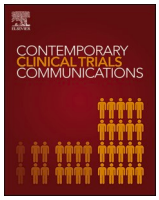
Contemporary Clinical Trials Communications 30 (2022) 101024

Contents lists available at ScienceDirect

Contemporary Clinical Trials Communications

journal homepage: www.elsevier.com/locate/conctc



The social robot companion to support homecare nurses: The guardian study protocol

Arianna Margaritini [a], Marco Benadduci [a], Giulio Amabili [a], Anna Rita Bonfigli [a], Riccardo Luzi [b], Katarzyna Wac [c], Henk Herman Nap [d], Elvira Maranesi [a,*], Roberta Bevilacqua [a]

[a] Scientific Direction, IRCCS INRCA, Ancona, Italy
[b] Medical Direction, IRCCS INRCA, Ancona, Italy
[c] Quality of Life Technologies Lab, University of Geneva, Switzerland
[d] National Expertise Centre Long-Term Care, Vilans, the Netherlands

ARTICLE INFO

Keywords:
Social assistive robot (SAR)
Older people
Informal and formal caregiver
AAL
Empowerement
User-centered design

ABSTRACT

Introduction: The reduction of the older people's self-sufficiency and the increase in the need for help in daily activities has a significant impact on the person and their caregivers. The primary objective of the GUARDIAN project is to enable the older people to live as long as possible at home, by means of the GUARDIAN socio-technical platform.

Methods: and Analysis: The GUARDIAN platform consists of two connected apps: one dedicated to the caregiver (Caregiver App) and one dedicated to the older people (Senior App), plus a robot (Misty II), to provide coaching in an engaging modality. The study is designed as a technical feasibility pilot to test the GUARDIAN system on a group of older people.

Discussions: The proposed solution reflects the real wants and needs of the older people person, increasing the acceptability of the system. In addition, the GUARDIAN project has the potential to have distinguished two phases of testing, so that changes can be made to the platform between the first and second phases, using data, both qualitative and quantitative, collected after the first phase.

Ethics and dissemination: The study was approved by the Ethic Committee of the IRCCS INRCA. It was recorded in ClinicalTrials.gov on the number NCT05284292.

1. Introduction

The demographic curve in Europe has been clear for several years now. In fact, it is estimated that in 2050 the number of over-65s will increase significantly, from 12% in 2015 to 22% in 2050 [1]. This demographic shift will bring with it the need to make changes in the economic, social and care management of the older people. First, as the average age increases, so does the tendency of the older people to want to live alone [2,3]. Indeed, it has been observed that the major concern of the over-65s is increasingly becoming the loss of autonomy and independence, related to their refusal to leave their homes and move, for example, to hospices [4]. Obviously, this trend will inevitably lead to a reduction in social network and engagement in social activities [5] and several researches have shown how social isolation and loneliness are important predictors of worsening health, both physical and mental, and thus mortality [6,7]. Actually, some studies have demonstrated how these two variables are linked to depression and anxiety [8,9], psychological distress [10], deterioration of cognitive function [11], as well as cardiovascular disease [12] and reduction of healthy and healthful behaviors [13].

The demographic trend will inevitably lead to an increase need of assistance from the population to the various national health systems, which will find it very difficult to respond to all requests due to a strong shortage of health workers [14].

Cognitive decline, physical frailty, and organic diseases limit the aging person's independence and thus increase the caregiver's workload [15] Another aspect to consider when talking about the consequences of aging, not only pathological, concerns all those daily activities that in old age become difficult for the person to perform independently. Activities such as remembering to take medication, following a proper diet, maintaining a routine as much as possible, proper sleep hygiene-these are just some of the main aspects to consider when talking about a

* Corresponding author.
E-mail address: e.maranesi@inrca.it (E. Maranesi).

https://doi.org/10.1016/j.conctc.2022.101024
Received 20 June 2022; Received in revised form 15 September 2022; Accepted 26 October 2022

person's autonomy and independence [16]. The reduction of the older people's self-sufficiency and the increase in the need for help in daily activities has a significant impact on the person and their caregivers [17]. The most common negative aspects include lifestyle changes, loss of self-esteem, caregiver burden and stigmatization, all of which can have a impact on health and quality of life [18]. As suggested in the literature [19,20] to try to maintain optimal cognitive and physical functions for as long as possible it is suggested to intervene on some factors, by encouraging a balanced diet, stimulating the development of regular physical activity, trying to maintain an adequate social network and being engaged in activities that stimulate cognition.

All this led to research into solutions in the field of technology [21,22], research that led to the concept of Ambient Assisted Living (AAL). The idea behind it is to make use of innovative technologies to support the older people and help them to live autonomously and independently, to keep themselves socially engaged and physically active, so as to improve their quality of life [23], and, at the same time, reduce the burden and workload on both families and the health care system [24]. Specifically, when referring to AAL, it refers to a set of technological solutions, such as sensors, computers, social robots, and telehealth devices, the purpose of which is to provide the person with greater well-being and health [25]. Depending on the person's needs, AAL technologies can then be useful to intervene during all stages of aging [26] by restoring the older person's control over his or her daily life, social, and environment [27], through tools such as wearable devices such as smartwatches or bracelets, fall detection devices, reminder devices, and smart homes. In this context, a key role is played by social robots, which can support the seniors by acting on multiple fronts, health care, companionship, assistance with physical activity, and social engagement [28,29]. These technologies appear to be promising in terms of acceptability and effectiveness [30] and it is from these premises that the GUARDIAN project is initiated.

The primary objective of the GUARDIAN project, funded by the Europe AAL programme, is to enable the older people to live as long as possible at home, by means of the GUARDIAN socio-technical platform.

The proposed project is significant in several respects. First, the use of GUARDIAN will allow older people to take an active role in self-management of the own health and the active participation in the decision-making process, by improving the quality of life, autonomy and prolonging the stay at home. Secondly, the project aims to improve the communication between the older people and careers.

The study is divided into two experimental phases, in order to allow the prompt resolution of usability problems as soon as they are detected by the older participants, to improve the overall user experience and guarantee the acceptance of the technological solution. The GUARDIAN platform consists of two connected apps: one dedicated to the caregiver (Caregiver App) and one dedicated to the older people (Senior App), plus a robot (Misty II), to provide coaching in an engaging modality. The application of the caregiver offers the opportunity to monitor the well-being and activities of the older person from remote, reducing its workload and improving the feeling of security of the caregivers.

Misty II is deployed in the homes of the older people, with aim of detecting the presence inside the home, reminding appointments, assisting in his daily activities and diminishing the sense of loneliness. The application dedicated to the caregiver receives the data and self-reports of the older people from the robot, in order to constantly offer an updated picture of the condition of the older people and to keep them informed about their condition and well-being. During the set-up phase, the participants decide the information to be shared with the caregivers. The project also includes the formal caregiver's perspective.

The trial will be carried out in three countries (Italy, Switzerland and the Netherlands). Table 1 shows the subjects recruited in the various countries participating in the trial.

Table 1
Experimental sites and number of subjects recruited in each site.

Experimental site	Alpha Phase	Beta Phase
Switzerland	4 seniors	10 seniors
Italy	4 seniors	10 seniors
the Netherlands	4 seniors	10 seniors
Total	**12 seniors**	**30 seniors**

Table 2
Outcomes and clinical assessments.

Outcome(s)	Clinical assessment
Primary: Acceptability of the Guardian platform	UTAUT [32]
Secondary: Reduction of the care load of the informal caregiver and the number of hours of care for the older people	Zarit Burden Interview [33]
Secondary: Impact of technology on users	Ad hoc questionnaire
Secondary: Perception of product ethics by the older people	Ad hoc questionnaire
Secondary: Caregiver's Decrease in Stress and Anxiety	General Anxiety Disorder-7 [34]
Secondary: Quality of life of the older people	EQ5D -5L [35]
Secondary: Feeling of being connected to others, of being able to have interpersonal relationships	Social Connectedness Scale
Secondary: Quality of life	SF-12 [36]

UTAUT= Unified Theory of Acceptance and Use of Technology; EQ5D -5L = European Quality of Life-Five Dimension-Five Level Scale; SF-12 = Short Form (12).

2. Methods and Analysis

2.1. Trial design

The study is designed as a technical feasibility pilot to test the GUARDIAN system on a group of older people. In both phases the presence of a formal caregiver is expected.

2.1.1. Alpha phase

In this phase, the users and their caregivers use a first version of the GUARDIAN platform, for three months. The results and feedback from the Alpha trial will give indications to improve and refine the platform. In this phase the robot Misty II, the Senior App and the Caregiver App will be tested.

The Senior App will allow the senior to:

- receive programmed reminders from the caregiver via the application at its own discretion
- communicate to the caregiver their general well-being and the activities carried out
- send self-reports about the quality of sleep
- receive tips for daily activities
- express needs and requirements
- send and receive messages from the caregiver.

The aim of the Senior Application is to provide direct feedback to the caregivers based on the seniors' answers, reported from the tablet application. The web application (guardian.jef.it) runs in every browser from which it is possible to download the app version, easily accessible by the shortcut on the tablet's home. The senior application is necessary because the robot-user communication is unidirectional: the communication channel is established from the robot to the user and not vice versa. The user can voluntarily report feedback or answer robot's requests through this application (Fig. 1). The questions to be answered are about: quality of sleep, wellbeing, meals and medication intake. Furthermore, on the home menu, other two buttons (volume settings and appointments) are present in order to adjust the volume of the robot and to view appointments. When a question is asked (i.e. displayed), the

Fig. 1. Senior App interface.

robot speaks it loud, since it is synchronized with the Senior Application. In the same way the robot congratulates or thanks the user when an answer is entered.

Each question can have one or multiple answers. In fact, after answering some questions negatively, the older adult can be asked to answer some follow-up questions (e.g. if the first question is "How are you feel?" and the senior answers "Not so good" follow-up question can be "Are you in pain?").

The login screen the tablet application is only shown at the installation phase, in order to avoid accidental logouts by the clients. The login is done by inserting the client Identification number (Client ID) generated in the Caregiver Application setup and the robot serial number (Robot Code). This process aims to "assign" the robot to the given client, disconnecting it from others if necessary. In addition, there is only one possible Senior Application connected to the user/robot at any given time.

The Caregiver App will help the caregiver to:

– stay up to date and informed about the status of the older person
– send reminders to the older people about proper nutrition
– reminding the older people of their commitments
– remind the older people when to take certain medications
– ask for feedback on sleep quality and overall health
– send and receive messages to and from senior.

The caregiver application is the instrument that aims to help the formal and informal caregiver to easily monitor seniors during their daily activity.

To easily cluster users, all participants will take a role in one or more Care networks. Actually, one senior is one care network, and that care network can contain multiple (in)formal caregivers. All caregivers belonging to the care network will have the ability to see the client overview and communicate with the older adult, according to permissions allowed by the older adult. The Administrator can add a new Senior, creating in this way a new network. On each network he can add/edit/remove users within a seniors' network. Each network has its own ID number, that is used to login a senior in the Senior App. To properly track senior and customize insights tracking for a senior, the Caregiver settings section will help caregivers to set up routines for each senior individually.

All data that is needed by or created via the caregiver application is stored in the Guardian database.

Caregiver user can define when senior users will be prompted with report requests, by defining interval during which this request will be active (e.g. one month), frequency of the request (e.g. every day), and time of the request. The Caregiver can define the exact time when that request will be prompted or the related action (e.g. reminding the medication after lunch).

The Caregiver App's back-end is the link between the caregivers' front-end application and the database. It is a so-called REST API which provides a number of actions, like "get the calendar" or "save this report", that can be launched by the front-end application. The back-end application receives the request from the front-end and performs all database actions necessary to send back the data or to save the update. The back end validates the request and the data, e.g., checking that the user is logged in and has access to the data, or that the data conforms to built-in rules.

The back-end application can send reminders and notifications using a built-in scheduler that regularly checks if a notification needs to be sent, based on the selections made by the caregiver, that are stored in the database. Notifications are sent in the form of emails.

Technological stack that is used for the Guardian Caregiver backend is:

- Java programming language
- Spring as development framework
- MySQL database
- Tomcat application server

The Caregivers front-end application is characterized by two parts:

- Guardian Management Tool
- Guardian Caregiver App.

The Guardian front-end caregiver App is the primary way how (in) formal caregivers will get information that was collected in the system. Each activity in the system is recorded in one of the Care networks. The caregiver app consists of some main sections:

- Overviews

In the overview section (in)formal caregiver can get an overall picture of how the senior is doing. By just looking in the dashboard graph caregiver can get information if the senior is needing his attention or not. An overview about senior's answers and self-reports is available in the form of a timeline graph populated with colored dots. In the overview it is possible to:

- Set the view per week or month
- Click through weeks/months
- See all the reports in the same graph (meals, medications, quality of sleep, wellbeing) or one field only;

The code of color is as follows:

- Green: Senior indicated that medication/meal has been taken or quality of sleep/wellbeing is positive
- Orange: Senior indicated that medication/meal hasn't been taken or quality of sleep/wellbeing is negative
- Red: No self-report is received

By pointing at the dot, it is possible to read details about that answer/self-report (e.g. if pointing at "wellbeing very bad", it will appear the cause in case the senior specified).

- Self-reports

The main way how Guardian will collect data is via self-reports. User can at any point in time by using the senior application report its own well-being, quality of sleep, medication, or food intake. If some report is not submitted in a defined period of time, the system will create a report request for a senior and ask him to submit a self-report. Also, caregivers can at any point in time via the Caregiver application request a senior to send him some information that is needed in his assessments.

- Reminders

The caregiver is able to set reminders and monitor if the senior is fulfilling that via the Caregiver app.

- Notifications

To ensure that Caregiver react on time, and based on the specified settings, the caregiver can receive an e-mail based on the number of times that a senior hasn't submitted a self-report and/or has indicated that medication/meal hasn't been taken and/or quality of sleep/well-being is negative. The same message as in the notification will also be displayed below the graph of the intake pattern.

- "[name senior] has not taken the medication [name medication] for [x] times in a row"
- "[name senior] has not submitted a self-report on medication [x] times in a row"

The GUARDIAN Socially Assistive Robot (SAR) will be able to:

– Detect the presence of the older people person in the room by voice recognition
– Communicate reminders and messages via a sound chosen at the installation stage
– Send feedback from the older people to the Caregiver App.

In fact, thanks to the built-in high-resolution camera on-the-edge face detection and face recognition capabilities are ensured. Misty has a built-in array of three far-field microphones that can use to record audio and get positional information about the sounds in her environment. With beamforming, you can filter out sounds (like music) that Misty detects at an unspecified angle. Finally, centered in Misty's visor is a high-resolution camera that can be used to take pictures and record videos. In order for the interaction between the older people and Misty II to be as smooth and natural as possible, audio and video systems will be integrated into the robot, so as to obtain information about the state of the older people from multiple channels at the same time.

The purpose of this Alpha phase is to understand how the older people react to the use of this new technology and what are the variables to keep under control and, possibly, to be changed. Technical changes will improve the overall experience of the older people with the GUARDIAN platform, especially the usability of the graphic interface, such as moving icons, color improvement, insertion of elements on the screen. These implementations will be carried out exclusively to increase patient engagement, to allow better communication of needs, moods and perceptions.

Specifically, we expect these changes to cover certain aspects:

– improved interface with more appropriate colors, volume setting, improved application architecture to improve application experience
– development of a motivational system that stimulates the patient to lead a more active and healthy life, proposing various types of activities.
– addition of monitoring of daily activities carried out by the older people.

The evaluations will be carried out at the Baseline (T0) and then every month, for three months (T1, T2, T3).

2.1.2. Beta phase

During this phase the platform will be tested for 3 months. The evaluations will be carried out each month, from the baseline to the end of the trial (T0, T1, T2, T3).

2.2. Study setting: the Italian site

The study will be conducted at the Clinical Unit of Neurology of the Istituto Nazionale Ricovero e Cura per Anziani IRCCS INRCA, Ancona, Italy. The last version of the current protocol is dated on September 3rd, 2021.

2.3. Participants

Once the informed consent is obtained in duplicate, the compliance with the criteria of inclusion and exclusion of the study will be verified and the baseline evaluation will be carried out with the questionnaires and clinical trials provided by the study design, and we will start with the trials planned by the study. The inclusion criteria will be:

- Aged 65 years and over;
- Capacity to consent;
- Mini Mental State Examination $\geq$24 [31];
- Have an informal caregiver to support you in carrying out the main daily activities;
- Healthy sight and hearing.

The exclusion criteria will be:

- Failure to meet the inclusion criteria;
- Concomitant participation in other studies;
- Lack of written informed consent;
- Lack of informal caregivers;
- Sight and hearing not intact.

2.4. Recruitment and procedure of the Italian setting

Patients will be selected by the outpatient department at the Clinical Unit of Neurology, of IRCCS INRCA, in the Ancona branch. These patients will be contacted to schedule a visit with the clinical team. Once the compliance with the inclusion and exclusion criteria of the study will be verified and the informed consent will be obtained, the doctor will proceed with the baseline evaluation. The trial will start in April 2022 and is expected to end in December 2022.

2.4.1. Alpha phase

The Alpha phase will be divided as follows:

2.4.1.1. Recruitment (R). The following activities will be carried out:

– Informing participants and signing informed consent

– Verification of inclusion/exclusion criteria
– Completion of the socio-demographic questionnaire.

2.4.1.2. Start of treatment visit (T0). The following activities will be carried out:

– Installation of the robot at the home of the older people
– Explanation of the platform to participants
– Meeting with the older people, the informal caregiver and the formal caregiver to determine what information to share about the older people
– Patient assessment with dedicated tools and questionnaires and demographic data.

2.4.1.3. Visit after the first, second and third months of the trial (T1, T2, T3). The following activities will be carried out:

– Control of the operation of the platform
– Patient interview, formal and informal caregiver
– Information collection through databases
– Patient assessment using scales and questionnaires.

2.4.2. Beta phase

The Beta phase will be divided as follows:

2.4.2.1. Recruitment (R). The following activities will be carried out:

– Patient information and informed consent
– Verification of inclusion/exclusion criteria
– Completion of the socio-demographic questionnaire.

2.4.2.2. Start of treatment visit (T0). The following activities will be carried out:

– Installation of the robot at the home of the older people
– Explanation of the platform to the care triad
– Meeting with the older people, the informal caregiver and the formal caregiver to determine what information to share about the older people
– Patient assessment with dedicated tools and questionnaires and demographic data.

2.4.2.3. Visit after the first, second and third months of the trial (T1, T2, T3). The following activities will be carried out:

– Control of the operation of the platform
– Patient interview, formal and informal caregiver
– Information collection through databases
– Patient assessment using scales and questionnaires.

A summary of all data collected and when these are collected is provided in Table 3, Table 4 and Table 5.

Table 3
Tools for collecting data from the subject during the Alpha and Beta phases.

Dimension	Scales	R	T0	T1	T2	T3
Ethical Design	On-line questionnaire		✔	✔	✔	✔
Technology Impact	Nurses Questionnaire		✔	✔	✔	✔
Health Perception	SF-12 [36]		✔	✔	✔	✔
Quality of Life	EQ5D -5L [35]		✔	✔	✔	✔
Technology Acceptance	UTAUT [32]		✔	✔	✔	✔
Social Connection	SCS [37]		✔	✔	✔	✔
Availability of payment	On-line questionnaire		✔	✔	✔	✔
Cognitive status	MMSE [38]	✔				
	Socio-demographic questionnaire	✔				

R = Recruitment; T0 = Start of treatment; T1 = after the first month; T2 = after two months; T3 = after three months; SF-12 = SF-12 Health Survey; EQ5D -5L = European Quality of Life-Five Dimension-Five Level Scale; UTAUT= Unified Theory of Acceptance and Use of Technology; SCS= Social Connectedness Scale; MMSE = Mini-Mental State Examination.

Table 4
Tools for collecting data from the informal caregiver during the Alpha and Beta phases.

Dimension	Scales	R	T0	T1	T2	T3
Caregiver burden	Zarit Burden Interview [33]		✔	✔	✔	✔
Stress and anxiety	GAD-7 [34]		✔	✔	✔	✔
Technology Acceptance	TAM [32]		✔	✔	✔	✔
Cognitive status	MMSE [38]	✔				
	Socio-demographic questionnaire	✔				
Technology Impact	Nurses Questionnaire		✔	✔	✔	✔

R = Recruitment; T0 = Start of treatment; T1 = after the first month; T2 = after two months; T3 = after three months; GAD-7 = Generalized Anxiety Disorder Scale; TAM = Technology Acceptance Model; MMSE = Mini-Mental State Examination.

Table 5
Tools for collecting data from the formal caregiver during the Alpha and Beta phases.

Dimension	Scales	R	T0	T1	T2	T3
Stress and anxiety	GAD-7 [34]		✔	✔	✔	✔
Technology Acceptance	TAM [32]		✔	✔	✔	✔
Time spent caring for the older people person	Reduction in the number of hours devoted to caring for the older people person (i.e. not to be understood as a reduction in the number of hours devoted to social relations with the person being cared for)		✔	✔	✔	✔
	Socio-demographic questionnaire	✔				
Technology Impact	Nurses Questionnaire		✔	✔	✔	✔

R = Recruitment; T0 = Start of treatment; T1 = after the first month; T2 = after two months; T3 = after three months; GAD-7 = Generalized Anxiety Disorder Scale; TAM = Technology Acceptance Model.

2.5. Intervention

The intervention involved two caregivers (one formal and one informal) and the patient. During installation, the operation of the applications (Senior App and Caregiver App) and the operation of the Misty Robot are shown. GUARDIAN platform was being installed by a team of researcher (a psychologist, a biomedical engineer and a physiotherapist).

Caregivers can enter reminders useful to the patient for maintaining his or her health such as taking medication, meals, and advice on physical activity. The informal caregiver also has the ability to remind the patient of appointments for the week. Caregivers (formal and informal) can update each other via chat and report any patient problems.

The patient responds to the reminder by interacting with the app installed on the tablet, which sends the feedback to the Caregiver App. Misty detects the older people' presence in the environment and sends the reminder only when the person is present.

2.6. Platform description

The GUARDIAN platform wants to enable the older people person to live as long as possible at home, supporting their autonomy, while reducing the caregiver's burden of care. The GUARDIAN platform consists of the Senior App, the Caregiver App and the Misty II robot.

2.6.1. Senior app

It is an easy-to-use application that will ask the older people for health status, whether they have carried out their daily activities, if they have taken pre-establish able drugs and if they have eaten properly. The application will generate self-reports that will be transmitted to the Caregiver App. The older people can self-report their activities or answer the questions via a tablet (Fig. 1). The tablet will be handed over by the research team to the older people, and once the trial is finished it will have to be returned.

2.6.2. Caregiver app

It is the application intended for the caregiver, in which (s)he can set up reminders for the older people about meals or drugs, send communications and ask for reports on his health. It is not necessary to download the app on your device, but simply connect to the website http:///caregiver-guardian.onlyoneif.com/authentication/login and log in with the credentials related to the robot. Fig. 2 shows an example screenshot in the caregiver application. This application will be used by both the informal caregiver and the formal caregiver (health care professional). GUARDIAN SAR.

The GUARDIAN SAR is the robot that will complete the platform. The GUARDIAN consortium agreed to use the Misty II robot. Misty II has a wide range of functionalities that can be activated by the site (http://sdk.mistyrobotics.com/), including face detection and recognition and listening and communication through voice. The robot will become a user stress sensor through interaction, voice, facial expressions and posture signals. The implementation of the user assessment requires the development of various sensors equipped on the robot (RGB camera, depth camera and microphone) that will also be used to perform human localization in the domestic/indoor environment. For security reasons, the ability to move will be disabled, so the robot will always remain in the same environment. The Machine Learning algorithms will be developed and used to improve the cognitive abilities of the robot in identifying the feelings of the older people and in making the robot in continuous learning, to improve the acceptance of the robot by the user himself.

In the Guardian trial, reminders will be sent via the robot and questions will be asked to the patient. The functions that will be activated by the robot will be only those of being able to talk and listen to the patient through the inputs that he will receive from the applications of the patient and the caregiver. Misty II will make sure that the patient is in the home by asking the patient "[Patient Name] are you here?" only if the patient responds in the affirmative will remind him of the reminder. Among the features of Misty II there is also that of moving through command, for security reasons this feature will be disabled (Fig. 3).

2.6.3. Platform operation

The applications will be connected through the GUARDIAN cloud (Fig. 4), on which all useful information and data will be stored, which will be protected and encrypted.

The GUARDIAN functionality and usability will be improved during the testing phases. The coaching module will be improved through motivational messages, finally, changes are also expected based on the results of users; this could include improvements to existing functionalities or, if necessary, the development of new functionalities within the scope of the project.

2.7. Outcomes

All outcomes will be measured following a standardized operating procedure. Table 2 shows the primary outcome and the secondary outcomes.

The tables below list the instruments used during the two phases of

Fig. 3. Misty II.

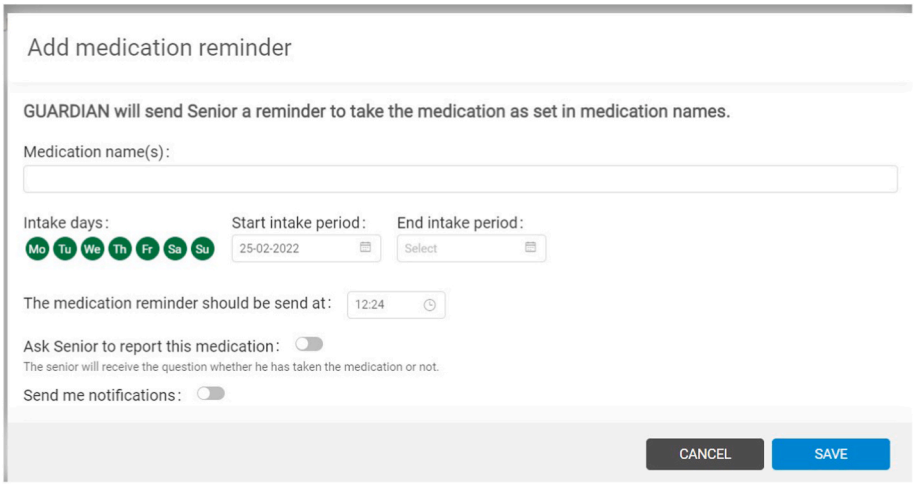


Fig. 2. Caregiver App: an example of the application.

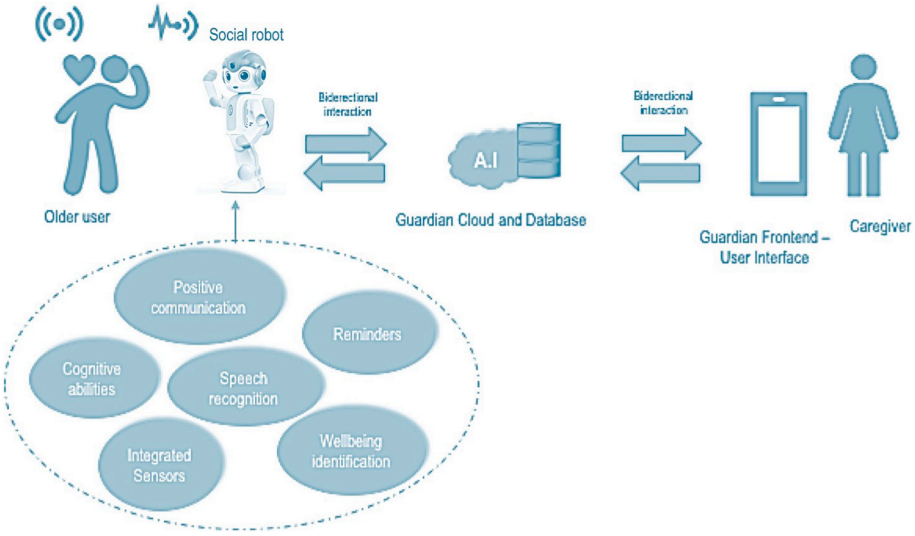


Fig. 4. Platform diagram.

the trial.

The evaluation process of the two phases will be the same. The table below shows the estimated dimensions, the instruments used and the time of assessment.

2.8. Risk management and mitigation

We do not expect any negative effects on the health of users related use of the technology platform. The hardware devices used are commercial devices (Misty II) and CE certified, the applications for older people and caregivers will be loaded on the hardware held by the users.

Technological dependence, especially on AI devices, represents a major ethical dilemma in today's society and scientific community. In order to limit the risk, the European Commission's international programmes have introduced guidelines for conducting studies that require the introduction of a new technology, called Responsible Innovation. The core principles of Responsible Innovation [39] are also applied within the GUARDIAN project. In particular, a strategy underlying the prevention of technological dependence is the inclusion of different actors around the older people, in the process of acquiring skills and daily use of technology. In this way, technological solutions such as those proposed by GUARDIAN, respond to the definition of socio-technological system rather than technological, since they are placed in a care context that does not involve the replacement of the caregiver but stimulates the user to play a leading role in the management of their health [40].

Among the features of Misty II is to be able to move inside the patient's home, a feature that, for safety reasons, will be disabled, so as to avoid it being an obstacle for the patient. However, subjects will be advised to place Misty II in a safe and stable position, protected from possible adverse events that could cause it to fall. Researchers will provide clear and detailed information on the terms of use of the technology platform and the services offered during the study. In this regard, it will be specified to the older people that the interaction with Misty II must take place only by the recruited subject and not by third parties that are in the house, so as to avoid that the results of the study are somehow polluted. The services proposed are intended to support the maintenance of correct living habits through information and suggestions and do not replace (in whole or in part) the support from professional services. Specifically, Misty II will remind the older people of taking the prescribed drugs, in no way will it suggest other drugs to take.

The possibility that the technology generates a wrong alarm or does not generate an alarm when predicted represents an inherent risk to technological systems which, in the case of GUARDIAN, can be mitigated through the customization of the system in the preliminary phase with the family caregiver, so that it can always monitor the trend and frequency of alarms during the day. During the installation of the technology, moreover, information will be provided to the caregiver about the limits of the technology, which can in no way replace the role of the familiar and formal assistant, but only assist in some activities.

Users who take part in the study will not incur any direct or indirect costs related to the use of the technology platform. The tablet will be provided to the subjects by the INRCA and must be returned to the research team at the end of the trial.

2.9. Data management

The project committed to the maintenance of participants' anonymity and confidentiality throughout all procedures, including screening, recruitment, testing, evaluation and dissemination procedures. Data collection, usage and storage procedures complied with national laws and the EU's General Data Protection Regulation (GDPR) including the commitment of participants' the right to access, right to be informed, right to withdraw, and right to data erasure. Data collection will be compliant with the principle of data minimization i.e. the collection of personal information from study participants will be limited to what is directly relevant and necessary to accomplish the specific goals of the testing and evaluation work packages. Data entry will be carried out using specific software, providing blocks and data entry checks, in order to reduce the number of entry errors. All screening data was will be discarded upon the project completion. During the testing procedures, all visual, auditory and sensory data that the robot collects and processes in order to function as planned will be discarded after the procedures have been completed. The exception to this is the collection of the number of interactions that the robot logs with each participant. However, these interactions will be anonymous. All research data shall be made openly available for secondary analysis 3 years after the project completion. The study findings will be used for publication in peer-reviewed scientific journals and presentations in scientific meetings. Summaries of the results will also be made available to investigators for dissemination within their clinics.

2.10. Data analysis

The first step of the data analysis will deal with the description of the sample. Continuous variables will be reported as either mean and

standard deviation or median and interquartile range on the basis of their distribution (assessed using Kolmogorov-Smirnov test). Categorical variables will be expressed as an absolute number and percentage. Mann-Whitney U tests (for non-normal distribution), or Chi-Square tests (normal or non-normal) will be used to compare the independent and dependent variables between the pre- and post-conditions, in addition to simple descriptive statistics (means, medians and SDs as appropriate).

In order to verify the achievement of the primary endpoint (i.e. Acceptability of the Guardian platform), subscales of the UTAUT will be calculated. Means and standard deviation or medians and iqr of the scores will be reported according to their distribution. Correlation coefficients (Pearson for normally distributed variables, Spearman for non-normally distributed variables) of the UTAUT sub-scales with the other rating scales at each stage of the study and with the main characteristics of the subjects will be calculated to check for potential determinants of higher acceptability.

3. Discussion

In this work, we have described an intervention protocol to evaluate the acceptability of the GUARDIAN platform in a group of older people.

Various technologies exist to support both the caregivers of the older people person, health professionals or family members, and the older people themselves [41]. In this context, it is therefore crucial that end users have the ability to decide what to let into their homes and what information they will accept to be captured [42]. Therefore, understanding what factors come into play in the acceptance process of a technology is of basic importance to increase the acceptance and use of these technological solutions [43]. Specifically, it was found that by using a user-centered approach, end users feel involved in the product design and development process [44].

This approach was also adopted in the GUARDIAN project, making end users participate in the development and design phases of the platform. In this way, the propose solution reflects the real wants and needs of the older people person, increasing the acceptability of the system. In addition, the GUARDIAN project has the potential to have distinguished two phases of testing, precisely so that changes can be made to the platform between the first and second phases, using data, both qualitative and quantitative, collected after the first phase. In this way the system can be improved based on real suggestions from end users.

However, there are also limitations to the applicability of such a platform. In fact, the acceptance of such a technological solution may be difficult for those older people who are not familiar with technology, compared to those who have used and use technological devices, such as smartphones or tablets, on a daily basis [45]. Therefore, it will be crucial to make the platform as smart as possible and, at the same time, to provide training sessions, prior to the installation of the platform at home.

4. Conclusion

In light of recent demographic changes, the need for new technology solutions in the field of elderly care is growing, and the GUARDIAN platform could have considerable potential in this regard. However, it is crucial to focus not only on the functionality and benefits of the system, but also and especially on the senior's perception and acceptability of a technology such as GUARDIAN. By following a user-centered approach from the earliest stages, we therefore expect positive feedback from the older person on the use of the platform. We also expect more collaboration from the senior's caregivers, as our proposed process puts the person first, thus respecting the older person as a human being with his or her wants and needs. In addition, by providing two phases of experimentation, we can ensure that users can touch upon the suggestions made during the first phase of experimentation during the second phase, again emphasizing the importance of putting their needs first.

Future studies conducted in the field of AAL should prefer an approach that involves end users from the early stages of project development, because only in this way can acceptability by those who will actually use the system in their daily lives, i.e., the elderly person, and cooperation from those who will interface with the platform to take care of the elderly person, i.e., the caregiver, be ensured. Acceptability of the platform and cooperation from the family member will then be key factors in the success of the project itself.

5. Ethics and confidentiality

The study was approved by the Ethic Committee of the Istituto Nazionale Ricovero e Cura per Anziani, (IRCCS INRCA) on the October 21, 2021. It was recorded in ClinicalTrials.gov on April 5, 2022 with the number NCT05284292. Any protocol modifications will be notified to the above-mentioned Ethic Committee. The same committee is in charge of data monitoring and periodically assesses the progress of the protocol and compliance with what was declared. The principles of the Declaration of Helsinki and Good Clinical Practice guidelines will be adhered to. Participants in this study provide written informed consent.

Author contributions

AM, RB, MB led the design and writing of the pilot RCT protocol. KW and HHN provided comments on the written protocol. EM and RB helped with the development of the participant identification plan and provided advice on other key study issues. MB helped with the design of the intervention. RB, EM and GA will lead the collection, management and statistical analysis of the data. All the authors contributed important intellectual content to the written protocol and approved the final version for publication.

Funding

The GUARDIAN (AAL-2019-6-120-CP) project received funds from the European Commission's Active and Assisted Living programme, co-financed by the consortium national funding agencies. For IRCCS INRCA, the project was co-financed by the Italian Ministry of Health under agreement AAL-2019-6-120-CP.

Declaration of competing interest

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

Data availability

Data will be made available on request.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.conctc.2022.101024.

References

[1] World Health Organization, Ageing and Health, 2018. https://www.who.int/news-room/fact-sheets/detail/ageing-and-health.
[2] L. Jamieson, R. Simpson, Living Alone: Globalization, Identity and Belonging, Palgrave Macmillan, London, 2013.
[3] V. Vimarlund, E.M. Borycki, A.W. Kushniruk, K. Avenberg, Ambient assisted living: identifying new challenges and needs for digital technologies and service innovation, Yearb. Med. Inf. 30 (1) (2021 Aug) 141–149, https://doi.org/10.1055/s-0041-1726492.
[4] S. Meyer, H. Mollenkopf, AAL in der alternden Gesellschaft - anforderungen, Akzeptanz und Perspektiven, in: Analyse und Planungshilfe, vol. 2, VDE-Verlag, Berlin. Offenbach, 2010.

[5] R. Latikka, R. Rubio-Hernández, E.S. Lohan, J. Rantala, F. Nieto Fernández, A. Laitinen, A. Oksanen, Older adults' loneliness, social isolation, and physical information and communication technology in the era of ambient assisted living: a systematic literature review, J. Med. Internet Res. 23 (12) (2021 Dec 30), e28022, https://doi.org/10.2196/28022.

[6] J.T. Cacioppo, L.C. Hawkley, Social isolation and health, with an emphasis on underlying mechanisms, Perspect. Biol. Med. 46 (3) (2003) S39–S52.

[7] J. Holt-Lunstad, T.B. Smith, M. Baker, T. Harris, D. Stephenson, Loneliness and social isolation as risk factors for mortality: a meta-analytic review, Perspect. Psychol. Sci. 10 (2) (2015 Mar) 227–237, https://doi.org/10.1177/1745691614568352.10/2/227.

[8] E. Courtin, M. Knapp, Social isolation, loneliness and health in old age: a scoping review, Health Soc. Care Community 25 (3) (2017 May) 799–812, https://doi.org/10.1111/hsc.12311.

[9] M.E. Beutel, E.M. Klein, E. Brähler, I. Reiner, C. Jünger, M. Michal, J. Wiltink, P. S. Wild, T. Münzel, K.J. Lackner, A.N. Tibubos, Loneliness in the general population: prevalence, determinants and relations to mental health, BMC Psychiatr. 17 (1) (2017 Mar) 97, https://doi.org/10.1186/s12888-017-1262-x.

[10] C. Paul, S. Ayis, S. Ebrahim, Psychological distress, loneliness and disability in old age, Psychol. Health Med. 11 (2) (2006) 221–232, https://doi.org/10.1080/13548500500262945.NKP4H48802610027.

[11] L. Fratiglioni, H. Wang, K. Ericsson, M. Maytan, B. Winblad, Influence of social network on occurrence of dementia: a community-based longitudinal study, Lancet 355 (9212) (2000) 1315–1319, https://doi.org/10.1016/S0140-6736(00)02113-9.S0140-6736(00)02113-9.

[12] N. Leigh-Hunt, D. Bagguley, K. Bash, V. Turner, S. Turnbull, N. Valtorta, W. Caan, An overview of systematic reviews on the public health consequences of social isolation and loneliness, Publ. Health 152 (2017) 157–171, https://doi.org/10.1016/j.puhe.2017.07.035.S0033-3506(17)30273-1.

[13] A. Hawton, C. Green, A.P. Dickens, S.H. Richards, R.S. Taylor, R. Edwards, C. J. Greaves, J.L. Campbell, The impact of social isolation on the health status and health-related quality of life of older people, Qual. Life Res. 20 (1) (2011 Feb) 57–67, https://doi.org/10.1007/s11136-010-9717-2.

[14] B.M. Kuehn, No end in sight to nursing shortage: bottleneck at nursing schools a key factor, JAMA 10 (298) (2007) 1623–1625.

[15] J. Afilalo, S. Karunananthan, M.J. Eisenberg, K.P. Alexander, H. Bergman, Role of frailty in patients with cardiovascular disease, Am. J. Cardiol. 103 (2009) 1616–1621, https://doi.org/10.1016/j.amjcard.2009.01.375.

[16] G. Cicirelli, R. Marani, A. Petitti, A. Milella, T. D'Orazio, Ambient assisted living: a review of technologies, methodologies and future perspectives for healthy aging of population, Sensors 21 (10) (2021) 3549, https://doi.org/10.3390/s21103549.

[17] Hsing-Yi Chang, et al., Impact of mental health and caregiver burden on family caregivers' physical health, Arch. Gerontol. Geriatr. 50 (3) (2010) 267–271, https://doi.org/10.1016/j.archger.2009.04.006.

[18] M.J. Bull, Factors influencing family caregiver burden and health, West. J. Nurs. Res. 12 (6) (1990 Dec) 758–770, discussion 771-6.

[19] A.F. Kramer, K.I. Erickson, S.J. Colcombe, Exercise, cognition, and the aging brain, J. Appl. Physiol. 101 (2006) 1237–1242.

[20] Tiia Ngandu, Jenni Lehtisalo, Alina Solomon, Esko Levälahti, Satu Ahtiluoto, Riitta Antikainen, Lars Bäckman, Tuomo Hänninen, Antti Jula, Tiina Laatikainen, Jaana Lindström, Francesca Mangialasche, Teemu Paajanen, Satu Pajala, Markku Peltonen, Rainer Rauramaa, Anna Stigsdotter-Neely, Timo Strandberg, Jaakko Tuomilehto, Hilkka Soininen, Miia Kivipelto, A 2 year multidomain intervention of diet, exercise, cognitive training, and vascular risk monitoring versus control to prevent cognitive decline in at-risk elderly people (FINGER): a randomised controlled trial, Lancet 385 (Issue 9984) (2015) 2255–2263.

[21] A. Hussain, P.A. Rivers, S.H. Glover, M.D. Fottler, Strategies for dealing with future Shortages in the nursing work-force: A review, Health Serv. Manag. Res. vol. 25 (2012) 41–47, https://doi.org/10.1258/hsmr.2011.011015.

[22] J.A. Mann, B.A. MacDonald, I.H. Kuo, X. Li, E. Broadbent, People respond better to robots than computer tablets delivering healthcare instructions, Comput. Hum. Behav. 43 (2015) 112–117, https://doi.org/10.1016/j.chb.2014.10.029.

[23] V. Vimarlund, E.M. Borycki, A.W. Kushniruk, K. Avenberg, Ambient assisted living: identifying new challenges and needs for digital technologies and service innovation, Yearb. Med. Inf. 30 (1) (2021 Aug) 141–149, https://doi.org/10.1055/s-0041-1726492.

[24] D. Calvaresi, D. Cesarini, P. Sernani, M. Marinoni, A.F. Dragoni, A. Sturm, Exploring the ambient assisted living domain: a systematic review, J. Ambient Intell. Hum. Comput. 8 (2017) 239–257, https://doi.org/10.1007/s12652-016-0374-3.

[25] G. Marques, Ambient assisted living and internet of things, in: P. Cardoso, J. Monteiro, J. Semiao, J. Rodrigues (Eds.), Harnessing the Internet of Everything (IoE) for Accelerated Innovation Opportunities, IGI Global, Hershey, PA, USA, 2019, pp. 100–115.

[26] G. Cicirelli, R. Marani, A. Petitti, A. Milella, T. D'Orazio, Ambient assisted living: a review of technologies, methodologies and future perspectives for healthy aging of population, Sensors 21 (10) (2021) 3549, https://doi.org/10.3390/s21103549.

[27] C. Siegel, A. Hochgatterer, T.E. Dorner, Contributions of ambient assisted living for health and quality of life in the elderly and care services–a qualitative analysis from the experts' perspective of care service professionals, BMC Geriatr. 14 (2014 Oct 18) 112, https://doi.org/10.1186/1471-2318-14-112. PMID: 25326149; PMCID: PMC4210571.

[28] L. Tickle-Degnen, M. Scheutz, R.C. Arkin, Collaborative Robots in Rehabilitation for Social Self-Management of Health, vol. 6, 2014.

[29] S.M. Rabbitt, A.E. Kazdin, B. Scassellati, Integrating socially assistive robotics into mental healthcare interventions: applications and recommendations for expanded use, Clin. Psychol. Rev. 35 (2015) 35–46.

[30] H.H. Nap, S. Suijkerbuijk, D. Lukkien, S. Casaccia, R. Bevilacqua, M.G. Revel, L. Rossi, L. Scalise, A social robot to support integrated person centered care, Int. J. Integrated Care 18 (2018) 120, https://doi.org/10.5334/ijic.s2120.

[31] J.R. Cockrell, M.F. Folstein, Mini-mental state examination, Princ. Pract. Geriatr. Psychiatr. (2002) 140–141.

[32] E. Ammenwerth, Technology acceptance models in health informatics: TAM and UTAUT, Stud. Health Technol. Inf. 263 (2019) 64–71.

[33] R. Chattat, V. Cortesi, F. Izzicupo, M.L. Del Re, C. Sgarbi, A. Fabbo, E. Bergonzini, The Italian version of the Zarit Burden interview: a validation study, Int. Psychogeriatr. 23 (5) (2011) 797–805.

[34] J. García-Campayo, E. Zamorano, M.A. Ruiz, A. Pardo, M. Pérez-Páramo, V. LópezGómez, et al., Cultural adaptation into Spanish of the generalized anxiety disorder-7 (GAD-7) scale as a screening tool, Health Qual. Life Outcome 8 (2010) 8.

[35] G. Hernandez, O. Garin, A.L. Dima, A. Pont, M. Martí Pastor, J. Alonso, E. Van Ganse, L. Laforest, M. de Bruin, K. Mayoral, V. Serra-Sutton, M. Ferrer, ASTRO-LAB Group. EuroQol (EQ-5D-5L) Validity in Assessing the Quality of Life in Adults With Asthma: Cross-Sectional Study. J Med Internet Res. 23;21(1) (2009) e10178.

[36] J. Ware Jr., M. Kosinski, S.D. Keller, A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity, Med. Care 34 (3) (1996) 220–233.

[37] C. Capanna, P. Stratta, A. Collazzoni, V. D'Ubaldo, R. Pacifico, G. Di Emidio, M. Ragusa, A. Rossi, Social connectedness as resource of resilience: Italian validation of the social connectedness scale - revised, J. Psychopathol. 19 (2013) 320–326.

[38] M.F. Folstein, S.E. Folstein, P.R. McHugh, "Mini-mental state". A practical method for grading the cognitive state of patients for the clinician, J. Psychiatr. Res. 12 (3) (1975) 189–198.

[39] Science, Innovation and Society: Achieving Responsible Research and Innovation SIS – RRI Deliverable 3.3 Stocktaking Study.

[40] R.A. Søraa, P. Nyvoll, G. Tøndel, E. Fosch-Villaronga, J.A. Serrano, The social dimension of domesticating technology: interactions between older adults, caregivers, and robots in the home, Technol. Forecast. Soc. Change 167 (2021).

[41] Sebastiaan T.M. Peek, Eveline J.M. Wouters, Joost van Hoof, Katrien G. Luijkx, Hennie R. Boeije, Hubertus J.M. Vrijhoef, Factors influencing acceptance of technology for aging in place: a systematic review, Int. J. Med. Inf. 83 (4) (2014) 235–248.

[42] S.L. Molony, The meaning of home: a qualitative meta-synthesis, Res. Gerontol. Nurs. 3 (2010), 291-30.

[43] S. Wulfovich, M. Fiordelli, H. Rivas, W. Concepcion, K. Wac, "I must try harder": design implications for mobile apps and wearables contributing to self-efficacy of patients with chronic conditions, Front. Psychol. (2019) 2388.

[44] A. De Vito Dabbs, B.A. Myers, K.R. Mc Curry, J. Dunbar-Jacob, R.P. Hawkins, A. Begey, M.A. Dew, User-centered design and interactive health technologies for patients, Comput. Inf. Nurs.: CIN 27 (3) (2009) 175–183.

[45] C.S.C. Lim, Designing inclusive ICT products for older users: taking into account the technology generation effect, J. Eng. Des. 21 (2010) 189–206.