DOI: 10.35772/ghm.2026.01063

From companion technologies to social care infrastructure: A multi-level perspective on loneliness-related support in dementia care in an era of artificial intelligence (AI)

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Abstract: Loneliness and social isolation are important psychosocial concerns in dementia care, but they are difficult to address through pharmacological treatment or episodic social activities alone. Companion technologies, including socially assistive robots, humanoid and conversational robots, avatars, virtual agents, and artificial intelligence (AI)-enabled companions, are increasingly discussed as possible aids for engagement and interaction. However, current evidence does not justify treating these technologies as standalone interventions that directly reduce loneliness in people with dementia. We argue that these technologies may be more appropriately considered not only as devices or interventions, but also as potential components of social care infrastructure: tools that can encourage individual engagement and mediate human relationships but that need to be integrated into care ecosystems. We propose the multi-level care with social technologies (MCST) model, which consists of three connected layers: individual engagement, relational interaction, and the care ecosystem. The model emphasizes that loneliness-related support is produced through the interaction between technology, human facilitation, care workflows, ethical governance, and feedback-based adjustment. This approach is especially relevant as dementia care systems face workforce constraints and an increasing need for home-based care, while psychosocial needs remain and may be overlooked in routine care. AI-enabled and large-language-model-based companions may expand possibilities for personalization and continuous engagement, but dementia-specific evidence remains preliminary and safety concerns are substantial. Future research should validate the MCST model in real-world dementia care and establish evaluation frameworks that address psychosocial outcomes, sustained use, safety, privacy, human oversight, and accountability.

***Keywords*:** dementia, loneliness-related distress, companion technologies, social care infrastructure, artificial intelligence (AI), perspective

1. Introduction

According to the World Health Organization (WHO), 57 million people were living with dementia globally in 2021, with approximately 10 million new cases occurring each year (*1*). As the number of people living with dementia continues to increase, dementia care increasingly requires attention to psychosocial needs that extend beyond cognition, diagnosis, and pharmacological symptom management. Loneliness and social isolation are particularly relevant because they are associated with depressive symptoms, reduced participation, poorer mental and physical health, and cognitive decline (*2-5*). Loneliness refers to the subjective gap between desired and actual relationships, whereas social isolation refers to limited social contact, social participation, interaction, or networks (*3,6*). For people with dementia or mild cognitive impairment, these experiences may be intensified by memory loss, difficulty communicating, reduced confidence, stigma, loss of one's previous role, and dependence on family members or professional caregivers.

Although loneliness is subjective, it is not merely an individual emotional state. It is also shaped by relational and environmental conditions. A person with dementia may feel lonely despite living with others if communication is difficult or interactions become task-focused. Conversely, supportive engagement may be possible even in institutional or home-based settings when care routines, family involvement, and activity opportunities facilitate connection. This means that loneliness-related support is a practical issue for dementia care systems to address: it requires sustained recognition of changing emotional responses and not merely the provision of occasional social contact.

Companion technologies have attracted attention as possible non-pharmacological approaches to address that issue. These include animal-like socially assistive robots, humanoid robots, conversational robots, artificial intelligence (AI)-enabled avatars, virtual agents, and other digital companions designed to stimulate interaction, provide comfort, or encourage participation in activities (*7,8*). Japan provides an important context for examining companion technologies in dementia care. In 2023, among the 19 OECD countries with available comparable data, Japan had the highest estimated prevalence of dementia among people age 65 years and over at 122 cases per 1,000 population, which is equivalent to approximately 12.2% of this age group (*9*). Japan has also developed dementia policy initiatives and has a long history of care-robot development, including PARO, an animal-like socially assistive robot (*10,11*). These conditions make Japan a relevant setting for considering how companion technologies can be integrated into dementia care systems. And yet the central question is not whether a device can alleviate loneliness by itself. A more relevant question is how such technologies can be embedded within human relationships and care systems to address loneliness-related needs safely, ethically, and sustainably.

This perspective therefore builds on existing discussions of assistive technologies, social care, and relationship-centered dementia care by considering companion technologies not only as devices or interventions but also as potential components of social care infrastructure. To elucidate this perspective, we propose the multi-level care with social technologies (MCST) model. The model clarifies how companion technologies may contribute to individual engagement, relational interaction, and care ecosystem governance, while informing research design, institutional decision-making, and care policy without overstating current evidence.

2. Current evidence and its limits in dementia care

When adopting the aforementioned perspective, we use a pragmatic functional classification informed by existing reviews of socially assistive robots and their applications in dementia care (*7,8,12*). We group companion technologies into four broad categories: animal-like socially assistive robots, humanoid robots, conversational robots, and AI-enabled or large language model (LLM)-based companion technologies. These categories are not mutually exclusive, as some devices combine embodiment, programmed dialogue, and AI-enabled interaction depending on their functions and implementation contexts. Their potential roles, risks, and implementation requirements across the three layers of the MCST model are summarized in Table 1.

Existing evidence suggests that companion technologies may help to achieve loneliness-related psychosocial outcomes, but it does not indicate that they are direct solutions for loneliness in dementia care (*8,12-14*). Among the technologies considered here, animal-like socially assistive robots, and PARO in particular, currently have the strongest evidence base (*11-14*). Their key mechanism is tactile and non-verbal emotional engagement through holding, stroking, sound, and responsive behavior (*11*). Studies and reviews have reported possible benefits in terms of anxiety, agitation, depressive symptoms, sleep, sociability, and the caregiver burden (*11-14*). However, findings on behavioral and psychological symptoms of dementia, cognition, quality of life, and loneliness itself remain inconsistent. Differences in intervention duration, human facilitation, frequency of use, dementia severity, and care setting limit generalizability and prevent the reaching of definite conclusions about a direct reduction in loneliness (*12-14*).

Humanoid robots and communication robots, such as Pepper and RoBoHoN, may encourage participation in activities, engagement in rehabilitation, conversation, and interaction with caregivers or other residents (*15-17*). Their value often lies in embodied social cues, predictable routines, and the ability to become a shared focus of attention (*18*). Conversational robots may also provide games, programmed dialogue, or simple cognitive and behavioral stimulation (*19,20*). Nevertheless, these technologies are highly dependent on usability, speech recognition, staff support, cost, maintenance, and inclusion in daily workflows (*17,21*). If these conditions are not met, the technology may be underused or may add a burden rather than provide support.

AI-enabled companions, including conversational agents, avatars, android robotic media, and potential large-language-model-based systems, create new possibilities for more personalized and continuous engagement. They could adapt the content of a conversation to the user's life history, preferences, emotional state, and response patterns. Early exploratory studies suggest possible effects on loneliness-related distress, anxiety, depressive symptoms, or communication, but the evidence remains preliminary and heterogeneous (*20,22*). Importantly, current dementia-specific evidence for generative AI and large language models is still insufficient. Their potential should therefore be presented as a future direction requiring validation, not as established effectiveness.

Across technology types, the consistent lesson is that benefits are unlikely to emerge from the device alone. Companion technologies may provide opportunities for engagement, but the meaning and safety of that engagement depend on human interpretation, facilitation, and supervision. They should therefore be evaluated beyond device-level outcomes, including their effects on relationships, care routines, staff workload, family involvement, and long-term sustainability. This supports

Table 1. Companion technologies in dementia care: roles, mechanisms, and implementation requirements

Technologies	Examples	Intended users	Care settings	Key mechanisms	Contributions	Implementation requirements
Animal-like socially assistive robots	PARO	People with dementia, including those with limited verbal communication or advanced cognitive impairment	Long-term care facilities, residential care settings, day-care centers	Tactile and non-verbal emotional engagement; sensory comfort through touching, holding, and stroking	Reducing anxiety, agitation, or depressive symptoms in some users; aiding comfort and sociability	Identification of appropriate users; regular but not excessive use; caregiver facilitation; monitoring of individual responses; integration into daily care routines
Humanoid robots	Pepper RoBoHoN	People with mild to moderate dementia; older adults who can respond to visual, verbal, or social cues; caregivers and staff involved in activities	Hospitals, rehabilitation units, long-term care facilities, day-care centers, residential care settings	Embodied social cues; voice interaction; gestures; facilitation of activity	Encouraging engagement in rehabilitation; initiating interactions with users, caregivers, and other residents	Staff training; cost and maintenance planning; workflow integration; adjustment to the user's cognitive status and user acceptance
Conversational robots	Pepper RoBoHoN	People with mild cognitive impairment or mild to moderate dementia; users who can engage in simple verbal interaction	Home care, residential care settings, day-care centers, long-term care facilities	Simple voice interaction; cognitive stimulation; predictable communication	Providing programmed conversations, games, and repeated interaction; offering cognitive and behavioral stimulation	Consistent speech recognition; design of simple and comprehensible interactions; personalization to the user's cognitive level; human monitoring; evaluation of sustained use
AI-enabled conversational companions	AI-enabled conversational robots, avatars, virtual agents, android robotic media	Potentially people with mild cognitive impairment or early-stage dementia, older adults at risk of loneliness, family caregivers, and care staff	Home care, residential care settings, digitally supported community care	AI-mediated dialogue; personalization; conversational continuity; data-informed engagement	Providing individualized and context-sensitive interaction; encouraging reminiscence and emotional expression; potentially alleviating loneliness-related distress and depressive symptoms; enabling data-informed modification of the level of engagement	Human supervision; control of hallucinations; privacy and consent safeguards; audit logs; escalation procedures; accountability framework; real-world validation before clinical or care-system claims

Data source: *Ref.* (*7,8,11-22,26-29*).

a shift from a device-centered view to an infrastructure-centered view.

3. Companion technologies as potential social care infrastructure

The concept of social care infrastructure emphasizes that companion technologies become meaningful when embedded in care relationships and organizational routines, where they aid with human care rather than replacing it. In dementia care, this may include prompts for conversation, opportunities for shared activities, comfort during periods of isolation, support for reminiscence, or signals that help caregivers notice changes in mood, responsiveness, or participation (*11,19,20,22*).

This way of viewing companion technologies is useful because loneliness-related needs are multidimensional (*2,3,23-25*). On the individual level, a person may need emotional reassurance, sensory comfort, or stimulation. On the relational level, the person may need mediated opportunities to interact with family, staff, or other users. On the ecosystem level, the care setting needs workflows, supervision, training, and governance to ensure that technologies are used appropriately. A companion robot or AI avatar cannot deal with these levels automatically. Its value depends on whether it is integrated into a broader care process.

Viewing companion technologies as social care infrastructure also prevents overly broad claims. A positive short-term response to a robot does not prove that loneliness has been reduced. Similarly, increased interaction during a session does not necessarily mean sustained social connection has taken place. The more appropriate claim is that these technologies may create entry points for engagement and relationship-building, which may in turn contribute to alleviating loneliness-related psychological distress in some users when supported by a responsive care environment.

This infrastructure perspective also distinguishes expectations among stakeholders: family members may seek reassurance, care staff may expect support for group activities or management of agitation, and facility managers may focus on workload, maintenance, and risk management. These expectations correspond to different layers of care. If the layer is not made explicit, a correct evaluation may be hampered: a technology may be judged ineffective because it does not reduce loneliness scores even though it improves participation, or it may be judged successful because users enjoy it briefly even though it is not sustainable in daily care.

4. The MCST model

The MCST model organizes companion technologies into three interconnected layers: individual engagement, relational interaction, and the care ecosystem (Figure 1). It draws on social frailty, relationship-centered care, and social ecological approaches (*23-25*) but focuses specifically on the role of companion technologies in loneliness-related support in dementia care. The model is intended to clarify how technology-related benefits may arise, where risks occur, and what should be evaluated before and during implementation.

Layer 1, individual engagement, refers to the direct responses of the person with dementia. Companion technologies may provide tactile, visual, auditory, or conversational stimuli that provide comfort or emotional reassurance or encourage participation in activities, curiosity, reminiscence, or a sense of security (*11-14,19,20,22*). Relevant evaluation domains include distress, anxiety, agitation, engagement, acceptance, confusion, discomfort, and adverse emotional reactions, rather than loneliness scores alone. The central question in this layer is whether the technology provides a safe and meaningful entry point for engagement for a particular person.

Layer 2, relational interaction, refers to the way technology mediates relationships with caregivers, family members, staff, and other users (*18,24*). A robot, avatar, or conversational agent may become a shared object of attention, a prompt for reminiscence, a bridge for communication, or an activity involving more than one person (*15-20*). In this layer, the technology is not a substitute for human contact. Its intended role is to make human interaction easier to initiate, sustain, or personalize. Evaluation should therefore include caregiver-user interaction, family participation, group activities, frequency of communication, the caregiver burden, staff perceptions, and whether the use of the technology enhances or unintentionally reduces human contact.

Layer 3, the care ecosystem, refers to the operational and ethical conditions that make Layers 1 and 2 safe and sustainable. These include staff training, workflow integration, maintenance, cost, documentation, data management, privacy safeguards, consent procedures, human supervision, escalation rules, and accountability (*21*). Without this layer, positive responses in Layer 1 or interactional benefits in Layer 2 may remain temporary, fragmented, or dependent on individual staff enthusiasm. For AI-enabled technologies, Layer 3 is especially important because inaccurate, inconsistent, or emotionally inappropriate responses may confuse or distress users whose memory, judgment, or ability to verify information is impaired (*26-29*).

The MCST model is dynamic rather than static. User responses in Layer 1 should be interpreted through relational interactions in Layer 2 and then translated into operational decisions in Layer 3. Caregivers may adjust the frequency, timing, type of activity, conversation content, supervision, or discontinuation criteria according to observed benefits and risks; Figure 1 represents this feedback loop. In this sense, the model shifts the question

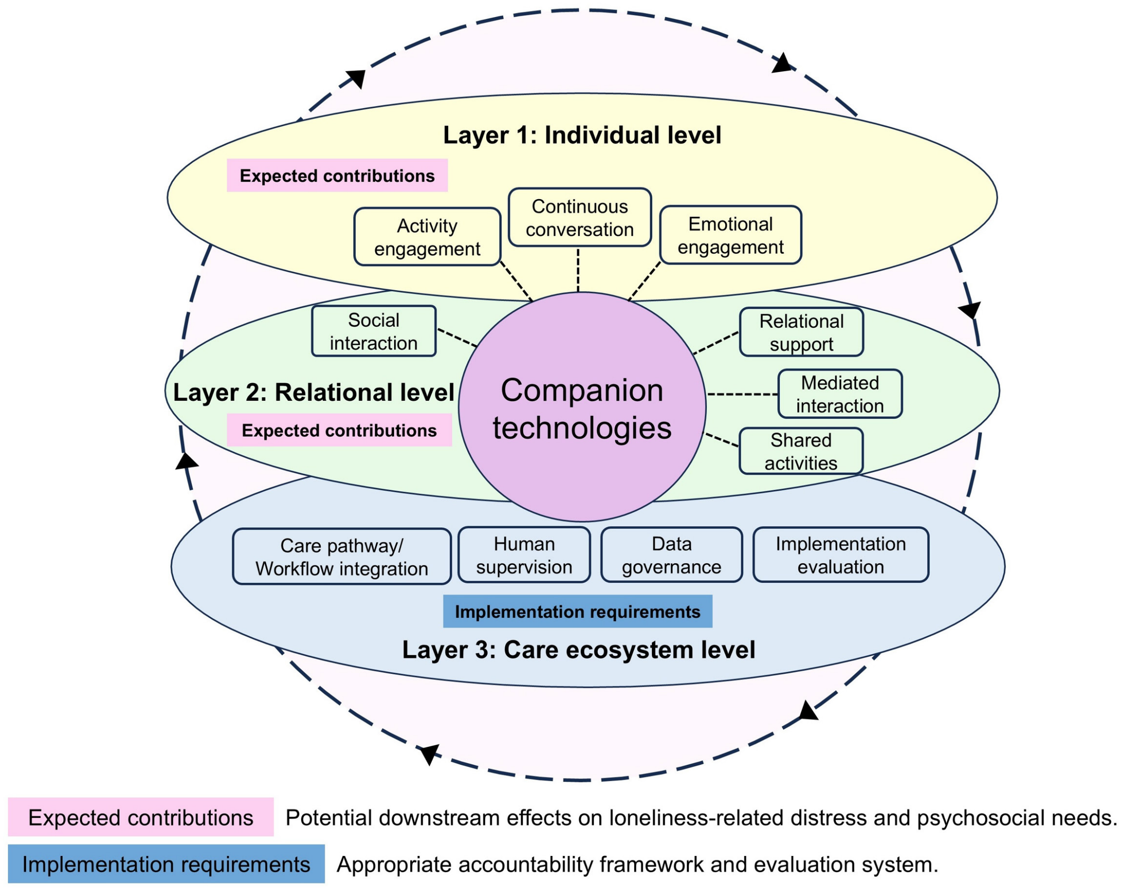

Figure 1. Concept diagram of the MCST model. Safe and sustainable engagement and interaction in Layers 1 and 2 are supported by the stability of Layer 3. The outer circular arrows indicate a feedback loop through which user responses and usage data are reviewed by care providers and used to adjust the level of engagement, supervision, and implementation.

from 'Does the device reduce loneliness?' to 'How can technology, relationships, and care systems work together to address loneliness-related needs?'

The model also helps identify levels of failure: poor personalization in Layer 1, engagement that remains disconnected from human contact in Layer 2, or unsustainable, unsafe, or burdensome implementation in Layer 3. This identification can inform research design, implementation planning, and institutional evaluation.

The same logic can guide outcome selection. Outcome selection should align with each layer: emotional response, distress, engagement, and adverse reactions for Layer 1, interaction patterns, caregiver involvement, shared activities, and human contact for Layer 2, and training, workflow, privacy, cost, maintenance, safety incidents, and accountability for Layer 3. By aligning outcomes with layers, the MCST model can make future studies more interpretable and reduce the risk of drawing broad conclusions from narrow indicators.

5. Future agenda for AI-enabled companion technologies in dementia care

Future research should clarify for whom, when, and for what purpose companion technologies are appropriate, recognizing differences in the stage of disease, communication ability, sensory function, personal history, the living environment, and preferences. They should also distinguish loneliness, social isolation, loneliness-related distress, depression, anxiety, behavioral and psychological symptoms, participation in activities, quality of life, caregiver burden, staff workload, and workflow impact. Longitudinal and real-world designs are needed to separate novel effects from sustained benefits and to examine discontinuation, maintenance, cost, and acceptability.

Second, AI-enabled companions require explicit human oversight. Personalization may improve engagement, but it also increases risks related to privacy, consent, emotional dependence, reduced human contact, and inappropriate reliance on machine-generated responses (*26,27*). Large language models can generate hallucinations or inconsistent statements, which may be particularly harmful to people with dementia (*28,29*). Practical safeguards should include audit logs, procedures for reviewing conversations, criteria for temporary suspension of use, escalation pathways when confusion or anxiety occurs, and clear designation of responsibility among developers, care facilities, clinicians, caregivers, and family members.

Third, implementation and regulatory evaluation should be linked to intended use and claimed outcomes. Technologies used only for daily engagement may be managed as assistive or care technologies. If, however, they are marketed, reimbursed, or implemented with claims of alleviating loneliness, depressive symptoms, or behavioral symptoms, encouraging participation in activities, alleviating the caregiver burden, or achieving other clinical and psychosocial outcomes, stronger evidence may be required under digital health, care-technology, or software-as-a-medical-device frameworks (*30,31*). The MCST model can help institutions specify what should be evaluated at the individual, relational, and ecosystem levels before broad implementation.

Finally, policy and practice should avoid a false choice between technology and human care. The key implementation question is not whether AI companions can replace caregivers but whether they can support caregivers, families, and care teams in recognizing and responding to psychosocial needs that are otherwise missed. This requires not only technical innovation, but also staff education, ethical governance, reimbursement discussion, and institutional accountability.

For this reason, implementation studies should report not only positive user responses but also non-use, withdrawal, technical failures, staff burden, and unintended consequences. Acceptability may vary by context, such as mealtimes, nighttime anxiety, or family visits; real-world evidence should therefore indicate the timing, facilitation, and adaptation of use. Such information would help the field move beyond general claims that companion technologies are beneficial toward a clearer understanding of how, for whom, and under what conditions they may help to provide loneliness-related support.

6. Conclusion

Companion technologies do not cure dementia, replace human relationships, or independently resolve loneliness. Their potential value lies in encouraging emotional engagement, mediating interaction, and improving the operational conditions of dementia care. The MCST model offers a conceptual framework for considering these technologies as potential components of social care infrastructure at the individual, relational, and ecosystem levels. Empirical validation of the MCST model in diverse care contexts and dementia stages, with transparent reporting of implementation conditions, needs to be done to keep claims in line with evidence. Future work should determine whether companion technologies, including AI-enabled systems, can address loneliness-related needs safely, ethically, and sustainably when embedded within human relationships and care systems.

Funding: This work was supported by a Grant-in-Aid from the Ministry of Education, Culture, Sports, Science, and Technology of Japan (24K14216).

Conflict of Interest: The authors have no conflicts of interest to disclose.

References

1. WHO. Dementia. *https://www.who.int/news-room/fact-sheets/detail/dementia* (accessed April 8, 2026).
2. Hajek A, König HH. Prevalence of loneliness and social isolation among individuals with mild cognitive impairment or dementia: Systematic review and meta-analysis. BJPsych Open. 2025; 11:e44.
3. National Academies of Sciences, Engineering, and Medicine. Social isolation and loneliness in older adults: Opportunities for the health care system. Washington, DC: The National Academies Press; 2020. *https://www.ncbi.nlm.nih.gov/books/NBK557964/* (accessed April 8, 2026).
4. Victor CR, Rippon I, Nelis SM, Martyr A, Litherland R, Pickett J, Hart N, Henley J, Matthews F, Clare L; IDEAL programme team. Prevalence and determinants of loneliness in people living with dementia: Findings from the IDEAL programme. Int J Geriatr Psychiatry. 2020; 35:851-858.
5. Cardona M, Andrés P. Are social isolation and loneliness associated with cognitive decline in ageing? Front Aging Neurosci. 2023; 15:1075563.
6. Berkman LF, Syme SL. Social networks, host resistance, and mortality: A nine-year follow-up study of Alameda County residents. Am J Epidemiol. 1979; 109:186-204.
7. Riches S, Azevedo L, Vora A, Kaleva I, Taylor L, Guan P, Jeyarajaguru P, McIntosh H, Petrou C, Pisani S, Hammond N. Therapeutic engagement in robot-assisted psychological interventions: A systematic review. Clin Psychol Psychother. 2022; 29:857-873.
8. Nichol B, McCready J, Erfani G, Comparcini D, Simonetti V, Cicolini G, Mikkonen K, Yamakawa M, Tomietto M. Exploring the impact of socially assistive robots on health and wellbeing across the lifespan: An umbrella review and meta-analysis. Int J Nurs Stud. 2024; 153:104730.
9. OECD. Health at a glance 2025: OECD Indicators. *https://doi.org/10.1787/8f9e3f98-en* (accessed April 8, 2026).
10. Ishihara M, Matsunaga S, Islam R, Shibata O, Chung UI. A policy overview of Japan's progress on dementia care in a super-aged society and future challenges. Glob Health Med. 2024; 6:13-18.
11. Shibata T, Wada K. Robot therapy: A new approach for mental healthcare of the elderly - A mini-review. Gerontology. 2011; 57:378-386.
12. Yu C, Sommerlad A, Sakure L, Livingston G. Socially assistive robots for people with dementia: Systematic review and meta-analysis of feasibility, acceptability and the effect on cognition, neuropsychiatric symptoms and quality of life. Ageing Res Rev. 2022; 78:101633.
13. Hsieh CJ, Li PS, Wang CH, Lin SL, Hsu TC, Tsai CT. Socially assistive robots for people living with dementia in long-term facilities: A systematic review and meta-analysis of randomized controlled trials. Gerontology. 2023; 69:1027-1042.
14. Rashid NLA, Leow Y, Klainin-Yobas P, Itoh S, Wu VX. The effectiveness of a therapeutic robot, 'Paro', on behavioural and psychological symptoms, medication use, total sleep time and sociability in older adults with dementia: A systematic review and meta-analysis. Int J Nurs

Stud. 2023; 145:104530.
15. Sato M, Yasuhara M, Osaka K, Ito H, Dino MJ, Ong IL, Zhao Y, Tanioka T. Rehabilitation care with Pepper humanoid robot: A qualitative case study of older patients with schizophrenia and/or dementia in Japan. Enfermería Clínica. 2020; 30 Suppl 1:32-36.
16. Zuschnegg J, Häussl A, Lodron G, Orgel T, Russegger S, Schneeberger M, Fellner M, Holter M, Prodromou D, Schultz A, Roller-Wirnsberger R, Paletta L, Koini M, Schüssler S. Psychosocial effects of a humanoid robot on informal caregivers of people with dementia: A randomised controlled trial with nested interviews. Int J Nurs Stud. 2025; 162:104967.
17. Cui L, Li Y, Yang X, Liu X, Zhang L, Hou L. Humanoid robot-assisted support for health care in older adults: Systematic scoping review. JMIR Aging. 2026; 9:e83849.
18. Broadbent E. Interactions with robots: The truths we reveal about ourselves. Annu Rev Psychol. 2017; 68:627-652.
19. Sugiyama H, Nakamura K. Temporary improvement of cognitive and behavioral scales for dementia elderly by shiritori word game with a dialogue robot: A pilot study. Front Robot AI. 2022; 9:941056.
20. Nagata Y, Satake Y, Yamazaki R, Nishio S, Suzuki M, Kanemoto H, Yamakawa M, Figueroa D, Maalouly E, Ishiguro H, Ikeda M. A conversational robot for cognitively impaired older people who live alone: An exploratory feasibility study. Psychogeriatrics. 2025; 25:e70076.
21. Papadopoulos I, Koulouglioti C, Lazzarino R, Ali S. Enablers and barriers to the implementation of socially assistive humanoid robots in health and social care: A systematic review. BMJ Open. 2020; 10:e033096.
22. Yamazaki R, Kase H, Nishio S, Ishiguro H. Anxiety reduction through close communication with robotic media in dementia patients and healthy older adults. J Robot Mechatron. 2020; 32:32-42.
23. Bunt S, Steverink N, Olthof J, van der Schans CP, Hobbelen JSM. Social frailty in older adults: A scoping review. Eur J Ageing. 2017; 14:323-334.
24. Nolan M, Brown J, Davies S, Nolan J, Keady J. The Senses Framework: Improving care for older people through a relationship-centred approach. Sheffield Hallam University. 2006. *https://shura.shu.ac.uk/280/1/PDF_Senses_Framework_Report.pdf* (accessed April 8, 2026).
25. Golden SD, Earp JA. Social ecological approaches to individuals and their contexts: Twenty years of health education & behavior health promotion interventions. Health Educ Behav. 2012; 39:364-372.
26. Sharkey A, Sharkey N. Granny and the robots: Ethical issues in robot care for the elderly. Ethics Inf Technol. 2012; 14:27-40.
27. Deusdad B. Ethical implications in using robots among older adults living with dementia. Front Psychiatry. 2024; 15:1436273.
28. Granstedt J, Kc P, Deshpande R, Garcia V, Badano A. Hallucinations in medical devices. AI in Medicine and Life Sciences. 2025; 100145.
29. Tanioka T, Yokotani T, Tanioka R, Betriana F, Matsumoto K, Locsin R, Zhao Y, Osaka K, Miyagawa M, Schoenhofer S. Development issues of healthcare robots: Compassionate communication for older adults with dementia. Int J Environ Res Public Health. 2021; 18:4538.
30. Ministry of Economy, Trade, and Industry. AI Guidelines for business Ver. 1.0 Compiled. 2024. *https://www.meti.go.jp/english/press/2024/0419_002.html* (accessed April 8, 2026).
31. Pharmaceuticals and Medical Devices Agency. Report on AI-based software as a medical device (SaMD). 2023. *https://www.pmda.go.jp/files/000266100.pdf* (accessed April 8, 2026).

Received April 28, 2026; Revised May 30, 2026; Accepted June 2, 2026.

Released online in J-STAGE as advance publication June 3, 2026.

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