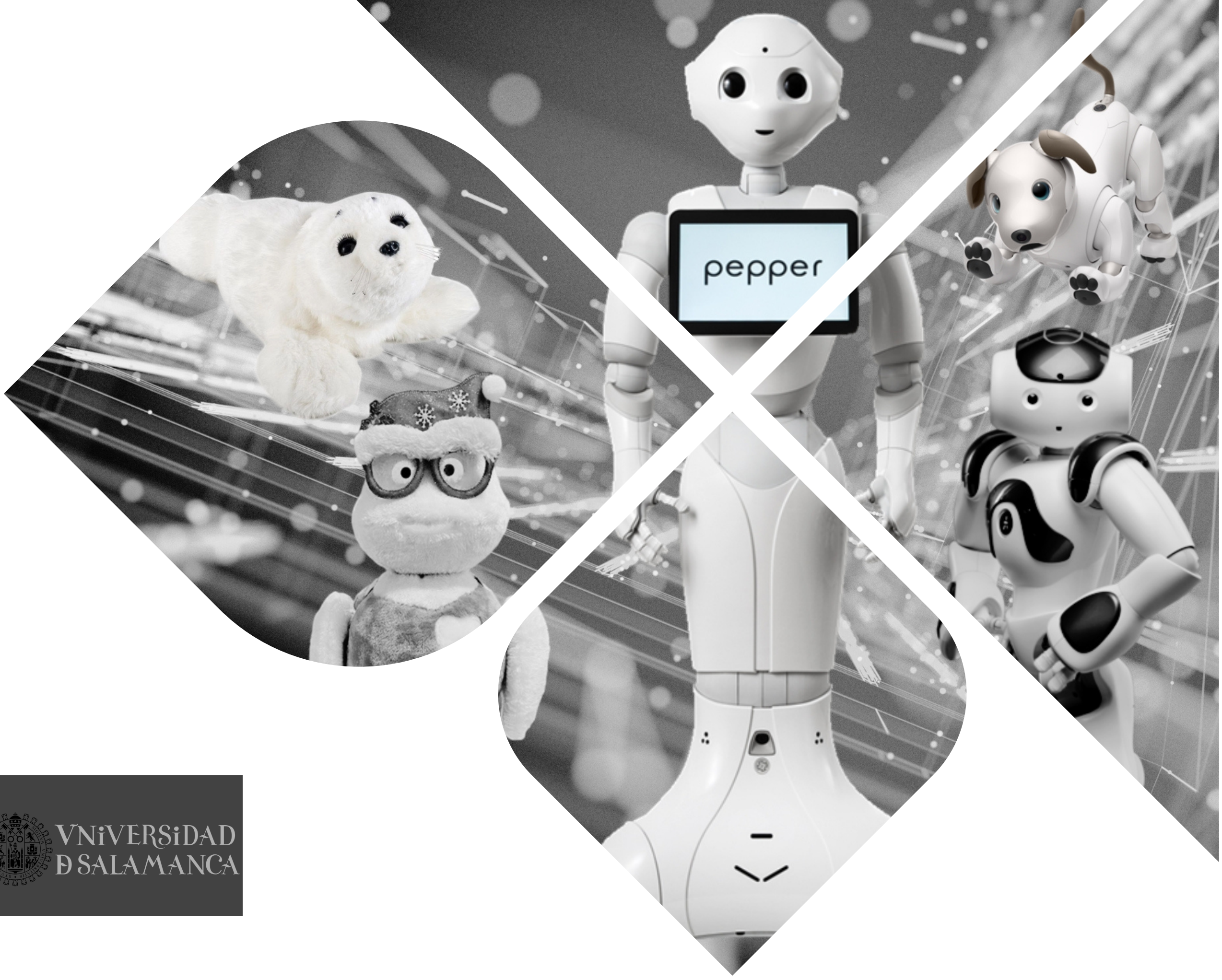

IMPROVING THE PRACTICAL USE OF SOCIAL ROBOTS FOR PEOPLE WITH DEMENTIA: TACKLING METHODOLOGICAL CHALLENGES IN DEVELOPMENT, EVALUATION, AND IMPLEMENTATION

DOCTORAL THESIS

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DOCTORAL THESIS

TESIS DOCTORAL

IMPROVING THE PRACTICAL USE OF SOCIAL ROBOTS FOR PEOPLE WITH DEMENTIA: TACKLING METHODOLOGICAL CHALLENGES IN DEVELOPMENT, EVALUATION, AND IMPLEMENTATION.

MEJORAR EL USO PRÁCTICO DE LOS ROBOTS SOCIALES PARA LAS PERSONAS CON DEMENCIA: ABORDAR LOS RETOS METODOLÓGICOS EN EL DESARROLLO, LA EVALUACIÓN Y LA IMPLEMENTACIÓN.

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2023

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Miss Aysan Mahmoudi Asl has completed under supervision the Doctoral Thesis: " **IMPROVING THE PRACTICAL USE OF SOCIAL ROBOTS FOR PEOPLE WITH DEMENTIA: TACKLING METHODOLOGICAL CHALLENGES IN DEVELOPMENT, EVALUATION, AND IMPLEMENTATION.**" to opt for the degree of Doctor with international mention from the University of Salamanca. This Doctoral Thesis is presented in the modality of Thesis by Compendium of Publications.

Salamanca, a 2 de Noviembre de 2023

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A mi Tierra, IRAN.

"Dementia teaches us to find beauty in the fragments and meaning in the moments that transcend memory."

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Abstract

Background: Positioned within the realm of digital health technologies, social robots emerge as a prospective avenue for enhancing the quality of life and social health of elderly adults and people with dementia (PwD). These robots offer companionship and social engagement, cognitive stimulation, learning and entertainment, monitoring and safety, assistance with daily activities and communication aid. Based on the existing literature, they are proven to improve social interactions, activity participation and engagement, and emotions in these target groups. It is crucial to adopt proper evaluation methodologies to study social robots and their effectiveness and implementation in this target group. Moreover, careful consideration of design and interaction methods, as well as ongoing customization, is essential to address these challenges and ensure that social robots effectively support and engage individuals with dementia in a meaningful and respectful manner.

Lately, a robotic platform called MINI has been designed and developed in the robotic lab of the University of Carlos III in Madrid with an aim to support seniors and provide cognitive and social stimulation for older adults, especially for those with cognitive impairment.

Aim: In this project, firstly, we aimed to review the methodologies used thus far in studies evaluating the feasibility, usability, efficacy, and effectiveness of social robots in clinical and social settings for elderly people, including persons with dementia. Secondly, we assessed the viewpoints of stakeholders and external contextual factors that could either facilitate or impede the introduction of the MINI social robot in Meeting Centres (MC) located in communities, aimed at providing support for PwD and their caregivers in the Netherlands and Spain. Thirdly, we investigated the acceptability and attitudes of the PwD and Mild Cognitive Impairments (MCI) towards the MINI robot. Lastly, we evaluated the usability and user experience of the MINI robot in the laboratory setting.

Methods: For the scoping review, dedicated search strings were developed. Searches in MEDLINE (PubMed), Web of Science, PsycInfo, and CINAHL were performed on August 13, 2020. To trace facilitators and barriers to the adaptive implementation of innovations in dementia care, an explorative qualitative study was conducted. Following the introduction of the MINI robot

11 stakeholders were interviewed in three MCs in the Netherlands and one in Spain, as well as stakeholders in health and welfare organizations in both countries. In total 12 adults with dementia participated in focus groups. The data were thematically analysed and narratively described. To evaluate the usability and acceptability of the MINI robot, mixed-method studies were conducted (acceptability; 22 | usability: 10 PwD and MCI, aged 65 and over). Individual interaction sessions lasted one month for acceptability and one day for usability.

Results: In the scoping review, forms of randomized controlled trials were the most applied designs. Feasibility and usability were often studied together in mixed methods or experimental designs and were most often studied in individual interventions. Feasibility was often assessed with the Unified Theory of the Acceptance and Use of Technology model. Efficacy and effectiveness studies used a range of psychosocial and cognitive outcome measures. However, the included studies failed to find significant improvements in quality of life, depression, and cognition. The most important (expected) facilitating factors mentioned by stakeholders appeared to be human resources, funding, the impact of the MINI robot on the users and programs of the MCs, characteristics of the innovation, and collaboration with other care and welfare organizations, whereas (expected) barriers mentioned concerned the physical context and the functionalities of the MINI robot, user context, and MCs activity policies. The results of the Almere questionnaire showed that there was generally support for the MINI robot, with somewhat higher post-test ratings for its acceptability. The MINI robot was regarded as a joyous companion, particularly for people living alone. While participants appreciated the robot, improvement suggestions were also offered for its features and functions. The usability study highlighted strengths in terms of quick learning, simple system and handling, and integration of functions, while also exposing areas for improvement and the need for clear guidance and expert assistance.

Conclusion: Enhancing the quality of studies in this domain necessitates a refined approach. Efficacy and effectiveness studies can benefit from robust randomized controlled trial designs, employing substantial sample sizes and individualized intervention sessions, while experimental designs hold promise for feasibility and usability investigations. Employing a mixed-method approach for data collection across all three goals - efficacy/effectiveness, feasibility, and usability - is recommended. The significance of drawing insights from multiple interaction sessions spanning at least one month cannot be understated, as it offers a pathway to unveil long-term impacts of social robots. The outcomes of this project hold transformative potential for a range of stakeholders, from meeting centres directors and managers to care and welfare organizations to consider elements that might hinder or facilitate the implementation of MINI robots in MCs. This research further guides the design and development of the MINI robot, matching its characteristics with the preferences and demands of PwD as well as fulfilling meeting centres policies, so promoting its effective integration and deployment. This project pioneers the assessment of the MINI robot's usability and acceptance among PwD and MCI in Spain, confirming its viability within clinical contexts. The insights gained provide a fresh perspective for advancing similar social robots designs and offer crucial guidance for tailoring robotic features to meet the specific requirements of end users.

Keywords: acceptability, cognitive impairments, dementia, implementation, methodologies, social robots, study design, usability.

Resumen

Antecedentes: Situados en el ámbito de las tecnologías sanitarias digitales, los robots sociales surgen como una posible vía para mejorar la calidad de vida y la salud social de los adultos mayores y las personas con demencia (PcD). Estos robots ofrecen compañía y compromiso social, estimulación cognitiva, aprendizaje y entretenimiento, supervisión y seguridad, asistencia en las actividades cotidianas y ayuda a la comunicación. Según la bibliografía existente, está demostrado que mejoran las interacciones sociales, la participación en actividades y el compromiso, y las emociones en estos grupos objetivo. Es crucial adoptar metodologías de evaluación adecuadas para estudiar los robots sociales y su eficacia y aplicación en este grupo destinatario. Además, es esencial considerar cuidadosamente los métodos de diseño e interacción, así como la personalización continua, para abordar estos retos y garantizar que los robots sociales apoyen e involucren eficazmente a las PcD de una manera significativa y respetuosa.

Últimamente, se ha diseñado y desarrollado una plataforma robótica llamada MINI en el laboratorio de robótica de la Universidad Carlos III de Madrid con el objetivo de apoyar a las personas mayores y proporcionar estimulación cognitiva y social a los adultos mayores, especialmente a aquellos con Deterioro Cognitivo Leve (DCL).

Objetivo: En este proyecto, en primer lugar, nos propusimos revisar las metodologías utilizadas hasta la fecha en los estudios de evaluación de la viabilidad, usabilidad, eficacia y efectividad de los robots sociales en entornos clínicos y sociales para personas mayores, incluidas las PcD. En segundo lugar, evaluamos los puntos de vista de las partes interesadas y los factores contextuales externos que podrían facilitar o dificultar la introducción del robot social MINI en Centros de Encuentro (CM) ubicados en comunidades, destinados a proporcionar apoyo a las PcD y a sus cuidadores en los Países Bajos y España. En tercer lugar, investigamos la aceptabilidad y las actitudes de las PcD y con DCL hacia el robot MINI. Por último, evaluamos la usabilidad y la experiencia del usuario del robot MINI en el laboratorio.

Métodos: Para la revisión del alcance, se desarrollaron cadenas de búsqueda específicas. Las búsquedas en MEDLINE (PubMed), Web of Science, PsycInfo y CINAHL se realizaron el 13 de agosto de 2020. Para rastrear los facilitadores y las barreras a la implementación adaptativa de

innovaciones en la atención a la demencia, se llevó a cabo un estudio cualitativo exploratorio. Tras la introducción del robot MINI, se entrevistó a 11 partes interesadas en tres CM de los Países Bajos y uno de España, así como a partes interesadas de organizaciones sanitarias y asistenciales de ambos países. En total, 12 adultos con demencia participaron en grupos de discusión. Los datos se analizaron temáticamente y se describieron de forma narrativa. Para evaluar la usabilidad y aceptabilidad del robot MINI, se realizaron estudios de métodos mixtos (aceptabilidad; 22 y usabilidad: 10 PcD y DCL, mayores de 65 años). Las sesiones individuales de interacción duraron un mes para la aceptabilidad y un día para la usabilidad.

Resultados: En la revisión del alcance, las formas de ensayos controlados aleatorios fueron los diseños más aplicados. La viabilidad y la usabilidad se estudiaron a menudo juntas en diseños de métodos mixtos o experimentales y se estudiaron con más frecuencia en intervenciones individuales. La viabilidad se evaluó a menudo con el modelo de la Teoría Unificada de la Aceptación y el Uso de la Tecnología. Los estudios de eficacia y efectividad utilizaron diversas medidas de resultados psicosociales y cognitivos. Sin embargo, los estudios incluidos no lograron encontrar mejoras significativas en la calidad de vida, la depresión y la cognición. Los factores facilitadores (esperados) más importantes mencionados por las partes interesadas parecían ser los recursos humanos, la financiación, el impacto del robot MINI en los usuarios y los programas de los MC, las características de la innovación y la colaboración con otras organizaciones de asistencia y bienestar, mientras que las barreras (esperadas) mencionadas se referían al contexto físico y las funcionalidades del robot MINI, el contexto del usuario y las políticas de actividad de los MC. Los resultados del cuestionario de Almere mostraron que, en general, el robot MINI gozaba de apoyo, con valoraciones posteriores algo más altas en cuanto a su aceptabilidad. El robot MINI se consideró un compañero alegre, sobre todo para las personas que viven solas. Aunque los participantes valoraron positivamente el robot, también hicieron sugerencias para mejorar sus características y funciones. El estudio de usabilidad puso de relieve los puntos fuertes en cuanto a rapidez de aprendizaje, sencillez del sistema y manejo, e integración de funciones, al tiempo que expuso los aspectos mejorables y la necesidad de una orientación clara y la asistencia de expertos.

Conclusiones: La mejora de la calidad de los estudios en este ámbito requiere un enfoque refinado. Los estudios de eficacia y efectividad pueden beneficiarse de sólidos diseños de ensayos controlados aleatorios, que empleen muestras de tamaño considerable y sesiones de intervención individualizadas, mientras que los diseños experimentales resultan prometedores para las

investigaciones de viabilidad y usabilidad. Se recomienda emplear un enfoque de métodos mixtos para la recopilación de datos sobre los tres objetivos: eficacia/efectividad, viabilidad y usabilidad. No se puede subestimar la importancia de extraer conclusiones de múltiples sesiones de interacción que abarquen al menos un mes, ya que ofrece una vía para desvelar las repercusiones a largo plazo de los robots sociales. Los resultados de este proyecto encierran un potencial transformador para toda una serie de partes interesadas, desde directores y gestores de centros de reunión hasta organizaciones de asistencia y bienestar social, con el fin de considerar los elementos que podrían dificultar o facilitar la implantación de los robots MINI en los MC. Esta investigación orienta además el diseño y desarrollo del robot MINI, ajustando sus características a las preferencias y demandas de las PcD, así como al cumplimiento de las políticas de los centros de reuniones, promoviendo así su integración y despliegue efectivos. Este proyecto es pionero en la evaluación de la usabilidad y aceptación del robot MINI entre PcD y DCL en España, confirmando su viabilidad en contextos clínicos. Los conocimientos adquiridos proporcionan una nueva perspectiva para avanzar en el diseño de robots sociales similares y ofrecen una orientación crucial para adaptar las características robóticas a las necesidades específicas de los usuarios finales.

Palabras clave: aceptabilidad, deficiencias cognitivas, demencia, implementación, metodologías, robots sociales, diseño de estudios, usabilidad.

Organization of the thesis

The RD 99/2011, of January 28th, regulates the official doctoral programmes. Likewise, the Doctoral and Postgraduate Commission, through article 17 of the Doctoral Regulations of the University of Salamanca, establishes and accepts as a possible doctoral thesis format, the modality by compendium of articles and/or publications in specialized journals. Therefore, this Doctoral Thesis is presented under this modality.

Articles

1. **Mahmoudi, A.**, Molinari Ulate, M., Franco Martin, M., & Van der Roest, H. (2022). Methodologies Used to Study the Feasibility, Usability, Efficacy, and Effectiveness of Social Robots for Elderly Adults: Scoping Review.

   Journal of Medical Internet Research, 24(8), e37434 DOI: https://doi.org/10.2196/37434

   Impact Factor 7.08

   Journal Citation Indicator Quartile: Q1

2. **Mahmoudi, A.**, Toribio-Guzmán, J. M., Van der Roest, H., Castro-González, Á, Malfaz, M., Salichs, M. A., & Martin, M. F. (2022). The usability and feasibility validation of the social robot MINI in people with dementia and mild cognitive impairment; a study protocol.

   BMC Psychiatry, 22(1), 760. DOI: https://doi.org/10.1186/s12888-022-04418-9

   Impact Factor: 4.144

   Journal Citation Indicator Quartile: Q2

3. **Mahmoudi, A.**, Kouters S., Castro-González, Á., Van der Roest, H., Franco Martin. & Dröes R.M, (2023). Potential Facilitators of and Barriers to Implementing the MINI Robot in Community-Based Meeting Centers for People with Dementia and Their Carers in the Netherlands and Spain: Explorative Qualitative Study.

   Journal of Medical Internet Research, 25: e44125, DOI: https://doi.org/10.2196/44125

   Impact Factor 7.08

   Journal Citation Indicator Quartile: Q1

Articles under review

1. **Mahmoudi, A.**, Toribio-Guzmán, J. M., Castro-González, Á., Castillo, J. C., Martin, F. A., Salichs, M. A., Van der Roest, H. & Franco Martin, M. Acceptability of the Social Robot MINI and Attitudes of People with Dementia and Mild Cognitive Impairment: A Mixed Method Study. **BMC Psychiatry.** Preprints DOI: https://doi.org/10.21203/rs.3.rs-3163743/v1

2. **Mahmoudi, A.**, Toribio-Guzmán, J. M., Castro-González, Á., Malfaz, M., Salichs, M. A., Van der Roest, H. & Franco Martin. Evaluating the User Experience and Usability of the MINI Robot for Older Adults with Mild Dementia and Mild Cognitive Impairment: Insights and Recommendations. **International Journal of Social Robotics**. Under review.

Collaboration

The PhD candidate contributed to different research projects during her PhD. Nonetheless, these collaborations won't be an object of the thesis defence (Supplementary Material 1).

1. Molinari Ulate, M., **Mahmoudi, A.**, Parra Vidales, E., Muñoz- Sánchez, J.L., Franco Martin, M., & Van der Roest, H. Digital health technologies supporting the application of comprehensive geriatric assessments in long-term care settings or community care: A systematic review. Digital Health, https://doi.org/10.1177/20552076231191008

2. Molinari Ulate, M., **Mahmoudi, A.**, Franco Martin, M., & Van der Roest, H. (2022). Psychometric Characteristics of Comprehensive Geriatric Assessments (CGAs) for long-term care facilities and community care: A Systematic Review. Ageing Research Reviews, 81. doi: https://doi.org/10.1016/j.arr.2022.101742

3. Koh, W. Q., Heins, P., Flynn, A., **Mahmoudi, A.**, Garcia, L., Malinowsky, C. & Brorsson, A. (2022). Bridging gaps in the design and implementation of social assistive technologies for dementia care: the role of occupational therapy. Disabilty and Rehabilitation: Assistive Technology, 1-9. doi: https://doi.org/10.1080/17483107.2022.2111610

4. Diaz Baquero, A. A., Franco-Martín, M. A., Parra Vidales, E., Toribio-Guzmán, J. M. Bueno-Aguado, Y., Martínez Abad, F., **Mahmoudi, A.**, Van der Roest, H. G. (2022). The Effectiveness of GRADIOR: A Neuropsychological Rehabilitation Programme for People with Mild Cognitive Impairment and Mild Dementia. Results of Randomized Controlled Trial After 4 and 12 Months of Treatment. Journal of Alzheimer's Disease, 86, 711-727. doi: https://doi.org/10.3233/jad-215350

Conference Contributions

The following publications were part of the dissemination of the PhD project. These publications won't be an object of the thesis defence.

1. Acceptability of the Social Robot MINI and Attitudes of People with Dementia and Mild Cognitive Impairment. Oral presentation. 33rd Alzheimer Europe Conference. Helsinki, Finland. (2023, October 16 – October18)
2. Potential facilitators and barriers of implementing the MINI social robot in MCs for people with dementia and carers in the Netherlands and Spain. Oral presentation. 32nd Alzheimer Europe Conference. Bucharest, Romania. (2022, October 17 – October 19)
3. Social robots in dementia care and methodologies to study them. Oral presentation. Congress of the Spanish Society of Psychogeriatrics. Valladolid, Spain. (2022, September 29 – October 1)
4. An occupational therapy perspective on the use of novel technology with people with dementia. Oral presentation. 18th WFOT Congress. Paris, France. (2022, August 28 – August 31)
5. Methodologies used to study the effectiveness of social robots in long-term and community care settings. Poster presentation. 21st Alzheimer's Association International Conference. Denver, USA. (2021, July 25 – July 28)

Other Publications

The following are short publications that were part of the doctoral candidate's work in DISTINCT project (Supplementary Material 2). These publications will not be an object of the thesis defense.

1. **A. Mahmoudi**, R. M. Dröes, et al. Ensure the appropriate methodology for evaluating social robots. Best Practice Guidance: Human Interaction with Technology in Dementia. Retrieved from https://www.dementiainduct.eu/guidance/recommendation/3.2.5.2/

2. **A. Mahmoudi**, R. M. Dröes, et al. Robotic platform features and applications need to be tailored to the needs and preferences of end-users before implementing them in community-based dementia care. Best Practice Guidance: Human Interaction with Technology in Dementia. Retrieved from https://www.dementiainduct.eu/guidance/recommendation

3. Technology used in DISTINCT. 3rd DISTINCT Newsletter. https://www.dementiadistinct.com/wp-content/uploads/2022/03/3rd-DISTINCT-Newsletter-Winter-2022_final-3.3.22.pdf

4. How Is the PhD Going? 2nd DISTINCT Newsletter. https://www.dementiadistinct.com/wp-content/uploads/2021/06/DISTINCT-Newsletter-Spring-2021-Final-version-1.pdf

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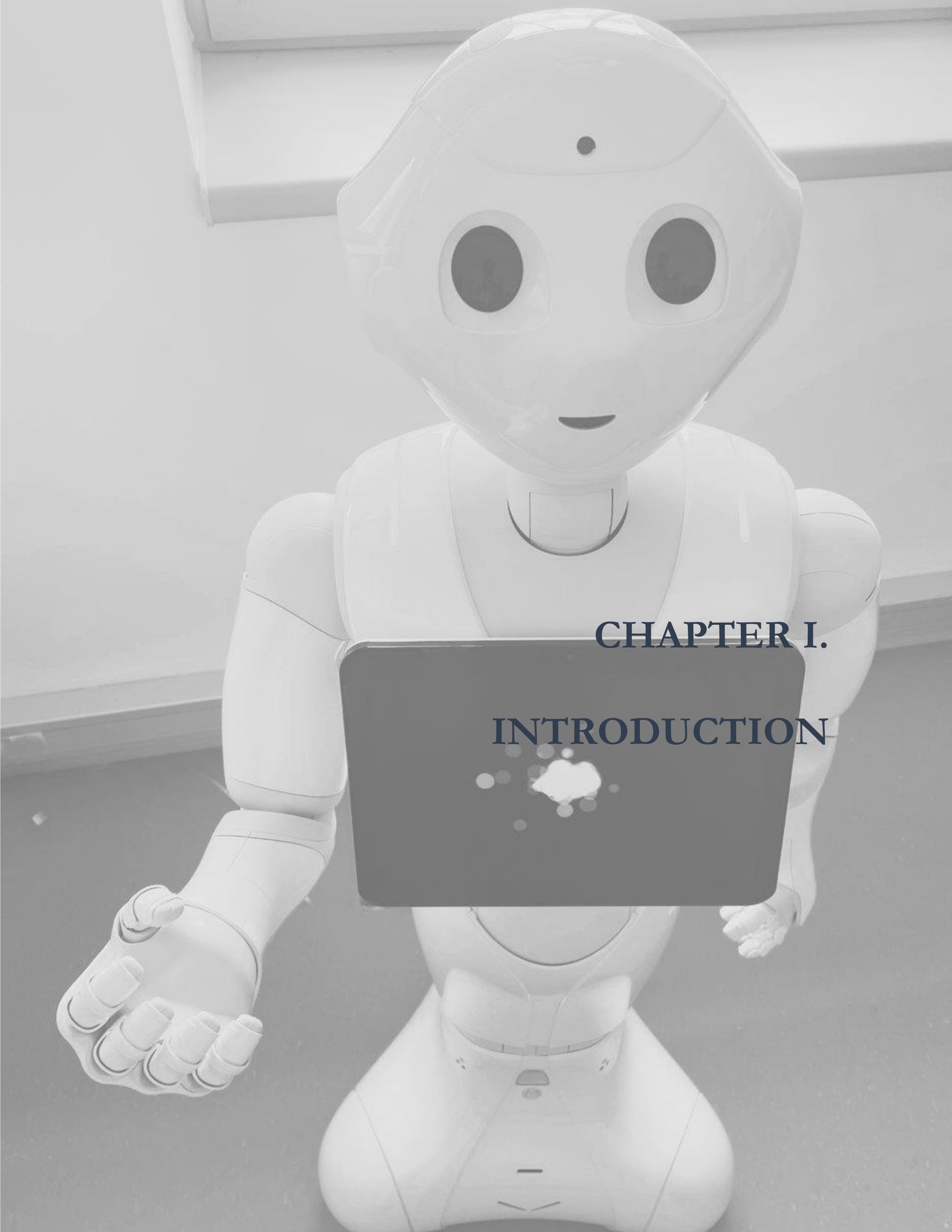


CHAPTER I.

INTRODUCTION

Dementia

In the next decades, we expect the world population to age, due to a combination of high life expectancy, low birth rates, and the baby boomer generation entering their elder years. By 2030 in Western Europe, 33% of the population will be over 60 years of age (Nations, 2015). Dementia is one of the most common neurodegenerative diseases, affecting over 55 million older people around the world, and is projected to double by 2050 (Gauthier, Webster, Servaes, Morais, & Rosa-Neto, 2022).

Dementia is being characterized by deterioration in memory, thinking, behavior, and the ability to perform everyday activities (Wimo & Prince, 2010). It is estimated that approximately one-third of people with dementia (PwD) live alone (Ebly, Hogan, Rockwood, & disorders, 1999). They experience unmet needs because of living alone and are at higher risk of faster deterioration. In addition, PwD living alone are considered at a higher risk of medication use problems, falls and injuries, inadequate self-care, activities of daily living, and reduced social networks (Meaney, Croke, Kirby, & sciences, 2005; Miranda-Castillo, Woods, & Orrell, 2010; Webber, Fox, & Burnette, 1994; Wilcox, 1995).

Intelligent Assistive Technologies (IAT) have been one of the growing bodies in dementia research (Dada, van der Walt, May, & Murray, 2021). IAT is an umbrella term including a range of digital devices such as smart home systems, tablets, smartphones, wearable devices, and humanoid robots. According to a systematic review, IAT has been suggested to empower people in the mild to moderate stages of dementia, supporting their independence for a longer time (Ienca et al., 2017). These Technologies have been implemented with some success to support social participation and self-management (Knapp M, 2022; Neal et al., 2021).

Socially Assistive Robots (SARs)

In the recent decades, technological advances coincided with the great health challenge of aging societies (Perrier, 2015). Emerging research in assistive technology focuses on developing social robots for older adults, with or without cognitive impairment, to enhance their quality of life (QoL) by enabling communication and social engagement (Mordoch, Osterreicher, Guse, Roger, &

Thompson, 2013). These robots are designed to offer social interaction, cognitive stimulation, and autonomy support, ultimately contributing to the wellbeing and independence of the elderly (Fan et al., 2016) and have proven to improve the emotions and mood, social interaction, and activity participation of PwD (Mahmoudi Asl, Molinari Ulate, Franco Martin, & van der Roest, 2022). However, the field is relatively young, and only a limited number of fully developed, commercially available options exist.

Socially assistive robots (SARs) fall into two primary categories: service robots and companion robots, each geared toward interaction and communication (J. Abdi, A. Al-Hindawi, T. Ng, & M. P. Vizcaychipi, 2018). SARs execute this function through interactive activities —utilizing touch sensors, cameras, robotic movements, tablets, and audio systems. In the companion robot subgroup, humanoid models like PEPPER and NAO offer sophisticated applications including recreational, cognitive, and assistance activities. Pet robots such as PARO, AIBO, and NECORO serve as substitutes for pets, delivering emotional and physiological stimulation, leading to mood enhancements and calming effects (Robinson, MacDonald, Kerse, & Broadbent, 2013).

MINI Robot

MINI, a recently developed humanoid robot from Carlos III University of Madrid, assumes the role of a social companion tailored for seniors, enhancing their daily lives whether at home or within nursing facilities. MINI adeptly communicates with humans through both verbal and nonverbal (touch, body lights, eyes status, tablet interface) means. This lightweight, compact, stationary robot dons a plush animal-like exterior. Its features include a speech-oriented microphone, touch sensors on the shoulders and belly for physical interaction, an RGB-D camera for visual and depth perception, expressive uOled eyes that convey emotional states, and a versatile tablet serving as both input (via fixed menus) and output display for application content. By engaging users through games and apps, MINI offers psychosocial and cognitive stimulation alongside safety, entertainment, and personalized aid. MINI is set up to ask certain queries, receive responses, and provide users with feedback on their performance (E. Salichs et al., 2018; M. A. Salichs et al., 2020; Velázquez-Navarroa et al.). Presently, MINI is in prototype mode and supports the Spanish language exclusively (See Figure 1).

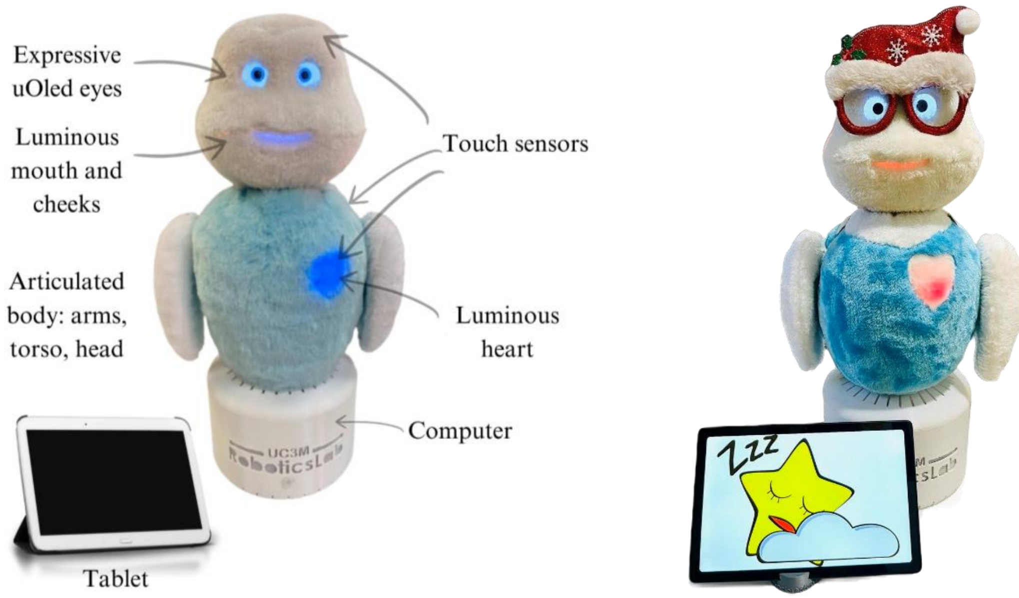


Figure 1. MINI robot

Methodologies to study the SARs

For successful implementation and large-scale uptake of social robots, or any psychosocial intervention, the feasibility, usability, and (cost-)effectiveness should be perceived as good by the end-users (PwD and healthy older adults), clinicians, and other stakeholders (for instance health care insurers and policymakers). The Monitoring and Evaluating Digital Health Interventions framework, recommends the following evaluations to take place to integrate and implement a digital health intervention; *Feasibility*, the study assesses whether the digital health system works as intended in a given context; *usability*, the study assesses whether the digital health system can be used as intended by users; *efficacy*, assess whether the digital health intervention can achieve the intended results in research (controlled) setting. and *effectiveness*, the study assesses whether the digital health intervention can achieve the intended results in a non-research (uncontrolled) setting (Organization, 2016).

Despite the rising interest in social robots, mainly after the covid pandemic, there is a limited evidence base for the effectiveness of social robots in elderly care. The methodological quality of studies on the effectiveness of social robots in elderly adults is still low, and inappropriate study designs, samples, form and duration of interventions, and way of data collection have affected the strength of the study outcomes (J. Abdi, A. Al-Hindawi, T. Ng, & M. P. J. B. o. Vizcaychipi, 2018).

Meeting Centre Support Programme (MCSP); facilitators and barriers of implementing the MINI robot

In response to providing social and health support programmes for PwD and reducing the adverse effects of dementia, already in 1993, the Meeting Centre Support Programmes (MCSP) for PwD and their carers was set up in the Netherlands. Recently, the MCSP has been adaptively implemented in several other European countries as well, i.e. in the UK, Poland, Italy, and Spain (van Rijn, Meiland, & Dröes, 2019). Currently, there are more than 180 MCs across the Netherlands and around 70 in other European countries. MCSP has been proven to be effective on psychosocial symptoms such as mood and depression, inactive and unsocial behavior, and quality of life as well as on the carer burden and delayed nursing home admission of PwD (Brooker et al., 2018; Rose-Marie Dröes, Breebaart, Ettema, Van Tilburg, & Mellenbergh, 2000; R-M Dröes et al., 2004; R-M Dröes, Meiland, Schmitz, Van Tilburg, & Health, 2006; Evans et al., 2020; Mazurek et al., 2019).

Several frameworks and guidelines have been suggested in literature to aid in the successful implementation of complex interventions: The MRC published a framework for the development and evaluation of complex interventions and to help researchers with methodological difficulties (Craig et al., 2008). The MRC also developed a guidance for process evaluation of the implementation of complex interventions which focuses on the influence that contextual factors, implementation factors, and mechanisms of impact may have on the outcome of interventions (Moore et al., 2015). The effectiveness of an intervention can be limited due to flaws in proper implementation (Vernooij-Dassen & Moniz-Cook, 2014). Hence, the MRC framework emphasises the importance of intervention implementation ingredients such as fidelity, dose, and reach and addresses issues such as management, structure, support, and training to shape proper intervention conditions. The term "mechanism of impact" refers to how the proposed intervention brings about the desired changes and how these outcomes might be repeated in future interventions of a similar nature. Understanding the "context" in which a complex intervention is taking place becomes important when external contextual elements may facilitate or impede proper implementation and as such may influence the intervention outcome.

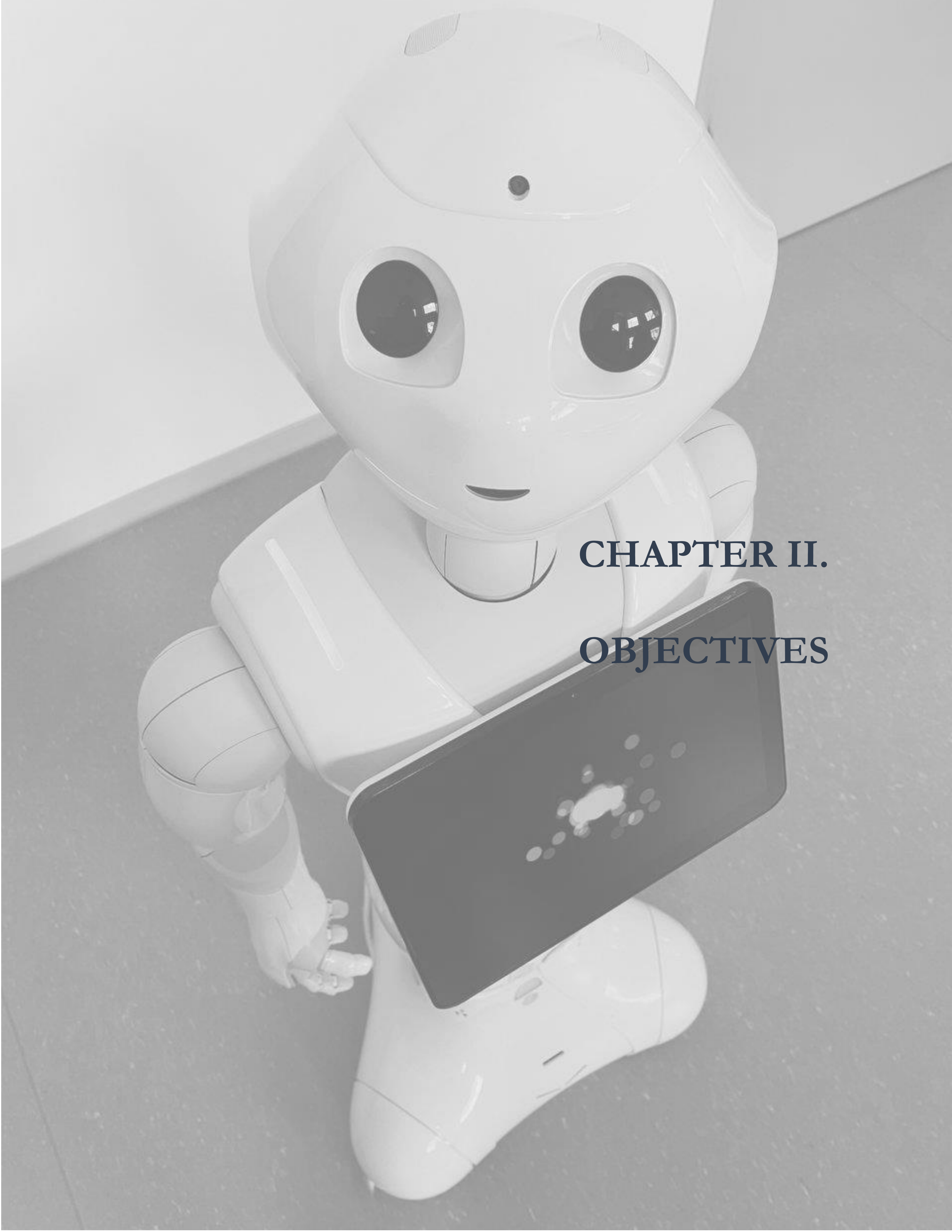
Another theoretical model to evaluate the implementation of complex interventions has been proposed by Meiland et al. (Meiland, Dröes, De Lange, Vernooij-Dassen, & Geriatrics, 2004). Their model is designed to trace facilitators and barriers to the adaptive implementation of innovative practices in dementia care, attuned to the local and regional conditions (Meiland et al., 2004). Preconditions, as well as the phases of preparation, execution, and continuation of implementation are covered by this theoretical framework. The preconditions refer to the existing conditions in the context where the intervention will be implemented, including characteristics of the innovation, operational conditions, human and financial resources and organizational conditions that can facilitate or impede the implementation of an intervention. In the preparation phase an assessment of the need for adaptively implementing the intervention and an inventory of the practical preparations required for successfully implementing the intervention are made and evaluated. With regard to the execution phase in which the intervention is started in practice, elements that interact with the high-quality execution of the intervention are evaluated. In the final phase, continuation, elements that contribute to an effective intervention are evaluated. The above-mentioned phases are further specified in the model on three levels: micro (user/primary process, e.g., personnel, training, management, care provider, person with dementia and informal carer), meso (collaboration between care providers/organizations, finances, division of tasks, collaboration with other organizations), and macro (structure of care system, laws, regulations and national and regional policies).

Acceptability and usability of social robots

To ensure the efficacy and adoption of social robots, it is crucial to ascertain their perceived usability, user-friendliness, and acceptability among potential users. The effectiveness of social robots hinges on the willingness of stakeholders to embrace their use. The intricate dimensions of physical, psychosocial, and behavioral interactions with social robots significantly contribute to the overall acceptance trajectory among users (Jenay M Beer et al., 2017). Technological attributes inherent to social robots emerge as pivotal determinants within the domain of usability metrics, with usability being considered a key predictor of a social robot's acceptability.

In the context of a usability study for social robots, the assessment revolves around how easily users can interact with the robot and achieve goals. This assessment places emphasis on user interface, controls, and the overall user experience to ensure accessibility and user-friendliness. Furthermore, understanding the user experience aids researchers and developers in designing robots that are not only technically functional but also emotionally and socially effective. Elements such as the robot's appearance, communication style, adaptability to individual preferences, and its ability to engage users in meaningful activities are crucial for optimizing effectiveness and acceptance, particularly in interventions for PwD.

A part of this project involves examining how individuals with dementia perceive and interact with robot. Given the complex nature of human-robot interactions, rigorous inquiries into the dynamics of interactions between social robots and this target population are imperative.



CHAPTER II.

OBJECTIVES

General objectives

The main aims of this project were:

1. To develop the state-of-the-art proof-of-concept of the methodologies to study the feasibility, usability, efficacy, and effectiveness of social robots for elderly adults.

2. To develop a proof-of-concept for the implementation of the MINI robot in PwD and MCI, with a focus on assessing its acceptability and usability in clinical settings, potential facilitators and barriers for implementing it in a community setting, understanding the attitudes and preferences of individuals with MCI and PwD towards the MINI robot, and identifying necessary modifications to enhance its overall effectiveness and adoption by end users.

Specific objectives by study

To achieve the main aims of the project, it was needed to conduct several studies with specific objectives, which are described as follows:

1. Scoping review

Comprehensive literature search to explore methodologies and study designs aimed at evaluating the feasibility, usability, efficacy, and effectiveness of social robots for elderly adults.

2. Implementation of the MINI robot in the MCs in the Netherlands and Spain

1.1. To investigate the attitudes of stakeholders to implementing the social robot MINI in community-based MCs for PwD and carers in the Netherlands and Spain.

1.2. To track potential facilitators, and hurdles to implementing the social robot MINI in community-based MCs for PwD and carers in the Netherlands and Spain.

3. **Acceptability of the MINI robot and attitudes of the PwD and MCI in a clinical setting in Spain**

3.1. To evaluate the acceptability of the MINI robot in clinical settings.

3.2. To explore the attitudes, needs and preferences of the PwD and MCI towards the MINI robot.

3.3. To identify key modifications required to enhance the acceptability of the robotic platform.

4.1. To evaluate the user experience and usability of the MINI robot in a clinical setting and identify necessary changes and modifications to enhance its performance.

4.2. To determine specific alterations required to optimize the robotic platform's usability and user friendliness.

CHAPTER III.

METHODOLOGY

This project comprises four different studies that were aligned to target the aims presented in the previous chapter. Each of them was developed with a specific methodology that is described in this section.

Literature search on the methodologies and study designs to evaluate the feasibility, usability, efficacy, and effectiveness of social robots for elderly adults. (Publication 1.)

Protocol Registration

The protocol of this scoping review was registered in Open Science Framework (OSF).

Search Strategy

Searches were conducted on August 13, 2020, in MEDLINE (PubMed), Web of Science, PsycInfo, and CINAHL databases. No time window was applied. Three search strings covering the topics "social robots," "community setting," and "elderly people" were constructed. For each database, reverent subject headings were adapted. For MEDLINE, we used the following strings and keywords: ((robotics[MeSH Terms] OR robot*)) AND ((humanoid OR companion OR social* OR "socially assistive" OR interact* OR android)), (((((((aging[MeSH Terms]) OR (aged[MeSH Terms])) OR (elderly[MeSH Terms])) OR (vulnerable population[MeSH Terms])) OR (senior)) OR (ageing)) OR (geriatric)) OR (old*), and (((((community health service[MeSH Terms]) OR (social support[MeSH Terms])) OR (residential facilities[MeSH Terms])) OR (independent living[MeSH Terms])) OR (social support[MeSH Major Topic])) OR ("community dwelling" OR "home dwelling" OR "care home" OR "in-home" OR "at home" OR "home-based" OR "home setting" OR "nursing home" OR home).

Selection Criteria

Publications potentially eligible for inclusion had to study a social robot that was physically embedded in an experimental or clinical study in people aged 65 or above. Studies were excluded if they were (1) conducted in an acute care setting; (2) conference abstracts, case studies, dissertations, books, or review papers; (3) published in a language other than English or Spanish; (4) solely reporting a robot design, development process, or theoretical models (5) stakeholder opinions on robots without any interaction; (6) involved in the implementation of new hardware or software or an assessment tool on a robot (such as assessing a fall detection sensor); and (7) involving telepresence robots with only video call features.

Selection Procedure

After the removal of duplicates, 2 reviewers (authors AM and MM) independently applied the inclusion and exclusion criteria in 3 steps, starting with screening titles, abstracts, and then full texts. The selections were compared, and in case of disagreement, discussed by the 2 reviewers. In cases where no consensus could be reached, a third reviewer was consulted (author HR).

Data Extraction

The literature was mapped according to the following areas of interest: author and country, robot name, the aim of the robot, aim of the study, type of outcome measure, study design, study sample, study setting, methodology of data collection, interaction scenario, relevant outcome measures, measurement instruments, results, and reported limitations of the study. Information was synthesized descriptively, and findings were narratively summarized according to the areas of interest.

The quality of the included articles was appraised independently by 2 authors (AM and MM), through the quality assessment of digital health interventions within the Monitoring and Evaluating Digital Health Interventions framework established by the World Health Organization (WHO) (Louie, McColl, & Nejat, 2014). The tool includes a list of methodological study criteria comprising (1) 23 essential criteria for all types of studies and (2) essential criteria for qualitative and quantitative studies (3 criteria each). The extent to which criteria were met by studies was rated by 3 independent researchers on a 3-point scale (0= poor, 1= fair, 2= good). We calculated the percentage of agreement between the ratings (Supplementary Material 3). We also applied this framework to categorize the studies according to their aims in 4 categories: (1) feasibility, (2) usability, (3) efficacy, and (4) effectiveness.

Potential facilitators and barriers to implementing the MINI robot in the MCs. (Publication 2.)

Study design, participants, and settings

An explorative qualitative design, using one-off semi-structured interviews with stakeholders other than PwD and focus groups with PwD, was employed to identify potential facilitators and barriers to implementing the MINI robot in PwD and people with MCI attending MCs in the Netherlands (N=3) and Spain (N=1). Participants were selected and recruited through the purposive sampling method. The participants interviewed in the Netherlands came from three MCs in the middle and west of the country: 12 people with mild to moderate dementia who were invited by the coordinator of the MC to participate in the focus group, and 9 professional stakeholders including the managers and activity therapists of the three MCs the chair of the Amsterdam section of the Dutch Alzheimer Association, and a senior policy advisor and coordinator of the social support domain of the municipality of Amsterdam. In Spain, the manager of the MC and the head of the Community Support Complex in Zamora participated.

MINI robot presentation

An introduction video clip of the MINI robot was produced in collaboration with the robotic laboratory of the University of Carlos III, Madrid, and translated into Dutch, adding a Dutch voice-over and subtitles, by researchers of Amsterdam UMC, location VUmc. The video provides information on the use and functionality of the MINI robot, as well as its software and application, and demonstrates a user interacting with the robot. This video was sent to participants via email as a YouTube video link before the interview day, accompanied by the study aim, a brief description of the MINI robot and the interview questions. The interviews were conducted in person, and participants were free to watch the video again before answering the questions.

For the PwD, the video was shown on a big screen TV/ projector screen during a focus group session, and general questions were asked about their opinion and attitudes toward the MINI robot (see Figure 2) .

Figure 2. The presentation of the MINI robot to the PwD in the MCs

Method of data collection

The interview questions were created based on the MRC guidance for process evaluation and Meiland et al.'s theoretical framework to trace facilitators and barriers regarding preconditions, and the preparation and execution phases of implementation at micro, meso, and macro levels, including contextual, implementation, and mechanism of (Meiland et al., 2004) impact factors. Figure 3 demonstrates how the two models were combined to create the theoretical framework of our explorative study. The semi structured interview questions for the stakeholders other

than the PwD are presented in Supplementary Material 4.

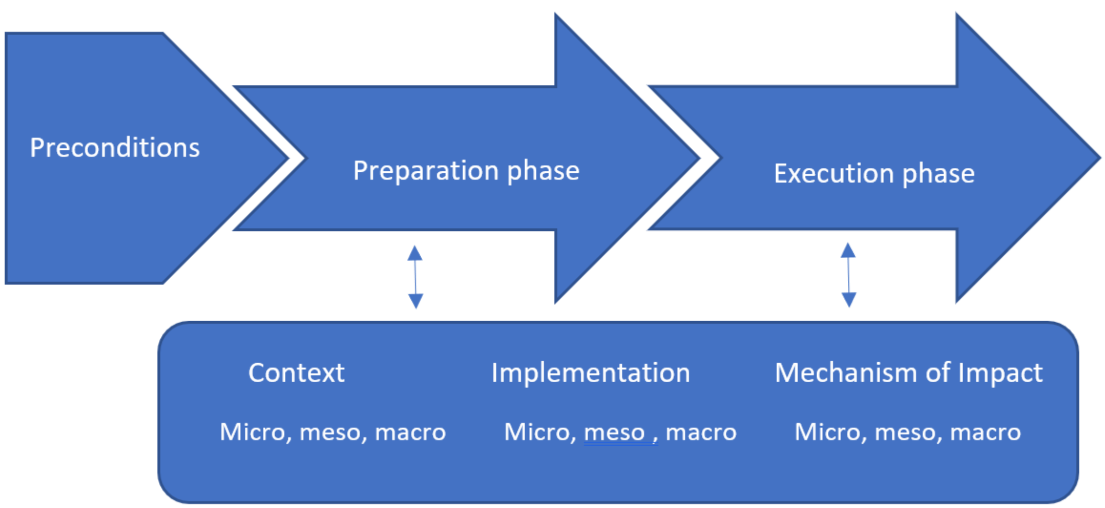


Figure 3. Combined model for tracing facilitators and barriers of implementation of the MINI robot based on the Medical Research Council's guidance for Process Evaluation and the model for tracing facilitators and Barriers of Meiland et al.

Two interviewers, the main researcher of the study (AM) and a local researcher in the Netherlands (SK), interviewed the stakeholders individually and took notes (quotes) of what was stated, and all interviews were audio recorded.

In the focus groups, the PwD discussed their general attitudes towards the implementation and application of the MINI robot in the MC. The local researcher (SK) interviewed and moderated the focus group sessions and the sessions were audio recorded.

Data analysis

The interviews were anonymously recorded by iPhone 13 voice recording App. The local researcher (SK) transcribed the audio recordings and translated them into English. The main researcher (AM) followed the same procedure for the interviews in Spain. The codes for facilitators and barriers regarding preconditions, preparation phase and execution phase, level (micro, meso, and macro), and factors associated with a context, implementation, and mechanism of impact were created. Following that, the study supervisor (RMD) and main researcher (AM) independently coded three interview transcripts, reviewed the disparities, and discussed them until consensus was reached. The other transcriptions and meeting notes were then further coded thematically by the main researcher (AM) using NVivo 12 software, and potential facilitators and barriers were summarized. The complete list of codes is presented in Supplementary Material 5.

Acceptability of the MINI robot and attitudes of the PwD and MCI in the clinical setting in Spain. (Publication 4.)

Study design

A mixed-method study design was employed to capture in-depth information on the MINI robot's acceptability of the PwD and MCI. Ethical approval for this study was obtained from the Zamora Ethical Committee (Number 574, 28/01/2022, Supplementary Material 6). This experiment's methodology was based on recent scoping reviews (He, He, & Liu, 2022; Mahmoudi Asl et al., 2022) and recommendations for evaluating social robots in elderly adults and PwD. The study protocol was published in the BMC Psychiatry journal (Asl et al., 2022).

Participants and setting

A list of eligible PwD and MCI older adults attending the memory clinic and workshops of the *INTRAS foundation* in Castilla y Leon, Spain was created. After the MINI robot's brief introduction and experiment explanation, 25 people volunteered to participate in the study. Three participants left after the first session, but 22 completed the study (13 women and 9 men | age range: 68-88 years). Table 1 describes the demographic characteristics of the participants.

The inclusion and exclusion criteria were as follows:

- Inclusion criteria:
    - PwD and/or MCI diagnosed by the public health system and following the DSM-5 criteria.
    - Aged 65 and over
    - Ability to read and write in Spanish
    - Ability to decision making
    - MMSE score ≤ 24
- Exclusion criteria:
    - Unstable medical conditions.

Measures

A survey questionnaire based on Heerink's Almere model (Heerink, Kröse, Evers, & Wielinga, 2010) was used to gauge acceptability (see Supplementary Material 7). The questionnaire comprises influencing factors, including Anxiety (ANX), Perceived Usefulness (USN), Perceived Adaptability (ADP), Perceived Enjoyment (ENJ), Perceived Ease of Use (EAS), Perceived Sociability (SOC), Attitude (ATT), Social Presence/ personality of the robot/social presence (PSN), and Trust (TRS).

Each item was scored using a Likert scale with a maximum of five points (Strongly Disagree = 1, Disagree = 2, Neutral = 3, Agree = 4, Strongly Agree = 5). It was designed for assessment of the perceptions of SARs by users during human-robot interaction, among elderly people. Several studies have proven a good validity and reliability for this questionnaire, in countries such as Canada (Louie et al., 2014), Switzerland (Lehmann, Ruf, & Misoch, 2021), and Poland (Piasek & Wieczorowska-Tobis, 2018).

Open-ended interview questions were designed to capture the positive and negative attitudes of the participants and any recommendations to improve/modify its features (see Supplementary Material 8).

Procedure

The participants and their next of kin were invited to the memory clinic and given the consent form to sign it. The participants came 2-3 times a week (based on their availability) to interact individually with the MINI robot for half an hour (See Figure 4). The experimenter presented the MINI robot during the first session, which was followed by the MINI robot introducing herself. They were free to choose from the apps and games and how to interact with the robot. After the first session ended (during one month), the participants were asked to complete the Acceptability questionnaire. Throughout the eight interaction sessions, the participants were free to choose which application/ game to use (See the applications interface in Figure 5). The experimenter provided the operating instructions anytime required. The whole experiment duration lasted about one month for each participant. Individual interviews and the acceptability questionnaire (post-survey) were administered at the end of the last session.

Figure 4. Interaction session with MINI

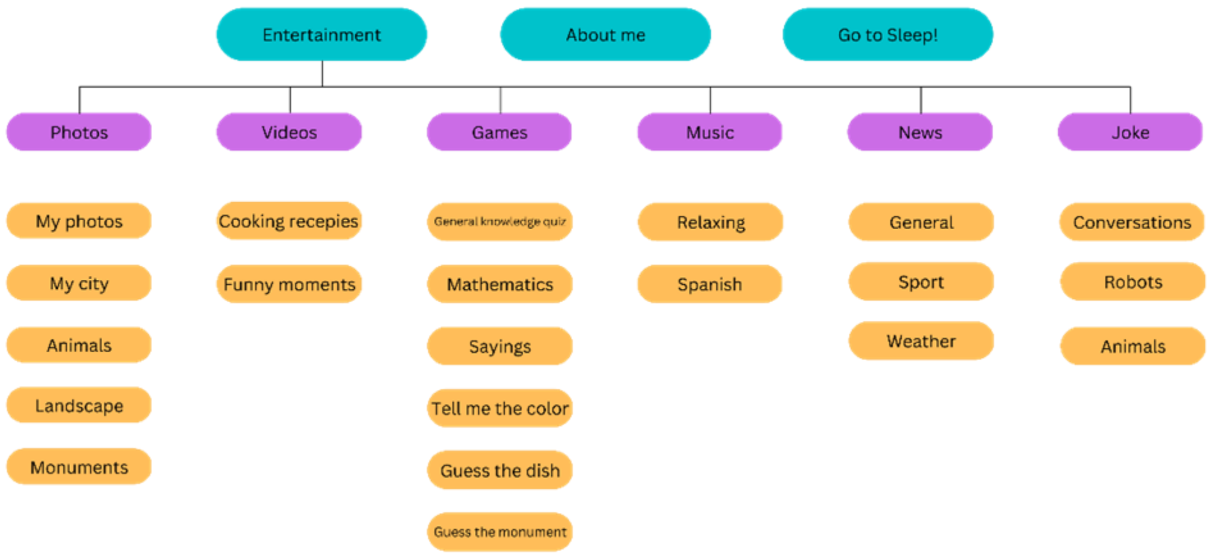


Figure 5. The MINI robot's user interface

Data analysis

For the responses of the participant to the Almere model questionnaire, descriptive analysis and graphic representation were performed using SPSS (version 24). Semi-structured interviews were analysed and coded using Nvivo 12 software. Two independent coders first identified the codes in the interview statements and generated emerging themes based on the interview contents, following the six-step approach of Braun and Clark (Braun & Clarke, 2006). The findings are described and presented thematically.

User experience and usability of the MINI robot in a clinical setting in Spain. (Publication 5.)

Participants and settings

A mixed-methods study approach was employed to evaluate the usability and UX of the MINI robot. Ten people with MD and MCI (M = 77.3 years and SD = 4.9) were enlisted for participation. The suggested inclusion criteria were as follows: Age 65 and above, being able to make decisions, being able to read and write, and not having any sense loss that would prevent the usage of the devices (e.g. blindness or deafness). Patients from the INTRAS Foundation's Memory Clinic and memory workshops were recruited to participate in the study, and the trial was undertaken within the controlled environment of the INTRAS Foundation's usability laboratory, situated in the locale of Zamora, Spain.

Procedure of the field test

Participants provided informed consent and socio-demographic information via a questionnaire before the test. Following that, the evaluator explained the approach and tasks associated with the MINI robot interaction. The test methodology required the engagement of just one participant at any one time, allowing for rigorous monitoring of their task performance and behaviour. The evaluation consisted of a series of predetermined activities divided into sub-tasks. Following the completion of these tasks, participants were invited to complete a questionnaire designed to assess the usability of the MINI robot. Notably, the field tests were thoroughly recorded by audio and video recordings, allowing for further thorough examination. The following protocol was followed throughout the user's interaction with the robot:

1. The user initiated the test by sitting before the robot and interacting after receiving task instructions. The test was initiated with the robot in a dormant state.
2. Interaction with MINI began with the user waking the robot with the phrase: "Hello MINI! Upon activation, the robot introduced itself to familiarise the user and allay any initial fears.
3. Subsequently, the robot inquired about the user's intended actions, with participants adhering closely to the provided instructions (conveyed on A4-sized sheets). The session encompassed nine distinct tasks, each employing varied forms of interaction; voice interaction (VI) and touch interaction (TI).
4. The chosen tasks and interaction methods are as follows:

Task 1: *Wake up the robot*. The participant has to wake up the robot by saying, “Hello, MINI” (VI).

Task 2: *See photos of my city*. See photos (VI) > From my city (VI). The robot shows through the tablet a series of pictures of the city. Once the test is over, the robot asks, “Did you like the activity?” (TI).

Task 3: *Guessing Meals*. Entertainment (TI) > Games (TI) > Guessing Meals (VI) Pictures are shown, and different regional dishes are asked about.

Task 4: *Stop the test*. Before the previous test ended, the participant had to stop the test. by tapping the robot on the shoulder. Then the robot would ask, “Do you want to continue with the activity?” (TI): “Why did you stop the test?” (TI).

Task 5: *Weather news.* News (VI) > Weather news (TI) The robot gives the weather forecast for the area. Once the test is over, the robot asks, “Did you like the activity?” (TI).

Task 6: *Robot suggestion.* The robot suggests a task to the participant (IT or IV). Once the test is over, the robot asks, “Did you like the activity?” (TI).

Task 7: *Relaxing music*. Music > Relaxing music The robot plays a piece of relaxing music.

Task 8: *Stop the test*. Before the previous test ended, the participant had to stop the test again (TI) by tapping the robot on the shoulder. Then the robot would ask, “Do you want to continue with the activity?” (TI) or “Why did you stop the test?” (TI).

Task 9: *Go to sleep*. when the robot asks. "What do you want to do?" the participant must say "Go to sleep" (VI).

Method of data collection

Data collection consisted of three phases: the administration of pre-test questionnaires to gather socio-demographic information, direct observations and video recordings, and post-test evaluation through questionnaires.

Sociodemographic survey: to gather relevant sociodemographic details from participants, including factors such as age, gender, educational background, extent of cognitive impairment, and utilization of information and communication technology (ICT).

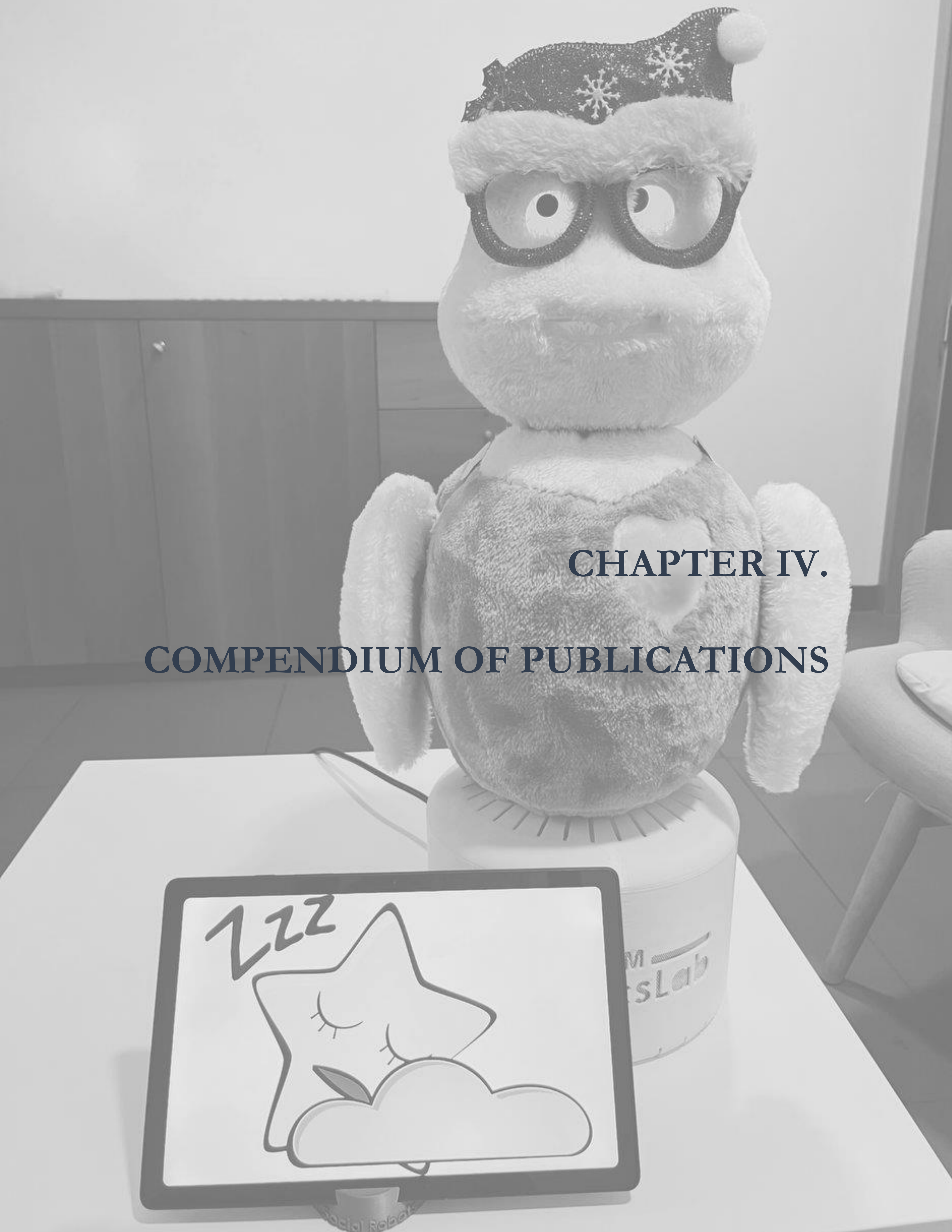
The System Usability Scale (SUS): a widely employed questionnaire-based tool developed by John Brooke in 1986 to evaluate the perceived usability of diverse products, services, and systems, spanning software, websites, applications, and technological devices. This approach has gained significant popularity in assessing user satisfaction and experience. The SUS utilizes a straightforward 10-item Likert scale questionnaire, systematically designed to capture users' subjective views on usability dimensions like ease of use, efficiency, learnability, and user-friendliness. Respondents rate their agreement level with statements related to the evaluated system. Post-questionnaire, scores are aggregated to form a usability score between 0 and 100, with higher scores indicating better perceived usability. The SUS serves as a quantitative tool to compare user satisfaction and usability across various systems, aiding in informed decision-making for enhancing the UX. In essence, the SUS is a vital resource for evaluating user perceptions and guiding design and usability improvements for more user-friendly products and systems (Brooke, 1996). The SUS test yields a score between 0 and 100, indicating how useful a device is for the user. A score of 68 points or above indicates good usability (see Supplementary Material 9).

Data analysis

During the field test, observation notes were recorded. Both direct and video observations were conducted to collect data on user performance, time to complete tasks, success rates, failure rates, incidents, user and robot behaviours, and other pertinent information. The preliminary scores for SUS were presented using basic descriptive statistics for each item, including mean scores, standard deviation, range, and mode. Furthermore, a total SUS score was computed for each participant, and the mean of all SUS scores was derived.

CHAPTER IV.

COMPENDIUM OF PUBLICATIONS



This section presents the compendium of publications that make up this project. The original publication is presented and, additionally, a Spanish translation of the title and abstract is included. Each publication is presented according to the scientific journal guidelines where they were published.

Publication #1. Methodologies Used to Study the Feasibility, Usability, Efficacy, and Effectiveness of Social Robots for Elderly Adults: Scoping Review

Publicación #1. Metodologías utilizadas para estudiar la viabilidad, usabilidad, eficacia y efectividad de los robots sociales para adultos mayores: Una revisión de alcance.

Aysan Mahmoudi Asl, Mauricio Molinari Ulate, Manuel Franco Martin & Henriëtte Van der Roest.

Resumen en español

Antecedentes: Están surgiendo nuevos campos de investigación para diseñar robots sociales para personas mayores. El objetivo de estos robots es mejorar la calidad de vida mediante la comunicación y la interacción social. Debido al deterioro cognitivo de las personas mayores, los robots sociales se consideran prometedores, sobre todo para las personas con demencia. Aunque los resultados de los estudios son esperanzadores, la calidad de los estudios sobre la eficacia de los robots sociales para las personas mayores sigue siendo baja debido a muchas limitaciones metodológicas.

Objetivo: Se pretende revisar las metodologías utilizadas hasta el momento en los estudios que evalúan la viabilidad, usabilidad, eficacia y efectividad de los robots sociales en entornos clínicos y sociales para personas mayores, incluidas las PcD.

Métodos: Se desarrollaron cadenas de búsqueda específicas. Se realizaron búsquedas en MEDLINE (PubMed), Web of Science, PsycInfo y CINAHL el 13 de agosto de 2020.

Resultados: En los 33 artículos incluidos, 23 robots sociales diferentes fueron investigados por su viabilidad, usabilidad, eficacia y efectividad. Un total de 8 (24,2%) estudios incluyeron a personas mayores de la comunidad, 9 (27,3%) incluyeron a residentes de centros de atención a largo plazo y 16 (48,5%) incluyeron a PcD. La mayoría de los estudios tenían un único objetivo, de los cuales 7 (21,2%) se centraban en la eficacia y 7 (21,2%) en la efectividad. Además, las formas de ensayos controlados aleatorios fueron los diseños más aplicados. La factibilidad y la usabilidad se estudiaron a menudo juntas en diseños de métodos mixtos o experimentales y se estudiaron con mayor frecuencia en intervenciones individuales. La viabilidad se evaluó a menudo con el modelo de la Teoría Unificada de la Aceptación y el Uso de la Tecnología. Los estudios de eficacia y efectividad utilizaron diversas medidas de resultados psicosociales y cognitivos. Sin embargo, los estudios incluidos no lograron encontrar mejoras significativas en la calidad de vida, la depresión y la cognición.

Conclusiones: Este estudio identificó varias deficiencias en las metodologías utilizadas para evaluar los robots sociales, lo que dio lugar a hallazgos ambivalentes en los estudios. Para mejorar la calidad de este tipo de estudios, los estudios de eficacia/efectividad se beneficiarán de diseños adecuados de ensayos controlados aleatorios con muestras de gran tamaño y sesiones de intervención individuales. Los diseños experimentales podrían funcionar mejor para los estudios de viabilidad y usabilidad. Para cada uno de los 3 objetivos (eficacia/efectividad, viabilidad y usabilidad) también recomendamos un método mixto de recogida de datos. La realización de varias sesiones de interacción durante al menos un mes podría ayudar a los investigadores a obtener resultados significativos y demostrar el impacto real a largo plazo de los robots sociales.

Palabras claves: ancianos; demencia; robots sociales; robots-mascota; entornos comunitarios; cuidados de largo plazo; métodos; revisión del alcance

Review

Methodologies Used to Study the Feasibility, Usability, Efficacy, and Effectiveness of Social Robots For Elderly Adults: Scoping Review

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Abstract

Background: New research fields to design social robots for older people are emerging. By providing support with communication and social interaction, these robots aim to increase quality of life. Because of the decline in functioning due to cognitive impairment in older people, social robots are regarded as promising, especially for people with dementia. Although study outcomes are hopeful, the quality of studies on the effectiveness of social robots for the elderly is still low due to many methodological limitations.

Objective: We aimed to review the methodologies used thus far in studies evaluating the feasibility, usability, efficacy, and effectiveness of social robots in clinical and social settings for elderly people, including persons with dementia.

Methods: Dedicated search strings were developed. Searches in MEDLINE (PubMed), Web of Science, PsycInfo, and CINAHL were performed on August 13, 2020.

Results: In the 33 included papers, 23 different social robots were investigated for their feasibility, usability, efficacy, and effectiveness. A total of 8 (24.2%) studies included elderly persons in the community, 9 (27.3%) included long-term care facility residents, and 16 (48.5%) included people with dementia. Most of the studies had a single aim, of which 7 (21.2%) focused on efficacy and 7 (21.2%) focused on effectiveness. Moreover, forms of randomized controlled trials were the most applied designs. Feasibility and usability were often studied together in mixed methods or experimental designs and were most often studied in individual interventions. Feasibility was often assessed with the Unified Theory of the Acceptance and Use of Technology model. Efficacy and effectiveness studies used a range of psychosocial and cognitive outcome measures. However, the included studies failed to find significant improvements in quality of life, depression, and cognition.

Conclusions: This study identified several shortcomings in methodologies used to evaluate social robots, resulting in ambivalent study findings. To improve the quality of these types of studies, efficacy/effectiveness studies will benefit from appropriate randomized controlled trial designs with large sample sizes and individual intervention sessions. Experimental designs might work best for feasibility and usability studies. For each of the 3 goals (efficacy/effectiveness, feasibility, and usability) we also recommend a mixed method of data collection. Multiple interaction sessions running for at least 1 month might aid researchers in drawing significant results and prove the real long-term impact of social robots.

(J Med Internet Res 2022;24(8):e37434) doi: 10.2196/37434

KEYWORDS

aged; dementia; social robots; pet-bots; community settings; long-term care; methods; scoping review

Introduction

In the next few decades, we expect the global population to age due to a combination of high life expectancy, low birth rates, and the baby boomer generation entering their senior years. By 2030, 33% of the population in Western Europe will be over 60 years of age [1]. Dementia is one of the most common neurodegenerative diseases that affects 50 million older people around the world, and it is projected to reach 155 million in 2050 [2].

Dementia is characterized by deterioration in memory, cognition, behavior, and ability to perform everyday activities [3]. It is estimated that approximately one-third of people with dementia live alone [4]. They experience unmet needs because of living alone and are at a higher risk of faster deterioration. In addition, people with dementia who live alone are considered at a higher risk of medication use problems, falls and injuries, inadequate self-care, trouble with activities of daily living, and reduced social networks [5-8].

In the past decades, technological advances coincided with the great health challenge of aging societies [9]. New research fields in assistive technology are dedicated to designing social robots for older adults with or without cognitive impairment to promote their quality of life (QoL) through communication and social interactions [10]. Social robots are intended to provide and facilitate social contact, psychosocial and cognitive stimulation, and have the potential to support elderly people to maintain their autonomy and independence and enhance their well-being [11].

Socially assistive robots (SARs) can be grouped into 2 main categories based on their feature and function: (1) service robots, and (2) companion robots [12]. The main task of these robots is to establish any form of interaction and communication. This function can be performed by SARs in multiple manners, such as through touch sensors, cameras, (robotic) body movements, tablet interfaces, and sound and speech systems. Within the subgroup of the companion robots, humanoid robots like Pepper and Nao provide users with advanced applications that provide leisure activities (music, photos, and games), cognitive and physical stimulation activities, and assistance with mental or physical tasks. Pet robots, such as PARO, AIBO, and NeCoro as substitutes for pets and companion animals are intended to provide emotional and physiological stimulation, have calming effects, and lead to mood improvements [13].

For the successful implementation and large-scale uptake of social robots or any other psychosocial intervention, their feasibility, usability, and cost-effectiveness should be perceived as good by the end users (people with dementia and healthy older adults), clinicians, and other stakeholders (eg, health care insurers and policy makers). The Monitoring and Evaluating Digital Health Interventions framework recommends evaluating 4 factors to integrate and implement a digital health intervention: (1) feasibility, to assesses whether the digital health system works as intended in a given context; (2) usability, to assess whether the digital health system can be used as intended by users; (3) efficacy, to assess whether the digital health intervention can achieve the intended results in a research (controlled) setting, and (4) effectiveness, to assess whether the digital health intervention can achieve the intended results in a nonresearch (uncontrolled) setting [14].

Despite the rising interest in social robots after the COVID-19 pandemic, there is limited evidence on the effectiveness of social robots in elderly care. The methodological quality of studies on the effectiveness of social robots in elderly adults is still low, and inappropriate study designs, samples, form, duration of interventions, and data collection methods have affected the strength of study outcomes [12].

Currently, there is no state-of-the-art proof of concept for study designs to evaluate the use of social robots for elderly people. Since the degenerative nature of dementia can cause methodological challenges, specific attention should be paid to studies that include people with dementia. To determine what the appropriate research methods are to study feasibility, usability, efficacy, and effectiveness, this article aims to review the methodologies used thus far in studies with social robots in clinical and social settings with elderly people to pave the way for future researchers in this field.

Methods

Protocol Registration

The protocol of this scoping review was registered in Open Science Framework (OSF) [15].

Search Strategy

Searches were conducted on August 13, 2020, in MEDLINE (PubMed), Web of Science, PsycInfo, and CINAHL databases. No time window was applied. Three search strings covering the topics "social robots," "community setting," and "elderly people" were constructed. For each database, reverent subject headings were adapted. For MEDLINE, we used the following strings and keywords: ((robotics[MeSH Terms] OR robot*)) AND ((humanoid OR companion OR social* OR "socially assistive" OR interact* OR android)), (((((((aging[MeSH Terms]) OR (aged[MeSH Terms])) OR (elderly[MeSH Terms])) OR (vulnerable population[MeSH Terms])) OR (senior)) OR (ageing)) OR (geriatric)) OR (old*), and (((((community health service[MeSH Terms]) OR (social support[MeSH Terms])) OR (residential facilities[MeSH Terms])) OR (independent living[MeSH Terms])) OR (social support[MeSH Major Topic])) OR ("community dwelling" OR "home dwelling" OR "care home" OR "in-home" OR "at home" OR "home-based" OR "home setting" OR "nursing home" OR home).

Selection Criteria

Publications potentially eligible for inclusion had to study a social robot that was physically embedded in an experimental or clinical study in people aged 65 or above. Studies were excluded if they were (1) conducted in an acute care setting;

(2) conference abstracts, case studies, dissertations, books, or review papers; (3) published in a language other than English or Spanish; (4) solely reporting a robot design, development process, or theoretical models (5) stakeholder opinions on robots without any interaction; (6) involved in the implementation of new hardware or software or an assessment tool on a robot (such as assessing a fall detection sensor); and (7) involving telepresence robots with only video call features.

Selection Procedure

After the removal of duplicates, 2 reviewers (authors AM and MM) independently applied the inclusion and exclusion criteria in 3 steps, starting with screening titles, abstracts, and then full texts. The selections were compared, and in case of disagreement, discussed by the 2 reviewers. In cases where no consensus could be reached, a third reviewer was consulted (author HR).

Data Extraction

The literature was mapped according to the following areas of interest: author and country, robot name, the aim of the robot, aim of the study, type of outcome measure, study design, study sample, study setting, methodology of data collection, interaction scenario, relevant outcome measures, measurement instruments, results, and reported limitations of the study. Information was synthesized descriptively, and findings were narratively summarized according to the areas of interest.

The quality of the included articles was appraised independently by 2 authors (AM and MM), through the quality assessment of digital health interventions within the Monitoring and Evaluating Digital Health Interventions framework established by the World Health Organization (WHO) [14]. The tool includes a list of methodological study criteria comprising (1) 23 essential criteria for all types of studies and (2) essential criteria for qualitative and quantitative studies (3 criteria each). The extent to which criteria were met by studies was rated by 3 independent researchers on a 3-point scale (0= poor, 1= fair, 2= good). We calculated the percentage of agreement between the ratings (Multimedia Appendix 1). We also applied this framework to categorize the studies according to their aims in 4 categories: (1) feasibility, (2) usability, (3) efficacy, and (4) effectiveness.

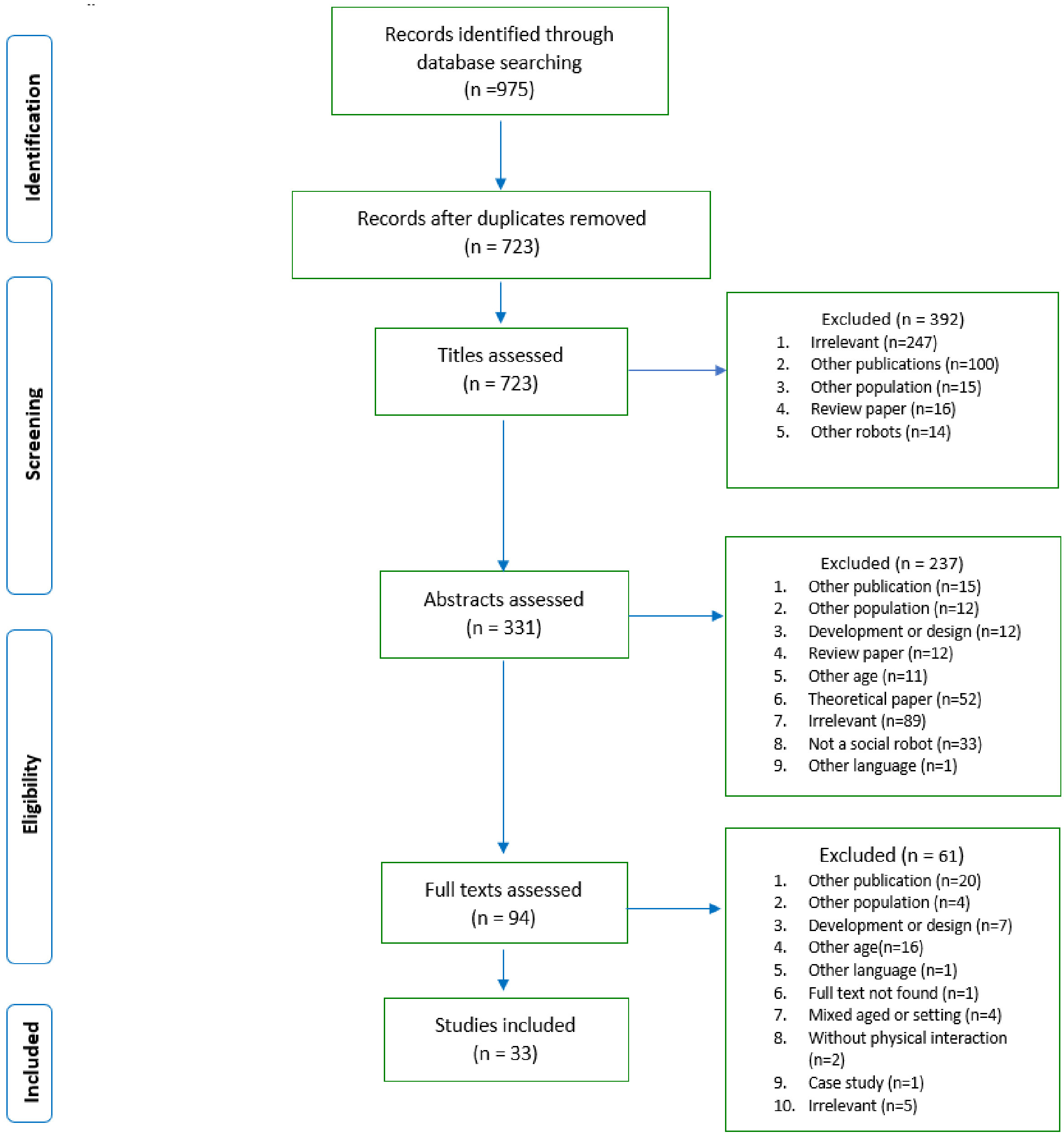
Results

General Findings

The search resulted in a total of 723 individual publications. After the screening process, 33 articles met the selection criteria (Figure 1). In 33 papers [11,16-45], 23 different social robots were evaluated among elderly adults and people with dementia in 13 different countries. Moreover, 19 studies specifically evaluated either feasibility, usability, efficacy, or effectiveness and were considered as single aim studies. The remaining studies (n=14) had multiple aims, evaluating 2 or 3 of the aforementioned study aims. Overall, feasibility was studied in 17 (51.5%) studies, usability in 13 (39.3%), effectiveness in 12 (36.3%), and efficacy in 10 (30.3%).

The quality appraisal identified that primary and secondary outcomes were clearly defined in all studies. Additionally, the methods of data collection were described well, but the eligibility of the participants was not reported in 12 (36.4%) papers. Moreover, 12 out of 33 (36.4%) papers did not present a clear description of the study design. Multimedia Appendices 2 and 3 show a summary of the characteristics, methodologies, and outcomes of the included studies.

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram for literature search.



Robots

Of the 23 different social robots, PARO (n=10, 30.3%), Nao (n=5, 15.1%), AIBO (n=2, 6%), and Hobbit (n=4, 12.1%) were the most often investigated.

Participants and Settings

Of the 33 identified studies, 16 (48.4%) focused on people with dementia [11,18,23,24,27,29-35,38,39,43,44], 9 (27.3%) were performed in samples of residents of long-term care facilities whose cognitive status was not mentioned [17,20,22,26,28,36,40,41,45], and the remaining 8 (24.2%) focused on elderly people living in the community whose cognitive status was also not clearly revealed [16,19,22,25,37,42,46,47]. Moreover, 4 (12.1%) studies additionally recruited care staff [22,24,26,38]. The age range of older adults was 65-98 years. Of the included studies, 3 (9.1%) did not report the number of participants [17,20,26]. The sample sizes used in the studies ranged from 5 to 139.

The social robots were studied in long-term facilities (n=17, 51.5%), private households (n=8, 24.2%), and laboratory settings (n=4, 12.1%). Additional settings were based in a care organization (n=1, 3%), a daycare center for dementia (n=1, 3%), and a health service facility (n=1, 3%). Four (12.1%) studies investigated the robots in 2 different settings [22,33,43,46].

Study Aims, Designs, and Outcome Measures

Single Aim Studies

Of the included studies, 3 (9.1%) focused solely on feasibility, using quasi-experimental designs [22,27,46], and 1 (3%) explicitly focused on usability in a private home setting [37]. Additionally, 7 (21.2%) studies aimed at studying efficacy [31-35,38,44], of which 2 (28.5%) applied a form of randomized controlled trial (RCT) design, 1 (14.3%) randomized crossover design, 1 (14.3%) pretest-posttest design, and the other 3 (42.8%) a form of quasi-experimental design. The effectiveness of the robots was explicitly studied in 8 (24.2%) articles [17,20,24,36,40,41,43,45] using randomized designs, with 1 (12.5%) RCT, 2 (25%) blocked RCTs, 2 (25%) quasi-experimental designs, 1 (12.5%) pretest-posttest design, 1 (12.5%) cross-sectional, and 1 (12.5%) qualitative study. The impact of robots was evaluated on QoL (n=6, 18.2%), mood and depression (n=6, 18.2%), behavioral (n=6, 18.2%) and neuropsychiatric symptoms (n=2, 6.1%), emotions and affect (n=5, 15.2%), cognition (n=4, 12,1%), engagement (n=8, 24.2%), participation and social interaction (n=8, 24.2%), care burden (n=1, 3%), loneliness (n=1, 3%), and physiological indicators (n=3, 9.1%). The sample size for the 22 studies with effectiveness/efficacy aims ranged from 11 to 139 participants, and 7 (31.8%) of these studies included samples of over 40 participants.

Multiple Aim Studies

A total of 14 (42.4%) studies had multiple aims. Of these, 7 (50%) focused on feasibility and usability [11,16,19,22,25,28,44], of which 3 (42.9%) applied a mixed methods design, and the remaining 4 (57.1%) applied either an experimental design or a field trial. Meanwhile, 3 (9.1%) focused on feasibility, usability, and effectiveness, and all applied a mixed methods design [26,29,39]. Additionally, 1 (3%) study investigated feasibility and efficacy and applied an experimental design [30], 1 (3%) focused on feasibility, usability, and efficacy using a pretest-posttest design [18], and 1 (3%) assessed the feasibility and effectiveness of the robot, applying a nonrandomized controlled trial design [22].

Study Aims and Settings

Only 5 (27.8%) of the 18 studies aiming to evaluate feasibility and/or usability were performed in nursing home settings; 5 (27.8%) were performed in laboratory settings, and the remaining 8 (44.4%) were performed in private households. In 7 (38.9%) of the 18 studies, people with dementia and those with cognitive impairment were included. In the remaining 11 (61.1%) studies, the cognitive status of the participants was not clearly indicated.

Of the 22 (66.7%) studies that focused on efficacy or effectiveness, all but 4 (81.8%) [29,33,39,47] were performed in long-term care settings. These 4 (18.2%) were performed in private households and a daycare facility. Of these studies, 13 (59.1%) included cognitively impaired samples, only 1 (4.5%) study included community-dwelling elderly persons without disclosing their cognitive status, and the remaining 8 (36.4%) included long-term care residents.

Study Interventions

Interaction between study participants and social robots was mostly investigated during individual sessions (n=18, 54.5%). In 12 (36.4%) studies, interactions were studied in group sessions. Only 3 (9.1%) studies applied both individual and group interactions [11,20,33], while 1 (3%) demonstrated the task performance of the robot without any close interaction with study participants [19]. Feasibility and/or usability (n=11, 33.3%) were mostly studied in individual settings (n = 8, 72.7%); 1 (9.1%) study was performed in a group, and 1 (9.1%) was applied to both individual and group settings. Individual (n=7, 21.2%) and group settings (n=6, 18.2%) were used most often to study efficacy and effectiveness (n=15, 45.5%); 2 (6.1%) studies applied the intervention individually and in a group. In studies with multiple aims, 4 (28.6%) individual and 2 (14.3%) group setting interventions were found. In 2 (6.1%) studies, social robots were available in the residents' lounge in nursing homes, and participants were free to interact with the social robots during scheduled time slots [22,45]. In 8 (24.2%) studies, the robots were installed in participants' private homes for a duration of 5 days to 3 months [16,27,29,33,37,39,44,47].

A total of 9 (27.3%) studies executed 1 or 2 interactive sessions [11,19,22-24,28,30,32,34], of which 6 (66.7%) investigated the usability and feasibility of the robot, 1 (11.1%) investigated effectiveness, and 2 (22.2%) investigated efficacy. Most of the studies conducted more than 2 interactive sessions: 5 (15.2%) studied feasibility and/or usability, 12 (36.4%) studied efficacy or effectiveness, and 8 (24.2%) were multiple aim studies. The interactive sessions ran from 10 to 90 minutes a day for a maximum of 4 months.

Data Collection

We identified 4 methods of data collection: (1) questionnaires (n=26, 78.8%), (2) observations (physical and videotape) (n=19, 57.6%), (3) interviews (n=13, 39.4%), and physiological measurements (n=3, 9.1%). Figures 2 and 3 show the data collection methods and the responsible administrator of data for the identified data collection methods, respectively.

Figure 2. Used methods of data collection for single and multiple aim studies.

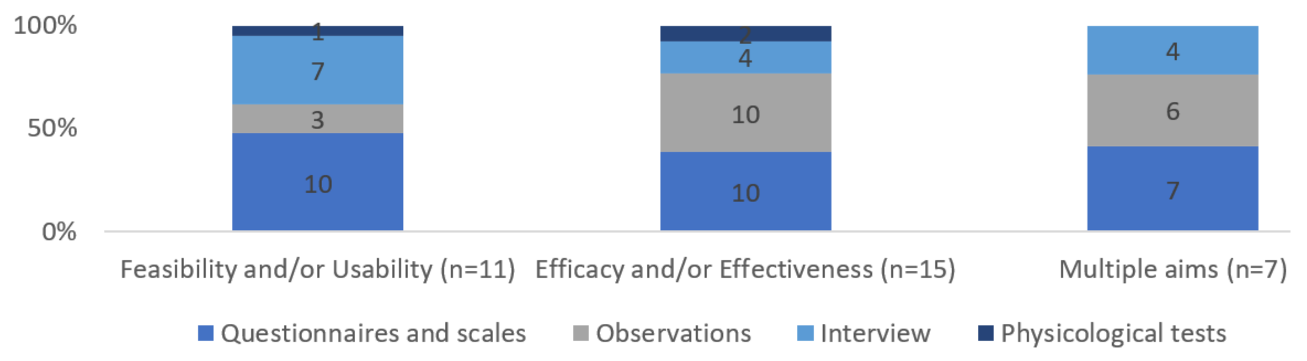
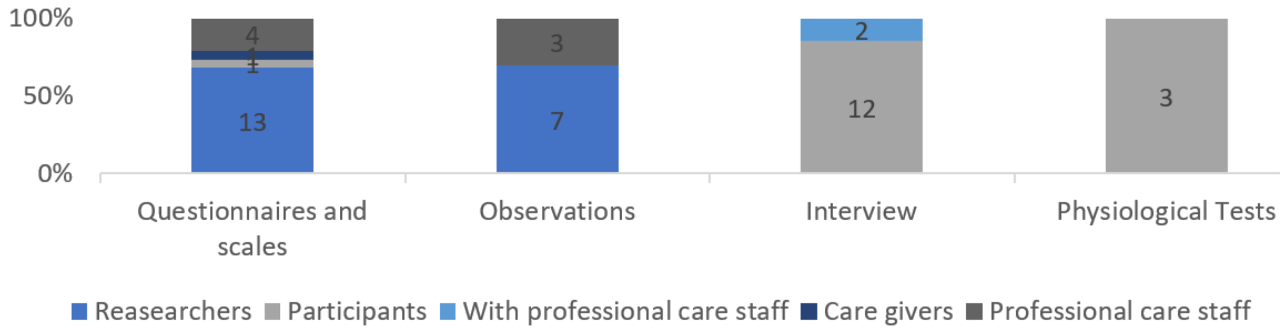


Figure 3. Responsible administrator of data for identified methods of data collection.



Measurement Instruments

Outcomes regarding feasibility were assessed with the Unified Theory of the Acceptance and Use of Technology (UTAUT) model adapted by Heerink [11,19,23,29,30,46,48], the Robot User Acceptance Scale, the Robot Attitude Scale, the Mind Perception Scale [21,47], and the Negative Attitudes Toward Robots Scale [16,37]. Of the included studies, 5 (15.2%) utilized questionnaires regarding robot functions and acceptance that were specifically developed for the study [19,22,23,25,46].

Studies exploring usability applied the System Usability Scale [22,25,28], a modification of the Usefulness, Satisfaction, and Ease of Use [26] scale, and the Technology Usage Inventory [39]. Two (6.1%) qualitative studies performed conversation and video analysis [27,28] to extract statements on acceptability and usability.

Efficacy and effectiveness outcomes were evaluated by a wide range of neuropsychosocial measurement instruments: (1) mood: Geriatric Depression Screening [49], the Cornell Scale For Depression in Dementia [50], Apparent Emotion Rating Instrument [51], University of California, Los Angeles (UCLA) Loneliness Scale [52], Observed Emotion Rating Scale [53]; (2) cognition: Montreal Cognitive Assessment [54], Mini-Mental State Examination [55]; (3) QoL: QoL Alzheimer Disease, Dementia QoL Questionnaire [56], QoL in Late-Stage Dementia [57]; (4) behavior: Neuropsychiatric Inventory [58], Gottfries-Bråne-Steen Scale [59], Apathy Evaluation Scale [60], Cohen-Mansfield Agitation Inventory [61], Apathy Inventory [62], Apathy Scale for Institutionalized People With Dementia Nursing Home Version [63]; (5) Participation and Interaction: Activity Participation Scale [40], and Assessments of Communication and Interaction Skills [64].

Among the studies applying questionnaires, 5 (19.2%) indirectly collected data via care staff and informal caregivers, and 13 (50%) directly collected data via the researchers.

Study Outcomes

Concerning social robots' feasibility outcomes, almost all studies (n=16, 94.1%) deemed social robots acceptable. Nevertheless, 1 (5.9%) study reported mixed results on acceptability by care staff [22], and 1 (5.9%) did not find any significant results on quantitative measurements for acceptability, but qualitative results were positive [16]. In 3 (17.6%) studies, the perceived agency [21,47] and perceived enjoyment [46] were found to decrease over time.

The reported usability (n=12, 36.4%) was overall positive, except in 2 (16.7%) studies in which the usability was negatively affected by technical issues or lack of robustness of the robots [28,37]. Only 3 (9.1%) studies assessed affordability for Hobbit and Nao, in which the participants did not consider the social robots affordable and were skeptical of buying them [25,28,37].

Most of the findings endorse the use of social robots by older adults. Improvements were mostly found in emotion and mood [20,31,33-35,38,44], engagement [24,29,30], and participation and social interaction [20,31-33,40,45]. Increased job satisfaction of staff [22], self-report pain reduction [38], and improved global psychiatric symptoms [43] were the other positive study outcomes. There were findings of reduced challenging behavior [20,31,34], sense of loneliness [17], and stress levels [45]. However, dementia symptoms like agitation and other problematic symptoms did not improve in 1 (3%) study [33].

Meanwhile, 4 (12.1%) studies did not find a significant impact on QoL [19,21,43,47]. Only 1 (3%) study found a moderate-to-large positive effect on QoL of people with dementia [35]. Social robot interventions also failed to significantly improve depression [18,21,43,47], perceived social support [18], medication adherence [47], and cognition [24]. There were mixed results regarding physiological measures, such as urine tests measuring stress levels and blood pressure [33,45]. No author declared a proven negative effect of social robots on older adults.

Reported Study Limitations

Of the 33 studies, 7 (21.2%) did not report any study limitations [16,17,23,25,30,42,46]. A wide range of limitations was reported, and the most common barrier considered in 17 (51.5%) studies was the small sample size, which was mostly reported for efficacy and effectiveness studies. In the feasibility and/or usability studies, the limitations were mainly attributed to technical problems or interaction difficulties. The use of unvalidated questionnaires, homogeneity in the sex of the study sample, inadequate observation, and short duration of interventions were reported as other limitations in general.

Quality Appraisal

The inter-rater agreement for the quality appraisal was 86.1%. Reports of the description of study design, bias, and enrollment procedure were mostly rated as “fair.” In most of the articles, the sampling methods, confounding factors, missing data in quantitative studies, and reflexivity of data interpretation in qualitative studies were poorly reported. Other criteria were mostly rated as “good” (Multimedia Appendix 1). The quality appraisal revealed unclear descriptions or insufficient details in 5 (15.2%) studies, especially those in disciplines other than health research [25,30,42,44,45].

Discussion

Principal Findings

The results of this scoping review revealed a variety of applied study methods in studies with social robots concerning study design, sample size, study setting, method of data collection, interaction scenario (the sequence, duration, and setting of the intervention), outcome measures, measurement instruments, study results, and reported limitations. Feasibility and usability were mainly studied on preprototype social robots in laboratory settings. Considering the relatively short history of the use of social robots in psychosocial interventions, it is crucial to determine the main features and functions of the robots to be considered in the design and development phase. Hence, usability, feasibility, and implementation should be strategic research aims. Fully developed robots such as PARO were evaluated in terms of effectiveness in real-world settings. Most of the identified studies aimed to determine the neuropsychosocial impact of social robots on older adults.

For the studies that explicitly fall within a feasibility and/or usability evaluation, researchers applied experimental, mixed method, and field trial designs, mostly applied outside nursing home care settings. This might imply that feasibility and/or usability for persons that are more severely cognitively impaired are currently understudied. Most of the studies verified the acceptability and usability of the robots within single or multiple interactive sessions in individual or group settings, and all these studies reported positive outcomes in varying degrees on the feasibility and/or usability of the social robots. The quantitative and qualitative data were collected mostly through questionnaires and interviews and a few by direct observation. Regarding this point, researchers should consider using the direct observational methodology to capture main factors of the interaction and emotional relationships fostered by robot use. Within the questionnaires and interview questions based on the UTAUT model, some concepts such as trust, anxiety, perceived enjoyment, and social support can change over time [37,46,47]. Therefore, longer use of the robots might reveal these changes and reduce the novelty effect over time [46].

Overall, efficacy and effectiveness studies were conducted on study populations either with cognitive impairment or residing in long-term care facilities. The studies with significant results [17,24,29-31,34-36,45] mostly employed experimental designs including RCTs and quasi-experimental designs with larger sample sizes and longer intervention periods compared to studies showing slight or no improvements. RCTs are likely to be the most appropriate design and a gold standard to confidently demonstrate that a specific intervention has resulted in a change in a process or a health outcome [14]. Biased assessment of outcomes and any confounding effects can be avoidable by large-scale RCTs. However, due to the degenerative character of dementia and personal differences in capacities of people with dementia, difficulties in randomizing subjects often arise [14]. Additionally, when using long study periods, the dropout rate might be high, as participants’ cognitive deterioration can hinder their continued participation in the study. On the other hand, when it is not feasible or ethical to conduct an RCT, a quasi-experimental design may serve best for collecting quantitative data. We also recommend randomized controlled block designs in the case of heterogeneous study samples. When, for instance, including people with dementia in studies with long intervention periods, the dementia levels alter. With a randomized controlled block design, some variables in different blocks can be controlled for, or comparable approaches can be applied within the blocks.

Studies targeting the efficacy and effectiveness of the robots delivered interventions diverged in format, duration, dosage, and location. Two (6.1%) studies [32,38] highlighted a need for individual intervention sessions tailored to users’ preferences and capacities, and the findings of another study confirmed this approach [65]. Additionally, individualized sessions could omit confounding factors by reducing the chance of interactions with the facilitator or other participants [66]. Group interventions may lower the odds of interaction between potential users and the robot, potentially lowering the effect of the intervention, especially when the intervention is delivered in a noisy setting with many participants [18]. The issues of small sample sizes and short interactions were considered major limitations in studies that failed to find significant results, and they are considered the toughest challenges for researchers in this field [66,67]. These limitations are often cojoined with the study setting. In nursing homes, a larger number of residents are often enrolled in a clinical trial, and the robots are not personalized but must be shared by the entire group. Whereas in private homes, studies are conducted with individuals or dyads, which creates better possibilities for personalization of the robot. Overall, the personalization of the intervention and alleviation of loneliness are 2 advantages of home-based clinical trials. However, there are some challenges to these types of studies, such as the need for several robots, implementation difficulty, and personalization, but it is nevertheless a step in the right direction. We observe a paradox, in that new or experimental robots are employed in research with low numbers of participants, whereas commercially available robots are tested on large study samples. Commercialization allows for better testing and evaluation, which is logical from an economical perspective. However, we urge that before robots are marketed, developers should study the feasibility and usability appropriately in the target group, as well as the effectiveness in a substantial study sample with sufficient power. After bringing the robot to the market, producers should continue to invest in studies to improve their product to tailor it optimally to their users. This should be a joined mission of producers and policy makers to improve the sustainability of health care systems.

Apart from the aforementioned limitations of the studies, some weak aspects of the study designs led to failure of the social robots' impacts. For instance, a mismatch between the studied construct and the main aim of the robot may lead to the poor conclusion that the robot is not efficient. An example of this is the studies on PARO that failed to demonstrate significant results for cognition, as PARO is not developed to stimulate cognitive functioning [31,33,41,43]. Additionally, to capture significant results in constructs such as cognition, QoL, and depression, a long intervention period is necessary because these are constructs that do not change very quickly. In studies with people with dementia, it might also be useful to study stability of these constructs instead of improvement, since it is inherent to the disease that these constructs deteriorate over time. Regarding the broad concept of QoL ranging from physical health to psychological state and social relationships, the application of a suitable QoL measurement instrument that corresponds to the robot's aim should be taken into account.

Implications For Efficacy and Effectiveness Studies

Appropriate RCTs with large sample sizes and individual interaction sessions running for longer than 1 month would serve best for such studies to draw relatively robust and reliable results.

Implications For Feasibility and Usability Studies

The study methods are similar for both aims, so researchers could apply the same design. Experimental designs with mixed methods of data collection are recommended for these studies. Multiple interaction sessions might reveal the changes in feasibility and usability.

Implication For Studies With Multiple Aims

We recommend performing separate studies for multiple aims since the study designs for each aim are comparable.

We gathered further practical recommendations through which future work may address existing shortcomings (Table 1). Regarding the mixed methods of data collection, studies suggest a combination of qualitative and quantitative methods for data collection, which will enable the researcher to capture different details in users' responses and address different aspects of the research question. A mixed methods approach was helpful in studies that could not derive positive results from quantitative data but did from qualitative data [16]. Regarding the difficulties of recruiting many users in case of availability of just a few robots, these mixed methods should be mandatory. Even though we did not find any negative results regarding the intervention dosage, there are shreds of evidence of highly intense intervention resulting in negative effects or exhaustion [18]. Hence, the dose response for specific measures remain an open question for future researchers.

Table 1. Further implications and recommendations for future studies.

Area of consideration	Type of study	Recommendation
Participant and setting	Efficacy/effectiveness	• Gender homogeneity • Different levels of dementia • Realistic environments
Intervention and data collection	Efficacy/effectiveness	• Multiple intervention sessions for longer than 1 month
	Feasibility/usability	• Initialization phase before trial
	All types of studies	• Well-trained observers and professionals • Tailored interventions • Include an intervention facilitator apart from an observer • Consistent observations • Standardized and validated measurement instruments • A client-centered approach to intervention design • A combination of qualitative and quantitative methods of data collection • Observational study when including people with severe dementia
Gap in the existing literature to be filled	Efficacy/effectiveness	• Best response-dosage of intervention for particular measure and participant condition • Characteristics of subjects who benefit most from the social robots

Limitations and Strengths

Although the use of social robots is promising to support people with dementia, we did not include dementia specifically in the search strings, since this scoping review focused on elderly people in general. However, we believe that our search captured most of the studies executed in the field of dementia because many of the identified studies included people with dementia in either mixed or specific study samples. However, some relevant studies on elderly people with dementia may be missing in this review, as well as may studies that are only traceable in databases that were not taken into account in this review. The searches were conducted in scientific databases deemed the most viable to retrieve valid and reliable results for this scoping review. The exclusion of studies focusing only on the development phase of social robots can be considered a limitation of this study. Some information on the evaluation of the feasibility and usability executed in the development stage might have been missed. In addition, studies on telepresence robots were excluded due to their relatively simple features. Compared to pet robots and humanoid robots, telepresence robots are limited in interactions with users, which occur merely through a touch screen, making use of visual and audio stimuli but omitting other sensory stimulation. Although mainly used for medical visits, some telepresence robots might support social functioning. Information on studies performed on these robots might have been missed.

Our study is the first scoping review on the methodologies for studying social robots in elderly people and people with dementia. The existing reviews on this topic mostly focus on design, use, effectiveness, facilitators, and barriers to the implementation of social robots [12,66,67,68-73]. This study might support future researchers to design a research study on social robots in elderly adults and answer some study design queries.

Conclusions

This review narratively synthesizes information on the methodology of studying social robots in elderly adults and people with dementia. Relevant recommendations were formulated, directed for studies with specific aims that may aid future researchers in developing adequate study designs to evaluate social robots, allowing for more reliable information on study outcomes. Our research leads us to the conclusion that more studies with large sample sizes are needed on the effectiveness of social robots in private households of elderly adults and people with dementia to demonstrate the actual usefulness of social robots on delaying institutionalization by improving QoL, cognition, and social contact, and counteracting loneliness. Most of the identified studies focused on usability, and the robots appeared to be favorably accepted in most cases. It is time to encourage investigations in private homes to supplement existing knowledge about the effectiveness of robots and personalization of their functions. We expect that additional research will corroborate the impact of social robots on loneliness, mood, QoL, and social health in people with dementia and the elderly.

Acknowledgments

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Conflicts of Interest

MFM has participated in clinical trials with Lundbeck, Acadia, Janssen, Otsuka, Angellini, Oxygen, Roche, Servier, Boehringer Ingelheim, and Gw Research Limited.

Multimedia Appendix 1

Quality appraisal of the included studies assessed by two independent reviewers.
[DOCX File , 56 KB-Multimedia Appendix 1]

Multimedia Appendix 2

Characteristics and methodologies of the studies.
[DOCX File , 43 KB-Multimedia Appendix 2]

Multimedia Appendix 3

Outcomes.
[DOCX File , 24 KB-Multimedia Appendix 3]

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Abbreviations

ADL: activities of daily living
ITN: innovative training network
LTCF: long-term care facility
OSF: Open Science Framework
QoL: quality of life
RCT: randomized controlled trial
SAR: socially assistive robot
UCLA: University of California, Los Angeles
UTAUT: Unified Theory of the Acceptance and Use of Technology
WHO: World Health Organization

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Publication #2. The usability and feasibility validation of the social robot MINI in people with dementia and mild cognitive impairment; a study protocol.

Publicación #2. La usabilidad y la validación de la viabilidad del robot social MINI en personas con demencia y deterioro cognitivo leve; un protocolo de estudio.

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Resumen en español

Antecedentes: Los robots sociales han demostrado resultados prometedores en cuanto al aumento de la salud social y el bienestar de las PcD y DCL. Según el marco de seguimiento y evaluación de las intervenciones de salud digital de la Organización Mundial de la Salud, los estudios de usabilidad y viabilidad son cruciales antes de implantar prototipos de robots sociales y demostrar su eficacia y efectividad. Este documento de protocolo pretende detallar el plan para llevar a cabo el estudio de usabilidad y viabilidad del robot MINI basándose en la metodología recomendada basada en la evidencia.

Métodos: En este estudio se aplicará un diseño experimental y un método mixto de recogida de datos. Se reclutarán 20 participantes mayores de 65 años con demencia o DCL. Se realizarán ocho sesiones de interacción con el robot, así como evaluaciones cualitativas y cuantitativas. La investigación se llevará a cabo en un laboratorio. Se han obtenido las autorizaciones éticas pertinentes. Esta investigación será valiosa para el desarrollo del robot MINI y su despliegue práctico en el mundo real, así como para la base de pruebas metodológicas en el sector de los robots sociales.

Discusión: En el invierno de 2022-2023, los resultados de este estudio estarán disponibles para su difusión. Este estudio ayudará a mejorar la metodología basada en la evidencia utilizada para

estudiar la viabilidad y usabilidad de los robots sociales en PcD y DCL, así como lo que se puede aprender para avanzar en el diseño de este tipo de estudios en el futuro.

Palabras clave: robots sociales, usabilidad, viabilidad, aceptabilidad, diseño de estudios, demencia

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STUDY PROTOCOL Open Access

The usability and feasibility validation of the social robot MINI in people with dementia and mild cognitive impairment; a study protocol

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Abstract

Background: Social robots have demonstrated promising outcomes in terms of increasing the social health and well-being of people with dementia and mild cognitive impairment. According to the World Health Organization's Monitoring and assessing digital health interventions framework, usability and feasibility studies are crucial before implementing prototype social robots and proving their efficacy and effectiveness. This protocol paper aims to detail the plan for conducting the usability and feasibility study of the MINI robot based on evidence-based recommended methodology.

Methods: In this study, an experimental design and a mixed method of data collection will be applied. Twenty participants aged 65 and over with dementia or mild cognitive impairment will be recruited. Eight sessions of interaction with the robot, as well as qualitative and quantitative assessments, will be accomplished. The research will take place in a laboratory. Ethical approvals have been acquired. This research will be valuable in the development of the MINI robot and its practical deployment in the actual world, as well as the methodological evidence base in the sector of social robots.

Discussion: By the winter of 2022–2023, the findings of this study will be accessible for dissemination. This study will aid to improve the evidence-based methodology used to study the feasibility and usability of social robots in people with dementia and mild cognitive impairment as well as what can be learned to advance such study designs in the future.

Keywords: Social robots, Usability, Feasibility, Acceptability, Study design, Dementia

Background

According to the Alzheimer Europe Yearbook 2019, about 9.8 million people are living with dementia in Europe, and this number is expected to double by the year 2050, affecting 18.8 million people [1]. According to demographic trends, Spain has one of the highest incidences of dementia, with 6.3% of those over 60 having the disease [2]. Northern European countries such as Norway and Sweden, as well as the United States, Japan, and the United Kingdom, share similar concerns, prompting them to take major steps toward potential solutions. Dementia is one of the most common neurodegenerative diseases causing a deterioration in memory, thinking, behavior, and the ability to perform everyday activities. Limited social interactions and small social networks are associated with the faster progression of dementia mutually and place people with dementia at a

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higher risk of experiencing adverse events [3]. Dementia causes a significant burden on caregivers and families and affects their health as well [4].

In a search for innovative dementia care strategies, a quite young field of research has been dedicated to social robots for people with dementia (PwD). The social robots are employed to enhance people's well-being, autonomy, and independence, thus enabling them to live independently for longer [5]. Socially assistive robots (SARs) may be categorized as service robots and companion robots. Companion robots such as Pepper, Nao, Zora, Hobbit, and Aibo have been frequently studied, yielding promising results in psychosocial domains such as improved emotions and mood, engagement, social interactions, participation for elderly adults, and PwD [6]. These interactive robots provide companionship and enhance social interactions, resulting in improved social health. In particular, Paro and Nao excelled in this role in a few studies, reducing feelings of loneliness, and improving mood and social interaction [6–8]. Despite promising results, there is no strong evidence based on the effectiveness of social robots on (neuro) psychosocial outcomes [9]. Thus far, the effectiveness of social robots on cognition and quality of life has not been proven [6]. Also, outcomes such as feelings of loneliness are less investigated compared to other subjective measures [6].

To ensure the efficacy and effectiveness of social robots, we must first determine whether they are perceived as usable and acceptable by potential users. Physical, psychosocial, and behavioral factors of interaction with a social robot have been shown in studies to contribute to the user's overall acceptance of the robot. The technological features of social robots play an important role in usability measures, and according to Mitzner et al. [10], usability is a perfect predictor of the social robot's acceptability.

Recently the Robotics Lab from Carlos III University of Madrid developed a plush-like desktop social robot, called 'MINI '[11]. MINI aims to support seniors and provide cognitive and social stimulation for older people with neurodegenerative diseases, especially for those with cognitive impairment. The robot can autonomously interact with humans through verbal and nonverbal communication. The MINI robot is a research platform that is not commercialized yet. Previous research on social robots recommended designing and developing social robots and tailoring the user interface and characteristics of the robot, to the needs and preferences of PwD [12, 13]. Furthermore, Bradwell et al. [14] proposed differences in preferences between robot developers and end users and encouraged researchers to involve end users in the design and development of social robots. Hence, we will conduct a trial study on PwD and people with mild cognitive impairment (MCI) to explore the usability and feasibility of MINI, as well as, its effect on the observed emotions during the interaction sessions. In this paper, we describe the protocol that will be followed to conduct the abovementioned trial study.

This testing will help to improve the MINI robots' technological features and functionalities, software, and user interface. The robot implementation will be feasible for individual implementation in clinics and research settings after the necessary features and functions have been added/ modified, enabling researchers to evaluate its impact and effectiveness in different scenarios and settings. We believe that by triggering positive emotions and reducing negative emotions, MINI will benefit PwD and MCI. The study procedure is based on the Standard Protocol Items: Recommendations for Interventional Trials (Guidelines) [15].

The purpose of this study is to evaluate 1) the usability and feasibility of the MINI robot for PwD and MCI, and 2) the effect of the MINI robot on the observed emotions in a laboratory setting. The current study aims to answer the following questions:

Methods

Objectives

The purpose of this study is to evaluate 1) the usability and feasibility of the MINI robot for PwD and MCI, and 2) the effect of the MINI robot on the observed emotions in a laboratory setting. The current study aims to answer the following questions:

1) Is MINI considered feasible and acceptable by PwD and MCI?
2) Is MINI usable for PwD and MCI in a research lab?
3) What are the attitudes of PwD and MCI towards MINI?
4) Does the MINI robot intervention trigger instant positive emotions and reduce negative emotions of PwD and MCI?
5) Are changes or modifications to the MINI robot software and hardware features required to improve its usability and feasibility?

Design

We will employ an experimental methodology and a mixed-method of data collection in this project, which will last for a month for each participant to accomplish the robot interaction sessions. To address the study's questions, quantitative and qualitative data will be collected using questionnaires, scales, observations, and interviews. The research team will select potential participants at recruiting sites ($n = 20$) based on exclusion/

inclusion criteria. The potential participants and their next of kin will be briefed about the study's topic and urged to sign a consent form. Primary and secondary outcomes will be evaluated at baseline and immediately following the interaction sessions. The methodology of this experiment is based on a recent scoping review [6] recommended methodology for testing the usability and feasibility of social robots.

Participants and settings

After the participant's identification and recruitment, the trial will be carried out by the research group at the research lab of Intras foundation, in Zamora, Spain. We will include people based on inclusion and exclusion criteria.

Inclusion criteria:

- PwD and/or MCI
- Aged 65 and over
- Ability to read and write in Spanish
- Ability to decision making
- MMSE score ≤ 24

Exclusion criteria:

- Unstable medical conditions.

Theoretical framework

The evaluation of the usability and feasibility of MINI will be conducted based on the following models: 1) Monitoring and evaluating digital health interventions framework by the World Health Organization. This framework is intended to guide digital health researchers to understand the different stages of monitoring and implementation of digital health interventions and evaluate them [16]. Based on this framework, the Acceptability study is defined within the feasibility concept. Figure 1 shows the evaluation and monitoring maturity of the MINI robot over time from a prototype to the implementation phase. 2) Almere model; This model is an extension and adaption of the Unified Theory of Acceptance and Use of Technology (UTAUT). In this model, 11 constructs are defined to measure the level of acceptance and usefulness of assistive social agents by elderlies [17]. Besides the functional evaluation of the technology, the Almere model evaluates social interaction-related variables such as perceived sociability and social presence [17].

Staff training

Before the intervention, all responsible research staff will receive MINI robot master training. In this training, the MINI robot will be presented with its functionalities, software use, put into operation, and switch off maintenance and troubleshooting. They will be responsible for any problem or question regarding the robot's functionalities. To consistent data collection, the researchers of the Intras foundation (IBIP) will train research staff regarding the method of data collection.

Pre-experimental phase

This will be carried out in a usability laboratory and users' interactions with the MINI Robot will be recorded. The users will perform a series of tasks and games in MINI robot for half an hour in one session.

To develop rigorous monitoring of the participants' interactions and behavior, the interaction sessions will be conducted individually. The sessions will also be audio and video recorded for further review. Each participant may have some prior Information Technology and telecommunications knowledge. Before starting the trial, participants and their next to kin will be asked to sign an informed consent. At the end of the usability session, they will have to complete the acceptability and usability questionnaire which we developed based on the *Almere Model*, an adapted model of the *Unified Theory of Acceptance and Use of Technology*, proposed by Heerink et al. [17] as well as the system usability scale [18].

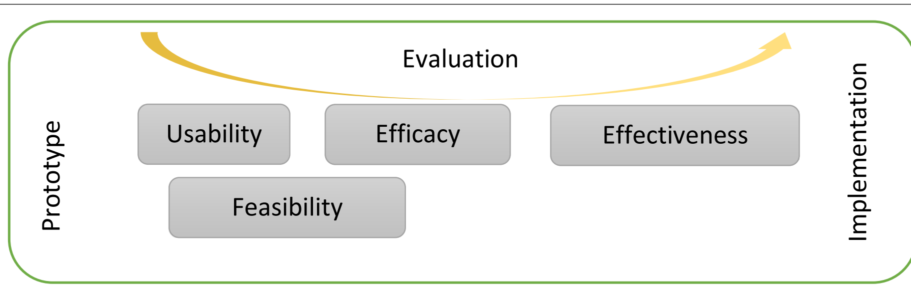

Fig. 1 The evaluation and monitoring maturity of the MINI robot over time

Experimental phase

During this phase which will last 1 month, the data will be collected from the participants interacting with the MINI robot. During the sessions, physical observations will be conducted by an independent observer and reported on a record sheet. This data will be analyzed and will serve to assess the problems encountered by users and the difficulties of implementing the robot.

During the interaction sessions, an independent observer will rate the observed affects and emotions using the OERS scale.

Post-experimental phase

The acceptability and usability questionnaire based on the Almere model will be completed after the trial is over. To gauge the general opinion on the MINI robot interactions, semi-structured interviews will be undertaken. Over the course of a month-long intervention, we will examine the efficacy of the MINI robot in enhancing positive emotions and reducing negative ones. The early, middle and last parts of the intervention period—10 minutes before and 10 minutes during the engagement with the robot—will all involve the observation of emotions.

Interaction sessions

MINI robot

MINI is a social robot specifically designed to assist and accompany elderly people in their daily life either at home or in a nursing facility. The robot can provide psychosocial and cognitive stimulation through mental and cognitive tasks and also provides services in the areas of entertainment and personal assistance. MINI is a lightweight, small-sized, stationary robot with a friendly appearance that is covered in faux fur. It is equipped with a microphone for speech-based communication, touch sensors in the shoulders and belly that allow the user to interact physically with MINI, an RGB-D camera to extract visual and depth information from the environment, uOled eyes, and a tablet that can work both as an input device (through fixed menus) and an output device, displaying photos, videos, music, and other applications. A default series of games and cognitive exercises are installed on the robot that can be extended and modified. MINI is programmed to ask certain questions, process the respond, and provide users with feedback on their performance [19, 20]. Currently MINI is in the prototype phase (See Fig. 2).

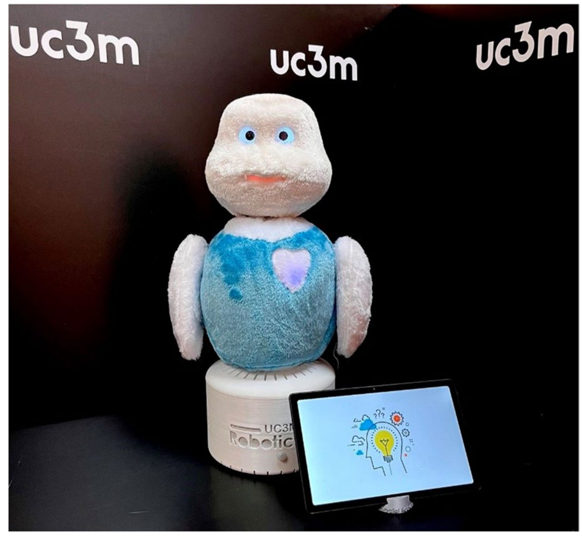

Fig. 2 MINI robot

Interaction scenario

For the intervention group, the MINI robot will be applied in the research lab. The intervention duration is a total of 1 month for each participant. The reason to conduct multiple interaction sessions is to eliminate the novelty effect [21] of the MINI robot that might affect the acceptability. The frequency of intervention sessions is two or three times a week based on the participant's availability, running for half an hour for each participant. An initialization phase before the intervention session will be undertaken, to get the participants familiar with the robot and learn how to interact with it. The user will perform a series of entertainment and memory games while a researcher will be moderating the sessions. MINI will initiate the interaction with the user by touching its shoulder and verbally encouraging them to choose an activity shown on the tablet. The interaction will continue through verbal and non-verbal channels. Six activities will be accomplished in 30 minutes and meanwhile MINI will give feedback as encouragement in case of successful accomplishment of the tasks and guidance in case of repeated failures.

Figure 3 demonstrates the user interface and applications list through which the user will interact with MINI.

Resources

The Intras Foundation in Zamora, Spain, will provide this study with a research lab as the research setting. The University of Carlos III of Madrid will provide the MINI robot and take the responsibility for technical support of the system. Human resources and materials will be supplied by the Memory clinic of Intras foundation in Zamora (IBIP). Other collaborating centers will be the Hospital Provincial of Zamora and the University of Salamanca, Salamanca, Spain.

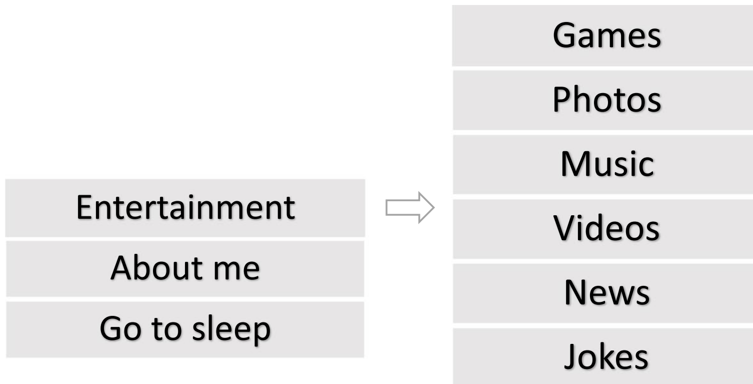

Fig. 3 The tablet user interface

Measurements

Acceptance and usability

The acceptance and usability will be measured using a survey questionnaire based on the *Almere Model* by Heerink [17] (Supplementary file 1). Areas of measure are as follows: Anxiety, trust, attitude, appearance of the robot, personality of the robot/ social presence, perceived enjoyment, ease of use, sociability, adaptability, and usefulness, as well as, specific functionalities of the robot. The relevant statement has been produced by the researchers (AM, JMT) for each area. A five-point Likert scale (Strongly Disagree = 1, Disagree = 2, Neutral = 3, Agree = 4, Strongly Agree = 5) will be utilized to score each statement. We will also measure usability by the well-developed System Usability Scale (SUS) [22] which consists of a 10-item questionnaire with a five-point Likert scale (Strongly Disagree = 1, Disagree = 2, Neutral = 3, Agree = 4, Strongly Agree = 5) five response options for respondents; from Strongly agree to Strongly disagree (Supplementary file 2).

Observed emotions

The observed emotions will be measured through the Observed Emotion Rating Scale (OERS) [23] (Supplementary file 3). Previously named the *Apparent Affect Rating Scale*, OERS is an observational tool for rating two positive emotions (pleasure and general alertness) and three negative emotions (anger, anxiety or fear, and sadness). Each item is accompanied by a list of the symptoms associated with that emotion and a drawing of a face demonstrating that emotion. The degree to which each emotion is expressed during a ten-minute observation period is rated on a scale of 1 (never) to 5 (always) (more than 5 min).

Table 1 Interview Questions

1.	What do you think about MINI? (e.g., appearance, feelings, the experience of using MINI)
2.	What does MINI do for you?
3.	Does MINI help you feel better?
4.	Is there anything you don't like about MINI?
5.	Is there any other game/ exercise you would like to do with MINI?
6.	I gave you MINI for 30 mins every session. Was this too long or too short? Was 2–3 days a week too frequent or not enough?
7.	Is there anything you would like to change about MINI?
8.	Is there anything else you would like to tell us about MINI?

Qualitative measurements

Semi-structured physical and video observations of participants' emotions and interactions will be conducted by researchers. Besides, individual interviews with participants will be organized to obtain in-depth information on their experiences and attitudes towards the robot. The interview questions are presented in Table 1.

Analysis

Quantitative data

Statistical analysis of the data will be performed through IBM SPSS v.24. Descriptive statistics of demographic and personal data will be presented and compared between groups. After the analysis of normal distribution and homogeneity of data, the repeated measures analysis of variance (ANOVA) will be conducted for pre-and post-intervention outcomes. If the distributional assumption were not satisfied nonparametric methods (Mann–Whitney U test, Kruskal-Wallis analysis of variance, Wilcoxon signed-rank test, calculation of Spearman's correlation coefficient, etc.) will be applied.

Table 2 Assessments

Activity/Assessment	Staff member	Time	Pre-study	Pre-study baseline	1	2
MMSE			X			
Acceptability questionnaire				X		
OESR				X	X	X
Interview						
Observation of interactions				X	X	X

Table 3 Project Timeline

Activity/month	Responsible	3	2	1	0	1	2	3
Project development	Primary researchers	X	X	X				
Ethical committee approval	Primary researchers			X				
Protocol preparation	Primary researchers	X	X	X				
Acceptability and usability study (AU-S)				X	X	X	X	
Participant's selection	Researchers responsible for AU-S			X				
Informed consent	Researchers responsible for AU-S			X				
User's testing	Researchers responsible for AU-S			X				
Incidence registration	Researchers responsible for AU-S				X	X	X	
Efficacy study						X	X	X
Participants selection	Responsible for interviewers			X				
Pre-evaluation	Interviewers				X			
Initialization session	Responsible for the study				X			
Intermediate evaluation	Responsible for the study				X	X	X	
Post evaluation	Interviewers						X	
Interview	Responsible for the study						X	
Data management and result		X	X	X	X	X	X	X
Database development	IBIP			X	X			
Data collection	Responsible for the study			X	X	X	X	
Data analysis	IBIP, USAL, UC3M						X	
Results and conclusion	Primary researchers						X	
Dissemination		X	X	X	X	X	X	X
Dissemination of results (Publications, conference presentation)	Primary researchers, UC3M						X	

Qualitative data

Thematic analysis will be performed for the data obtained from the focused group interviews employing Microsoft excel by the six-step approach of Braun and Clarke [24] as follows; 1) become familiar with data, 2) Generate initial codes, 3) Search for themes, 4) Review themes, 5) Define themes, 6) Write-up. After the interviews are transcribed, the coding of the data will be performed by Nvivo 12 software and the result will be thematically presented. Tables 2 and 3 demonstrate the timetable of the quantitative and qualitative evaluations and projects, respectively.

Discussion

This study will be an important contribution to the field of social robots in dementia care. Our study will be the first usability and acceptability trial of the MINI robot in a research lab with PwD and MCI. By using the Almere Model, the most complete acceptance model, observations, and interviews, it is intended that this study would capture the most significant aspects of usability and acceptability. With the aid of the trial's findings, the designers, developers, and researchers of the robot will be able to further refine the MINI robot for the next extensive efficacy and implementation.

The small-scale efficacy study will be valuable in examining the effects of the MINI robot on immediate positive and negative emotions while live interactions. Positive emotions and reduced negative emotions during the interaction by enabling a meaningful engagement with the MINI robot will support the overall social health and wellbeing of PwD and MCI.

Abbreviations
AAL: Ambient assisted living; ANOVA: Analysis of variance; ICT: Information and communication technology; MCI: Mild cognitive impairments; OERS: Observed affects and emotions; PwD: People with dementia; UTAUT: Unified theory of acceptance and use of technology.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12888-022-04418-9.

Additional file 1. Almere model base questionnaire for Acceptability.

Additional file 2. System Usability Scale.

Additional file 3. Observed Emotions Rating Scale.

Acknowledgments
Not applicable.

Dissemination policy
Results of this study are expected to be available by winter 2022–23. The research result will be published in open-access international scientific professional, psychiatry, dementia, and technology journals. Since the study is a part of the DISTINCT project, results will be disseminated on the DISTINCT project website and relevant platforms.

Authors' contributions
Concept of the research: AM, JMT, MFM, HVR, ACG, MM, MAS. Design of the protocol: AM, JMT, HVR. Design of the MINI robot interventions: AM, JMT, ACG, MM. Supervision and coordination: MFM. MAS. Recruitment and trial management: AM, JMT. All authors have read and approved this manuscript before submission.

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Availability of data and materials
Not applicable.

Declaration

Ethics approval and consent to participate
Zamora Health Area Medication Research Ethics Committee approved the research protocol under registration number 574. The foreseeable risks and inconveniences of the research are acceptable of the expected benefits. The planned procedure for information and obtaining informed consent is considered adequate. Participants and their next to kin will be requested to sign an informed consent form before the study begins.

Consent for publication
Not applicable.

Competing interests
No competing interest was declared.

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Publisher's Note

Publication #3. Potential Facilitators of and Barriers to Implementing the MINI Robot in Community-Based Meeting Centers for People with Dementia and Their Carers in the Netherlands and Spain: Explorative Qualitative Study.

Publicación #3. Facilitadores y barreras potenciales para la implementación del robot MINI en centros de reunión comunitarios para personas con demencia y sus cuidadores en los Países Bajos y España: Estudio cualitativo exploratorio.

Aysan Mahmoudi Asl, Suzanne Kouters, Álvaro Castro-González, Henriëtte Henriëtte Van der Roest, Manuel Franco Martin & Rose-Marie Dröes.

Resumen en español

Antecedentes: Los robots sociales como una forma de tecnologías de salud digital, se utilizan para apoyar la atención emocional, cognitiva y física y han mostrado resultados prometedores en la mejora del bienestar social en las PcD mediante el impulso de las emociones, las interacciones sociales y la participación en actividades.

Objetivo: El objetivo era investigar la actitud de las partes interesadas y los posibles facilitadores y obstáculos para la implementación del robot social MINI en Centros de Encuentro (CE) comunitarios para PcD y cuidadores en los Países Bajos y España.

Métodos: Se llevó a cabo un estudio cualitativo exploratorio basado en la guía del Consejo Británico de Investigación Médica para la evaluación del proceso de implementación de intervenciones complejas y el Modelo para rastrear los facilitadores y obstáculos de la implementación adaptativa de innovaciones en la atención a la demencia. Tras la introducción del robot MINI se entrevistó a 11 partes interesadas en tres CE de los Países Bajos y uno de España, así como a partes interesadas de organizaciones sanitarias y asistenciales de ambos países. En total, 12 adultos con demencia participaron en grupos de discusión. Los datos se analizaron temáticamente y se describieron de forma narrativa.

Resultados: La opinión general de las partes interesadas y su interés por el robot MINI fueron positivos. Los factores facilitadores más importantes (esperados) mencionados por las partes interesadas parecían ser los recursos humanos, la financiación, el impacto del robot MINI en los usuarios y los programas de los CE, las características de la innovación y la colaboración con otras organizaciones de atención y bienestar, mientras que las barreras (esperadas) mencionadas se referían al contexto físico y las funcionalidades del robot MINI, el contexto del usuario y las políticas de actividad de los CE.

Conclusiones: Los resultados informarán a las partes interesadas profesionales, como los directores y gerentes de los CE, así como a las organizaciones de atención y bienestar, sobre el empleo práctico del robot MINI en el CE. Además, nuestra investigación ayudará a los desarrolladores del robot MINI a adaptar sus características a las preferencias y demandas de las PcD y a las políticas de los CE, lo que contribuirá a la adopción y el despliegue efectivos del robot MINI.

Palabras clave: demencia; centros de encuentro; deterioro cognitivo leve; robots sociales.

Original Paper

Potential Facilitators of and Barriers to Implementing the MINI Robot in Community-Based Meeting Centers for People With Dementia and Their Carers in the Netherlands and Spain: Explorative Qualitative Study

Aysan Mahmoudi Asl[1], MSc; Suzanne Kouters[2], MSc; Álvaro Castro-González[3], PhD; Henriëtte Van der Roest[4], PhD; Manuel Franco Martin[1,5], MD; Rose-Marie Dröes[6], Prof Dr

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Abstract

Background: Social robots, as a form of digital health technologies, are used to support emotional, cognitive, and physical care and have shown promising outcomes in enhancing social well-being in people with dementia (PwD) by boosting emotions, social interactions, and activity participation.

Objective: The goal is to investigate the attitude of stakeholders and potential facilitators and the barriers to implementing the social robot MINI in community-based meeting centers (MCs) for PwD and carers in the Netherlands and Spain.

Methods: Based on the British Medical Research Council guidance for process evaluation of the implementation of complex interventions and the model for tracing the facilitators of and barriers to the adaptive implementation of innovations in dementia care, an explorative qualitative study was conducted. Following the introduction of the MINI robot, 11 stakeholders were interviewed in 3 MCs in the Netherlands and 1 in Spain, as well as stakeholders in health and welfare organizations in both countries. In addition, 12 adults with dementia participated in focus groups. The data were thematically analyzed and narratively described.

Results: Overall, the stakeholder opinion and interest in the MINI robot were positive. The most important (expected) facilitating factors mentioned by stakeholders appeared to be human resources, funding, the impact of the MINI robot on the users and programs of the MCs, characteristics of the innovation, and collaboration with other care and welfare organizations. However, the (expected) barriers mentioned concerned the physical context and functionalities of the MINI robot, the user context, and MC activity policies.

Conclusions: The findings will inform professional stakeholders, such as MC directors and managers, as well as care and welfare organizations, on the practicality of using the MINI robot in MCs. Furthermore, our research will aid MINI robot developers in tailoring its features to PwD's preferences and demands and MC policies, which will contribute to the MINI robot's effective adoption and deployment.

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KEYWORDS

dementia; meeting centers; mild cognitive impairment; social robots

Introduction

Dementia has been identified as 1 of Europe's most complex public health diseases, which impacted 14.1 million people in 2019, and has been highlighted as a public health priority [1]. As a response to providing social and health support programs for people with dementia (PwD) and reducing the adverse effects of dementia, the Meeting Centre Support Programme (MCSP) for PwD and their carers was set up in the Netherlands in 1993. Recently, the MCSP was adaptively implemented in several other European countries as well (the United Kingdom, Poland, Italy, and Spain) [2]. Currently, there are more than 180 MCs across the Netherlands and around 70 in other European countries. The MCSP has been proven to be effective in the case of psychosocial symptoms, such as mood and depression, inactive and unsocial behavior, and quality of life, as well as the carer burden and delayed nursing home admission of PwD [3-8].

Intelligent assistive technologies (IAT) are a growing body in dementia research [9]. "IAT" is an umbrella term including a range of digital devices, such as smart home systems, tablets, smartphones, wearable devices, and humanoid robots. According to a systematic review, IAT have been suggested to empower people in the mild-to-moderate stages of dementia, supporting their independence for a longer time [10]. Humanoid robots, as the third generation of social robots, communicate with humans through verbal and nonverbal interactions. They have the potential to improve the mood, social interaction, and activity participation of PwD [11]. However, due to the early stage of this field, few of them are fully developed and commercially available.

MINI is a humanoid robot recently developed at the University of Carlos III of Madrid. This social robot is designed to assist and accompany older adults in their daily lives at home or in a nursing facility and stimulate their cognitive functions. The robot can provide psychosocial and cognitive stimulation through games and cognitive tasks, in addition to services in the areas of safety, entertainment, and personal assistance.

Because the MINI robot may be valuable for the target group of MCs, we explored the interest of key stakeholders in MCs in the Netherlands and Spain, as well as possible facilitators of and barriers to the robot's deployment in MCs.

Several frameworks and guidelines have been suggested in the literature to aid in the successful implementation of complex interventions. The Medical Research Council (MRC) published a framework for the development and evaluation of complex interventions and to help researchers with methodological difficulties [12]. The MRC also developed a guidance for process evaluation of the implementation of complex interventions, which focuses on the influence that contextual factors, implementation factors, and mechanisms of impact may have on the outcomes of interventions [13]. The effectiveness of an intervention can be limited due to flaws in proper implementation [14]. Hence, the MRC framework emphasizes the importance of intervention implementation ingredients, such as fidelity, dose, and reach, and addresses issues such as management, structure, support, and training to shape proper intervention conditions. The term "mechanism of impact" refers to how the proposed intervention brings about desired changes and how these outcomes might be repeated in future interventions of a similar nature.

Understanding the context in which a complex intervention takes place becomes important when external contextual elements may facilitate or impede proper implementation and as such may influence the intervention outcome.

Another theoretical model to evaluate the implementation of complex interventions was proposed by Meiland et al [15]. Their model is designed to trace the facilitators of and barriers to the adaptive implementation of innovative practices in dementia care, attuned to local and regional conditions [15]. Preconditions, as well as the phases of preparation, execution, and continuation of implementation, are covered by this theoretical framework. Preconditions refer to existing conditions in the context where the intervention will be implemented, including characteristics of the innovation, operational conditions, human and financial resources, and organizational conditions that can facilitate or impede the implementation of the intervention. In the preparation phase, the need for adaptively implementing the intervention is assessed and an inventory of the practical preparations required for successfully implementing the intervention is created and evaluated. Regarding the execution phase in which the intervention is started in practice, elements that interact with the high-quality execution of the intervention are evaluated. In the final phase, continuation, elements that contribute to an effective intervention are evaluated. The above-mentioned phases are further specified in the model on 3 levels: micro (user/primary process, eg, personnel, training, management, care provider, person with dementia, and informal carer), meso (collaboration between care providers/organizations, finances, division of tasks, collaboration with other organizations), and macro (structure of the care system, laws, regulations, and national and regional policies).

In this study, we used both the MRC guidance for process evaluation and the model to trace the facilitators of and barriers to adaptive implementation of innovative practices in dementia care in order to explore the facilitators of and barriers to the implementation of MINI in MCs for PwD and their carers. In this research, we did not include the continuation phase, since the robot has not yet been implemented in the MCs.

The research questions were:

- What are the potential facilitators of and barriers to the implementation of the MINI robot in MCs for PwD and carers in the Netherlands and Spain?
- Do any of the robot's features need to be improved for successful implementation in MCs?

- What is the attitude of PwD and other stakeholders in MCs toward the MINI robot?

Methods

Study Design, Participants, and Setting

An explorative qualitative design, using one-off semistructured interviews with stakeholders other than PwD and focus groups with PwD, was used to identify potential facilitators of and barriers to implementing the MINI robot for PwD and people with mild cognitive impairment attending MCs in the Netherlands (N=3) and Spain (N=1). Participants were selected and recruited through the purposive sampling method. The participants interviewed in the Netherlands came from 3 MCs in the middle and west of the country: 12 people with mild-to-moderate dementia who were invited by the coordinator of the MCs to participate in the focus groups and 9 professional stakeholders, including the managers and activity therapists of the 3 MCs, the chair of the Amsterdam section of the Dutch Alzheimer Association, and a senior policy advisor and coordinator of the social support domain of the municipality of Amsterdam. In Spain, the manager of the MC and head of the Community Support Complex in Zamora participated.

MINI Robot Presentation

MINI autonomously communicates with humans through verbal and nonverbal interactions. It is a lightweight, small-size, stationary robot covered in plush fabric with an animal appearance. It is equipped with a microphone for speech-based communication, touch sensors in the shoulders and belly that allow the user to interact physically with MINI, an RGB-D camera to extract visual and depth information from the environment, organic light-emitting diode (OLED) eyes to express the robot's emotional state, and a tablet that can work both as an input device (through fixed menus) and as an output device, displaying the content of the apps. A series of games and cognitive exercises are installed on the robot that can be extended and modified. MINI is set up to pose certain queries, obtain answers, and provide users with feedback on their performance [16-18]. Currently, MINI is in the prototype phase and programmed for the Spanish language only (see Figure 1).

An introduction video clip of the MINI robot was produced in collaboration with the robotic laboratory of the University of Carlos III of Madrid and translated into Dutch, adding a Dutch voice-over and subtitles, by researchers of the Amsterdam University Medical Center. The video provides information about the use and functionality of the MINI robot, as well as its software and application, and demonstrates a user interacting with the robot. This video was sent to participants via email as a YouTube video link before the interview day, accompanied by the study aim, a brief description of the MINI robot, and interview questions. The interviews were conducted in person, and participants were free to watch the video again before answering the questions.

For the PwD, the video was shown on a big-screen TV/projector screen during a focus group session, and general questions were asked about their opinions and attitudes toward the MINI robot (see Figure 2).

Figure 1. MINI robot developed by the University of Carlos III of Madrid (UC3M).

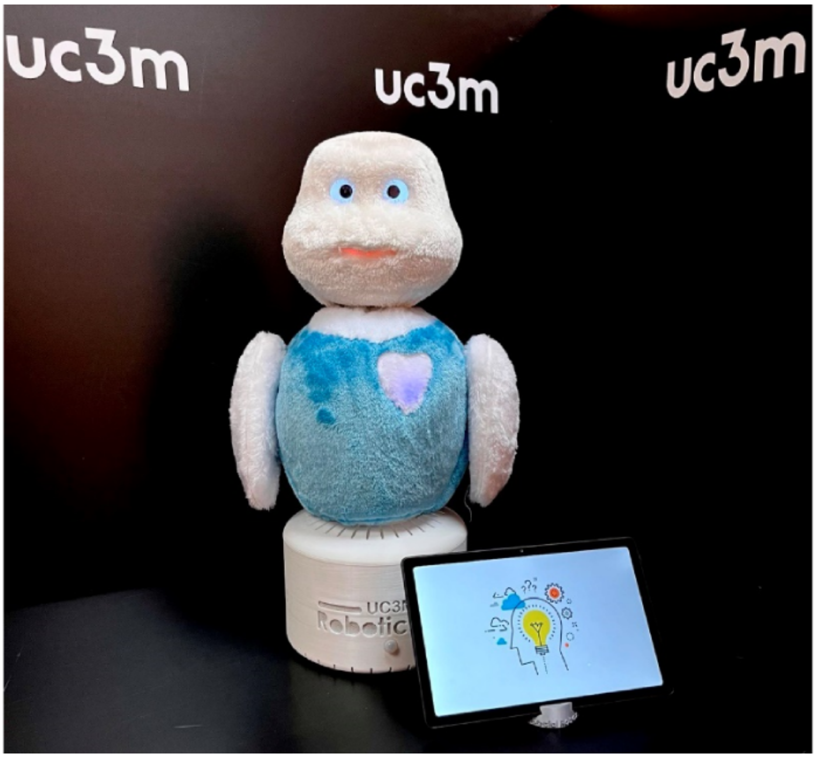


Figure 2. Presentation of the MINI robot to the PwD in the MCs. MC: meeting center; PwD: people with dementia.

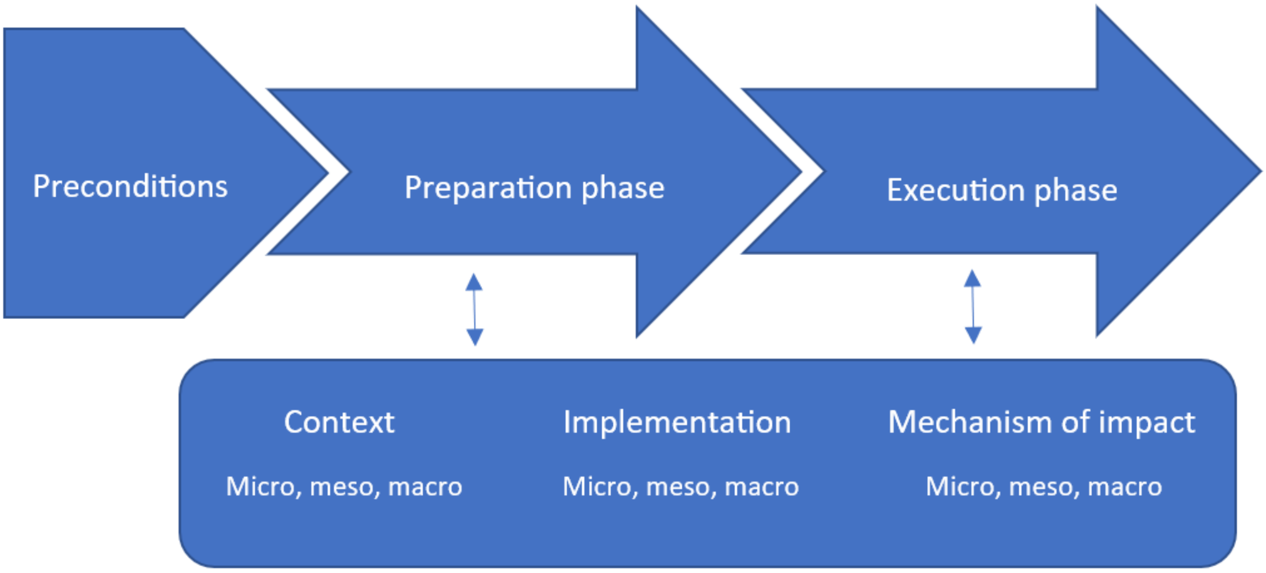
Data Collection

The interview questions were created based on the MRC guidance for process evaluation and Meiland et al's [15] theoretical framework to trace facilitators and barriers regarding preconditions and the preparation and execution phases of implementation at micro-, meso-, and macrolevels, including contextual factors, implementation factors, and mechanisms of impact. Figure 3 demonstrates how the 2 models were combined to create a theoretical framework of our explorative study. The semistructured interview questions for the stakeholders other than the PwD are presented in Multimedia Appendix 1.

Two interviewers, the main researcher of the study (author AM) and a local researcher in the Netherlands (author SK), interviewed the stakeholders individually and took notes (quotes) of what was stated, and all interviews were audio-recorded.

In the focus groups, the PwD discussed their general attitudes toward the implementation and application of the MINI robot in the MCs. The local researcher (SK) interviewed and moderated the focus group sessions, and the sessions were audio-recorded.

Figure 3. Combined model for tracing the facilitators of and barriers to implementation of the MINI robot based on the Medical Research Council's guidance for process evaluation.



Data Analysis

The interviews were anonymously recorded using the iPhone 13 voice recording app. The local researcher (SK) transcribed the audio recordings and translated them into English. The main researcher (AM) followed the same procedure for the interviews in Spain. Codes for facilitators and barriers regarding preconditions, preparation and execution phases, level (micro, meso, macro), and factors associated with the context, implementation, and mechanism of impact were created. Subsequently, the study supervisor (author RMD) and main researcher (AM) independently coded 3 interview transcripts, reviewed disparities, and discussed them until consensus was reached. The other transcriptions and meeting notes were then further coded thematically by the main researcher (AM) using QSR NVivo 12 software, and potential facilitators and barriers were summarized. The complete list of codes is presented in Multimedia Appendix 2.

Ethical Considerations

Ethical approval was not sought for this study. This aligns with the Medical Research Involving Human Subjects Act (Wet Medisch wetenschappelijk onderzoek met mensen, WMO) in the Netherlands [19] as interview studies are beyond its scope. Additionally, no personal data were collected. All participants were fully informed of the study and what was being asked of them. Verbal informed consent was obtained from individuals before the study.

Results

Participants

In total, 11 interviews were conducted with 11 stakeholders: 4 (36%) MC managers, 4 (36%) activity therapists of the MCs, the chair of the Amsterdam section of the Dutch Alzheimer Association (n=1, 9%), a senior policy advisor/coordinator of the social support domain of the municipality of Amsterdam (n=1, 9%), and the head of the psychiatry unit of the Community Support Complex and manager of the MC in Zamora (n=1, 9%). Additionally, 12 Dutch PwD attended the focus group discussions.

Facilitators of and Barriers to Implementation of the MINI Robot

In this section, a summary of the facilitators and barriers in existing preconditions as well as those associated with the 3 process evaluation components (ie, contextual factors, implementation factors, and mechanisms of impact) in both preparation and execution phases are outlined (see Tables 1-4).

Table 1. Existing conditions facilitating or impeding the implementation of the MINI robot.

Precondition	Facilitators	Barriers
Characteristics of the innovation	• Entertaining (M1[a]) • Improving self-esteem (LG[b]) • Fun and enjoyable (M1) • Reminiscence activity (M1) • Stimulating and activating (A[c]) • Reduces the care burden of caregivers and professionals (M2[d]) • Complementary/additional activity (M1, A)	• No substitution for the human being • Individualized use • May substitute human interactione • Constant need for supervision[e]
Operational preconditions	• N/A[f]	• Need for a technical person (M1)
Human and financial resources	• Existing budget from the municipality (M1) • Decision-making inside the organization (M1) • No need for approval from higher-level parties in the organization (M1) • Available donations from tech companies (M1) • Available staff and volunteers (M1)	• Busy activity therapist (A)
Organizational conditions	• No need for insurance for using the robot in the MC (M1)	• No quiz-like activities and games policy of the MC (M1, A) • Permission required from the directors (M1)

[a]M1: meeting center (MC) manager.

[b]LG: local government.

[c]A: activity therapist.

[d]M2: manager/director of other care/welfare organization.

[e]As stated by people with disabilities (PwD).

[f]N/A: not applicable.

Table 2. Contextual factors: potential facilitators and barriers, and recommendations for improvement.

Factor	Facilitators	Barriers	Recommendations for improvement
Hardware and physical context of the MINI robot	• Cute appearance (M1[a])	• It should look like a pet or human but not in between (A[b]) • Monotonous voice (M1) • 2 user interfaces making it complex to use: the robot and the tablet (M1) • Not a cute face (M1) • Not a nice appearance[c] • Childish appearance[c]	• Moving eyes (M1) • Expressing emotions (eg, laughing at jokes; M1) • Less toy-looking (A) • Change the appearance (M1) • Should look like a child or young adult but not too childish or baby-looking (M1) • Huggable and soft touch[c] (A) • 2 versions of the robot's look: puppet and adult look (A) • Use of special fabric that cleans itself (A) • Changeable clothing (A) • Clear voice[c] • Slow and short sentences[c] (M1) • Use of bright colors[c] (M1) • Add some hair[c]
Functionalities and software context of the MINI robot	• Possibility to add new apps (M2[d]) • Interesting software (M1, M2) • Not too difficult (M1)	• Too many options on the tablet screen could be confusing (M1, A) • Features of the robot for individual settings (M1) • No reaction to people's emotions (A) • Too much explanation by talking (M1) • No feelings[c]	• Expressing emotions (eg, lighting to the jokes) (M1) • Medication reminder (LG[e], M2) • Make the games more complicated (M2) • An alarm of accidents, fire, etc (M2) • Simple robot without a need for too many explanations (M1) • Robot in a group setting acting as a member of the group (M1) • Pictures from the local city (A) • Support and guidance in performing daily tasks (LG)
Users of MCs	• N/A[f]	• Higher functions of the brain damaged so not suitable for people in MCs (M1, A) • Repetitions of instructions needed by users (A)	• N/A
Setting and activities of MCs	• N/A	• No quiz-like activities and games policy of the MCs (M1, A) • Not playing games in the MCs (main activity is to socialize) • Normal activities such as music and art (M1, A)	• N/A
Other settings	• Could be helpful in other settings such as nursing homes or private homes where people are truly alone • Can get used to the robot in MCs and then want to have it at home (M2)	• N/A	• N/A

[a]M1: meeting center (MC) manager.

[b]A: activity therapist.

[c]As stated by people with disabilities (PwD).

[d]M2: manager/director of other care/welfare organization.

[e]LG: local government.

[f]N/A: not applicable.

Table 3. Implementation factors: potential facilitators and barriers.

Factor	Facilitators	Barriers
Insurance	• Insurance probably possible for some people (M1[a])	• Insurance is difficult to reach (M1)
Human resources and supervision	• Volunteers of Digi Café can help with implementation (M1) • Clear instructions for using the robot (M1) • Getting used to the robot (M1)	• Need for support from a caregiver besides the robot (A[b]) • Need for a technical person to fix the robot (M1)
Funding	• Many organizations gifting to elderly adults (M1) • A medical general practitioner (GP) can recommend a technology (M1) • The university can promote new interventions (M1) • The municipality can provide funding (LG[c]) • The care organization can provide financial resources (M1) • The social support domain of the municipality of Amsterdam supports financial aid for such projects (LG)	• The technology must be necessary to get insured (M1)
Effectiveness	• Evidence of efficacy necessary (M1) • The MINI robot in line with the Amsterdam Vital and Healthy program (LG)	• N/A[d]
Collaboration of organizations	• Collaboration with welfare and health organizations can help implement the MINI robot (LG) • Doe-Mee Huis[e] and Bakkershuise can help with implementation (M1) • Collaboration with the Alzheimer Association can help implement (M2[f])	• N/A

[a]M1: meeting center (MC) manager.

[b]A: activity therapist.

[c]LG: local government.

[d]N/A: not applicable.

[e]Community-based day centers.

[f]M2: manager/director of other care/welfare organization.

Table 4. Mechanism of impact: facilitators and barriers.

Factor	Facilitators	Barriers
MCs[a]	• An MC with a robot would be interesting (M1[b]) • The robot can be attractive and change the routines of the MC (M1) • Fun and promoting social interactions (M1) • Engaging the person in the group could affect their mood (M1) • They will have more conversations (about the robot) with their partner in the MC (M1) • Helpful to relax and make jokes (M1) • Fun and entertaining (M1) • Helps against cognitive deterioration (M1) • Helps to stay active (M1)	• Will not decrease the burden on professionals/caregivers (M1, M2[c]) • Will not decrease loneliness (M1, M2)
Other settings	• Social interactions (M1) • People will have more conversations (about the robot activities) with their partners at home (M1) • Could be helpful for people living alone (M1, M2)	• N/A[d]

[a]MC: meeting center.

[b]M1: MC manager.

[c]M2: manager/director of other care/welfare organization.

[d]N/A: not applicable.

Preconditions

Although the stakeholders' views on the features of the MINI robot were somewhat divergent, most of them supported the use of the MINI robot in MCs or other environments, such as private or resident homes. Several existing facilitators were noted in terms of human and financial resources. A few impeding factors were noted for operational and organizational conditions. Table 1 presents the existing facilitators and barriers for the 4 precondition components.

The Microlevel

Introduction of the MINI Robot (Preparation Phase)

Obtaining consent from the directors of the MCs' to implement the MINI robot for PwD visiting the MCs may be considered the first step in the preparation phase. However, the majority of MC managers claimed that they could make this decision on their own without seeking permission from their superiors. The stakeholders suggested various ways to inform PwD about the new MINI robot intervention, including social media groups, educational events, phone calls, and emails. The chair of the Alzheimer Association suggested the MINI robot be presented at conferences first so that various stakeholders may become familiar with it.

> *It's very important to see how you can get people on board so that they don't immediately put the brakes on.* [Policy advisor of the social support domain of the municipality]

Human Resources and Training (Preparation Phase)

Every member of the MCs' staff may participate in the MINI robot's implementation, depending on their willingness to use such technologies in the MCs. The MC managers stressed the importance of training their staff as facilitators of the intervention so that they may manage the robot and provide users with instructions on how to use it. They all believed that users would not be able to communicate with the robot on their own.

> *I cannot leave those people alone. Because they don't know what to do. You always have to be with them.* [MC activity therapist]

Frequency of Use (Execution Phase)

The management and activity therapists largely agreed to use the robot 3 days per week or as often as the users desire to interact with it. One of the MC managers said that it might take several weeks to get users accustomed to the robot before using it regularly.

Adjustments to the Robot (Preparation Phase)

Regarding the robot's software, hardware, and functions, people had a wide range of comments to improve its features (see also Table 2). All interviewees recognized the opportunity for development in the aforementioned areas.

Regarding the software interface, it was frequently noted that the ease of use and simplicity of the functions would make it easier for PwD to interact with the robot, because they are not accustomed to using such technologies and could become confused if given too many options, lengthy usage instructions, or a cluttered screen interface. The robot would integrate effectively into the MCs if it could speak and converse socially, respond to people's emotions, and act naturally.

> *It would be great if the robot reacts to the people when, for instance, they say, I'm feeling sad today. I'm feeling really sad, that he reacts to that.* [MC manager]

> *It would be helpful if the robot could express emotions, for instance, that he can laugh.* [MC manager]

> *I think it would be nice when it can have social talks about anything.* [MC manager]

Since the MCs' support program is group oriented, individual activities do not often take place. One manager saw the current features of the robot interacting with 1 user in an individual setting as a barrier to implementation and suggested adapting the robot for a group setting.

> *The robot will be an individual activity unless you could use it in a group setting for at least 2 people, not just 1 individual!* [MC manager]

Concerning the robot's hardware and appearance, the interviewees found it attractive but believed there is a need for improvement to make it more acceptable to older adults (see also Table 1). A few interviewees were not sure whether the robot is an agent that resembles a human or an animal and thought the appearance was somewhere in the middle. Additionally, some people preferred the robot to look like a young adult and disliked the childish look. Moreover, one of the activity therapists suggested that the robot's voice be clearer and slower, communicating through brief sentences. Another activity therapist recommended using special fabric for the robot's clothes that cleans itself and does not require regular washing, or even changeable clothing, ensuring safe hygiene if people touch and embrace the robot (see Table 1).

Impact of the Robot on the MCs (Execution Phase)

Except for 1 MC, all other MCs recognized the MINI robot's potential to impact them. Depending on how the robot is programmed, it can stimulate cognitive functions, keep people more alert and active, and even improve their mood. The interactions with the robot were viewed by some of the stakeholders as a fun, entertaining, and engaging activity that might even encourage dialogues between participants, as well as dialogues between participants and caregivers/therapists. One of the MC managers was hesitant to deploy the MINI robot because it did not seem to fit with the MC's norms and regular activities: they do not undertake activities that focus on stimulating high-level brain processes, as they do not want PwD to be confronted with their disabilities or fail. A few of the stakeholders thought that the robot could play a role in alleviating loneliness in persons who live alone in their private homes.

> *Getting less lonely in the MC is not expected, but I do think it may result in less deterioration…I do think that helps…It's especially important to keep people stay active.* [MC manager]

A few of the stakeholders did not expect that the MINI robot would benefit care and welfare professionals; however, there were many supportive remarks from the rest of the stakeholders: The MINI robot intervention might provide an extra variety of activities in the MCs and may reduce the workload and time spent by the professionals and caregivers with PwD. It could encourage social interaction and conversations between PwD and formal/informal caregivers in the MCs, according to 1 of the managers.

> *Robots cannot replace the therapies but can be a complement for doing all their activities in another way.* [MC manager]

The Mesolevel

Collaborations With Other MCs and Health Care/Welfare Organizations (Preparation and Execution Phases)

The implementation of such technologies could be promoted by collaborations outside the MCs through the university and even a general practitioner. In terms of providing human resources and encouraging implementation, Doe-Mee Huis, Bakkershuis, and Digi Café (community-based day centers) could serve as facilitators. In Spain, a collaboration between the MC, the Alzheimer Association, and other foundations may help with the robot's implementation.

The Macrolevel

Financial Resources (Preparation and Execution Phases)

Several external resources were discussed in the interviews to obtain sufficient financial resources in order to purchase and implement the MINI robot. However, some of the stakeholders highlighted that financial support would be contingent on the robot's proven effectiveness and necessity. The municipality, the social support domain of the municipality, and the care organization exploiting the MCs were mentioned in the Netherlands as potential sources of financial support. In addition, as a facilitator for introducing such technologies, 1 of the stakeholders pointed to the Amsterdam dementia-friendly city program and that nowadays people are more open to using such technologies for PwD. In addition, a manager confirmed that some corporations provide such technologies as a gift to PwD. One of the managers also suggested the option of splitting the cost of the robot across several MCs or departments of the care organization by sharing it.

> *That's also a bit the trend in the Netherlands now—that you connect care and welfare—to bring down the expensive care costs…then people can live with some quality of life at home, for as long as possible.* [Social support policy advisor]

In Spain, supported by social security, the majority of health care expenses are covered by the government, and in the event of proven effectiveness, funding can be received from the government and various foundations.

Coverage of Health Insurance (Preparation Phase)

Although there is no need for the users of MCs to pay separately for using a robot there, in the case of demonstrated effectiveness, as noted before, health insurance may be willing to cover the costs of using the robot in both MCs and the private homes of PwD.

> *It is always interesting to see in pilots how things work…our city is also very open to that—to try new things out.* [Social support policy advisor]

Information Available on Health Policy or Legislation (Preparation Phase)

None of the stakeholders were aware of any existing policy in the Netherlands or Spain that supports the application of technologies such as social robots for PwD.

Focus Group Interviews With PwD

PwD in the Dutch MCs had various reactions to the MINI robot, although most of them had doubts about using it. They were unaware of all of the robot's specific capabilities and applications, since only a few functions of the robot were demonstrated in the presentation video. Some thought the robot was a nice and adorable doll machine to have in the MC. Some were skeptical of deploying it, seeing it as something for the younger generation or those in the early stages of dementia. They said they had never used such technology before, and several even claimed they had no idea how to operate smartphones. One participant was concerned that human engagement might be replaced by robot interaction:

> *I am afraid that you will lose contact with real people a bit if you constantly fixate on the robot…it helps you, it looks nice, and then what? Will you then get on better with other people?*

One of the participants emphasized that they would rather play a normal game in the MC instead of playing with a robot.

> *Playing games! People can do that anyway; they don't need the robot for that.*

Regarding the robot's looks, there were differing opinions: some people thought the robot was attractive, while others did not. They also liked the robot to speak in short, concise sentences and to speak slowly.

Discussion

Principal Findings

This study provides insight into facilitating and impeding factors for the implementation of the social robot MINI in MCs for PwD and their carers in the Netherlands and Spain. Several influencing factors were found in preconditions, and the preparation and execution phases at 3 levels (micro, meso, and macro), associated with contextual factors, implementation factors, and mechanisms of impact. The most important (potential) facilitating factors noted by the stakeholders seemed to be human resources, funding, the impact of the MINI robot on the users and program of the MCs, characteristics of robotic interventions, and collaboration with other organizations. The (potential) barriers mentioned concerned the physical context and the functionalities of the MINI robot, the user context, and activity policies of MCs.

Facilitators

The overall characteristics of the robotic intervention were well recognized by the stakeholders as potentially benefitting PwD in several ways: by keeping them active and alert, by entertaining them and stimulating their cognitive functions, and, most importantly, by having fun and participating in enjoyable activities. Based on a recent systematic review, social robots might benefit people with mild-to-moderate dementia with psychosocial symptoms and agitation [20]. Another scoping review revealed the impact of social robots on the mood and emotions, activity participation, and social interaction of PwD [11]. The stakeholders also saw the potential for loneliness relief by using the MINI robot among PwD living alone. However, research in this area is rare, and most existing pilots have been conducted in laboratory settings.

The positive views on the potential impact of the MINI robot intervention in the MCs could be supported by recent studies on other social robots in similar environments in daycare centers for PwD. A recent randomized controlled trial [21] on the PARO robot with PwD in daycare centers showed improved facial expression and better communication with staff. This was 1 of the most commonly highlighted impacts in MCs by professional stakeholders that may promote interaction between MC users and staff and a pleasant and pleasurable variety of activities.

Another facilitating aspect that was frequently mentioned regarding the preconditions and the preparation phase was human resources. Participants felt that almost all the MC staff, including activity therapists, volunteers, and internship students, could facilitate the MINI robot's implementation and promote its use in the MCs. To modify and tailor the robotic intervention, the background and training of the intervention facilitators should be considered.

Considering the high cost of purchasing social robots and maintenance [22], the available and possible funding resources to support the implementation of the MINI robot in MCs were conceived as a key facilitator. The stakeholders believed that there is a budget available to purchase digital technologies, as well as organizations/institutions to refund or donate the MINI robot. In the literature, the high cost of social robots has been widely acknowledged as a practical issue by users, family members, stakeholders, organizations, and researchers [23-26]. Thus, by sharing a social robot in daycare centers, equal access for older adults and PwD can be promoted [27].

Barriers

Regarding the characteristics of the MINI robot, hardware and software were much discussed. Most professional stakeholders and PwD considered the MINI robot's hardware and software to be a hindrance. In terms of the appearance and physical body of the robot, there is room for modifications/improvements to make it more attractive and better usable. One of the studies on social robots [28] showed that the users appreciated both the mechanical human-like and the mechanical animal-like appearance of the robots. This might support the opinion of some of the stakeholders who did not like the current ambiguous appearance of the MINI robot—neither being animal nor human but rather a mixture. Some stakeholders voiced concerns about the monotonous and rather fast-speaking robot and perceived it as a machine-like agent that may raise both usability and acceptability challenges for PwD who are trying to follow the dialogue. In a recent study on the Pepper robot [29], considering user opinions of the tablet interface, the researcher recommended large buttons and text sizes for easy usability for older adults. To ensure trouble-free interaction, they also suggested a simple and clear tablet user interface.

The main impediment in 1 of the MCs was the position on games and activities for PwD. The MC staff was opposed to using any form of quiz-like game or other activity that requires semantic memory in order to prevent PwD from having to confront their disease and failure. However, the rest of the professional stakeholders were optimistic about the robotic intervention to keep PwD active and alert. In a recent systematic review, the negative attitude of professionals and relatives was shown as a barrier to social robot implementation [30].

Limitations and Strengths of the Study

This study has several limitations that must be noted. First, the MINI robot's capabilities were introduced and demonstrated through a video clip, which may have limited the understanding of the robot's characteristics and functioning. A video presentation may not be able to replace hands-on encounters with the robot and may impact attitude and trust in the robot. Second, the video clip did not show the entire sequence of games and apps that the robot provides. This may also have had an impact on the stakeholders' perceptions. Third, only an inventory of *potential* facilitators and barriers could be made, as the MINI robot was not yet implemented in the MCs. This requires cautiousness regarding the study's findings. Study of the facilitators of and barriers to implementing the MINI robot should therefore be repeated after improving the prototype and the actual physical implementation. Fourth, there were no participants with dementia in Spain and the sample size for PwD in the Netherlands was small. In Spain, currently, only 1 MC has been established. People in the MC in Spain at the time of the study were involved in another research experiment, making a focus group interview with them practically impossible.

The strengths of the study were that we interviewed a wide range of stakeholders, ensuring that all points of view were well represented. The interview scheme was built on 2 theoretical frameworks, which ensured that all components necessary for successful implementation were addressed in the interviews.

Scientific, Clinical, and Societal Relevance of the Study

The scholarly significance of this study stems from the fact that it is the first to investigate the potential facilitators of and barriers to adopting the MINI robot in MCs for PwD and carers in the Netherlands and Spain. This benefits robotic intervention research and clinical practice in 2 ways: First, to effectively install the robot and enhance its usability and acceptance as viewed by end users, the robot's creators need feedback from both professional stakeholders and PwD about the MINI robot itself and its functionalities. Second, by identifying possible facilitators of and barriers to the adoption and implementation of the MINI robot in an early phase, the directors and managers of MCs may facilitate the process later. Our study discovered that most professional stakeholders and PwD perceive the robotic intervention favorably and feel it is feasible to apply the MINI robot in MCs in the Netherlands and Spain. However, we also uncovered a few roadblocks, most of which involve the MINI robot's characteristics, that can be addressed. The societal relevance of this study is that it provides a better understanding of the implementation of the MINI robot or similar social robots in the local context in MCs in the Netherlands and Spain. Based on current research on the influence of social robots in daycare centers on promoting activity participation, emotions, engagement, and social interaction, the successful implementation of the MINI robot will contribute to the enhancement of PwD's mental and social health.

Recommendations for Future Studies

Continued study on the MINI robot's deployment and influence on PwD in MCs is crucial to establish its usability, feasibility, and efficacy in a real-world context. To achieve this goal and maximize the benefits of robotic interventions for PwD, the MINI robot engineers and researchers need to tailor the robotic platform to the end users' needs and preferences, the dynamics of group interactions, and the MCs' activity policies and settings.

Conclusion

This study provides insight into the facilitating and impeding factors for the MINI robot's implementation in MCs in the Netherlands and Spain. The findings will inform professional stakeholders, including the directors and managers of the MCs and care and welfare organizations, about the feasibility of the MINI robot in MCs. Moreover, our research will assist the MINI robot developers in adapting its characteristics to the preferences and demands of PwD as well as to the MCs' policies, which will contribute to the effective adoption and implementation of the MINI robot.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Interview questions.
[DOCX File , 21 KB-Multimedia Appendix 1]

Multimedia Appendix 2

List of codes.
[DOCX File , 19 KB-Multimedia Appendix 2]

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Abbreviations

IAT: intelligent assistive technologies
MC: meeting center
MCSP: Meeting Centre Support Programme
MRC: Medical Research Council
PwD: people with dementia

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Publication #4. Acceptability of the Social Robot MINI and Attitudes of People with Dementia and Mild Cognitive Impairment: A Mixed Method Study.

Publicación #4. Aceptabilidad del Robot Social MINI y Actitudes de Personas con Demencia y Deterioro Cognitivo Leve: Un estudio de método mixto.

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Resumen en español

Antecedentes: Los robots sociales se consideran una solución prometedora y un apoyo en las áreas emocional, mental y física para las PcD y DCL. La adopción y los resultados efectivos de los robots sociales pueden depender en gran medida de la actitud y la aceptación de este grupo destinatario y deben tenerse en cuenta desde las fases primarias de diseño y desarrollo.

Objetivo: El presente estudio pretende evaluar la aceptabilidad y las actitudes de las PcD y DCL hacia el MINI robot y conocer sus expectativas.

Método: Se llevó a cabo un estudio de métodos mixtos en un entorno clínico, con 22 PcD y DCL, con edades comprendidas entre los 68 y los 88 años. Durante un mes, los participantes participaron en ocho sesiones de interacción individual con el robot. El cuestionario de Almere sirvió para evaluar la aceptabilidad antes y después del uso del robot. Al final del estudio, los participantes completaron entrevistas semiestructuradas sobre sus actitudes hacia el robot MINI.

Resultados: un total de 22 PcD y DCL completaron el estudio y participaron individualmente en ocho sesiones de interacción con el MINI robot. Los datos del cuestionario de Almere mostraron que las personas estaban a favor del MINI robot y los valores medios de las valoraciones fueron ligeramente superiores en el postest, excepto en el constructo social "presencia/personalidad del robot/presencia social". De los datos de las entrevistas surgieron una serie de ideas que revelaron

la aceptación y satisfacción con el uso del MINI robot en entornos clínicos. Los participantes consideraron que el MINI robot era un compañero divertido y agradable, sobre todo para las personas que viven solas. Aunque se apreciaron las características del robot, se hicieron algunas sugerencias para mejorar la plataforma robótica.

Conclusiones: Esta investigación confirma la aceptación del robot MINI y la opinión positiva de la población objetivo hacia la interacción con el robot MINI en entornos clínicos. La investigación presentada en este artículo puede aportar nuevas ideas para mejorar el diseño de los robots sociales y sugerencias para ajustar las características de la robótica a los deseos, necesidades y preferencias de los usuarios.

Palabras clave: aceptabilidad; deficiencias cognitivas; demencia; robots sociales.

Acceptability of the Social Robot Mini and Attitudes of People with Dementia and Mild Cognitive Impairment: A Mixed Method Study

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Research Article

Keywords: acceptability, cognitive impairments, dementia, social robots

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Abstract

Background: Social robots are considered a promising solution and support in emotional, mental, and physical areas for people with dementia (PwD) and mild cognitive impairments (MCI). Social robots' effective adoption and outcome may largely depend on this target group's attitude and acceptance and should be taken into account since the primary stages of design and development. The present study aims to evaluate the acceptability and attitudes of the PwD and MCI towards the Mini robot and understand their expectations.

Methods: A mixed-method study was conducted in a clinical setting, with 22 community-dwelling people with dementia and mild cognitive impairment, aged 68-88 years. During the course of a month, the participants engaged in eight sessions of individual interaction with the robot. Pre- and post-evaluation of acceptability were conducted utilizing the Almere questionnaire. Participants completed semi-structured interviews on their attitudes towards the Mini robot at the end of the study.

Results: A total of 22 PwD and MCI completed the study and individually participated in eight sessions of interaction with the Mini robot. The data from the Almere questionnaire showed that people were in favour of the Mini robot and the mean values of the ratings were slightly higher in the post-test, except for the social 'presence/ personality of the robot/social presence' construct. A collection of ideas emerged from interview data that revealed acceptance and satisfaction with using the Mini robot in clinical settings. Participants viewed the Mini robot as a delightful companion, particularly for those who live alone, as a wonderful advantage.

Although the robot's features were appreciated, some suggestions for improving the robotic platform were made.

Conclusion: This research confirms the Mini robot acceptance and the target population's positive opinion towards interacting with Mini robot in clinical settings. The research presented in this article may provide new insights into improving social robots' design and suggestions for adjusting the robotics' features to the users' desires, needs and preferences.

Introduction

Social robots are often referred to as the forms of autonomous robots in the human embodiment that offer social interactions with people (1). In recent years, there has been an increase in demand for social robots in healthcare, service (2), education, and entertainment, which has propelled the revolution of this technology (3). Nowadays, we witness an expanding number of emerging social robots and research from academia and industry.

In recent years, social robots have been deployed to serve a variety of human target groups ranging from toddlers to elderly. However, while it is commonly assumed that these technological advances are appropriate for younger generations, research shows that social robots are more positively perceived and accepted by older people than in other domains, such as education for children (4). Indeed, in recent years, the employing of social robots for people with dementia (PwD) and mild cognitive impairments (MCI) has been a focus of research (5, 6). The purpose of the application of social robots in these target groups has been associated with one of the following service domains: companionship, personal assistance, rehabilitation, and safety (7). Robots are anticipated to become more crucial in maintaining elderly people's autonomy and well-being and improving the overall quality of life. Currently, an increasing number of emerging studies in the field of social robots in dementia care focus on the acceptability and attitudes of end users, caregivers, and professionals- since the adoption of the robots might be rather slower in older target populations (8). The social robots' acceptability constitutes an essential focal point, and it is because they could be effective and well adopted only if the stakeholders embrace and accept using them. Furthermore, the target population of PwD and MCI and their interactions with social robots are critical and should be thoroughly studied. So far, the adoption of robots among elderly adults with dementia and cognitive limitations has been generally favourable, with more people eager to use and test robotic technology (9–11).

Recently, a robotic platform called Mini was designed and developed in the *Robotics Lab* of *Carlos III University* in Madrid to support seniors and provide cognitive and social stimulation for older people with neurodegenerative diseases, especially those with cognitive impairment (12). This small-sized desktop robot is covered in plush fur and equipped with a speech recognition system, touch sensors on the shoulders and belly, an RGB-D camera to analyse the depth of the environment, and uOled eyes. A tablet interface serves as an input and output device to display information and multimedia content. To enhance expressiveness, the robot can move its base, arms, neck, and head (13, 14) (Fig. 1). With these interfaces, the robot is capable of handling interactions with the user through verbal and nonverbal channels.

The robot Mini includes a series of skills/exercises to engage and interact with users, as shown in Fig. 2. The service offer was developed through a co-creation approach -involving the developers, researchers and end-users- and is centered on the needs and preferences and abilities of older adults with cognitive impairments in order to achieve the Mini robot's objective of being a social companion.

Several theoretical models are proposed by professionals in psychology, sociology, and computer science in response to a demand for theoretical acceptance models to examine all elements of people's views on such new technologies. One of these models is the *Almere model* (15), whose basis is to validate the unified theory of acceptance and use of technology (16). This model provides a succinct quantitative measurement that reflects on the complex psychological states of individuals (especially among elderly people) as they adopt new technologies.

The main contribution of this work was to assess the acceptability of the Mini robot and attitudes towards it in PwD and MCI after one month of direct exposure in a clinical setting. This work was the first acceptability study with a mixed method to capture qualitative and quantitative information. We intended to capture the most significant aspects of the acceptability of the Mini robot.

Methods

Study design

A mixed-method study design was employed to capture in-depth information on the Mini robot's acceptability of the PwD and MCI. Ethical approval for this study was obtained from the Zamora Ethical Committee (Number 574, 28/01/2022). This experiment's methodology was based on a recent scoping review and recommendations for evaluating social robots in elderly adults and PwD (6). The study protocol of this research was previously published in the BMC Psychiatry journal (17).

The current study aimed to evaluate the acceptability and attitudes of the PwD and MCI towards the Mini robot and to answer the following questions:

1. Is Mini considered acceptable by PwD and MCI?
2. What are the attitudes of PwD and MCI towards Mini?
3. Do the software and hardware elements of the Mini robot need to be modified to increase acceptability?

Participants and setting

A list of eligible PwD and MCI older adults attending the memory clinic and workshops of the *INTRAS foundation* in Castilla y Leon, Spain was created. After the Mini robot's brief introduction and experiment explanation, 25 people volunteered to participate in the study. Three participants left after the first session, but 22 completed the study (13 women and 9 men | age range: 68–88 years). Table 1 describes the demographic characteristics of the participants.

The inclusion and exclusion criteria were as follows:

- Inclusion criteria:
    - PwD and/or MCI diagnosed by the public health system and following the DSM-5 criteria.
    - Aged 65 and over
    - Ability to read and write in Spanish
    - Ability to decision making
    - MMSE score $\leq$ 24
- Exclusion criteria:
    - Unstable medical conditions.

Table 1
Demographic characteristics of the participants

Age, years	77.27 ± 4.72
Education level	
Primary school	9 (10.2)
Secondary school	1 (1.1)
High school	3 (3.4)
University degree	9 (10.2)
Gender	
Female	13 (19.7)
Male	9 (13.6)
MMSE	22.7 ± 1.55
Frequency of usage of the digital devices*	
Never	8 (34.1)
Rarely	4 (20.5)
Sometimes	5 (22.7)
Always	5 (22.7)

Data are presented as “Number (%)” or “mean ± SD”.

*e.g., smart phones, tablets and, personal computer.

Measures

A survey questionnaire based on Heerink’s Almere model (15) was used to gauge acceptability (see supplementary file 1). The questionnaire comprises influencing factors, including Anxiety (ANX), Perceived Usefulness (USN), Perceived Adaptability (ADP), Perceived Enjoyment (ENJ), Perceived Ease of Use (EAS), Perceived Sociability (SOC), Attitude (ATT), Personality of the robot/ Social Presence (PSN), and Trust (TRS).

Each item was scored using a Likert scale with a maximum of five points (Strongly Disagree = 1, Disagree = 2, Neutral = 3, Agree = 4, Strongly Agree = 5). It was designed for assessment of the perceptions of SARs by users during human-robot interaction, among elderly people. Several studies in countries such as Canada (18), Switzerland (19), and Poland (20) have demonstrated strong validity and reliability in senior adult samples for this questionnaire. The questionnaire's broad use is additional evidence of its validity.

Open-ended interview questions were designed to capture the positive and negative attitudes of the participants and any recommendations to improve/modify its features (see supplementary file 2).

Procedure

The participants and their next of kin were invited to the memory clinic and given the consent form to sign it. The participants came 2–3 times a week (based on their availability) to interact individually with the Mini robot for half an hour (See Fig. 3). The experimenter presented the Mini robot during the first session, which was followed by the Mini robot introducing herself. They were free to choose from the apps and games and how to interact with the robot. After the first session ended (during one month), the participants were asked to complete the Acceptability questionnaire. Throughout the eight interaction sessions, the participants were free to choose which application/ game to use (See the applications interface in Fig. 1). The experimenter provided the operating instructions anytime required. The whole experiment duration lasted about one month for each participant. Individual interviews and the acceptability questionnaire (post-survey) were administered at the end of the last session.

Data analysis

For the responses of the participant to the Almere model questionnaire, descriptive analysis and graphic representation were performed using SPSS (version 24). Semi-structured interviews were analysed and coded using Nvivo 12 software. Two independent coders first identified the codes in the interview statements and generated emerging themes based on the interview contents, following the six-step approach of Braun and Clark (21). The findings are described and presented thematically.

Results

Almere model questionnaire

In general, participants expressed a positive attitude towards the robot with slightly higher level of acceptability in the post-test, except for Social Presence/ personality of the robot/social presence. Figure 4 illustrates the mean values with standard errors of mean for pre and post-test for the Almere model constructs.

Except for the personality of the robot/social presence ($\mu = 2.97 \pm 1.43$ to 1.65 ± 1.21), the mean values for all the constructs increased over time. The mean value for Anxiety as a negative construct also decreased slightly ($\mu = 2.0 \pm 1.1$ to 1.7 ± 0.88). The mean value for the Personality of the robot/social presence decreased by a 1.32 score after one month of interaction. Perceived Enjoyment ($\mu = 4.02 \pm 0.68$ | 4.41 ± 0.81), Sociability ($\mu = 4.00 \pm 0.68$ | 4.24 ± 0.77), Attitude ($\mu = 3.69 \pm 0.88$ | 3.90 ± 0.95) and Trust ($\mu = 3.82 \pm 1.00$ | 4.34 ± 0.81) received the highest rates ($\mu = 4 \leq$). The participants scored Perceived Usefulness ($\mu = 3.30 \pm 1.11$ | 3.776 ± 1.08), Adaptability ($\mu = 3.35 \pm 0.71$ | 3.94 ± 0.52) and Ease of Use ($\mu = 3.00 \pm 1.03$ | 3.90 ± 0.95) moderately high ($\mu = 3$ to 4). The lowest rated construct was the Personality of the robot/Social presence ($\mu = 3 \geq$). The least and biggest mean value changes across time were for Anxiety and Personality of the robot/social presence, respectively.

Interviews

Three primary highlighted themes enabled us to capture participants' attitudes towards the Mini robot: Attitudes towards the Mini robot and robotic intervention, potential effects/ benefits, and suggested modification to the robot's features.

Theme I: Attitudes towards the Mini robot and robotic intervention

The participants generally had a positive attitude towards the Mini robot and appreciated the Mini robot interventions, as seen by their remarks. They thought the robot was nice and cute and that using it felt good. However, one participant stated that he would rather talk to a human than a robot unless nobody is around.

The robot is very nice and makes me laugh …

As long as I have my wife, I do not need it (Mini)!

A few participants mentioned that the Mini robot would be ideal for people who live alone and have no one to talk to and that Mini could serve as a companion at home.

Well, for a person who is alone and has nobody to talk to, Mini is good for having a conversation!

One participant raised an ethical/societal concern regarding being directed by or under the watchful eye of a robot in a domestic setting. Still, he had no problem in a clinical/care setting.

It is not a good idea tying me down to have this guy (Mini) standing around the home, dictating things to me, but in the clinic, it is fine.

One of the participants stated that depending on their conditions, degree of cognitive impairment, needs, and preferences of individuals, the robot could suit someone or not.

The photo activity, which included photos of the city, landmarks, animals, and landscapes, was commonly mentioned as the participants' favourite activity with the robot.

Theme II: Potential effects/benefits

Few comments were made by the participants regarding the possible effects of the robot on them and how the robot makes them feel. They stated that the robot was nice and funny and prompted relaxing feelings and making them laugh. They perceived the robot as a cutting-edge technology to help them for staying active and learning new things.

I think it is funny and relaxes you.

The robot helps you feel better!

It is another instrument to teach you about your culture and country. A curious means for learning!

It makes me feel neither better nor worse! It is a machine; you (the interviewer) understand me, but the machine does not.

Theme III: Suggested modification to the robot's features

Few participants said they liked the robot as it was and did not offer any suggestions for improving it. The participants were unsure of the gender of the Mini robot and whether it was human or animal. Some people adored the feminine voice and tone, but preferred the slower pace of speech to better comprehend. The body coloure and the faux fur fabric textures were appreciated. The most popular applications were those with rich multimedia content, such as videos, images, and music. A few suggested ideas to modify/improve it and add new applications/ games. A series of new app and games such as chess and music cloud were suggested to be installed on the platform. Some participants expressed their willingness to be challenged by games with higher difficulty levels. Few participants would prefer the robot to incorporate environmental control functions, such as heat control or turn on the radio/TV, in case the robot is used at home.

I do not like the arms. They look fragile!

You can enhance the smile by adding more colour to the mouth. It is not enough now!

A mathematic operation game with mutual matches may be handy: him versus me and me versus him!

For home applications, it would be nice if it could turn on the TV/radio or control the environment temperature, for example!

It would be great if he played a requested song, such as one of Elvies Presley!

Is it possible to improve the monotonous voice? I believe a woman's voice is more understandable for older adults due to the higher voice pitch.

Playing chess with the robot would be fun!

Discussion

The opinions expressed by PwD and MCI, which were gathered through the Almere model-based questionnaire and interviews, were used to investigate the acceptability of the Mini robot and gauge the participants' attitudes towards the robot. The quantitative data revealed that, except for perceived social presence, participants tended to rate the attributes of the Almere model in a range from neutral to extremely favourable. However, at the end of the trial, participants perceived the Mini robot as a less socially present agent than their initial impression. The Mini robot received the highest ratings for enjoyment, sociability, trust, and overall attitude and the lowest for anxiety.

Participants showed little anxiety at the start of the study and far fewer anxiety at the end of it. According to the qualitative remarks, one of the aspects that might be linked to low anxiety is that the robot was appealing aesthetically and seemed less like a machine. People appreciated the color, soft touch, and cover cloth of the robot, when had to interact to the robot via touch sensors. A recent study revealed that a robot's attractive appearance might also attract the attention of PwD (22).

Interestingly, the enjoyment construct achieved an overall higher score at the end of eight sessions when the novelty effect might have worn off. However, some studies suggest that the more extended use of the robot might result in diminished enjoyment over time (23, 24). Finding a balance between a response dose to achieve a specific outcome (e.g., to improve mood) and, at the same time, maintain or boost enjoyment may be one of the challenging issues facing researchers in this field.

The robot's verbal communication abilities enhanced its perceived sociability, and according to the statements in the interviews, the participants found the Mini robot a pleasant and fun agent to converse with. This leads us to conclude that a robot with fun and amusing conversation features and the ability to carry on smoothly with a robust speech recognition system can be considered more sociable. Graaf et al. (25) consider the sociable behaviour is one of the most important factors that encourages the long-term use of the social robots and recommends developers to incorporate the knowledge of human-human interaction to the design of social robots.

The participants initially discounted the social presence of the robot and gave it a neutral rating, but after eight sessions of interaction, they had already formed the opinion that the robot does not arouse feelings. Of course, they did not concur that the robot was alive. Torta et al. (23) proposed that a humanoid robot's small size can diminish its social presence since humans are taller. It should be noted that the Mini robot was commonly referred to as a doll and did not truly impress the participants as real person. A small-sized robot may reduce the perceived social presence, yet research (9) has shown that large-sized robots could be conceived as a substitute for human care, prompting elderlies to reject them. Despite technical issues during some sessions (e.g., frozen or not responding robot), the participants managed to accustom themselves to the interaction interface of the robot and how to operate it. The increase in the ease of use indicates that the simplicity of usage of the robotic system might become more evident over time. Several recent studies suggest that a solid robot software and hardware system, as well as direct exposure and a longer duration of interaction, may be essential in boosting perceived ease of use (26–28).

Our respondents were neutral to quite positive about the usefulness of the Mini robot and scored it higher at the end session. One of the statements in the Almere questionnaire is about the willingness to adopt and use the robot at home. Looking at the ratings of these statements and the remarks they made in the interviews, we could conclude that the participants were hesitant about adopting the Mini robot due to the lack of need. Only a few of them expressed the willingness to use it at home. This shares similarities with several previous studies (29, 30) that introduced the lack of need, fear of reduction of human contact, deskilling, and new dependence on machines as factors shrinking perceived usefulness. Additionally, previous studies (29, 31) raised the stigma issue of adopting assistive technologies and put forward destigmatising the use of assistive technologies with the encouragement of caregivers and professionals. Blackman et al. (32) hypothesised that a social robot with a universal design with an add-on module on-demand feature (e.g., combined with a vacuum cleaner) would make it less noticeable that the robot is for people with special needs, thereby destigmatising it.

It is interesting to note that several participants were open to using the robot in clinical settings and agreed that the Mini robot was an entertaining agent through which they could play games and activities, learn stuff and stay active. This parallels the finding of a recent study (33) on the Mini robot in the Netherlands on stakeholders' attitudes towards implementing the Mini robot in the meeting centres. While the findings showed that the majority of participants appreciated the robot's look, hardware, and software, some participants believed that there was still room for anthropomorphising the robot, improving/modifying the appearance and voice, and adding other games and features. In the current literature (33–35), findings on the preferred robotic appearance-regarding the shape and size are mixed or inconsistent. However, the bulk of research hypothesizes that non-human-like robots with tiny sizes are more acceptable than those that resemble a human embodiment (35). We argue that altering the robot's characteristics to make it friendlier and nice talking, more endearing, with less machine-like and mechanical movements would appeal to most people's tastes and encourage interaction. Also, graded games and entertainment activities combined with multimedia content like pictures, music, and videos would draw more interest from elderly adults.

This study was one of the first hands-on and extended contacts with the Mini robot that contributes to the attitudes and acceptance of PwD and MCI and might be helpful in the social robots' advancement and their application in dementia care. Although widely accepted, this study suffers from certain limitations. First, people's views were shaped during the eight sessions of interaction in clinical settings, which might vary in a real-world experience and even after more prolonged use. Second, the technical issues of the robot might affect people's opinions negatively. So, this led us to plan to expand our work to conduct more extensive studies in residential facilities and private home settings with a robust and advanced version of the robot to make it more effective in dementia care.

Conclusion

This is the first study exploring the acceptability and attitudes of PwD and MCI towards the Mini robot in Spain. Thereby, we can attest to the Mini robot's acceptance and the target population's favourable perception of its use in clinical settings. We conclude that extended interaction with Mini robot would result in slightly better acceptance regarding most of the acceptability domains- in particular the perceived ease of use. To capture the user's admiration, technical difficulties must be addressed, and the robots' conversational abilities must be optimised. The research presented in this article may offer fresh perspectives on advancing the Mini robot design and advice for tailoring the robotics' features to the end goal requirements and preferences of the users.

Abbreviations

MCI
Mild cognitive impairments
PwD
People with dementia

Declarations

Ethics approval and consent to participate

The Zamora Health Area Medication Research Ethics Committee, under registration number 574, accepted the research protocol. The anticipated dangers and difficulties of the research outweigh the predicted benefits. The proposed approach for providing information and getting informed consent is deemed sufficient. Before the research begins, the informed consent was obtained from the participants and their next of kin. All methods were carried out in accordance with the relevant guidelines and regulations of the Declaration of Helsinki.

Consent for publication

Informed consent for the use of images and videos for future publications was obtained from the participants.

Competing interests

No competing interest was declared.

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Authors' contributions

Concept of the research: AM, JMT, MFM, HVR, ACG. Design of the protocol: AM, JMT, HVR, MFM. Design of the MINI robot interventions: AM, JMT, ACG. Supervision and coordination: MFM, MAS. Recruitment and trial management: AM, JMT. Data analysis: AM, MFM, JMT. First draught of a manuscript: AM, ACG, FAM, JCC. All authors have critically reviewed and approved this manuscript before submission.

Availability of data and materials

All data generated or analysed during this study are included in this manuscript.

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Figures

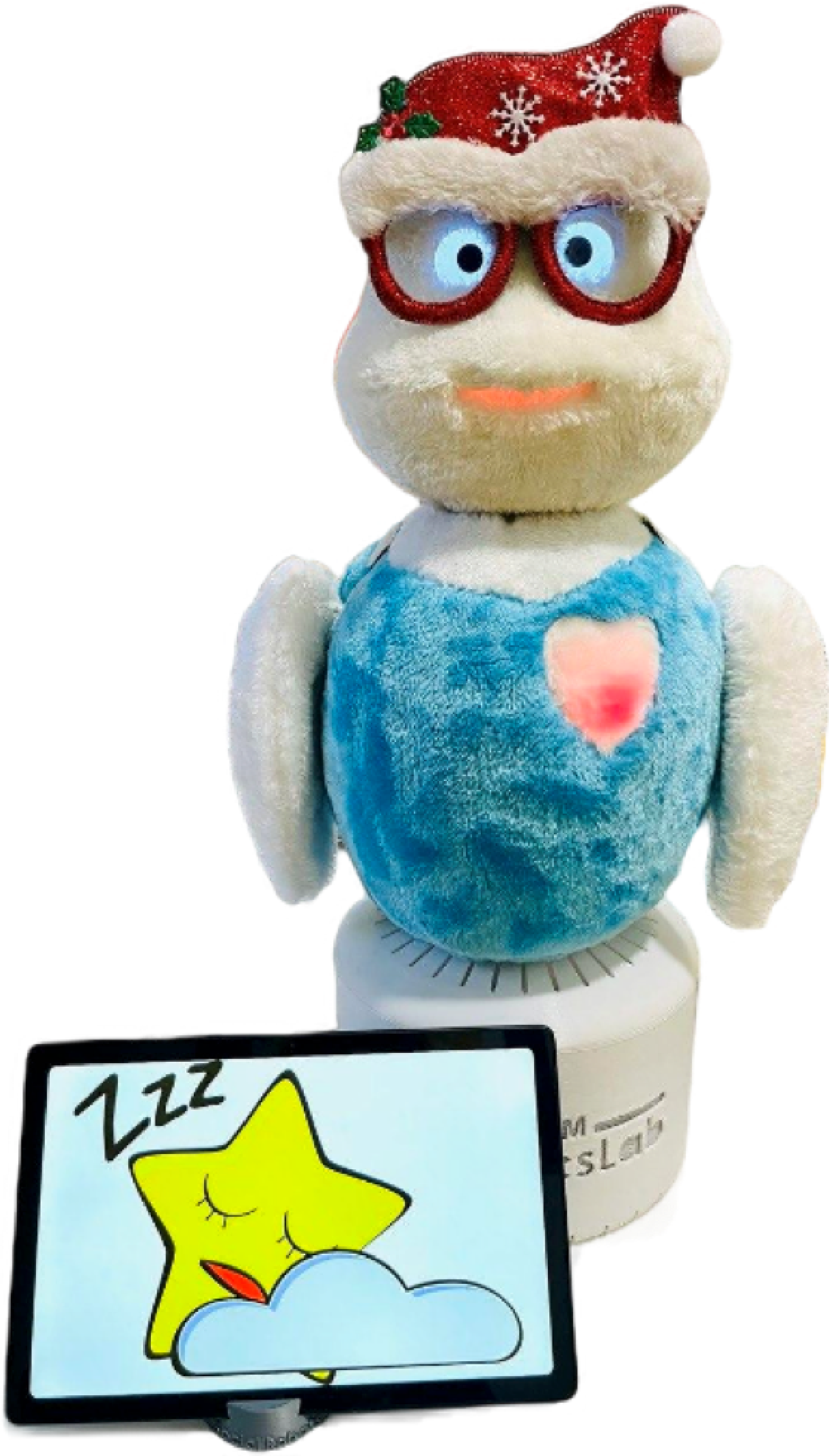

Figure 1

Mini robot.

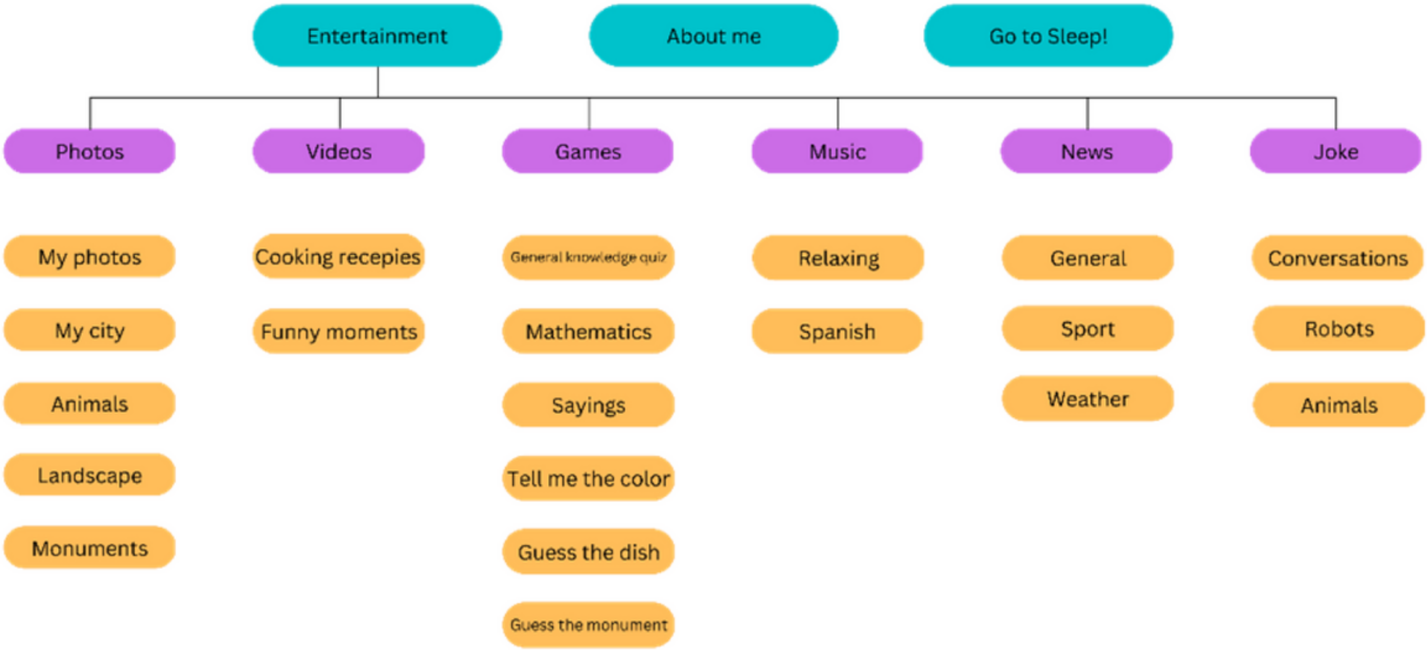

Figure 2

Mini robot user interface.

Figure 3

The participant interacting with Mini

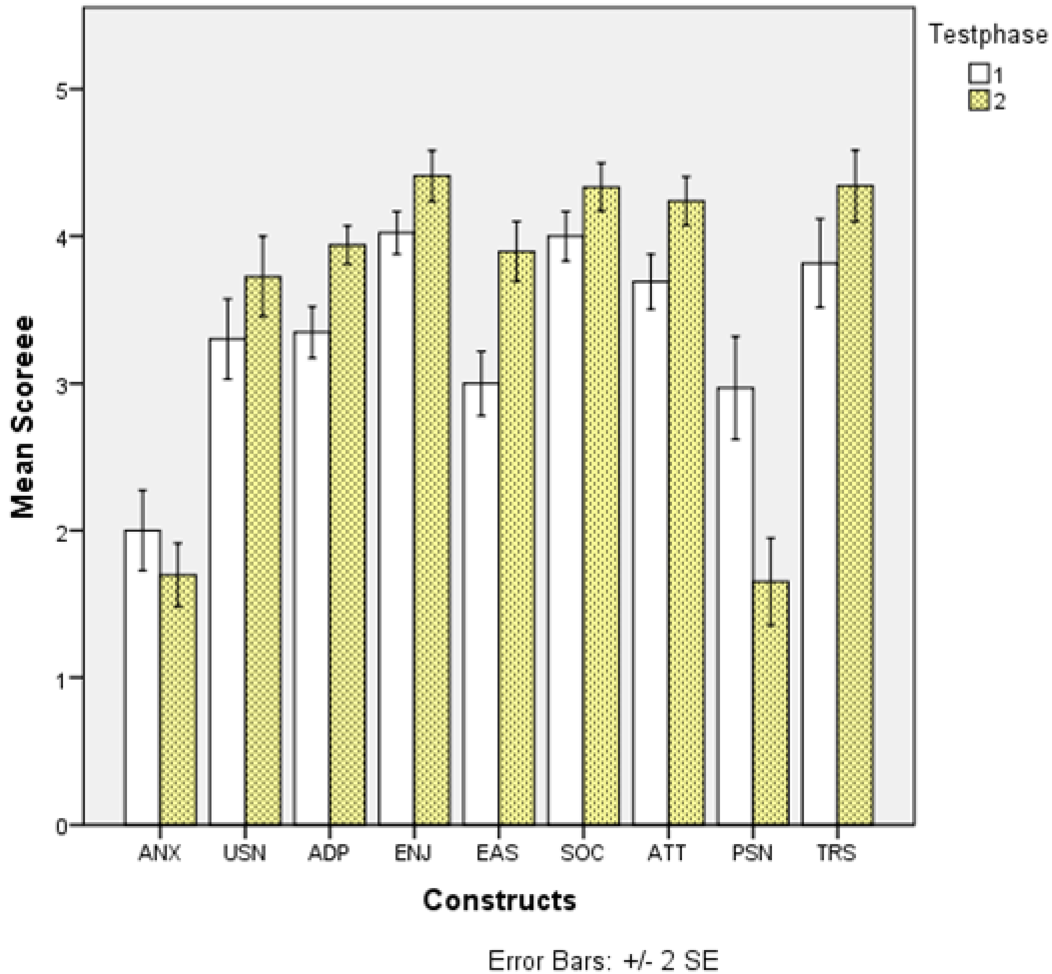

Figure 4

Almere model pre and post-test results; Mean values and Error bars.

Supplementary Files

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- Supplementaryfile.1.pdf
- Supplementaryfile.2.docx

Publication #5. Evaluating the User Experience and Usability of the MINI Robot for Older Adults with Mild Dementia and Mild Cognitive Impairment: Insights and Recommendations.

Publicación #5. Evaluación de la experiencia del usuario y la usabilidad del robot MINI para personas mayores con demencia leve y deterioro cognitivo leve: Ideas y recomendaciones.

Aysan Mahmoudi Asl, José Miguel Toribio-Guzmán, Álvaro Castro-González, Miguel A. Salichs, Henriëtte Van der Roest & Manuel Franco Martin.

Resumen en español

Antecedentes: En los últimos años, la integración de sistemas robóticos en diversos aspectos de la vida cotidiana se ha hecho cada vez más común. Con el continuo avance de estas tecnologías, la necesidad de garantizar interfaces fáciles de usar e interacciones fluidas se hace aún más acuciante. Para que los robots sociales aporten realmente un valor duradero a los seres humanos, una experiencia de usuario (UX) favorable se perfila como un requisito previo esencial.

Objetivo: El objetivo de este artículo es evaluar la usabilidad del robot MINI, destacando sus puntos fuertes y sus áreas de mejora a partir de los comentarios de los usuarios y su rendimiento.

Método: En un entorno de laboratorio controlado, se llevó a cabo un estudio cualitativo de método mixto con diez individuos mayores de 65 años diagnosticados con demencia leve (DM) y DCL. Los participantes participaron en sesiones individuales de interacción con el robot MINI, completando tareas cognitivas siguiendo instrucciones escritas. Las grabaciones de vídeo y audio documentaron las interacciones, mientras que los cuestionarios de la Escala de Usabilidad del Sistema (SUS) posteriores a la sesión cuantificaron la percepción de usabilidad. Se siguieron directrices éticas, garantizando el consentimiento informado, y los datos se sometieron a análisis cualitativos y cuantitativos, aportando información sobre la usabilidad del robot MINI para este grupo demográfico.

Resultados: El estudio aborda los continuos retos que presentan las tareas, especialmente para los individuos con DM, enfatizando la importancia del apoyo al usuario. La mayoría de las tareas requieren interacciones tanto verbales como físicas, lo que indica que los individuos con DM se enfrentan a retos cuando cambian de método de respuesta dentro de las subtareas. Estas complejidades tienen su origen en la selección y el uso de métodos de respuesta, incluidas las dificultades con el reconocimiento de voz, el tacto de la tableta y los sensores táctiles. Estos retos persisten en todas las tareas, ya que las personas con DM tienen dificultades para comprender las instrucciones de la tarea y proporcionar respuestas correctas, y las personas con DCL tienen dificultades para utilizar los dispositivos de respuesta, a menudo debido a las limitaciones del reconocimiento de voz del robot. Se han identificado deficiencias técnicas. Los resultados de la Escala de Usabilidad del Sistema (SUS) indican percepciones positivas, aunque hay puntuaciones más bajas para la asistencia de expertos y el aprendizaje previo al uso. La puntuación media SUS de 68,3 sitúa la usabilidad del dispositivo en la categoría de "buena".

Conclusiones: Nuestro estudio examina la usabilidad del robot MINI, revelando puntos fuertes en el aprendizaje rápido, la sencillez del sistema y el funcionamiento, y la integración de funciones, al tiempo que destaca áreas de mejora. El diseño cuidadoso y las modificaciones son esenciales para un compromiso significativo con las personas con demencia. El robot podría ser beneficioso para las personas con DM y DCL si se dispone de instrucciones claras y detalladas y de la orientación de expertos.

Palabras clave: usabilidad, experiencia de usuario, robots sociales, demencia, deterioro cognitivo leve.

Evaluating the User Experience and Usability of the MINI Robot for Older Adults with Mild Dementia and Mild Cognitive Impairment: Insights and Recommendations.

Original paper

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Authors' contributions: Conceptualization and methodology: AMA, JMT; Robot interface and task design: ACG, MM; Field test and data collection: AMA, JMT; Data analysis: AMA, JMT; Writing, review and editing: All; Supervision: MFM, MAS, HVR.

Abstract

Background: In recent years, the integration of robotic systems into various aspects of daily life has become increasingly common. With these technologies continuing to advance, the imperative of ensuring interfaces that are user-friendly and interactions that flow seamlessly becomes even more pronounced. For social robots to genuinely provide lasting value to humans, a favourable user experience (UX) emerges as an essential prerequisite.

Aim: This article aimed to evaluate the usability of the MINI robot, highlighting its strengths and areas for improvement based on user feedback and performance.

Method: In a controlled lab setting, a mixed-method qualitative study was conducted with ten individuals aged 65 and above diagnosed with mild dementia (MD) and mild cognitive impairment (MCI). Participants engaged in individual MINI robot interaction sessions, completing cognitive tasks as per written instructions. Video and audio recordings documented interactions, while post-session System Usability Scale (SUS) questionnaires quantified usability perception. Ethical guidelines were followed, ensuring informed consent, and the data underwent qualitative and quantitative analyses, contributing insights into the MINI robot's usability for this demographic.

Results: The study addresses the ongoing challenges that tasks present, especially for MD individuals, emphasizing the importance of user support. Most tasks require both verbal and physical interactions, indicating that MD individuals face challenges when switching response methods within subtasks. These complexities originate from the selection and use of response methods, including difficulties with voice recognition, tablet touch, and tactile sensors. These challenges persist across tasks, with individuals with MD struggling to comprehend task instructions and provide correct answers and individuals with MCI struggling to use response devices, often due to the limitations of the robot's speech recognition. Technical shortcomings have been identified. The results of the System Usability Scale (SUS) indicate positive perceptions, although there are lower ratings for expert assistance and pre-use learning. The average SUS score of 68.3 places device usability in the "good" category.

Conclusion: Our study examines the usability of the MINI robot, revealing strengths in quick learning, simple system and operation, and integration of features while also highlighting areas for improvement. Careful design and modifications are essential for meaningful engagement with people with dementia. The robot could be of benefit to people with MD and MCI if clear, detailed instructions and expert guidance are available.

Keywords: usability, user experience, social robots, dementia, mild cognitive impairments.

Introduction

Social robots are commonly known as autonomous robots that possess human-like characteristics and engage in social interactions with humans [1]. Over the past few years, there has been a rising need for social robots in sectors such as healthcare, service [2], education [3], and entertainment. This surge in demand has driven a significant advancement in this technology [4]. We are currently witnessing an increase in the number of new social robots, accompanied by research initiatives from both academic and industry areas.

Social robots have found diverse applications, catering to a broad spectrum of human demographics spanning from children to elderly. It reveals that social robots have been favourably received and embraced by the elderly adults, as opposed to their acceptance in other realms like children's education [5].

In recent times, there has been a notable focus on the utilization of social robots for people with dementia (PwD) and mild cognitive impairments (MCI) [6, 7]. Social robots offer a ray of hope for PwD by providing companionship and engagement, alleviating feelings of isolation and loneliness [8]. These robots can enhance cognitive functions through interactive games, memory prompts, and personalized activities, contributing to the overall well-being of dementia patients [9]. With their ability to provide reminders for medication, appointments, and daily routines, social robots empower PwD and MCI to maintain a sense of independence and control over their lives. Social robots can reduce caregiver burden by assisting in routine tasks, allowing caregivers to focus on providing emotional support and strengthening their relationship with the person with dementia [10]. Through stimulating interactions, reminiscence therapy, and emotional support, social robots create a conducive environment for improved emotional states and enhanced communication.

The UX and usability of these robots are rooted in their intuitive interfaces, enabling users to communicate and interact seamlessly. This blurs the boundaries between humans and machines, ensuring overall satisfaction and the system's effectiveness. Through advanced sensors and artificial intelligence, social robots can perceive and respond to human gestures, expressions, and speech, creating an immersive and personalized UX. This tailored interaction enhances engagement, making tasks like companionship, education, and assistance more enjoyable and efficient [11]. The evolving design of these robots focuses on user-centred principles, aiming to minimize complexity and optimize ease of use. As a result, the realm of social robotics continues to redefine the boundaries of technological interaction by creating intuitive, meaningful, and emotionally resonant experiences for users across diverse contexts.

Even though interacting with social robots can be entertaining, it could pose specific challenges for PwD and MCI, stemming from problems such as memory and language deficits and their special needs. Careful consideration of design and interaction methods, as well as ongoing customization, is essential to address the challenges and ensure that social robots effectively support and engage this target group in a meaningful and respectful manner [12]. Assessing the usability and UX of the robot agent should commence early in the development process, enabling adjustments or substitutions in its attributes and operations to ensure a favourable UX prior to market launch [13].

Lately, a robotic system named MINI has been designed and developed within the Robotics Lab research group at Carlos III University in Madrid. Its primary objective is to assist seniors, offering cognitive and social engagement to elderly individuals affected by neurodegenerative disorders, particularly those dealing with cognitive decline [14]. The robot has the ability to initiate user engagement using both spoken and non-spoken methods. This compact, desktop robot is enveloped in synthetic fur and furnished with a speech recognition mechanism, touch-sensitive areas on its shoulders and heart, an RGB-D camera for assessing depth in the surroundings, expressive uOLED eyes, and a tablet-based interface serving as an input and output mechanism to showcase software content. The robot's head and arms have movement restricted to a single dimension [15, 16] (see Figure 1).

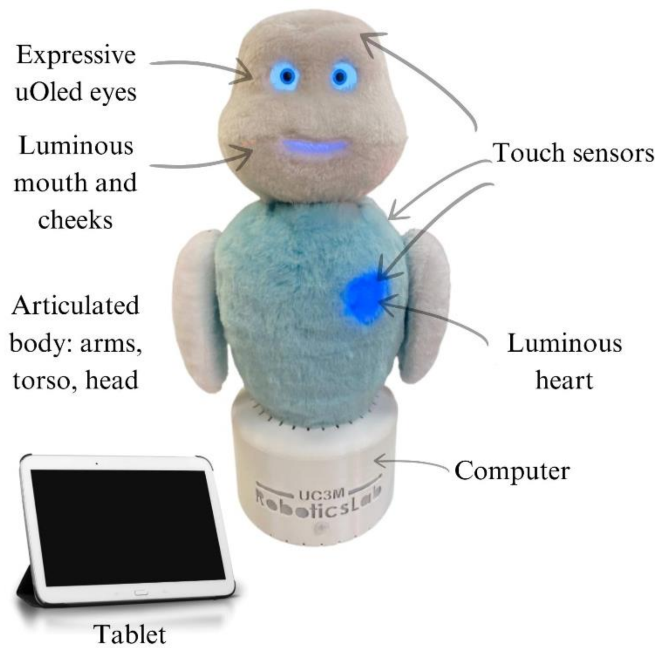

Figure 1. MINI robot components

A series of games and activities are designed and integrated into the robotic platform. Figure 2 demonstrates an overview of the app and games provided by the MINI robot. The service has been designed in a co-creation process and is centred on the needs and preferences of elderly adults and to fulfil the goal of a social companion for the MINI robot.

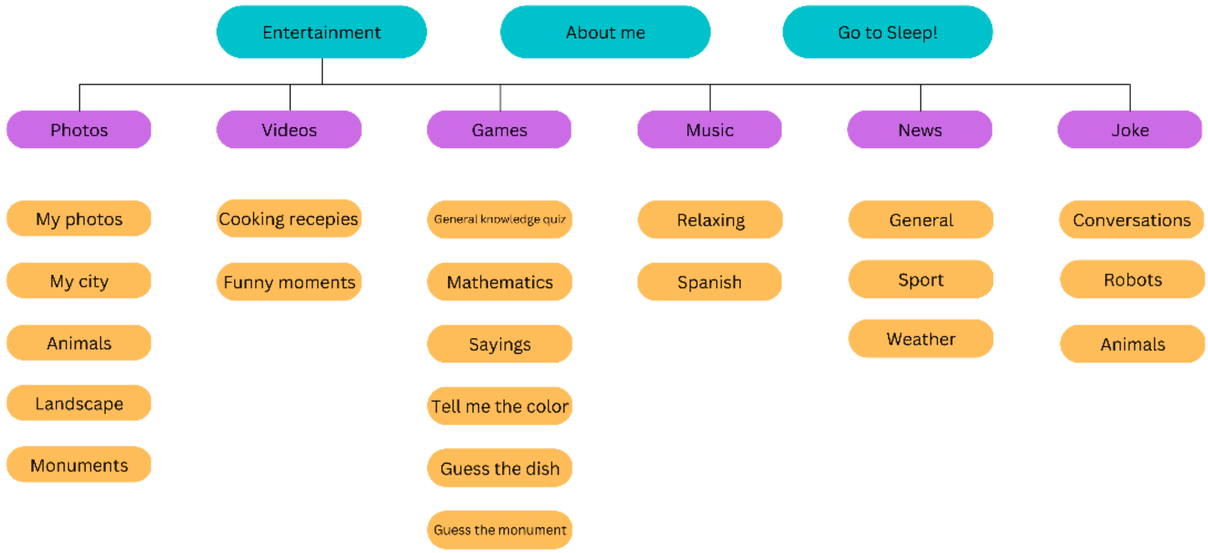

Figure 2. MINI robot apps categorized: Blue for general categories, purple for entertainment types, and orange for specific activities within each.

Methods

Participants and settings

A mixed-methods study approach was employed to evaluate the usability and UX of the MINI robot. Ten people with MD and MCI (M = 77.3 years and SD = 4.9) were enlisted for participation. The suggested inclusion criteria were as follows: Age 65 and above, being able to make decisions, being able to read and write, and not having any sense loss that would prevent the usage of the devices (e.g. blindness or deafness). Patients from the INTRAS Foundation's Memory Clinic and memory workshops were recruited to participate in the study, and the trial was undertaken within the controlled environment of the INTRAS Foundation's usability laboratory, situated in the locale of Zamora, Spain. Ethical approval was previously obtained from Zamora Health Area Medication Research Ethics Committee, under registration number 574.

Procedure of the field test

Participants and/or their next of kin provided informed consent and socio-demographic information via a questionnaire before the test. Following that, the evaluator explained the approach and tasks associated with the MINI robot interaction. The test methodology required the engagement of just one participant at a time, allowing for rigorous monitoring of their task performance and behaviour. The evaluation consisted of a series of predetermined activities divided into sub-tasks. Following the completion of these tasks, participants were invited to complete a questionnaire designed to assess the usability of the MINI robot. Notably, the field tests were thoroughly recorded by audio and video recordings, allowing for further thorough examination. The following protocol was followed throughout the user's interaction with the robot:

1. The user initiated the test by sitting before the robot and interacting after receiving task instructions. The test was initiated with the robot in a dormant state.
2. Interaction with MINI began with the user waking the robot with the phrase: "Hello MINI! Upon activation, the robot introduced itself to familiarise the user and allay any initial fears.
3. Subsequently, the robot inquired about the user's intended actions, with participants adhering closely to the provided instructions (conveyed on A4-sized sheets). The session encompassed nine distinct tasks, each employing varied forms of interaction; voice interaction (VI) and touch interaction (TI).
4. The chosen tasks and interaction methods are as follows:

Task 1: *Wake up the robot*. The participant has to wake up the robot by saying, “Hello, MINI” (VI).

Task 2: *See photos of my city*. See photos (VI) > From my city (VI). The robot shows through the tablet a series of pictures of the city. Once the test is over, the robot asks, “Did you like the activity?” (TI).

Task 3: *Guessing Meals*. Entertainment (TI) > Games (TI) > Guessing Meals (VI) Pictures are shown, and different regional dishes are asked about.

Task 4: *Stop the test*. Before the previous test ended, the participant had to stop the test. by tapping the robot on the shoulder. Then the robot would ask, “Do you want to continue with the activity?” (TI): “Why did you stop the test?” (TI).

Task 5: *Weather news.* News (VI) > Weather news (TI) The robot gives the weather forecast for the area. Once the test is over, the robot asks, “Did you like the activity?” (TI).

Task 6: *Robot suggestion.* The robot suggests a task to the participant (IT or IV). Once the test is over, the robot asks, "Did you like the activity?" (TI).

Task 7: *Relaxing music*. Music > Relaxing music. The robot plays a piece of relaxing music.

Task 8: *Stop the test*. Before the previous test ended, the participant had to stop the test again (TI) by tapping the robot on the shoulder. Then the robot would ask, "Do you want to continue with the activity?" (TI) or "Why did you stop the test?" (TI).

Task 9: *Go to sleep*. when the robot asks. "What do you want to do?" the participant must say "Go to sleep" (VI).

Method of data collection

Data collection consisted of three phases: the administration of pre-test questionnaires to gather socio-demographic information, direct observations and video recordings, and post-test evaluation through questionnaires.

Sociodemographic survey: to gather relevant sociodemographic details from participants, including factors such as age, gender, educational background, extent of cognitive impairment, and utilization of information and communication technology (ICT).

The System Usability Scale (SUS): a widely employed questionnaire-based tool developed by John Brooke in 1986 to evaluate the perceived usability of diverse products, services, and systems, spanning software, websites, applications, and technological devices. This approach has gained significant popularity in assessing user satisfaction and experience. The SUS utilizes a straightforward 10-item Likert scale questionnaire, systematically designed to capture users' subjective views on usability dimensions like ease of use, efficiency, learnability, and user-friendliness. Respondents rate their agreement level with statements related to the evaluated system. Post-questionnaire, scores are aggregated to form a usability score between 0 and 100, with higher scores indicating better perceived usability. The SUS serves as a quantitative tool to compare user satisfaction and usability across various systems, aiding in informed decision-making for enhancing the UX. In essence, the System Usability Scale is a vital resource for evaluating user perceptions and guiding design and usability improvements for more user-friendly products and systems [17]. The SUS test yields a score between 0 and 100, indicating how useful a device is for the user. A score of 68 points or above indicates good usability.

Data analysis

During the field test, observation notes were recorded. Both direct and video observations were conducted to collect data on user performance, time to complete tasks, success rates, failure rates, incidents, user and robot behaviours, and other pertinent information. The preliminary scores for SUS were presented using basic descriptive statistics for each item, including mean scores, standard deviation, range, and mode. Furthermore, a total SUS score was computed for each participant, and the mean of all SUS scores was derived.

Results

User testing; Observations

An assessment of several elements influencing correct test performance was considered as follows:

- Difficulty in understanding the exercise methodology (DEM): The user does not correctly understand what he/she has to do in the exercise.

- Difficulty in recognising the response method (DRM): The user does not know which device to use to answer. For example, in those cases in which the user tries to answer by voice when the method of response is through the buttons on the tablet screen.

- Difficulty in using the device corresponding to the response method (DUR): The user does not know how to use the response device, or there is difficulty for the robot to understand him/her.

- Difficulty with the content of the response (DCR): The user does not know the correct answer (or does not know what to answer).

These difficulties may arise at the beginning of each task and, depending on the case, persist during the test. Therefore, it is important to take into consideration the help that users may have received in the different tasks.

Table 2 indicates the percentage of participants that needed assistance from the instructor at the start of each task with "comprehending the written instructions of each task" and "response method (verbally or touch)". As can be observed, the level of required help from the instructor in people with MD is often higher than in MCI. Furthermore, both people with MD and MCI needed more help with the response method than with the instructions. Tasks that required reacting via the robot's touch sensors (4a and 8a) needed more help in both groups.

The majority of the tasks required both verbal and physical interactions. Table 1 shows that when there is a shift in response method between subtasks, individuals with MD have greater issues and require more assistance.

Table 1. Percentage of participants who have required help from the instructor in the completion of each task

			MCI (%)		MD (%)		Total (%)	
			Help from instructor		Help from instructor		Help from instructor	
Task	**Sub-task**	**Form of required response**	**Comprehend the instructions**	**Response method**	**Comprehend the instructions**	**Response method**	**Comprehend the instructions**	**Response method**
1	Wake up MINI	V	0.0	20.0	0.0	20.0	0.0	20.0
2	a. Watch photos	V	0.0	40.0	40.0	60.0	20.0	50.0
	b. Photos of my city	V	0.0	0.0	0.0	20.0	0.0	10.0
	c. Did you like the activity?	T	20.0	20.0	60.0	40.0	40.0	30.0
3	a. Entertainment	T	40.0	40.0	40.0	60.0	40.0	50.0
	b. Games	T	20.0	20.0	0.00	60.0	10.0	40.0
	c. Guess food	V	20.0	20.0	40.0	40.0	30.0	30.0
4	a. Pause the activity	T	60.0	60.0	100.0	100.0	80.0	80.0
	b. Do you want to continue with the activity?	T	20.0	80.0	20.0	60.0	20.0	70.0
	c. Why you stopped the activity?	T	0.0	40.0	0.0	80.0	0.0	60.0
5	a. News	V	0.0	20.0	20.0	40.0	10.0	30.0
	b. Weather news	T	20.0	0.0	20.0	0.0	20.0	0.0
	c. Did you like it?	T	0.0	0.0	0.0	20.0	0.0	10.0
6	a. Robot's randomly suggested activity	V/T	0.0	0.0	0.0	40.0	0.0	20.0
	b. Did you like the activity?	T	0.0	60.0	0.0	60.0	0.0	60.0
7	a. Music	V	20.0	40.0	40.0	60.0	30.0	50.0
	b. Relaxing music	T	0.0	0.0	0.0	60.0	0.0	30.0
8	a. Pause the activity	T	20.0	40.0	60.0	60.0	40.0	50.0
	b. Do you want to continue with the activity?	T	20.0	20.0	20.0	20.0	20.0	20.0
	c. Why you stopped the activity?	T	0.0	0.0	0.0	40.0	0.0	20.0
9	a. Go to sleep	V	0.0	40.0	0.0	60.0	0.0	50.0

T:Touch; V:Verbal.

Regarding the response method, as explained in the difficulties that may arise, it is necessary to distinguish between problems caused by the user not knowing exactly which devices he/she has to answer (DRM) (for example, waiting for the buttons to appear on the screen when in fact he/she has to answer by voice) and problems caused by the use of the response device itself (DUR). Considering the second aspect, the following issues were noticed:

- Micros (voice): Because the MINI's speech recogniser is not always turned on, users must wait until the robot beeps before responding. This caused confusion since many users responded too quickly. There were also instances where users did not vocalise correctly (e.g. too soft voice, spelling the answer) resulting in the robot being unable to comprehend them, even though they reacted adequately to what was asked of it.

- Screen-Tablet (touch): Although this device did not cause any problems, there were some instances where users did not tap the screen button properly because they did not tap it with their fingertips, but with their fingernails, or they pressed it too quickly and loosely, causing the tablet to not process it.
- Touch sensors: The main issue with this kind of response was that users had difficulty determining where they needed to touch the robot in order to activate the sensors.

Evidently, all these issues manifested themselves equally during task completion. The level of success achieved by the distinct groups in each task, along with the corresponding challenges that emerged, are detailed in Table 2. On one hand, it's evident that the MD group encountered challenges mainly linked to response uncertainty (DCR) and complexities in grasping the task methodology (DEM), rather than the actual response method (DRM). The MCI group encountered similar difficulties to the MD group, albeit with more pronounced struggles in using the response device (DUR). Importantly, a noteworthy portion of these challenges stemmed from the robot's struggles in comprehending the provided answers.

Table 2. Percentage of success and difficulties encountered for each task

			MCI					MD				
Task		R	%SC	%CD	Dif.	%PC	Dif.	%SC	%CD	Dif.	%PC	Dif.
1	Wake up MINI	V	60.0	40.0	40.0% DEM	0.0	-	100.0	0.0	-	0.0	-
2	Watch photos	V	40.0	40.0	40.0% DUR	20.0	20.0% DUR	60.0	40.0	20.0% DUR 20.0% DRM	0.0	-
	Photos of my city	V	60.0	0.0	-	40.0	40.0% DUR	80.0	0.0	-	20.0	20.0% DUR
	Did you like the activity?	T	60.0	40.0	40.0% DUR	0.0	-	0.0	60.0	20.0% DRM 40.0% DUR	40.0	40.0% DUR
3	Entertainment	T	40.0	60.0	40.0% DRM 20.0% DUR	0.0	-	80.0	20.0	20.0% DRM	0.0	-
	Games	T	60.0	20.0	20.0% DEM	20.0	20.0% DEM	60.0	40.0	20.0% DEM 20.0% DRM	0.0	-
	Guess food	V	20.0	20.0	20.0% DRM	60.0	40.0% DRM 20.0% DEM	40.0	40.0	20.0% DRM	20.0	20.0% DCR
4	Pause the activity	T	20.0	80.0	80.0% DEM	0.0	-	0.0	100.0	100.0% DEM	0.0	-
	Do you want to continue with the activity?	T	100.0	0.0	-	0.0	-	80.0	20.0	20.0% DRM	0.0	
	Why you stopped the activity?	T	40.0	20.0	20.0% DCR	40.0	40.0% DCR	20.0	0.0	-	80.0	80.0% DCR
5	News	V	60.0	40.0	20.0% DUR 20.0% DRM	0.0	-	100.0	0.0	-	0.0	-
	Weather news	T	60.0	40.0	40.0% DUR	0.0	-	60.0	0.0	-	40.0	40.0% DEM
	Did you like it?	T	40.0	60.0	20.0% DUR 40.0% DCR	0.0	-	80.0	20.0	20.0% DRM	0.0	-
6	Robot's randomly suggested activity	V/T	60.0	20.0	20.0% DCR	20.0	20.0% DEM	60.0	40.0	40.0% DCR	0.0	-
	Did you liked the activity?	T	20.0	20.0	20.0% DUR	60.0	60.0% DCR	60.0	0.0	-	40.0	40.0% DCR
7	Music	V	60.0	40.0	40.0% DUR	0.0	-	80.0	0.0	-	20.0	20.0% DEM
	Relaxing music	T	60.0	0.0	-	40.0	40.0% DEM	100.0	0.0	-	0.0	-
8	Pause the activity	T	40.0	60.0	60.0% DEM	0.0	-	20.0	80.0	80.0% DEM	0.0	
	Do you want to continue with the activity?	T	100.0	0.0	-	0.0	-	80.0	20.0	20.0% DCR	0.0	
	Why you stopped the activity?	T	60.0	20.0	20.0% DCR	20.0	20.0% DCR	40.0	0.0	-	60.0	60.0% DCR
9	Go to sleep	V	20.0	40.0	40.0% DUR	40.0	40.0% DRM	80.0	0.0	-	20.0	NA

SC: successfully completed; CD: completed with difficulty; PC: partially completed; DCR: difficulty with the content of the response; DEM: difficulty in understanding the methodology of the exercise; DRM: difficulty in recognizing the response method; DUR: difficulty in using the response method; R: Response; T: Touch; V: Verbal; Dif.: Difficulty.

Furthermore, specific technical deficiencies were identified as a result of our analysis (Table 3). It is essential to clarify that we are only disclosing the game-specific issue detected during the field test. It is possible that additional imperfections existed within other games that were not selected and played by the user during this particular testing phase.

Table 3. MINI robot related issues

General issues	Game specific issues
The robot …	**The robot …**
… was unable to recognize the speech. … got frozen. … does not close the eye in sleeping mode. … wakes up and starts another session without being called or touched. … says "I did not hear you well" in case the user is quiet and not answering verbally at all. … does not recognize the response of the user in case they say "I do not know" and keeps repeating the question.	… does not give enough time to calculate the math operation. … does not speak fluently asking mathematical questions (instructor had to repeat the question). … does not give enough time to order the word in the "Sayings" game. … during the "Tell me the colour" game, asks for the matching colour and shows the photos on the tablet with delay. … in the "guess monument" and "guess the food" games, asks questions and does not provide the answers options immediately.

System Usability Scale

In order to provide a more comprehensive examination of the SUS score, an item-by-item analysis was conducted to determine the direction of participants' responses. The descriptive data for the items can be found in Supplementary Material 1. The items were both positively and negatively oriented. Negative items were numerically inverted so that the mean, on a scale of 1-5, represents the lowest to highest level of agreement for all items.

Figure 3 shows the SUS questionnaire mean scores for each item. It can be seen that the majority of the ratings supported the usability of the MINI robot. Of particular note are the items that received the highest levels of agreement, including the users' belief that the majority of people would quickly learn how to use it (4.40), that the system was not cumbersome to use (4.40), that they will use it frequently (3.90), that the system's various features were well integrated (3.90), and that there was no perception of excessive complexity in the system (3.90).

The lowest ratings were assigned to the need for expert assistance in operating the robot (3.00) and the need to learn many things before utilising the system (3.20). There were no negative ratings in the mean scores (3>).

The SUS test gives a total score between 0 and 100, indicating how useful a device is to the user. A score of 68 ≤ indicates favourable usability. With an average SUS score of 68.3 out of 100, the device falls into the "good" usability category (68–80.3).

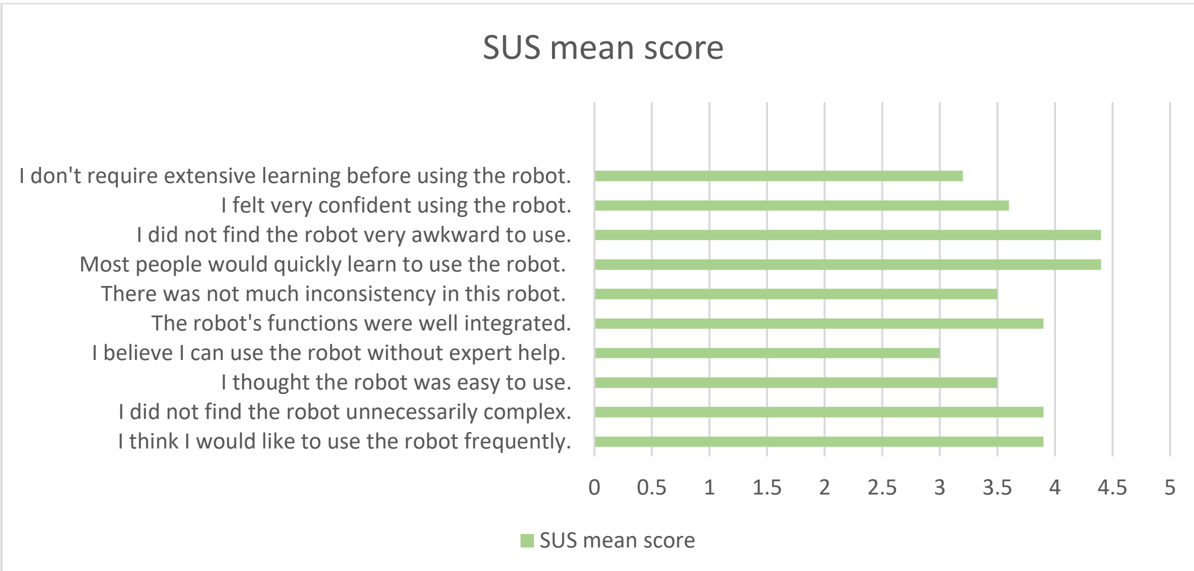

Figure 3. SUS score for each Item.

Discussion

In this study, we evaluated the UX and usability of the MINI robot and the challenges that might arise during the human-robot interactions with individuals with MD and MCI in laboratory settings. The qualitative and quantitative data gathered from the field test observations and video analysis revealed several facets of the robot interface that should be considered when employed to serve these target groups.

Based on our observational data, it became evident that individuals encountered difficulties in comprehending written instructions for task completion, responding verbally or through touch, and providing answers to the robot's queries. The findings offer valuable insights into the participants' reliance on instructor assistance for each task, focusing on both comprehending written instructions and responding appropriately, whether verbal or tactile. In particular, tasks requiring interaction via the robot's touch sensors (tasks 4a and 8a) show an increased need for assistance in both groups, highlighting the innate complexity of touch-based interactions. The fact that the users could not immediately complete the task could be associated with unfamiliarity with the robot, not knowing exactly how and where to touch, or confusion in shifting the interaction method (verbally to touch and vice versa). Notably, instances where a transition in response method occurs between subtasks tend to evoke heightened challenges for individuals with MD, resulting in an increased need for external support.

Turning attention to the response method itself, as elaborated upon in the context of potential difficulties, it is imperative to differentiate between challenges arising from user confusion, recognizing response methodology (DRM), and challenges stemming from the use of the response device (DUR). Regarding the issues encountered in the response method, we noticed that the majority of them were caused by the user's confusion to use the response device, or the robot having difficulty recognising the answer due to its limitations in comprehending speech. Issues regarding the micros, touch sensors and tablet interface emerged in similar studies with social robots [9, 18]. The poor speech recognition system has always been listed as the main usability issue in most research on social robots with speech capabilities [8, 9, 18, 19]. So far, social robots lack the ability to engage in seamless conversations with users. At the same time, this target group is not used to such conversational agents. Consequently, there is an urgent need for significant improvements in the speech recognition system. It is therefore imperative to incorporate an initialisation or trial phase to ensure optimal and efficient use of the robot.

Concerning task performance, particularly in the MD group, difficulties are more often caused by not knowing the correct answer (DCR) and difficulty understanding the task methodology (DEM) than by the subtleties of the response method (DRM). Hence, our suggestion is to provide explicit usage instructions using uncomplicated language, ensuring readability and accessibility for individuals with MD and MCI. Another study of the MINI robot [20] found that stakeholders preferred activities that were not similar to quizzes to avoid potential conflicts with cognitive challenges. However, some participants in this study expressed their readiness for moderately challenging tasks. Consequently, it is essential for developers to adjust the difficulty levels of task content to accommodate the cognitive status and preferences of users. This was previously suggested by the developers of the MINI robot [21, 22] regarding personalisation of human-robot interaction.

The challenges faced by the MLD and MCI groups highlight the intricate relationship between cognitive abilities, device operability, and the overall success of human-robot interactions. These findings emphasize the crucial importance of designing user-friendly interfaces, clear user instructions, and interpretive capabilities within robotic systems to improve overall usability and facilitate seamless user engagement.

The overall SUS score indicates a high usability level, verifying the system's effectiveness and alignment with user expectations. The majority of participants perceived minimal difficulty with learning to use the robot, operational complexity, and interaction with the MINI robot, and would like to use the robot frequently. Additionally, they acknowledged the smooth integration of system functionalities and perceived the system's complexity as manageable. Less favourable ratings were assigned to the perceived need for expert help in operating the robot and the need for pre-use learning. This aligns with their performance and accomplishments and the obstacles they encountered in achieving tasks during the field test. Relatively lower scores in feeling confident operating the robot, the robustness of the robotic system, and perceived ease of use may be mainly due to technical issues and design problems inherent in the robot. In another study [23] that explored the acceptability of the MINI robot, the perceived ease of use rating after one month of interaction was either similar to or slightly higher than in our current study. This observation leads us to conclude that prolonged interaction could potentially lead to an increase in perceived ease of use.

Based on our results and observations, we suggest a list of modifications for the robot's future versions (Table 4). MINI is a research platform which is under a continuous evolution and these suggestions will improve the UX when interacting with the robot. Considering that MINI’s verbal communication relies on state-of-the-art software for recognizing the user’s utterances and synthetizing its messages, our suggestions for speech interface can be extended to other smart artifacts (such as smart speakers or smart phones) aimed at offering verbal interactions.

Table 4. Suggested modifications to the MINI robot

Area	Suggestion
Speech interface	- Enhance the speech recognition system - Allow the robot to promptly listen and identify user speech right after posing a question. - Enable the robot to recognise the phrase "I don't know" and provide an appropriate response in return. - Enhance the smoothness and clarity of the robot's speech and vocal output.
Game related	- Improve the time limit for responding in games like "Mathematics" and "Sayings" where more time is required to guess the answer. - Design different difficulty levels within games where it is applicable (e.g., "General knowledge quiz".
General system	- Ensure seamless correspondence between the robot's spoken content and the displayed information on the tablet interface. - Eliminate undesired and unrelated behaviours from the robot.

Limitations of the study

In conclusion, our study involved a sample of 10 participants. While this number of participants was sufficient to conduct a usability test, from a scientific perspective [24], its potential impact on the broader generalisability of our findings warrants consideration. Secondly, this study was conducted using specific apps and games that were predefined. Therefore, the results should be interpreted with caution when projecting to different versions of the robot with alternative apps and games. Different features of other apps and games could potentially influence the usability dynamics of the robot.

Conclusion

In conclusion, our study deeply examines the MINI robot's UX and usability challenges. The robot has strengths in easy learning, simple operation, and seamless feature integration, but also highlights areas for improvement, including general system, game and apps and voice related features. The author assumes that using the MINI robot effectively requires clear and detailed instructions and expert guidance. By making suggested changes and listening to users, developers can improve the robot's usability and UX, ensuring the overall effectiveness. This process can turn the MINI robot into a more user-centered system. To overcome challenges, careful design and interaction methods, along with ongoing adjustments, are essential. This comprehensive approach ensures social robots can effectively engage individuals with dementia in a meaningful and respectful manner.

Abbreviations

MD: Mild dementia

MCI: Mild cognitive impairment

PwD: people with dementia

SUS: System Usability Scale

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Data availability

Some data are not publicly available because the data contains information that could compromise research participant privacy.

Declarations

Ethics approval

Approval was obtained from the ethics committee of Zamora Health Area Medication Research Ethics Committee, under registration number 574. The procedures used in this study adhere to the tenets of the Declaration of Helsinki.

Consent to participate

Written informed consent was obtained from the participants and / or their next of kin.

Conflicts of Interest

No conflict of interest was declared.

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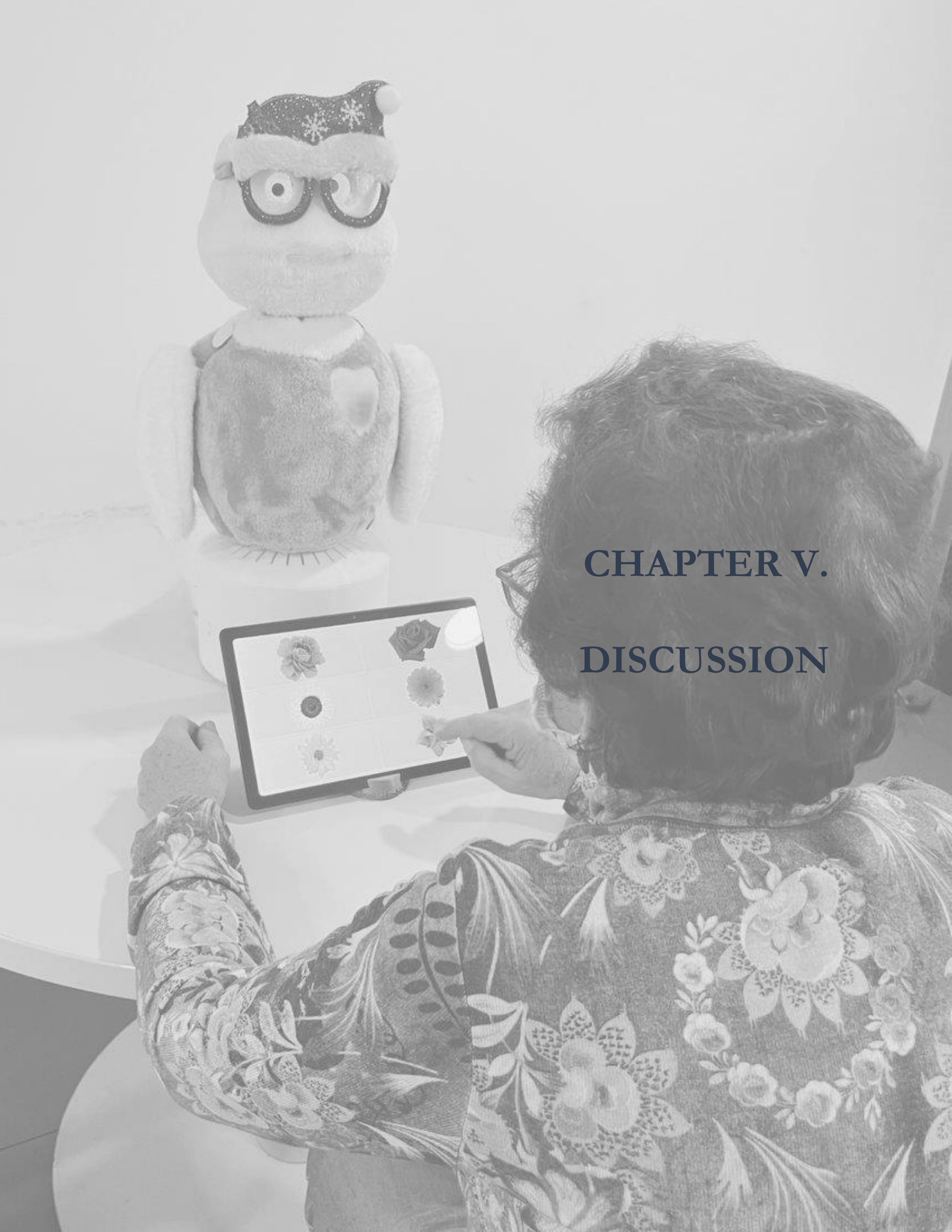


CHAPTER V.

DISCUSSION

Social robots in elderly adults and people with dementia

In the field of digital health, similar to many other technologies such as smartphones, computer-assisted interventions, virtual realities and wearable devices, social robots in older adults are becoming an object of research with certain questions to be addressed. The idea of using social robots is very much in the area of companionship, psychosocial and physical assistance for older adults, especially those with dementia and MCI. Dementia is a progressive cognitive decline that can lead to social isolation and loneliness, which can exacerbate symptoms and negatively impact the overall well-being of people with this condition. Social robots aim to address these challenges by providing companionship, engagement and assistance in a variety of ways (Yu, Sommerlad, Sakure, & Livingston, 2022).

According to the scoping review conducted at the beginning of this project (Mahmoudi Asl et al., 2022), the social robots have quite fulfilled their role as a companion to improve this target group's mood, social interaction, activity participation and engagement. However, if we desire social robots to assist us beyond their current role as a companion – e.g., to improve cognitive functions, depression, and quality of life- the current versions of social robots might require further modifications or advancement.

The idea to employ the social robots as a fun and cheerful companion in PwD and MCI was reinforced in the study we conducted in the Netherlands (Mahmoudi Asl A, 2023), in which the stakeholders including the managers of MCs, health and welfare professionals and end-users considered the MINI robot as an entertaining agent, offering both activating and relaxing activities, making them feel better. The similar comments received from PwD and MCI in the study of the acceptability of the MINI robot in Spain, would be a double guarantee for the role of MINI and similar social robots in this target group.

It's important to note that social robots should not replace human interaction and caregiving entirely. Instead, they should be viewed as complementary tools to support and enhance the overall quality of life for individuals with dementia and their caregivers. The successful integration of social robots into dementia care requires careful consideration of individual needs and preferences, as well as ongoing evaluation and refinement of these technologies.

Methodologies to study the social robots

The literature review emphasises the critical importance of employing a robust study design when investigating methodologies for studying social robots. This robust study design serves two key purposes:

Effective social robot development: In the initial stages of social robot development, it is imperative to create a version that aligns with the specific user profile, needs, and preferences. To achieve this, collaboration among developers, researchers, health professionals, and end users is essential. They must engage in a co-creation process, wherein the right methods and considerations are applied to ensure that the social robot is designed effectively and tailored to meet the user's requirements.

Revealing immediate and long-term effects: To gain insights into both the immediate and long-term impacts of social robots, and to pave the way for broader adoption within the community while ensuring sustainability, it is vital to make thoughtful choices in study designs right from the outset. By doing so, researchers can gather comprehensive data on the robot's effects, enabling them to assess its effectiveness and potential benefits over time.

To monitor and evaluate digital health interventions, WHO recommends to launch a feasibility and usability study of the prototype and progress toward the efficacy in the research environment, followed by effectiveness and implementation in everyday life environments (Organization, 2016). Our suggestions for appropriate study designs vary depending on the aim and type of the study. Therefore, separate studies should be conducted for each aim to comprehensively address every critical aspect of the investigation. It is worth noting that prolonged use of social robots might potentially unveil alterations in outcomes and provide a dependable response to research inquiries. Efficacy and effectiveness studies should be undertaken in the form of RCTs involving substantial sample sizes and individual interactions. The study procedures are consistent for both feasibility and usability, allowing researchers to use a unified design. In this context, the use of experimental designs supplemented with mixed methods for collecting data appears to be an advantageous strategy. Furthermore, multiple interaction sessions have the potential to reveal subtle alterations in feasibility and usability dynamics. However, due to the existing gap in the research (Mahmoudi Asl et al., 2022) to reveal the best response dosage of intervention for particular measures and characteristics of subjects who benefit most from the social robots, there might be methodological challenges and a long way to go in the direction of this argumentation. Given the fact that the majority of the research in this field is held in the labs (Mahmoudi Asl et al., 2022), we strongly encourage the researchers to design their studies beyond the walls of the research labs- e.g., in nursing homes, daycare centres, private households- where they confront the real-life challenges and can better perceive the impact and use of the social robots in PwD and MCI. Likewise, this project might continue its own way after the PhD career towards this direction.

Potential facilitators and barriers to implementing the MINI robot in the MCs

In the project's next phase, a study based on the two frameworks – MRC and Meiland et al. (Craig et al., 2008; Meiland et al., 2004)- and by means of focus groups and interviews with stakeholders revealed the potential facilitating and hindering factors to a successful implementation of the MINI robot in the MCs and daycare centres in PwD. Several influencing factors were tracked in preconditions, preparation and execution phases at three levels (micro, meso, and macro), associated with contextual, implementation, and mechanism of impact aspects.

The overall characteristics of the robotic intervention as one of the crucial factors in preconditions were noted as a potential facilitating factor benefitting the stakeholders in several ways. For robotic interventions, the stakeholders considered notable impacts both on the users and carers (e.g., relaxing and fun activities, reducing care burden). The human resources as well as available and anticipated funding resources in both the precondition and preparation phases turned out as other facilitating factors. The stakeholders expressed a positive view on the collaboration between health and welfare organizations that might aid the successful implementation of the MINI robot.

Some features associated with the current version of the robot might trigger challenges that lie ahead when starting to implement the MINI robot in the MCs. To avoid such challenges, the researchers should evaluate the needs and preferences of the participants of the MCs. Qualitative research with end-users and care professionals is essential before and during the robot development phase. This will ensure the acceptance and effectiveness of the robot in such contexts. Plus, researchers might avoid designing games and quiz-like activities for use on social robots, in line with the activity policy of the MCs, confronting persons with dementia with their shortcomings in activities that have high cognitive and memory function demands. Instead, fun, enjoyable, and relaxing applications and games would be most appealing and beneficial. Given the preference for group activities in the MCs over individual activities, it is crucial to integrate the robot into a group setting so that it can interact with multiple users. For example, a multi-player game could allow two or more individuals to interact with a social robot at the same time.

Acceptability of the MINI robot

We launched the acceptability study of the MINI robot in a labratory setting in Spain. We employed a robust methodology based on our previous literature review (Mahmoudi Asl et al., 2022) for the acceptability study. Nevertheless, several existing studies (J. M. Beer et al., 2017; Fischinger et al., 2016) on the acceptability of the social robots conducted a short interaction period of -one or two sessions -, we gave an interaction of almost one month for each participant and compared the ratings of the pre and post-test of the Almere questionnaire.

It was interesting to observe that the ratings increased/decreased at post-test in favour of the robot's acceptance in almost all constructs except for the "personality of the robot/ social presence". However, in some similar research (E. Broadbent et al., 2016; Elizabeth Broadbent et al., 2014; Pripfl et al., 2016) the concepts related to acceptability, such as perceived agency and enjoyment, received lower ratings when evaluated over an extended period of use. To maintain the enjoyment level, it is crucial to determine the best intervention does to avoid exhaustion. We argue that a longer exposure to the robot might improve the acceptance, in particular, decrease anxiety and increase ease of use. According to a study (Torta et al., 2014) the size and anthropology of the robot might influence perceived social presence. However, the small size of robot might have affected the “Social presence/ Personality of the robots”, but the literature shows that bigger robots in human shapes are mostly rejected by the elderlies.

One of the notable aspects of the enquiry, was the “perceived usefulness” of the robot at home settings. However, the ratings slightly increase but the average rating score remained around neutral for this construct. we could conclude that the participants were hesitant about adopting the MINI robot due to the lack of need. A similar comment was received during the interviews in the previous study in the Netherlands. However, stakeholders other than PwD, considered the MINI robot useful for people living alone. Previous studies (Dosso et al., 2022; Wu et al., 2014) introduced the lack of need, fear of reduction of human contact, deskilling, and new dependence on machines as factors shrinking “perceived usefulness”. Additionally, some studies (Park, Chang, Lee, & Lee, 2019; Wu et al., 2014) raised the stigma issue of adopting assistive technologies and put forward destigmatising the use of assistive technologies with the encouragement of caregivers and care professionals. Blackman et al. (Blackman & Society, 2013) hypothesised that a social robot with a universal design and an add-on module on-demand feature (e.g., combined with a vacuum cleaner) would make it less noticeable that the robot is for people with special needs, thereby destigmatising it. On the other hand, it was interesting to witness in both studies in the Netherlands (Mahmoudi Asl A, 2023) and Spain, that several participants expressed their willingness to use the robot in clinical settings and agreed that the MINI robot was a fun and enjoyable agent through which they could play games and activities, learn stuff and stay active.

From our conducted studies, diverse user opinions on MINI's appearance and voice posed challenges in forming definitive conclusions. Nonetheless, we can offer assurance to MINI's researchers and developers: altering characteristics for a friendlier talker (voice tone and speech content), less machine-look and movements, would encourage interaction. Graded games, new apps and multimedia content could enhance the robot’s acceptance and admiration among elderly adults.

User experience and usability of the MINI robot

The UX and usability of the MINI robot were evaluated in laboratory settings, focusing on interactions with individuals with MD and MCI. Key findings highlighted several challenges in human-robot interactions:

Difficulty Comprehending Instructions: Participants faced challenges in understanding written instructions for task completion, indicating a need for clear and simplified language to enhance comprehension.

Reliance on Instructor Assistance: Both groups heavily relied on instructor assistance, particularly when tasks involved interaction through touch sensors, suggesting complexity in touch-based interactions. Transitioning between verbal and touch interactions posed challenges, especially for those with MD.

Response Method Challenges: Challenges emerged from user confusion in using response devices and the robot's limitations in comprehending speech. Speech recognition issues were a recurring problem, highlighting the need for significant improvements in this aspect.

Task Difficulty and Content: Difficulty in understanding tasks and not knowing the correct answers were more significant contributors to task performance issues than response method intricacies. Tailoring task difficulty to users' cognitive status and preferences is crucial.

User-Friendly Interfaces: The study emphasised the importance of designing user-friendly speech interface and interpretive capabilities in robotic systems to enhance usability and user engagement.

The overall SUS score indicated good usability, confirming alignment with user expectations. Participants found the MINI robot easy to learn and operate, with smooth integration of system functionality, and wanted to use it frequently. In a consistent pattern observed across various studies (Olde Keizer et al., 2019; Pripfl et al., 2016), people struggled with feeling confident when using robots. This was often because they were worried about whether the robot was reliable or robust. Technical and design problems made these challenges worse, as users had to deal with unexpected malfunctions, confusing interfaces, or other usability issues. However, there is a glimmer of hope in these discoveries. When users spent more time interacting with the robots, they gradually became accustomed to them and felt more at ease. This suggests that familiarity and experience may enhance ease of use over time, as seen in the acceptability study of MINI, which found an increase in ease of use at the end of the study.

These results emphasis the importance of ongoing enhancements in all-purpose robotic systems, speech recognition technology, vocal characteristics, applications, and games, as well as the delivery of clear instructions for use to boost usability and user contentment in human-robot interactions. This is especially crucial for those with cognitive impairments such as MD and MCI.

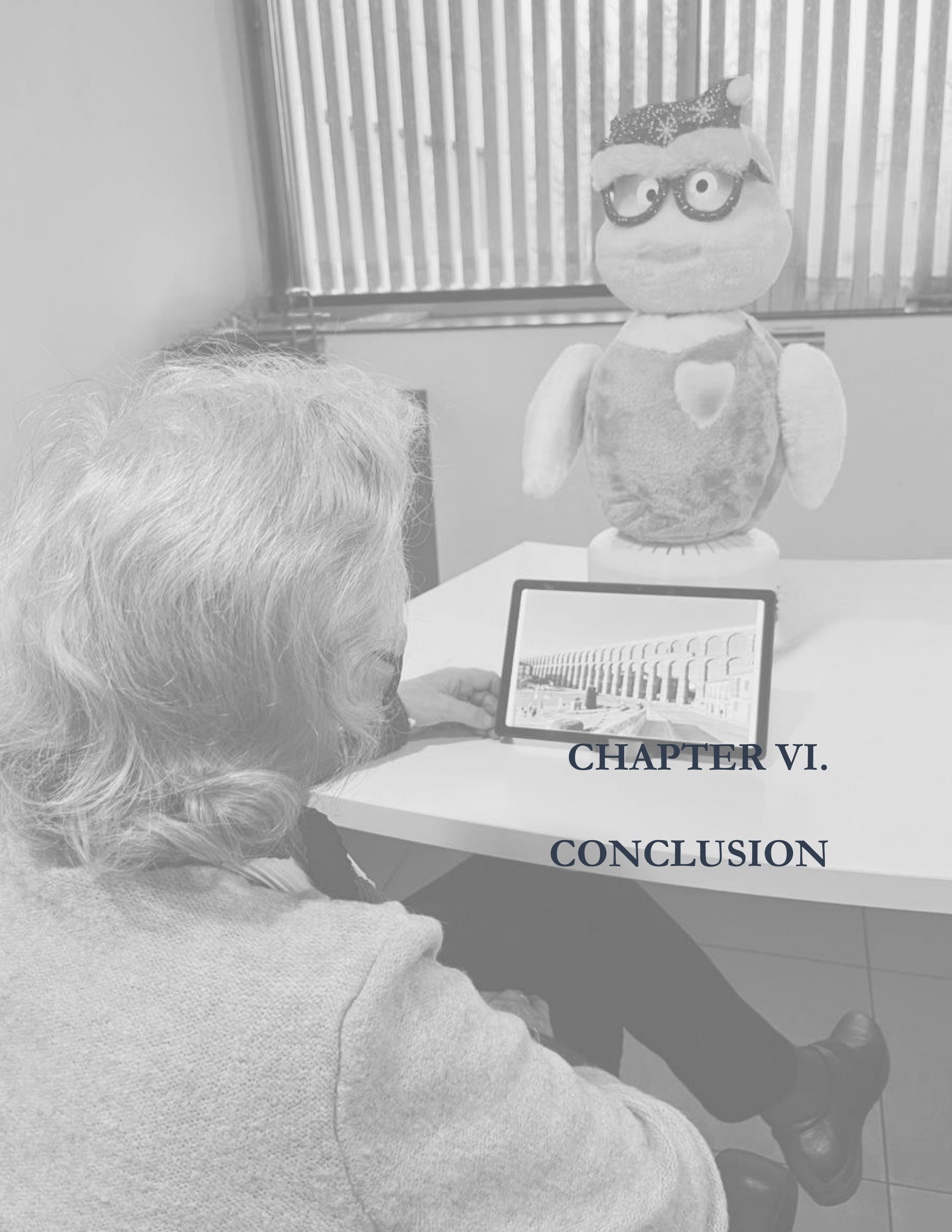
Strengths and limitations of the project

Each study describes its own strengths and limitations in their respective publications (see Chapter IV). This section, however, delves into the overarching strengths and limitations of the entire project, accompanied by insightful recommendations to further propel this avenue of research.

The strengths of this project are anchored in a robust three-part scientific framework that was meticulously employed to conduct the studies. Our deliberate selection of steps and method establishment, aligned with these frameworks, ensured the attainment of dependable outcomes. An early-stage literature review served as a vital touchstone, offering guidance for study design and methodology in subsequent project phases.

Moreover, the inclusion of stakeholders from diverse backgrounds within the health and social care sectors in the Netherlands and Spain enriched our perspective, enabling a comprehensive assessment of MINI robot implementation in community-based centers like MCs. The involvement of the public and patients granted us invaluable insights into prevailing policies and regulations in both countries. Additionally, this engagement allowed us to glean the perspectives of end-users with varying cultural contexts and lifestyles, thereby contributing to the refined design and development of the MINI robot.

The primary challenge faced by this project was the stringent restrictions enforced due to the COVID-19 pandemic. This situation not only brought about halts and delays from the project's inception but also curtailed our access to critical settings such as nursing homes, hospitals, and private households, primarily due to the vulnerability of the target population. Originally, the project aimed to carry out studies within these environments, extending to efficacy and effectiveness investigations of the MINI robot. Consequently, our stakeholders and end users, particularly PwD and MCI, was significantly limited, resulting in relatively smaller sample sizes for the conducted studies.



CHAPTER VI.

CONCLUSION

This project comprised a series of essential studies aimed at initiating the use and implementation of a social robot, specifically the MINI robot, with older adults and people PwD. Following established frameworks in digital health intervention evaluation, we meticulously followed a sequence of steps. The scoping review conducted at the outset of the project served as a foundational guidepost, informing our methodological approach to address each question that arose when designing the studies of the MINI robot. This was followed by a careful assessment of potential facilitators and barriers to the implementation of the MINI robot into community-based centres for PwD, such as MCs. The final phase of the project was an evaluation of the user experience, usability and acceptability of the MINI robot in a laboratory setting.

Several overarching conclusions can be drawn from our project:

First, bridging the gaps in the existing literature on social robots requires the implementation of scientifically rigorous methods and study designs. A specific focus should be given to each of the intended outcomes. Efficacy and effectiveness studies will benefit from robust RCT designs with large sample sizes and individualised intervention sessions. Meanwhile, experimental designs seem most appropriate for feasibility and usability studies. In pursuing each of these three objectives (efficacy/effectiveness, feasibility and usability), we advocate the use of a mixed methods approach to data collection. In addition, prolonged engagement through multiple interaction sessions over at least a month could potentially yield significant results, revealing the true long-term impact of social robots. Given the preponderance of studies focusing on usability and feasibility, it is imperative that extensive effectiveness studies be conducted in community settings and, in particular, in private households. This approach will confirm the tangible impact of social robots on people's daily lives.

Secondly, with regards to the implementation of the MINI robot in MCs, our findings offer valuable insights for professional stakeholders, including directors, managers of MCs and care and welfare organisations. We discovered a diverse landscape of potential factors influencing the implementation of the MINI robot in MCs for people with dementia. On the one hand, crucial factors facilitated the implementation of the robot, with recognition of its potential impact on PwD to engage, stimulate cognitive functions and alleviate loneliness. In addition, stakeholders emphasised the crucial role of human resources, available funding, and the collaborations of care and welfare organisations in supporting the implementation of the robot.

Conversely, notable barriers also emerged. These encompassed concerns about the robot's hardware and software, including its appearance and communication interface, which may require modifications to enhance usability and acceptability. Additionally, divergent attitudes among care staff regarding activity policies for PwD posed a potential challenge to implementation, reflecting critical professional attitudes toward the MINI robot in the MCs. In conclusion, the majority of professional stakeholders and PwD participants showed a positive reception towards the robotic intervention, expressing its viability within MCs in the Netherlands and Spain. While the MINI robot holds promise in enriching the lives of PwD, addressing these potential barriers and leveraging the potential facilitating factors will be essential to maximising its potential in real-world care environments. The outcomes of this study provided valuable guidance to the developers of the MINI robot, aiding them in aligning the robot's features with the preferences and needs of PwD and the policies of MCs. Research involving end-users and care professionals should be an ongoing process throughout the development and implementation of the robot.

Thirdly, we confirm the MINI robot's favourable reception among users in clinical settings and their willingness to interact with it. Participants generally held a favorable view of the robot, citing attributes like enjoyment, sociability, and trustworthiness. Extended interaction improves acceptance, especially in decreasing anxiety and increasing perceived ease of use. However, it is worth noting that the robot was not perceived as socially present or lifelike, possibly due to its size but, research has demonstrated that smaller robots are generally better accepted. While initial views on the robot's usefulness were neutral, they improved by the study's end. Still, participants hesitated to adopt it at home due to a perceived lack of need. In clinical settings, participants were more open to using the robot for activities and engagement. To enhance acceptance, suggestions included improving the robot's appearance, voice, and expanding its apps and games options. The findings from the acceptability study offer new perspectives for improving the design of MINI and similar social robots, suggesting adaptations to meet users' wishes, needs and preferences. To this end, developers should enhance the robot's conversational features and abilities and enrich its multimedia content, design graded games and new apps, for a better accepted robot.

Finally, we evaluated the UX and usability of the MINI robot. While it showed promise with quick learning, simple system and operation and, seamless integration of features, there are areas for improvement, including the general system, games and apps, and speech-related features. Effective use may require clear instructions and expert guidance. By enhancing the system's functionalities and listening to users, developers can improve the UX and make the MINI robot more effective. This requires careful design and ongoing adaptation, and it ensures meaningful engagement with PwD and MCI.

Our path does not end with the conclusion of this Ph.D. project; rather, it is a stepping stone towards our larger goal. Our future plans include launching a larger-scale initiative aimed at realising our ultimate goal: the broad, impactful, and long-term integration of MINI and similar robots into the community.

Abbreviations

AAL: Ambient Assisted Living

ADL: Activities Of Daily Living

ADP: Perceived Adaptability

ANOVA: Analysis of variance

ANX: Anxiety

ATT: Attitude

CE: Centro de Encuentro

DCL: Deterioro Cognitivo Leve

DL: Dementia Leve

EAS: Perceived Ease of Use

ENJ: Perceived Enjoyment

ICT: Information And Communication Technology

ITN: Innovative Training Network

LTCF: Long-Term Care Facility

MD: Mild Dementia

MCI: Mild Cognitive Impairment

MRC: Medical Research Council

OSF: Open Science Framework

PcD: Personas con Dementia

PSN: Social Presence/ personality of the robot/social presence

QoL: Quality of Life

RCT: Randomized Controlled Trial

SAR: Socially Assistive Robot

SOC: Perceived Sociability

TRS: Trust

UCLA: University of California, Los Angeles

UTAUT: Unified Theory of the Acceptance and Use of Technology

UMC: University Medical Centers

USN: Perceived Usefulness

VUmc: VU University Medical Center

WHO: World Health Organization

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Supplementary Material

Review article

DIGITAL HEALTH

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Digital health technologies supporting the application of comprehensive geriatric assessments in long-term care settings or community care: A systematic review

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Abstract

Objective: To provide high-quality elderly care, digital health technologies (DHTs) can potentially assist in reaching the full capacity of comprehensive geriatric assessments (CGAs) to improve communication and data transfer on patients' medical and treatment plan information and health decision-making. This systematic review aimed to describe the evidence on the feasibility and usability, efficacy and effectiveness, and implementation outcomes of DHTs developed to facilitate the administration of CGAs for long-term care settings or community care and to describe their technical features and components.

Methods: A search strategy was conducted in three databases, targeting studies evaluating the DHTs facilitating the administration of CGAs used in long-term care settings or community care. Studies in English and Spanish published up to 5 April 2023 were considered.

Results: Four DHTs supporting the administration of the CGAs were identified. Limited information was found on the technical features and required hardware. Some of the barriers identified regarding usability can be overcome with novel technologies; however, training of health professionals on the assessments and staff knowledge regarding the purpose of the data collected are not technology related and need to be addressed.

Conclusions: Barriers regarding usability were related to experienced difficulties navigating the software, unstable network connectivity, and length of the assessment. Feasibility obstacles were associated with the lack of training to use the DHT, availability and accessibility to hardware (e.g. laptops), and lack of insight into the clinical benefits of collected data. Further research must focus on these areas to improve the implementation and usefulness of these DHTs.

Keywords

Digital health technology, comprehensive geriatric assessment, long-term care, community care, ageing, multidisciplinary assessment

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Introduction

Ageing is associated with comorbidity, polypharmacy, and declining physical and cognitive functioning, causing frail elderly people to receive multiple treatments and interventions from healthcare providers with different specialisms working in different sectors (e.g. community care, acute care, and long-term care). Declining health and the risk of developing functional and cognitive impairment have implications on the quality of life and capacity for independence and autonomy of the older adult population.[1,2] This complex interplay between factors related to clients, care professionals, and care sectors yields comprehensive information on elderly persons' health status, highlighting the need for a high degree of coordination and accurate communication between healthcare providers and clinical interventions to provide quality older-adult-integrated care.[3] This could improve the early identification of individuals at risk of (further) decline, facilitating adequate and timely treatment, care plans, and clinical decision-making.[4,5]

To tackle the aforementioned complexities, comprehensive geriatric assessments (CGAs) have become an important assessment tool in elderly care, as they capture multiple domains and focus on the variety of complex problems experienced by frail older people.[1,4,6,7] CGAs are considered multidimensional assessments that support multidisciplinary care teams in clinical decision-making and personalized care planning to address the needs of older people and their families and carers, emphasizing functional status and quality of life.[2,4,8,9]

A wide range of benefits of the utilization of CGAs in elderly care has been documented, such as reductions in hospitalizations, admissions to long-term care facilities (LTCF), functional decline, and mortality[4,8,10]; prevention of negative health outcomes, such as shortened survival times and care dependency[2]; or supporting improvements in care planning and quality of care.[1] However, as a result of the higher percentage of transitions between care settings in older populations, associated with the complexities of an ageing population and the shift from institutional care to home care (HC) delivery,[3,11,12] accurate communication of medical information and treatment plans have become fundamental to provide quality elderly care.[3] For this reason, to reach the full potential of CGAs, their implementation should be supported by electronic data systems that provide relevant output and enable information sharing within multidisciplinary teams of care professionals and multiple care settings in a timely manner, thereby optimizing the coordination of care and avoiding potential discrepancies in terms of the completeness and reliability of data collection.[13–15]

Digital health refers to the general use of a variety of information and communication technologies (ICTs), big data, genomics, and artificial intelligence (AI) to address health needs and to improve the health, well-being, and care of people.[16–19] Digital health technologies (DHTs) are intended to enhance people's health and well-being and to improve health and social care systems.[20,21] The variety of digital tools includes, amongst others, the adoption and use of computer platforms, software, mobile apps (mHealth), wearable devices, electronic health records, telemedicine or telehealth, robotics, and monitoring and sensor devices.[19,20,22] The employment of DHTs can potentially assist in reaching the full capacity of CGAs and overcome the constraints of data transfer between settings and stakeholders.[14,15] Involving DHTs in healthcare systems has been shown to improve the availability, quality, and use of data for healthcare decision-making and offer opportunities for the sustainability of healthcare systems by providing better insight into the quality and efficiency of care delivery.[16,23] However, concerns have been raised regarding the overwhelming diversity of available digital health tools and the limited evidence on their impact on health systems and a person's well-being.[16]

A previous scoping review identified a lack of publications on web-based applications for frailty assessments in older adults and limited data regarding their time efficiency, security, algorithm efficiency, environmental requirements, and browser requirements.[24] Also, the lack of comprehensive instructions, training materials, and materials to support the interpretation of the results was also highlighted.[24] Nonetheless, the web-based assessment tools showed several advantages such as their convenience and ease of completing the assessments, the implementation of highly friendly user interfaces by most tools identified, and the high cost efficiency of most of the applications.[24]

Despite this initial attempt to identify the challenges and opportunities of web-based applications for the assessment of older adults, the scoping review excluded the diversity of digital tools comprised under the term DHTs. Additionally, it focused exclusively on frailty, excluding other potential DHTs covering a wider range of functional domains such as those provided by CGAs, where frailty scales are also embedded.[24] For this reason, we aimed to describe the evidence on DHTs that have been developed to facilitate the administration of CGAs and describe their technical features and components and address the feasibility and usability, efficacy and effectiveness, and implementation outcomes of the DHTs.

Methods

Eligibility criteria

Studies considered eligible for inclusion in this review focused on the feasibility, usability, efficacy, effectiveness, or implementation of DHTs supporting CGAs for long-term care settings or community care. Searches were conducted up to 5 April 2023 in the following databases: PubMed,

Table 1. Inclusion/exclusion criteria for the search strategy.

Inclusion criteria	Exclusion criteria
The CGA must be one single multidisciplinary test or assessment tool	An assessment that consists of a collection of tests or assessments or stand-alone instruments assessing one domain (e.g. depression)
Studies describing and/or assessing the feasibility, usability, efficacy, effectiveness, or implementation of DHT use for the applicability or for performing a CGA	Studies published in languages other than English or Spanish
The DHT is developed for use in clinical practice	DHTs that support entirely self-report instruments
Any DHT supporting the application of a CGA in long-term care settings or community care	Publications such as conference abstracts, case studies, protocols, dissertations, books, and systematic reviews
The instrument supported by the DHT targets people 55 years old or above	DHTs that support instruments for acute care, mental healthcare, palliative care, hospitalized settings, or transfer between any of the aforementioned settings

CGA: comprehensive geriatric assessment; DHT: digital health technology.

CINAHL, and Web of Science. Only studies in English and Spanish were considered eligible. See Table 1 for inclusion and exclusion criteria.

Search strategy

A list of free text keywords and Medical Subject Headings (MeSH) was developed by two authors (MMU and HGvdR) for PubMed. Subsequently, the list was translated to the correspondent-controlled vocabulary headings and appropriate syntax of the other databases. The following search strategy was used:

CGA. 'geriatric assessment' (MeSH Major Topic) OR 'geriatric assessment/methods' (MeSH Major Topic) OR 'geriatric assessment' OR 'geriatric evaluation' OR 'geriatric instrument' OR GA OR 'comprehensive geriatric assessment' OR CGA OR 'multidimensional geriatric assessment' AND

Setting. 'residential facilities' (MeSH Major Topic) OR 'Community Health Centers' (MeSH Major Topic) OR 'Community health services' (MeSH Major Topic) OR 'long-term care' (MeSH Major Topic) OR 'elderly care' OR 'residential facilit*' OR 'long-term care facilit*' OR 'LTCF' OR 'geriatric care' OR 'aged care' OR 'home care' OR 'primary care' OR 'senior center*' OR 'residential care' OR 'community care' AND

DHT. 'internet' (MeSH Major Topic) OR 'telemedicine' (MeSH Major Topic) OR 'software' (MeSH Major Topic) OR 'digital*' OR 'internet' OR 'electronic*' OR 'computer*' OR 'automat*' OR 'software' OR 'web' OR 'web-based' OR 'mHealth' OR 'telehealth' OR 'mobile' OR 'eHealth' OR 'online' OR 'app*'

Selection procedure

After duplicate removal, the remaining publications were divided amongst three pairs of authors (six reviewers in total), who screened the titles independently according to the inclusion and exclusion criteria. Within each pair, the screening was compared, deviations were discussed, and agreement was sought. The abstracts of potentially eligible publications were screened by two authors independently (MMU and AM), leading to the final full-text review stage. As the last step, the same authors checked the full texts for eligibility (see Figure 1). In case of discrepancies, a third author (HGvdR) made the final decision to include or exclude the study.

The data extracted from the studies were performed by one author (MMU). The following data were extracted from the final selection: (a) author and year of publication; (b) name of the DHT, (c) name of the CGA; (d) technical features; (e) stage of maturity; (f) aim of the study; (g) study design; (h) country; (i) care setting; (j) description of the study sample (size, female percentage, mean age, and standard deviation); (k) outcomes; and (l) main findings.

State of evaluation (outcome variables)

The state of evaluation aims to determine whether the DHT under evaluation is functioning, is effective or is ready for scale-up,[17] in other words, if the DHT is feasible, usable, and effective or if it can be implemented on larger scales. According to the WHO,[17] the definitions of these outcomes are as follows: (1) the feasibility assesses whether the DHT works as intended in a given context; (2) the usability assesses if the DHT can be used as intended by the users; (3) the efficacy assesses if the DHT can achieve the intended results in a controlled research setting; (4) the effectiveness assesses whether the DHT can achieve the intended results in an uncontrolled (non-research) setting; and (5) the implementation assesses the uptake, integration, and sustainability of the DHT for a specific context (includes policies and practices).

Stage of maturity

The maturity life cycle of DHTs ranges from a concept to a fully developed and functioning platform that is ready for

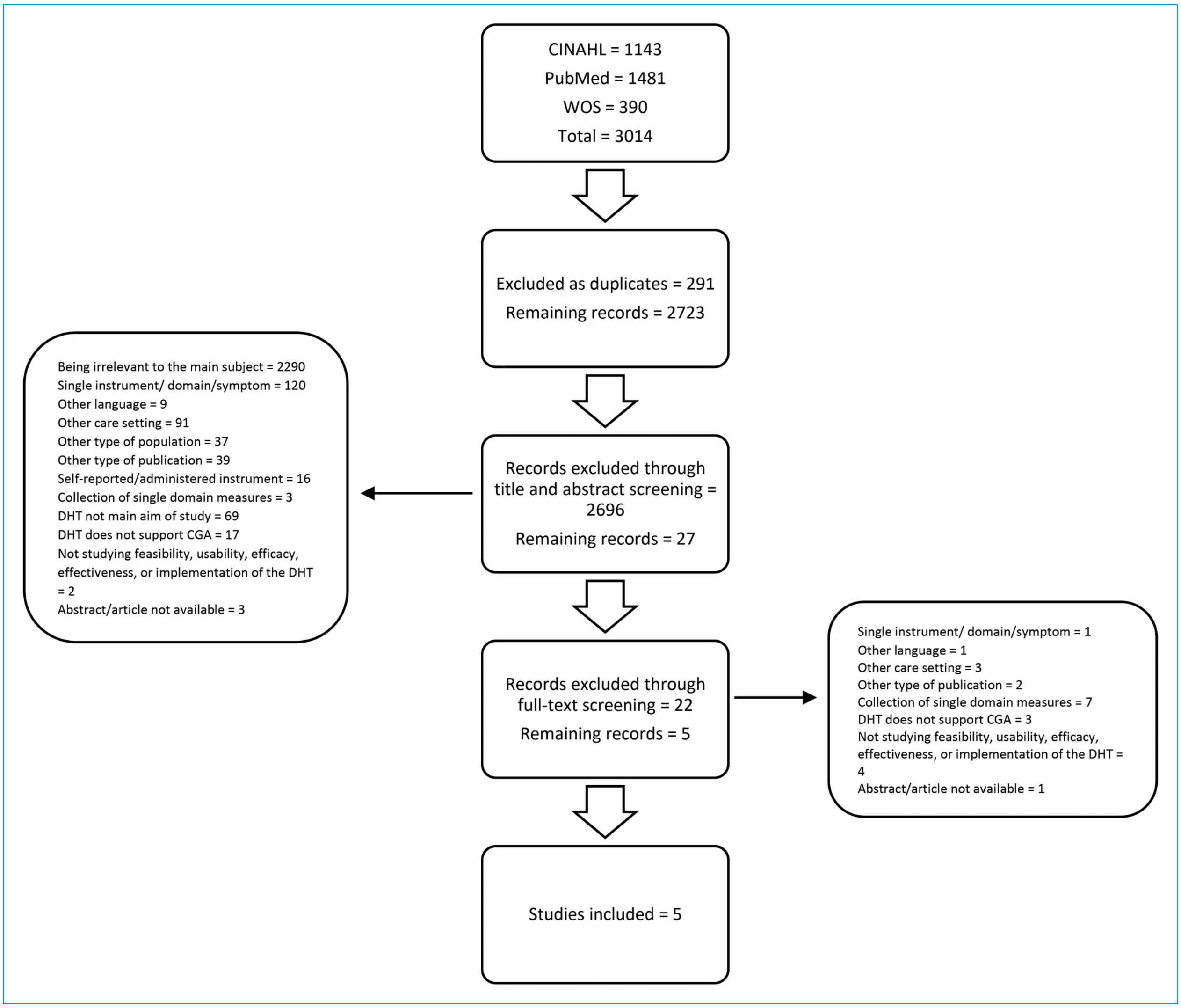

Figure 1. PRISMA flow diagram.

upscaling, providing insight regarding if the DHT has been developed and evaluated for the first time or if it is mature to undergo scale-up.[17] In brief, the different stages of maturity as described by WHO[17] are as follows:

Pre-prototype. This includes hypothesis building, needs/context assessment, and testing of usability/feasibility and technical stability.

Prototype. The user-focused designs are created and tested, as well as the functionality, technical stability, and usability. Improvements are examined.

Pilot. This examines the digital intervention in controlled research settings to assess if it produces the expected effect.

Demonstration. The evaluation is done under some restricted population/region conditions but does not take place in controlled settings.

Scaled-up. At this step, the intervention is ready to be implemented widely across multiple settings or at the population level.

Integration and sustainability. This is the final stage where the intervention is already being used in a broader system, and other supporting features to enhance the impact of the intervention at a large scale are assessed (such as policies, financing, human resources, interoperability, etc.).

Risk of bias (quality assessment)

The quality of the studies was evaluated by two raters through the 'mERA Methodological Criteria'.[17] This tool contains two sections: (a) essential items that must be evaluated for all studies, independent of study type (23 items), and (b) items specifically for qualitative (3 items) or quantitative (3 items) research. In the case of mixed method studies, items from both categories (quantitative and qualitative) were used.

For this study, each item was rated according to the degree to which the study met the criteria (0 = no, 1 = partial, and 2 = fully). When an item was not applicable to a particular study, the item was not considered in the calculation of the summary score. The summary score was calculated for each study by summing the total score obtained from the relevant items and dividing it by the total possible score. According to this scoring system, results are between 0 and 1: if closer to 0, the methodology is considered poor, and scores closer to 1 indicate a stronger methodology.

Results

After duplication removal, the titles and abstracts of 2723 records were screened, of which 2696 records were excluded. The remaining 27 studies were analysed through a final full-text review. After the final screening, five papers were included for analysis (see Figure 1, PRISMA flowchart, and Supplementary Material, PRISMA Checklist).

The feasibility and usability of the MDS-HC© Electronic web-based interface and the interRAI electronic assessment tools were assessed by one study each.[25,26] Kim et al.[27] studied the effectiveness of the System for Person-centered Elder Care (SPEC). Vanneste et al.[28,29] focused on studying the implementation of the BelRAI (Table 2).

Study outcomes (feasibility, usability, efficacy and effectiveness, and implementation)

Five studies on four different DHTs developed to support the implementation of CGAs for long-term care settings or community care were identified: (a) MDS-HC© Electronic web-based interface,[25] (b) interRAI electronic assessment tools,[26] (c) SPEC,[27] and (d) BelRAI.[28,29] The SPEC was studied in LTCF and the four other DHTs in community care. The DHTs support three CGAs, the minimum data set home care (MDS-HC), the interRAI long-term care facilities (interRAI LTCF), and the interRAI home care (interRAI HC) (Table 3). Two platforms were studied in Belgium (the MDS-HC© and the BelRAI), one in New Zealand (the interRAI electronic assessment tools), and one in South Korea (SPEC) (see Table 2).

The MDS-HC© and the interRAI electronic assessment tools were at the feasibility and usability stage of evaluation and were in the prototype and scaled-up state of maturity, respectively. The other two platforms, SPEC and BelRAI, have been studied in uncontrolled settings. The SPEC was investigated at the stage of maturity of demonstration and the effectiveness state of evaluation. The BelRAI was in the integration/sustainability stage of maturity and at the implementation state of evaluation.

Regarding how feasible and useful professionals perceived the DHTs, Duyver et al.[25] and Smith et al.[26] found mixed results. Regarding usability, nurses and other healthcare professionals found the interRAI electronic assessment tool software useful and beneficial, as it improved their performance. The DHT helped them gain a broader perspective of the individual's situation and needs and supported them in gathering the relevant information for professionals to provide good care. However, the assessment was considered too long and tiresome.[26] The MDS-HC© was tested amongst general practitioners, who did not report added value regarding their management and empowerment, but they considered activated triggers that warn of clinical risks in clients in the MDS-HC© (clinical assessment protocols (CAPs)) as clinically relevant.[25]

Reported facilitators for implementing a DHT were familiarity with the DHT and ease of use[26] and clear and coherent presentation of the items.[25] Usability barriers were related to experienced difficulties navigating the software,[25] unstable network connectivity, and length of the assessment.[26] Feasibility obstacles were associated with the lack of training to use the DHT, availability and accessibility to hardware (e.g. laptops), and lack of insight into the clinical benefits of collected data.[26]

The effectiveness of a DHT was only studied for the SPEC by Kim et al.[27] The use of SPEC was shown to have a significant positive impact on the quality of care in nursing homes. This was measured via a composite score of quality indicators, showing reductions in care problems of 8.1% and 11.1% for an unadjusted model and a confounder-adjusted model, respectively.[27] Decreases were also observed in secondary health and functional outcomes, such as ADL late-loss worsening, cognitive decline, communication decline, new or persistent delirium, and worsening of behavioural problems.[27]

In terms of implementation, the BelRAI was the only DHT that was studied. Analyses showed that seven out of the 18 domains reported lower completion rates[28] (see Table 2 for the specific domains). The authors attributed this amongst others to the incapability of the assessors due to insufficient training, insufficient information required by other caregivers, and lack of time to complete the assessment during the first house visit. Missing data at follow-up assessments were related to worse health status at baseline, higher risks of decline, admission to LTCF, and mortality.[29] The authors point out that missing data could be an indicator of poor quality of care. The responsibility for data collection was not adequately distributed amongst health professionals involved in the care of a client and relied mainly on nurses.[28]

Technical features and components of the DHTs

The MDS-HC© and BelRAI were web-based interface applications, while the interRAI electronic assessment tools and SPEC were software. The used hardware for the interRAI electronic assessment tools was laptops. For the other

Table 2. Characteristics and data extracted from the studies.

Authors/year	Duyver et al. (2010)[25]	Smith et al. (2013)[26]	Vanneste et al. (2015)[28]	Vanneste et al. (2016)[29]	Kim et al. (2020)[27]
Name of DHT	MDS-HC© Electronic web-based interface	interRAI electronic assessment tools	BelRAI	BelRAI	SPEC
Name of CGA	MDS-HC	MDS-HC	interRAI HC	interRAI HC	interRAI LTCF
Technical features	- Web-based interface - Login and password required - Possible to add data from other caregivers - Automatic result calculation	- Software (unspecified) - Data synchronizes with national data warehouses - Automatic calculation of risk triggers	- Web-based application - Available in Belgium's official languages - Possible to invite caregivers to assess their areas of expertise - Reveals conflicting and dubious answers - System to prevent erroneous completion - Software obliged to answer all items - Offers an online support platform to facilitate assessment and enhance multidisciplinarity and training of professionals	-Web-based application -Available in Belgium's official languages - Possible to invite caregivers to assess their areas of expertise - Reveals conflicting and dubious answers - System to prevent erroneous completion - Software obliged to answer all items - Offers an online support platform to facilitate assessment and enhance multidisciplinarity and training of professionals	- ICT - Enhanced integrated care model - A computerized care management software - It uses a cloud-based information system - Offer an individualized need/risk profile report, a profile-based care plan, and a care plan checklist - Allow interdisciplinary case conferences and multidisciplinary and integrated care management
Stage of maturity	Prototype	Scaled-up	Integration/sustainability	Integration/sustainability	Demonstration
Aim of the study	To examine the feasibility and added value of the MDS-HC© and explore barriers and facilitators for its implementation in the community	To identify the barriers and the organizational support required for the adoption of the platform through unit/service managers and end users	To examine the assessment completion using the BelRAI and possible causes for the incomplete assessments and their consequences on care quality	To study the characteristics of the missing data prevalence at 6-month follow-up and the profile differences between individuals with and without missing data	To examine the impact of the SPEC on the quality of care of older residents in Korean nursing homes
Study design	Mixed method study design	Phenomenology study design	Cross-sectional study design	Observational study of data	Stepped-wedge crossover clustered randomized controlled trial study design

(continued)

Table 2. Continued.

Authors/ year	Duyver et al. (2010)[25]	Smith et al. (2013)[26]	Vanneste et al. (2015)[28]	Vanneste et al. (2016)[29]	Kim et al. (2020)[27]
Country	Belgium	New Zealand	Belgium	Belgium	South Korea
Care setting	Community healthcare	Healthcare services	HC	HC	Nursing home
Study sample (*N*, female %, mean age, SD)	41 first-year general practitioner trainees	Five nursing and allied health professionals (all females; ages ranged from 30 to 69)	Nurses, occupational therapists, social workers, psychologists, physiotherapists, speech therapists, and physicians, caring for frail, community-dwelling elderly 65 years and older	Nurses, occupational therapists, social workers, psychologists, physiotherapists, speech therapists, and physicians, caring for frail, community-dwelling elderly 65 years and older	Control period sample: 482 older nursing home residents (80.3% female; mean age 82.7y ± 7.3y) Intervention period sample: 431 older nursing home residents (80.9% female; mean age 83.1y ± 7.5y)
Outcomes	Feasibility and added value: Technical acceptability Clinical relevance of the tool Management and optimization of healthcare planning Valorization of the role of the GP	Performance expectancy Effort expectancy Social influence Facilitating condition	Completeness of items Health professionals responsible for the completeness of the assessment	Institutionalization Death Scales performance Trigger CAPs	Primary outcome: quality of care (reported via a composite score of QIs) Secondary outcomes: a set of individual QI variables All QIs represent care problems
Main findings	37 participants completed the study. Participants agreed that items are presented clearly and coherently and logically. Difficulties regarding the steps to take in the software were experienced. CAPs were considered clinically relevant when	The platform was perceived as useful and beneficial as several considered that it improves their performance; however, the assessment was considered too long. Practice makes it easier to use. Constant connectivity and lighter hardware	Lower completion scores were seen in items of functional status (Section G), disease diagnoses (Section I), oral and nutritional status (Section K), medications (Section M), treatment and procedures (Section N), responsibility (Section O), and discharge potential and overall status (Section R). The proportion of responsibility	Missing data at follow-up were related to more impairment and depressive symptoms at baseline, higher likelihood of declining, increased likelihood of improving when the problem was addressed, and higher chance of dying and being admitted into residential care.	Quality of care significantly changed as the composite QI score decreased either in the unadjusted and confounder-adjusted models (8.1% and 11.1% decrease, respectively). Regarding the secondary outcomes, intervention significantly decreased ADL late-loss worsening (−31.1%), cognitive decline (−32.5%),

(continued)

Table 2. Continued.

Authors/ year	Duyver et al. (2010)[25]	Smith et al. (2013)[26]	Vanneste et al. (2015)[28]	Vanneste et al. (2016)[29]	Kim et al. (2020)[27]
	activated. In terms of management and empowerment of the GPs, the platform was not considered adding any value.	technology were seen as potentials for improvement. Main barriers were related to lack of access to hardware and consistent network connectivity, the need for ongoing training in the use of interRAI systems, and not knowing the purpose of the data collected.	for ensuring the completion of the assessments by professionals was nurses (62.1%), occupational therapists (21.5%), social workers (9.9%), psychologists (4.8%), physiotherapists (1.4%), speech therapists (0.3%), and physicians (<0.1%).		communication decline (−39.4%), new or persistent delirium (−44.7%), and behaviour problem worsening (−33.4%). Significant similar values were identified at the 3- and 6-month time-specific intervention effects. The intervention effect was larger for moderate and severe cognitive impairment and severe ADL limitations.

ADL: activities of daily living; CGA: comprehensive geriatric assessment; DHT: digital health technology; GP: general practitioner; ICT: information and communication technology; interRAI LTCF: interRAI long-term care facilities; interRAI HC: interRAI home care; MDS-HC: minimum data set home care; SPEC: System for Person-centered Elder Care; QI: quality indicator.

Table 3. CGAs supported by the DHTs identified.

DHT	CGA supported
MDS-HC© Electronic web-based interface	MDS-HC
SPEC	interRAI LTCF
interRAI electronic assessment tools	MDS-HC
BelRAI	interRAI HC

CGA, comprehensive geriatric assessment; DHT: digital health technology; interRAI LTCF: interRAI long-term care facilities; interRAI HC: interRAI home care; MDS-HC: minimum data set home care; SPEC: System for Person-centered Elder Care.

DHTs, information about required hardware was not reported. Only for the SPEC, it was mentioned to be computerized. Multiple access for data collection, allowing access to multiple health professionals and caregivers to single assessments for data entry, was reported for the MDS-HC© and the BelRAI. The SPEC was reported to allow multidisciplinary and integrated care management; however, multiple access for data collection was not reported. No information regarding user access was obtained for the interRAI electronic assessment tools. The data of the interRAI electronic assessment tools were stored in national data warehouses, and the SPEC was reported to use cloud-based data storage. For the MDS-HC© and BelRAI, no information on data storage was reported. All DHTs enabled the calculation of composite outcomes and scales, reflecting clinical outcomes and risks of decline.

Other technical characteristics were described for the BelRAI, such as revealing conflicting and dubious answers, preventing erroneous completion, and the obligation to answer all items, and it has an online support platform for assessors. In the case of the SPEC, it offers an individualized needs/risk profile report, a profile-based care plan, and a care plan checklist.

Quality of the studies

An initial interrater agreement of 86.2% was reached by two reviewers for the quality appraisal of included studies. The total quality score for the studies ranged between 0.62 and 1.00 (Table 4). The main weaknesses in the quality of identified studies were found in the participant eligibility and sampling, which was only mentioned in Kim et al.[27]; participant recruitment, reported in Kim et al.[27] and Smith et al.[26]; and enrolment, described in Duyver et al.[25] and Kim et al.[27] See Table 4 for a detailed overview of the quality appraisal.

Discussion

To provide high-quality elderly care, accurate communication of the patients' medical and treatment plan information has been identified as fundamental.[3,30] For this reason, we aimed to describe the evidence on the feasibility and usability, efficacy and effectiveness, and implementation outcomes of DHTs developed to facilitate the administration of CGAs for long-term care settings or community care and to describe their technical features and components.

Little information regarding technical features and hardware characteristics that could provide insight into the functioning of the platforms was reported. Only Smith et al.[26] reported using laptops; however, the used software was not specified. In terms of the description of the platform, more features were identified for the BelRAI and the SPEC as compared to the other two DHTs.

Three of the four platforms were studied in community care settings, supporting two CGAs, the MDS-HC and the interRAI HC. Only the SPEC was studied for LTCF and supports the interRAI LTCF. These results raise a concern in terms of how many CGAs are being supported by DHTs, as in this study, only the interRAI family of CGAs was identified, even when a previous systematic review reported a total of three CGAs for long-term care and seven for community care.[31] According to Molinari-Ulate et al.,[31] the interRAI family of instruments is the most studied CGA in the scientific literature in both settings, which could explain why there is evidence of the DHTs supporting them. Nonetheless, we cannot conclude if the lack of scientific literature reporting on DHTs supporting the remaining CGAs is because they are not being supported by DHTs or because of a lack of studies and evidence on their feasibility and usability, efficacy and effectiveness, and implementation. The limited research publications in this area have been also highlighted in a previous scoping review studying the web-based applications for the assessment of frailty in older adults.[24]

A lack of studies in this regard could lead to poorly designed systems jeopardizing patients' safety and contributing to psychological stress for users, including burnout and low morale.[30,32,33] Two of the studies included in this review identified outcomes associated with this problem. Vanneste et al.[28] identified that several sections were less completed than others, which might lead to concerns regarding decision-making, quality of care, interventions, and care planning, as they are supported by the assessments' results. Also, Vanneste et al.[29] considered that missing data could be related to lower quality of care, as they identified that the group with missing data at follow-up had worse health status at baseline, were more functionally impaired, showed more depressive symptoms, had a higher risk of health problems (such as cardiorespiratory conditions, undernutrition, dehydration, etc.), and reported an increased risk of mortality and institutionalization when missing data were found in the 6-month follow-up. Additionally, the identified high responsibility of nurses for the completion of assessments[28] associated with the perception of lengthy and time-consuming assessments[25,26]

Table 4. Results of quality assessment.

Study		Duyver et al.[25]	Smith et al.[26]	Vanneste et al.[28]	Vanneste et al.[29]	Kim et al.[27]
Introduction	Rationale	2	2	2	2	2
	Objectives	2	2	2	2	2
	Logic model	2	2	2	2	2
Methods	Study design	0	2	0	2	2
	Outcomes	2	2	2	2	2
	Data collection methods	2	2	2	2	2
	Participant eligibility	0	0	0	2	0
	Recruitment	0	2	0	2	0
	Bias	2	1	1	2	0
	Sampling	0	0	0	2	0
	Setting and locations	0	0	1	2	1
	Comparator	N/A	N/A	N/A	2	2
	Data sources	2	2	2	2	2
Results	Enrolment	2	0	0	2	0
	Description of the study population	0	2	1	2	1
	Reporting on outcomes	2	2	2	2	2
Discussion	Summary of evidence	2	1	2	2	2
	Limitations	2	2	2	2	2
	Generalizability	2	2	0	2	0
	Conclusions	2	2	2	2	2
Conflicts	Funding	2	0	2	2	2
	Ethical considerations	2	2	2	2	2
	Competing interests	2	0	2	2	2
Quantitative study	Confounding	0	N/A	0	2	2
	Statistical methods	2	N/A	2	2	2
	Missing data	0	N/A	0	2	2

(continued)

Table 4. Continued.

Study		Duyver et al.[25]	Smith et al.[26]	Vanneste et al.[28]	Vanneste et al.[29]	Kim et al.[27]
Qualitative study	Analytical methods	N/A	2	N/A	N/A	N/A
	Data validation	N/A	2	N/A	N/A	N/A
	Reflexivity of account provided	N/A	2	N/A	N/A	N/A
Sum		34	36	31	38	52
Score		0.68	0.72	0.62	0.73	1

could lead to overloading the workload of healthcare professionals and contradicts one of the basic premises of a CGA, the multidisciplinary cooperation to achieve high-quality care.

The results gathered from the studies of feasibility and usability reported some important barriers that could affect the implementation of these DHTs in care practice. Regarding usability, the following barriers were reported: (a) difficulties navigating the software, (b) length of the assessments, and (c) inconsistent network connectivity. In terms of feasibility, (d) availability and accessibility to appropriate hardware, (e) the need for ongoing training to perform the assessment correctly, and (f) the lack of staff knowledge regarding the information collected and its purpose were identified as potential obstacles. Some of these barriers might be overcome nowadays as the DHTs could include novel technologies that have evolved since their publication; for example, there are multiple and novel wearable and lighter devices that can be carried around instead of laptops; network connectivity is constantly evolving in terms of coverage, speed, and consistency; novel software and apps might be able to perform offline assessments; technology can support multiple access for data entry and break down long assessment instruments facilitating a more efficient and multidisciplinary administration; and guidelines and recommendations on the assessment and development of DHTs have been developed.[16,34,35] Nonetheless, there are some barriers that are associated with the training of the healthcare workforce, such as the training of health professionals on assessments and staff knowledge regarding the purpose of the data collected. These barriers were also highlighted by Chang et al.[24] who described a lack of comprehensive instructions, training materials, and materials to support the interpretation of the results in web-based applications used for the assessment of frailty in older populations. As these obstacles are not technology related, they need to be addressed by the healthcare systems and policymakers.

Some of these barriers can be tackled by considering the major priorities for strengthening DHTs identified by Sheikh et al.[30] For example, the lack of staff understanding of the information collected and its purpose could be approached by building capacity for managing and analysing data through investing in data science, quality improvement, and health informatics training for the workforce and by incorporating new professionals such as data scientists and clinical informaticists that jointly work with healthcare professionals and patients.[30] Also, engaging the healthcare task force and patients in DHTs' design and development, research, and implementation process will inform developers on design and evaluation issues, which could translate into early amendments, reducing costs before releasing the system.[30,36] This also could lead to more engaging and user-friendly systems[37] that could be more aligned with the needs of the different stakeholders and the context of their healthcare systems.

Identified features that reinforced the usability, effectiveness, and implementation of DHTs supporting the application of CGAs were as follows: (a) utilization of a safe data storage warehouse, such as clouds; (b) inclusion of automatic alerts, notifications, or a continuous check for item completion in the DHTs; (c) access allowance for multiple healthcare professionals on individual assessments in the DHT, avoiding to rely on one professional to complete the CGA but using the expertise of each team member; (d) provisioning of individualized profile reports of needs and risks and personalized care plans; and (e) automatic calculation of the composite outcomes and scales. Assuring the security and privacy of the data and improving the exchange of information between healthcare organizations have been also identified as major priorities for enhancing the implementation of DHTs in healthcare systems.[30]

By embedding novel technologies into DHTs supporting the administration of CGAs, such as AI and robotics, the accuracy and efficacy of these identified features could be increased, for example, by including a graphical representation of the person's health profile and status or by providing real-time people's information and feedback from large databases that can facilitate the development of machine learning algorithms.[38] Through this learning health system, clinically relevant information regarding the progression or deterioration of the person can be obtained and could improve timely decision-making and quality and personalization of care.[30,38,39]

Limitations and future research

The results presented in this review describe the state of the art of the DHTs supporting the administration of CGAs for long-term care settings or community care. The oldest study was published in 2010, and technology has evolved since then. Some of the limitations reported in this review might have been solved; however, information on potential updates and increased maturity of these DHTs not published in selected databases were not taken into account in this review.

We identified limited information regarding technical features and hardware characteristics needed for the proper functioning of the DHTs. The reported characteristics are based on the information available in the articles. Descriptions are often incomplete, missing relevant information that can lead to better insight regarding factors contributing to the usability, feasibility, and effectiveness of the DHTs in care practice, such as devices needed for the administration of the assessments, which functions the platform performs (e.g. automatic calculation of outcomes, alerts, notifications, and notes), or the possibility to involve different disciplines in the assessment. Similarly, there is a lack of studies targeting the implementation of these DHTs on a large scale. Further investigation is required to dig into the technological features of these DHTs and how to fit them into general information systems of health or social care. The relevance of using these tools for improving the quality of care makes it necessary to prove their usability, implementation, and usefulness in clinical settings, which will become relevant for clinical decisions and policymakers.

The scope of this review did not cover any costing implementation analysis of the DHTs. None of the studies included were reviewing this area; however, we consider it very important for future studies to include cost-effectiveness as a relevant outcome as it could improve health and policy decision-making regarding the available platforms. Similarly, due to the limited information and the number of studies identified, it is very difficult to provide a comparison between the DHTs reported. Only one platform was developed for long-term care and the other three for community care, and the description in terms of technological features, hardware characteristics, and other relevant data to provide a helpful comparison is very limited. Additionally, the healthcare systems where the DHTs have been studied might differ substantially as the studies were performed in three different countries on three different continents (Belgium, New Zealand, and South Korea). For this reason, this review provides recommendations and describes different barriers identified from the DHTs included in an attempt to offer some guidelines for future developers and policymakers.

Only studies in English and Spanish were considered, omitting other possible DHTs developed that have been reported in different languages. Also, our definition of a CGA excludes those DHTs that support multidimensional assessments that consist of a collection of single-domain measures, tests, or assessments. For example, digitized frailty assessments or indices were not addressed and not included in the search terms, as we considered that they do not cover the whole spectrum of domains included in the CGAs. Insights on these DHTs that might contribute to improvements of DHTs for CGAs are lacking in this study.

To the best of our knowledge, there are other commercial platforms available. However, studies on usability, feasibility, efficacy, effectiveness, or implementation were not identified. One of the authors contacted several companies that developed and deployed these platforms to inquire about performed studies on these topics. According to the responses received, no studies have been performed on these DHTs.

Even though DHTs are considered essential in collecting, processing, and reporting outcomes relevant to daily care practice, we only identified studies of DHTs supporting the interRAI suite of instruments from all the CGAs identified in Molinari-Ulate et al.[31] For further development of DHTs for this goal and to support optimal utilization of valuable CGAs to improve the quality of care, more insight is required into how care professionals use DHTs and their outputs efficiently, in such a way that it supports daily care practice.

Considering the barriers and limitations reported in this review, there is still a lot of room for improvement regarding the development and implementation of DHTs supporting the application of CGAs in LTCF or community care. Further research should focus on solving the barriers reported in this review, study the functionality of the platforms in up-to-date devices (such as tablets, mobiles, smartwatches, etc.), and focus on the integration of data from CGAs with monitoring data acquired via novel technologies such as wearable technology devices and AI within the DHT.

Conclusions

Data on DHTs supporting the application of CGAs in LTCF or community care are limited, with only five studies and only the interRAI family of CGAs being supported. These studies reported on barriers regarding usability, mainly concerning inconsistency in network connectivity; technical issues leading to inappropriate, inconsistent, and missing data; duration of the assessment; feasibility obstacles such as the availability and accessibility to appropriate devices; and lack of training and knowledge regarding the information collected and its purpose.

Regarding effectiveness, the results of one study reported a significant impact on the quality of care in long-term care settings and a decrease in ADL late-loss worsening, cognitive decline, communication decline, new or persistent delirium, and worsening of behavioural problems. In terms of implementation, the incompleteness of some sections was attributed to insufficient training, insufficient information required by other caregivers, and lack of time to complete the assessment. Responsibility for data collection was identified as not adequately distributed amongst health professionals, relying mainly on nurses.

Recommendations that might enhance the usability, effectiveness, and implementation of these platforms are accessibility to the individual's assessment by multiple healthcare professionals and allowance to break down the sections according to the professional expertise to share the assessments' responsibility; the use of safe data storage, such as clouds; automatization of a real-time calculation of the scales and outcomes with a graphical representation of the person's profile and health status; automatic alerts, notifications, and continuous monitoring for item completion; and provisioning of personalized care plans according to the data collected.

Limited information reporting on the technical features, required hardware, and lack of implementation studies of DHTs limits the conclusions of this review. Further research must focus on these areas to improve the implementation and usefulness of these DHTs to support the application of CGAs in the healthcare system.

Contributorship: MMU, HGvdR, and MAF-M conceptualized and designed the review. MMU, AM, EP-V, J-LM-S, MAF-M, and HGvdR screened the titles of the records resulting from the search. MMU and AM screened the abstracts and full text of the records that remained after title screening. MMU and AM evaluated the records for risk of bias. MMU extracted the data from the included studies, and it was verified by HGvdR. MMU, HGvdR, and MAF-M drafted and critically revised the manuscript. HGvdR and MAF-M provided overall study supervision. All authors authorized the final version of the manuscript that was submitted. All authors read and approved the final manuscript.

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Review

Psychometric characteristics of comprehensive geriatric assessments (CGAs) for long-term care facilities and community care: A systematic review

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A R T I C L E I N F O

Keywords:
Long-term care
Community care
Comprehensive geriatric assessment
CGA
Reliability
Validity

A B S T R A C T

Background: Comprehensive Geriatric Assessments (CGAs) have been incorporated as an integrated care approach effective to face the challenges associated to uncoordinated care, risk of hospitalization, unmet needs, and care planning experienced in older adult care. As they assessed different dimensions, is important to inform about the content and psychometric properties to guide the decisions when selecting and implementing them in practice. This systematic review provides a comprehensive insight on the strengths and weaknesses of the CGAs used in long-term care settings and community care.

Methods: A systematic search was conducted in PubMed, CINAHL, and Web of Science Core Collection. Studies published up to July 13, 2021, were considered. Quality appraisal was performed for the included studies.

Results: A total of 10 different CGAs were identified from 71 studies included. Three instruments were reported for long-term care settings, and seven for community care. The content was not homogenous and differed in terms of the detail and clearness of the areas being evaluated. Evidence for good to excellent validity and reliability was reported for various instruments.

Conclusions: Setting more specific and clear domains, associated to the special needs of the care setting, could improve informed decisions at the time of selecting and implementing a CGA. Considering the amount and quality of the evidence, the instrument development trajectory, the validation in different languages, and availability in different care settings, we recommend the interRAI LTCF and interRAI HC to be used for long-term facilities and community care.

1. Background

Societies and health systems are being challenged by the current demographic transition to ageing populations, arising the need for adjustments and responses from all sectors, including public health (WHO, 2015, 2018). The complexity of older adult care associated to comorbidities, polypharmacy, multiple treatments and interventions from different health care providers, socioeconomic status, and the risk of developing functional and cognitive impairment, have implications on the quality of life and capacity for independence and autonomy of the older adult population (Bernabei et al., 2008; World Health Organization, 2015). For facing this panorama, health care professionals and public health policymakers must pursue the development of healthcare approaches that place older people's needs and preferences in the centre of service delivery (WHO, 2015).

Integrated care has been considered as an effective alternative approach to the traditional and standard service delivery, improving the quality of older adult care and positively impacting rates of institutionalization and costs (Johri et al., 2003; McDonald et al., 2013; World Health Organization, 2015). A method in which different care levels and

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services are integrated across health care and long-term care settings covering the needs and preferences of older adults along their life course (World Health Organization, 2015). It comprises three key features, a case-management system that assess the individual's needs according to a person-centred perspective, a comprehensive care plan which aim to assist people on their treatment and care decisions, and an effective transfer of information among caregivers and settings aiming to improve coordination and integration of care (World Health Organization, 2015).

Following this approach, Comprehensive Geriatric Assessments (CGAs) became important interventions in geriatric care (Ellis et al., 2011; Pilotto et al., 2017). CGAs incorporate the main pillars of an integrated care approach and are being defined as a process of care including a coordinated multidimensional and multidisciplinary assessment, facilitating the clinical decision for the formulation of a personalized care plan to address the needs and concerns of the older person (and their family and carers) (Pilotto et al., 2017; British Geriatrics Society, 2019).

The interdisciplinary and integrated care process approach, centres its attention on the person and relatives, leading to a holistic evaluation of core domains. As this care process approach considers multiple areas of an individual, care professionals and policy makers must be aware of CGA's psychometric flaws and fortes to be able to take reliable decisions on care planning and health policy outcomes, aiming to optimize care quality. For this reason, the aim of this systematic review is to provide insight into the content and psychometric characteristics of CGAs used in long-term care settings and community care.

2. Methods

2.1. Literature search

A systematic literature search was conducted in three databases, PubMed, CINAHL and Web of Science Core Collection for studies up to July 13, 2021 (search strategy and studies selection procedure are available in Methods A.1). See Table 1 for inclusion and exclusion criteria. Reference lists of selected studies and relevant systematic reviews were scanned for potentially eligible primary studies.

2.2. Data extraction

One author (MMU) extracted the data from the final selection of papers. The following information was gathered: a) name of CGA; b) authors/year; d) description of sample; e) country; f) study setting; g) study design; h) aim of the study; i) type of validity/reliability; and j) main findings. Scale, items, indices, or domains were also extracted from the relevant studies.

Results on the domains covered by the CGAs were reported, followed by results on the evaluation of the reliability/validity of 1) complete CGAs; 2) specific domains and items; 3) scales and indexes; and 4) outcomes relevant for organization of care and clinical decision making. The domains of the CGAs were obtained from the description of the areas assessed in the papers, and from the forms or questionnaires, when available. To avoid bias on the domains' description, those areas related to demographic or administrative data (e.g., Identification, Background or Assessment information) were excluded from this analysis, as they might not be reported in the papers but included in the forms.

2.3. Risk of bias

The quality of the studies was assessed independently by two authors (MM and AM) using the "STANDARD QUALITY ASSESSMENT CRITERIA" for quantitative studies (Kmet et al., 2004) and percentage of agreement was calculated. Subsequently, the same two raters discussed the disagreements and came with a final consent agreement. Further detailed regarding the risk of bias methodology is provided in Methods A.1.

2.4. Interpretation of test scores

The validity and reliability outcomes were obtained according to the aims of the studies and the primary outcomes identified. When outcomes were unclear or multiple outcomes were reported, the researcher selected the one that best reflected the main result of the study (e.g., main scales outcomes rather than subscales). To avoid differences on the interpretation of the psychometric outcomes between the studies, the reviewers decided to use a standardized criterion based on the literature (available in Methods A.1).

3. Results

3.1. Literature search

After duplicates were removed, the titles and abstracts of 1226 records were screened, of which 115 records were analysed in detail by full text. Finally, 47 records were included in the review. After scanning the reference lists of selected studies, 24 additional studies were considered as eligible primary studies. In total, 71 papers were included in the final results (Fig. 1. PRISMA flow diagram).

3.2. Risk of bias

Two raters (MM and AM) scored the quality of the 71 papers, obtaining a 78.97% of agreement. The scores ranged from 0.50 to 1 (1 maximum score), with an average score of 0.83 (Table A.1).

3.3. CGA characteristics

Ten different CGAs were identified: three focused on long-term care settings and seven focused on community care (see Table 2). Table 3 shows the number of domains assessed by each CGA and the number of studies that used criterion measures and the number of criterion measures used to validate some of their domains. The areas validated and the criterion measures used for their validation are available in Table A.2.

3.4. Psychometric characteristics of the CGAs

The following section describes the reliability and validity results. The first subsection describes the results of the long-term care facilities instruments, followed by the community care. Each subsection starts with the reliability results followed by validity findings. Results are

Table 1
Inclusion and exclusion criteria used for the study selection.

Inclusion Criteria	Exclusion Criteria
The Comprehensive Geriatric Assessment instrument must be one single test or assessment tool	An assessment that consists of a collection of single domain measures, tests or assessments, or stand-alone instruments assessing one domain (e.g, depression)
The study should report on the validation or reliability of the instrument	Studies published in languages other than English or Spanish
The instrument must target specifically people of 55 years and older	Publications such as conference abstracts, case studies, protocols, dissertations, books and systematic reviews (however, references from selected SRs were checked) If the entire instrument is self-report. Instruments developed for acute care, mental health care, palliative care, primary care or hospitalized settings. Also, those instruments that assessed transfer from or to any of the aforementioned care setting.

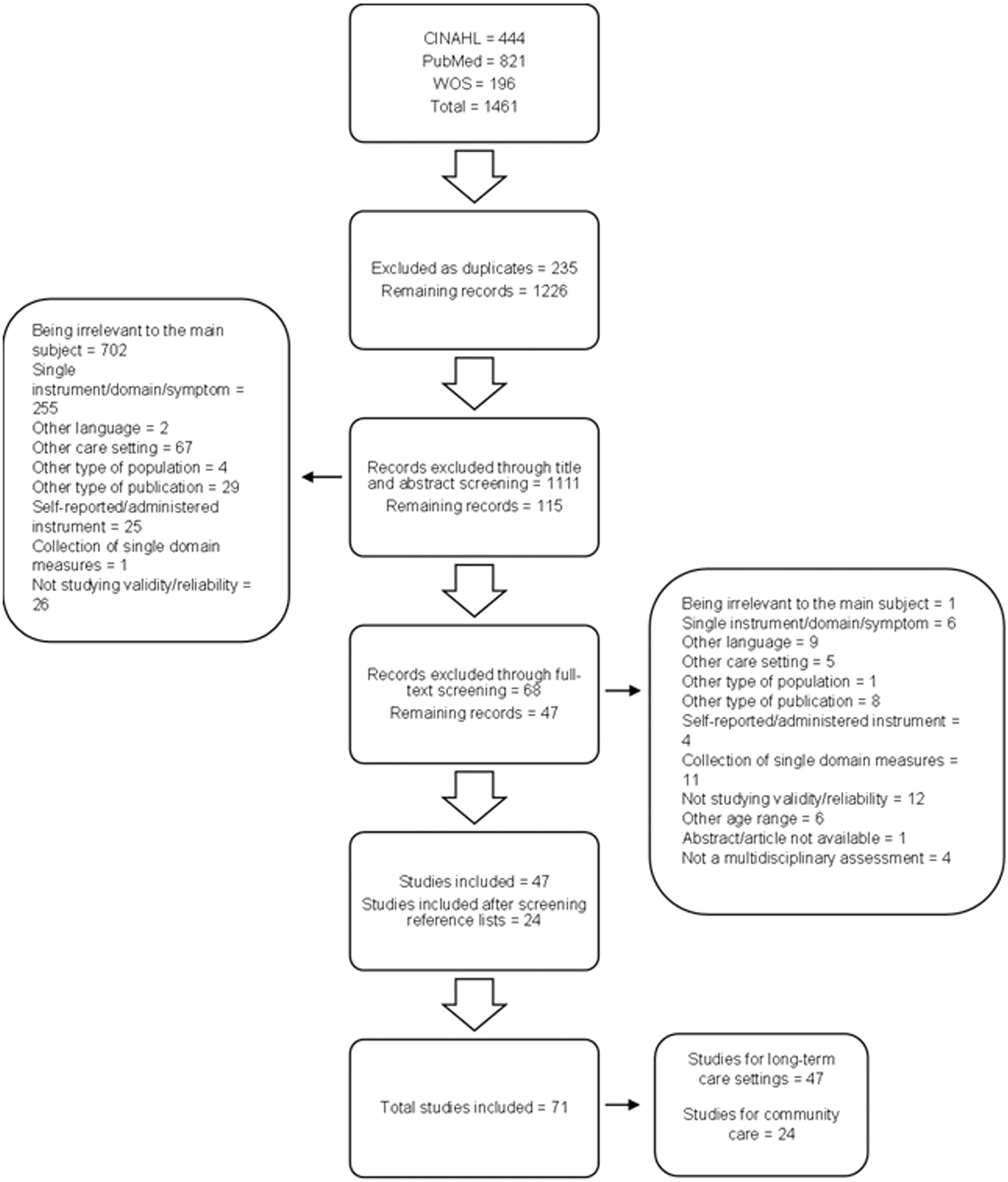

Fig. 1. PRISMA flow diagram.

described according to the four approaches identified to study the psychometric characteristics: a) complete CGAs; b) specific domains or items; c) specific scales or indices; and d) outcomes relevant for clinical decision making and organization of care. The psychometric evidence for outcomes relevant for organization of care and clinical decision making are described in a separate subsection.

3.5. *CGAs for long-term care settings*

3.5.1. *Reliability results*

The reliability of the complete CGA RAI-MDS and subsequent updated versions (n = 8), and CPAT (n = 1), was studied (Table A.3). Good to excellent inter-rater reliability was reported for more than 91.7% of the

Table 2
CGAs identified in the review, according to their care setting.

Long-term care setting	Community care
Resident Assessment Instrument-Minimum Data Set (RAI-MDS) (Morris et al., 1990) [a]RAI-MDS 2.0 (Morris et al., 1997b) [a]RAI-MDS 2.1 Chinese version (Chou et al., 2001) [ab]MDS 3.0 (Saliba and Buchanan, 2012) [a]interRAI Long-term Care Facilities (LTCF) v.9.1 (Hirdes et al., 2008) [a]interRAI LTCF Korean Version (Kim et al., 2015)	Comprehensive Assessment and Referral Evaluation (CARE) (Gurland et al., 1977)
VALutazione GRAFica (ValGraf) Residential version (Gigantesco et al., 1995)	Older American's Resources and Services (OARS) Multidimensional Functional Assessment Questionnaire (OMFAQ) (Fillenbaum and Smyer, 1981) [a]OARS-OMFAQ Spanish version (Fibla et al., 1996)
Care Planning Assessment Tool (CPAT) (Fleming, 2008) [a]J-CPAT Japanese version (Kanegae et al., 2010)	Philadelphia Geriatric Center Multilevel Assessment Instrument (MAI) (Lawton et al., 1982)
	Popovich Scale (Grubba et al., 1990) Outcome and Assessment Instrument Set (OASIS) (Shaughnessy et al., 1994) RAI-MDS Home Care (HC) (Morris et al., 1997a) [a]RAI-MDS HC Chinese version (Kwan et al., 2000) [a]RAI-MDS HC Swiss version (Ludwig and Busnel, 2017) [a]interRAI HC (Hirdes et al., 2008) [a]interRAI HC Korean version (Kim et al., 2015) Community Assessment of Risk Instrument (CARI) (Clarnette et al., 2015)

[a] Are considered as subsequent versions of the original instrument.
[b] The MDS 3.0 is an updated version of RAI-MDS and RAI-MDS 2.0, however, it was not developed by the interRAI network.

items for the CPAT (Fleming, 2008).

The RAI-MDS inter-rater reliability improved with every updated version. Originally, reliability was reported to be fair to moderate for more than half of the items (Hawes et al., 1995; Morris et al., 1990), and for the core set of items of the RAI-MDS in several countries (Sgadari et al., 1997). For the revised items and 83% of the new items in version 2.0, good to excellent inter-rater reliability was reported (Morris et al., 1997b); for version 3.0, good to excellent inter-rater reliability was found for the majority of the new and modified items (Saliba and Buchanan, 2012). The latest version, the interRAI LTCF and its Korean version (Hirdes et al., 2008; Kim et al., 2015), reported good to excellent inter-rater reliability for more than 90% of the items, and an international study reported excellent average test-retest reliability and good average inter-rater reliability (Onder et al., 2012).

The reliability of domains was reported for the RAI-MDS (n = 1), and the J-CPAT (n = 1), and *for the items* of RAI-MDS and its subsequent version 2.0 (n = 3) (Table A.4). For the 16 studied domains of the RAI-MDS, inter-rater reliability was moderate for 11, good for one, and poor for four (Hawes et al., 1995). The inter-rater and test-retest reliability for the eight J-CPAT domains were reported to be in the adequate range (Kanegae et al., 2010).

For specific RAI-MDS items related to urinary incontinence, moderate to good inter-rater reliability was reported, except for one item that was reported as poor; excellent inter-rater reliability was found for identifying different gradations of incontinence (Resnick et al., 1996). Oral/dental items reported poor or none inter-rater reliability between nursing staff and dental assessment, except for one item reporting good inter-rater reliability (Jockusch et al., 2021). Excellent test-retest reliability was found for all RAI-MDS 2.0 pain items (Fisher et al., 2002).

Table 3
Number of domains included in the CGAs, number of studies using criterion measures, and number of criterion measures used for validation.

Care setting	Name of CGA	# of domains assessed by the CGA	# of studies that included criterion measures	# of criterion measures or gold standards used for validation
Long-term Care	RAI-MDS	15	14	37
	RAI-MDS 2.0	16	7	11
	MDS 3.0	16	2	2
	ValGraf	8	1	2
	CPAT	8	2	4
	interRAI LTCF	17	0	0
Community Care	CARE	3	0	0
	OARS-OMFAQ	5	1	4
	MAI	7	0	0
	Popovich Scale	4	1	2
	OASIS	4	2	5
	RAI-MDS HC	16	5	7
	interRAI HC	18	3	5
	CARI	3	0	0

Note: RAI = Resident Assessment Instrument; MDS = Minimum Data Set; ValGraf = Valutazione Grafica; CPAT = Care Planning Assessment Tool; LTCF = Long Term Care Facilities; CARE = Comprehensive Assessment and Referral Evaluation; OARS-OMFAQ = Older American's Resources and Services Multidimensional Functional Assessment Questionnaire; MAI = Philadelphia Geriatric Center Multilevel Assessment Instrument; OASIS = Outcome and Assessment Instrument Set; HC = Home Care; CARI = Community Assessment of Risk Instrument.

The reliability of scales from the RAI-MDS and subsequent versions (n = 8), and the CPAT (n = 1), *and for the indices* derived from the RAI-MDS (n = 2), was reported (Table A.5). From the eight scales of the CPAT, internal consistency was adequate for all, except for the Psychiatric Symptom Scale (Fleming, 2008).

Internal consistency was in the acceptable range for the following RAI-MDS and subsequent versions 2.0 and Korean interRAI LTCF scales: CPS, MDS-Cognition Scale (MDS-COGS), Challenging Behaviour Profile Scale (CBP) (except for one subscale), Communication, Pain and ADL (Gerritsen et al., 2008; Gruber-Baldini et al., 2000; Kim et al., 2015; Mor et al., 2011). The scales for Social Engagement, Mood, Behaviour, and Pain Scale did not reach acceptable levels for internal consistency (Mor et al., 2011). Internal consistency of the depression scales were reported as follow: insufficient for the DRS in the RAI-MDS 2.0, but acceptable in the RAI-MDS (Anderson et al., 2003; Hsiao et al., 2015), acceptable for the Depression Scale in the Korean interRAI LTCF (Kim et al., 2015), and for the composite depression measure (sum of all items in section E1, E1SUM) in version 2.0 (Koehler et al., 2005).

Inter-rater reliability was reported as excellent for all eight scales from the CPAT (Fleming, 2008). To screen dementia, the cut-off point 2 or higher of the MDS-COGS of the RAI-MDS showed high specificity, but lower sensitivity than cut-off point 1. For the cut-off point of 2, interrater and test-retest reliability for a negative screen was found to be high, but moderate for a positive screen (Zimmerman et al., 2007). For the CBP from the RAI-MDS 2.0, overall inter-rater reliability was reported as fair (Gerritsen et al., 2008). Poor to moderate test-retest reliability was shown for the DRS of RAI-MDS 2.0 (Anderson et al., 2003).

Only the reliability of indices from the RAI-MDS was studied, reporting good to excellent inter-rater reliability for seven indices (Casten et al., 1998), and an acceptable internal consistency for the Social Engagement Index (Mor et al., 1995).

3.5.2. Validity results

The validity of the complete CGA was only reported for the construct validity of the ValGraf, indicating that 52.9% of the variance was explained by 13 factors (Pascazio et al., 2009) (Table A.3).

The validity of domains was assessed for the RAI-MDS (n = 2), the CPAT (n = 1), and the ValGraf (n = 1), and *for the items* from the RAI-MDS and subsequent updated versions (n = 10) (Table A.4). Three studies of RAI-MDS and version 2.0 included samples with individuals with the characteristics of the conditions that were being validated, two of them determining the condition through previous medical diagnoses (Hendrix et al., 2003; Liang et al., 2011). Even though this was not specifically reported for the CPAT, the study sample included people from dementia and rehabilitation care settings (Kanegae et al., 2010). For the ValGraf this was not described.

The criterion validity for the RAI-MDS Behaviour and ADL domains reported medium to large effect sizes, also poor to fair agreement between RAI-MDS ADL assessments and the criterion measure (Lum et al., 2005; Snowden et al., 1999). For the CPAT Japanese version, the domains of Confusion, Self-help, Physical Problems, and Care dependency reported large effect sizes when compared against criterion scales (Kanegae et al., 2010). The concurrent validity for the Functional and Cognitive domains of the ValGraf reported large effect sizes (Pascazio et al., 2009).

Results from the validation of items from the RAI-MDS and subsequent updated versions reported difficulties on identifying their specific conditions. Risk of undernutrition and mood anxiety symptoms items from the RAI-MDS were found to underreport these conditions (Liang et al., 2011; Simmons et al., 2002). The same results have been reported for the mood indicators items from the RAI-MDS 2.0 (Hendrix et al., 2003). However, improvements in the validity of items on cognition, mood, behaviour and depression in version 3.0, and higher agreement with criterion measures as compared to the RAI-MDS 2.0 items, was reported (Saliba and Buchanan, 2012). Validity problems have been also reported for the oral/dental (Hoben et al., 2016; Jockusch et al., 2021), fall (Hill-Westmoreland and Gruber-Baldini, 2005), and pain items (Fisher et al., 2002) of the RAI-MDS 2.0.

Diagnostic accuracy for falls was in the acceptable range for only one of the two fall items (Hill-Westmoreland and Gruber-Baldini, 2005). Similar difficulties were described for the urinary tract infection (UTI) items (Stevenson et al., 2004).

Test content validity for the oral health section of the interRAI LTCF and interRAI HC was considered incomplete and items not clearly worded. Four items were considered as relevant, and two items were considered as feasible (Krausch-Hofmann et al., 2019).

The validity of scales was assessed for the CPAT (n = 1), and for the RAI-MDS and subsequent versions (n = 15), and *for the indices* from the RAI-MDS (n = 4) (Table A.5). The CPAT sample was selected from specific dementia care units, while for nine studies of the RAI-MDS and version 2.0 samples included individuals with the conditions determined before the study, four of them established by medical diagnoses (Anderson et al., 2003; Liang et al., 2011; Morris et al., 1994; Zimmerman et al., 2007).

The CPAT scales validated against criterion measures were Confusion and Self-help, which reported large effect sizes (Fleming, 2008). In the case of RAI-MDS and subsequent versions, all Cognition Scales (MDS-COGS, CPS, and Brief Interview for Mental Status), the Pain Scale, and two subscales of the CBP reported large effect sizes and good/-excellent agreement against criterion measures (Fries et al., 2001; Gerritsen et al., 2008; Gruber-Baldini et al., 2000; Hartmaier et al., 1994, 1995; Morris et al., 1994; Saliba et al., 2012). However, a medium effect size between the CPS and the Mini-Mental State Examination (MMSE) (Snowden et al., 1999), and a fair agreement between the CPS and the 7-item Global Deterioration Scale were described (Hartmaier et al., 1994). Small to medium effect sizes were found for the divergent validity from the MDS-COGS and the CPS (Gruber-Baldini et al., 2000).

The criterion validity for the DRS reported inconsistencies. One study reported a large correlation against the Geriatric Depression Scale-Short From (GDS-SF) (Hsiao et al., 2015), however, another study found some contradictory results using the same criterion measure (Liang et al., 2011). Also, the DRS did not correlate with standard measures or small to medium effect sizes as shown in two studies (Anderson et al., 2003),(Koehler et al., 2005).

Construct validity for the DRS and the CPS reported acceptable factor loadings, and the CPS also met the criteria for simplicity and face validity (Hsiao et al., 2015),(Morris et al., 1994). For the CBP, construct validity reported that it is formed by four subscales, and it was also identified as strong predictor of one year mortality (Gerritsen et al., 2008; Hsiao et al., 2015; Mor et al., 2011).

Regarding the diagnostic accuracy, AUC was excellent for CPS, MDS-COGS, and the Brief Interview for Mental Status (BIMS) (Hartmaier et al., 1994, 1995; Saliba et al., 2012), with the exception of one study that reported an insufficient AUC for the MDS-COGS (Zimmerman et al., 2007). The AUC for the DRS was also insufficient and for the Fracture Risk Scale not good (Hsiao et al., 2015; Ioannidis et al., 2017). These results are related to the Sensitivity and Specificity values reported for the different scales, which described high values for all Cognition Scales (Hartmaier et al., 1994, 1995; Morris et al., 1994; Saliba et al., 2012; Zimmerman et al., 2007), but inconsistencies and low values for the DRS that did not reach the expected minimum (Anderson et al., 2003; Hsiao et al., 2015). Also, it was identified that the DRS under detects the prevalence of depression compared to the GDS-SF (Hsiao et al., 2015).

For the RAI-MDS indices, large effect sizes were demonstrated for Cognition, ADL, Time Use and Social Engagement (Lawton et al., 1998; Mor et al., 1995), while medium and small correlations for Problem Behaviours and Depression when compared against criterion measures (Lawton et al., 1998). Discriminant validity was also demonstrated for all these indices (Lawton et al., 1998). Construct validity for Social engagement, Cognition, ADL and Time Use reported acceptable factor loadings, however, most factors failed to be replicated within a cognitive impaired sample (Casten et al., 1998; Mor et al., 1995). Lastly, Depression and Cognition were associated with the psychiatric diagnosis of depression and strongly with a dementia diagnosis, respectively (Lawton et al., 1998). Four models of mortality risk indices were validated, reporting that the Flacker models were more reliable predictors and better discriminators of mortality risk than the MDS-Mortality Risk indices (Kruse et al., 2010).

3.6. CGAs for community care

3.6.1. Reliability results

The reliability of the complete CGA was studied for the OASIS (n = 3), RAI-MDS HC and subsequent interRAI HC version (n = 5), and CARI (n = 1) (Table A.3). Two studies reported good to excellent inter-rater reliability for the OASIS (Hittle et al., 2004; Madigan and Fortinsky, 2004), nonetheless, in another study was reported poor to moderate inter-rater reliability for more than 60% of its items (Kinatukara et al., 2005).

Good to excellent inter-rater reliability has been reported for the RAI-MDS HC and interRAI HC in several countries (Hirdes et al., 2008; Kim et al., 2015; Kwan et al., 2000; Morris et al., 1997a). Data reliability reported inaccurate records in demographic and height or weight variables of the interRAI HC (Schluter et al., 2016).

Lastly, the majority of the items included in the CARI reported poor to fair inter-rater reliability (Clarnette et al., 2015).

The reliability of domains of the CARE, OASIS and CARI was targeted by three studies (Table A.4). For CARE domains, poor to excellent reliability was found, with the Psychiatric Dimension performing the best of the three domains (Gurland et al., 1977). OASIS domains internal consistency was within the acceptable range only for the functional domain (Madigan and Fortinsky, 2000), while intra-rater reliability was good to excellent for the affect and behavioural domains, and fair to good for the clinical and functional domains (Madigan and Fortinsky, 2000).

Inter-rater reliability of the CARI was poor to fair for their three domains and low agreement was reported for risk outcomes (Clarnette et al., 2015).

The reliability of scales or indices from the RAI-MDS HC and interRAI HC (n = 5), Popovich Scale (n = 1), OARS-OMFAQ (n = 1), and MAI (n = 1), were reported (Table A.5).

Internal consistency was studied for eight scales of the RAI-MDS HC Chinese version and six scales of the interRAI HC Korean version. Of the tested scales, the Pain, Communication, and Instrumental Activities of Daily Living (IADL) involvement and capacity Scales of both CGAs, and the Activities of Daily Living (ADL) and Depression Scales of the interRAI HC Korean version, reported internal consistency reliability withing acceptable ranges (Kim et al., 2015; Kwan et al., 2000; Leung et al., 2011, 2012). For all the scales of the Popovich Scale, inter-rater reliability reported large effect sizes (Grubba et al., 1990), while for the OARS-OMFAQ, it was good for the majority of the scales except for the Physical Health scale (Fillenbaum and Smyer, 1981).

Regarding the reliability of the indices, the Frailty Index of the RAI-MDS HC (Mor et al., 1995) and all indices of the MAI reported acceptable internal consistency (Lawton et al., 1982; Ludwig and Busnel, 2017)). Large effect sizes for test-retest reliability and moderate to good inter-rater reliability was also described for all scales of the MAI (Lawton et al., 1982).

3.6.2. Validity results

The validity of the complete CGA was reported only for the convergent validity of the OASIS (n = 1), indicating several inconsistencies between the OASIS and the criterion measure (Kinatukara et al., 2005) (Table A.3).

The validity of domains was studied for the OASIS (n = 2), and for the mortality data of the interRAI HC (n = 1), *and for the items* of the oral health section of the interRAI HC (n = 1) (Table A.4). When compared against gold standards, functional items of the OASIS reported medium to large effect sizes for the composite scores of ADL and IADL, large effect sizes were described for the cognitive functioning items, and moderate for the depressive symptoms items (Tullai-McGuinness et al., 2009). Regarding construct validity, only the functional domain reported adequate performance (Madigan and Fortinsky, 2000).

The criterion validity of the mortality data of the interRAI HC was reported to be consistent (Schluter et al., 2016). The test content validity of the oral health section was considered as incomplete and items not clearly worded; only four items were considered as relevant, and only two items were considered as feasible (Krausch-Hofmann et al., 2019).

The validity of scales was studied for the RAI-MDS HC and interRAI HC subsequent version (n = 7), OARS-OMFAQ (n = 2), and Popovich Scale (n = 1), and *for the indices* from the RAI-MDS HC (n = 3), and the MAI (n = 1) (Table A.5). The two studies validating the interRAI HC scales included samples with individuals diagnosed by the condition being assessed (Gee et al., 2021; Penny et al., 2016); for the other CGAs, this condition was not identified in their studies.

The criterion validity of the ADL, IADL, and Cognition Scales of the RAI-MDS HC reported large effect sizes (Carpenter et al., 2005; Landi et al., 2000). However, for the RAI-MDS HC Mood scale and the interRAI HC Depression Rating Scale (DRS), no correlation and a medium effect size were reported against the criterion measure, respectively (Carpenter et al., 2005; Penny et al., 2016). For the Economic, Mental Health, Physical Health, and Self-care capacity Scales of the OARS-OMFAQ and the Cognitive, Physical health and Social resources Subscales of the Popovich Scale, large effect sizes were reported (Fillenbaum and Smyer, 1981; Grubba et al., 1990).

Regarding content validity, RAI-MDS HC was reported to have higher data completion and better domain coverage compared to current used assessment instruments (Carpenter et al., 2005). Concerning construct validity, a good factorial structure was reported for the IADL involvement and capacity Scale and Negative Mood Scale of the RAI-MDS HC Chinese version (Leung et al., 2011, 2012). The OARS-OMFAQ Spanish version revealed a similar factor structure to the original English version, with some differences in the Self-care and Mental Health Scales (Fibla et al., 1996). For the Popovich Scale, the Economic Subscale construct validity was demonstrated (Grubba et al., 1990).

The diagnostic accuracy revealed excellent and inadequate Areas Under the Curve (AUCs) for the Cognitive Performance Scale (CPS) and the DRS of the interRAI HC, respectively (Gee et al., 2021; Penny et al., 2016). The sum between sensitivity and specificity reached the minimum expected value for the CPS but not for the DRS (Gee et al., 2021; Penny et al., 2016). In the case of the Changes in Health, End-stage disease, and Signs and Symptoms scale (CHESS), results showed it to be a strong predictor for hospitalization (Campitelli et al., 2016).

The Frailty Index of the RAI-MDS HC, was found as a strong predictor of mortality risk, admission to a long-term care facility, hospitalizations, and falls (Burn et al., 2018; Campitelli et al., 2016; Ludwig and Busnel, 2017). The studies on the seven indices from the MAI described large effect sizes for internal validity and concurrent validity, while small to large effect sizes for criterion validity for all indices with exception for the Cognition and Perceived Environment indices (Lawton et al., 1982).

3.7. Outcomes relevant for clinical decision making and organization of care

The RAI-MDS and subsequent version 2.0, interRAI-LTCF, and RAI-MDS HC and subsequent version also generate outcomes relevant for clinical decision making and organization of care. None of the other identified CGAs validated similar outcomes.

For *clinical decision making*, the Resident Assessment Protocols (RAPs) from the RAI-MDS reported reliable detection of two different urodynamic diagnosis (Resnick et al., 1996). In its Chinese version, four RAPs, Cognitive loss, ADL, Communication and Mood Symptoms, reported good concurrent validity and inter-rater and test-retest reliability (Chou et al., 2001). For the new version of the RAPs, the Clinical Assessment Protocols (CAPs) from the RAI-MDS HC, four of the 30 CAPs reported good to excellent validity, the remaining CAPs reported slight and fair agreements (Kwan et al., 2000).

RAI-MDS triggers for the detection of undernutrition were validated (Beck et al., 2001). They reported those triggers to be able to identify relevant characteristics of this condition in comparisons with those participants with no triggers (Beck et al., 2001).

For *organization of care*, the Resource Utilization Groups (RUG-III) from the RAI-MDS reported to be able to differentiate between residents according to intensity of care needs, validating RUGs with the level of Registered General Nurses care time (Carpenter et al., 2003). The Finish version of the RUG-III for version 2.0, explained 38.2% of the variance of total patient cost per diem; also, they found an ambiguity in terms of the inter-rater reliability as it varied from fair to good according to the type of professionals, agreement was slightly better when assessors were personal nurses, as compared to personal nurse and outsider evaluator (Björkgren et al., 1999). For the interRAI HC version, good convergent validity with the Resource Utilization in Dementia instrument (RUD-Lite) (Wimo et al., 1998) for the estimations of societal costs of care (including healthcare and nursing, welfare and informal care) derived from interRAI-HC data was reported (van Lier et al., 2016).

Applicable for quality improvement and benchmarking purposes, the 22 Quality Indicators (QIs) from the RAI-MDS 2.0 reported fair to excellent inter-rater reliability, except for two (Mor et al., 2003). Except for three of the 100 single items used for measuring the quality indicators, good to excellent inter-rater reliability was reported for all (Mor et al., 2003). In addition, the content validity of the QIs reported pressure ulcers as the most practice sensitive QI; variations were found between the QIs considered as most sensitive for physician and nursing care, while none of them were considered to be most sensitive for policy/decision makers (Estabrooks et al., 2013).

Lastly, the accuracy of the RAI-MDS in identifying hospitalization events and payment sources was evaluated, reporting that the RAI-MDS is not ideal for the identification of these elements without the support of supplemental information from claims data (Cai et al., 2011).

4. Discussion

This systematic review aimed to provide insight into the content and psychometric characteristics of CGAs to enable potential users to make an informed decision when a CGA is considered to be implemented.

We found that some of the CGAs included broad domains which makes it difficult to identify what they are specifically assessing. On the contrary, other assessments were more specific or clearer by referring and evaluating the domains in more detail. We consider it necessary to be more specific on the domains as these are screening tools that could identify risk factors for potential deterioration and take into account the complexity associated with older adult care, which is associated with comorbidity, polypharmacy, multiple treatments, etc., and could guide clinical decision making and interventions (Bernabei et al., 2008; World Health Organization, 2015; Scanlan, 2005), so if the information is clear, and the dimensions and warnings are well defined, the relevant clinical information will be gathered by the clinicians. This approach also allows to compare how comprehensive a CGA is against proposed lists of domains that are considered relevant to be evaluated by a CGA (Pilotto et al., 2017; British Geriatrics Society, 2019) and could facilitate the clinicians and policy makers decision on which instruments are more suitable for their specific situation and aim.

By acknowledging the comprehensiveness of the CGAs, a big amount of data could be gathered supporting improvements and developments of algorithms that could be used to incorporate automatic learning to extract and identify useful information through large databases (Dipnall et al., 2016). Consequently, this could guide the development of decision models for medical and care procedures, such as prognosis, diagnosis, and treatment planning, which should be embedded into CGAs as systematic support components (Góngora et al., 2018), optimizing personalized treatments and improving evidence-based decisions making among clinicians and scientists, identifying the causes of unmet care of older adults and more effective treatment approaches (Góngora et al., 2018).

The most studied instruments for long term care were the RAI-MDS and its subsequent versions, and for community care were the RAI-MDS HC and subsequent version, and OASIS. The RAI-MDS and RAI-MDS HC and their subsequent versions have been studied, validated, and adapted globally. Only the CPAT and OARS-OMFAQ were adapted for other non-English speaking countries, but not reaching the global covering of the interRAI network instruments. Another distinguishing feature was that interRAI instruments used specific population samples clinical characteristics (e.g., depression, cognition, dementia) necessarily to validate the outcomes of interest.

Although the number of studies and psychometric results positively support the RAI-MDS and subsequent versions for its used in long-term care facilities as compared to the other identified CGAs, some considerations must be made. Its reliability improved along the evolution to the next versions, reporting good to excellent results in the later stages. Overall, the main strengths rely on the psychometric characteristics of the Cognition, ADL, Time Use, and CBP items, and the outcomes relevant for clinical decision making and organization of care (e.g., RAPs and RUG III); however, flaws remain on items such as oral/dental problems, risk of undernutrition, urinary tract infection, and depression and mood.

For community care, the difference on the number of studies validating the CGAs was not as vast as for long-term care settings, and the psychometric characteristics appear to achieve high standards for all, except for the CARI and the CARE. However, some considerations must be contemplated: a) The CARE, the CARI, the MAI and the OARS-OMFAQ were not reported to be validated against gold standards or criterion measures; b) the CARE, the CARI, the Popovich Scale, the OASIS, and the OARS-OMFAQ were studied with suboptimal study designs, using small samples; c) items of the scales of the Popovich Scale and OASIS were validated against OARS-OMFAQ scales as the criterion measure, for which strong psychometric evidence is not available; d) inconsistency was revealed on the validation and reliability of the OASIS, some studies reported high values but this was not confirmed by other studies; and e) the RAI-MDS HC and subsequent version reported similar flaws to the aforementioned for the RAI-MDS and subsequent versions on areas such as mood and depression and the oral health section.

In this review mainly studies performed in high income countries have been included. Studies on CGAs performed in low to middle income countries, such as African, Southeast Asian, and Latin-American countries have not been found, despite Spanish language was one of the inclusion criteria. This might imply that in these regions, where health systems are not optimally developed, an integrated care approach towards ageing has not been implemented yet, despite that these regions are also confronted with an ageing population (Prina et al., 2019).

4.1. Strengths and limitations

The strength of this review relies on reporting on a comprehensive panorama of the CGAs available for long-term and community care, with insights on the psychometric properties, the content, and the variety of instruments. The results presented here support reliable decision-making on care planning and health policy outcomes, impacting the vulnerable older adult population that live in these care settings.

Several limitations regarding this systematic review must be considered. First, our definition of a CGA encompassed single multidisciplinary assessment instruments targeting different domains, not a conglomerate of single domain instruments assessing each area individually or those developed for being used for one single discipline. Therefore, a number of CGAs used in practice might not be included in our results. This definition of a CGA might be closer to the integrated care approach proposed at the introduction (Johri et al., 2003; McDonald et al., 2013; World Health Organization, 2015), which focusses on the facilitation of data sharing across care settings, offering a core set of items avoiding different score systems, and thereby facilitating an easy transfer between care settings. Second, several statistical methods and strategies were used to assess the psychometric characteristics, however we proposed a single criterion to report, compare and analyse these results. Also, we only used specificity, sensitivity, and AUC regarding diagnostic accuracy. Third, CGAs in other languages than English and Spanish were not considered. Finally, some of the study designs and types of validity and reliability presented at the tables are according to the researchers' judgements as they were underreported by some of the studies.

5. Conclusion

The timely detection of clinical problems, side effects or comorbidity is strategic for a good quality care, so, it is highly relevant to considered reliable tools with clear and specific domains to support clinical decisions.

Due to the study characteristics such as the sample size, number of studies, instrument development trajectory, validation in several countries, and availability in different care settings, we recommend the interRAI LTCF and interRAI HC to be used for long-term care facilities and community care, respectively. Also, it has been demonstrated their potential for predicting mortality, hospitalizations, admission, urinary infections, and detecting cognitive problems, falls, and nutritional risk factors. Nonetheless, health care professionals must be aware of the flaws reported for mood, depression, oral health, risk of undernutrition, and urinary tract infection.

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CRediT authorship contribution statement

MMU, HR, and MF conceptualized and designed the review. MMU and AM screened the titles and abstracts of the records resulted from the search. MMU and AM evaluated the records for risk of bias. MMU extracted the data from the included studies, and it was verified by HR. MMU, HR, and MF drafted and critically revised the manuscript. HR and MF provided overall study supervision. All authors authorized the final version of the manuscript that was submitted. All authors read and approved the final manuscript.

Conflict of interest

MF and HR are fellows of interRAI Network (www.interRAI.org). HR is a co-author in one of the studies included in this review, however, she was not involved in the risk of bias assessment, which was performed independently by MMU and AM.

Data availability

No data was used for the research described in the article.

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Not applicable.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.arr.2022.101742.

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Bridging gaps in the design and implementation of socially assistive technologies for dementia care: the role of occupational therapy

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ABSTRACT

Dementia is a global health challenge, and people living with dementia (PLWD) are especially susceptible to reduced engagement in meaningful occupations, including social participation. In the past few decades, socially assistive technologies continue to be developed amidst a rapidly evolving technological landscape to support the social health of PLWD and their caregivers. Examples include social robots, virtual reality, smart home technology, and various digital technologies, such as mobile applications for tablets and smartphones. Despite an increasing body of research and interest in this field, several gaps relating to the design and implementation process of socially assistive technologies continue to undermine their relevance for PLWD in daily life. In this paper, some of these gaps are highlighted and the role of occupational therapy in the design and implementation of socially assistive technology is presented. In the design process, occupational therapists are uniquely skilled to advise and advocate for the tailoring and personalisation of technology to address the occupational needs of PLWD. In the implementation of socially assistive technologies, occupational therapists are skilled to educate, train, and conduct ongoing evaluations with PLWD and their caregivers, to incorporate socially assistive technologies into their routine and daily lives. We recommend that occupational therapists should continue to be acquainted with such technologies through continuous professional development and educational curricula. Moreover, we highlight the necessary collaboration between occupational therapists, technology developers, and researchers to enhance the process of designing and implementing socially assistive technology, so that their relevance for PLWD and their caregivers can be maximised.

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➤ **IMPLICATIONS FOR REHABILITATION**

- Developers and designers of socially assistive technology should consider the disease trajectory of different types of dementia, as well as the different needs, abilities, preferences, occupations and routines of people living with dementia (PLWD) and/or their caregivers.
- Collaborations between technology developers, researchers, and occupational therapists should take place iteratively throughout the process of designing and implementing socially assistive technology to maximise their relevance and applicability for people living with dementia and their caregivers.
- To continue enhancing the current role of occupational therapy in socially assistive technology provision, occupational therapists should keep up to date with socially assistive technology that are being developed to support the social health of PLWD.

Introduction

Dementia is expected to affect 152 million people worldwide by 2050 and has been highlighted as a global health priority by the World Health Organisation [1]. It is characterised by a decline in one or more cognitive domains, which include complex attention, executive functioning, learning, memory, language, perceptual skills, and social cognition [2]. While there are different types of dementia, most are progressive in nature. During the prodromal stage, people living with dementia (PLWD) may continue to live independently with or without support [3]. Cognitive and functional decline, as well as behavioural changes, often become more apparent through the moderate and advanced stages of dementia [4]. Such decline may limit their ability to engage in meaningful occupations, which are defined as the things that people need to, want to, and are expected to do in their everyday lives [5]. PLWD often experience reduced meaningful social engagement, leading to loneliness and social isolation as the disease progresses [6]. However, being engaged in personally meaningful social activities, such as meeting friends and family, is an important determinant of successful adaptation and ageing whilst living with a chronic disease [7,8], including dementia. Furthermore, successful engagement in meaningful social activities can result in reduced responsive behaviours such as

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agitation, shadowing, and repetitive questioning [9,10]; provide a feeling of connectedness with self, others, and the environment; and promote life satisfaction and quality of life for PLWD [6,8].

Technology plays a relevant role in supporting individuals to live well with dementia [11]. Over the last few decades, there has been a growing body of research that focussed on developing and evaluating assistive technology (AT) for PLWD [12–14]. The COVID-19 pandemic has further accelerated the research on and the use of AT, which has been paramount in enhancing the social health of PLWD during periods of social distancing restrictions [15,16]. Assistive technology may be defined as "any item that enables a person with a disability to complete a task that they would otherwise be unable to do" [17,p.525]. AT can range from everyday technology such as alarm clocks and telephones, to information and communication technology [18]. However, we will focus specifically on socially assistive technology. In this paper, we define socially assistive technology as AT that is specifically designed for and/or used to promote social health among PLWD by enhancing their capacities to 1) fulfil their potential and obligations, 2) manage life with some degree of independence, and 3) participate in social activities [7,19].

Recent evidence shows that different types of socially assistive technology have been used to enhance the social health of PLWD [20–22]. Everyday technology, such as mobile phones, has been increasingly leveraged as digital medium for a myriad of applications to benefit the social health of PLWD [20,21,23]. Common examples include *Skype* and *Zoom*, which have been used to enhance social connections [24,25]. With continued digitalisation, robotics, virtual reality (VR) and smart home technology also have emerged as novel technologies to support PLWD to engage in different social activities [26,27]. Despite the growing interest in this field, a recent scoping review has highlighted several factors which hindered the application and adoption of socially assistive technology in daily life [27]. Pertinent issues relate to their design and implementation processes, which can limit their relevance for PLWD and uptake in their daily life. Furthermore, the use of socially assistive technology for PLWD can be a double-edged sword. While it is intended to enhance social connections and productivity, it can also simultaneously isolate or alienate the intended users [11] if used improperly, or designed without considering the (current and changing) functional capacities and needs of PLWD and their caregivers. Therefore, it is important to reflect on the gaps in the design and implementation of socially assistive technologies and suggest considerations for practice that will enhance their adoption.

Occupational therapy

Occupational therapy is a healthcare profession that is uniquely positioned to promote engagement in meaningful occupations, and to enhance the social health of PLWD through 1) supporting the maintenance and remediation of their skills and abilities; and 2) modifying their activities or environment [28]. Occupational therapy is the leading healthcare profession in the prescription and provision of AT, as evidenced by findings of an international survey that involved participants from 52 countries [29]. Occupational therapists work with a wide range of population, including children [30] and adults with disabilities [31], older adults [32], and individuals with chronic health conditions such as dementia [33]. One of the key roles of occupational therapists entails assessing, prescribing, educating, and training individuals and their family members to use AT in their daily lives [33–35]. This has played an important role in equipping users with the relevant skills and confidence to use AT and reducing the likelihood of technology abandonment [36]. For instance, in Ireland, occupational therapists lead Memory Technology Resource Rooms to educate, support and prescribe AT for PLWD and their care partners. Similar services are available in other countries, such as the UK [37] and Australia [38].

The current role of occupational therapy lies mostly in the provision of AT that aims to enhance physical or cognitive health [29]. As such, it is a logical extension for occupational therapists to familiarise with and be more involved in AT to enhance social health, a (relatively) newer field of technology development. This will position occupational therapists in a better stead to introduce such technology to PLWD. In similar regard, information about the knowledge and expertise of occupational therapists should be actively disseminated to technology developers and researchers, to raise awareness of the role of occupational therapy in the design and implementation of socially assistive technology, and to advocate for the inclusion of occupational therapists in these processes.

The primary objective of this paper is to propose practicable considerations for bridging pertinent gaps relating to the design and implementation of socially assistive technology for PLWD and their caregivers from an occupational therapy lens, and to highlight the necessary collaboration between occupational therapists, technology developers and researchers. Firstly, a brief overview of socially assistive technology will be presented. These examples include social robots, digital technologies, virtual reality, and smart home technology. Each technology will be described, along with the current state of evidence on their impacts on social health. Next, current gaps and limitations to their design and implementation will be highlighted. Finally, practical considerations for addressing these gaps will be proposed, based on literature supplemented with the authors' clinical and professional expertise. The authors comprise a panel of experienced and internationally diverse occupational therapy clinicians, researchers, and educators from the 1) Dementia: Intersectoral Strategy for Training and Innovation Network for Current Technology (DISTINCT) consortium, which focuses on conducting research on using technology to support the social health of PLWD; 2) the Science Foundation Ireland (SFI) Centre for Research Training in Digitally Enhanced Reality (D-Real), which focuses on research involving the use of digital technology; and 3) the Division of Occupational Therapy at Karolinska Institutet, Sweden.

Socially assistive technologies and their impacts

Social robots

Social robots are developed to facilitate and maintain social networks between people, reduce social isolation, and provide an array of services for PLWD, such as cognitive training and affective therapy [39]. Social robots may be categorised as socially assistive, telepresence, or pet robots based on their functions [27]. Socially assistive robots have several functions alongside their function to enhance social networks, such as providing medication reminders. Examples of such robots include *Nao* and *Pepper*, which have been used across different dementia care settings [40,41]. Next, telepresence robots incorporate a video conferencing platform to facilitate and maintain social interaction. Examples of telepresence robots include *Giraff* and *Double*, which have been used in countries such as Australia and Finland [42,43]. Finally, pet robots are designed to resemble and behave like pets. They are intended as substitutes for live animals to provide physiological and emotional benefits for people with dementia [44]. Examples include *PARO* (seal), *JustoCat* (cat), *AIBO* (dog robot), and *Pleo* (dinosaur). Several studies have been conducted to investigate the impact of the aforementioned social robots on PLWD. Synthesised findings suggest that social robots had positive impacts on the psychosocial domains of older adults - including PLWD - such as reducing loneliness, and enhancing social engagement interaction [44–46].

Digital technology and virtual reality

Several phone- and tablet-based interventions continue to be developed, refined, and/or evaluated for PLWD and their caregivers to promote their social health [20,21]. Some examples include *Photoscope*, a digital person-centered artistic photo-activity to enhance the social interaction between PLWD in long-term care facilities and their informal caregivers [47], and *I-CARE*, a tablet-based system to enhance the dyadic relationships between community-dwelling PLWD and their informal caregivers [48]. Other examples of digital technology interventions that leverage more established technology platforms include digital gaming technologies, such as exergames [49] or games using iPads, Nintendo Wii, and Nintendo DS [15]. Findings from recent systematic reviews suggest that such digital technologies show promise in enhancing social participation and social support, and reducing social isolation and loneliness among PLWD [20,21]. They also show potential in enhancing social interaction between PLWD and their (informal) caregivers [15,47–49] and support engagement in meaningful social activities [48,50].

Virtual reality (VR) is a novel technology involving a "computer-simulated real or imagined environment that enables users to experience the sensation of being present in a different physical place" [51,p. 558]. VR provides a unique, novel, and safe virtual world for PLWD to participate in meaningful or reminiscent activities including social activities [52] that may be difficult for PLWD and their caregivers in daily life, due to physical or logistical difficulties. VR may be conducted individually or in a group-based setting to increase opportunities for social interaction, socialisation, and social engagement [53,54]. A qualitative evidence synthesis on PLWD's experiences and perceptions of using VR revealed that it can provide a means of unlocking the PLWD's connections with formal, informal caregivers and peers [26]. Sociability outcomes were reported when using VR with others and resulted in sustained sociability where the PLWD reflected on the experience and anticipated subsequent use with peers [26].

Smart home technology

Smart home technology broadly refers to the connection and automation of appliances and devices within a home environment *via* the internet. This connectivity of devices *via* the internet – known as the Internet of Things [55] - uses sensors to monitor and effect change to enhance individuals' experiences of living at home. In the context of dementia, smart home technology has been designed and used to monitor, support and maximise independent living abilities, and to support social connections [56–58]. Some examples include *Amazon Echo* and *Alexa* which are available off-the-shelf, the *Rosetta* [59], and *Dem@Care* systems [60], which are more recently developed (or being developed) for PLWD and their caregivers. A recent review showed that while only a handful of studies have been conducted to evaluate their effectiveness on PLWD [61], there is some evidence of positive impact on performance in activities of daily living, amongst other health outcomes such as depression and anxiety.

Existing knowledge gaps and considerations for practice

> To be leaders, we (occupational therapists) can bring our expertise and understanding of meaningful human occupation into the discourse, design, and implementation of technologies [62,p. 281].

Designing socially assistive technology

Despite their potential, there are several gaps and challenges to the design of these socially assistive technologies. A recent scoping review outlined several barriers related to the design features of such technologies for older adults and PLWD such as complex user interfaces and unclear or unpredictable actions [27]. Technology developers play a crucial role in designing technologies for PLWD. However, due to a different disciplinary focus, they do not often have experience working with PLWD and use other models than social and humanistic models and frameworks to guide their design process [33]. This could lead to the omission of design features that are integral for supporting PLWD and their caregivers [63]. For instance, in a pilot study by Barrett and colleagues [64], PLWD experienced difficulties using a socially assistive robot, as the user interface required PLWD to raise their arms to access the touchscreen from a seated position. This physical movement proved to be physically challenging, as the older population often experiences frailty [65]. In turn, caregivers had to provide support to overcome such challenges [64]. Given that a key driver behind the development of such technologies is to alleviate care provision, it is ironic that caregivers have to provide additional support to PLWD to account for such design limitations. Moreover, the functions of socially assistive technologies do not always align with the occupational needs of PLWD [26,27,66,67]. For instance, in a study by Orejana *et al* [68], users were provided with a socially assistive robot to support them in different aspects of daily life, such as providing medication reminders and providing entertainment. However, some of these features were not relevant as the users were still capable of self-management. This highlights that personalising and tailoring the functions of socially assistive technologies to the individual abilities, needs, and fluctuating emotions of PWLD, remains a pertinent technology development gap [69].

While strides have been made to include healthcare professionals, such as nurses and medical staff, in the development and research on technology, technology developers appear to be unaware of the role, expertise, and impact of occupational therapists in assistive technology provision for PLWD [70]. Although other healthcare disciplines have parallels in terms of their positionality and philosophy of care, the occupational therapy profession can offer a unique, occupation-focussed perspective. Occupational therapists work closely with PLWD and their caregivers to assess and design interventions, including AT prescription, to support their participation in meaningful (and social) occupations. Assessments are often guided by occupational therapy conceptual models, which serve as frame of references to gain a holistic understanding about an individual [71]. For instance, the Person-Environment-Occupation (PEO) model [72] guides comprehensive considerations about the person with dementia (e.g., personal values, physical, cognitive, and social abilities), their environment (e.g., their physical, institutional and social environments, such the extent of support from caregivers), their occupations (e.g., daily routines), and how each may evolve over the life trajectory. Another example is the Human Activity Assistive Technology (HAAT) model that is often used to guide assessments of the dynamic interactions considering the person, the activity (i.e., occupations), the context (i.e., environment) and the assistive technology (i.e., environment) [73].

While important, an occupation-focussed perspective is not always taken into account when designing socially assistive technology for PLWD. As dementia progresses, the types of occupations that an individual and their caregivers engage in often change due to diminishing abilities [74]. However, there has been insufficient consideration about this aspect of dementia during the design process, which has led to technology abandonment by PLWD and their caregivers [75]. By the same note, while a familiar and predictable life routine has a profound influence on the function of PLWD [76], considerations about how the technology can be designed to align with the daily routines of PLWD and their caregivers are often precluded from the design process [77]. Rather, they are expected to "fit" the AT in their lives [13]. The findings from an ethnographic study describing the use of smart home technology with PLWD and their caregivers exemplify the abovementioned points [78]. In the study, an individual with dementia had to don a wearable device which was unfamiliar to her and her routine, which led to infrequent use. Using the technology also required the individual to activate a device, a task that warrants several cognitive functions such as attention and working memory – which decline as part of the disease trajectory. In turn, her caregiver had to request an alternative wearable device, and "remind" her to use it. These omissions highlight the importance of integrating occupational therapy expertise to address pertinent gaps in the design of socially assistive technologies. Activity analysis is a core occupational therapy skillset involving thorough analysis of the demands of an activity and identifying the necessary skills for activity engagement [79]. In the context of socially assistive technologies, activity analysis may address important design features, such as user interfaces, that cater to the abilities and daily needs of PLWD.

Implementing socially assistive technology

Implementing a technology refers to putting it to use in practice in daily lives. Even though technology may prove to be effective for people with dementia in a research study, successful implementation in daily life goes beyond research evidence that demonstrates their effectiveness [27]. Similar to the gaps highlighted in the technology design process, the mismatch between the socially assistive technology and the dynamic needs (i.e., existing and changing needs) of PLWD and their caregivers have challenged their uptake. Previous studies have highlighted this as an important predictor of AT abandonment [80–82]. Insufficient facilitation, knowledge, and training to support PLWD and their caregivers to integrate AT into their daily routines have also challenged implementation efforts [12]. For instance, Gibson *et al.* [18] found that family members were unclear about when technology should be introduced to PLWD. In another study, Chang and colleagues [83] found that users had poor engagement with a social robot in a group setting without facilitation by a therapist.

Deliberate efforts must be made to bridge these gaps to enhance their implementation. Like the role of occupational therapy in the provision of other ATs, occupational therapists should be consulted to identify and match the "right" socially assistive technology to the "right" individuals (i.e., PLWD and/or their caregivers). This will involve discussions to identify activities that are meaningful to PLWD and/or their caregivers, assessing the functional capacities of PLWD, and assess the ability of the AT to address their dynamic social needs and wants [9,10,84–86]. These considerations may inform the prescription of socially assistive technology and supporting interventions, to empower PLWD and their caregivers to engage meaningfully with the technology. In consideration of the progressive nature of dementia, it is also necessary to factor in regular re-assessments of the needs and abilities of PLWD and their caregivers [87]. While these constitute key elements of current occupational therapy practice – given a rapidly evolving technological landscape – occupational therapists should actively acquaint themselves with evolving and emerging socially assistive technology to ensure that they are well-informed to advise on suitable and desirable AT for PLWD and their caregivers.

Thereafter, formal and/or informal caregivers should be coached to support PLWD through problem-solving, identifying, and simplifying steps required to use and embed the socially assistive technology in their daily lives [88,89]. These are important strategies to enhance PLWD's abilities to participate in activities [88]. Such interventions may encompass the use of strengths-based approaches [90], caregiver training, activity gradation and modifications [88], and other cognitive strategies such as a combination of errorless learning and spaced retrieval [91,92].

When implementing socially assistive technology in a group-based setting, for example in a day-care or residential setting, it is also necessary to carefully consider group dynamics [93], such as the attributes of PLWD who are participating, group size, and the similarities or differences in their values or abilities. Correspondingly, skilled facilitation is necessary to enhance group processes [93,94], to ensure that PLWD can engage meaningfully with the socially assistive technology in the group setting. In one study, group facilitation techniques supported older adults' engagement with a social robot [83]. These group facilitation techniques included carefully tailoring the social and physical environment to the older adults' abilities. Occupational therapy clinicians and trained occupational therapy assistants can contribute to this gap by tailoring and facilitating group-based use of socially assistive technology, or by training other healthcare professionals to facilitate group-based use of socially assistive technology.

Discussion

We provided an overview of socially assistive technologies that have been (and are being) developed to benefit the social health of PLWD, such as social robots, digital technologies, virtual reality, and smart home technology. Although more controlled studies with larger sample sizes and more rigorous designs are needed, several studies highlight their promise [20,21,26]. We also identified several gaps in their design and implementation and discussed ways in which the unique skills of occupational therapists, and their focus on PLWD and their caregivers' daily lives and occupational engagement, could be used to bridge these gaps.

Given that engagement with AT by PLWD is potentially a transformative, health-promoting occupation in itself, as well as the means by which PLWD may influence their own health, it is incumbent on the profession of occupational therapy to contribute its theoretical and practice expertise to this emerging aspect of health and social care. Occupational therapy "enablement skills" of adapting, advocating, coaching, collaborating, consulting, coordinating, designing/building, educating, engaging, and specialising [95] would all be called upon in various ways at various stages along the design to implementation pathway. At the design phase, collaboration and consultation with interdisciplinary teams, including occupational therapists, can improve the design of adaptive interfaces and functionality to meet the (changing) needs of PLWD and their caregivers. This approach could further support the development of participatory and co-design methodologies. At the implementation phase, occupational therapists' skills in educating and coaching

Table 1. Recommendations to enhance the design and implementation of socially assistive technologies.

A) Designing socially assistive technology	
Gaps	*Considerations for bridging the gaps*
1. **Not considering (and anticipating) the current and evolving needs, preferences, abilities, and occupational preferences of PLWD and their caregivers** Dementia is progressive; this means that the abilities of PLWD to engage in their day-to-day routines can change over time. Correspondingly, their needs and ability of PLWD and their caregivers to interact with and use the technology can also evolve rapidly. 2. **Not aligning the function of socially assistive technology with the occupational needs of PLWD and their caregivers** Each individual and their caregiver may have different needs and preferences. Therefore, a tailored approach to technology development is needed. 3. **Not aligning socially assistive technology with the daily (and familiar) routines of PLWD and their caregivers** Familiar routines are important for PLWD (and their caregivers), as such considerations about how technology can be designed to align with the routine of PLWD and their caregivers have to be made explicit.	• Technology developers and occupational therapists (researchers, educators, and/or clinicians) could reach out to each other to collaborate in the (iterative) process of designing technology. The outreach may be done through clinical services or national representative organisations for the occupational therapy profession. • Technology developers and researchers could consider the disease trajectory of different dementias, and understand the implications on the functional abilities and needs of PLWD and their caregivers. • Technology developers and researchers could consult with occupational therapists who have knowledge of holistic and occupation-based models to enhance the comprehensiveness of considerations for technology design in relation to PLWD and their occupations. Examples include the Person-Environment-Occupation (PEO) model and the Human Activity Assistive Technology (HAAT) model. • Occupational therapists could engage in professional development and further education to keep up to date with emerging technology and advocate for active occupational therapy involvement. • Educators could consider educating about socially assistive technology within the occupational therapy educational and professional development curriculum.
B) Implementing socially assistive technology	
Gaps	*Considerations for bridging the gaps*
1. **Not facilitating PLWD and their caregivers to choose the "right" socially assistive technology** Different socially assistive technology may suit different PLWD and their caregivers, depending on their unique preferences and needs. For example, a socially assistive technology with medication reminder functions may not as relevant or appropriate for PLWD in residential facilities, or for caregivers who are keen to support PLWD in medications without technology. 2. **Not facilitating and training to support PLWD and their caregivers to integrate socially assistive technology into their daily routines** Routines are important for PLWD. There is an insufficient focus on how the technology can be integrated into the daily lives of PLWD and their caregivers. 3. **Not facilitating the use of socially assistive technology in dementia care facilities** In dementia care facilities, the use of technology may occur in a group setting.	• Technology developers and researchers could consider establishing a relationship with national assistive technology clinics and services to inform clinicians about emerging technologies, to support the uptake of these technologies by PLWD and their caregivers. • Occupational therapists could consider: (i) collaborating with technology developers and researchers to design comprehensive assessments to match and to tailor the socially assistive technology to PLWD and their caregivers, and (ii) developing a clear intervention plan to train and equip them with the skills and confidence to use the technology in their daily lives. • Occupational therapists and service providers (e.g., assistive technology clinics and providers) could factor in regular re-assessments of the changing needs and diminishing abilities of PLWD and their caregivers to determine the suitability of the socially assistive technology over time. • Service providers (e.g., healthcare providers, dementia care facilities) could work with occupational therapists to design and facilitate the use of socially assistive technology in shared/group-based settings. An example includes group-facilitation techniques.

users, designing and coordinating programmes, consulting with health systems, and advocating at the policy level could improve the adoption, engagement, and spread of socially assistive technologies in the everyday life of PLWD and their caregivers [96]. Examples of such initiatives may include the development of targeted educational and training materials that are tailored to PLWD and their caregivers, care providers, and health systems.

Despite the rapid technological advancements in socially assistive technology intended to enhance the social health of PLWD and their caregivers, such technologies have ironically not become a part of mainstream dementia care. They have not been widely adopted by healthcare professionals, including occupational therapists. Despite having a well-established role in traditional AT provision, occupational therapists seem to be less informed of socially assistive technologies that continue to be developed, and their potential to influence the social health of PWLD [33,69]. Therefore, alongside efforts that should be made to involve occupational therapists in the design and implementation of socially assistive technology, efforts should also be made to move socially assistive technology into clinical practice and the education curriculum for the next generation of healthcare professionals, including occupational therapy clinicians. Subsequently, strategies at the education and post-qualification level should be developed to sustain this movement. Including contextualised learning in education curricula for healthcare professionals, such as the use of simulation [97], could be one strategy to ensure readiness for using socially assistive technologies in practice.

We also echo calls from the Human-Computer Interaction (HCI) research community to embrace interdisciplinarity for the benefit of end-users. Occupational therapists, like HCI researchers and other healthcare professionals, share an obligation to aim for the highest ethical standards in research and practice. These collaborative actions we propose here could have far-reaching implications in terms of improving digital equity and occupational justice; PLWD should have the rights and opportunities to leverage on socially assistive technology to support their engagement in meaningful occupations [98]. Therefore, we encourage both occupational therapy and HCI practitioners to reach out to each other to avoid this blind spot and to work together collaboratively in this mutual endeavour. Occupational therapists specialising in roles as dementia researchers themselves could be most effective in bridging the gap between the two communities of HCI researchers and behavioural scientists with an occupational therapy background. Furthermore, we recognise the need to include people with dementia and their caregivers in the development of technology for PLWD and related research as experts by experience. In recent studies, people with dementia expressed the wish to participate in research regarding interventions and technologies addressing their social health [69,99]. Moreover, involving PLWD in the development of supportive technology has been shown to facilitate the personalisation of functions to end-users [100,101].

Recommendations

We have highlighted several gaps in the current design and implementation of socially assistive technologies for PLWD, and have suggested considerations for practice based on our expertise as occupational therapists and researchers in the field of using technology to improve the social health of PLWD supported by the literature. A summary of the considerations that are relevant for technology developers, HCI practitioners, occupational therapists, and other professions included in the design and implementation of socially assistive technologies for PLWD, can be found in Table 1. These occupations-based considerations are important steps that could bridge pertinent gaps in existing design and implementation processes, and maximise the relevance of socially assistive technology for PLWD and their caregivers.

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The Effectiveness of GRADIOR: A Neuropsychological Rehabilitation Program for People with Mild Cognitive Impairment and Mild Dementia. Results of a Randomized Controlled Trial After 4 and 12 Months of Treatment

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Abstract.
Background: Computer-based cognitive training programs have been developed with promising results on the maintenance/improvement of cognitive performance in people with dementia.
Objective: The objective was to evaluate the effectiveness of the cognitive rehabilitation program "GRADIOR" in people with mild cognitive impairment and mild dementia.
Method: This study was a single-blind multicenter randomized clinical trial. Participants were recruited from hospitals/day centers. The experimental group (EG) and control group (CG) received computer-based cognitive training (CCT) and routine daily care, respectively. Outcome measures at T_0: baseline, T_1: at 4 months, T_2: at 12 months were compared within and between-groups.

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Results: Significant differences or important effect sizes were detected at the intragroup and intergroup level for most variables, observing a trend of improvement and/or maintenance at 4 months by Visual Reasoning of Cambridge Cognitive Examination (CAMCOG), Digit and Arithmetic of WAIS-III, Semantic Verbal Fluency, Mini-Mental State Exam (MMSE), Trail Making Test (TMT)-A-Mistakes and at 12 months by Visual Reasoning of CAMCOG, Digit Symbol of WAIS-III, TMT-B-mistakes, Visual Memory of Rivermead Behavioural Memory Test, Lexical Verbal Fluency-P, Yesavage's Geriatric Depression Scale (GDS), TMT-A-time scales whose objective was to evaluate some executive functions and/or the memory. The CG presented a worsening trend for most of the measures towards 12 months. There was also a significant interaction between "time and group" for MMSE ($F = 8.971$; $p = 0.03$; $\eta^2 = 0.019$) and the GDS ($F = 3.414$; $p = 0.04$; $\eta^2 = 0.041$), as well as small effect sizes for TMT-A-time ($F = 1.641$; $p = 0.21$; $\eta^2 = 0.021$) and TMT-A-mistakes ($F = 0.908$; $p = 0.41$; $\eta^2 = 0.019$).
Conclusion: CCT with GRADIOR has been proved to benefit cognitive functions (ISRCTN:15742788).

Keywords: Cognitive training, dementia, mild cognitive impairment, randomized controlled trial, rehabilitation

INTRODUCTION

Dementia is a neurodegenerative disease that is characterized by a series of cognitive [1, 2], emotional [3], physical [4], and social [5] deficits, which gain visibility as the disease progresses through its various stages. Mild cognitive impairment (MCI) has been regarded as an early stage of dementia, although it not always evolves in such direction. An individual with MCI could develop dementia if several risk factors converge [6, 7]. Hence, an early diagnosis of MCI is essential [8] to start therapy, which, although it cannot revert the symptoms, some of them can help preserve cognitive condition and/or delay cognitive decline.

People with dementia (PwD) can be treated with pharmacological therapy [9] and also with psychosocial therapies, the latter of which are aimed at physical, cognitive, social, and emotional, or even family unit rehabilitation [10].

One of the challenges of these psychosocial interventions is that they are difficult to implement, both because of their cost and because of the expertise these require. In this regard, new technologies offer the possibility of changing and improving such interventions so that these might be more accessible [11]. Examples of this are the e-Salud interventions, aimed at providing support for activities of daily living (ADL) [12, 13] or at improving the cognitive and emotional condition of PwD [14].

The improvements observed involve cognitive functions such as attention [15–17], memory [16, 18, 19] and executive function (EF) [15, 20] in people with MCI and dementia. Likewise, other studies have mentioned improvements in social and emotional aspects, such as anxiety levels [15] and depression [21].

Although the scientific literature includes a broad variety of studies on the effectiveness of computer-based cognitive training (CCT) programs [21, 22], it is necessary to strengthen the evidence base of the usefulness of this type of intervention. The lack of methodological rigor associated with limitations such as sample size [23] and short CCT periods [24, 25] hinders the gathering of solid evidence [26]. Therefore, it is necessary to further assess the "effectiveness" of these interventions using randomized controlled trials (RCT).

The aim of this study is to evaluate the effectiveness of a CCT program (GRADIOR) on cognition and emotional condition in people with MCI and mild dementia by conducting an RCT [27]. This study will only present the effectiveness results associated with the GRADIOR intervention up to 4 and 12 months. The follow-up period at 16 and 24 months, as well as the results associated with some secondary measures, will be published later.

METHODS

Study design

The design used was a simple-blind, multicenter, RCT (ISRCTN:15742788) [28]. Our design initially included four parallel groups [27]. However, the development of the ehcoBUTLER platform was initially part of a European project that failed to become ready for our RCT. Therefore, we decided not to include it. This led to a change in the number of parallel groups, the allocation ratio, and the sample size.

The sample population was recruited between June 2018 and December 2019. The participants

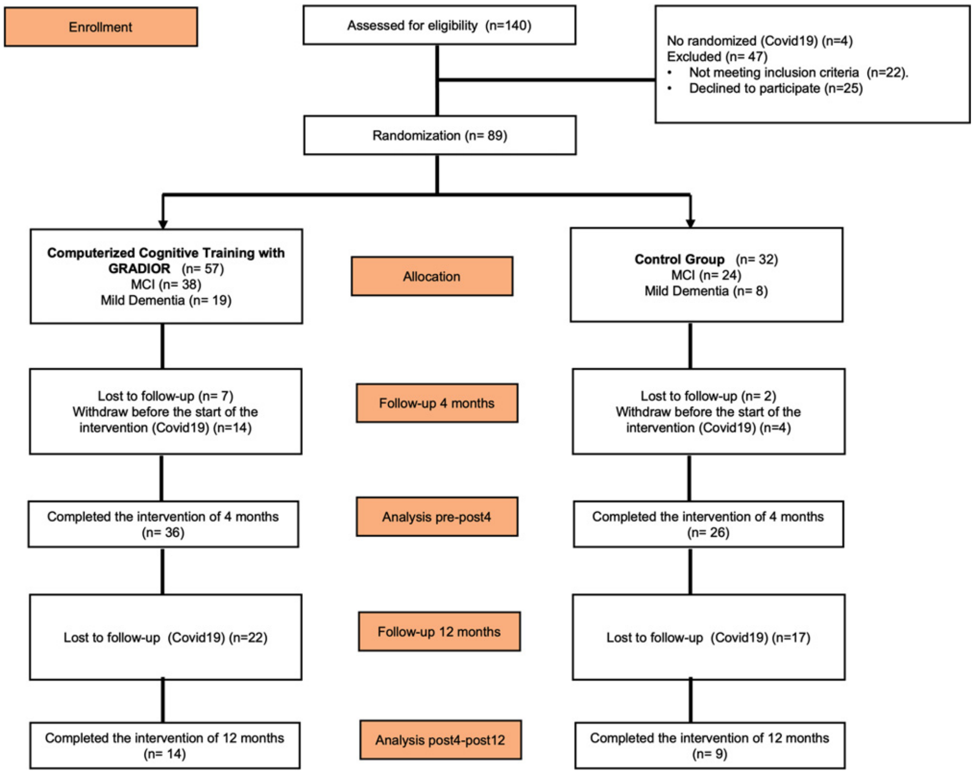

Fig. 1. Recruitment and randomization process.

were randomized (1:2) to one of the two study groups by a simple random assignment (Fig. 1). We used a computer-generated random number sequence through the Epidat 4.1 program. An independent researcher generated the assignment. The evaluators were neuropsychologists who were blinded. The inter-rater reliability was ($\alpha = 99.1\%$). The therapists who supervised each session and the participants were not blinded. Participants agreed to participate prior to randomization and without knowing which group they would be assigned. The individuals in the experimental group (EG) attended two or three weekly CCT sessions (depended on each center) using GRADIOR over a 12-month period, whereas those in the control group (CG) received usual care.

This study was multicenter because it involved daycare centers, memory clinics, and hospitals in the Spanish regions of Castile and León, and Galicia. The study was approved on May 17, 2017, by the Medication Research Ethics Committee of health-care area of Zamora (Number:387-E.C). Informed consent was obtained from all the participants and caregivers.

Participants

Eighty-nine people participated in this study. These were randomly assigned to the experimental ($n = 57$) and control ($n = 32$) group. The dropout rate for this study before 4 months was 10%, although 20% of the participants did not start the intervention due to the onset of the COVID-19 pandemic. The final sample consisted of 62 participants who completed 4-months of intervention. Only 23 participants completed the scheduled 12 months, which could not be completed by the rest of participants because of the outbreak of the COVID-19 pandemic (Fig. 1).

Participants were aged 60–90 and were clinically diagnosed with MCI according to Petersen [29] and with mild dementia according to the Diagnostic and Statistical Manual of Mental Disorders (DSM-V) [30]. A psychogeriatrician and neurologist made the diagnosis according to the criteria mentioned above and considering the patient's medical history. The MCI types were amnestic, and types of dementia included were as follows: Alzheimer's disease, vascular dementia, mixed and frontotemporal dementia. Scores obtained on the Mini-Mental State Exam

(MMSE) were additional: MMSE ≤ 27 for MCI, and MMSE: $20 \leq x \leq 25$ for mild dementia, adjusting each score according to the participant's age and level of education [31]. A score of ≤ 5 on Yesavage's Geriatric Depression Scale (GDS) was required, each participant should participate voluntarily, have a reference caregiver, and be fluent in speaking and understanding Spanish.

On the other hand, the participants were excluded when they had severe physical comorbidities, significant sensory disturbances (hearing-visual), neurological disorders (Huntington's disease, traumatic brain injury, Parkinson's disease), clinically significant psychopathological disorders (depression, anxiety, bipolar disorder, psychosis), and/or a history of psychoactive substance use (alcohol, tobacco).

Neuropsychological assessment

The participants of both groups were assessed at three different moments throughout the intervention (T_0: at baseline, T_1: at 4 months, and at T_2: 12 months of intervention). The cognitive scales used for the main outcome measurements were the MMSE [32], the cognitive subscale of the Alzheimer's Disease Assessment Scale [33], TMT-A-B [34], the Clock Drawing Test [35], Digit Symbol, Arithmetic and Digits of the Wechsler Adult Intelligence Scale (WAIS-III) [36], Visual Memory of the Rivermead Behavioural Memory Test (RBMT) [37], Visual Reasoning of the Cambridge Cognitive Examination (CAMCOG) [38], and Verbal Fluency Test [39, 40]. Secondary result measurements were associated with GDS [41]. These instruments have been described in greater detail in the protocol published on the RCT [27].

Computer-based cognitive training with GRADIOR

GRADIOR is a computer-based cognitive training program. It is a program that provides good usability and user experience [42–49]. This program includes a wealth of orientation, memory, attention, perception, EF, reasoning, and calculation exercises. It allows the design and customization of intervention plans according to the type and level of the patient's cognitive disorder [45, 50]. The cognitive intervention plan for this RCT was designed according to the cognitive profile (Supplementary Figure 1) and the level of difficulty for each exercise was adjusted to the cognitive level of each people. The participants attended two or three weekly 30-min sessions over a 12-month period. The sessions were carried out in specialized rooms with computers in daycare centers, memory clinics, and hospitals.

Statistical analysis

The statistical analysis was conducted using the Statistical Package for the Social Sciences software package (SPSS) [51]. The Shapiro-Wilk Test of normality was used, taking sample size into account to identify the type of distribution of each of the variables. The comparison between the EG-CG was performed using the Mann-Whitney U Test for two independent samples to check whether there were significant differences between both groups regarding at each of the times T_0–T_1–T_2 (intergroup). The Wilcoxon signed-Rank Test was used to compare the cognitive performance between times T_0–T_1 and T_1–T_2 for each of the groups, which allowed the identification of changes over time (intragroup). The significance threshold set for each of the analyses was ≤ 0.05.

To run the repeated measures ANOVA Test, it was necessary to verify the assumptions of homoscedasticity ($p \geq 0.05$) and sphericity ($p \geq 0.05$). The Greenhouse-Geisser correction was used in those cases where homoscedasticity was not met. The assumption of sphericity was tested using Mauchly's Test of Sphericity. The repeated measures ANOVA analysis allowed us to see the time factor (changes over time in the sample in general) and the interaction between factors "time versus study group" (differences between the two groups over time) and "time, clinical group, and study group" (differences over time with respect to the study group and the clinical group).

RESULTS

Sample characteristics

The sample that completed 4 months of intervention consisted of 62 individuals. The mean age was 74.73 ± 6.63 and 27.4% were men. The mean number of years of education was 9.36 ± 2.68, and 66.1% ($n = 41$) of the individuals had a diagnosis of MCI, and 33.9% ($n = 21$) of mild dementia. The final sample comprised a total of 23 individuals who completed the 12 months of CCT. Of these, 26.1% were men. The mean age was 76.30 ± 7.69 and the mean number of years of education was 9.96 ± 3.11. Of the sample, 60.9% ($n = 14$) and 39.1% ($n = 9$) of the individuals were diagnosed with MCI and with mild dementia, respectively. However, there were no significant differences between EG-CG regarding age, years of education, sex, or clinic group at 4 or 12 months (Table 1).

Comparison between groups for each condition (T_0–T_1–T_2) (intergroup)

The Shapiro-Wilk Test revealed that most of the variables were not normally distributed, which led to the use of the Mann-Whitney U Test. There were no significant differences between the two groups as to T_0, T_1, and T_2. However, a medium-moderate effect size (d = 0.460) was found for Visual Reasoning of CAMCOG in T_1 ($n = 23$), the EG performing better than the CG (2.07 ± 1.14 and 2.00 ± 1.50, respectively). Small effect sizes in T_1 were found for TMT-B-Time (d = 0.317) and Arithmetic of WAIS-III (d = –0.302), and in T_2 for Visual Memory of RBMT (d = –0.317) and Digit Symbol of WAIS-III (d = 0.302) (Table 2).

Evolution of cognitive-psychological performance for each group (intragroup)

The Shapiro-Wilk Test revealed that most of the variables were not normally distributed for either group during T_0–T_1 and T_1–T_2. Based on this and on sample size within each group, the Wilcoxon signed-rank Test was conducted (Table 3).

Regarding the changes seen between T_0 and T_1 for EG, we highlight an improvement trend of EG during T_1. In this way, we find a small effect sizes for Visual Reasoning of CAMCOG (d = –0.172), WAIS-III Digits (d = –0.123), WAIS-III Arithmetic (d = –0.244), and Semantic Verbal Fluency (SVF) (d = –0.273), and medium-moderate for Lexical Verbal Fluency M (d = –0.310), MMSE (d = –0.439), and TMT-A-Mistakes (d = 0.436). However, a worsening trend was only detected in TMT-B-Time with a medium-moderate effect size (d = 0.362)

On the other hand, we observed that for the T_1–T_2 condition in EG, there was a trend of improvement with small effect sizes for CAMCOG-Visual Reasoning (d = –0.111) and WAIS-III Digit Symbol (d = –0.200), medium-moderate for TMT-B-mistakes (d = 0.359) and RBMT-Visual Memory (d = –0.364), moderate for Lexical Verbal Fluency (LVF-P) (d = –0.489) and GDS (d = 0.538), and there were significant differences ($p = 0.02$) and a large

Table 1

Characterization of the sample in the experimental group (EG) and control group (CG)

Variable		Test T ($n = 62$)			CG		EG		Test W ($n = 23$)			CG		EG	
		T/χ^2	p	Cohen's d	N	M±SD	N	M±SD	W/χ^2	p	Cohen's d	N	M±SD	N	M±SD
Age		1.54	0.13	0.395	26	76.23 ± 6.56	36	73.64 ± 6.56	79.50	0.31	0.262	9	79.22 ± 6.98	14	74.43 ± 7.78
Education		0.01	0.99	0.003	25	9.36 ± 2.86	34	9.35 ± 2.60	66.00	0.85	0.048	9	10.44 ± 3.68	14	9.64 ± 2.79
Sex	Women	3.259	0.07		22 (84.6%)		23 (63.9%)		0.115	0.74		7 (77.8%)		10 (71.4%)	
	Men				4 (15.4%)		13 (36.1%)					2 (22.2%)		4 (28.6%)	
Clinic Group	MCI	0.965	0.33		19 (73.1%)		22 (61.1%)		0.175	0.68		5 (55.6%)		9 (64.3%)	
	Dementia				7 (26.9%)		14 (38.9%)					4 (44.4%)		5 (35.7%)	

$^*p \leq 0.05$; $^{**}p \leq 0.01$; CG, control group; EG, experimental group; MCI, mild cognitive impairment.

Table 2
Mann-Whitney U test. Intergroup comparison (EG and CG) during each time (T_0, T_1, T_2)

Test	T_0			T_1			T_1			T_2		
	N = 62						*N* = 23					
	W	*p*	Cohen's d	W	*p*	Cohen's d	W	*p*	Cohen's d	W	*p*	Cohen's d
MMSE	509	0.56	0.088	482	0.85	0.030	56.500	0.70	–0.103	69.000	0.73	0.095
ADAS-Cog	456	0.87	–0.026	425.5	0.55	–0.091	66.000	0.87	0.048	66.000	0.87	0.048
TMT A Time	400	0.28	–0.145	527	0.37	0.126	73.500	0.41	0.167	69.000	0.71	0.095
TMT-A Mistakes	480	0.83	0.026	522	0.33	0.115	70.500	0.65	0.119	68.000	0.67	0.079
TMT B Time	456.5	0.85	–0.025	485.5	0.78	0.037	83.000	0.16	**0.317**	76.000	0.33	0.206
TMT-B Mistakes	477.5	0.90	0.020	414.5	0.44	–0.114	64.000	0.97	0.016	72.000	0.59	0.143
WAIS-III: Digits	483.5	0.83	0.033	416.5	0.46	–0.110	79.000	0.32	0.254	58.500	0.80	–0.071
WAIS-III: Digit Symbol	540	0.30	0.154	481	0.85	0.028	59.000	0.82	–0.063	82.000	0.24	**0.302**
WAIS III: Arithmetic	553	0.22	0.182	501	0.38	0.133	44.000	0.24	**–0.302**	67.000	0.82	0.063
CAMCOG: Visual Reasoning	428	0.56	–0.085	538.5	0.31	0.151	92.000	0.07	**0.460**	52.000	0.50	–0.175
RBMT: Visual Memory	396	0.30	–0.154	462.5	0.94	–0.012	63.500	1.000	0.008	43.000	0.20	**–0.317**
CDT Order	451.5	0.97	–0.008	552.5	0.22	0.181	79.500	0.29	0.262	56.000	0.68	–0.111
CDT Copy	473.5	0.94	0.012	468.5	0.70	0.060	74.500	0.48	0.183	68.500	0.74	0.087
SVF	510.5	0.31	0.155	482	0.55	0.090	50.500	0.83	–0.065	54.500	0.61	–0.135
LVF-P	478.5	0.59	0.083	528.5	0.19	0.196	65.000	0.45	0.204	62.500	1.000	–0.008
LVF-M	474.5	0.63	0.074	427	0.56	–0.088	62.000	0.59	0.148	73.000	0.54	0.159
LVF-R	502.5	0.37	0.137	482	0.85	0.030	52.500	0.94	–0.028	53.000	0.55	–0.159
GDS	444	0.74	–0.051	425.5	0.55	–0.091	58.000	0.77	–0.079	74.000	0.50	0.175

*$p \leq 0.05$; **$p \leq 0.01$; ADASCog, Alzheimer's disease Assessment Scale: cognitive subscale; CAMCOG, Cambridge Cognition Examination; CDT, Clock Drawing Test; GDS, Geriatric Depression Scale; LVF, Lexical Verbal Fluency; MMSE, Mini-Mental State Examination; RBMT, Rivermead Behavioural Memory Test; SVF, Semantic Verbal Fluency; T_0, baseline; T_1, at 4 months of intervention; T_2, at 12 months of intervention; TMT, Trail Making Test; WAIS-III, Wechsler Adult Intelligence Scale.

effect size (d = –1000) for TMT-A-time. However, slight worsening tendencies were also detected for the WAIS-III Arithmetic with moderate effect sizes (d = 0.636) and, a high effect size with a significant difference for the MMSE (*p* = 0.01; d = 0.868) and LVF-M (*p* = 0.03; d = 1000).

Regarding the CG, this exhibited an improvement trend during T_1 and had small effect sizes for Digit Symbol (WAIS-III) (d = –0.281), LVF-M (d = –0.289), LVF-R (d = –0.294), WAIS-III Arithmetic (d = –0.327), medium-moderate for TMT-B-mistakes (d = 0.382), moderate for TMT-A-Time (d = –0.552) and WAIS-III Digits (d = –0.636), this last variable with significant differences (*p* = 0.01). And this group showed a worsening tendency for TMT-A-mistakes (d = –0.258).

On the other hand, the CG also showed an improvement trend in T_2 with moderate effect sizes for RBMT-Visual Memory (d = –0.500), medium-high for TMT-A-mistakes (d = 0.700), and a large for TMT-B-Time (d = –1000). However, CG showed a worsening trend during T_2 with small effect sizes for WAIS-III Digit Symbol (d = 0.200), LVF-M (d = 0.267), and GDS (d = –0.286), medium-moderate for SVF (d = 0.429), moderate for CAMCOG-Visual Reasoning (d = 0.500), WAIS-III Arithmetic (d = 0.583), and Clock Drawing Test (CDT)-Copy (d = 0.600), medium-high for WAIS-III Digits (d = 0.694) and CDT-Order (d = 0.667).

Repeated measures ANOVA

Most of the variables met the assumption of homoscedasticity. For the cases in which this principle was not fulfilled, we applied the Greenhouse-Geisser correction [52]. Thus, variance in the CG and in the EG in each of the variables for T_0–T_1–T_2 was the same. Most of the variables also met the assumption of sphericity, except for AdasCog-total, TMT-B-Time-Mistakes, and WAIS-III Digit-Symbol. After running the repeated measures ANOVA, the effect of the time factor (T_0, T_1, T_2) was significant on the cognitive performance associated with the tests: Digits (F = 3.632; *p* = 0.04; $\eta^2 = 0.030$) and Arithmetic of WAIS-III (F = 4.372; *p* = 0.02; $\eta^2 = 0.038$) (Table 4). Therefore, cognitive performance was not the same in the three times recorded and we identified an increase in cognitive performance at 4 months and a slight decrease at 12 months in the general sample. Although, we can say that they remained around the average, so their performance was not low (Fig. 2).

There was a statistically significant interaction between time and study group (experimental and

Table 3
Wilcoxon signed-rank test. Intragroup comparison (EG-CG) with respect to cognitive performance between T_0–T_1 and T_1–T_2

Test	Group	p	Cohen's d	T_0 ($n=62$)		T_1 ($n=62$)		p	Cohen's d	T_1 ($n=23$)		T_2 ($n=23$)	
				N	$\bar{x} \pm SD$	N	$\bar{x} \pm SD$			N	$\bar{x} \pm SD$	N	$\bar{x} \pm SD$
MMSE	Control	0.20	**–0.337**	26	24.15 ± 4.16	26	24.81 ± 4.06	1.000	–0.048	9	24.11 ± 4.46	9	24.22 ± 4.97
	Experimental	0.05*	**–0.439**	36	24.28 ± 2.54	36	24.97 ± 2.91	0.01**	**0.868**	14	25.21 ± 2.33	14	23.43 ± 2.56
ADAS-Cog	Control	0.58	0.134	26	14.88 ± 7.75	26	14.31 ± 7.29	0.57	**0.250**	9	17.11 ± 10.52	9	16.44 ± 13.14
	Experimental	0.62	–0.103	35	14.00 ± 4.99	35	14.43 ± 6.48	0.40	–0.275	13	12.69 ± 4.03	14	14.29 ± 4.01
TMT A Time	Control	0.07	**–0.552**	25	7.80 ± 5.61	22	9.09 ± 6.66	0.89	–0.133	7	10.71 ± 10.97	8	13.75 ± 14.33
	Experimental	1.00	–0.007	33	11.21 ± 11.32	35	13.43 ± 16.21	0.03*	**–1.000**	14	9.29 ± 10.72	14	11.79 ± 11.87
TMT-A Mistakes	Control	0.47	**–0.258**	26	0.54 ± 1.07	25	0.64 ± 1.19	0.27	**0.700**	9	0.89 ± 1.54	9	0.22 ± 0.44
	Experimental	0.17	**0.436**	36	0.42 ± 0.77	36	0.25 ± 0.44	1.000	–	14	0.21 ± 0.43	14	0.14 ± 0.36
TMT B Time	Control	0.79	0.106	9	14.44 ± 11.02	10	15.00 ± 9.13	0.37	**–1.000**	3	15.00 ± 13.23	2	25.00 ± 7.07
	Experimental	0.25	**0.362**	11	15.91 ± 18.68	15	15.33 ± 11.26	1.000	0.333	5	14.00 ± 9.62	5	10.00 ± 6.12
TMT-B Mistakes	Control	0.19	**0.382**	17	1.59 ± 1.42	20	1.40 ± 1.31	0.53	0.333	5	1.20 ± 1.79	7	2.14 ± 1.77
	Experimental	0.34	0.214	28	2.14 ± 1.46	31	2.23 ± 1.52	0.29	**0.359**	12	2.25 ± 1.66	12	1.83 ± 1.53
WAIS-III: Digits	Control	0.01**	**–0.636**	26	10.65 ± 2.17	25	11.48 ± 2.20	0.09	**0.694**	9	11.44 ± 2.46	9	10.11 ± 3.14
	Experimental	0.59	–0.123	36	10.47 ± 2.61	36	10.58 ± 2.95	0.96	0.036	14	10.57 ± 2.14	14	10.57 ± 2.74
WAIS-III: Digit Symbol	Control	0.25	**–0.281**	23	10.17 ± 2.06	23	10.35 ± 2.21	0.85	0.200	8	11.00 ± 2.45	8	10.75 ± 2.66
	Experimental	0.76	–0.081	36	9.83 ± 2.87	35	10.11 ± 2.41	0.62	**–0.200**	14	9.57 ± 2.28	14	9.79 ± 1.72
WAIS III: Arithmetic	Control	0.24	**–0.327**	26	10.50 ± 2.34	25	10.68 ± 2.67	0.15	**0.583**	9	10.44 ± 2.92	9	9.00 ± 3.74
	Experimental	0.25	**–0.244**	36	9.75 ± 3.08	36	10.22 ± 2.82	0.08	**0.636**	14	10.36 ± 2.10	14	9.00 ± 3.11
CAMCOG: Visual Reasoning	Control	0.75	–0.100	26	2.00 ± 1.10	25	1.96 ± 1.06	0.59	**0.500**	9	2.00 ± 1.50	9	1.78 ± 1.56
	Experimental	0.45	**–0.172**	36	2.22 ± 1.42	35	2.43 ± 1.20	0.80	–0.111	14	2.07 ± 1.14	14	2.14 ± 1.29
RBMT. Visual Memory	Control	0.84	–0.058	26	7.00 ± 3.02	25	6.84 ± 3.01	0.26	**–0.500**	9	6.11 ± 3.18	9	6.78 ± 3.03
	Experimental	0.70	0.089	36	7.94 ± 2.10	36	7.78 ± 2.38	0.33	**–0.364**	14	7.71 ± 2.09	14	8.43 ± 2.41
CDT-Order	Control	0.40	–0.212	26	7.25 ± 2.74	25	7.56 ± 2.07	0.22	**0.667**	9	7.56 ± .2.78	9	6.72 ± 3.09
	Experimental	0.62	–0.117	34	7.35 ± 2.24	36	7.60 ± 2.38	0.88	–0.073	14	7.57 ± 2.70	14	7.64 ± 2.06
CDT-Copy	Control	0.81	–0.068	26	8.81 ± 1.86	25	8.76 ± 1.93	0.35	**0.600**	9	8.44 ± 2.86	9	8.00 ± 3.43
	Experimental	0.58	0.133	36	9.10 ± 1.14	36	8.99 ± 1.50	0.88	0.073	14	9.00 ± 1.51	14	9.00 ± 1.00
SVF	Control	1.00	0.000	25	7.80 ± 3.28	25	7.56 ± 3.37	0.37	**0.429**	9	7.67 ± 3.97	9	7.33 ± 4.00
	Experimental	0.21	**–0.273**	34	7.03 ± 2.88	34	7.62 ± 3.59	0.80	0.109	12	8.75 ± 3.86	14	8.43 ± 2.82
LVF-P	Control	0.51	–0.162	25	7.72 ± 3.55	25	8.16 ± 3.22	1.000	–0.067	9	8.00 ± 4.30	9	7.67 ± 4.12
	Experimental	0.55	–0.129	34	7.56 ± 3.04	34	7.82 ± 2.76	0.21	**–0.489**	12	7.33 ± 2.77	14	8.29 ± 3.02
LVF-M	Control	0.24	**–0.289**	25	7.48 ± 3.66	25	8.28 ± 3.69	0.68	**0.267**	9	8.78 ± 4.27	9	8.44 ± 3.88
	Experimental	0.18	**–0.310**	34	7.68 ± 3.44	34	8.26 ± 3.42	0.03*	**1.000**	12	8.25 ± 4.11	14	7.71 ± 4.03
LVF-R	Control	0.24	**–0.294**	25	8.84 ± 2.53	25	9.40 ± 2.90	0.78	0.200	9	8.89 ± 3.66	9	8.00 ± 3.39
	Experimental	0.38	–0.200	34	8.50 ± 2.57	34	8.97 ± 2.58	0.89	0.061	12	8.83 ± 2.52	14	8.93 ± 2.92
GDS	Control	0.69	–0.105	26	3.42 ± 3.23	25	3.32 ± 3.09	0.59	**–0.286**	9	2.89 ± 2.20	9	3.22 ± 2.17
	Experimental	0.49	–0.153	36	3.86 ± 3.66	36	4.19 ± 3.81	0.10	**0.538**	14	4.14 ± 3.98	14	3.07 ± 3.27

*$p \leq 0.05$; **$p \leq 0.01$; ADASCog, Alzheimer's disease Assessment Scale: cognitive subscale; CAMCOG, Cambridge Cognition Examination; CDT, Clock Drawing Test; GDS, Geriatric Depression Scale; LVF, Lexical Verbal Fluency; MMSE, Mini-Mental State Examination; RBMT, Rivermead Behavioural Memory Test; SVF, Semantic Verbal Fluency; TMT, Trail Making Test; T_0, baseline; T_1, at 4 months of intervention; T_2, at 12 months of intervention; WAIS-III, Wechsler Adult Intelligence Scale.

Table 4
Levene's test, sphericity, and ANOVA. Comparison of cognitive performance between T_0, T_1–T_2 ($n = 23$)

Test	LEVENE'S TEST						SPHERICITY		ANOVA					
	T_0		T_1		T_2				T_0–T_1–T_2			T_0–T_2 Group		
	F	p	F	p	F	p	χ^2	p	F	p	η^2	F	p	η^2
MMSE	22.402	< 0.00	5.943	0.02	8.983	0.01	4.965	0.08*	2.165	0.13	0.011	8.971	0.03*	0.019
ADAS-Cog	2.543	0.13*	2.562	0.12*	13.533	0.00	152.552	< 0.00	0.630	0.44	0.010	0.610	0.44	0.009
TMT A Time	0.402	0.55*	27.517	< 0.00	7.713	0.01	5.567	0.06*	0.532	0.59	0.007	1.641	0.21	**0.021**
TMT-A Mistakes	0.703	0.41*	11.803	0.00	0.863	0.36*	1.844	0.40*	2.424	0.10	0.050	0.908	0.41	**0.019**
TMT B Time	1.292	0.27*	0.055	0.82*	2.228	0.15*	12.752	0.00	0.535	0.52	0.004	1.564	0.23	0.012
TMT-B Mistakes	0.301	0.59*	0.299	0.59*	0.861	0.36*	59.117	< 0.00	2.504	0.13	0.035	0.206	0.66	0.003
WAIS-III: Digits	0.316	0.58*	0.021	0.58*	0.394	0.54*	0.911	0.63*	3.632	0.04*	0.030	3.285	0.18	0.014
WAIS-III: Digit Symbol	28.398	< 0.00	8.209	0.01	8.241	0.01	181.195	< 0.00	1.590	0.22	0.012	1.584	0.22	0.012
WAIS III: Arithmetic	0.364	0.55*	0.505	0.49*	0.304	0.59*	2.321	0.31*	4.372	0.02*	0.038	0.380	0.69	0.003
CAMCOG: Visual Reasoning	0.003	0.96*	0.270	0.61*	0.072	0.79*	1.833	0.40*	0.156	0.86	0.002	0.307	0.74	0.003
RBMT: Visual Memory	2.996	0.10*	2.155	0.16*	1.510	0.23*	2.996	0.22*	2.308	0.11	0.018	0.002	1.0	< 0.001
CDT Order	0.0435	0.52*	0.007	0.93*	3.685	0.07*	0.601	0.74*	0.938	0.40	0.010	1.009	0.97	0.011
CDT Copy	4.436	0.05	5.510	0.03	7.100	0.02	0.385	0.83*	0.394	0.68	0.002	0.598	0.55	0.003
SVF	4.221	0.05*	0.394	0.54*	3.342	0.08*	1.062	0.59*	0.655	0.53	0.005	0.920	0.41	0.007
LVF-P	0.546	0.47*	5.239	0.03	2.978	0.10*	5.544	0.06*	1.821	0.18	0.019	0.334	0.72	0.003
LVF-M	0.064	0.80*	0.193	0.67*	0.115	0.74*	1.111	0.60*	1.572	0.22	0.010	0.535	0.59	0.003
LVF-R	0.682	0.42*	2.490	0.13*	0.263	0.61*	5.684	0.06*	0.547	0.58	0.006	0.344	0.71	0.004
GDS	0.236	0.63*	4.104	0.06*	1.386	0.25*	5.368	0.07*	1.697	0.20	0.020	3.414	0.04*	0.041

$n = 23$. Test of Levene $p \geq 0.05$*; Sphericity $p \geq 0.05$*; ANOVA $p \leq 0.05$*; CAMCOG, Cambridge Cognition Examination; CDT, Clock Drawing Test; LVF, Lexical Verbal Fluency; MMSE, Mini-Mental State Examination; RBMT, Rivermead Behavioural Memory Test; SVF, Semantic Verbal Fluency; TMT, Trail Making Test; WAIS-III, Wechsler Adult Intelligence Scale; GDS, Geriatric Depression Scale.

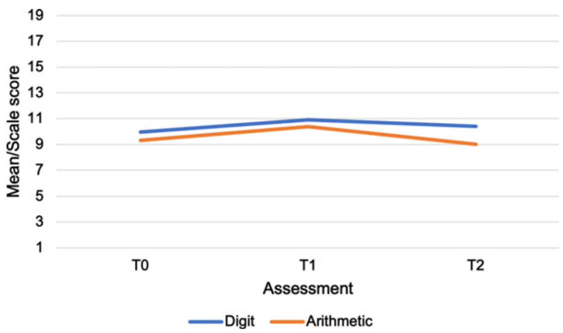

Fig. 2. Analysis with ANOVA. Time factor for Digits and Arithmetic of the Wechsler Adult Intelligence Scale (WAIS-III).

control) in patient performance on the following tests: MMSE (F = 8.971; $p = 0.03$; $\eta^2 = 0.019$) and the GDS (F = 3.414; $p = 0.04$; $\eta^2 = 0.041$) (Table 4). This analysis showed that the cognitive performance of EG patients was less positively influenced by training than CG patients at the 12-month evaluation in MMSE. While the opposite occurred for the GDS (Fig. 3). Also, small effect sizes were found between time- study group interactions for the following variables: TMT-A-time (F = 1.641; $p = 0.21$; $\eta^2 = 0.021$) and TMT-A-mistakes (F = 0.908; $p = 0.41$; $\eta^2 = 0.019$) (Table 4, Fig. 3).

Also, we found a significant interaction and a low-medium effect size between time, study group, and clinical group for the variable CDT Order (F = 3.455; $p = 0.04$; $\eta^2 = 0.033$) (Table 5). This analysis showed that people with MCI in the EG maintained their cognitive performance over a long time and even improved in the case of people with mild dementia, while people with MCI and mild dementia in the CG tended to decrease their performance with relation to time (Fig. 4).

On the other hand, a low-medium effect size was found for CAMCOG visual reasoning (F = 2.753; $p = 0.08$; $\eta^2 = 0.030$) and medium for TMT-B-Mistakes (F = 1.731; $p = 0.20$; $\eta^2 = 0.068$) (Table 5). So, people with MCI and mild dementia of the EG improved their performance in TMT-B-Mistakes over time compared to the CG that decreased in the case of people with MCI or was maintained in the case of people with mild dementia. With respect to Visual Reasoning of CAMCOG, people with EG MCI improved their performance over time compared to CG, contrary to what happened with people with mild dementia (Fig. 4). No adverse effects of GRADIOR were reported in people with MCI and mild dementia.

DISCUSSION

The purpose of this RCT was to find out the effects of a GRADIOR CCT program on cognitive

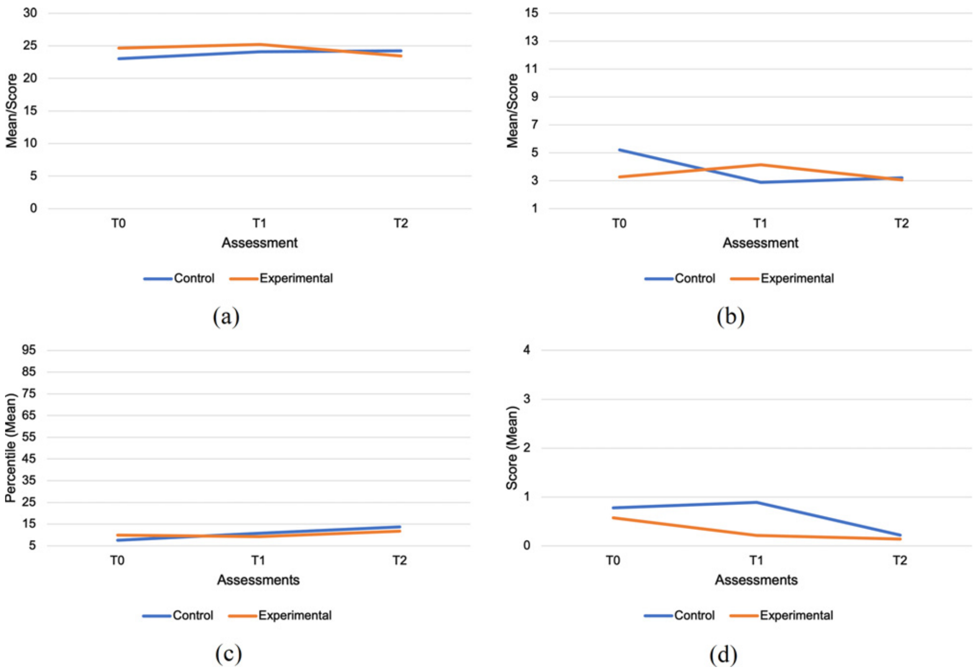

Fig. 3. Analysis with ANOVA. Time and group study (Experimental and Control) interaction for a) Mini-Mental State Examination (MMSE), b) Geriatric Depression Scale (GDS), c) Trail Making Test (TMT) A Time, and d) TMT A mistakes.

Table 5
Levene's test, sphericity, and ANOVA. Comparison of cognitive performance between T_0, T_1–T_2 ($n = 23$) according to the clinical group (MCI and mild dementia) with respect to the study group (experimental and control)

Test	Levene's Test						Sphericity		ANOVA		
	T_0		T_1		T_2				T_0–T_2* Study Group* Clinic Group		
	F	p	F	p	F	p	χ^2	p	F	p	η^2
MMSE	1.377	0.28*	2.923	0.06*	1.533	0.24*	3.129	0.21*	1.758	0.19	0.008
ADAS-Cog	2.202	0.12*	1.640	0.22*	1.903	0.17*	5.798	0.06*	0.725	0.49	0.003
TMT A Time	1.477	0.26*	2.574	0.09*	1.981	0.16*	17.127	<0.001	0.597	0.56	0.011
TMT-A Mistakes	3.244	0.06*	3.145	0.06*	87.750	<0.001	2.000	0.37*	0.714	0.50	0.015
TMT B Time	–	–	–	–	–	–	–	–	–	–	–
TMT-B Mistakes	6.304	0.01	6.299	0.01	7.231	0.01	1.292	0.52*	1.731	0.20	**0.068**
WAIS-III: Digits	0.026	0.99*	1.322	0.30*	0.830	0.49*	2.430	0.30*	1.087	0.34	0.008
WAIS-III: Digit Symbol	0.940	0.44*	3.362	0.04	4.378	0.02	0.406	0.81*	1.566	0.22	0.009
WAIS III: Arithmetic	1.267	0.31*	2.270	0.11*	0.602	0.62*	1.437	0.49*	1.891	0.17	0.017
CAMCOG: Visual Reasoning	0.891	0.46*	0.909	0.45*	0.367	0.78*	1.024	0.60*	2.753	0.08	**0.030**
RBMT: Visual Memory	1.026	0.40*	0.308	0.82*	0.911	0.45*	3.737	0.15*	0.543	0.59	0.004
CDT Order	0.163	0.92*	4.251	0.02	0.585	0.63*	1.411	0.49*	3.455	0.04*	**0.033**
CDT Copy	2.113	0.13*	3.444	0.04	6.063	0.00	0.572	0.75*	1.175	0.32	0.006
SVF	1.612	0.22*	0.568	0.64*	1.783	0.19*	1.188	0.55*	0.192	0.83	0.001
LVF-P	2.377	0.10*	2.589	0.09*	2.793	0.07*	5.601	0.06*	0.958	0.39	0.010
LVF-M	1.665	0.21*	4.235	0.02	0.670	0.58*	0.316	0.85*	0.039	0.96	<0.001
LVF-R	0.675	0.58*	2.265	0.11*	0.776	0.52*	4.855	0.09*	1.017	0.37	0.011
GDS	0.149	0.92*	1.391	0.28*	0.887	0.47*	5.000	0.08*	0.175	0.84	0.002

$n = 23$. Test of Levene $p \geq 0.05$*; Sphericity $p \geq 0.005$*; ANOVA $p \leq 0.05$*; CAMCOG, Cambridge Cognition Examination; CDT, Clock Drawing Test; LVF, Lexical Verbal Fluency; MMSE, Mini-Mental State Examination; RBMT, Rivermead Behavioural Memory Test; SVF, Semantic Verbal Fluency; TMT, Trail Making Test; WAIS-III, Wechsler Adult Intelligence Scale; GDS, Geriatric Depression Scale.

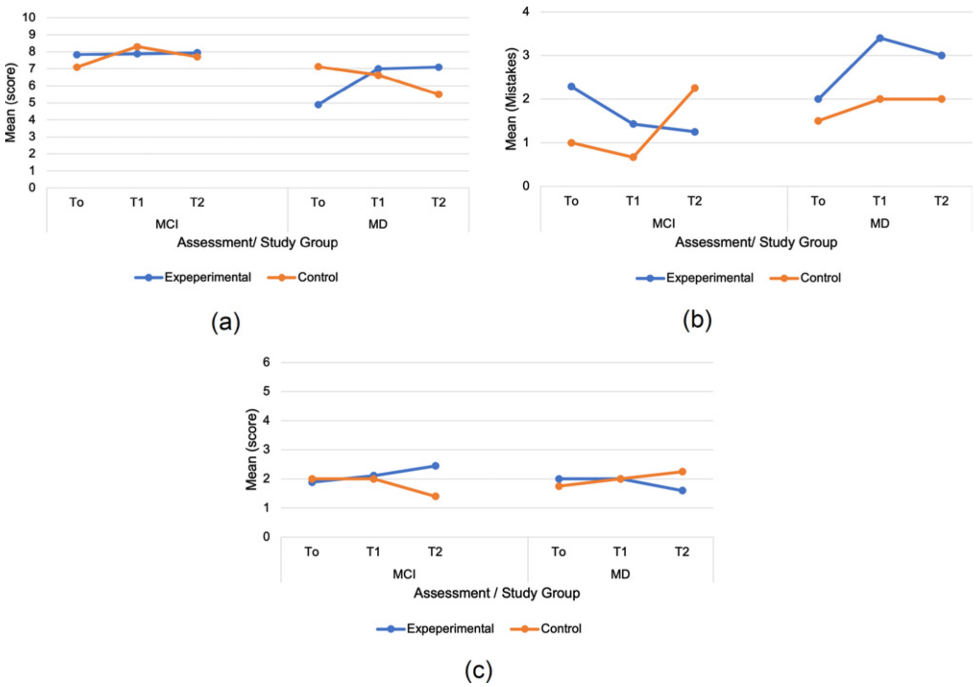

Fig. 4. Analysis with ANOVA. Time, Clinical Group (MCI and Mild dementia), and Study Group (Experimental and Control) interaction for a) Clock Drawing Test (CDT) Order, b) Trail Making Test (TMT) B mistakes, and c) Visual Reasoning of Cambridge Cognition Examination (CAMCOG).

and emotional aspects in people with MCI or mild dementia. Regarding the general cognitive performance obtained from the MMSE, an instrument used for the selection and during the follow-up evaluations in the sample, we observe an improvement trend at 4 months with respect to the baseline and a worsening trend at 12 months with respect to 4 months in the EG. Although this seems to underestimate the effect of CCT at first, it was important for us to evaluate cognitive functions and processes by using different specific tests for this objective.

One of the cognitive functions most evaluated was EF. In this order of ideas, both groups exhibited alterations in *visual reasoning* (CAMCOG) at the beginning of the study, which could be attributed to the sample's low educational level. However, the EG had a better performance than the CG in visual reasoning (CAMCOG) at 4 months (intergroup). Also, we saw longitudinal changes in cognitive performance within each group (intragroup). The CG showed a deterioration trend towards 12 months compared to 4 months, while the EG slightly improved at 4–12 months of CCT. Likewise, with respect to the EG, we found that people with MCI improved their performance while people with mild dementia worsened over time compared to the CG.

This could be explained because the GRADIOR cognitive training plan included activities such as puzzles; possibly this allowed training this EF. This means that the treatment contributed to a slight improvement in this process, preventing an even greater deterioration in the EG.

Our results suggesting an improvement trend in selective-sustained attention (evaluated by TMT-A-mistakes) at 4 months with respect to baseline and thereafter in processing speed (evaluated by TMT-A-time) at 12 months with respect to 4 months in people attending the GRADIOR sessions. Also, the results showed an interaction between "time and study group"; in this way, the EG slightly worsens its performance in TMT-A-time at 4 months, but makes fewer errors at 12 months, compared to CG, where the opposite happens. This means that these people found "doing it well" more important than "doing it fast" and therefore prioritized and intensified their attention capacity while performing the task. The improvement in attentional processing has also been noted in other studies such as that by Hagovská et al. [17] after 10 weeks of CCT and González-Palau et al. [16] after 12 weeks of combined (cognitive and physical) training delivered to healthy older adults and older adults with MCI.

The improvement in processing speed has been explained as the result of stimulation associated with social interaction in people with MCI [20]. According to our study, the improvement in processing speed after 12 months with respect to 4 months in the EG could have been due to the increase in social interaction during the CCT. The way in which GRADIOR was applied, in a shared room where users worked with their customized programs [50], probably favored the increase in social interaction among the people with MCI and mild dementia that attended the CCT [44, 53]. Further research is required to define the relationship between processing speed and social interaction.

The EG showed an improvement in *selective-divided attention, alternation, cognitive flexibility, inhibitory control*, and *cognitive flexibility* (evaluating processes by the TMT-B-mistakes) after 12 months of CCT with respect to 4 months (intra-group). Likewise, the results highlighted that the group of people with MCI and mild dementia associated with the EG improved in these processes over time compared to the CG. Studies also mentioned an enhancement in these processes in people with MCI [20]. This could be explained by the fact that GRADIOR is a CCT program that includes one of the basic training principles: "feedback" [54]. GRADIOR delivers feedback on the individual's performance in each of the activities, which offers the person the chance to "learn" and correct the mistake immediately and/or soon after making it [50].

In the field of neuropsychology, mistakes of omission or commission are a relevant source of qualitative information in the assessment of cognitive processes. People with MCI or mild dementia are often aware of these mistakes and, therefore, probably of their deficits. The purpose of any treatment, CCT or therapeutic process is that the patient, depending on the level of decline, be aware of his/her deficit. If otherwise, we would be dealing with anosognosia [55, 56].

As compared to the TMT-A, the EG took longer in completing the TMT-B at 4 months, which suggests low processing speed, although this decreases with age [57, 58]. The EG probably made more mental checks to avoid mistakes and were more aware of their difficulties, something that could be observed with greater precision during the evaluation at 12 months, which contributed to these results, considering the complex nature of the task of the B-condition of the TMT.

The overall improvement in EF after using a CCT program was also noted by Shatil et al. [59], although these authors only included healthy older adults in their study. In our study, there were also changes associated with EF such as fluency, categorization, and monitoring of performance evaluated by SVF and LVF, although these were observed at two different stages of the intervention. While the EG showed an improvement trend at 4 months in SVF tasks, at 12 months, this same group improved in LVF-P tasks. This was not so in the CG. This is interesting, the form of gradual improvement in verbal fluency, semantic fluency being the first to show improvement and then phonological fluency. The latter being in most cases the most compromised in PwD [60].

Calculation and numerical reasoning (WAIS-III Arithmetic) were one of the best-preserved functions in people with MCI and mild dementia at baseline. Both groups showed an improvement trend at 4 months and a slight worsening at 12 months. In this regard, the improvement was greater in the EG and the worsening in the CG. It is worth noting that one of the reasons why calculation is one of the best-preserved abilities among this population group could be related to their living conditions and, especially, to the need of developing and training this ability due to its multiple uses in various areas of daily living, from activities like shopping to more professional uses. Therefore, activities of daily living contribute to preserving the most frequently used functions.

One of the commonly deteriorated functions in people with MCI and mild dementia is memory [57, 61]. We only managed to perceive an improvement trend at 12 months with respect to 4 months in visual recognition tasks (RMBT) in both groups. Nevertheless, the EG obtained better results than the CG at 12 months. This is in line with the study conducted by Hwang et al. [62], where a significant increase in visual recognition was reported in people with Alzheimer's disease. It is a simple cognitive task that seems to benefit from any psychosocial intervention, both the usual and the more specific using GRADIOR. Moreover, considering that people with MCI accounted for a large percentage of our sample, recognition tasks were often better retained than free-recall ones [63].

Different studies have also reported significant alterations in the working memory (WM) of people with MCI and mild dementia [64, 65]. In our study, WM at 4 months appeared well-preserved in both groups, although the EG improved at 12 months in

Digit-Symbol test of WAIS-III compared to 4 months (intragroup). CG worsened at 12 months with respect to 4 months in two tests (Digit and Digit-Symbol of WAIS-III) (intragroup).

According to Hyer et al. [18], the WM in people with MCI improved after 7 weeks of CCT. Studies based on shorter periods of CCT and focused on WM only report improvements in this function in people with MCI [19, 24]. Other studies noted changes in the two variants of the WAIS-III Digits Test. Cavallo et al. [14] found that performance was better in forward and backwards spans of the Digits test at 12 weeks of CCT and that it was maintained at 6 months in people with Alzheimer's disease. This last finding was not explicit in our study, where the overall score on the WAIS-III Digits Test was considered.

Regarding *Visuoconstructive ability* of CDT, both groups performed similarly at baseline and at 4 months. However, the CG showed a worsening trend at 12 months with respect to 4 months, while the EG maintained similar levels of performance at 4–12 months (although the latter was not significant). However, a significant interaction was found which made it relevant that the EG of people with MCI maintained their performance and the group of people with mild dementia slightly improved at 4 months and maintaining over time compared to people with MCI and mild dementia of CG, this group decreased their performance.

Finally, the EG experienced an improvement in *mood* at 12 months of CCT with respect to 4 months. Also, there was a significance interaction between the CG-EG with a small effect size, where the EG scored better than the CG on the GDS at 12 months. Our findings are even related to meta-analyses such as that by García-Casal et al. [21] who also mentioned a small effect size on the improvement of depression in PwD after a CCT program. Or also, studies that reported an improvement in mood in people with MCI [16], even if others consider that this improvement is not possible [66].

Recommendations and limitations

The results reveal that the functioning and improvement of both groups at 4 months was similar, these data being inconclusive as to the short-term benefits of using this CCT program. Only after 12 months of CCT did the results show slight improvement and/or maintenance trends in certain cognitive processes and mood, with moderate-large effect sizes and, in certain cases, statistical significance in EG. In contrast, the CG showed greater worsening tendencies towards 12 months.

The above might be explained based on how the CCT GRADIOR was implemented: the first 3 months of CCT consisted of a standard plan, after which treatment was tailored to each individual's cognitive level over the 12 months. Such customization could have provided more benefits and effectiveness insofar as it was adjusted to the cognitive needs and characteristics of each participant. GRADIOR suggests and recommends a series of criteria to serve as the basis to make changes in the difficulty level of each task [50].

Flak et al. [67] suggested a comparison between customized and nonadaptive training and their influence on the WM of patients with MCI. Nevertheless, they found no changes after 5 weeks of CCT. By contrast, the study by Peretz et al. [68] proved the effectiveness of a customized CCT plan at 3 months on improving visuospatial WM, visuospatial learning, and sustained attention in older adults. While these studies provide an interesting approach, it would be advisable to consider in any cognitive training, the design of a training plan personalized to the individual's cognitive profile and characteristics.

Another relevant aspect was that the sample consisted of people with MCI, which is sometimes spontaneously reversible, and mild dementia, whose natural progress is not towards rapid decline. The benefits of applying a specific program CCT such as GRADIOR in cases of MCI and mild dementia will be more relevant when applied over long periods of time [24], against what is commonly the case with the implementation of these programs in studies based on few weeks of intervention [26, 69].

Lee et al. [25] recommended studies with longer periods of CCT be undertaken. Nevertheless, it is necessary to be aware of the difficulties involved in completing RCTs with older adults and long CCT programs. Such studies are often challenged by different factors that may be biological (high rates of mortality), physical (mobility alterations), contextual (little understanding of the family about the disease and its treatment), psychological (emotional disturbances that hinder treatment adherence), social (stigma associated with the person's social network), environmental (pandemic outbreak), and economic (lack of funding, high costs of human resources and infrastructures).

The relevance of this RCT is its 12-month length, so that, in addition to customizing the CCT, the purpose was continuity in time with frequent sessions over an extended period to test whether there were significant changes in cognitive processes and/or if they were maintained over time. If so, the use of a continuous CCT program would be related to the progressive nature of the neurodegenerative process that occurs in dementia, although this process varies among individuals and CCT cannot guarantee full recovery of cognitive processes.

One of the study's limitations is that the sample was small. Although the initial sample was 89 people, only 62 individuals managed to complete the 4 months and our attempt to have the sample complete the 12 months was hampered by the consequences of the outbreak and the extension in time of the COVID-19 pandemic.

The pandemic led to the closure of many public health centers and, therefore, the people undergoing the CCT with GRADIOR stopped attending the sessions. Only 23 individuals managed to complete the 12-months scheduled for the CCT before the pandemic began and therefore, the CG people on the waiting list were unable to start the treatment. This situation helps to redefine its current implementation and strengthens lines of research that are already in progress to consolidate the use of portable devices at home to make these programs more accessible to older adults [70], developing CCT programs based on a user-center methodology [71], and implementing digital literacy programs to bridge the digital divide [72]. Shatil et al. [59] suggested TV-based computer literacy training for older adults. Nevertheless, it will be necessary to develop devices.

We are aware that CCT is not the only treatment option for people with MCI and mild dementia, since the literature includes studies assessing the effectiveness of these cognitive programs combined with physical training programs [73] or other approaches such as reminiscence therapy [74] on different alterations associated with the disease. Dementia is a neurodegenerative disease that causes changes at different functional levels [75], so it would be interesting to engage in future studies to assess the effectiveness of GRADIOR in combination with other types of program [44]. In short, we believe that a multidisciplinary approach could prove more beneficial for this population [10].

GRADIOR can be considered a promising CCT program, it is a 1) flexible program that has not only been developed to be used with people with dementia, but also with people with other neurological and/or psychiatric pathologies; 2) it is easy to use for people with little knowledge in technology; 3) useful, due to its effectiveness, degree of usability [47] and level of user experience [48]. Specifically, it allows the 4) construction of a neuropsychological profile of each user from a neuropsychological evaluation that can be carried out from the same program; 5) design and implementation of a cognitive stimulation plan based on altered processes and the user's cognitive level; 6) adjustment of the treatment plan according to the user's cognitive performance.

Also, and considering our results, the use of GRADIOR is recommended in people with MCI and mild dementia for long periods of time. Cognitive training should be continuous and maintained over time due to the characteristics of the cognitive deterioration that these people present. We consider that its interruption could have a negative impact on the cognitive state of the person.

Implications

This study has important methodological, clinical, and practical implications in the field of neuropsychology, new technologies, and dementias. Methodological implications in terms of trying to imply a representative sample size and with it the multiple factors that could make sample collection difficult, which could be taken into consideration by future studies. Also, the application and implementation of a "GRADIOR" CCT program for long periods of time (12 months) and its positive influence on the maintenance of cognitive processes. Both the sample size and the continuity of treatment are two factors that any clinical trial whose objective is to evaluate the effectiveness should try to incorporate. These are also factors that have constituted part of the limitations of most of the studies currently published on the subject.

Perhaps the scope of this RCT could be questioned due to the changes in the design mentioned in the methodology session and the final size of the sample, but we consider that this RCT maintained its methodological rigor and presented an effort to want to overcome the limitation associated with the short training time proposed in most RCTs. We know that maintaining an RCT of 12 months requires a cost of great magnitude with respect to human, technological, and infrastructure resources. But above all, maintaining the level of sample motivation for them to attend the CCT sessions requires, for example, that the CCT be interesting and personalized to the needs of the people. And although we reported a sample loss around 12 months, this was not due to the nature of the RCT, but to the impossibility of continuing due to external factors, specifically due to COVID-19.

Regarding the clinical implications, cognitive rehabilitation has proven to be a field that responds to certain needs of people with dementia from the use of pencil and paper to the design and development of CCT programs such as GRADIOR that contribute to training, maintenance, and improvement of cognitive performance and delay of progressive deterioration in people with dementia. GRADIOR is a program that is adapted to the type and level of cognitive impairment, aspects that contribute not only to its effectiveness, but also to its usability. The use of tools such as GRADIOR makes the work of the therapist easier, who could have a session with several patients at the same time.

Likewise, this study indicates a tool, whose practical implication corresponds to its degree of accessibility that prevents these people from starting a cognitive training plan. Although this point is currently being improved, to increase its degree of accessibility. Likewise, this study contributes to future studies on effectiveness with respect to methodological aspects.

Conclusion

Some intergroup differences in cognitive performance were detected with respect to each of the evaluation times, visual reasoning (CAMCOG) being one of them. Likewise, improvement trends were identified at the intragroup level between baseline, 4 months, and 12 months for EG with respect to most of the cognitive processes evaluated by the different tests and although something similar happened for CG at 4 months, this same group showed changes and a tendency to worsen towards 12 months in most of the tests. We also highlight the interaction between "time and group", showing GRADIOR a positive impact on mood (GDS) and sustained attention (TMT-A-mistakes) in EG. And a significant interaction between "time, study group, and clinic group" for the CDT Order, highlighting the positive impact of the GRADIOR sessions in people with MCI and mild dementia of EG.

The effects seem to be more significant in those cases where the 12-month treatment was completed, which is why it is advisable to use this type of programs for long periods to test their effects. Many patients were unable to complete the scheduled sessions because of the COVID-19 pandemic, which also highlights the relevance of implementing these intervention programs through more accessible technologies.

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SUPPLEMENTARY MATERIAL

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INDUCT
Interdisciplinary Network for Dementia Utilising Current Technology

DISTINCT
dementia: intersectorial strategy for training and innovation network for current technology

Best Practice Guidance

Human Interaction with Technology in Dementia

Recommendations based on the research conducted in
the Marie Sklodowska Curie InnovativeTraining Network INDUCT, Deliverable D6.2 (paper version)/D6.5 (web version) V6.2 Final
and
the Marie Sklodowska Curie InnovativeTraining Network DISTINCT
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Due to the long documents, the relevant pages have been extracted.

- ***Robotic platform features and applications need to be tailored to the needs and preferences of end-users before implementing them in community-based dementia care*** [3.1.6.7]

Guidance: To successfully integrate social robotic platforms in community-based dementia care, such as Meeting Centres for people with dementia and carers and daycare centres, their features and applications need to be tailored to the needs and preferences of the end-users, the dynamics of group interactions, and the Meeting Centres' activity policies and settings.

Explanation and Examples: Research through focus groups and interviews with stakeholders on potential facilitators and barriers in the implementation of the social robot MINI indicated that for a successful implementation of social robots in Meeting Centres and daycare centres for people with dementia, it is expected to be crucial for social robot designers and developers to consider the following recommendations to guide the design of the robotic platform:

- Evaluate the needs and preferences of the participants of Meeting Centre. Qualitative research with end-users and care professionals is essential before and during the robot development phase. This will ensure the acceptance and usefulness of the robot in such contexts.
- Given the preference for group activities in Meeting Centres over individual activities, it is crucial to integrate the robot into a group setting so that it can interact with multiple users. For example, a multi-player game could allow two or more individuals to interact with a social robot at the same time.
- Avoid designing games and quiz-like activities for use on social robots to avoid, in line with the activity policy of Meeting Centres, confronting persons with dementia with their shortcomings in activities that have high cognitive and memory function demands. Instead, fun, enjoyable, and relaxing applications and games would be most appealing and beneficial.

Keywords: Social robots, community setting, Meeting Centres, dementia, daycare centres, mild cognitive impairment.

Target group: Researchers, social robot designers, and developers

Type of evidence

Aysan Mahmoudi (DISTINCT ESR13)
Original article on conditions of successful implementation of the MINI robot in Meeting Centres for people with dementia and carers

References

Mahmoudi A, Franco Martin M, Van der Roest H, Castro-González A, Kouters S, Dröes RM. (2023). Potential facilitators and barriers to implementing the MINI robot in community-based meeting centres in the Netherlands and Spain. JMIR Preprints 8/11/2022:44125.
doi: https://doi.org/10.2196/preprints.44125

▪ ***Ensure the appropriate methodology for evaluating social robots*** [3.2.5.2]

Guidance: Ensure that the methodology for the evaluation of social robots for older adults with and without dementia is appropriate for the purpose of the study, to strengthen the results of the study.

Explanation and Examples: Social robots are seen promising for supporting daily functioning and promoting overall social health of cognitively impaired older people, particularly those with dementia. Our scoping review into methodologies used to study the feasibility, usability, efficacy, and effectiveness of social robots for elderly adults with and without dementia showed that, despite promising results, the quality of studies remains low due to various methodological limitations. We have therefore formulated recommendations focusing on different types of studies that can help future researchers develop appropriate study designs to evaluate social robots, allowing for more reliable information on study outcomes:

- For *feasibility* and *usability* studies an experimental design with mixed-methods of data collection (qualitative and quantitative) are recommended. Multiple interaction sessions with the social robot are recommended as they may reveal changes in feasibility and usability, when the novelty effect gradually fades and people get used to the robot.
- Appropriate designs for *efficacy* and *effectiveness* studies are RCTs, or quasi-experimental designs when randomization is not feasible. Sample sizes should be sufficiently large, and individual interaction sessions with the social robot running for more than one month would serve best for such studies to obtain relatively robust and reliable results. Efficacy and effectiveness should only be studied in fully functioning social robots.
- It is strongly recommended not to combine different aims in one study. The preferred designs to study the feasibility and usability of a social robot, differ significantly from the designs needed to study efficacy or effectiveness.

Keywords: Social robots, community setting, methodologies, study design, feasibility, usability , efficacy, effectiveness

Target group: Researchers, social robot designers

Type of evidence

Aysan Mahmoudi (DISTINCT ESR13)
Scoping review

References

Aysan Mahmoudi Asl, Mauricio Molinari Ulate, Manuel Franco Martin; Henriëtte van der Roest (2022). Methodologies Used to Study the Feasibility, Usability, Efficacy, and Effectiveness of Social Robots For Elderly Adults: Scoping Review. J Med Internet Res 2022;24(8):e37434 https://doi.org/10.2196/37434

DEMENTIA: INTERSECTORIAL STRATEGY FOR TRAINING AND INNOVATION NETWORK FOR CURRENT TECHNOLOGY

Welcome to the winter newsletter!

Time flies and we are in our third DISTINCT year already. So much has happened since our last update. In spite of difficult times and the COVID-19 still ongoing, we have been working hard on our projects. Our enthusiasm for our projects and being able to be involved in dementia care has certainly been fruitful. This newsletter is filled with lots of exciting information on things that have happened in the last months to the DISTINCT projects and the ESRs.

Grab a cup of coffee or tea, sit back and relax, and enjoy the third DISTINCT newsletter.

Warmest greetings from the editors – Gianna (ESR10) and Aysan (ESR13)

Pascale Heins (ESR11)

During the past months, I worked on a qualitative interview study on the experiences of community-dwelling people with dementia regarding their social out-of-home participation. I conducted dyadic interviews with people with dementia and their informal caregivers. In collaboration with Gianna (ESR10), I am currently analysing the interview data. Furthermore, I conducted my virtual secondment at Karolinska Institutet (Stockholm, Sweden) and visited the secondment institution for two weeks in October 2021. Right now, I am working on a paper resulting from this secondment. The paper is related to the concerns of community-dwelling people with dementia when participating in social out-of-home activities. Besides, I am working in collaboration with the ESRs with an Occupational Therapy background on a position paper on the role of occupational therapists in the design and implementation of emerging technologies for people living with dementia. At the same time, I am working on a protocol and ethics application for my feasibility trial that will evaluate the potential effects of the mobile application 'Viamigo' on the social participation of people with dementia (see: https://www.viamigo.be).

Wei Qi Koh (ESR12)

The overall purpose of my project is to identify strategies for implementing pet robots in nursing homes for residents with dementia (pet robots are a technology-based substitute for live animals). The first steps are to gain a thorough understanding of the barriers and facilitators that influence their uptake in real world practice. To achieve this, we synthesised literature in the field, and also conducted a qualitative study. The latter involved in-depth, one-to-one interviews with key stakeholders in several nursing homes in Ireland. We are in the process of analysing the data, and expect to be able to share our findings by spring 2022. Moving forward, these findings will also inform the development of our subsequent modified Delphi study, which is expected to commence in spring 2022. On a more personal basis – after nearly 2 years of living with the pandemic, work-from-home somewhat feels more normalised. But I look forward to a (hopefully) less virtual 2022, and seeing more of the lovely fellow ESRs in person 😉

Aysan Mahmoudi (ESR13)

Recently I submitted my scoping review article and got the ethical approval for the feasibility and efficacy study of MINI. We are designing a living lab for the robot deployment. This lab will be one of the sites for our first trial study. Also, I'm running my secondment plan at VUmc, Amsterdam, and am so excited to work with Professor Rose-Marie and her nice team. The plan is to identify the potential facilitators and barriers to implementing the MINI robot in the meeting center in the Netherlands. The recruitment for the first trial of the MINI robot will start as soon as I get back to Spain."

Technology used in DISTINCT

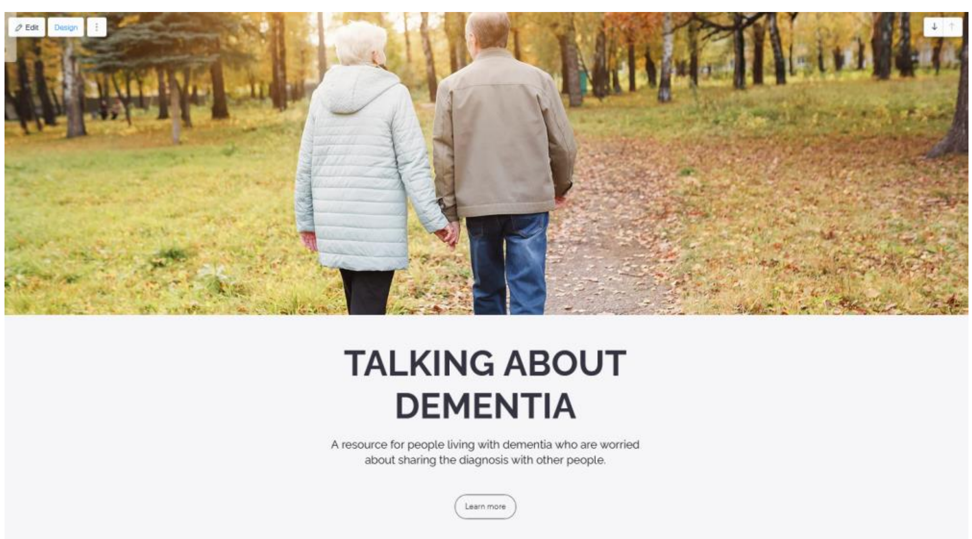
We all know DISTINCT has something to do with technology, and some ESRs are even developing and/or testing some kind of technological innovations. But have you ever wondered what kind of technology some ESRs are actually working on or with? So did we! Read on to find out more.

Example photo representing the ACP website

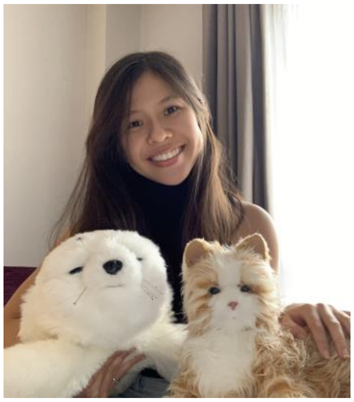
Fanny Monnet (ESR3) – Vrije Universiteit Brussel

As part of my DISTINCT project, we are developing an advance care planning (ACP) website for people with dementia and their families. We are working with an IT partner and are using an agile development approach, meaning that we are building the website in several iterations, before testing it as a whole. We are currently mid-way through the development process.

Gianna Kohl (ESR10)- University College London

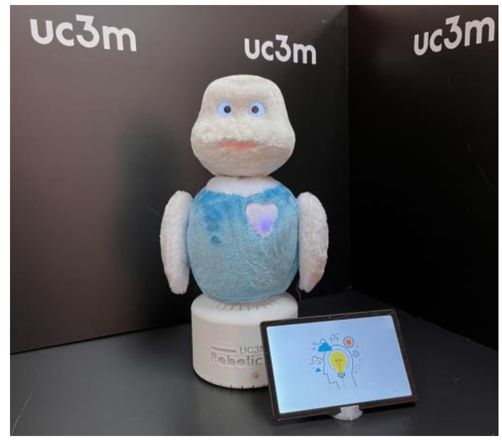


I am working on the adaptation of an existing group-based face-to-face intervention called “Who to tell, how and when” into a web-based intervention. The original intervention has been developed at University College London and is aimed at people affected by dementia who are fearful or worried about disclosing the dementia diagnosis to their social networks. The intervention exists of three sessions that participants go through. The overall aim is to be confident in deciding whether or not to tell other people about the diagnosis.



Wei Qi Koh (ESR12) – National University of Ireland Galway

I am looking into the implementation of pet robots, and here are two of the robots: PARO (left), a baby harp seal, and the Joy for All cat (right).



Aysan Mahmoudi (ESR13)- IDES

"*My name is Mini Maggie, but normally everyone calls me Mini as Mickey Mouse's girlfriend!! Hahaha! I'm here to have a fun time with you. I'm 5 years old, so I'm tiny, but cute*." Says Mini.

Mini is designed for psychosocial and cognitive stimulation and to provide entertainment for people with dementia.

Simone Anna Felding (ESR4) – German Center for Neurodegenerative Diseases

I am studying social robots in my PhD. In my ethnographic fieldwork I am focusing on pet robots and especially the JoyForAll cats and dogs.

Jaroslav Cibulka (ESR8) – Czech Technical University

I am working on the design, development and testing of PetBot, a pet-like care-bot to help people with dementia in their daily routine. A picture of the "PetBot squad" is shown on the right.

Wei Qi Koh (ESR12)

Presentations:
- Koh, W.Q., Ang, X.H.F., & Casey, D. (2021) *Recommendations for Implementing Pet Robots for People with Dementia in Nursing Homes: A Mixed Methods Study Protocol* [Poster presentation]. 31st Alzheimer's Europe Conference 2021
- Koh, W.Q., Whelan, S.A., Heins, P., Casey, D., Toomey, E., & Dröes, R.M. (2021). *Experiences and perceptions of using a low-cost pet robot for older adults and people with dementia* [Poster presentation]. The Gerontological Society of America's 2021 Annual Scientific Meeting.
- Koh, W.Q., Felding, S.A., Budak, K.B., Toomey, E., & Casey, D. (2021). *What are the barriers and facilitators affecting the implementation of social robots for older adults and people with dementia: A scoping review*. 4th UK Implementation Science Conference. (Best rapid oral-poster presentation)

Publications:
- Koh, W.Q. et al. (2021). Exploring Barriers and Facilitators to the Implementation of Pet Robots for People with Dementia in Nursing Homes: A Qualitative Research Protocol. *International Journal of Qualitative Methods*, *20*, 16094069211047059.
- Koh, W.Q., Felding, S.A., Budak, K.B. et al. (2021). Barriers and facilitators to the implementation of social robots for older adults and people with dementia: a scoping review. *BMC Geriatrics*, *21*(1), 1-17.
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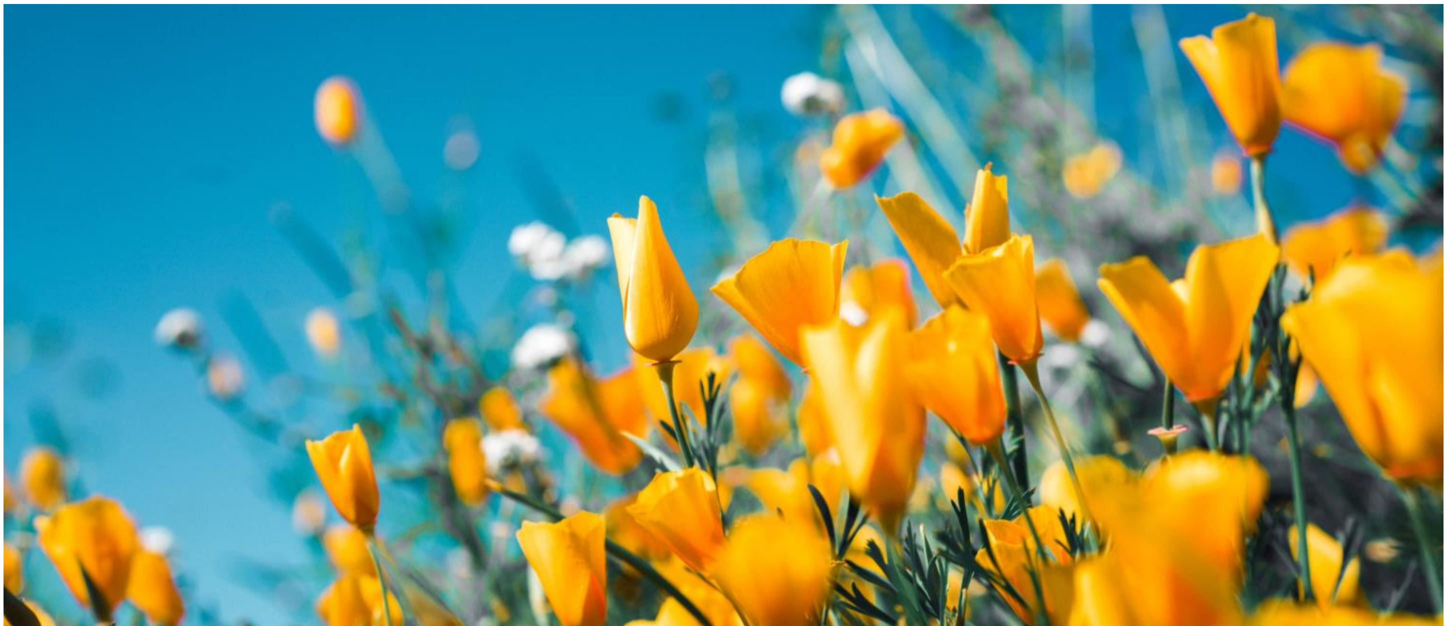
- The Irish Times. (2021). Social robots could address future skills shortage in care sector. 21 January 2021, Available here
- Koh, W.Q. 'DISTINCT project researchers find that low-cost robots may have potential to improve the psychosocial health of people with dementia.' Alzheimer Europe Newsletter, 2021, issue 3. Available here

Aysan Mahamoudi (ESR13)

Presentations:
- Mahmoudi et al. (2021, July 26-30). *Methodologies used to study the effectiveness of social robots in long-term and community care settings* [Poster presentation]. Alzheimer's Association International Conference, Denver, CO, United States.
- Molinari Ulate*, M., Mahmoudi, A. et al. (2021, July 26-30). *Comprehensive Geriatric Assessments for long-term and home care settings and digital platforms available to support their applicability: A systematic review* [Poster presentation]. Alzheimer's Association International Conference, Denver, CO, United States
- *The use of social robots in dementia care* [Oral presentation]. Neuropsychology module, University of Salamanca, Spain.
- *The use of social robots in dementia care and mental health* [Oral presentation]. Community care course, Provincial Hospital of Zamora, Spain.
- The use of social robots in dementia care [video clip]. SIDECAR project
- Project presentation at Trimbos-instituut, the Netherlands.

Publications:
- Submitted: *Methodologies Used to Study the Feasibility, Usability, Efficacy, and Effectiveness of the Social Robots in Clinical and Social Care Settings for Elderly Adults: A Scoping Review.*

DEMENTIA: INTERSECTORIAL STRATEGY FOR TRAINING AND INNOVATION NETWORK FOR CURRENT TECHNOLOGY



Welcome Back!

Autumn and Winter have passed since the last time we met.
Such a long time! But we are finally back!

It has been nine months since our last newsletter, and we are happy to meet you again with GREAT NEWS. Despite the challenging times we are living in, DISTINCT research teams have adapted and strengthened ties between each other. Our efforts and enthusiasm are producing results and we want to share it with you through our second newsletter. Just keep scrolling down and check some of our achievements, publications, posters, secondments, collaborations, and more.
Take your time, sit, and enjoy!

Click on the picture to interact!

Spring and the Editors of the Newsletter #2 - Mauricio (ESR7) and Pascale (ESR11) - Welcome You!

ESR-12: Wei Qi Koh

The overarching aim of my project is to look into implementation strategies for implementing pet robots for people with dementia in nursing homes. My team and I have recently completed a literature review to understand the barriers and facilitators that can affect the implementation of social robots. In addition, we have also consolidated evidence on the use of low-cost pet robots for people with dementia. Currently, I am working towards actualising the first phase of my empirical research, which has been approved by the research ethics committee. In this phase, I will conduct qualitative interviews with key stakeholders - such as people with dementia, organisational leaders and care professionals from nursing homes - to understand their perceptions of barriers and facilitators that can affect the implementation of pet robots. For now, we are finalising the logistics of this process, and I hope to start recruiting participants in May.

ESR-13: Aysan Mahmoudi Asl

Currently I'm revising the last draft of my scoping review article and hopefully will submit it on late May. In addition, I'm working on the study protocol of Mini robot to be presented in ethical committee in the near future and then submit the protocol article in Trials. We are also designing a living lab for the robot deployment. This lab will be one of the sites for the effectiveness and usability study of the Mini robot. As soon as we get the ethical approval, we will start the participants recruitment and study procedure. I'm also planning my secondment, the date and form of doing that with Prague team. Probably it's going to be both in-person and virtual, starting after the 3rd DISTINCT school.

ESR-14: Josephine Rose Tan

My project 'Known in the Nursing Home' has 3 phases- first is the design and development of the Fotoscope app, second is the examination of the effects of the app and the Fotoactivity intervention via trials in the nursing home, and third is the wider implementation of the intervention. Currently we are in the second phase. In February 2021, together with two healthcare organizations, we began the trials with 4 nursing home residents with dementia, adapting our protocol completely to remote/online methods. We've encountered several challenges along the way with doing everything remotely- from collecting informed and consent forms, training the carers and student observers, to remotely gathering data from the resident with dementia, the carers, and the family members. We are very thankful for all those involved in our project however, as we are still able to progress with the project.

ESR-15: Kübra Beliz Budak

I am about to submit a scoping review to the Disability and Rehabilitation journal, with the title "Can technology impact loneliness in dementia? A scoping review on the role of assistive technologies in long-term care". I collaborated with three ESRs: Simone, Golnaz, and Viktoria. I also collaborated with Wei on her scoping review.

I am also about to submit my ethical proposal to the University Witten/Herdecke, which is a prerequisite for PhD.

I am doing my secondment with Alzheimer Europe at the moment and currently I am contributing to expand a database on intercultural care.

I am preparing the protocol for the next steps of my research which are Delphi and focus groups.

Supplementary Material 3. Quality appraisal of the included studies assessed by two independent reviewers

Study	Introduction			Methods										Results							Conflicts			Quantitative study			Qualitative criteria			Quality scores
	Rationale	Objectives	Logic model	Study design	Outcomes	Data collection methods	Participant eligibility	Recruitment	Bias	Sampling	Setting and location	Comparator	Data sources	Enrolment	Description of study population	Reporting on outcomes	Summary of evidence	Limitations	Generalizability	Conclusions	Funding	Ethical considerations	Competing interests	Confounding	Statistical methods	Missing data	Analytical methods	Data validation	Reflexivity of account provided	
Bajones, et al [16]	2	2	2	1	2	2	2	0	1	1	1	N/A	2	1	2	2	2	0	0	2	0	0	0	0	1	0	2	2	0	1.4
	2	2	0	2	2	2	2	0	2	0	2	N/A	2	1	1	2	2	0	0	2	2	2	2	0	1	0	2	2	0	
Banks, et al [17]	2	2	2	0	2	2	1	2	1	0	1	2	2	0	0	2	2	0	0	2	0	1	0	0	2	0	N/A	N/A	N/A	1.1
	2	2	2	1	2	2	2	2	0	0	1	2	2	0	0	2	2	0	0	2	0	1	0	0	2	0	N/A	N/A	N/A	
Barrett, et al [18]	2	2	0	1	2	2	2	2	2	N/A	1	N/A	2	2	2	2	2	2	2	2	2	2	2	0	2	0	N/A	N/A	N/A	1.7
	2	2	0	2	2	2	2	2	2	N/A	1	N/A	2	2	2	2	2	2	2	2	2	2	2	0	2	0	N/A	N/A	N/A	
Beer, et al [19]	2	2	2	0	2	2	0	2	2	0	2	2	2	0	2	2	2	2	2	2	2	0	0	0	2	0	2	2	0	1.6
	2	2	2	2	2	2	0	2	2	0	2	2	2	0	2	2	2	2	2	2	2	2	0	0	2	0	2	2	0	
Birks, et al [20]	2	2	0	1	2	1	0	0	1	N/A	2	N/A	0	0	0	2	2	2	2	2	0	2	2	N/A	N/A	N/A	2	2	0	1.2
	2	2	0	2	2	2	0	0	0	N/A	2	N/A	0	0	0	2	2	2	2	2	0	0	2	N/A	N/A	N/A	2	2	0	
Broadbent, et al [21]	2	2	0	2	2	2	0	2	1	N/A	2	2	0	2	2	2	2	1	0	2	2	2	0	0	2	0	N/A	N/A	N/A	1.4
	1	2	0	1	2	2	0	2	1	N/A	2	2	2	2	2	2	2	2	0	2	2	2	0	0	2	0	N/A	N/A	N/A	
Broadbent, et al [47]	2	2	0	2	2	2	0	2	0	0	2	2	2	2	2	2	1	1	0	1	2	2	0	0	2	0	0	0	0	1.2
	2	2	0	2	2	2	1	2	2	0	2	2	2	2	1	2	1	0	0	2	2	2	0	0	2	0	0	0	0	
Cavallo, et al [22]	2	2	0	0	2	2	2	2	2	0	1	2	2	2	2	2	2	2	1	2	2	0	2	0	2	0	N/A	N/A	N/A	1.6
	2	2	0	1	2	2	2	2	2	0	1	2	2	2	2	2	2	2	1	2	2	2	2	0	2	0	N/A	N/A	N/A	
Cavallo, et al [23]	2	2	2	0	2	1	2	2	0	0	1	N/A	0	0	2	2	2	0	0	2	2	0	0	0	0	0	N/A	N/A	N/A	1.1
	2	2	2	1	2	2	2	2	0	0	1	N/A	0	0	2	2	2	0	0	2	2	2	0	0	0	0	N/A	N/A	N/A	
Chu, et al [24]	2	2	2	2	2	2	0	0	2	N/A	1	N/A	2	0	2	2	2	1	0	2	0	2	0	0	2	0	N/A	N/A	N/A	1.2
	2	2	2	2	2	2	0	0	2	N/A	1	N/A	2	0	2	1	2	2	0	2	0	1	0	0	0	0	N/A	N/A	N/A	
Fan, et al [11]	2	2	2	0	2	2	0	0	0	0	0	2	2	0	2	2	2	2	2	2	2	2	0	0	2	0	N/A	N/A	N/A	1
	2	2	2	1	2	2	0	0	0	0	0	0	2	0	0	2	2	2	0	2	0	2	0	0	2	0	1	0	0	

Continued

Section	Study	Fischinger, et al [25]		Huisman, et al [26]		Koh, et al [31]		Inoue, et al [27]		Keizer, et al [28]		Khosla, et al [29]		Khosla, et al [30]		Kramer, et al [32]		Liang, et al [33]		Libin, et al [34]		Moyle, et al [35]	
Introduction	Rationale	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	Objectives	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	Logic model	2	0	1	2	2	0	2	2	2	2	2	2	2	2	2	2	2	0	2	2	2	0
Methods	Study design	0	0	1	2	2	2	1	0	1	0	1	2	0	0	1	2	2	2	1	2	2	2
	Outcomes	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	Data collection methods	2	2	2	2	2	2	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	Participant eligibility	1	1	0	0	2	2	0	2	2	2	0	0	0	0	2	2	2	2	0	0	2	2
	Recruitment	0	0	0	0	2	2	0	0	2	2	2	2	0	0	2	2	2	2	2	2	2	2
	Bias	0	0	1	1	0	0	1	0	1	1	1	1	0	0	1	1	1	0	1	1	1	0
	Sampling	0	1	N/A	N/A	2	2	0	0	0	0	0	0	0	0	0	0	2	0	0	0	2	2
	Setting and location	0	2	2	2	1	2	0	0	0	2	2	2	1	2	1	1	2	2	0	1	2	2
	Comparator	N/A	N/A	N/A	N/A	2	2	N/A	N/A	2	2	N/A	N/A	N/A	N/A	2	2	2	2	2	2	2	2
	Data sources	0	0	2	2	2	2	0	2	2	2	2	2	2	2	0	0	2	2	2	2	2	2
Results	Enrolment	0	0	0	0	2	2	0	0	0	2	0	0	2	2	1	1	2	2	0	2	0	0
	Description of study population	0	0	2	1	2	2	2	2	2	1	2	1	2	2	1	0	2	2	2	1	2	2
	Reporting on outcomes	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	Summary of evidence	1	2	2	2	2	2	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	Limitations	2	0	2	2	2	2	2	2	2	2	2	2	0	0	1	2	2	2	2	2	2	2
	Generalizability	0	0	2	2	2	2	0	2	2	2	0	0	2	2	2	2	2	2	0	2	0	2
	Conclusions	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	2	2	2
Conflicts	Funding	2	2	2	2	0	0	2	0	2	2	0	0	0	0	0	0	2	2	2	2	2	2
	Ethical considerations	0	0	2	2	2	2	0	0	2	2	2	2	0	0	0	2	2	2	0	0	2	2
	Competing interests	0	0	2	2	0	0	0	0	2	2	0	0	0	0	0	0	2	2	0	0	2	2
Quantitative study	Confounding	0	0	0	0	0	0	N/A	N/A	0	0	0	0	0	0	0	2	0	0	0	0	0	2
	Statistical methods	0	0	0	0	2	2	N/A	N/A	2	2	0	0	2	2	2	2	2	2	2	2	2	2
	Missing data	0	0	0	0	0	0	N/A	N/A	0	0	0	0	0	0	0	0	0	0	0	0	2	2
Qualitative criteria	Analytical methods	N/A	N/A	2	2	N/A	N/A	1	1	1	1	2	2	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Data validation	N/A	N/A	0	0	N/A	N/A	0	0	0	0	2	2	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Reflexivity of	N/A	N/A	0	0	N/A	N/A	0	0	0	0	0	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Quality scores	1		1.3		1.5		1.1		1.5		1.2		1.2		1.4		1.7		1.4		1.8	

Continued

Study	Introduction			Methods										Results							Conflicts			Quantitative study			Qualitative criteria			Quality score
	Rationale	Objectives	Logic model	Study design	Outcomes	Data collection methods	Participant eligibility	Recruitment	Bias	Sampling	Setting and location	Comparator	Data sources	Enrolment	Description of study population	Reporting on outcomes	Summary of evidence	Limitations	Generalizability	Conclusions	Funding	Ethical considerations	Competing interests	Confounding	Statistical methods	Missing data	Analytical methods	Data validation	Reflexivity of	
Obayashi, et al [36]	2	2	2	2	2	2	2	2	2	0	2	2	2	2	2	2	2	2	2	2	2	2	2	0	2	0	N/A	N/A	N/A	1.8
	2	2	2	2	2	2	2	2	2	0	2	2	2	2	2	2	2	2	2	2	2	2	2	0	2	0	N/A	N/A	N/A	
Pripfl, et al [37]	2	2	0	0	2	1	2	2	1	0	0	N/A	0	0	2	2	1	2	0	1	2	2	2	0	2	0	2	0	0	1.4
	2	2	0	1	2	2	0	2	1	0	2	N/A	0	0	1	2	1	2	2	2	2	2	2	2	2	0	2	0	0	
Pu, et al [38]	2	2	0	2	2	2	2	2	1	2	1	N/A	2	0	2	2	2	2	0	2	2	2	2	N/A	N/A	N/A	2	2	0	1.8
	2	2	2	2	2	2	2	2	1	0	2	N/A	2	0	2	2	2	2	2	2	2	2	2	N/A	N/A	N/A	2	2	0	
Schussler, et al [39]	2	2	2	2	2	2	2	2	1	2	2	2	2	N/A	N/A	N/A	N/A	2	2	N/A	2	2	2	0	2	0	2	0	0	1.5
	2	2	0	2	2	2	2	2	1	2	2	2	2	2	N/A	N/A	N/A	N/A	N/A	N/A	2	2	2	0	2	0	2	0	0	
Valenti, et al [43]	2	2	2	2	2	2	2	2	2	0	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	N/A	N/A	N/A	1.7
	2	2	2	2	2	2	2	2	2	0	2	2	2	2	0	2	2	2	2	2	2	2	2	0	2	0	N/A	N/A	N/A	
Sung, et al [40]	2	1	2	2	2	2	2	2	1	0	1	2	2	0	2	2	2	2	2	2	0	2	0	0	2	0	N/A	N/A	N/A	1.6
	2	2	2	2	2	2	2	2	1	0	1	2	2	0	2	2	2	2	2	2	2	2	0	2	2	0	N/A	N/A	N/A	
Thodberg, et al [41]	2	2	2	2	2	2	2	2	1	0	1	2	2	2	2	2	2	2	0	0	2	2	0	0	2	0	N/A	N/A	N/A	1.5
	2	2	0	2	2	2	2	2	1	0	2	2	2	2	2	2	2	2	0	2	2	2	0	0	2	0	N/A	N/A	N/A	
Torta, et al [46]	2	2	2	0	2	2	0	2	1	0	2	N/A	2	0	1	2	2	0	0	2	2	0	0	2	2	0	0	0	0	1
	2	2	2	2	2	2	0	2	1	0	2	N/A	2	0	0	2	2	0	0	2	2	0	0	0	2	0	0	0	0	
Wada, et al [44]	2	2	2	0	2	2	0	0	1	0	2	N/A	2	2	2	2	2	1	0	2	0	2	0	0	2	0	N/A	N/A	N/A	1.2
	2	2	2	0	2	2	0	0	0	0	2	N/A	2	0	2	2	2	2	2	2	0	2	0	0	2	0	N/A	N/A	N/A	
Wada, et al [45]	2	2	2	0	2	2	0	0	1	0	2	0	2	0	2	1	1	0	0	2	0	0	0	0	2	0	N/A	N/A	N/A	1
	2	2	2	0	2	2	0	0	0	0	2	0	2	0	2	2	2	2	2	2	0	0	0	0	1	0	N/A	N/A	N/A	
Zsiga, et al [42]	2	2	2	0	2	2	2	2	0	0	1	N/A	2	0	2	2	1	0	0	2	2	2	2	0	1	0	N/A	N/A	N/A	1.3
	2	2	2	0	2	2	2	2	0	0	1	N/A	1	0	2	2	2	0	2	2	2	2	2	0	1	0	N/A	N/A	N/A	

Note. The highlighted rows indicate the second reviewer's scores. Total agreement percentage= 86.11

The quality of included articles was appraised independently by two authors, through the quality assessment of digital health interventions within the Monitoring and Evaluating Digital Health Interventions framework established by the World Health Organization (WHO) [14].

<table>
<tr><td colspan="3">Supplementary Material 4. Interview Questions</td></tr>
<tr><td colspan="2">Conditions</td><td>Preparation phase</td></tr>
<tr><th>Area</th><th>Ask</th><td rowspan="5">Micro
I. Where would you get the funding for this intervention? (M1)
II. What do you need to prepare for the robot implementation? (M1, C)
III. What adjustments do you think you need to make to the intervention so that it will work effectively in your meeting center? (M1, C, A, T) Remember:
O Change software content/activities.
O Adjusting the hardware.
O Difficulty of the games and exercises
IV. Could someone (or a team) from outside your organization help you implement the intervention? (C, M1)
V. Who could be responsible for and involved in the implementation of the robot in daily practice? (M1, C, A)
VI. How would you inform the participants and caregivers of your meeting center and caregivers about the implementation of this new intervention? (M1, C)

O Information meetings.
O Email.
O Phone calls
O Newsletter
Meso
VII. Would a collaboration between the meeting centers and other healthcare organizations/systems help to implement the robot (jointly)? (M1, M2, LG)
Yes, namely ……………………
……
New

Macro
VIII. What needs to be done to obtain approval from your organization for the implementation of the robot? (C, M1, M2)
Is there anything else you would like to discuss or comments you would like to make about the robot or its implementation in meeting centers?</td></tr>
<tr><td>Features of the intervention</td><td>1. What do you think of the intervention? (All stakeholders)
2. Would deploying the robot in your meeting center be of added value for the participants or the healthcare professionals? Yes, No, If so, in what sense?

A) For participants:
O participating in a fun activity
O memory training
O amusement
O social interaction
O having fun
O else …………………………
B) For healthcare providers:
O additional range of activities
O getting familiar with ICT
O else …………………………
If not, why not?
3. Do you think this intervention fits the interests/needs/capabilities of the participants? (All stakeholders)
4. What do you think of the complexity of the intervention/robot for the participants (A)
O Simple O Easy to learn O Complicated O Very complicated

5. What do you think of the quality of the intervention/robot? (A, M1, M2T)
O Poor O Moderate O Good O Very good
6. Do you think the intervention in the meeting center will have an effect on the participants? (A, M1) (if no, see also III)
Yes No
Yes, namely:
O improved memory
O more active/alert
O less lonely
O more social interaction/
O improved mood
7. How well does the intervention match the values and norms within the meeting centre? (A, M1)
O Not at all O Partly O Good O Very good.

8. Do you think the intervention will/can replace or supplement an existing program component, activity or process? (A, M1)
Oh yes, namely …………
Oh no</td></tr>
<tr><td>Time and other organizational conditions</td><td>1. How much time do you think it will take for the full implementation of the robot in the meeting center, taking into account all organizational procedures to be followed? (M1, T)
O Less than 3 months O 3 to 6 months O More than 6 months

2. How often do you plan to use the robot in the meeting center?
O Less than 3 days a week O More than 3 times a week O Every day</td></tr>
<tr><td>Financing and personnel</td><td>1. Which people in your organization do you think could play an important role in the implementation of the social robot? (M1, C)
O Manager organization
O Activity Therapist
O Program coordinator
O IT department
2. Do you expect to have or be able to acquire sufficient financial resources to implement and offer the intervention? (M1) (if No, I)
3. Do you think health insurance covers the use of the robot (as an aid)? (M1, M2, LG)</td></tr>
<tr><td>Organizational conditions</td><td>1. What kind of health policy or legislation do you think applies to (co-)finance implementation of such technologies in the meeting center? (M1, M2, LG)</td></tr>
<tr><td colspan="3">Remark. C: program coordinator, A: activity therapist, M1: meeting center manager, M2: manager/director other care/welfare organization T: ICT specialist, LG: local government</td></tr>
</table>

Supplementary Material 5. List of Codes

Precondition phase A

- If the intervention fits the interests/needs/capabilities of the participants (precondition/characteristic of the intervention) A-1
- If the intervention matches the values and norms within the meeting centre (precondition/characteristic of intervention) A-1
- The intervention will/can replace or supplement an existing program component or activity (precondition/characteristic of the Intervention) A-1
- Complexity of the intervention (precondition/characteristic of the Innovation) A-1
- Quality of the intervention/robot (precondition/characteristic of the Innovation) A-1
- Added value for the participants (precondition/characteristic of the innovation) A-1
- Added value for the healthcare professionals (precondition/characteristic of the innovation) A-1
- Time required for the full implementation (precondition/time and other operational preconditions) A-2

Preparation phase B

- Adjustments to the robot that make it more effective in the meeting center (preparation phase/micro/context) B-1.1
- The way of informing people about the robot (execution phase/ micro/ implementation) B-1.2
- Preparation for implementation (preparation phase/micro/meso/maco) B-1.2, B-2.2, B-3.2
- What needs to be done to obtain approval (preparation phase/meso/context) B-2.1
- Collaboration between the meeting centers and other healthcare organizations/systems (preparation and execution phase/ meso/context) B-2,1, C-2.1
- Ability to acquire sufficient financial resources (preparation and execution phase/meso/implementation) B-2.2
- People from outside that can help with implementation B-2.2, C-2.2
- Responsible people for the implementation (preparation and execution phase/meso/implementation) B-2.2, C-2.2
- Coverage of health insurance (preparation and execution phase/macro/Implementation) B-3.2
- Information on available health policy or legislation for implementing such technologies in meeting centers (Preparation and Execution phase/macro/context) B-3.1, C-3.1

Execution phase C

- Effect of the robot on the participants of the meeting center (execution phase/micro/mechanism of impact) C-1.3
- Frequency of implementing the robot (execution phase/micro/implementation) C-1.2
- People in your organization who could play an important role in the implementation (execution/micro/implementation) C-1.2

- People from outside that can help with implementation (preparation phase and execution phase/ meso/implementation) B-2.2, C-2.2
- Responsible people for the implementation (preparation and execution phase/meso/implementation) B-2.2, C-2.2
- Collaboration between the meeting centers and other healthcare organizations/systems (preparation and execution phase/ meso/context) B-2,1, C-2.1

Dña. Teresa de Portugal y Fernández del Rivero, Presidenta del Comité de Ética de Investigación con Medicamentos del Área de Salud de Zamora

CERTIFICA

Que este Comité ha evaluado el Proyecto de Investigación Nº **de Registro 574,** Investigador principal: D. Manuel Franco Martín del Servicio de Psiquiatría y Salud Mental del Complejo Asistencial de Zamora, titulado:

USABILIDAD, ACEPTABILIDAD Y EFICACIA DE UN ROBOT SOCIAL PARA MEJORAR LAS EMOCIONES Y LA SENSACIÓN DE SOLEDAD EN PERSONAS MAYORES CON DETERIORO COGNITIVO LEVE Y DEMENCIA LEVE

y considera que:

Se cumplen los requisitos necesarios de idoneidad del proyecto en relación con los objetivos del estudio.

Los riesgos y molestias previsibles de la investigación son aceptables en relación con los beneficios esperados.

El plan de reclutamiento de sujetos previstos es adecuado.

Se considera adecuado el procedimiento previsto para información y obtención del consentimiento informado.

Por tanto, este Comité acepta que dicho proyecto sea realizado por D. Manuel A. Franco Martín, del Servicio de Psiquiatría y Salud Mental del Complejo Asistencial de Zamora.

El Comité tanto en su composición como en los PNTs, cumple con las normas de BPC (CPMP/ICH/135/95) y con el Real Decreto 1090/2015.

La composición actual del CEIm del Área de Salud de Zamora es la siguiente:

PRESIDENTE:

Dña. Teresa de Portugal Fernández del Rivero (Oncóloga. Hospital Provincial de Zamora)

VICEPRESIDENTE:

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D. Carlos Ochoa Sangrador (Pediatra Hospital Virgen de la Concha. Responsable de la Unidad de Apoyo a la Investigación. Hospital Virgen de la Concha de Zamora)

Dña. Soledad Sánchez Arnosi (Diplomada en Enfermería).

D. Alfonso Díaz Madero (Farmacéutico. Departamento de Farmacia de Atención Primaria. Complejo Asistencial de Zamora)

Dña. Mª del Rosario Rodríguez López (Licenciada en Derecho. Funcionaria de Carrera de la Excma. Diputación Provincial de Zamora, área de Servicios Sociales) Independiente. Miembro Lego. DELEGADO DE PROTECCIÓN DE DATOS.

Dña. Teresa Peral Delgado (Licenciada en Derecho. Directora Provincial del Instituto de la Seguridad Social de Zamora Miembro Comité de Ética Asistencial) REPRESENTANTE DE LOS INTERESES DE LOS PACIENTES.

Dña. Alicia Lorenza Bouzada Rodríguez. (Graduada en Enfermería. Enfermera en el Centro de Salud de Toro.)

D. Luis Alberto de Vega Martín.(Medicina Familia y Comunitaria. Médico de Atención Primaria del Centro de Salud de Camarzana de Tera)

D. Enrique Coscaron Blanco. (Otorrinolaringólogo Hospital Virgen de la Concha)

D. José Camilo Martínez Alonso. (Alergólogo. Jefe de Servicio de Alergología del Hospital Virgen de la Concha.

D. Francisco Javier Domínguez Belloso. (Farmacólogo Clínico. Psiquiatra en el Hospital Rio Hortega de Valladolid).

En la reunión se cumplió el quórum preceptivo legalmente.

*En el caso de que se evalúe algún proyecto del que un miembro sea investigado/colaborador, este se ausentará de la reunión durante la discusión del proyecto.
USABILIDAD, ACEPTABILIDAD Y EFICACIA DE UN ROBOT SOCIAL PARA MEJORAR LAS EMOCIONES Y LA SENSACIÓN DE SOLEDAD EN PERSONAS MAYORES CON DETERIORO COGNITIVO LEVE Y DEMENCIA LEVE
Se ausentó de la deliberación de este estudio D. Manuel Franco Martín

Zamora, 28 de enero de 2022

C.E.I.m
ÁREA DE SALUD
DE
ZAMORA

Fdo.: Dña. Teresa de Portugal y Fernández del Rivero
Presidenta del CEIm del Área de Salud de Zamora

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Supplementary Material 7. Almere Model Questionnaire

		5	4	3	2	1
		Completely agree	**Relatively agree**	**Neutral**	**Somewhat disagree**	**Completely disagree**
1	When using the robot I have been afraid of making mistakes with it.					
2	When using the robot I was afraid of breaking something					
3	The robot scares me					
4	I think it's a good idea to use the robot.					
5	I would like to have the robot at home					
6	If I had the robot at home I would use it often					
7	I think the robot can be adapted to what I need					
8	I think the robot will only do what I need at a time when particular					
9	I think the robot will help me when I need it					
10	I like that the robot talks to me.					
11	I like doing things with the robot.					
12	I find the robot nice.					
13	The robot seems boring to me					
14	I think I will quickly know how to use the robot					
15	The robot seems easy to use					
16	I think I can use the robot without help					
17	I think I can use the robot when someone is around to help					
18	I find the robot a pleasant conversation partner					
19	I find it pleasant to interact with the robot					
20	I feel that the robot understands me					
21	I think the robot is cute					
22	I think the robot is useful to me					
23	I should have the robot					
24	I think the robot would be good entertainment					
25	I feel like the robot has life					
26	I feel that the robot is not a real person					
27	Sometimes the robot seems to have real feelings					
28	The robot inspires me confidence					
29	The robot seems smart to me					

Supplementary Material 8. Interview Questions	
1.	What do you think about Mini? (e.g., appearance, feelings, the experience of using Mini)
2.	What does Mini do for you?
3.	Does Mini help you feel better?
4.	Is there anything you don’t like about Mini?
5.	Is there any other game/ exercise you would like to do with Mini?
6.	Is there anything you would like to change about Mini?
7.	Is there anything else you would like to tell us about Mini?