55)
	75-84	15,210 (34.61)
	85-	3,004 (6.84)
Insurance (n, %)	National health insurance	42,103 (95.38)
	Medical care	2,038 (4.62)
Insurance premium (n, %)	0 (no income)	2,653 (6.04)
	1-4	11,204 (25.5)
	5-8	14,592 (33.21)
	9–10 (highest)	15,493 (35.26)
Long-term care insurance beneficiary (n, %)		3,566 (8.12)
Disability (n, %)		6,478 (14.74)
Death		3,910 (8.9)
CCI score (n, %)	0	32,132 (73.12)
	1	8,908 (20.27)
	2+	2,902 (6.6)
Comorbidities (n, %)	Hypertension	13,951 (31.75)
	Ischemic heart disease	2,106 (4.79)
	Heart failure	531 (1.21)
	Cerebrovascular disease	2,915 (6.63)
	Diabetes mellitus	3,612 (8.22)
	Chronic kidney disease	562 (1.28)
	Chronic Obstructive Pulmonary Disease	1,969 (4.48)
	Parkinson's Disease	394 (0.9)
	Arthritis (Rheumatoid and osteoarthritis)	4,180 (9.51)
	Fracture	749 (1.7)
	Hyperlipidemia	10,945 (24.91)
	Dementia	2,221 (5.05)
	Depression	1,182 (2.69)
	Other psychiatric diseases*	3,450 (7.85)
Mean number of comedication** (mean, sd)		3.15 (3.60)
Number of comedication	0	12,622 (28.72)
(n, %)	1-4	19,136 (43.55)
	5–9	10,222 (23.26)
	10+	1,962 (4.44)
Comedication (n, %)	Antithrombotics (coagulation, platelet)	9,880 (22.5)
	, J	

^{*}Psychiatric diseases other than depression. **Number of co-medications was assessed 1 month before cohort entry. \$Co-medication was assessed 1 month before cohort entry, and antithrombotics and systemic steroids were remaining medications that potentially affected outcomes after excluding all exposures (PIM drugs).



higher than that of the exposure days per individual (940 vs. 260 d). Mean days of each exposure period was 46 d (± 123); the highest risk was observed on days 1–7 (37.8%), the risk was similar on 8–14 d and 15–30 d at 16.6%, while the lowest risk was observed at 60 d and over (13.9%). The mean number of PIM drugs prescribed over the whole study period, regardless of their categories per individual was 7.34 (± 4.60). Number of PIM drugs in each exposure period was 2.15 (± 1.43), and one PIM drug was predominantly prescribed (52.67%) (Table 2).

The mean number of outcomes per individual was as follows: hospitalization, ED visits, and both were 1.87(±1.78), 0.48 (±1.86), and 2.34 (±2.54), respectively. A total of 3,910 (8.90%) death events occurred during the study period, and mean days to death was 867.5 (±379.6) d. In the Poisson regression analysis, both hospitalization and ED visits were significantly higher during the exposure period (IRR 1.99, 95% CI:2.11-2.17), and the post-exposure period (IRR 1.41, 95% CI:1.38-1.44) than the non-exposure period. The risk of ED visits related to PIM use was lower during the post-exposure period than the non-exposure period. All adjusted models using time-variant covariates for each year (age, insurance, income, long-term care insurance eligibility, CCI score, comorbidity, and number of co-medications) presented results similar to those of the unadjusted model (Table 3). We also determined the risk of hospitalization and ED visits according to segmented PIM exposure periods. The risk was the highest during the first exposure period (1-14d), and decreased over time, including over the post-exposure period (Table 4).

3.3. Risk estimation by PIM drug categories

Among the PIM categories, pain medication was used the most, by 89.5% of individuals, followed by anticholinergics (82.72%) and gastrointestinal (GI) medications (54.13%) (Table 5). When we distinguished the PIM exposure by PIM drug categories and compared their effects with controls, all PIM categories presented a significantly increased risk of hospitalization and ED visits, with risks ranging from 1.18 (other PIM) and 1.68 (anticholinergics) to 2.19 (pain medication), even after adjusting for all time-variant covariates in the Poisson regression model (Figure 3).

TABLE 2 Information of exposures per individual older adult (N=43,942).

Variables	
Total observation days (mean, sd)	1,351.6 (247.3)
Total non-exposure days (mean, sd)	940.1 (343.9)
Total exposure days (mean, sd)	260.9 (303.0)
Total post-exposure days (mean, sd)	150.7 (99.3)
Days of each non-exposure period (mean, sd)	168.6 (232.0)
Days of each exposure period (mean, sd)	46.0 (123.3)
Days of each exposure period (N, %)	
1–7	94,115 (37.8)
8-14	41,422 (16.6)
15–28	35,479 (14.2)
29–56	37,659 (15.1)
57+	40,509 (16.3)
Days of each post-exposure period (mean, sd)	27.6 (2.7)
Number of exposure periods in total study period per individual (mean, sd)	5.67 (3.59)
Number of PIM drugs in total study period, mean (sd)	7.34 (4.60)
1-4 (N, %)	13,792 (31.39)
5-9 (N, %)	17,679 (40.23)
10-41 (N, %)	12,471 (28.37)
Number of PIM drugs per each exposure period, mean (sd)	2.15 (1.43)
1 (N, %)	23,146 (52.67)
2 (N, %)	5,094 (11.49)
3-4 (N, %)	33,171 (13.30)
5–28	1,659 (3.68)

3.4. Subgroup analysis stratified by the number of co-medication

We conducted subgroup analysis to examine the PIM effects stratified by the numbers of co-medication. All results remained similarly significant in hospitalization and ED visits but the PIM effects seemed to decrease gradually depending on the increasing number of co-medications demonstrating that PIM and polypharmacy collectively affected the outcome events (Table 6).

3.5. Sensitivity analysis

We also performed a sensitivity analysis to confirm the robustness of the results of this study, using only the first exposure episode and its outcome. We found a similar trend in all risk estimations for the outcome events. After adjusting for time-variant covariates, the model remained significant in all evaluations, and the magnitude of the risk was similar to the results including all recurrent exposures, as presented in Table 7.

4. Discussion

In this study, we found that compared to the non-exposure period, the risk of hospitalization and ED visits increased by 1.99 and 1.41 times during the exposure and post-exposure periods using the SCCS model after adjusting for potential time-variant covariates over an average of 1,352 follow-up d (3.70 y). These results were similar to, albeit with a bit of reduced risk, that of a previous Korean study that reported that the risk of hospitalization (odds ratio 2.25, 95% CI 2.09–2.44) and ED visits (odds ratio 1.59, 95% CI 1.50–1.67) was higher in older adults who took at least one PIM than in controls (24). The slight difference may be due to variations in the study design and subject characteristics, and older adults included in this

TABLE 3 Risk of hospitalization and ED visit associated with PIM use.

Period	Number of events	Person-years	Incident rate (95% CI)	Crude IRR	Adjusted IRR
All events (n=43,9	142)				
Non-exposure	56,572	113,098	0.5 (0.5, 0.5)	1	1
Exposure	33,644	31,384	1.07 (1.06, 1.08)	2.14 (2.11, 2.17)	1.99 (1.95, 2.03)
Post-exposure	12,797	18,129	0.71 (0.69, 0.72)	1.41 (1.38, 1.44)	1.41 (1.37, 1.44)
Hospitalizations (n =38,701)				
Non-exposure	44,071	98,711	0.45 (0.44, 0.45)	1	1
Exposure	27,247	28,462	0.96 (0.95, 0.97)	2.14 (2.11, 2.18)	2.01 (1.97, 2.04)
Post-exposure	10,822	15,869	0.68 (0.67, 0.69)	1.53 (1.5, 1.56)	1.55 (1.52, 1.59)
ED visits (n =12,69	95)				
Non-exposure	12,501	32,661	0.38 (0.38, 0.39)	1	1
Exposure	6,397	9,416	0.68 (0.66, 0.7)	1.77 (1.72, 1.83)	1.69 (1.6, 1.79)
Post-exposure	1,975	5,501	0.36 (0.34, 0.37)	0.94 (0.89, 0.98)	0.89 (0.83, 0.95)

^{*}IRR and 95% CI were estimated using Poisson regression model. §Adjusted IRR was presented by adjusting for age group, insurance, income, long-term care, disability, CCI score, comorbidity, and co-medication information by the year change.

TABLE 4 Risk of hospitalization and ED visits associated with PIM use by segmented exposure period.

Period	Number of events	Person-years	Incident rate (95% CI)	Crude IRR	Adjusted IRR
All events ($n = 43$,942)				
Non-exposure	56,572	113,098	0.5 (0.5, 0.5)	1	1
Exposure1	11,220	6,860	1.64 (1.61, 1.67)	3.27 (3.2, 3.34)	3.29 (3.21, 3.37)
Exposure2	3,855	3,461	1.11 (1.08, 1.15)	2.23 (2.16, 2.3)	2.2 (2.12, 2.28)
Exposure3	4,298	4,048	1.06 (1.03, 1.09)	2.12 (2.06, 2.19)	2.04 (1.97, 2.11)
Exposure4	14,271	17,015	0.84 (0.83, 0.85)	1.68 (1.65, 1.71)	1.46 (1.42, 1.5)
Post1	7,591	9,121	0.83 (0.81, 0.85)	1.66 (1.62, 1.7)	1.69 (1.65, 1.74)
Post2	5,206	9,008	0.58 (0.56, 0.59)	1.16 (1.12, 1.19)	1.17 (1.14, 1.21)
Hospitalizations	(n = 38,701)				
Non-exposure	44,071	98,711	0.45 (0.44, 0.45)	1	1
Exposure1	9,110	6,053	1.5 (1.47, 1.54)	3.37 (3.3, 3.45)	3.39 (3.31, 3.47)
Exposure2	3,104	3,089	1.01 (0.97, 1.04)	2.25 (2.17, 2.33)	2.22 (2.14, 2.31)
Exposure3	3,481	3,652	0.95 (0.92, 0.98)	2.13 (2.06, 2.21)	2.06 (1.99, 2.14)
Exposure4	11,552	15,668	0.74 (0.72, 0.75)	1.65 (1.62, 1.69)	1.45 (1.41, 1.49)
Post1	6,460	7,984	0.81 (0.79, 0.83)	1.81 (1.77, 1.86)	1.85 (1.79, 1.9)
Post2	4,362	7,885	0.55 (0.54, 0.57)	1.24 (1.2, 1.28)	1.26 (1.22, 1.3)
ED visits (n =12,6	595)				
Non-exposure	12,501	32,661	0.38 (0.38, 0.39)	1	1
Exposure1	2,110	2,066	1.02 (0.98, 1.06)	2.67 (2.55, 2.79)	2.65 (2.48, 2.82)
Exposure2	751	1,031	0.73 (0.68, 0.78)	1.9 (1.77, 2.05)	1.89 (1.72, 2.07)
Exposure3	817	1,200	0.68 (0.63, 0.73)	1.78 (1.66, 1.91)	1.74 (1.59, 1.9)
Exposure4	2,719	5,119	0.53 (0.51, 0.55)	1.39 (1.33, 1.45)	1.27 (1.19, 1.37)
Post1	1,131	2,768	0.41 (0.38, 0.43)	1.07 (1, 1.13)	1.06 (0.98, 1.14)
Post2	844	2,733	0.31 (0.29, 0.33)	0.81 (0.75, 0.87)	0.79 (0.73, 0.87)

*IRR and 95% CI were estimated using Poisson regression model. \$Adjusted IRR was presented by adjusting for age group, insurance, income, long-term care, disability, CCI score, comorbidity, and co-medication information by the year change. #Exposure1(day0-day14), exposure2 (day15-day28), exposure3 (day29-day56), and exposure4 (day57-day_end).

TABLE 5 Information of exposures and risk of hospitalization and ED visits by PIM category.

PIM exposures by PIM category	
Anticholinergics (N, %)	36,349 (82.72)
Cardiovascular (N, %)	2,346 (5.34)
Central nervous system (N, %)	17,625 (40.11)
Gastrointestinal (N, %)	23,785 (54.13)
Pain medications (N, %)	39,322 (89.49)
Other PIM (N, %)	6,583 (13.98)

^{*}Other PIM categories included anti-infectives, antithrombotics, genitourinary, and endocrine medications.

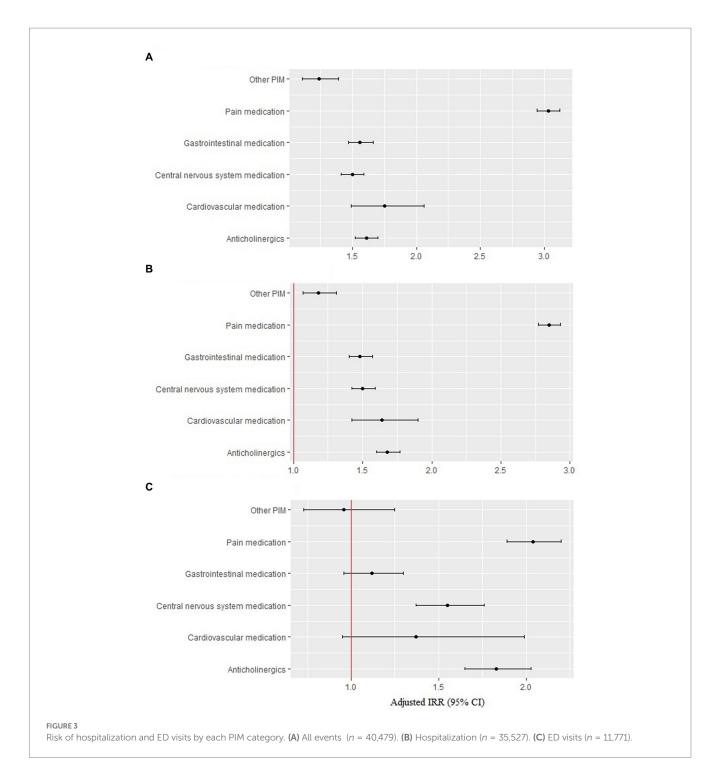
study may have been comparatively healthier at cohort enrollment because they were required to satisfy the 6 month non-PIM user criteria (see Figure 1).

The US retiree health care data presented similar risk with this study that taking one or more of the PIM by Beers or NCQA lists were 1.8 to 1.9 times more likely to have a hospital admission after adjusting for age, sex, number of prescriptions overall, and comorbid disease severity (25). The recent systemic review and meta-analysis also

reported that PIM was associated with increased odds of adverse drug event-related hospital admissions (adjusted OR 1.91, 95% CI 1.21–3.01) (26).

In total, older adults in this study had 261 d (0.72 per y) of PIM exposure, and had multiple exposure periods, mean number of exposure periods was 5.67 during the whole study period meaning PIM prescriptions were predominant, recurrent, and consistent. The risk of all outcomes decreased gradually when the exposure period was divided by PIM prescription days. Exposure 1 (day 1–14) had the highest risk of outcome events, presenting 3.29 times increased risk, which reduced gradually to 1.17 times in post exposure period 2. Based on these findings, older adults who tolerated longer periods of PIM prescriptions might have a reduced risk of hospitalization or ED visits attributable to PIM. Residual effects still existed, given that the post-exposure period also showed an increased risk. Therefore, follow-up monitoring is still needed after discontinuation of PIM in older adults, and close monitoring and introduction of patient education regarding PIM-related adverse events should be practiced in the early period of PIM prescriptions in older adults.

The highest risk was caused by pain medication, which was prescribed to 89.5% of older adults, followed by anticholinergics (82.72%) and then GI tract medications (54.13%).



Pain medications included nonsteroidal anti-inflammatory drugs (NSAID), muscle relaxants, and narcotic analgesics (pethidine and pentazocine). Clinical guidelines from medical societies, including the American Geriatric Society (AGS), recommend using NSAIDs with caution and limiting their use to the lowest effective dose and shortest duration. When NSAIDs are used, common gastrointestinal, renal, and cardiovascular side effects should be routinely monitored (27–29). Chronic use of all NSAIDs, including high dose aspirin, should be avoided because of the risk of gastrointestinal bleeding (30), which was four fold in the older adults (31). High cardiovascular risk (32) and renal side effects of NSAIDs are major concerns in older adults owing

to vasoconstriction and reduced renal perfusion via inhibition of prostaglandin and thromboxane synthesis by NSAID. It can eventually induce electrolyte imbalance, edema, high blood pressure, chronic kidney disease, acute interstitial nephritis, and renal papillary necrosis, and reduce the glomerular filtration rate (33). However, NSAID-induced gastroduodenal ulcers can be prevented by the use of GI protective agents, such as misoprostol, H2-receptor antagonists (H2RA), or proton pump inhibitors (PPI) (34). This might explain why a high rate of GI medications were prescribed to older adults in this study.

Gastrointestinal drugs are composed of gastric antispasmodic metoclopramide and proton pump inhibitors (PPI,

TABLE 6 Subgroup analysis by number of comedication.

Periods		Adjusted IRR by number	of comedication group	
	0 (n=12,622)	1-4 (n=19,136)	5-9 (<i>n</i> =10,222)	10+ (n=1,962)
All events				
Non-exposure	1	1	1	1
Exposure	2.24 (2.19, 2.3)	2.18 (2.14, 2.23)	1.85 (1.8, 1.9)	1.62 (1.54, 1.71)
Post-exposure	1.44 (1.39, 1.49)	1.42 (1.38, 1.46)	1.47 (1.41, 1.52)	1.35 (1.24, 1.46)
Hospitalizations				
Non-exposure	1	1	1	1
Exposure	2.26 (2.19, 2.33)	2.19 (2.14, 2.24)	1.87 (1.82, 1.93)	1.57 (1.48, 1.66)
Post-exposure	1.59 (1.53, 1.66)	1.53 (1.48, 1.58)	1.6 (1.54, 1.67)	1.39 (1.28, 1.52)
ED visits				
Non-exposure	1	1	1	1
Exposure	1.86 (1.76, 1.97)	1.84 (1.75, 1.93)	1.55 (1.46, 1.64)	1.55 (1.37, 1.76)
Post-exposure	0.91 (0.83, 0.99)	0.97 (0.9, 1.04)	0.94 (0.85, 1.03)	1.01 (0.82, 1.24)

TABLE 7 Sensitivity analysis using only first exposure episode.

Periods	All events (<i>r</i>	n=43,942)	Hospitalizatio	ons (n=38,701)	ED visits (r	=12,695)
	Crude IRR	Adj. IRR	Crude IRR	Adj. IRR	Crude IRR	Adj. IRR
3-levels						
Non-exposure	1	1	1	1	1	1
Exposure	2.19 (2.14, 2.25)	1.97 (1.88, 2.06)	2.22 (2.15, 2.28)	2 (1.92, 2.09)	1.68 (1.58, 1.78)	1.58 (1.39, 1.81)
Post-exposure	1.54 (1.48, 1.60)	1.49 (1.41, 1.57)	1.67 (1.6, 1.75)	1.66 (1.58, 1.75)	0.98 (0.88, 1.08)	0.89 (0.75, 1.06)
7 levels						
Non-exposure	1	1	1	1	1	1
Exposure1	4.12 (3.95, 4.30)	4.07 (3.86, 4.29)	4.31 (4.11, 4.51)	4.3 (4.09, 4.53)	3.12 (2.82, 3.45)	3.01 (2.57, 5.53)
Exposure2	2.6 (2.41, 2.79)	2.43 (2.23, 2.65)	2.62 (2.41, 2.84)	2.49 (2.28, 2.72)	2.2 (1.86, 2.6)	2.1 (1.66, 2.68)
Exposure3	2.3 (2.14, 2.47)	2.08 (1.92, 2.27)	2.38 (2.2, 2.57)	2.18 (2, 2.38)	1.68 (1.41, 2.01)	1.58 (1.26, 1.98)
Exposure4	1.62 (1.56, 1.67)	1.37 (1.29, 1.44)	1.61 (1.55, 1.68)	1.37 (1.3, 1.44)	1.24 (1.14, 1.35)	1.13 (0.98, 1.31)
Post1	1.9 (1.8, 2)	1.9 (1.78, 2.02)	2.09 (1.98, 2.21)	2.12 (2, 2.25)	1.11 (0.97, 1.27)	1.06 (0.87, 1.28)
Post2	1.18 (1.11, 1.26)	1.17 (1.08, 1.26)	1.25 (1.17, 1.34)	1.27 (1.17, 1.36)	0.84 (0.72, 0.99)	0.8 (0.64, 0.98)

^{*}Exposure1(day0-day14), exposure2 (day15-day28), exposure3 (day29-day56), and exposure4 (day57-day_end).

dexlansoprazole, esomeprzole, etc.). Gastrointestinal antispasmodic drugs are highly anticholinergic, but still play many roles in the treatment of older adults. Proton pump inhibitors were also sometimes prescribed to patients without gastrointestinal hemorrhage or peptic ulcers (4).

Anticholinergic-acting medications are commonly prescribed to approximately one-third of older adults in the primary care population (35). In fact, a study using the Beers criteria found that 39.9% of older adults with dementia on an outpatient basis were prescribed anticholinergic drugs classified as potentially inadequate (36). The side effects of anticholinergic drugs are related to their action on central and/or peripheral cholinergic receptors (37) and vary depending on the anticholinergic drug load and individual vulnerability. Anticholinergics are associated with chronic comorbidities (38), urinary incontinence, arterial hypertension (39), impaired health status, and anxiety and mood disorders (40). In addition, anticholinergics are associated with worse cognitive and functional performance in a dose-response pattern (41). Among patients with

mild cognitive impairment (MCI) or dementia treated in memory clinics, 44.7% were taking anticholinergic drugs, and 11.7% received a high anticholinergic load (42). Given that the burden of Alzheimer's disease and dementia is increasing rapidly worldwide due to aging (43), anticholinergic prescriptions in older adults will require additional safety precautions.

However, for certain clinical syndromes, the benefits of anticholinergics are greater than their risks, and their prescription can be considered adequate for the older adults in some cases, such as psychotropic drugs (35). In nursing homes, the most prevalent anticholinergics were cardiovascular drugs, followed by antipsychotics and antidepressants (44, 45).

Deprescribing is the process of tapering or stopping drugs to minimize polypharmacy and improve patient outcomes. Evidence for the efficacy of deprescribing has emerged from randomized trials and observational studies. The main strategies are drug reconciliation, drug prioritization by benefit-risk assessment, implementation of discontinuation regimens, and patient monitoring plans (46, 47).

Based on a previous study, the willingness of older adults with polypharmacy towards deprescribing was not associated with PIM use. These results suggest that patients may be unaware of PIMs. This implies the need to raise patients' awareness about PIMs through education to implement deprescribing in daily practice (48). Interestingly, in this study, when we stratified the PIM use outcomes by the number of co-medications, the PIM effects on the outcome of interests were attenuated by the increased number of co-medications. This result implies that not only PIM but also polypharmacy collectively results in adverse drug events in older adults which warrants further consideration of deprescribing strategy.

Meanwhile, several randomized clinical trials have demonstrated the efficacy of pharmacist interventions in correcting PIMs (49, 50), long-term discontinuation of PIMs (51), and reduction in the number of medications prescribed (52). As the prevalence and type of PIMs vary by country and healthcare setting (53), contextualized measures based on these variations should be developed in each country.

We implemented the SCCS method, which provided an alternative epidemiological study design to investigate the association between transient exposure and an outcome event. The method allows only cases to be included in the study and has the advantages that no separate controls are required and any fixed confounder is automatically controlled (21). We observed an increased risk in hospitalizations and ED visits in older adults due to PIM use and risk differentiation in PIM categories and PIM exposure period stratification.

Nevertheless, the study has several limitations. First, since we selected patients who did not have a PIM prescription for 6 months before cohort enrollment to account for new PIM users, the enrolled individuals were comparatively healthy with low CCI scores and low rates of chronic complex conditions. Thus, the results of this study may be an underestimation of real-world effects. Second, due to the base of SCCS only comprising cases can have limitations such as not portraying the comparison from control subjects. Third, we sought to represent the general overview of PIM outcomes in older adults using PIM categories in the Beers criteria 2019 (Supplementary Table S1), however, the other criteria in others in Beers 2019 should be studied further as well to delineate PIM use outcomes in older adults in detail. Fourth, we used the psychiatric drug prescription record to capture psychiatric diseases due to the limitation of insurance claim data which does not provide highly confidential psychiatric disease ICD codes in Korea, which might overestimate the numbers of comorbid psychiatric diseases in our datasets based on potential off-label use of psychiatric drugs. We tried to find the off-label psychiatric drug use trend in older adults in Korea, however only articles on off-label antidepressant use among adolescents and pediatric patients were found (54–56). They reported prevalent off-label antidepressant use in these populations, and we can assume off-label psychiatric drug use might be prevalent in older adults as well as reported by previous studies from other countries (57, 58). However, the adjusted model overall presented similar results to the unadjusted model in this study, the covariate overestimation might not count toward altering the results. Finally, due to the nature of recurrent PIM use in older Korean adults, the essential SCCS requirement that exposure should not affect subsequent exposures was not fully guaranteed. However, by performing sensitivity analyses by only including the first PIM exposure, we portrayed results similar to those of the analysis with recurrent and consistent PIM exposures.

5. Conclusion

Hospitalization and ED visits were greatly increased following PIM use in older adults. Thus, close monitoring of PIM use in older adults and implementation of deprescribing strategies for PIM use in the future are strongly recommended.

Data availability statement

Publicly available datasets were analyzed in this study. This data can be found here: https://nhiss.nhis.or.kr/bd/ab/bdaba022Oeng.do National Health Insurance Service-Elderly Cohort Database (NHIS-ECDB).

Author contributions

JL: conceptualization, data analysis, and manuscript revision. SohJ: conceptualization, manuscript draft, and revision. SuhJ: conceptualization and manuscript revision. SunJ: funding acquisition, conceptualization, and manuscript revision. All authors contributed to the article and approved the submitted version.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

The Supplementary material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpubh.2023.1080703/full#supplementary-material

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Bidirectional association between functional disability and multimorbidity among middle-aged and older adults in Thailand

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Objectives: The purpose of this study was to assess the bidirectional association between multimorbidity (MM) and functional disability among middle-aged and older adults in a longitudinal study in Thailand.

Methods: We analyzed longitudinal data of participants aged 45 years and older from two consecutive waves (in 2015 and 2017) of the Health, Aging, and Retirement in Thailand (HART). Functional disability was assessed with a 4-item activity of daily living (ADL) scale. Logistic regression analysis was conducted to assess the association between baseline functional disability and incident MM (\geq 2), and baseline morbidity and incident functional disability.

Results: The results indicate that a total of 1,716 individuals without morbidity at baseline and 3,529 without functional disability at baseline were included. At follow-up, 16.7 and 20.0% of functional disability cases and 7.1 and 3.6% of nonfunctional disability cases developed 2 morbidities and 3 or more morbidities, respectively, and 6.6% of MM cases and 4.0% of non-MM cases developed a functional disability. In the final logistic regression model adjusted for education, income, age, marital status, sex, smoking tobacco, body mass index (BMI), alcohol use, physical activity, and social engagement, functional disability at baseline was positively associated with incident MM (\geq 2) (adjusted odds ratio [aOR]: 2.58, 95% CI: 1.42–4.72), and MM (\geq 3) at baseline was positively associated with incident functional disability (aOR: 1.97, 95% CI: 1.13–3.43).

Conclusion: Multimorbidity and functional disability were bidirectionally associated.

KEYWORDS

multimorbidity, functional disability, longitudinal study, Thailand, bidirectional

Introduction

There has been a demographic and epidemiological transition that has increased aging and noncommunicable diseases in low- and middle-income countries (LMICs) (1) such as Thailand (2-5). This may include multimorbidity (MM) (co-existence of >2 chronic conditions) and functional disability in LMICs, including Thailand, which are an increasing burden on the healthcare systems (6-13). In a study among aging adults in six LMICs (i.e., China, India, Ghana, South Africa, Mexico, and Russia), the prevalence of MM was 45.5% (based on conditions: "angina, arthritis, asthma, chronic back pain, chronic lung disease, diabetes, edentulism, hearing problems, hypertension, stroke, visual impairment") (14), and among older adults (≥50 years) in the six LMICs, the prevalence of MM (based on "arthritis, stroke, angina, diabetes, chronic lung disease, asthma, and hypertension") was 17.4% in China, 25.2% in India, 16.6% in Ghana, 23.4% in South Africa, 45.3% in Mexico, and 23.6% in Russia (15). In a small community-based study among older adults (≥60 years) in southern Thailand, the prevalence of MM was 16.8% (16) and in national surveys, among older adults (≥60 years) in 2007 the prevalence of MM was 14.7% ("hypertension, heart disease, diabetes, cancer, stroke, and paralysis") (17) and in 2018, 30.4% (MM: "cancer, diabetes, hypertension, stroke, asthma, or another self-named chronic disease) (18).

According to the World Health Organization (19), 15% of the global population is estimated to be disabled in 2011 (19). Among older adults (≥50 years) in the six LMICs, the prevalence of functional disability (1+ activities of daily living [ADLs] limitation) ranged from 16.2% in China to 55.7% in India (15). In a national survey among people aged 60 years and older in Thailand in 1997, the prevalence of long-term disability was 19% (20). Among older adults (60 years) in Thailand in 2011, 2.7% had difficulty with the ADL item dressing and 2.2% with eating (21); in 2014 and 2017, 7.6% had difficulty with at least one (of 8) ADL item (22, 23). In a small study in rural Thailand, the prevalence of severe disability among older adults was 11.9% (24).

Multimorbidity is implicated in various negative health outcomes, such as increased mental morbidity, disability, increased healthcare utilization, adverse drug events, and death (7, 25–27). Similarly, functional disability is associated with increased hospitalization (28), poor self-rated quality of life (29), and mortality (30, 31). Previous studies have shown that demographic factors, such as older age and female sex (32), lower socioeconomic status (6, 9), and lifestyle factors, such as smoking (33), alcohol use (32, 33), physical inactivity (32, 34), body weight status and obesity (32, 35), and lack of social engagement (36, 37) were associated with MM. Furthermore, demographic factors, such as older age (15, 29) and female sex (29, 38, 39), lower socioeconomic status (38, 40), lifestyle factors,

such as smoking (41), alcohol use (42), physical inactivity (40, 43, 44), body weight status and obesity (40, 41), low social capital (15) and low social interaction (44) were associated with functional disability.

Most studies have investigated MM and incident functional disability (45-48), but few studies have investigated functional disability and incident MM, and bidirectional associations between MM and functional disability (7, 49). A study on the bidirectional association between MM and functional disability among older adults in China (including the chronic conditions: "hypertension, diabetes, cancer, chronic lung disease, cardiovascular disease, emotional or psychiatric disease, stomach or other digestive diseases, arthritis or rheumatism, kidney disease, liver disease, memory-related disease, and asthma") and Europe (including 9 diseases: "hypertension, diabetes, cancer, chronic lung disease, cardiovascular disease, emotional of psychiatric disease, stomach or duodenal ulcer, and arthritis or rheumatism") (7) found that across 2 longitudinal studies, functional disability and MM were bidirectionally associated. In the China (CHARLS) and Europe (SHARE) study, nationally representative cohorts were followed from 2011 to 2015, showing that participants with ADL/IADL disability at baseline were at a higher risk of developing MM and people with MM at baseline were at a higher risk of developing ADL/IADL disability in a dose-response fashion (7). Several longitudinal studies have investigated the determinants of MM and functional disability separately (49, 50), rather than studying both simultaneously (49). It is suggested that shared modifiable risk for both MM and functional disability exist, which should be further investigated (49).

To gain better knowledge of the association between MM and functional disability in Southeast Asia, the aim of this study was to assess the bidirectional association between MM and functional disability among middle-aged and older adults in a longitudinal study in Thailand. In particular, the study had two objectives, namely, (1) to estimate the association between functional disability at baseline and incident MM and (2) to estimate the association between morbidity counts at baseline and incident functional disability.

Methods

Participants and procedure

This study analyzed longitudinal data from two consecutive waves (2015 and 2017) of the Health, Aging, and Retirement in Thailand (HART). In a national sample from five regions and Bangkok and its vicinity, one adult (\geq 45 years) per household was randomly selected using a multistage sampling design [refer to (51) for further details]. The 2015 (N=5,616) and 2017 surveys included 3,708 members of the 2015 HART cohort (92 died during a follow-up or 4.3% of the baseline respondents

were in the study area; 1,554 moved away from the study area; 270 declined participation; and the response rate: 72.3% and the retention rate: 66.03%). A total of 3,708 participants who responded to the 2015 and 2017 surveys were included in the study, and 3,646 had complete information on our variables of interest (MM and functional disability). Participants were interviewed at their homes by trained field workers using the paper-and-pencil (PAPI) questionnaire in wave 1 and computer-assisted personal interviewing (CAPI) in wave 2.

Measures

Outcome variables

Chronic physical conditions were evaluated by self-reported healthcare provider diagnosed conditions, including hypertension, diabetes, lung diseases, emphysema, cardiovascular diseases, heart disease, heart failure, rheumatism, arthritis, bone diseases, low bone density, osteoporosis, kidney diseases, cancer, liver diseases, emotional/nervous or psychiatric disease, brain diseases, Alzheimer's disease, and visual and hearing impairment. MM was defined as having two or more chronic diseases, and non-MM as having none or one physical chronic disease.

Functional disability was measured based on a 4-item (eating, bathing, dressing, and washing) modified ADL index (52). Responses ranged from 0 = "able to do it all by myself" to 3 = "need help for all steps." Functional disability was defined as any of the four items not being able to do all by themselves (Cronbach's $\alpha = 0.94$ at wave 1 and 0.90 at wave 2).

Covariates

Sociodemographic data included educational level, sex, age, marital status, and income quartile. Education was grouped into (1) no formal education, (2) elementary school, and (3) more than elementary school (middle school, high school, vocational diploma or 2-year diploma degree, bachelor's degree, or higher than bachelor's degree). "The income quartile was calculated based on annual income from employment, own business, agricultural/livestock/fishing business, short-term or contract work, financial support from family, remuneration/pension income from the government fund, occupational pension fund, private pension fund, social security/welfare income, income e from government living allowance, veteran's welfare benefit, other welfare assistance income, and income from other sources, into four groups 1 = 0 to <13,000 Thai Baht, 2 = 13,000 to $<50,000, 3 = 50,000 \text{ to } <140,000, 4 = \ge 140,000 \text{ Thai Baht}$ (Average exchange rate in 2015: 1 US=34.2 Baht)" (53).

Tobacco smoking was sourced from the item, "Have you ever smoked cigarettes?" (response options: "1 = yes, and still smoke now, 2 = yes, but quit smoking, and 3 = never").

Alcohol use was assessed with the question, "Have you ever drunk alcoholic beverages such as liquor, beer, or wine?" (response options: 1 = yes, and still drinking now, 2 = yes, but do not drink now, and 3 = never).

Past week physical activity or exercise (frequency: "How often do you exercise?" (days a week) and duration of any type: "On the day you exercise, how long do you exercise?" (minutes) (54)) was grouped into "none = inactivity, 1–149 min/week = low activity, and ≥150 min/week = high activity." (55).

Body mass index (BMI) was based on self-reported body weight and height and was classified using Asian cutoff criteria into "underweight ($< 18.5 \text{ kg/m}^2$), normal weight ($18.5-22.9 \text{ kg/m}^2$), overweight ($23-24.9 \text{ kg/m}^2$), and obesity ($25+\text{kg/m}^2$)" (56).

Social engagement included six items of formal and one item of informal social engagement (defined as at least one activity in the past month) (53, 57). Formal social engagement included religious, occupational, and cultural organizations; alumni or parent association or association of people from the same hometown; volunteer; and political organizations. Responses were coded as "1 = daily to at least once a month" and "0 = once a year or never." Informal social engagement was determined with the following questions: (1) "In the past year, do you have any close friends or relatives who live nearby and have a close relationship with? (Please refer to the only person whom you meet most often)" and (2) "If so, how often do you meet with them in person (number of times per day, week, month, year, other, never)?" Informal social engagement was defined as "1 = having a close friend or relative who lives nearby and have a close relationship with and having met that person at least in the past 1 month" and "0 = not having a close friend or relative or meeting a close friend less than once a month in the past year" (53).

Data analysis

The proportion of older adults with incident MM (those who have MM at wave 2 and are without morbidity at wave 1) and incident functional disability (those who have a functional disability at wave 2 and are without functional disability at wave 1) is presented with frequencies and percentages. Pearson's chisquare tests are used to compare baseline characteristics among groups. The first logistic regression model estimated odds ratios (ORs) and confidence intervals (CIs) between functional disability at baseline and incident MM, and the second model compared morbidity counts at baseline and incident functional disability. Three models are presented for incident MM and incident functional disability. The first model is unadjusted; in the second model, adjustments are made for age, income, sex, education, and marital status, and in the third model, adjustments are made for model 2 variables plus smoking, physical activity, BMI, alcohol use, and social engagement. The selection of covariates is based on a previous review of the literature (6–8, 14, 15, 25, 29, 32–44). A value of $p \le 0.05$

was considered statistically significant. All statistical analyses were performed using StataSE version 15.0 (College Station, TX, USA).

Results

Baseline sample characteristics

The analytic baseline sample included 3,638 individuals aged 45 years and older. The prevalence of MM was 23.5%, and the prevalence of functional disability was 3.2%. Both MM and functional disability increased with age, decreased with higher education, decreased with higher income, decreased with alcohol use and smoking, and decreased with being married or cohabiting. MM was higher in women than in men but functional disability did not differ by sex. MM increased with increased body weight and functional disability was greater among those with underweight and who were physically inactive. The social engagement did not significantly differ by MM and functional disability (refer to Table 1).

Incident sample characteristics

In the first model that estimates incident morbidity, a total of 1,716 individuals without morbidity were included from baseline, with 30 (1.8%) having a functional disability at baseline. At follow-up, 16.7% and 20.0% of functional disability cases and 7.1 and 3.6% of nonfunctional disability cases developed 2 morbidities and 3 or more morbidities, respectively. Middleaged and older adults with functional disability at baseline had a significantly higher prevalence of morbidity counts at follow-up (p < 0.001). Those with higher incident morbidity counts were likely older, were unmarried, had less income, had no social engagement, and were not currently smoking tobacco or using alcohol than those without or with lower morbidity counts (refer to Table 2).

In the second model that estimates incident functional disability, a total of 3,529 individuals without a functional disability were included from baseline, with 1,115 (30.1%), 607 (16.4%), and 270 (7.3%) having 1, 2, and 3 or more morbidities at baseline. At follow-up, 6.6% of MM cases and 4.0% of non-MM cases developed a functional disability. Furthermore, 3.4% of 0, 4.9% of 1, 5.5% of 2, and 9.4% of 3 or more morbidity cases developed a functional disability. Middle-aged and older adults with physical MM at baseline had a significantly higher prevalence of functional disability at follow-up (p < 0.002), and those with higher morbidity counts at baseline had a significantly higher prevalence of functional disability at follow-up (p < 0.001). Those with incident functional disability were likely to be older, had lower education, were unmarried, had lower income, were not currently using alcohol, were less

physically active, and were more likely underweight than those without functional disability (refer to Table 3).

Odds ratios for bidirectional associations between functional disability and multimorbidity

In the final logistic regression model adjusted for education, income, age, marital status, sex, smoking tobacco, BMI, alcohol use, physical activity, and social engagement, functional disability at baseline was positively associated with incident MM (\geq 2) (adjusted OR [aOR]: 2.58, 95% CI: 1.42–4.72), and MM (\geq 3) at baseline was positively associated with incident functional disability (aOR: 1.97, 95% CI: 1.13–3.43) (refer to Table 4).

Discussion

The first longitudinal study investigates the bidirectional associations between MM and functional disability in Southeast Asia. Consistent with two studies in China and Europe (7), we found that MM (hypertension, diabetes, lung diseases, emphysema, cardiovascular diseases, heart diseases, heart failure, rheumatism, arthritis, bone diseases, low bone density, osteoporosis, kidney diseases, cancer, liver diseases, emotional/nervous or psychiatric diseases, brain diseases, Alzheimer's disease, and visual and hearing impairment) and functional disability were bidirectionally associated with middleaged and older adults in Thailand. These associations were independent of BMI, sex, marital status, age, education, income, smoking, physical activity, alcohol use, and social engagement.

We found some differences between the present study and the two previous studies (CHARLS and SHARE), namely, the associations between baseline functional disability and incident MM, and the associations between baseline MM and incident functional disability were weaker in this study than in CHARLS and SHARE (7). We believe that the major contributor to this difference was due to the significantly lower sample size in our study compared to CHARLS and SHARE, which includes a shorter follow-up period (2 years) compared to the CHARLS and SHARE study (4 years). In addition, although the type and number of morbidities and covariates assessed in this study were similar to CHARLS and SHARE, covariates in our study may have had a differential effect. For example, after including all covariates in the model, the effect of MM (3+) on functional disability was reduced from 2.9 to 2.0.

In a systematic review, the main consequences of MM were disability and functional decline (48), which may occur due to damage in multiple organs and systems (7, 58). Conversely, older adults with a functional disability may engage in less health behavior, such as physical activity, are less likely to

TABLE 1 Baseline sample characteristics, HART, 2015.

Variables	Subcategories	San	nple	Morl	oidity		Functional disability	
			1	2	≥3	P-value		P-value
		N (%)	N (%)	N (%)	N (%)		N (%)	
All		3,638	1,098 (30.2)	596 (16.4)	260 (7.1)		115 (3.2)	
Age (in years)	45-54	672 (18.5)	149 (22.2)	58 (8.6)	14 (2.1)	< 0.001	4 (0.6)	< 0.001
							11 (1.1)	
							20 (2.2)	
	55-64	985 (27.1)	295 (29.9)	142 (14.4)	41 (4.2)		80 (7.6)	
	66-74	926 (25.5)	300 (32.4)	166 (17.9)	81 (8.7)			
	75 or more	1,055 (29.0)	354 (33.6)	230 (21.8)	124 (11.8)			
Sex	Female	1,942 (53.4)	610 (31.4)	358 (18.4)	156 (8.0)	< 0.001	62 (3.2)	0.907
	Male	1,696 (46.6)	488 (28.8)	238 (14.0)	104 (6.1)		53 (3.1)	
Education	None	238 (6.6)	69 (29.0)	66 (27.7)	24 (10.1)	< 0.001	26 (10.9)	< 0.001
	Elementary	2,811 (77.4)	877 (31.2)	464 (16.5)	213 (7.6)		77 (2.7)	
	>Elementary	582 (16.0)	149 (25.6)	65 (11.2)	23 (4.0)		12 (2.1)	
Marital status	Not married	1,478 (40.6)	471 (31.9)	274 (18.5)	132 (8.9)	< 0.001	75 (5.1)	< 0.001
	Married/cohabiting	2,159 (59.4)	627 (29.0)	322 (14.9)	128 (5.9)		40 (1.9)	
Income quartile	Low	867 (23.8)	275 (31.7)	180 (20.8)	81 (9.3)	< 0.001	32 (3.7)	< 0.001
	Lower middle	922 (25.3)	329 (35.7)	176 (19.1)	75 (8.1)		55 (6.0)	
	Upper middle	952 (26.2)	248 (26.1)	136 (14.3)	68 (7.1)		20 (2.1)	
	High	897 (24.7)	246 (27.4)	104 (11.6)	36 (4.0)		8 (0.9)	
Alcohol use	Never	2,939 (80.8)	917 (31.2)	507 (17.3)	213 (7.2)	< 0.001	102 (3.5)	0.002
	Past	260 (7.1)	71 (27.3)	42 (16.2)	36 (13.8)		11 (4.2)	
	Current	439 (12.1)	110 (25.1)	47 (10.7)	11 (2.5)		2 (0.5)	
Smoking tobacco use	Never	2,912 (80.0)	915 (31.4)	498 (17.1)	210 (7.2)	< 0.001	97 (3.3)	< 0.001
	Past	287 (7.9)	91 (31.7)	47 (16.4)	33 (11.5)		16 (5.6)	
	Current	439 (12.1)	92 (21.0)	51 (11.6)	17 (3.9)		2 (0.2)	
Physical activity	None	2,112 (58.1)	599 (28.4)	362 (17.1)	158 (7.5)	0.180	94 (4.5)	< 0.001
	1-149 min/week	935 (25.7)	309 (33.0)	144 (15.4)	63 (6.7)		18 (1.9)	
	≥150 min/week	591 (16.2)	190 (32.1)	90 (15.2)	39 (6.6)		3 (0.5)	
Body mass index	Normal	1,230 (37.5)	357 (29.0)	163 (13.3)	68 (5.5)	< 0.001	39 (3.2)	< 0.001
	Under	352 (10.7)	103 (29.3)	59 (16.8)	22 (6.3)		24 (6.8)	
	Overweight	653 (19.9)	206 (31.5)	99 (15.2)	41 (6.3)		11 (1.7)	
	Obesity	1,041 (31.8)	322 (30.9)	207 (19.9)	103 (9.9)		21 (2.0)	
Social engagement	No	242 (6.7)	69 (28.5)	50 (20.7)	21 (8.7)	0.177	9 (3.7)	0.609
	Yes	3394 (93.3)	1028 (30.3)	546 (16.1)	239 (7.0)		106 (3.1)	

access and adhere to medical care independently, have a higher BMI, and experience more psychological distress than those without functional disability (7). Another possibility is that specific mechanisms of biological aging influence both MM and functional disability. For example, physical inactivity increases both MM and functional disability (49). This leaves the question of possible shared modifiable risk factors for both functional disability and MM, which is subject to further research.

This study found among individuals aged 45 years and older, a prevalence of MM of 23.5%, which is higher than in a study among older adults (\geq 60 years) in southern Thailand

(16.8%) (16) and in a national survey among older adults (\geq 60 years) in Thailand (14.7%) (17). The lower rate of MM in the latter study may be attributed to fewer morbidities (six) included in the survey (17). The prevalence of MM (23.5%) was higher than in China (17.4%) and Ghana (16.6%), similar to South Africa (23.4%) and Russia (23.6%), lower than in India (25.2%) and Mexico (45.3%) (15), and much lower than among predominantly older adults from six LMICs (45.5%) (14). Reasons for some of these differences are attributable to the different number of morbidities included; for example, in the six-country study, a lower prevalence of MM was

TABLE 2 Sample characteristics of participants with incident morbidity, Thailand, 2015–2017.

Variables	Subcategories		Incident r	norbidity		P-value
		0 (n = 1,118)	1 (n = 403)	2(n = 123)	$\geq 3 \ (n = 70)$	
		N (%)	$N\left(\% ight)$	N (%)	$N\left(\% ight)$	
Age (in years)	45-54	349 (76.5)	83 (18.2)	23 (5.0)	1 (0.2)	< 0.001
	55-64	357 (69.2)	118 (22.9)	29 (5.6)	12 (2.3)	
	66-74	231 (59.2)	99 (25.4)	35 (9.0)	25 (6.4)	
	75 or more	181 (51.4	103 (20.3)	36 (10.2)	32 (9.1)	
Sex	Female	560 (66.9)	179 (21.4)	60 (7.2)	38 (4.5)	0.196
	Male	558 (63.6)	224 (25.5)	63 (7.2)	32 (3.6)	
Education	None	51 (63.8)	20 (25.0)	3 (3.8)	6 (7.5)	0.409
	Elementary	839 (65.4)	293 (22.8)	97 (7.6)	54 (4.2)	
	>Elementary	226 (65.1)	88 (25.4)	23 (6.6)	10 (2.9)	
Marital status	Not married	377 (61.6)	148 (24.2)	50 (8.2)	37 (6.0)	0.006
	Married/cohabiting	740 (67.3)	254 (23.1)	73 (6.6)	33 (3.0)	
Income quartile	Low	229 (65.4)	74 (21.1)	29 (8.3)	18 (5.1)	0.036
	Lower middle	202 (58.9)	88 (25.7)	32 (9.3)	21 (6.1)	
	Upper middle	331 (65.5)	124 (24.6)	35 (6.9)	15 (3.0)	
	High	356 (69.0)	117 (22.7)	27 (5.2)	16 (3.1)	
Alcohol use	Never	858 (64.7)	307 (23.1)	101 (7.6)	61 (4.6)	0.044
	Past	67 (59.3)	34 (30.1)	6 (5.3)	6 (5.3)	
	Current	193 (70.4)	62 (22.6)	16 (5.8)	3 (1.1)	
Smoking tobacco use	Never	841 (64.1)	311 (23.7)	102 (7.8)	59 (4.5)	0.014
	Past	69 (59.0)	32 (27.4)	9 (7.7)	7 (6.0)	
	Current	208 (73.2)	60 (21.1)	12 (4.2)	4 (1.4)	
Physical activity	None	667 (65.7)	231 (22.8)	77 (7.6)	40 (3.9)	0.842
	1-149 min/week	270 (64.3)	100 (23.8)	30 (7.1)	20 (4.8)	
	≥150 min/week	181 (64.9)	72 (25.8)	16 (5.7)	10 (3.6)	
Body mass index	Normal	433 (66.7)	149 (23.0)	47 (7.2)	20 (3.1)	0.855
	Under	109 (63.7)	42 (24.6)	11 (6.4)	9 (5.3)	
	Overweight	197 (63.3)	79 (25.4)	20 (6.4)	15 (4.8)	
	Obesity	274 (65.9)	92 (22.1)	33 (7.9)	17 (4.1)	
Social engagement	No	58 (56.9)	24 (23.5)	16 (15.7)	4 (3.9)	0.007
	Yes	1,059 (65.9)	377 (23.4)	107 (6.7)	65 (4.0)	
Functional disability	No	1,092 (66.0)	386 (23.3)	117 (7.1)	59 (3.6)	< 0.001
	Yes	10 (33.3)	9 (30.0)	5 (16.7)	6 (20.0)	

found with fewer conditions, and in the same study, a higher prevalence was found with a higher number of MM (e.g., the inclusion of vision and hearing impairment). Moreover, a higher morbidity rate may be related to the symptom-based and physical measurements of morbidities, while our study relied only on self-reported healthcare provider diagnosed morbidities.

Furthermore, this study found among individuals aged 45 years and older, a prevalence of functional disability of 3.2% (4.3% of individuals aged 60 years and older), which is lower than in two national surveys in Thailand in 2014 and 2017 (7.6%) (22, 23). A major reason for the almost double higher prevalence of functional disability in these two latter surveys

compared to our study may be attributed to the difference in the number of items of the functional disability measure (our study only used 4 items, while the two surveys reported here used 8 items). Measuring functional disability with more items increases the likelihood of finding more functional limitations. Compared to these prevalence rates of functional disability in Thailand (<10%), much higher rates were found among older adults (\ge 50 years) in the six LMICs, namely, China (16.2%), India (55.7%), Ghana (44.0%), South Africa (38.6%), Mexico (38.8%), and Russia (43.1%) (15).

Furthermore, we found that consistent with previous research (6, 9, 15, 29, 32, 38, 40), both MM and functional

TABLE 3 Sample characteristics of participants with incident functional disability, Thailand, 2015-2017.

Variables	Subcategories	Incident funct	ional disability	P-value
		No $(n = 3364)$	Yes $(n = 163)$	
		N (%)	N (%)	
Age (in years)	45-54	656 (98.2)	12 (1.8)	< 0.001
	55-64	955 (97.8)	21 (2.2)	
	66-74	869 (95.8)	38 (4.2)	
	75 or more	884 (90.6)	92 (9.4)	
Sex	Female	1,790 (95.2)	90 (4.8)	0.616
	Male	1,574 (95.6)	73 (4.4)	
Education	None	196 (92.5)	16 (7.5)	0.003
	Elementary	2,604 (95.1)	133 (4.9)	
	>Elementary	558 (97.7)	13 (2.3)	
Marital status	Not married	1,321 (94.0)	84 (6.0)	0.002
	Married/cohabiting	2,042 (96.3)	79 (3.7)	
Income quartile	Low	782 (93.5)	54 (6.5)	< 0.001
-	Lower middle	814 (93.9)	53 (6.1)	
	Upper middle	900 (96.4)	34 (3.6)	
	High	868 (97.5)	22 (2.5)	
Alcohol use	Never	2,698 (95.0)	142 (5.0)	0.012
	Past	237 (94.8)	13 (5.2)	
	Current	429 (98.2)	8 (1.8)	
Smoking tobacco use	Never	2,688 (95.4)	129 (4.6)	0.747
	Past	257 (94.5)	15 (5.5)	
	Current	419 (95.7)	19 (4.3)	
Physical activity	None	1,915 (94.8)	105 (5.2)	0.002
	1-149 min/week	871 (94.9)	47 (5.1)	
	≥150 min/week	578 (98.1)	11 (1.9)	
Body mass index	Normal	1,135 (95.3)	56 (4.7)	0.011
•	Under	302 (92.1)	26 (7.9)	
	Overweight	623 (96.7)	21 (3.3)	
	Obesity	978 (95.7)	44 (4.3)	
Social engagement	No	225 (96.6)	8 (3.4)	0.371
	Yes	3,137 (95.3)	155 (4.7)	
Multimorbidity (≥2 vs. 0–1)	No	2,605 (96.0)	109 (4.0)	0.002
, := ,	Yes	759 (93.4)	54 (6.6)	
Multimorbidity	0	1,599 (96.6)	57 (3.4)	< 0.001
,	1	1,006 (95.1)	52 (4.9)	
	2	537 (94.5)	31 (5.5)	
	3 or more	222 (90.6)	23 (9.4)	

disability increased with age, decreased with higher education, and decreased with higher income. In line with previous studies (32), the prevalence of MM was higher in women than in men, while functional disability did not differ by sex, as found previously (29, 38, 39). The prevalence of MM and functional disability was higher among those who were physically inactive, which is consistent with previous research (32, 34, 40, 43, 44). Consistent with previous studies (32, 35), MM was higher

among those with a higher BMI (obesity) and consistent with a study in India (59), underweight was higher among those with functional disabilities. Furthermore, we found that past smoking and past alcohol use were higher among those with MM and functional disability, meaning that individuals with MM and/or functional disability may have stopped smoking and/or alcohol use. Contrary to some previous research (15, 36, 37, 44), we did not find that MM and functional disability decreased social

TABLE 4 Odds ratios for bidirectional associations between functional disability and multimorbidity (MM).

Baseline variable	Follow-up variable	Model	1	Mode	12	Model	3
		OR (95% CI)	P-value	OR (95% CI)	P-value	OR (95% CI)	P-value
Functional	MM	Odds ratios for the					
disability		association between					
		functional disability					
		at baseline and					
		incident MM					
Yes	≥2	1 (Reference)	< 0.001	1 (Reference)	< 0.001	1 (Reference)	0.002
		2.32 (1.92-5.44)		2.47 (1.45-4.22)		2.58 (1.42-4.72)	
MM	Functional	Odds ratios for the					
	disability	association between					
		MM at baseline and					
		incident functional					
		disability					
0	No	1 (Reference)	0.058	1 (Reference)	0.459	0 (Reference)	0.325
1	Yes	1.45 (0.99-2.13)	0.035	1.16 (0.78-1.72)	0.404	1.23 (0.81-1.86)	0.593
2		1.62 (1.03-2.54)	< 0.001	1.22 (0.77-1.92)	0.012	1.15 (0.70-1.89)	0.017
3 plus		2.91 (1.76–4.81)		1.95 (1.16–3.26)		1.97 (1.13–3.43)	

Model 1: unadjusted; Model 2: adjusted for age, sex, marital status, education, and income; Model 3: adjusted for Model 2 variables plus body mass index, physical activity, smoking, alcohol use, and social engagement.

engagement. This result may be related to the overall very high prevalence of social engagement (>93%), and a stricter measure of social engagement could have produced different results.

Strengths and limitations of the study

The study used a national cohort study with large sample size and adjusted for various confounding social, health, and demographic factors. Study limitations include that MM was assessed by self-reported diagnosed chronic conditions, and functional disability was only measured with a modified shorter version of the ADL scale. We could have distinguished between milder and more severe functional disabilities due to the small sample sizes. Moreover, this study had a 2-year follow-up period, hindering us from measuring long-term associations.

Conclusion

Baseline MM (\geq 3) increases the risk of incident functional disability and baseline functional disability increases the risk of incident MM (\geq 2) among middle-aged and older adults in Thailand. Given these findings, health services should be reoriented to tailor interventions to people with MM to prevent and control future functional disabilities, and interventions targeting people with functional disabilities may help prevent and control MM in middle and late adulthood in Thailand.

Data availability statement

Publicly available datasets were analyzed in this study. This data can be found here: Data is publicly available at Gateway to Global Aging Data, Health, Aging, and Retirement in Thailand: https://g2aging.org/?section=study&studyid=44.

Ethics statement

The studies involving human participants were reviewed and approved by Ethics Committee in Human Research, National Institute of Development Administration—ECNIDA (ECNIDA 2020/00012). The patients/participants provided their written informed consent to participate in this study.

Author contributions

SP, KP, and DA contributed to the design, implementation of the research, and wrote the manuscript. KP analyzed the results. All authors contributed to the article and approved the submitted version.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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The implementation of community-based programs in Vietnam is promising in promoting health

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Background: Low-and middle-income countries mostly have ageing populations with many unmet economic, social, or health-related needs, Vietnam being an example. Community-based support in Vietnam, organized as Intergenerational Self-Help Clubs (ISHCs) based on the Older People Associations (OPA) model, can help to meet these needs by the provision of services for various aspects of life. This study aims to assess the implementation of the ISHCs and whether successful implementation is associated with more member-reported positive health.

Methods: We used the RE-AIM (*Reach, Effectiveness, Adoption, Implementation, and Maintenance*) framework to evaluate the implementation using multiple data sources: ISHC board surveys (n=97), ISHC member surveys (n=5,080 in 2019 and n=5,555 in 2020), focus group discussions (6; n=44), and interviews with members and board leaders (n=4).

Results: Reach ranged between 46 and 83% of ISHCs reaching target groups, with a majority of women and older people participating. Regarding Effectiveness, members indicated high satisfaction with the ISHCs. Adoption scores were high, with 74%–99% for healthcare and community support activities, and in 2019, higher adoption scores were associated with more members reporting good positive health. In 2020, reported positive health slightly decreased, probably due to the influence of the COVID-19 pandemic. A total of 61 ISHCs had consistent or improving Implementation from 2019 to 2020, and confidence in Maintenance was high.

Conclusion: The implementation of the OPA model in Vietnam is promising regarding its promotion of health and may help to tackle the needs of an ageing population. This study further shows that the RE-AIM framework helps to assess community health promotion approaches.

KEYWORDS

community-based programs, community-based health promotion, ageing, health promoting activities, positive health, older people associations, RE-AIM evaluation framework

1. Introduction

Community-based support for older people in low-and middleincome countries has proven to be promising in the promotion of wellbeing and socio-economic circumstances of older people (1). Ageing is a major global trend that transforms societies and healthcare around the world. This demographic trend proceeds more rapidly in low-income countries than in high-income countries (2) due to declining fertility and mortality as well as increased life expectancy (3). In the context of low-and middle-income countries, resources are often scarce, and policies and care to be provided are not yet specified for older populations, resulting in several challenges such as poor access to and availability of healthcare for older people (4). Vietnam is one of the top 10 countries that experiences the highest rate of population ageing (5, 6), with 12% of the total population being aged 60 years and older, and by 2050 this is expected to rise to more than 25% (7). The majority of older people have unmet economic, social, or health-related needs (8).

To meet the needs of an increasing group of older people, the concept of Older People Associations (OPAs) has been implemented throughout Southeast Asia (9). OPAs have a holistic approach, utilizing the resources and skills that older people have to provide effective social support and facilitate activities. OPAs focus on 10 overarching core areas, as shown in Figure 1; the OPAs' implementation is country specific. The theoretical basis of the OPAs relates to the concept of "Positive Health" (see Figure 1) (11). According to this positive health model, bodily functioning, mental wellbeing, meaningfulness, quality of life, participation, and daily functioning are all dimensions that establish personal health. The multifunctional approach of the OPAs is to organize activities and provide services to meet all of these "Positive Health" dimensions. After the initial success of OPAs in Cambodia in enhancing living conditions (8), neighboring countries started applying this model as well (12).

In Vietnam, OPAs are implemented as Intergenerational Self-Help Clubs (ISHCs) (13), which are co-created with the target groups, focusing on the potential of the areas and specific challenges of the community following the dimensions of positive health (12). The ISHC is a national model covering all provinces. Community members become engaged via community-orientated activities, i.e., village meetings or loudspeaker announcements. Five members are chosen per ISHC by other members to form the management board, and priority is given to female and older people and to people with economic or social disadvantages. The ISHCs receive support and resources from NGOs and local funds, such as training and equipment, to carry out activities, and they collaborate with commune health stations regarding health activities, such as screening. Their area of focus is determined in consultation with the members. ISHCs promote multiple aspects, such as psychosocial health, healthy and active lifestyles, economic development, rights and entitlements, and self-help and peer support, i.e., helping each other in the community and improving members' livelihoods. Moreover, ISHCs organize social, cultural, and self-reliance activities and offer legal support and

Abbreviations: ISHCs, Intergenerational Self-Help Clubs; OPA, Older People Associations; RE-AIM, Reach, Effectiveness, Adoption, Implementation, and Maintenance; FGD, Focus group discussion; e.g., exempli gratia—Latin phrase meaning "for example": i.e., id est—Latin phrase meaning "that is".

homecare volunteer-based services. The ISHCs can have effects on health if implemented properly. Relevant aspects of the implementation of ISHCs include reaching community members and specific target groups, representativeness, the perceived effects for the members, embracement of the ISHCs in the communities, implementation consistency, becoming part of routine organizational practices, and maintaining effectiveness. Apart from gray literature evaluations (14), scientific evidence on how ISHCs achieve this is mostly lacking.

The ISHCs' implementation aspects align with the dimensions of the RE-AIM framework (15). The RE-AIM framework is a planning and evaluation framework that addresses dimensions of individualand organizational-level outcomes that relate to program impact and sustainability, namely: Reach, Effectiveness, Implementation, and organizational and individual Maintenance (16) (see Figure 2). The RE-AIM framework has been developed to address issues, dimensions, and steps in the implementation process that can facilitate or impeded success and translate scientific evidence for public health and policy (15). RE-AIM includes a focus on the design, dissemination, and implementation process that can either facilitate or impede success in achieving a broad and equitable populationbased impact, which aligns with the OPA-model. This study has two aims: to assess (1) the implementation of the ISHCs with the use of the RE-AIM framework and (2) whether successful implementation is associated with more members reporting good positive health.

2. Methods

2.1. Study design

This mixed-method study was conducted among 97 ISHCs in nine provinces in the northern region of Vietnam in 2019 and 2020. Around 80% of the ISHCs were located in the countryside, 11% in an urban or semi-urban area, and 9% in a mountainous area. These ISHCs were established one to three years before the study took place. ISHC management board surveys and member surveys were conducted, and focus groups discussions (FGDs) and interviews were held with members and group leaders. Data were collected by HelpAge International (HAI), an international NGO involved in the implementation of the ISHCs. Multiple data sources were assessed to study the individual- and organizational-level outcomes of the ISHCs in 2019 and 2020 with both quantitative and qualitative data, yielding in-depth evidence on the RE-AIM and positive health dimensions. We applied the RE-AIM framework to address the first aim with ISHCs board surveys, FGDs, and interviews and the concept of positive health to address the second aim with the members surveys.

2.2. Sample and procedure

We assessed the two aims using four data sources, namely, ISHC management board surveys, member surveys, focus groups discussions (FGDs), and interviews.

2.2.1. ISHCs management and board surveys

The first source, the ISHCs management board surveys, incorporated surveys from 97 ISHCs performed in 2019 and 2020.



These surveys addressed the performances of the ISHCs, i.e., whether each club reached the targets that were set by HAI and the Vietnamese Association of the Elderly (VAE), a social organization that collaborates with HAI and supports the ISHCs. The survey had 19 indicators with specific targets (see Supplementary Table S1 for targets) that were set to ensure the ISHCs could operate sustainably and independently without support from HAI and VAE.

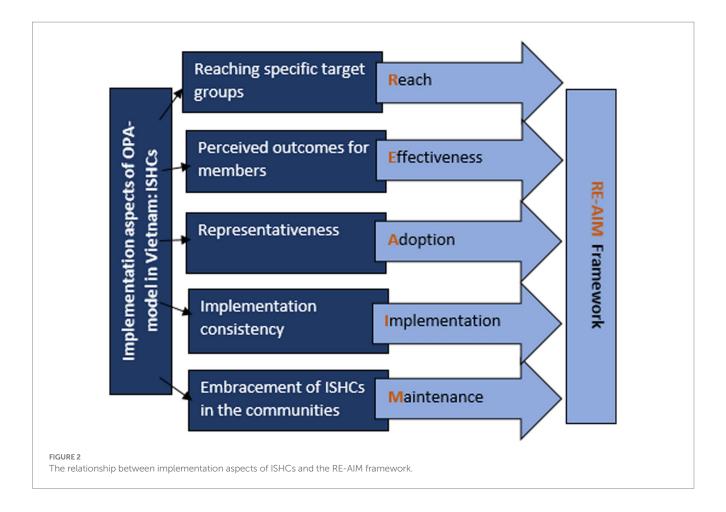
2.2.2. Members surveys

The second source, the members surveys, consisted of cross-sectional structured surveys of members of the same 97 ISHCs in 2019 (n=5,080) and 2020 (n=5,555). The questions addressed satisfaction with and outcomes of ISHCs membership regarding organized activities, such as "On a scale of $0(=not\ at\ all)$ to 10(=very) how much do you like the monthly organized meeting?," and positive health, such as "Do you think your health behavior changed due to participation in the ISHC?" All ISHC members were invited to participate in the survey. All questions of the survey concerned the previous 12 months of membership, and therefore, participants were included if they were a member for at least 1 year. Table 1 provides an overview of the background characteristics of the members who

filled in the surveys. The average age was 60 years, and in total, 22% in 2019 and 23% in 2020 were male. Two to 8% had a disability (2019: 8% and 2020: 2%), and almost 70% were poor to near poor (2019: 66% and 2020: 68%).

2.2.3. Focus group discussions and interviews

The third and fourth sources were six FDGs (n=44) and four interviews (n=4), respectively. The FGDs were held with a total of 44 participants, ranging between 3 and 12 participants per discussion and with ages between 53 years and 80 years. Participants were included if they were members, group leaders, or volunteers at ISHCs from a coastal area, a mountainous area, a rural area, an urban area, or two semi-urban areas. In total, there were 23 male and 21 female participants. The topics discussed in the FGDs were experiences and satisfaction of the members with participation, changes in life due to participation, barriers and facilitators to participation in the clubs, and future perspectives on their participation. The interviews were held with two chairpersons of the VAE, a health center official and an official at the Vietnamese Fatherland Front. Participants were included based on their involvement in the organization and management of the clubs. The topics discussed in the interview covered experiences



and perspectives on the organization, management, and sustainability of the ISHCs. The interviews and FGDs were held in 2019.

2.3. Measures

Table 2 gives an overview of the RE-AIM dimensions used to address the first aim, displaying the definition, data source, and operationalization of each dimension. We measured the dimension Reach by describing to what extent the ISHCs reached 70% female, 70% older, and 70% poor or disadvantaged people. Moreover, we measured **Effectiveness** in the qualitative studies as satisfaction with ISHCs, including rating satisfaction with participation in the ISHCs on a scale of 0-10 (0=not satisfied at all, 10=very satisfied). We measured the dimension Adoption as the extent to which the ISHCs achieved the targets set by VAE and HAI (see Supplementary Table S1 for targets). Furthermore, we measured Implementation as the differences in achieved targets over 2019 and 2020. Finally, we measured Maintenance as the experiences within the interviews (organizational level) with chairpersons and group leaders on the topics of management and sustainability and within the focus group discussions (individual level) with members on the topics of personal experiences and willingness to remain as members.

Table 3 gives an overview of the positive health dimensions used to address the second aim, displaying the belonging aspects and operationalization of each dimension. We measured **Bodily functioning** by perceived improved health behavior and improved

health status, which were recoded into improved health, Sense of purpose by improved perceived level of confidence, Participation by perceived improved feeling of unity/solidarity, Quality of life by perceived improved quality of life, Mental wellbeing by disability status (in hearing, seeing, mobility, remembering, focus, self-care, and communication) and Daily functioning by perceived improved rights and entitlement. All the variables were dichotomized. We further computed a summary measure of positive health by summing the scores on all the dimension variables and then dichotomizing these using the median as the cut-off, with a score equal to the median and above indicating good health. The variable Good Positive Health was created by the proportion of members reporting good positive health per ISHC. The implementation aspects Reach and Adoption were created by a summary measure of the operationalized indicators. Implementation was measured by the change of the overall adoption score from 2019 to 2020, which was categorized into decline (=0) and consistent or improvement (=1).

2.4. Analysis and reporting

2.4.1. Qualitative analysis and reporting

First, we reported on the implementation of the ISHCs following the dimensions of the RE-AIM framework. The dimensions *Effectiveness* and *Maintenance* were qualitatively analyzed by content analysis of the FGDs and interviews, in which the data were categorized, grouped, coded, and themed under effectiveness, positive

TABLE 1 Background characteristics of member surveys in 2019 and 2020 per province.

Provinces ^a	₽	2	33	4	2	9	7	∞	6	Total
Year					20	2019				
Male n (%)	89 (18)	137 (26)	144 (26)	129 (22)	165 (25)	131 (16)	130 (22)	83 (22)	124 (24)	1,123 (22)
Age µ (range)	60.2 (27–80)	59.4 (23–82)	61.5 (26–91)	62 (25–84)	56.4 (26-82)	60.5 (21–86)	60.3 (28–89)	64.4 (26–87)	58.7 (26–87)	60.2 (21–91)
Not/slightly disabled n (%)	484 (98)	480 (92)	464 (83)	497 (93)	639 (97)	730 (89)	519 (88)	333 (88)	515 (98)	4,611 (92)
Poor to near poor n (%)	488 (99)	329 (63)	379 (68)	412 (74)	442 (67)	495 (60)	365 (62)	306 (81)	350 (67)	3,367 (66)
Year					20	2020				
Male n (%)	115 (22)	145 (27)	149 (26)	123 (20)	164 (24)	184 (21)	146 (24)	146 (23)	126 (24)	1,298 (23)
Age μ (range)	60.6 (31-81)	60.9 (24–83)	62.3 (14-92)	63 (24–87)	57.7 (27–83)	60.1 (28–86)	61.2 (29-90)	62.7 (27–90)	60.1 (27-81)	60.9 (14-92)
Not/slightly disabled n (%)	513 (99)	538 (99)	540 (94)	594 (98)	654 (97)	854 (99)	(601 (99)	623 (97)	528 (99)	5,445 (98)
Poor to near poor n (%)	358 (69)	390 (72)	384 (67)	414 (68)	392 (58)	609 (71)	421 (69)	470 (73)	357 (67)	3,794 (68)
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Bac Ninh $(n = 495 \times 2019/n = 517 \times 2020)/2$. Hai Duong $(n = 521 \times 2019/n = 540 \times 2020)/3$. Hai Phong $(n = 558 \times 2019/n = 570 \times 2020)/3$. Hai Phong $(n = 536 \times 2019/n = 677 \times 2020)/3$. Hai Phong $(n = 521 \times 2019/n = 677 \times 2020)/3$. Ninh Binh $(n = 538\ 2019/n = 608\ 2020)$ /8. Thai Binh $(n = 379\ 2019/n = 643\ 2020)$ / 9. Vin Phuc $(n = 524\ 2019/n = 530\ 2020)$ and negative experiences, expectations, maintenance, and sustainability. Qualitative analyses were carried out with Atlas.ti 23.

2.4.2. Quantitative analysis and reporting

The dimensions Reach, Adoption, and Implementation were quantitatively analyzed using the management board surveys and members surveys of the ISHCs. Second, we analyzed whether successful implementation was associated with more members reporting good positive health by using linear regression analyses, crude and mutually adjusted. Included in the analyses were good positive health, Reach, Adoption, and Implementation. Implementation was only included in the analysis for 2020, because it was measured by the change from 2019 to 2020. We cross-checked the analysis using the mean scores of positive health. A p-value of <0.05 (two-tailed) was considered statistically significant for all associations. The analyses were performed separately for 2019 and 2020. All quantitative measurements and analyses were carried out with IBM SPSS Statistics 28.

3. Results

3.1. The implementation of the ISHCs according to the RE-AIM framework

3.1.1. Reach

Reach was measured in the survey according to what extent the ISHCs realized the target of reaching the proportions of 70% female, 70% older, and 70% poor or disadvantaged people. Table 4 gives an overview of ISHCs per province that reached these targets in 2019 and 2020. Most groups in both 2019 and 2020 reached the targets of 70% for participating female, older, and poor or disadvantaged people. Between 60% and 90% in 2019 and 70% and 90% in 2020 of the ISHCs reached the female target. Between 50 and 100% of the ISHCs reached the target of 55 years and older members. The target for poor or disadvantaged people was achieved by 58% in 2019 and 46% of the ISHCs in 2020. In 2020, more ISHCs reached the target set for female and 55 years and older participants compared to 2019.

3.1.2. Effectiveness

Effectiveness was measured in the FGDs by satisfaction and further experiences with participation in the clubs. In the FGDs, participants expressed being very satisfied with the ISHCs, with almost 75% of participants rating their satisfaction between 9 and 10. Participants in the urban and semi-urban areas gave the highest scores for satisfaction compared to the other areas. Table 5 gives an overview of the positive and challenging experiences of the participants per area. In the coastal and rural areas, economic development for the members and for the community as whole is mentioned as a positive outcome of their membership. In the mountainous, urban, and semi-urban areas, the participants mentioned that membership improved their social life and feeling of unity and solidarity by helping others in the community. Other positive outcomes mentioned by the participants were feeling healthier, having a more active lifestyle, feeling more confident, and enjoying cultural and social activities due to membership. In the mountainous and one of the semi-urban areas, the high rate of female participants leading to stronger female opinions is mentioned as a challenge. In the rural area, the participants mentioned that certain groups saw limited benefits, such as disabled and disadvantaged

TABLE 2 The included variables and operationalization per RE-AIM dimension and the used data source for the first aim.

Dimension	Definition	Data source	Operationalization
Reach	Types of people who participated in the programs, also defined as the extent to which the target groups were covered.	ISHCs surveys	70–70-70% formula reached per province.
Effectiveness	Members' experiences with participating in the club.	Focus group discussions	Satisfaction and experiences with ISHCs.
Adoption	Defined as characteristics of the ISHCs and description of ISHCs reaching targets.	ISHC surveys	Description ISHCs achieving targets on 16 indicators. ^a
Implementation	The extent to which the ISHCs were consistently implemented over 2 years.	ISHC surveys	Description of differences in achieved targets for adoption between 2019 and 2020.
Maintenance	Organizational level: defined as evidence of embedding ISHCs into routine operations and budgets.	Interviews	Description of experiences with sustainability and management.
	Individual level: defined as evidence of sustaining benefits and participants' intentions to continue the program.	Focus group discussions	Description of personal experiences and willingness to retain membership of ISHCs.

 $^{^{\}rm a} See$ Supplementary Table S1 for targets set for the 16 indicators.

TABLE 3 The included variables and operationalization per positive health dimension for the second aim.

Positive health dimension	Belonging aspects	Operationalization
Bodily functioning	Feeling healthy, physical condition, sleeping pattern, exercising, eating pattern	Perceived improved health behavior and improved health status, recoded into improved health
Sense of purpose	Feeling confident, accepting life, wanting to achieve ideals	Perceived improved level of confidence
Participation	Social contacts, being taken seriously, support of others, belonging	Perceived improved feeling of unity/solidarity
Quality of life	Enjoyment, being happy, feeling good, well-balanced, safe	Perceived improved quality of life
Mental wellbeing	Being able to remember things, to concentrate, communicate, handle changes, and having control,	Disability status (in hearing, seeing, mobility, remembering, focus, self-care, and communication)
Daily functioning	Knowledge about own limitations, health, money, time management, being able to ask for help	Perceived improved rights and entitlement.

^aThe dimensions of positive health were measured with the members surveys.

TABLE 4 Results of ISHCs reaching targets set for female, poor to near poor, and older people participation per provinces for 2019 and 2020.

Year	Reach 70% target	1 ª	2ª	3ª	4ª	5ª	6ª	7ª	8ª	9ª	Total
2019	Female	8 (89%)	6 (60%)	9 (90%)	9 (90%)	10 (71%)	12 (80%)	9 (90%)	6 (60%)	9 (90%)	77 (79%)
n (%)	55 years and older	8 (89%)	5 (50%)	10 (100%)	10 (100%)	6 (43%)	11 (73%)	9 (90%)	7 (70%)	7 (70%)	72 (74%)
	Poor or disadvantaged	7 (78%)	2 (20%)	7 (70%)	7 (70%)	5 (36%)	12 (80%)	6 (60%)	6 (60%)	3 (30%)	56 (58%)
2020	Female	8 (89%)	8 (80%)	7 (70%)	9 (90%)	12 (86%)	13 (87%)	7 (70%)	8 (80%)	9 (90%)	80 (83%)
n (%)	55 years and older	7 (78%)	7 (70%)	9 (90%)	10 (100%)	7 (50%)	11 (73%)	8 (80%)	10 (100%)	8 (80%)	76 (78%)
	Poor or disadvantaged	4 (44%)	4 (40%)	2 (20%)	6 (60%)	5 (36%)	9 (60%)	6 (60%)	7 (70%)	3 (30%)	45 (46%)

^{*}Provinces: 1. Bac Ninh (n=9)/2. Hai Duong (n=10)/3. Hai Phong (n=10)/4. Hanoi (n=10)/5. Hoa Binh (n=14)/6. Hung Yen (n=15)/7. Ninh Binh (n=10)/8. Thai Binh (n=10)/9. Vin Phuc (n=10).

people, due to lack of (financial) resources. Other challenges mentioned by the participants were the varying commitment and participation of the members and the loans not being high enough.

3.1.3. Adoption

Adoption was measured as the degree to which ISHCs reached targets for 16 indicators (see Supplementary Table S1 for targets). The ISHCs achieved high scores on Adoption, especially for healthcare activities such as physical exercise and healthcare check-ups, namely 74%–91% in 2019 and 79%–98% in 2020 (Supplementary Table S1). The ISHCs in the rural and mountainous

areas achieved the highest scores for the adoption of healthcare activities and urban areas the lowest. Moreover, the ISHCs highly achieved targets regarding homecare volunteers supporting the community (2019: 97% and 2020: 99%) and community support (2019: 100% and 2020: 96%). The ISHCs in mountainous areas scored highest on adoption scores for other activities and the ISHCs in urban areas the lowest. The targets set for number of members (55% in 2019 and 60% in 2020) and in 2020 monthly-organized meetings (5%) and sources of income (60%) were reached the least, with the ISHCs in the coastal area scoring relatively better and in the urban area relatively poorly.

TABLE 5 Overview of experiences with ISHCs membership.

Area	Experiences with membership			
Coastal	Positive: Health improvement due to healthier lifestyle (more exercise, healthier diet, and check-ups). More sharing and exchange between male and female			
	community members. More opportunities due to loan attainment.			
	Challenging: The continuous participation and commitment of members varied.			
Rural	Positive: Social and cultural activities result in happiness. More health knowledge, such as self-care. More economically developed.			
	Challenging: Limited benefits for some groups of people due to the lack of (financial) resources.			
Mountainous	Positive: Knowledge about health and rights and entitlement improved. Feeling healthier. Feeling more united by helping the community.			
	Challenging: More female participants compared to male leading to the stronger presence of female opinions.			
Semi urban	Positive: Feeling more united by helping others. Feeling more confident and resourceful. The role of older people is emphasized.			
(1)	Challenging: Loans are not high enough.			
Semi-urban	Positive: Reaching the disadvantaged people in the community. More economically development in the community. United feelings. Feeling more confident.			
(2)	Challenging: More female participants compared to male leading to the stronger presence of female opinions.			
Urban	Positive: Improved social life. Opportunity to help others and social security. More confidence and feeling healthier.			
	Challenging: In a big community, it is impossible to reach everybody.			

3.1.4. Implementation

Implementation was measured by the differences in the reach of the targets for adoption between 2019 and 2020. Implementation of the ISHCs, i.e., ISHCs fidelity including the consistency of adoption scores, improved: more ISHCs reached the targets in 2020 compared to 2019. In total, 61 ISHCs had similar or improving implementation. In particular, homecare volunteers and community support activities increased, with 99% of the ISHCs achieving the targets in 2020. The number of ISHCs reaching targets for healthcare activities decreased slightly in 2020. Furthermore, those organizing monthly meetings dropped from 57% in 2019 to 5% in 2020. The ISHCs in the coastal and urban areas improved the most in 2020 compared to 2019 in achieving their targets and the (semi-)urban areas improved the least.

3.1.5. Maintenance

Organizational maintenance was measured by experienced sustainability and management in the individual interviews and individual maintenance as personal experiences and willingness to retain membership of ISHCs in the FGDs.

3.1.5.1. Organizational

The interviewed participants were confident in the maintenance of the ISHCs (Supplementary Table S2). Most participants indicated that the ISHCs had detailed plans to remain active and to expand to more areas by working on advocacy towards local governments and other associations for funding. All participants indicated the replication of ISHCs in other areas because of spillover effects, e.g., due to members sharing experiences and knowledge with non-members, more areas want to implement the ISHC-model. Expressed concerns were that despite the recognition of their effectiveness by local authorities, resources for funding and training were limited. Mentioned improvements to maintain were organizing activities in the evening for daytime workers and attracting more male participants. One participant indicated the limited loan value in their ISHC, making it unattractive to become a member.

3.1.5.2. Individual

All the participants of the FGDs indicated that the ISHCs could be maintained and sustainable in the future. The members indicated that younger people would follow the older people, in accordance with the Vietnamese saying: "Young shoots spring up when bamboos grow old." The challenges mentioned were the non-ISHCs members not supporting the clubs because they do not understand the purpose, do not like the high female participant rate and the opinions of the female participants, and the lack of resources. To maintain, sustain, and expand the ISHCs, the participants identified the need for more (financial) resources and training of (young) volunteers.

3.2. Association of implementation with member-reported positive health

In 2020, the proportion of members reporting good positive health was slightly lower than in 2019 (Supplementary Table S3).

Table 6 presents the associations between the implementation aspects and reported positive health. In 2019, in the crude and mutually adjusted models, the implementation aspect *Adoption* was positively associated with reporting good positive health (crude: $B=2.21;\,0.76;\,3.66$ and mutually adjusted: B=1.94(0.228;3.643) and B=1.94(0.234;3.655)). This indicates that the ISHC groups with higher adoption scores (i.e., ISHCs achieving targets on 16 indicators) had more members reporting good positive health. No significant association was found for *Reach* and good positive health. In 2020, no significant associations were found for *Reach*, *Adoption*, or *Implementation* and reported positive health.

The results of cross-checking the association of implementation aspects and the mean score of positive health were similar (Supplementary Table S4).

4. Discussion

We assessed the implementation of the Older People Associations (OPA) model in Vietnam with the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework and the association of the degree of implementation with members reporting good positive health. We found that the *Reach* of the Intergenerational Self-Help Clubs (ISHCs) was adequate for poor, female, and older people. Members were very satisfied with ISHCs, showing high *Effectiveness*. *Adoption* was similarly adequate, especially for healthcare activities, and *Implementation* increased over time.

TABLE 6 Associations of implementation aspects with reported good positive health: results of regression analyses leading to regression coefficients (B) and 95% confidence intervals.

	Crudeª B (95% CI)	Adjusted ^b B (95% CI)			
Implementation aspects 20	19ª				
Reach	-1.95 (-6.915;3.010)	-2.02 (-6.882;2.838)			
Adoption	1.94 (0.228;3.643)*	1.94 (0.234;3.655)*			
Implementation aspects 2020 ^b					
Reach	4.90 (-1.510;11.317)	4.42 (-2.026;10.856)			
Adoption	-0.861 (-3.916;2.193)	-1.87 (-5.226;1.517)			
Implementation	7.415 (-3.329;18.158)	10.895 (-1.453;22.360)			

^{*}Significant by p < 0.05.

Moreover, *Maintenance* was good and, regarding sustainability, promising. The ISHCs improved on all RE-AIM framework aspects in 2020 compared to 2019. We further found that higher adoption was associated with more frequent reporting of having good positive health in 2019.

This study shows good implementation of the OPA model and multiple benefits for its members. This corresponds with other research on the OPAs showing positive effects on multiple levels of members' lives (14). Moreover, the finding that training and education is important for the maintenance and sustainability of ISHCs confirms findings on other community-based interventions in other Southeast Asian countries (17, 18). However, to our knowledge, this is the first study to evaluate the implementation of ISHCs with the RE-AIM framework, in which group-level and member-level outcomes of the ISHCs were studied with a mixedmethod approach. Using the RE-AIM framework with qualitative and quantitative data on individual- and organizational-level outcomes corresponds with what is done in the ISHCs and has provided evidence for scaling up these community-based approaches. This contributes to the applied research and literature on the RE-AIM framework and community-based approaches in general.

Regarding vulnerable groups, we found that the OPA model reaches people that are most vulnerable to the arising issues of ageing, namely, older, female, disabled, and disadvantaged people. In Vietnam, the care of older people is mostly provided by the family (17), and children are often seen as a guarantee of older age security. However, this ageing trend in Vietnam is jeopardizing this traditional safety net as there are more older persons with chronic diseases in need of support and care. The demand for non-family support and caregiving for older persons is increasing, and the availability of social services to meet this demand is limited (17). In the OPAs, this demand is partly met by delivering homecare to the most vulnerable members and non-members by providing health check-ups and health promotion and education. Moreover, the OPAs promote older people's participation in communities, the inclusion of older people with disabilities, and the participation and leadership of older female people, as well as for non-members (19). This corresponds with our findings that the ISHCs meet this demand by highly adopting healthcare and community support activities and showing improvement in perceived health.

For 2019, we found that the ISHCs with higher adoption scores had more members reporting good positive health, but we could not confirm this for 2020 even though adoption improved in this year. A possible explanation for this finding could be that the data for this study were collected during the COVID-19 outbreak in 2020 in the northern region of Vietnam, which had the highest rate of cases and deaths due to the pandemic (20, 21). This could have halted the improvement of perceived health. Research has associated the COVID-19 restrictions with psychological impacts such as depression and anxiety (21). This is especially the case for older people as in the early stage of the COVID-19 outbreak, the disease had been predominantly portrayed as affecting mostly older adults, leading to the social marginalization and segregation of older people (22). The ISHCs include relatively many older people, and the halting of the improvement of perceived health could reflect that. Moreover, in 2020, the ISHCs organized fewer monthly sessions, most likely due to COVID restrictions. This could have affected the reporting change in perceived health due to less active participation in the ISHCs.

4.1. Strengths and limitations

A strength of this study is that we used multiple quantitative and qualitative data sources, allowing triangulation, which strengthens the validity of the findings. Another strength is the use of data from multiple ISHCs, covering multiple provinces over 2 years, and the possibility of linking the board surveys with the members of the same ISHCs.

A limitation is our use of self-report data, which may have introduced information bias, i.e., giving socially desirable information due to feeling the need to maintain a positive and harmonious relationship with the interviewer (22). However, data were filled in anonymously, reducing the likelihood of such bias. In addition, the study was set up for internal evaluation, not as a longitudinal study, meaning individual changes could not be measured.

4.2. Implications

We found that ISHC-model reaches the most vulnerable people to arising issues in Vietnam, such as a high incidence of disability and chronic diseases, poor access to healthcare, higher medical costs, low coverage of social protection, and insufficiency of family support (23), which implies that the ISHC-model is promising to promote health and to reach several vulnerable groups. To further confirm the applicability of the ISHCs, future research in other regions is needed.

Our research shows how the RE-AIM framework can be used for evaluating the implementation of community-based approaches. Community-based programs are real-world settings (24), and therefore, the RE-AIM framework is seldomly applied (25). This addresses a significant gap in implementation science and RE-AIM literature, providing a valuable tool for funders and researchers to have an insight into real-world evaluations (26). We encourage researchers to use a similar approach of researching the implementation of health promotion in community-based programs.

We found high confidence in the maintenance of the clubs; however, to maintain self-help community-based interventions such as the ISHCs, training and training resources are highly important (27). To impart stronger conclusions about the clubs and their

^aCrude analysis: bivariate analysis.

bMutually adjusted analysis: multivariate analysis.

training, we suggest studying the effectiveness of the training and the materials. Research into the effectiveness of the training can provide stronger conclusions about the ISHCs and their effectiveness. We found that future funding of the ISHCs is seen as a challenge for maintenance, possibly having implications for sustainability. The ISHCs are financed by a combination of loan interest, membership fees, collective income generation, and external funding by (mostly) non-governmental organizations. These findings can strengthen the awareness of financial and resource support from local agencies.

We were the first to assess the implementation of ISHCs using the RE-AIM framework, including facilitators and barriers, during the COVID-19 pandemic. This implies a need to confirm our findings by other studies. Preferably, such a replication study would make use of longitudinal data and cover other countries in Asia too as the OPA-model has been implemented widely. This can support policies to improve the positive health of older people throughout Asia.

5. Conclusion

This study showed that the implementation of community-based programs in Vietnam is promising for promoting public health. The OPA model is a feasible community-based support program that has been successfully implemented in Vietnam. The results show the ISHCs reach a vast majority of female, older, and disadvantaged people and lead to high member satisfaction, high adoption of healthcare and community activities, high confidence in maintenance, and improvement of implementation. This study shows the potential of the OPA model for improving the health of older people and of the RE-AIM framework for assessing the implementation of community health promotion approaches.

Data availability statement

The original contributions presented in the study are included in the article/Supplementary materials, further inquiries can be directed to the ZP, z.e.pardoel@umcg.nl.

Ethics statement

The studies involving human participants were reviewed and approved by HelpAge International. The patients/participants provided their written informed consent to participate in this study.

Author contributions

NV and LP were involved in the preparation and data collection. ZP, JK, and JL conceptualized the study. ZP led the data analysis, wrote

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the initial draft of the manuscript, produced the tables, and incorporated contributing author feedback into the paper. JL, SR, RL, and MP contributed to all the drafts and manuscript. All authors contributed to the article and approved the submitted version.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

The Supplementary material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpubh.2023.1182947/full#supplementary-material

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The Vietnamese version of the Home Falls and Accidents Screening Tool (HOME FAST) - A preliminary study of validity and inter-rater reliability

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Introduction: The Vietnamese Home Falls and Accidents Screening Tool (HOME FAST) was developed to measure the number of home hazards present in the homes of older Vietnamese people and the risk of falls.

Methods: The HOME FAST and the HOME FAST manual were translated into Vietnamese by an independent translator and underwent backward translation by local health professionals into English to evaluate the accuracy of the translation. A panel of 14 Vietnamese health professionals evaluated the validity of the HOME FAST translation and rated the clarity and cultural relevance of each item. Ratings were evaluated using the content validity index (CVI). Reliability in ratings of the HOME FAST was evaluated using intra-class correlations (ICC), and ratings took place within the homes of two older Vietnamese people by six assessors.

Results: In all, 22 out of 25 Vietnamese HOME FAST items were considered to have met content validity standards using the CVI. The ICC for home visit one was 0.94 (95% CI 0.87-0.97) and for home visit two was ICC 0.95 (95% CI 0.91-0.98) indicating high reliability.

Discussion and conclusion: Bathroom items showed the most inconsistency in ratings indicating cultural differences in bathing activities. Descriptors of HOME FAST items will be reviewed for use in Vietnam to account for cultural and environmental differences. A larger pilot study is planned with older people living in the community in Vietnam to include calendar ascertainment of falls to determine if home hazards are associated with falling.

KEYWORDS

accidental falls, home hazards, assessment, cultural translation, validity, expert panel

Introduction

The population of Vietnam is aging with the proportion of older people predicted to grow from 11 to 28.5% by 2050 (1, 2). The prevalence of frailty is also increasing as the Vietnamese population ages, putting older people at risk of falls (3). Globally, falls in the older population is a major public health problem with numerous serious physical and psychosocial consequences that can lower quality of life (4). Vietnam is classed as a lower middle income country area (5), and a recent World Health Organization report (6) identified that globally, 75% of fatal falls among older people (aged 70 years and over) occur in low and middle-income countries. One

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Vietnamese study located in Danang found that 51% of their sample had reported a fall, and 64% reported fear of falls (7), therefore investigating falls risks is important to prevent falls in the home.

Added to this, Vietnam has an aging population with a declining fertility rate and increasing life expectancy (8). The fastest population growth is for older people over the last 30 years, and life expectancy from aged 60 of 20 years is similar to Thailand, Indonesia and Malaysia (9). Furthermore, the proportion of older people living with younger family members is decreasing, and while poverty has declined, a proportion of older people continue to live in poverty, especially in rural areas (9). Overall, the population in the ASEAN region is growing at an accelerated rate, with the population of 649 m outpaced only by China and India (10). The aging population of south-east Asia is predicted to surpass the proportion of the aging populations in North America and Europe (11).

Falls will become a major health issue in Vietnam as the population ages as age is a key risk factor for falling (12). Published studies on falls in older people is limited in Vietnam–for instance in a review of 15 randomized controlled trial falls studies in Asia there were none identified from Vietnam (13). In a scoping review of falls studies in south-east Asia (11), two published studies out of 37 were from Vietnam. One was retrospective observational study (14) and the other was a longitudinal intervention study (15). Both studies evaluated the relationship between visual problems and falls. The study reported female gender and living alone as significant factors. The interventional study found that corrective cataract surgery was effective in reducing subsequent falls.

The Home Falls and Accidents Screening Tool (HOME FAST) consists of 25 items related to features of the home environment and an older person's functioning within the home (16). Each item is rated according to its capacity to put an individual at risk of falling. The HOME FAST was designed to be used by a health professional who scores each item as a hazard or not. The number of hazards putting a person at risk of falls are counted and a score of online or over means a higher risk of falls (17). The HOME FAST compares well with other measures of the home environment and demonstrates good psychometric properties and clinical utility (18). However, it is unknown how the HOME FAST can translate linguistically and culturally to a Vietnamese population. There may be some key differences in the home environments for older people in Vietnam, such as types of flooring surfaces and lighting, and poorly maintained public environments (13), which will need to be evaluated as part of the translation process. To design interventions to prevent falls, it is critical to be able to identify the kinds of home hazards that exist for Vietnamese older people using a valid tool.

Therefore, this study aimed to (i) translate the HOME FAST into Vietnamese, (ii) evaluate the validity of the Vietnamese HOME FAST in terms of clarity and relevance, and (iii) evaluate the reliability of the Vietnamese HOME FAST.

Methods

The study used mixed methods:

(i) Forward and backward translation

The HOME FAST was first translated from English to Vietnamese by an independent translator, and the Vietnamese authors examined any inconsistencies in the translation. The Vietnamese version was then back translated to English and an

expert panel of authors and Vietnamese health professionals checked the final version to be tested (19).

(ii) Validity assessment of the Vietnamese HOME FAST

An expert panel of 14 Vietnamese speaking health professionals completed a survey to assess the linguistic validity of each of the items on the Vietnamese version of the HOME FAST (See Figure 1).

Ratings of 0–1.5 were considered not relevant/clear, 2–4.5 somewhat relevant/clear, 5–7.5 quite relevant/clear and 8–10 very relevant/clear.

The survey included ratings on the clarity and relevance of each of the items using a 0 to 10 Likert scale (e.g., 0=low clarity, 10=high clarity). Items in the Vietnamese version of HOME FAST were modified according to the written comments provided by the respondents. The content validity index (CVI) was used to evaluate the validity of each item. The CVI is the total number of experts giving a rating of 3 or 4 (relevant) divided by the total number of experts. When six or more experts are used, I-CVI values should not be less than 0.78 (20).

(iii) Reliability assessment of the Vietnamese HOME FAST

Two home visits were conducted with six health professionals independently completing the Vietnamese HOME FAST overall score for each one. The health professionals involved participated in a workshop to train them in the use of the HOME FAST prior to the home visits which was led by the developer of the tool who spoke English and an interpreter was used to ensure everyone understood the process of assessment. As there were more than two raters an intra class correlation (ICC₂) was used (two-way random effects model) to evaluate agreement on ratings. The ICC was also appropriate as continuous scores were being compared.

Ethical approval was given by the University of Sydney Human Research Ethics Committee (Approval number 2020/018).

Results

The final version of the Vietnamese HOME FAST was agreed and is available at https://stopfallsathome.com.au/resources/.

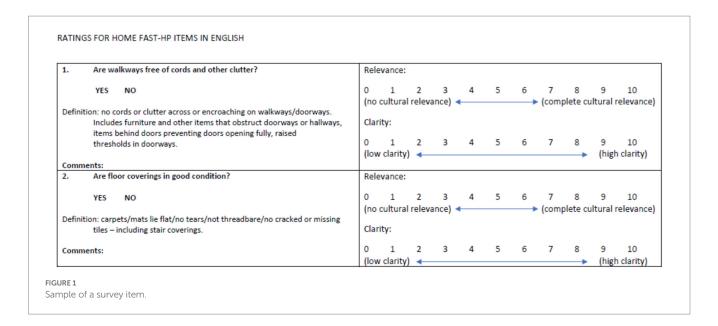
Validity of the Vietnamese HOME FAST

While all items were scored over seven for clarity, cultural relevance had lower scores for bathroom items (bath transfers, grab rails in the bathroom and use of non-slip mats) – see Figure 2. The content validity index (CVI) for each HOME FAST item is presented in Table 1. Only three items did not meet the usual threshold of a CVI of 0.78.

Reliability assessment of the Vietnamese HOME FAST

For the first home visit conducted with six raters the total HOME FAST scores given by raters ranged from 8 to 14 out of 25 items. The

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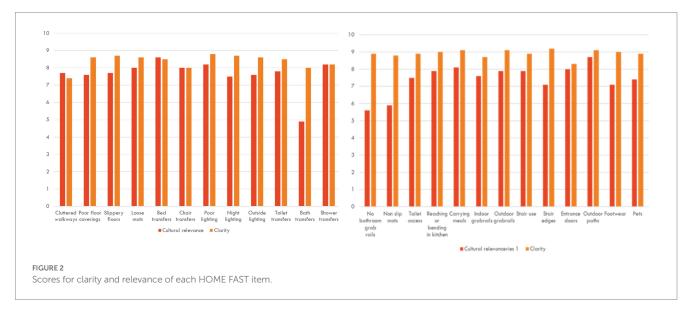


TABLE 1 Content validity index for HOME FAST items.

Cluttered walkways (1.0)	Outdoor step rails (1.0)	Shower transfers (1.0)	
Loose mats (1.0)	Bed transfers (1.0)	Outdoor paths (1.0)	
Toilet transfers (0.93)	Slippery floors (0.93)	Entrance doors (0.93)	
Chair transfers (0.93)	Toilet access (0.93)	Reaching/bending (0.93)	
No night lighting (0.93)	Carrying meals (0.93)	Poor floor coverings	
		(0.86)	
Stair edges (0.86)	Stair use (0.86)	Poor lighting (0.86)	
Indoor step rails (0.86)	Pets (0.86)	Outside lighting (0.79)	
Footwear (0.79)			
Non-slip mats (0.77)	Bathroom grab rails	Bath transfers (0.57)	
	(0.77)		

percentage agreement for each HOME FAST item ranged from 67 to 100%, and there was 100% agreement for 15 HOME FAST items. For

the second home visit, also conducted with six raters (not the same raters as in the first home visit) the total HOME FAST score ranged from 11 to 15 out of 25 items. The percentage agreement for each item ranged from 67–100%, and there was 100% agreement for 14 items. The bathroom items with the low CI scores identified in Table 1 also demonstrated inconsistency in rating from the home visits.

The ICC for the HOMEFAST overall score conducted at home visit one among six raters was 0.94 (95% CI 0.87–0.97) and for home visit two was ICC 0.95 (95% CI 0.91–0.98) indicating high interrater reliability.

Discussion

This study aimed to develop and evaluate the validity and interrater reliability of the Vietnamese version of the HOME FAST. These preliminary findings confirm the utility of the translated version of the Vietnamese HOME FAST and its use in practice as a valid and reliable

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tool by health professionals. Further larger studies are needed to fully evaluate the psychometric properties of this tool with a Vietnamese population.

In the developed world, where most of the research on falls has taken place, there is evidence that unsafe home environments are associated with an increased risk of falls for older people, and that modifying the home to remove hazards can reduce falls (21-23), although there is less evidence in Asian settings and Vietnam in particular (11, 13). Falls can have serious consequences in terms of injury, cost and future care (22), and being able to measure hazards in the home associated with the risk of falls is essential to implement interventions to prevent falls. The HOME FAST is one such measurement and has been recommended by systematic reviews (18, 24). The HOME FAST has evidence of reliability (25), validity (26), responsiveness and predictability with respect to future falls of older people (27). The scoring of the HOME FAST has also been validated (17). This work was conducted in developed countries, therefore making the HOME FAST available in Vietnamese is the first step in developing evidence-based fall prevention strategies in Vietnam, rather than depending on more informal non-standardized ways of evaluating falls risk in the home for Vietnamese older people.

The findings of this study indicated there were cultural differences in the use of the home environment, such as the lower CVI for bathroom-related items such as the use of a bath, bath rails and bathmats, and a low score given for the relevance of bath transfers. Home environmental factors vary according to geography, culture, and architectural design (18). During these two initial home visits, it was obvious that bathtubs were not a usual feature of traditional Vietnamese homes and showers were much more frequently used. This would account for the low scores for cultural relevance and the low CVI for these items. As there is a not-applicable option on the HOME FAST for these items, this could be used in homes where there is no bathtub, and the structure of the HOME FAST can be preserved. More homes in the future might be expected to be built with Westernstyle bathrooms therefore, making these items more relevant. These findings are consistent with other studies where the HOME FAST has been translated and evaluated in other languages and cultural settings such as Chinese (28), Persian (29), Bahasa Melayu, Mandarin, and Tamil (30). No items were removed from the HOME FAST in these translated versions (30). Another study translated the self-report version of the HOME FAST into Mandarin for use in Hong Kong (31) and removed three items that were not considered culturally relevant to crowded living conditions in Hong Kong and merged two more items resulting in 20 items for the translated version. In this case a self-reported version may have required more clarification for older people to interpret the items themselves resulting in changes to the HOME FAST items.

The scores given for the two home visits indicated that with the exception of one rating the overall HOME FAST scores were nine or over, suggesting that the older people assessed were at high risk of falls (17). The inter-rater reliability findings from this study were very positive, and the ICC results were better than a previous Australian study evaluating the reliability of the HOME FAST (25) that reported an ICC of 0.82 (95% CI, 0.66–0.91) for the overall HOME FAST score. Training of raters is an important component of maximizing

inter-rater reliability in the use of an assessment tool (32). A training manual for the HOME FAST is available at and was also translated into Vietnamese for this study. Face to face training sessions were also undertaken prior to the home visits, which may have contributed to the ICC findings. Previous studies have also suggested that effective home environmental assessments and modifications should be conducted by occupational therapists to prevent falls in older people (21-23). In Vietnam, the occupational therapy profession is in its initial development phase, so there is a shortage of appropriate health professionals who can undertake screening of older people at risk of falling. The HOME FAST was developed to allow any trained health professional to undertake an assessment of falls risk in the home of older people (33). A Vietnamese version of the HOME FAST has provided a tool that can be used in health professional practice in Vietnam and can be used as an outcome measure in ongoing research. The tool is tool now ready to be applied in a large study to further assess the validity, responsiveness and predictability of home hazard identification related to subsequent falls in Vietnam.

Conclusion

The availability of a Vietnamese HOME FAST will now allow the home environments of older Vietnamese people to be evaluated according to their risk of falls. A larger pilot study is now planned with older people living in the community in Vietnam. The use of the Vietnamese HOME FAST will allow health professionals to identify home environmental risks and which features need to be modified.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving human participants were reviewed and approved by the University of Sydney Human Research Ethics Committee. Written informed consent for participation was not required for this study in accordance with the national legislation and the institutional requirements.

Author contributions

LM and VL contributed to conception and design of the study, and organised the ethics approval. LM undertook the funding application, organized the database, performed the statistical analysis, and wrote the first draft of the manuscript. VL, DN, and TD undertook the forward and backward translation activities, organized the training

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for the raters, and the home visits. All authors contributed to manuscript revision, read, and approved the submitted version.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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