A dashboard for managing an eco-system and people with dementia: the HAAL study protocol.

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Abstract

Dementia is a syndrome characterized by a wide spectrum of symptoms and needs. There is no cure for this syndrome that represents a major challenge to society in terms of quality of life for those affected, and in terms of workload and stress burden for those who take care of them. The HAAL project aims to improve quality of life of both people with dementia and their formal and informal caregivers, by providing a personalized set of devices to the person with dementia, along with a dashboard designed for carers to monitor and manage the older person. The HAAL eco-system consists of a dashboard which integrates, aggregates, and analyses heterogeneous data gathered from different devices designed for and tested with people with dementia. The study is designed as a technical feasibility pilot to test the HAAL eco-system in three countries: Italy, the Netherlands, and Taiwan. The primary interest is to assess the impact of the HAAL platform on caregivers' workload and end users' quality of life, that will be measured through ZARIT, GAD-7 and EQ-5D scales. Then, the field trials also focus on the usability of the HAAL ecosystem, evaluated through the SUS scale. The HAAL field trial, is an innovative feasibility study focused on the impact of a complex technological ecosystem designed for people with dementia and their caregivers. The HAAL eco-system aims to relief stress at work for formal and informal caregivers, to improvein the perceived quality of life for informal caregivers and person with dementia, and to reduce the care load for the formal caregivers.

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A dashboard for managing an eco-system and people with dementia: the HAAL study protocol.

Abstract

Background: Dementia is a syndrome characterized by a wide spectrum of symptoms and needs. There is no cure for this syndrome that represents a major challenge to society in terms of quality of life for those affected, and in terms of workload and stress burden for those who take care of them.
Objective: The HAAL project aims to improve quality of life of both people with dementia and their formal and informal caregivers, by providing a personalized set of devices to the person with dementia, along with a dashboard designed for carers to monitor and manage the older person.
Methods: The HAAL eco-system consists of a dashboard which integrates, aggregates, and analyses heterogeneous data gathered from different devices designed for and tested with people with dementia. The study is designed as a technical feasibility pilot to test the HAAL eco-system in three countries: Italy, the Netherlands, and Taiwan.
Conclusions: The HAAL field trial, is an innovative feasibility study whose primary objectives are to assess the stress relief at work for formal and informal caregivers, the improvement in the perceived quality of life for informal caregivers and person with dementia, the reduction in care load for the formal caregivers. The study also evaluates the usability and the acceptance of the technological eco-system.
Trial Registration: The study was approved by the Ethic Committee of the IRCCS INRCA in Italy (protocol number: 3750/2023) and by the Institutional Review Board of the National Cheng Kung University Hospital in Taiwan (protocol number: B-ER-112-026). It was recorded in ClinicalTrials.gov on the number NCT06307197.

Keywords: older people; dementia; dashboard; technology for elderly; digital health; e-health; innovation in healthcare.

Introduction

Background

Dementia is a chronic neurodegenerative syndrome characterized by deficits in cognitive functions, associated with the loss of daily function and with mental and behavioral disorders. The World Health Organization (WHO) counts 10 million of new diagnosis of dementia every year worldwide [1]. These numbers are confirmed in two critical regions like Europe and Asia. In Europe, there were 7,7 million cases in 2001, that are expected to double by 2040 [2]. In Taiwan the trend is even worse: the number of people diagnosed with dementia is expected to double each 20 years, exceeding 0,6 million in 2050 [3]. Neuropsychiatric symptoms like apathy, social withdrawal, disinhibition, agitation, psychosis, and wandering are a source of stress and negatively affect the quality of life of both the person with dementia and their caregiver [4]. There is no cure for Alzheimer's disease, although psychosocial interventions have been shown to be effective in improving the quality of life and psychological well-being of people with dementia [5-8]; moreover, they are considered the treatment of choice for the management of psychological and behavioral disorders [9,10]. Neuro-cognitive disorders, in particular dementia, represent a major challenge for the society. Efforts to reduce the burden for caregivers, as well as for the society at large are imperative. Nordberg et al (2005) [11] showed that the amount of informal care received by people with dementia is as much as six times greater compared to formal care, with supervision constituting the largest proportion of the total informal care provided. Older people generally report higher preferences for their home over

other living arrangements and from the societal point of view this can contribute to burden of care, e.g. for their families. Dementia caregivers are at high risk of care burden, anxiety and stress, which exposes them to a higher rate of mortality compared to non-caregivers (Vitaliano et al, 2003) [12]. Thus, promoting ageing in place for people with dementia should not constitute a strategy to shift the burden of care from the formal care services to the informal caregivers. Instead, efforts should focus on reducing caregiver stress. Part of the difficulties and stress related to caregiving might be prevented by new Information and Communication Technologies and by developing innovative support services for these people. This corresponds closely with the recent EU strategy on long-term care [13] as well as the recent Horizon 2020 Work Programme [14], both emphasizing the key role of novel ICT systems in supporting the independent living of older people, as a complement to support from other persons. Previous large-scale evaluation, such as the Whole Demonstrator System in the UK [15] did not include patients with cognitive impairment, even if, for instance, Alzheimer is among the most burdensome disease for the European Society [16]. These data have the potential to inform regional and national policy makers, allowing to the introduction of innovative and cost-effective interventions in order to reduce the burden of Alzheimer's Disease on public finances and single families.

The HAAL project

The HAAL project (AAL-2020-7-229-CP, funded by the European Commission) aims to develop an ecosystem where smart care technologies are embedded in a unique and innovative platform able to support older people ranging from early to late dementia and their (in)formal caregivers. The services that are developed in HAAL can support people with dementia (PwD) to stay longer in their own residences with some degree of independence, supporting the final aim of decreasing the workload of caregivers, while improving the quality of care. The project aims to achieve this goal through four main actions: care assistance, monitoring, notification, and prevention. Care assistance is provided by supporting PwD's independence on a daily basis and maintain their well-being. In practice, it is provided through reminders of daily activities, cognitive and physical stimulation, communication with informal and formal caregivers, and an alert button for emergency cases. Monitoring is meant for collecting behavioral data continuously to support remote monitoring of a PwD, in order to provide more targeted care based on data patterns. The information includes PwD's lifestyle patterns of activeness, falling status, location, quality of sleep and performance for rehabilitating exercises.
Notification service consists of sending real-time notifications to caregivers in case of behavioral deviation. The alarm is triggered by data provided through the monitoring device, which could recognize the lifestyle patterns of the users. Behavioral deviation includes also delayed medication and languishes, while emergency cases include falling, wandering and a patient getting lost. Finally, HAAL invests on prevention, to avoid undesirable accidents or irreversible deterioration. This service runs in parallel with the alarm, by using longitudinal behavioral data to predict the risk of falling, getting lost, dementia progression, and other frailty symptoms.

Goal of the study

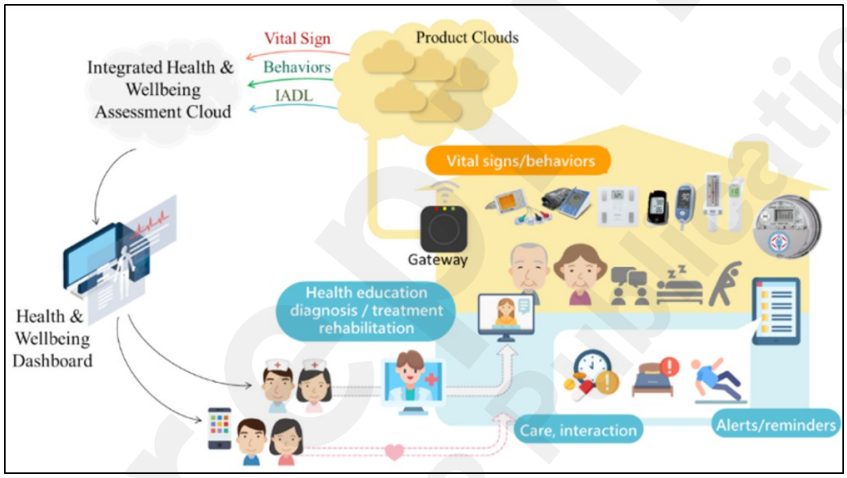
This paper presents the HAAL field trial, a feasibility study whose primary objectives are: to assess the stress relief at work for formal and informal caregivers, the improvement in the perceived quality of life for informal caregivers (IC) and person with dementia, the reduction in case load for the formal caregivers (FC) and the increased cost-effectiveness of the HAAL solution in comparison to the available services. Secondarily, the study aims to assess the usability and acceptance of the HAAL platform for both PwD and caregivers. The purpose of this project is to present and share with the scientific community the HAAL innovative ecosystem and the related field trial protocol for testing it worldwide (Italy, the Netherlands and Taiwan) with caregivers and people with dementia in real scenarios.

Methods

The HAAL platform

The HAAL platform, deeply presented in this section, is composed of 6 smart technologies designed for people affected by dementia (an interactive game for cognitive training, a social robot, a GPS tracking system, a lifestyle monitoring system, an alarm system, and a smart mattress) and 1 dashboard – consisting of a web application - to be installed on tablet or PC. Since in the transition from early to middle dementia, PwD start losing capabilities to comprehend some digital interaction (social robots, interactive games), each user benefits of a combination of such devices, according to its own needs. The dashboard, that is used by the (in)formal caregiver, receives, analyses, and show data acquired and processed by those devices through machine learning (ML) algorithms to detect and determine the health status of the PwD. The platform has been preliminarily tested in lab by Morresi et al. [17] and then underwent successfully the usability test [18].
The figure below (Fig. 1) shows the platform architecture.

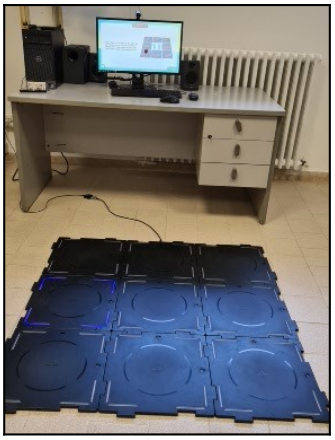
Figure 1. HAAL platform



Whiztoys

WhizToys, displayed in Figure 2, is nine, lightweight, portable motion-sensing floor tiles arranged to form a 3x3 square. They can be connected to a television to display game instructions on the screen. The game combines physical activity and cognitive training. The game is considered a serious gaming gym, that can be personalized. This could prevent cognitive function decline or slow down the progression of the mild cognitive impairment (MCI) stage. Older adults could participate in different cognitive games, such as music, numbers, colors, and spelling, simply by walking and stepping on tiles. In addition to providing multi-sensory stimulation such as visual, light, and sound, the app also allows caregivers to choose a game type and difficulty level. The app also provides individual user accounts and stores the game results in the cloud for subsequent evaluation and analysis. Basically, the input variables include peoples' movement and their background information such as age and gender. The primary output of the WhizToys game app includes steps total playtime for a game, memory time for the memory-training games, frequency of use, correction rate of the game, length of steps, and time of the time up and go results. The app also provides individual user accounts and stores the game results in the cloud for subsequent evaluation and analysis.

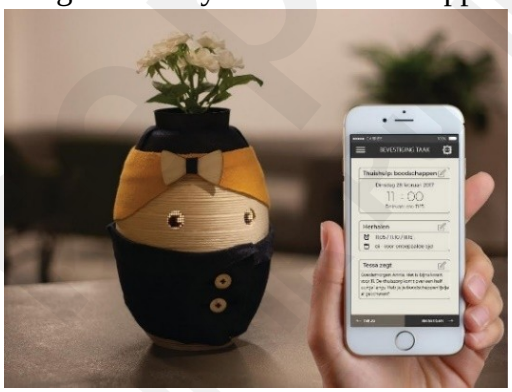
Figure 2. WhizToys



Tinybot

Tinybot, displayed in Figure 3, is a small social robot named Tessa, able to provide verbal guidance to older adults on daily activities. Tessa has her own speaker and microphone to communicate with the user, and is able to understand yes/no answers. Tessa helps people with orientation by given personal reminders, suggests activities, or instructions for certain tasks; Tessa helps people getting active again by providing spoken suggestions and by playing personal music. In fact, caregivers can schedule the tasks and personalize the spoken messages and instructions spoken by Tessa, which helps PwD to structure their days. Informal caregivers use a simple web-app (accessed via https://my.tinybots.nl/) to write messages for Tessa and schedule these messages at specific times.

Figure 3. Tinybot and its web-app.



Kompy Pico

Kompy Pico, displayed in Figure 4, is a GPS tracker that can be used to localize or call someone and to set a geofence. . It is a personal device that the user can wear as a necklace, attached to the belt or kept in the pocket, and it is provided with: GPS, Bluetooth, and Wi-Fi. The device is precise in determining the location both in indoor and outdoor locations. The Kompy Pico provides direct communication between the PwD and the (in)formal caregiver, that can be called through the alarm button. The caregiver receives directly the alarm notification on the mobile application Mopas, available on both Google Play and Apple Store. As soon as the alarm goes off, the exact position of the PwD is sent to the caregiver. The caregiver can set “safe zone”, which are specific areas outside of which the user is not expected to be and therefore the alarm can be sent. All the activities of the PwD of the last 60 days can be tracked and logged in the app.

Figure 4 Kompy Pico

Sensara

Sensara HomeCare has eight wireless sensors that can be installed in toilets/bathroom(s), kitchen, exit door(s), hall and in the living room to monitor older person's daily activities. The sensors are unobtrusive, battery operated and privacy friendly. Due to smart (self-learning) algorithm design, the system supports automatically all possible customer lifestyles. After 2 weeks of use, the algorithm is able to distinguish the person's daily activities and set a baseline behavior. Sensara informs the (in)formal caregivers via a smartphone app if something goes wrong. When caregivers want to zoom in on trends, they can see how things are going in the long run. Otherwise, they can check on what is going in the present on the events list.

Figure 5 Sensara

Cogvis AI

CogvisAI, displayed in Figure 6, is a medium-size sensor to be mounted on a wall of a room that makes use of 3D smart sensors to analyze behavior. Based on this data, an alarm can be sent in critical situations: when an inhabitant leaves the space or falls. Furthermore, it can be sensed if someone is in the bed or not. Cogvis AI mainly focuses on the later stage of dementia, in which older adults have a problem wandering or falling. Furthermore, the device is coupled to a specific account, from which the (in)formal caregiver can see the status of the device and settings for which detections a notification should be send to whom.

Figure 6. Cogvis AI

WhizPad

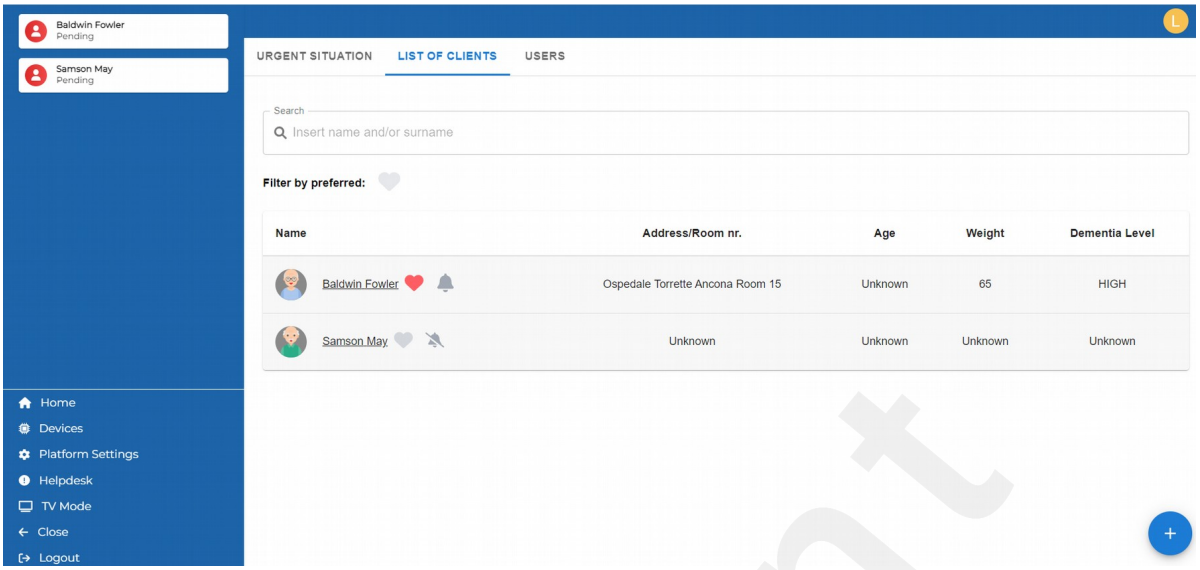
WhizPad is a comfortable mattress made by temperature-sensitive pressure-relieve foam to prevent from pressure ulcers (see Figure 7). WhizPad is a thin mattress pad made of memory foam and conductive textile materials. WhizPad counts more than 30 sensing areas installed, that provide an ON/OFF signal, which means that whenever they are activated they provide a binary output (ON = sensor is activated, OFF = sensors is not activated). Data coming from pressure sensors are processed and fed in ML algorithm for posture identification of the patient. Given the event algorithms implemented in a bedside data processor, the pressure signals collected by WhizPad can be used to detect on/off bed, sleep posture, movement counts, and respiration rate. Integrated with information and communication systems, caregivers can maintain awareness of older adults' daily activities and needs by using their mobile devices to access the WhizPad for real-time monitoring and historical data record of bed-related activities, as well as receiving service reminders and alerts for abnormal events.

Figure 7. WhizPad

Dashboard

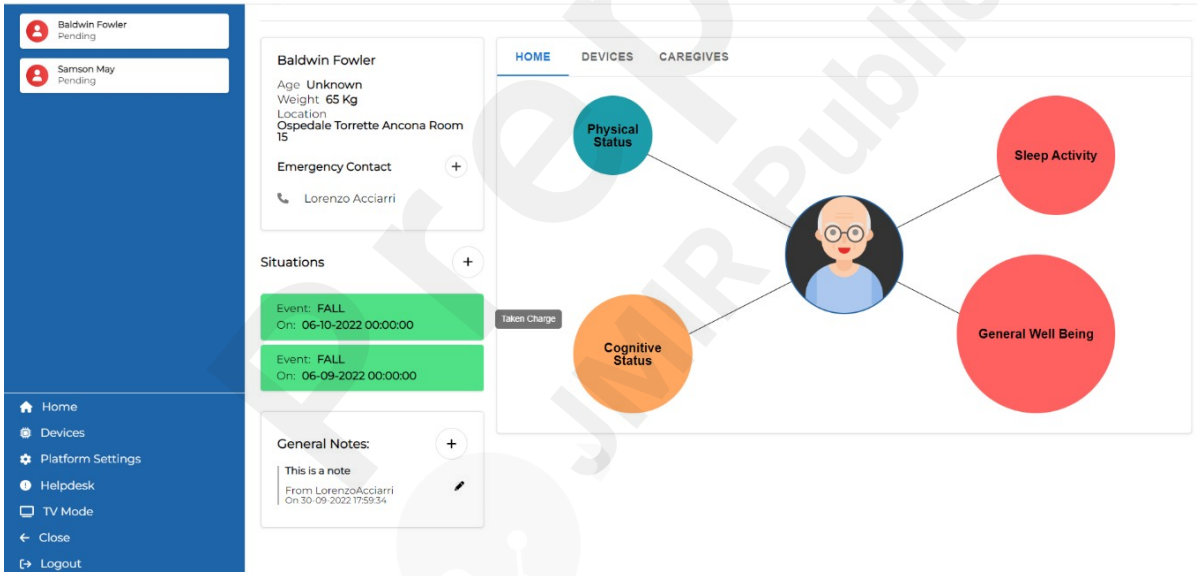
The core of the HAAL project is the development of the dashboard, which focuses on the well-being of the PwD. In fact, the dashboard integrates heterogeneous data from abovementioned smart care products and processed by a ML algorithm. The dashboard primarily focuses on descriptive analyses with relatively low complexity and a low level of automation. The indices provided by the smart care products are categorized into "vital sign indices", "behavior indices", and "instrumental activities daily living (IADL) indices". Based on public standards (i.e. set by WHO) and personal patterns (established by everyday measurements), the assessment algorithm ranks the indices into four levels: great, normal, attention, and abnormal. Based on the rules which the level worse than others is marked as the final status. Notably, each profile has four statuses: high urgency (need action at that time), low urgency (may need attention), offline (adopted devices are not working or connected), and normal (no detected deviation). These statuses are shown in four colors: red, orange, blue and green respectively. Besides, the deviations and/or accidents require action from formal caregivers. Each situation contains three levels of response status: requiring (need responding), attending (when a caregiver responds) and being already attended (when a caregiver marks the situation as safe). The second branch for medical workers would focus on giving a quick overview of several clients and urgent notifications. The dashboard is designed to be displayed on a television or a personal working computer. The notification is sent to a working mobile phone. The health and response statuses are consistent with the first branch. The following figures (7 – 11) show the various screens of the dashboard, in order to understand what the caregiver can see and do on it. The caregiver, through the menu "List of Clients" (shown in Figure 7), has an overview of clients whom (s)he is caring. Moreover, there is data about age, weight, level of dementia, and location of the patient.

Figure 7. HAAL Dashboard homepage.



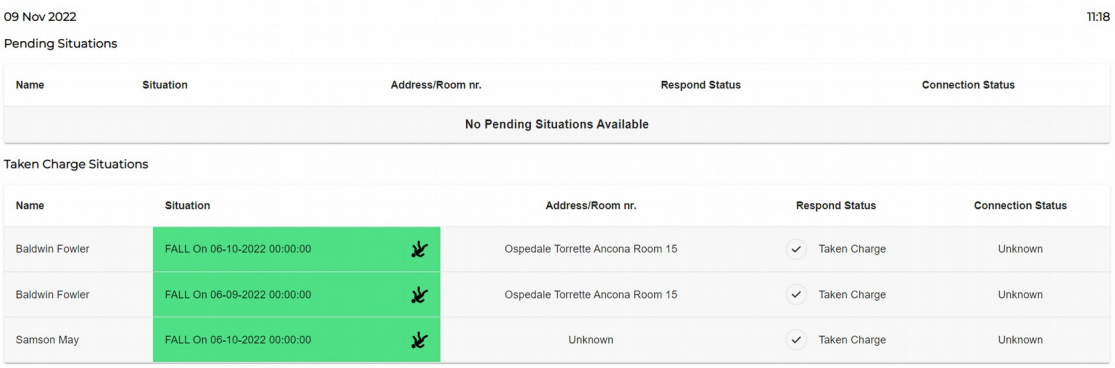
Then, the caregiver can select one single patient and get an overview of its situation, coded by color and dimension of the following aspects: physical status, sleep activity, cognitive status, and general wellbeing, as shown in the figure below. In the same screen (Figure 8), the caregiver has information about pending situations, general notes (that are added by the caregiver itself), and emergency contacts of the patient.

Figure 8. HAAL dashboard. Overview of a single patient



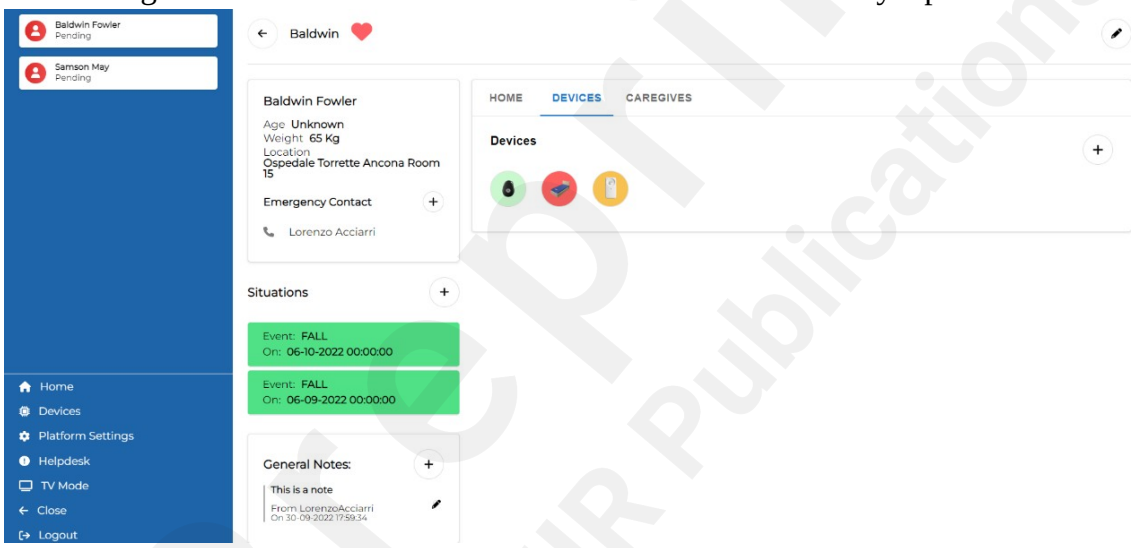
In the “Situations” window, shown in Figure 9, the caregiver can view who is requiring intervention. In this case all the situations were already taken in charge (in fact, the situation are shown in green). The kind of situation is written in the column “situation”, and also location and connection status are shown.

Figure 9 HAAL dashboard. Overview of situations.



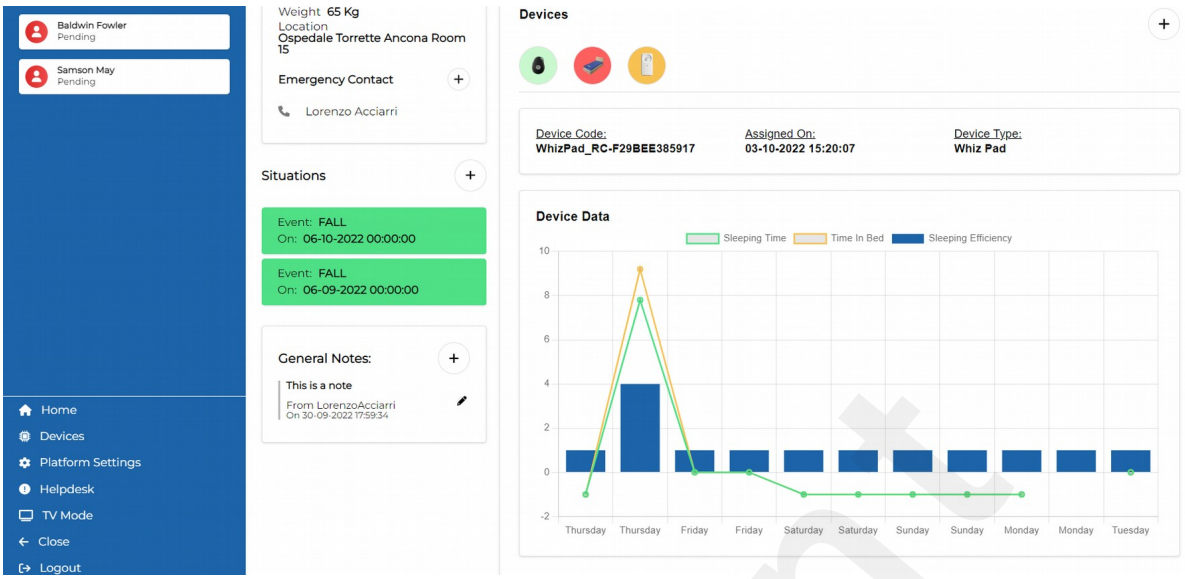
In the device menu, displayed in Figure 10, it is possible to see what are the devices used by the patient. The colour (given by the round of the device) codes the level of alert related to each device. In the figure below, the analysis of data collected by Whizpad is alarming (red), whereas there is a warning related to Sensara, and no problem from GPS tracker.

Figure 10. HAAL dashboard. Overview of devices used by a patient.



Then, the caregiver can explore a single device to get insights about the collected and analyzed data. In the figure below (Figure 11), analysis of data collected by Whizpad is shown.

Figure 11. HAAL dashboard. Data analysis of a device.



The field trial

The field trial was conducted as a case series (uncontrolled longitudinal study), with a before and after design where the observations are made on a series of enrolled individuals, receiving the intervention described below with no control group, with data collected before and after the installation and use of the technical solution. The field trial was also conducted in two phases – alpha and beta – where prototype 1 and 2 of HAAL dashboard were tested respectively. Both phases were run at the same way in terms of duration and activities carried out, as well as interviews. The field trial procedure will be divided into four different phases, after the recruitment of the participants: Baseline evaluation (T1), First evaluation (T2), Second evaluation (T3) and Final evaluation (T4), with the aim of collecting data as described in Textbox 1:

Textbox 1. Field trial phases.

1. Recruitment phase: the recruitment protocol included general information on the subjects, in particular, health status and cognitive condition. The information was collected with the help of the caregiver/family member if needed.
2. Baseline evaluation consisted of the first real contact with the users and their families, before the start of the field trial.
3. First evaluation (after one month of use): the aim of this phase is to analyze the usability and acceptability of the system, after a short period of use. The evaluation of the system usability was conducted adopting qualitative and quantitative techniques.
4. Second evaluation (after two months of use): the aim of this phase is to analyze the usability and acceptability of the system, after a short period of use. The evaluation of the system usability was conducted adopting qualitative and quantitative techniques.
5. Final evaluation (after three months of use): the aim of this phase is to collect useful information on the whole benefits perceived by the users after a meaningful period of use of the system. The final evaluation was conducted after the system de-installation, to detect and analyses the impact of the system in the daily life of the older people and their family and to gain knowledge on elderly technology acceptance and usability issues and provide methodological approach for further studies in the field.

Recruitment

In the dementia care context for HAAL, three groups of end-users were involved, such as people with dementia, informal caregivers and formal caregivers. People with dementia (PwD) vary between mild cognitive impairment (MCI) to severe stages of dementia. This intellectual deterioration can be measured using the Global Deterioration Scale (GDS) that defines seven cognitive decline stages and four stages of dementia [19]. A total of 45 participants took part in alpha test, while 90 participants were recruited for the beta test. The recruited end users are reported in Table 1 grouped by their category, phase of study, and country.

Table 1. End users recruited for the field trials in the three pilot sires.

End users	Italy		The Netherlands		Taiwan	
	Alpha	Beta	Alpha	Beta	Alpha	Beta
PwD	5	10	5	10	5	10
GDS 2-4	none	none	none	none	5	10
GDS 5	5	10	none	none	none	none
GDS 6-7	none	none	5	10	none	none
Informal caregivers	5	10	5	10	5	10
Formal caregivers	5	10	5	10	5	10
TOTAL	15	30	15	30	15	30

In Italy, the end-users were recruited from the Neurology Unit and Alzheimer Assessment Unit (Memory Clinic) of the IRCCS INRCA. The research team had the possibility to meet the families of patients with dementia and to present them the project and the modalities of a possible participation.

The researchers of Vilans – a private organization for digital health – recruited participants via the care organization Livio, established in the Enschede region, in the Netherlands.

In Taiwan, two research institutes actively participated in the HAAL field trials. The Yuan Ze University (YZU) recruited participants at Bianciao Veteran Dementia Nursing Home, while the National Cheng Kung University (NCKU) recruited the end users from day-care centres established by Schuhe Social Welfare Foundation.

Older people with dementia

Once the informed consent was obtained in duplicate, the compliance with the criteria of inclusion and exclusion of the study was verified and the baseline evaluation was carried out with the questionnaires and clinical trials provided by the study design.
The inclusion and exclusion criteria are reported in Textbox 2:

Textbox 2. Inclusion and exclusion criteria for people with dementia.

The inclusion criteria were:
1. aged 65 years and over;
2. capacity to consent;
3. score at the Global Deterioration Scale (GDS) as follows: GDS 2-4 (Group A), GDS 5 (Group B), GDS 6-7 (Group C);

4. have both an informal and a formal caregiver to support in carrying out the main daily activities;
5. healthy sight and hearing.

The exclusion criteria were:

1. active implantable medical device incorporated;
2. failure to meet the inclusion criteria;
3. concomitant participation in other studies;
4. lack of written informed consent;
5. lack of informal caregivers;
6. sight and hearing not intact.

Informal caregiver

Informal caregivers are mostly family members or daily references of the people with dementia. Connections between informal caregivers and clients are private and not via a care organization. Informal caregivers are concerned about the well-being of the PwD and they provide emotional or practical support regularly. Although it is easier to live nearby the PwD, informal caregivers do not necessarily need to live close by PwD. Informal caregivers are included in the HAAL project since they play an important role in the daily life of the PwD. Moreover, the informal caregivers can fulfil caring tasks to reduce the burden of formal caregivers. A good collaboration between informal caregivers and formal caregiver is needed as the informal caregivers can be the link between the client and the formal caregiver.

The inclusion and exclusion criteria are reported in Textbox 3:

Textbox 3. Inclusion and exclusion criteria for informal caregivers.

The inclusion criteria were:

1. being the informal caregiver of a person with cognitive impairment or dementia in stage, following the GDS groups;
2. availability of time to participate;
3. visiting the assisted person at least two times a week or living with him/her.

The exclusion criteria were:

1. active implantable medical device incorporated;
2. lack of familiarity with apps and/or minimal digital literacy;
3. failure to meet the inclusion criteria;
4. concomitant participation in other studies;
5. lack of written informed consent.

Formal caregivers

Care professionals or formal caregivers are professionally responsible for dementia care. They are trusted agents for people with dementia and have direct contact with older adults and provide care when needed.

In Italy, the formal caregivers are case manager, neurologist, psychotherapist, occupational therapist, and nurse. The case manager is responsible of the organization. The neurologist is a specialized medical doctor who diagnoses the disease and prescribes the treatment. The psychotherapist leads the intervention, whereas the nurses and the occupation therapists act as assistant. These professionals may be especially found in day care, but they are available in residential home care as well. People at severe stage of dementia are suggested to move to a care home.

In the Netherlands, the formal caregivers are case managers or nurses. In another word, they are local district nurses, and case managers have a specialisation in dementia care. Nurses are responsible for non-diagnosed seniors, while case managers would be assigned for people with dementia diagnosis and take part in long-term care provision. They will provide home care in the early and middle stages

of dementia until the person needs more intensive professional care for daily tasks. Then, in the severe stage, the case managers would suggest the transition to a care home to receive professional caregiving.

In Taiwan, the care of PwD is first evaluated by the case managers of the long-term care management centres supervised by Ministry of Health and Welfare. The case managers are well-trained physicians, physical therapist, occupational therapist, nurse, and social workers. After the assessment, the case managers will arrange related follow-up care services for PwD. The follow-up care services include home care, day care centres, institutional care, group homes, psychiatric wards for the elderly, institutional respite services, etc.

Textbox 4. Inclusion and exclusion criteria for formal caregivers.

The inclusion criteria were:
1. being the formal caregiver of a person with cognitive impairment or dementia in stage, following the GDS groups;
2. availability of time to participate;
3. work experience of at least 4 years in the field.

The exclusion criteria were:
1. failure to meet the inclusion criteria;
2. concomitant participation in other studies;
3. lack of written informed consent.

Outcomes

The field trials aim to assess the feasibility of implementing the HAAL platform in the assistance of PwD of any stage. For this reason, the primary interest is to assess the impact of the HAAL platform on caregivers' workload and end users' quality of life, as described in Textbox 5. Then, the field trials also focus on the usability and cost-effectiveness of the HAAL solution, as shown in Textbox 6.

Textbox 5. Primary outcomes of the study.

1. Reduction of the care load of the formal and informal caregivers through ZARIT Burden Interview [20];
2. Formal and Informal caregivers' decrease in stress and anxiety through the General Anxiety Disorder-7 [21];
3. the improvement in the perceived quality of life for informal caregivers and person with dementia through EQ-5D [22];

Textbox 6. Secondary outcomes of the study

1. usability of the platform for formal and informal caregivers through System Usability Scale [23] and semi-structured interview;
2. the increased cost-effectiveness of the HAAL solution in comparison to the available services through semi-structured interview.

For these reasons, the protocol includes study specific questions on demographics, attitudes towards and acceptance of the HAAL platform technology, as well as questions regarding demands and cost. All scales used are validated in the pilot-sites' languages and suitable for administration for the patients recruited in the study. The tables below (Table 2 to Table 5) summarize the different tools adopt with each end-user group, in all the phases of the study:

Table 2. Tools and dimensions of the PwD protocol at stage 2-4 of GDS.

Dimension	Tool	R	T1	T2	T3	T4

Cognitive status	GDS [19]	X				X
Socio-demographics	Ad-hoc questions		X			
eHealth literacy	eHEALS [24]		X			
Attitude towards technology	ATDPA-E [25]		X			
Quality of life	EQ-D5 [22]		X	(VAS)	(VAS)	X
Usability	SUS		X	X	X	X
Usability	Ad-hoc questions			X		X
Usability	Desirability cards			X		X
Acceptability	Ad-hoc questions					X

R=recruitment; T1=baseline; T2=first evaluation; T3= second evaluation; T4=final evaluation; GDS=Geriatric Depression Scale; eHEALS= The eHealth Literacy Scale; ATDPA-E= Assistive Technology Device Predisposition Assessment, Scale E; EQ-D5=Euro Quality of life; SUS=System Usability Scale; VAS=Visual Analogue Scale

Table 3. Tools and dimensions of the PwD protocol at stage 5 and 6-7 of GDS.

Dimension	Tool	R	T1	T2	T3	T4
Cognitive status	GDS [19]	X				X
Socio-demographics	Ad-hoc questions		X			
Quality of life	EQ-D5 [22]		(VAS)	(VAS)	(VAS)	(VAS)
Usability	Ad-hoc questions			X		X
Acceptability	Ad-hoc questions					X

R=recruitment; T1=baseline; T2=first evaluation; T3= second evaluation; T4=final evaluation; GDS=Geriatric Depression Scale; eHEALS= The eHealth Literacy Scale; ATDPA-E= Assistive Technology Device Predisposition Assessment, Scale E; EQ-D5=Euro Quality of life; SUS=System Usability Scale; VAS=Visual Analogue Scale

Table 4. Tools and dimensions of the Informal caregiver protocol.

Dimension	Tool	R	T1	T2	T3	T4
Socio-demographics	Ad-hoc questions	X	X			
eHealth literacy	eHEALS [24]		X			
Attitude towards technology	ATDPA-E [25]		X			X
Social support	Lubben scale [26]		X			
Quality of life	EQ-D5 [22]		X	(VAS)	(VAS)	X
Caregiver burden	ZARIT [20]		X	X	X	X
Anxiety and stress	GAD-7 [21]		X	X	X	X
Usability	SUS [23]			X		X
Usability	Ad-hoc questions			X		X
Usability	Desirability cards			X		X
Acceptability	Ad-hoc questions					X
Demand & cost information	Ad-hoc questions					X

R=recruitment; T1=baseline; T2=first evaluation; T3= second evaluation; T4=final evaluation; GDS=Geriatric Depression Scale; eHEALS= The eHealth Literacy Scale; ATDPA-E= Assistive Technology Device Predisposition Assessment, Scale E; EQ-D5=Euro Quality of life; ZARIT= Zarit Burden Interview; GAD-7: General Anxiety Disorder – 7; SUS=System Usability Scale; VAS=Visual Analogue Scale

Table 5. Tools and dimensions of the Formal caregiver protocol.

Dimension	Tool	R	T1	T2	T3	T4
Socio-demographics	Ad-hoc questions	X	X			
eHealth literacy	eHEALS [24]		X			
Attitude towards technology	ATDPA-E [25]		X			X
Quality of life	EQ-D5 [22]		X	(VAS)	(VAS)	X
Caregiver burden	ZARIT [20]		X	X	X	X
Anxiety and stress	GAD-7 [21]		X	X	X	X
Usability	SUS [23]			X		X
Usability	Ad-hoc questions			X		X
Usability	Desirability cards			X		X
Acceptability	Ad-hoc questions					X
Demand & cost information	Ad-hoc questions					X

R=recruitment; T1=baseline; T2=first evaluation; T3= second evaluation; T4=final evaluation; GDS=Geriatric Depression Scale; eHEALS= The eHealth Literacy Scale; ATDPA-E= Assistive Technology Device Predisposition Assessment, Scale E; EQ-D5=Euro Quality of life; ZARIT= Zarit Burden Interview; GAD-7: General Anxiety Disorder – 7; SUS=System Usability Scale; VAS=Visual Analogue Scale

Statistical Analysis

The first step of the data analysis deals with the description of the sample. Continuous variables are 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 are expressed as an absolute number and percentage. Mann-Whitney U tests (for non-normal distribution), or Chi-Square tests (normal or non-normal) are 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. caregivers' burden), subscales of the ZARIT questionnaire are calculated. Means and standard deviation or medians and interquartile ranges of the scores are reported according to their distribution. Correlation coefficients (Pearson for normally distributed variables, Spearman for non-normally distributed variables) of the sub-scales with the other rating scales at each stage of the study and with the main characteristics of the subjects are calculated to check for potential determinants of higher acceptability, as secondary endpoint of the project.

Discussion

In the face of an ageing population and the emergence of neurological diseases compromising the autonomy of the elderly, which increasingly involve families in caregiving responsibilities, interventions are needed to support these caregiving activities and enhance the quality of life for both the patient and their caregiver. One solution has been identified in the HAAL platform, designed to support older people ranging from early to late dementia and their (in)formal caregivers. The services that are developed in HAAL have the potential to enable individuals diagnosed with dementia to maintain longer periods of residence in their own homes, thereby fostering a certain level of autonomy. This aligns with the overarching objective of alleviating the burden on caregivers, all the while enhancing the standard of care provided.

The study design allows to test the solution for relative long period (three months) and to exploit feedback coming from alpha phase to improve the prototype that is then tested in beta phase. The same process has been done previously through usability test in which professional workers tested

the dashboard prototype 1 [18]. Thus, this protocol applied to prototypes 2 and 3 of the HAAL dashboard. The iterative user-centered design characterized all the HAAL project stages, starting from co-creation with end users (both primary –i.e. formal caregivers – and secondary –i.e. PwD) till the presented field trials. The main challenges of this study are represented by the cultural and healthcare systems differences among the three pilot sites and two continents. The HAAL platform is ambitious as it aims to work for managing people of any degree of dementia in different care settings. For these reasons, and given the low number of end users recruited, it has been decided to recruit only one category of PwD in each pilot-site. In fact, this methodology allows to reduce the number of variables to take into account when analyzing results.

Several technological devices are available on market and tested for this target group, however very few ecosystems are in place and used by healthcare facilities, institutions or systems. In this regard, the current challenge is to embed and aggregate different technologies to provide quick and intuitive information that can effectively support (in)formal caregivers in managing people with dementia, relieving their stress partially. Moreover, the need extends beyond mere access to information; it encompasses the development of comprehensive support systems that cater to the dynamic needs of caregivers and individuals with dementia alike. These systems must go beyond the provision of basic information and extend to offering personalized guidance, respite services, and community resources. By fostering a collaborative environment where caregivers feel empowered and supported, these initiatives not only enhance the quality of care provided but also contribute to the overall well-being of both caregivers and care recipients. Within this framework is the HAAL project with the main objective of assessing the stress relief at work for formal and informal caregivers, the improvement in the perceived quality of life for informal caregivers (IC) and person with dementia.

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Conflicts of Interest

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

Abbreviations

WHO: World Health Organization
PwD: People with Dementia
ML: Machine Learning

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