An Ambient Assisted Living platform for supporting aging in place of prefrail and frail older adults: Rationale, HomeAssist plaform, quasiexperimental design, and baseline characteristics

Hélène Sauzéon, Arlette Edjolo, Helene Amieva, Charles Consel, Karine Pérès

Original Paper

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Authors : Sauzéon[1, 2], H., Edjolo[1], A., Amieva[1], H., Consel, C[, 2]., Pérès[1], K.,

1. INSERM, Bordeaux Population Health Research Center, UMR 1219, Univ. Bordeaux, F-33000 Bordeaux, France
2. Inria, Talence, France

Corresponding Author:
Hélène Sauzéon
Address : Inria Bordeaux Sud-Ouest, 200 avenue de la Vieille Tour 33405 Talence, France
E-mail : Helene.sauzeon@inria.fr / Helene.sauzeon@u-bordeaux.fr

Authors' Emails:

Helene.amieva@u-bordeaux.fr
Charles.consel@inria.fr
arlette.edjolo@u-bordeaux.fr
karine.peres@u-bordeaux.fr

Abstract

Background: Ambient Assisted Living (AAL) technology is expected as a promising way for prolonging the aging in place. Very few evidence-based results are provided support to its real value, notably for frail older adults who have high risk of autonomy loss and of entering in nursing home.
Objective: HomeAssist (HA) is a human-centered AAL platform offering a large set of applications for three main age-related need domains (Activities of Daily Living, Safety and Social participation), relying on a basic set of entities (sensors, actuators...). The HA intervention involves monitoring as well as assistive services to support independent living at home. The primary outcomes measures are related to aging in place in terms of effectiveness (institutionalization and hospitalization rates) and efficiency (everyday functioning indices). Secondary outcomes measures include indices of frailty, cognitive functioning, and psychosocial health of participants and their caregivers. Every 6 months, user experience and attitudes towards HA are also collected in equipped participants. Concomitantly, HA usages are collected.
Methods: A study assessing the HA efficacy has been designed and is now conducted with 131 older adults aged 81.9 (±6.0) years (from autonomous to frail) who lived alone. The study design is quasi-experimental with a duration of 12 months optionally extensible to 24 months. It includes equipped participants, matched with non-equipped participants (n= 474). Follow-up assessments occurred at 0, 12 and 24 months.

Results: The expected results are to inform the AAL value for independent living, but also to yield informed analysis on AAL usages and adoption in frail older individuals.

Keywords: Ambient assisted living technology ; Aging and frailty ; independent living, effectiveness study

Introduction

Frailty is a common geriatric syndrome characterized by age-related declines in both physical and cognitive reserve, as well as physiological function, leading to increased vulnerability for adverse health outcomes [e.g., 1]. According to the physical phenotype proposed by Fried [2], frailty refers to individuals meeting at least three of the five following criteria: weakness, slowness, low level of physical activity, self-reported exhaustion, and unintentional weight loss. In the community-dwelling elderly population, the frail and pre-frail individuals represent around 40% of people aged over 65 [3]. Frail Individuals (FI) being at higher risk of disability, hospitalization and institutionalization [4, 5], are recognized as an optimal target population for the implementation of effective programs to prevent dependency [3] or even to reach a successful aging path [6]. In this line, as highlighted by the World Health Organization (WHO) in its healthy ageing concept, environments, in interactions with intrinsic capabilities, play substantial role in developing or maintaining functional ability that enables wellbeing in older age [7]. In this FI population, environmental support can be a relevant approach to incite and facilitate the Activities of Daily-Life (ADLs), and then to contribute to reduce or delay their functional degradation and foster and extend aging in place in good conditions [8].

Assistive Technologies for ADLs refer to all technical forms of environmental support, that provide an adaptation of the environment to make it more accommodating for persons with impairments [9]. Despite of the enthusiasm for Assistive Technologies (AT), several issues remain to be resolved. First, all the studies published so far on AT suffer from a lack of empirical evidence of their efficacy, mostly due to shortcomings related to study designs (small sample size, irrelevant or not standardized measures, short follow-up duration, no control group, etc) [e.g., 10, 11]. Second, despite the many technological innovations available to assist older adults in their daily life [10], their silo-based nature makes it challenging to aggregate them as older adults require more services to assist an increasing number of ADLs due to multiple, various and evolving task-needs, particularly in the frailty context. Indeed, restricted capability to perform ADL remains extremely patient-dependent (individual and occasion variabilities) [6]. As a result, personalized multiple intervention programs are more efficient to slow down the impact of frailty progression (cognition, autonomy, quality of life) than usual intervention programs [12]. A third limitation related to the silo-based approach, is a too restricted contextualizing of assistive services (situation awareness). Hence, such services are not flexible and are delivered irrespective of the actual

person's needs for a given situation, rendering them unsuited or even obstructive for performing ADL [13]. Finally, informal and formal caregivers are important resources for community-dwelling FI, acting as "human support for ADLs" [14, 15]. Thus, the assessment of Ambient Assisted Living (AAL) benefits should integrate measures related to caregiver's efficiency.

To move forward the Assistive Technologies field, we designed a clinical trial assessing an AAL-based multi- services assistance, called HomeAssist, dedicated to support FI in their three main needs' domains: ADL, safety and social participation. We expected that the HomeAssist use would result in a better everyday functioning (main efficacy criterion: Instrumental ADL score), and a lower rate of institutionalization as well a better self-perceived health (as secondary efficacy criteria) compared to older adults living in the community not benefiting from HomeAssist. This paper reports the process used to design HomeAssist and describes the clinical trial design.

Methods

The different phases of the construction of the HomeAssist study: An AAL Platform for frail individuals (FI)

From Design to Pilot studies

The HomeAssist design was primary based on a human factors-centered approach to designing, introducing and assessing an AAL platform amongst FI.

First, we formed a multidisciplinary scientific consortium with internationally known researchers, whose expertise ranges from Smart Homes to Aging. Second, the consortium worked closely with networks of stakeholders on aging in place, at all levels (territorial/municipal services setting aging policies, care/support service for aging in place and family caregivers) for an operational HA deployment. Our public partners included: Solidarity & Autonomy National fund, regional health agency, Regional retirement fund, public planners of dependency allowance for 4 departmental councils and municipal home care services. We also had the following private partners: non-profit community and private home care services, telecare companies, and private home adaption service. Finally, we performed a large needs analysis amongst 525 older adults living at home and benefiting from home care services in order to identify their needs in daily living, in terms of instrumental (meal preparation, medication, etc) and basic (dressing, grooming etc.) ADL with a French

analog of ADL assessment [16, 17, 68]. Additionally, a subgroup of this sample (N= 50) and their caregivers have been more thoroughly interviewed for probing their perceived AT needs [18]. For both targets, daily-living activities, safety and social linking have emerged. Nonetheless, safety and social linking were perceived as need domains still more crucial than that of everyday activities, in particular when older adults exhibited a physical functioning decline.

The HomeAssist platform

From this extended needs analysis, we developed the HA platform of connected objects which overall purpose is to promote independent living in place for the FI while regulating the caregiver's burden. Hence, HA proposes many apps in the three key domains of everyday life, as follows: *Daily activities* (including activity monitoring, daily-routine monitoring, appointment and event reminders, *etc.), Home or personal safety* (entrance monitoring, stove monitoring, light path, and no-activity alert to caregiver when no user's answer, *etc.)* and *Social participation* (Photo sharing with family, collaborative games, videoconference, simplified mailing system, i.e., voice recording to send message and speech synthesizer to read the messages out loud,[19], simplified email information about local events, TV programming, *etc*) (for details see, [20], See a video presentation: https://www.youtube.com/watch?v=-Lc1jzrMg6c). HA offers an online catalog of applications for aging in place. The older adults and the caregivers were asked to determine what and how activities should be assisted by selecting the appropriate assistive applications and configuring them with respect to the person's needs and preferences. The resulting set of applications forms a personalized assistive support for an individual. Additionally, to respond to evolving needs, our platform allows to stop/remove applications easily and to install new ones from the online catalog (**Figure 1**).

Figure 1 *: Examples of assistive applications from our online catalog*

Sensors and actuators

Technically, monitoring and assistive applications rely on an infrastructure of devices

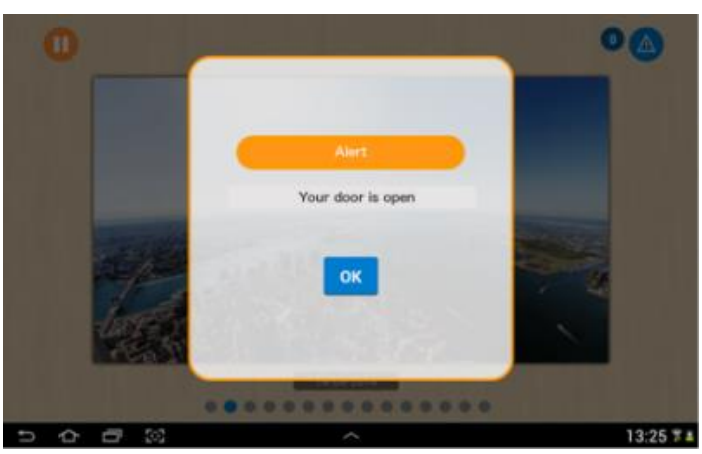
and Web services deployed at the home of each user. The HA platform relied on a set of sensors and actuators, as well as two touchscreen tablets (**Figure 2**). Indeed, several entities are required for running the HA services: (1) wireless sensors (motion and contact sensors, smart electric switches), and two tablets, and (2) software services (agenda, address book, mail agent, and photo agent). Three types of sensors were used in our platform: contact sensors enabling to detect when a door or a drawer is opened or closed; electric meters sensing electric consumption of electric appliances and enabling to remotely turning it on or off; and motion sensors collecting timed information when motion is detected in their sensing range. These sensors were chosen for being small, wireless, cheap and respecting users' privacy. Sensors are placed in strategic locations: kitchen, bedroom, bathroom, and near the entrance (**Fig. 2**). The situation awareness provided by daily-routines monitoring service (i.e., passive user interactions) is a key property of HA for ensuring relevant assistive services by: 1) answering queries such as "is the person asleep?"; 2) recognizing ADLs; 3) automatically detecting alerting situations such as door opened during the night; and 4) identifying specific behavior changes which may indicate, for instance, a decline in health status such as changes in ADL routine or a reduction in the number of goings out of the home [21, 22].

***Figure 2**: Content of the HomeAssist platform: **Left** : Example of sensors deployment; **Right**: A set of sensors, an online catalog of assistive applications and two touchscreen tablets (main and secondary tablets)*

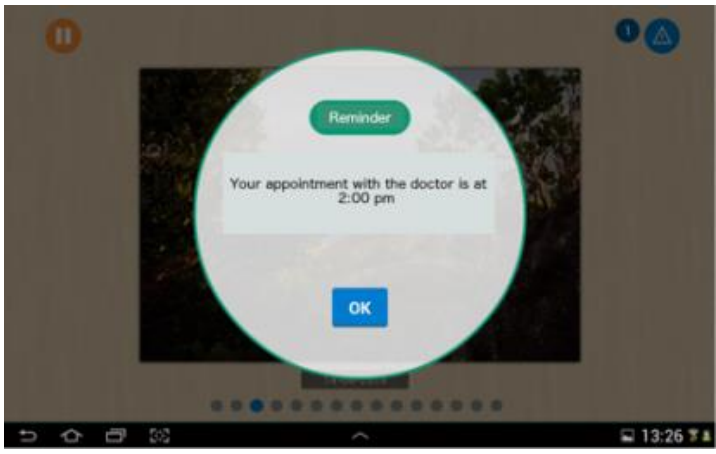
Two touchscreen tablets

Regarding *active user interactions*, users were interacting with the platform via two touchscreen tablets, operating under Android OS, that we redesigned following guidelines for older population (e.g., ISO/TR 22411; [23]) and prior user testing relative to objective and subjective measures of usability, use learning and self-reported user experience [24, 19, 25].

Importantly, HA services revolve around a unifying and simplified interface suited for older adults [24]. For instance, for the main tablet where are displayed the assistance notifications, the notification system exploits the preference of older adults for simple interactions and optimize their cognitive resources by using a multimodal coding of notifications (tones, shapes, colors, and text). All assistive applications are required to interact with the user via either a critical or a non-critical notification, depending on the risk level of the situation. Each type of notification employs a specific multimodal coding, as illustrated by **Fig. 3a** and **Fig. 3b**, respectively displaying a critical and a non-critical notification.



(a)



(b)

(c)

(d)

***Figure 3**: (a) Critical notification; (b) Non-critical notification; (c) List of unattended notifications and (d) Pause feature of notification system.*

This approach makes it easier to discriminate between the notification types. Furthermore, the user follows a dedicated procedure for each type of notification. Critical notifications (**Fig. 3a**) use a loud volume and only disappear when the situation is resolved; it can contact a caregiver via a text message after a pre-defined period of time to seek for help. In contrast, non-critical notifications (**Fig. 3b**) use a soft tone; they disappear after being displayed for a set period of time and get added to a list of unattended (non-critical) notifications. An example of such a list is displayed in Fig. 3c. This mechanism allows a user to disregard a notification if it occurred while they

were performing another task. If the condition that raised a non-critical notification does not hold (e.g., the door of the fridge was closed), then this notification is suppressed from the list of unattended notifications. To respect user self-determination [20], the notification system can be deactivated by the users themselves for a predefined period, for example when the user is visited by someone, as depicting on the **Fig.3d.**

The secondary tablet provides social participation services. To make it easier to use these services, a simplified application launcher has been specially developed (**Fig. 2 above**). This launcher offers the applications in the form of a page containing 3 applications. A simple click on the icon of the application opens it. Five pages can be created and the user navigates from page to page with a simple gesture of the finger mimics the leafing through a book. The launcher updates itself as it is used and orders the applications on the pages according to their use frequency so that the user can find the applications that are used most often more quickly.

The pilot HomeAssist study.

A pilot study has been conducted in 17 HomeAssist equipped FI compared to 17 non-equipped FI to assess the feasibility of the HA concept and to collect preliminary results regarding its acceptance and elicited user experience (usability, satisfaction, etc.). The results showed that HA was well adopted (highly accepted and usable) by the FI and their families or caregivers [20, 21]. Moreover, after six and nine months of follow-up, benefits measures of self-determination behaviors and IADL scores [26] were higher in equipped FI [20, 27, 28]. For instance, with normalized scores, at 9 months, the equipped group did not change its IADL score while the control group lost 1 standard deviation. Additionally, the objective burden of caregivers to support care receiver's ADL increased in the control group after the follow-up period while it did not increase in the equipped group, even though the subjective burden remained unchanged [27, 28].

Overview of expected functions of HA services

The HA is an implementation of general principles highlighted by an ecosystemic approach applied in the context of environmental gerontology that stresses the study of environment–aging relations through the synergy of multiple disciplines and professionals (e.g., psychologists, epidemiologists, technologists, allied health professionals, community planners, social policy makers). The common goal is the development of preventive and ameliorative interventions, targeting both the individual and environmental factors to provide a better ''fit'' between FI and their home, thus supporting aging in place as well as good

quality of life. Therefore, the HA aims at providing services related primarily to *promoting aging in place (independent living and well-being) and* secondarily, *improving the efficiency of the caregiving environment*.

Accordingly, HA services support autonomous realization of daily tasks including socialization activities, which is known to be related to independent living capabilities, and then older adult well-being. In original way, applications support self-regulation and self-determination in helping the users to conform to their own daily routines via sensor-based activity monitoring and assistive supports (*e.g.,* activity reminders).

The online HA catalog also offers applications materializing a caregiving proxy for a number of actions, including mutualizing the planning of care services, gathering information on older adult activities, reminding of activities and appointments, monitoring potentially unsafe activities and situations.

Overview of HA Study

Objectives

The objectives of HA trial will be to perform a field study for testing in real conditions the use the HA-AAL in a sample of older persons (frail or not) living alone at home and, then for assessing the impact and efficacy of HA in terms of aging in place and the efficiency of caregiving environment.

Consequently, the primary outcome is an aging in place-related measure, through the functional status. Secondary criteria of HA efficacy are also studied, including institutionalization, hospitalization, as well as measures of health scales (self-efficacy, quality of life, routinization, etc.), general cognitive status, memory and executive functioning. Additionally, caregivers-related measures are included to assess the impact of our platform in their daily delivery of services (*e.g.,* feeling of burden assessment, psychological health of caregivers) and reassurance regarding the situation of the older person.

Design

To test the impact and efficacy of HomeAssist, we designed a quasi-experimental study which started in 2017 including 131 older adults, ranging from autonomous to frail (i.e, cognitive or physical frailty, or both) equipped with HA and 439 matched controls recruited in Aquitaine territories (not equipped of HA), forming part of an existing population based-based cohort on aging (the City-study, [32]) . A total of 73 older adults and their family or formal caregivers participated to our proposed field study during a period of 12 months, and

optionally 24 months (n=18).

The study protocol was approved by the National Commission of Informatics and Liberty (CNIL) and the Ethics COERLE committee of the French National Institute of Informatics and Mathematics (Inria), as protecting participants and data accordingly.

Follow-up assessments for clinical outcomes (effectiveness on aging in place measures and on caregiver burden measures) occurred at 0 and 12 months, and optionally at 24 months. Follow-up assessments for user experience, attitudes and HA usages were also collected in equipped participants every 6 months (0, 6, 12 months, and optionally at18 and 24 months, see Figure 4).

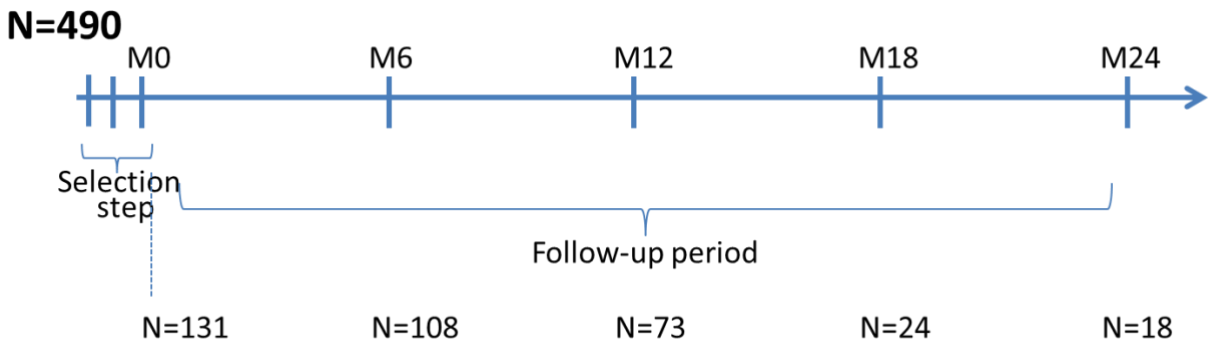


***Figure 4**: Timeline of recruitment and follow-up of HA condition..*

Eligibility criteria

Firstly, the participants had to be 65 years of age or older; live alone in an independent community setting (with an equal selection in urban, semi-urban & rural locations); have a MMSE score over 23 [29]; be able to understand the use of applications and devices included in the HA platform; be ambulatory (with/-out cane/walker); have an available, reliable formal and informal caregiver (contact frequency > 4-5 hours/week); and be able to understand for signing the informed consents.

In addition, they had to have pre-frailty or frailty syndrome according to the SEGA scale [30].

The exclusion criteria were as follows: Living in institution (nursing homes); living with a partner; having an upcoming relocation project; suffering from Dementia; having visual or hearing loss or any other conditions limiting HA use; having current serious or unstable medical condition or any personal condition that may limit follow-up visits.

Description of the HA intervention

HA condition

Together with best standard care and counselling, after participant and caregiver needs have been adequately assessed at the baseline visit, an individualized assistive program was designed by selecting the appropriate HA apps. Each participant's home in the HA condition is equipped of a HA kit including sensors, actuators and two tablets as described before. The HA installation is done by a technico-clinician trained for assistive needs' collecting, HA installation and training. During the installation phase, the objective was to adapt and customize the platform to each person and housing. From a technical point of view, the necessary steps included: settings and personalization of the assistive apps (e.g., fill the calendar, add family contacts) and platform's testing. The clinician's goal was to make explicit and record older adults' everyday routines, desired assistive services and preferences, notably in terms of both critical and non-critical notifications and the notification sharing with one caregiver. The presence of a caregiver (family, friend, home care professional) was greatly advised, both for reducing older adult's stress and for helping the older adult to declare his/her preferences. Overall, each participant was equipped with both daily-routine monitoring service and a set of self-choose assistive services among the HA services library. During the training phase, the technico-clinician introduced the different features of the platform on a step-by-step basis, during four monthly sessions of 75 minutes based on concrete scenario uses: two sessions for learning the notification system on the primary tablet and the two remaining for all the services on the secondary tablet (mailer, internet browser, game, visioconferencing, etc.). This instructional strategy was used successfully in other studies (e.g., [31]). Again, the presence of a caregiver was advised, who could learn from the techno-clinician professional, offered later a support in case of usage of technical issues. At the end of the training phase, we gave the older user a paper-based manual, reminding the different features and uses of the platform. The manual was made by the collective work of the research team, in a sake of clarity. For the experimental phase, a 24/7 hotline was provided to the participants for any question or difficulty. Some problems were solved remotely but some required personal visits such as the changes of sensors battery, the loss of internet connection, and the participants' incorrect use of the tablet, leading to malfunction.

Constitution of the HomeAssist sample

For HomeAssist, several recruitment methods have been used as advertisements in local media, interactions with home services for aging in place, attendance to senior associations.

The analysis of the recruitment data indicated that the most fruitful recruitment process was the home services specialized for older adults (**Table 1**). These home services were equally located in rural, semi-rural and urban areas.

In total 510 persons accepted to participate to the selection phase following the eligibility criteria. Finally, 131 subjects were equipped by the HA solution and accepted to be included into the trial.

Protocol and timeline procedure for HA condition

For each participant, several visits are planed: one for eligibility; two for the personalized installation of HA services, from 4 to 6 visits for training and from 1 to 2 visits for each follow-ups.

- **Eligibility and baseline assessment-** Eligibility criteria were screened in two steps. First, the participants who were interested in participating contacted the study coordinator who screened the first eligibility criteria (age, independent home; living arrangements, and geographical area of residence). Then the eligibility visit was conducted at the participant's home with a technico-clinician to apply the whole of eligibility criteria (cognitive and functional status, frailty level, etc.) and the procedure for collecting informed consent. For this eligibility visit, the person was advised to be accompanied by a person of trust, or even by a close person who frequently assists him/her (family, neighbor, friend, etc.). The presence of a relative had a threefold objective: to reassure the elderly person, to help the elderly person, if necessary, to make his or her decision to enter the study or not, and finally to invite this relative to participate as well. A period of 7 days of reflection was given to the pair of participants to formulate their own decision.

When the eligibility visit was successful, the other visits were then scheduled.

-HomeAssist service selection- First, the technico-clinician carried out the steps to open an internet line for each participant included. The costs associated with this opening were covered by the research program and the participant had nothing to pay for 12 months, but its renewal for another 12 months was at the participant's expense if he/she wanted to continue the experimentation.

The choice of assistive services was based on a needs' questionnaire where each need was associated to a pictorial description of corresponding HA service. This questionnaire was divided into two parts. The first part questioned the needs in terms of daily routine, everyday activities and safety for which assistive services are provided on the main tablet. For **daily routine**, four types of activities were monitored (getting up and going to bed, the three meal

activities, bathing activities and dressing activities), the performance of these activities was monitored every day and an assessment was reported to the person in a pictorial way where each activity is evaluated in the form of traffic lights (Green: 80% of the activity has been performed; Orange: 50 to 79% of the activity has been performed; Red: less than 50% of the expected activity). Each participant can then choose to have a reminder of each one of their routine activities on the main tablet and/or to send the daily activity report to the caregiver of their choice. Moreover, **reminder services** were offered as the medication intake, or reminders of any activities (medical appointments, hairdresser's appointments, leisure activities, etc.) or events (relatives' birthdays, a TV show, local social events, etc.). To this end, a simplified diary application has been specially developed so that both family caregivers and Technico-clinicians technicians enabled to quickly and easily enter the activities and events to be recalled and their recurrence. For **safety**, several notification services are offered: monitoring of household appliances, unintentional opening of the front door or fridge, abnormal absence of activities in the home during the day, repeated night-time getting ups. Also, a service for activating a light path during night-time rising is offered. For each notification/reminder-based service chosen, the participant decided whether the notification was critical or not. If the notification had a critical status, the participant can choose whether the notification is sent by SMS to phone of their informal caregiver. Finally, the first part of the questionnaire ended with the participant's choice of the **photos** displayed on the main tablet and their regular updates. To do this, the participant indicated which relatives could send photos, and if no relatives were present, the participant indicated his or her interests from which photos were extracted from free photo libraries. The second part of questionnaire referred to **social participation** services provided by the secondary tablet. These services concerned Internet browser, communication applications (visioconferencing, simplified mailer) and, various applications such as TV program guides, simple games (card games, puzzles, crossword puzzles, etc.) or interactive ones (scrabble, card games, etc.), shopping services (food, clothing, etc.), banking or public services applications (income tax, social assistance, etc.). From the overall, each HA service setup was personalized. The minimal setup included at least the daily routine monitoring service with no activity reminder notification, one to two security applications (most often, door alert and no daytime activity alert), two to three social participation applications (simplified mailer, internet browser, and games), and photo sharing on the main tablet. The questionnaire-based service selection could be updated each 6 weeks during the home visit by the clinical technician.

-HomeAssist installation: When the services were chosen, the second home visit was

organized with a home automation technician to install the HA platform in the participant's home and test that the platform was working properly. All participants had stylus available to interact with the tablets as needed (according to our pilot study, some very old participants had fingertips that did not allow operational contact with the tablet). During the same time, the clinical technician initiated the training phase.

-Training, practice of HomeAssist services- The training phase for using HA services was gradual. The use of the services offered by the main tablet (daily activities, and safety related services) was first targeted. Essentially, simulations of assistance scenarios lasting 10 minutes placed the participant in a situation of active interaction with the notification (critical vs. non-critical) and pause features of HA (for details see [20, 21]). The technico-clinician was provided with a scale to evaluate the quality of the response (time taken and number of errors, omissions and commissions), and if this was unsatisfactory, then the simulations were repeated. A maximum of three repetitions was sufficient to obtain understood and appropriate interactions from the participant. The technico-clinician left a very pictorial user manual of the services, specially designed for the participants and on which a dedicated space allowed the participant to annotate any comments and difficulties encountered with the services provided by the main tablet. During this first training phase, only the main tablet support services chosen by the participant were active. A week later, a third visit was arranged by the technico-clinician who checked with the person and the user manual to see if any use difficulties had been encountered with the HA. If so, then the first phase of training was replayed. If this was not the case, the second phase of training began, which focused on the use of social participation services on the secondary tablet. Here again, scenario simulations were proposed on the same principle as the first training phase aimed at the proper use of the application launcher, the opening of an application and its use. This second phase lasted longer, 20 - 30 minutes, because for the e-mail and videoconference applications, the technico-clinician entered the person's desired contacts and carried out numerous tests with them. As for services from the main tablet, a picture-based user manual for the secondary tablet was provided to each participant (a usability expert initially designed both of user manuals). At this time, all the social participation services on the secondary tablet were active. At the 4th visit, the technico-clinician checked to see if the person was having difficulty with the secondary tablet. As the interfaces of the selected applications (especially the applications not designed by us) had very heterogeneous designs, often the 2nd training phase had to be replayed during this 4th visit. When this was not the case, the 3rd phase of the training could be initiated. The latter always consisted of simulated usage scenarios but

mixing the services of the main tablet with those of the secondary tablet. If the participant's interactions with the platform were appropriate, then the training ended. If not, a fifth visit was scheduled. Hence, HA training took a minimum of four sessions (one per week) and a maximum of six.

- **A support hotline** - Throughout the training and the duration of the study, a 24/7 support hotline was available to all participants. A smart phone was dedicated for this purpose with a technico-clinician on duty. All participants received a "check-in" call at 1 week, 1 month, 6, 12, 18, and 24 months.

Furthermore, actimetric data were collected thank to HA system for the equipped participants (**Table 3**).

Impact and efficacy of HA: measurements of the assessment

The assessment is divided into two parts, i.e., Health and HA device parts.

Health part of the assessment

Tables 2 depicts all the measures. As shown, the participants completed a *screening questionnaire* that assessed basic demographic information, and their living home conditions. These measures will serve as potential moderating variables in our analyses.

They also completed the primary Efficacy follow-up battery including frailty-related ratings, independent living capabilities, self-perceived health for the participant and for the informal caregiver (**Table 2**).

***Frailty* ratings** are based on i) nutritional status with Mini-Nutritional Assessment [36] including the Body Mass Index (BMI) and the brachial and calf perimeters indices ;ii) The Short Physical Performance Battery (SPPB[37]) including four physical exercises: Five Chair Stands testing the lower body strength; Static Balance Testing; Timed Get Up and Go Test for assessing agility and dynamic balance; and Gait Speed Testand iii) Sensory abilities rating, particularly visual acuity and hearing.

Additionally, for a better covering of multidimensionality of frailty, mental health (depression symptoms on the Center for Epidemiologic Studies-Depression CES-D scale [48], cognitive functioning (MMSE to assess global cognitive performances, [29]) the Isaacs Set Test for verbal fluency [68], the Benton test to evaluate visual memory [69],) and executive functions with the TMT A and TMT B [70] and everyday cognitive difficulties self-rated or hetero-rated by the caregiver (**Table 2**). The measures chosen were based on evidence indicating that these psychological abilities play a role in the causation and aggravation of the frailty [45, 46] and they are also related to adoption of technology [47]. Hence, these

measures were included to examine if mental and cognitive health can predict HA uses and then mediated HA benefits across time.

Independent living capabilities are firstly evaluated by collecting the possible nursing home admission and with a questionnaire assessing each 6 months the critical events threating independent living such as the number of falls, the number and duration of hospitalization and the number of chronic diseases. Second, older adults' everyday functioning is assessed by two scales: the Preferences for Routinization Scale (EPR, [38]) assesses the routinization of activities of daily life (ADL) and behaviors, i.e., the execution of behaviors or activities (e.g., sleep and meal schedules, organization of personal objects, social exchange) in the same rhythm or way over time; the routinization preferences are documented as a marker of age-related vulnerability [39]; the IADL scale [26], answered by both the participant and their informal caregiver assesses the older adults' everyday functioning in instrumental ADL; We also chose to perform hetero-evaluations of older adults' functional status, as frail older adults are shown to be sometimes not accurate in self-evaluating their everyday difficulties (e.g., [40]).

Older adults' Self-perceived health is scored with two scales : first, the General Self-Efficacy Scale [41] rating the belief in one's competence to cope with a broad range of stressful or challenging demands and second, the Short Form-36 (SF-36) questionnaire assessing the health-related quality of life [42], that entails eight dimensions (physical functioning, physical limitations, body pain, general health, vitality, social functioning, limitations due to emotional problems, and mental health) and provides two summary scores, namely physical score and mental score. These two scores are also good proxies of the self-reported exhaustion dimension into frailty [43].

Caregivers' Self-perceived health is scored with two scales: first, the Short Form-36 (SF-36, [42]) questionnaire assessing the health-related quality of life, and second the Zarit Burden Inventory [44] (Zarit et al., 1980) assessing subjective caregiver burden that can be defined as the experience of "enduring stress and frustration" by those who care for individuals with reduced autonomy (e.g., [44]).

The primary outcome measures for the trial include changes at 12 months (and optionally at 24 months) in everyday functioning (self-perceived and perceived by informal caregivers measured with the IADL scale) (**Table 2**). Other measures are secondary outcomes.

Table 2: Description of the assessment batteries.

Measure-related objective	Assessed construct	Name of Measure	Measure Description
Screening measures	**Survey screening**	Survey screening	Included questions related to their age, gender, wedding status, education, , experience with computers, living arranges, recruitment sources.
Efficacy measures	**Physical Frailty**	MNA [33]	*The MNA* assesses the nutritional status, especialy diet, body mass index and unintentional weight loss. An MNA score < 24 identifies patients requiring a multidisciplinary geriatric intervention. When this latter is successful, then the *Body Mass indices.* First, the Body Mass Index (BMI) was calculated according to the standard formula [BMI=mass (kg)/(height (m))^2]. The BMI is scored from 0 to 3 with higher values indicating higher BMI values. Second, the brachial and calf perimeters are scored from 0 to 2 with higher values indicating higher lean mass values. Summed, the two indices provide a score from 0 to 5, with a higher score indicating a better body mass.
		SPPB [37]	*Five Chair Stands* (lower body strength): The participant is asked to stand up from a chair five times without using their arms. The time is recorded and the test is scored from 4 - the participant takes less than 11.1 sec to complete the task to 0 – the participant is unable to perform task. *Static Balance Testing* consists of three sorts of standing: side-by-side stand, semi-tandem stand and tandem stand; each of them scored from 4 – the participant holds the three standing positions for more than 10 sec; to 0 – the participant did not attempt any standing position. *Timed Get Up and Go Test* (agility and dynamic balance). This test consists of rising from a chair, walking three meters, turning around, walking back to the chair, and sitting down. Time in seconds to complete the task is recorded. The task is scored as followed: 1 – the task is completed in more than 30 sec, 2- the task is completed from 20 to 30 sec, and 3 - the task is completed in less than 10 sec (in this case, mobility is considered normal). *Gait Speed Test* corresponds to a timed 4-meter walk. It is scored from 4 – time is less than 4.82 sec – to 0 – the participant was unable to do the walk.
		Sensory abilities	*Vision/hearing impairments.* are assessed with a three-point 3 Likert-type scale, ranging from 0 to 2 (where 0 corresponds to the highest sensory loss). So, sensory scale provided score ranged from 0 to 4 with higher scores indicating better sensory functions.
	Activities limitations in daily life	Nursing home admission and critical events	*Nursing home rate.* During the follow-up, we register the Nursing home admission event for computing the rates Nursing home Admission at 12 months and optionally at 24 months. *Critical events*. We collect each 6 months, the occurrence of falls, the number of hospitalized days and the number of chronic illness.
		EPR [38]	*Preferences for Routinization Scale* (EPR) is the French analog of Routinization scale (Reich and Zautra, 1991). It is composed of 10 items with 5-point Likert scales assessing daily life habits and behaviors (e.g., sleep and meal schedules, organization of personal objects, social exchange) such as "I like to move and to change activities" or "I prefer to get up and to go to bed at the same time every day." The degree of agreement with different sentences is rated and the total score is from 10 to 50, higher scores representing greater preferences for routinization.
		IADL scales* [26]	*Self-assessed IADL scale.* is constituted by 24 items screening for difficulties regarding several ADL, based on a 5-point Likert scale, a higher score indicating a greater range of difficulties. Hetero-evaluated IADL Scale is completed by the caregiver and the scoring is similar to that for self-assessed IADL scale.
	Self-perceived Health	GSE test [41]	*General Sel-efficacy test*. is a 10 item questionnaire such as : "Thanks to my resourcefulness, I know how to handle unforeseen situations," and "When I am confronted with a problem, I can usually find several solutions." Scoring is done by adding the responses made to the 10 items. Possible responses are "not at all true", "hardly true", "moderately true", and "exactly true", yielding a total score between 10 and 40.
		SF36 [42]	*Short 24 Form-36 (SF-36) questionnaire.* is used for assessing the health-related quality of life in the older participants. This questionnaire is self-administrated and consists of 36 items, covering eight dimensions (physical functioning, physical limitations, body pain, general health, vitality, social

			functioning, limitations due to emotional problems, and mental health) and provides two summary scores, namely physical score and mental score.
	Caregiver's self-perceived Health	ZBI* [44]	*Zarit Burden Interview (ZBI).* is a 22-item self-administered questionnaire assessing burden associated with functional/behavioral impairments and home care context. The items have content validity and take into account common areas of concern such as health, finances, social life and interpersonal relations.
		SF36 [42]	*Short 24 Form-36 (SF-36) questionnaire.* is used for assessing the health-related quality of life in the caregivers. This questionnaire is self-administrated and consists of 36 items, covering eight dimensions (physical functioning, physical limitations, body pain, general health, vitality, social functioning, limitations due to emotional problems, and mental health) and provides two summary scores, namely physical score and mental score.
	Mental Health	CES-D [48]	*Center for Epidemiologic Studies - Depression Scale* is used to assess depressive symptomatology in the older participants. It consisted in a 20-item scale with scores ranging from 0 to 60, a score above 17 was considered as indicating the presence of depressive symptomatology.
	Cognitive functioning	MMSE [29]	*Mini-Mental State Examination* is used as an index of global cognitive performance. It comprises orientation in time and space, registration, calculation, recall and language items, with total score on the MMSE ranging from 0 to 30.
		CDS [49]	*The Cognitive Difficulties Scale (CDS)* is a 38-item self-report measure of subjective complaints regarding immediate and delayed memory, attention, language, temporal orientation, and psychomotor abilities.
		Cognitive Scales [27,28,29,20,31]	• *The Benton Visual Retention test* (BVRT) is used to assess visual memory, visual perception and/or visual construction. After the presentation for 10 seconds of a stimulus card displaying a geometric figure, subjects are asked to choose the initial figure among four possibilities; 15 figures are successively presented. The score ranges from 0 to 15. • *The Free and Cued Selective Reminding Test* (FCSRT) is used to assess verbal memory. It provides a measure of memory under conditions that control attention and cognitive processing, in order to obtain an assessment of memory not confounded by normal age-related changes in cognition. • *The Trail Making test (TMT)* is used to assess visual attention and task switching. In the Trail Making Test, Part A (TMT-A) the task is to connect randomly located circles with numbers (1–25) in numerical order as fast as possible. In the Trail Making Test, Part B (TMT-B) the task is to connect alternately circles with numbers (1–13) and letters (A–L) in their respective sequence as fast as possible. • *The Isaac set test (IST)* is used to assess language skills and executive functions. It consists in generating words belonging to 4 semantic categories (cities, fruits, animals, and colors,10 words each) in 15, 30 and 60 seconds, total IST score ranging from 0 to 40. • *The Stroop test* is used to assess working memory and attention. The test involves a control task for which participants have to name as quickly as possible the color of dots (Dot condition—Card 1), the color of the ink in which neutral words are printed (Word condition—Card 2), and the color of the ink in which color names are printed (Interference condition—Card 3). The increase in time taken to perform the latter task compared with the control task is the Stroop interference effect. For each condition, the completion time and the number of errors are compiled, and interferences scores are derived by calculating the ratio between the time required to name the color of the ink in the Word and the time required to name the color of dots in the Dot conditions (low interference), and the ratio between the time required to name the colors in the Interference and the Dot conditions (high interference).

*Notes. * Primary oucomes*

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HA device part of the assessment

An additional set of measures is provided for participants equipped with the HA system. **Tables 3** depicts all these measures. This additional assessment aims to study across time (at 0, 6, 12 months, and optionally at 18 and 24 months) the user's HA needs, the user's HA

perception, and the HA uses and usages, and their possible relationships and the evolution over time. The HA uses and usages are assessed through active interactions with the HA platform to which are added passive interactions, in particular the monitoring of activity in the home via motion sensors or door/drawer contactors. These later measures are called HA-related measures.

As shown in **Table 3**, participants in HA condition completed a HA-related follow-up battery covering the user's HA needs and HA experience/perception to which are added HA-related measures.

- **The *user's HA needs***: are scored with six scales including the assessment of self-determined behaviors, coping and compensation strategies, and risk profile of frailty.

The **self-determined behaviors** are assessed with the modified Arc's Self-Determination Scale [50] providing measures of autonomy, self-regulation, psychological empowerment and self-realization. This measure is motivated by our previous results from our pilot study revealing that the self-determination-based design (e.g., self-choice of assistive services) of HA system is a successful way to enhance the self-determined behaviors across time while increasing the positive experience of technology use [20].

In the same vein, two scales are used for rating **coping and compensation strategies** in everyday life setting: i) The PIC (Personality in Intellectual Aging Context, [51] comprises Locus of Control subscales which estimate the elderly's sense of control in performing everyday activities (e.g., "my problem solving ability depends on how healthy I am") with three dimensions: Powerful others, Internal, Chance. Some findings revealed that older adults with an internal locus of control are more inclined to accept new technologies and to exhibit technology use (e.g., [52]); ii) The Memory compensation questionnaire *(*MCQ, [53]*)* measures individual differences in the tendency to select particular strategies and to overcome perceived or real cognitive losses, especially regarding everyday memory functioning. Precisely, this scale assesses three main compensation mechanisms and the individual's awareness for these mechanisms as defined in compensation theory [54]: 1) the substitution mechanisms which is replacing a declining technique by a new one or doing something in a different way; 2) the remediation mechanisms which require investing more time and effort to adapt and overcome losses; 3) the accommodation strategies which aim to reduce the mismatch between environmental demands and personal skills by adjusting one's goal; and 4) the personal insight and the beliefs regarding memory losses referring to the extent to which the individual is aware of changes in the compensation's needs (i.e. external, internal, reliance, time and effort) over the 5–10 years prior to testing. Overall, MCQ provides a good

approximate of need of external supports such as HA system enable to do through multiple forms of activity or goal –related reminders.

Frailty-related risk profile was assessed using three scales. First, the SEGAm (modified Short Emergency Geriatric Assessment) instrument validated for use among community-dwelling subjects [55, 56]. This instrument establishes a risk profile of frailty and provides reporting of problems and factors that may influence functional decline, including age, social environment, drugs, mood, perceived health, history of falls, nutrition, comorbidities, IADL, mobility, continence, feeding and cognitive functions. Second, there are some evidence showing that frailty benefits from sleep quality improvement along advanced ages, particularly the interventions over circadian rhythm [57]. As HA system can provide external support for good sleep habits, the quality of sleep is measured with the Pittsburgh Sleep Quality Index (PSQI, [58]) which rates subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication and daytime dysfunction. Finally, social isolation or loneliness being also reported as risk factor of frailty (59),we also explored social networks, using the Lubben Social Network Scale [60] which assessas structural (e.g., network size), interactional (e.g., contact frequency) and functional components (e.g., purpose of support) of an individual's family and friendship ties and was specially developed for older adults [61].

- **The *user's HA experience:*** is assessed with three scales assessing user experience user satisfaction, and HA usefulness for family caregiver, respectively. The Attrackdiff questionnaire [62] decomposes user experience into five dimensions: ergonomic quality, hedonic quality, appealingness, anxiety and safety perception, and social influence. Second, the QUEST 2.0 questionnaire [63] measures user satisfaction with assistive technologies with two components, "Device" (hardware aspects) and "Services" (software aspects). The third scale is the IADL support scale which is an adaptation of the Lawton scale presented earlier. This adaptation aims to assess the HA usefulness for the family caregiver in terms of burden for IADL support. Importantly, we do not use technology acceptance questionnaire derived from the Technology Acceptance Model (TAM) that stresses the perceived usefulness and perceived ease of use as the main attitudinal factors towards HA technology acceptance (e.g., [63]). Indeed, technology acceptance in older adults is predicted by user characteristics (e., health status), rather than attitudinal factors [64]. As a result, we decided to measure technology acceptance beyond the two main attitudinal factors of TAM including dimensions related to user experience and satisfaction and perceived usefulness for caregivers using Attrackdiff, QUEST 2.0 and IADL support tools.

- The HA-related measures: deliver three categories of indicators regarding participant in their living space. First, passive interactions with HA provide actimetric data. The actimetric data quantify at the beginning of the experiment, and every 6 months, the level of activity in the home (quantity and duration of daytime and night activity), where this activity takes place in the home (bedroom, bathroom, living room and kitchen), the approximate level of nutrition-related activity with a specific monitoring of fridge opening and closing and the level of activities out of home (approximated by the number of exits from the home each day and their duration).

HA uses and usages are assessed thanks to active interactions with the HA platform, and more particularly with the primary and secondary tablets. The use behaviors of HA assistive services are quantified through the received notifications (critical and non-critical), the participant answers to these notifications, and the system pause occurrences. Such measures make it possible to objectify the intensity of the support provided by the platform but also its invasive or inappropriate interactions (pause of the system by the user). The uses and usages of the secondary tablet are quantified in terms of use diversity (number of opening apps) and associated usages according to the classification by Olson et al. in 2011 [65], i.e., "internet search", "communication", "financial management", "health services", "home equipment"; "leisure", "shopping" and "transport". The indicators were collected across a period of 6 months.

Table 3: Description of the additional assessment batteries for HA condition.

Measure-related objective	Assessed construct	Name of Measure	Measure Description

User's HA needs	**Motivation, Coping and compensation strategies**	Arc's Self-Determination Scale [50]	*The Arc's Self-Determination Scale*. is a 72-item scale which assesses self-determinated behaviors. It is composed of four dimensions: the first one measures autonomy (32 items), the second measures self-regulation (9 items), the third dimension assesses psychological empowerment (15 items) and the last dimension measures self-realization including self-awreness and self-knowledge (14 items). Seventeen items of this scale are excluded because of their inappropriateness with respect to the topic of our study (in particular, items related to working conditions) ; the 55-selected items can be found in Dupuy et al., 2016. The final scale is composed by 55 items, including 26 items for measuring autonomy, 4 items for self-regulation, 10 items for empowerment and 15 items for self-realization. The items are scored the same way as the original Arc's scale, where a higher score indicates a better self-determination performance. Participants underwent this questionnaire tests twice times, i.e. before the HA installation (baseline measurement), and at 12 months after the HA installation, and optionaly at 24 months after the HA installation.
		PIC [51]	*The Personality in Intellectual Aging Context (PIC) scale*. provides Locus of Control subscales. These scales consist of 12 items and estimate the elderly's sense of control in performing everyday activities (e.g., "my problem solving ability depends on how healthy I am") with three dimensions: Powerful others, Internal, Chance. Responses are scored on a 6-point Lickert scale ranging from 6 (strongly agree) to 1 (strongly disagree). Each dimension is scored from 12 to 72, higher scores indicating greater beliefs in internal/chance/other control of one's capabilities. Participants underwent this scale twice times, i.e. before the HA installation (baseline assessment), and at 12 months after the HA installation, and optionaly at 24 months after the HA installation.
		MCQ[53]	*The Memory compensation questionnaire.* is a seven-factor scale measuring individual differences in the tendency to select particular strategies and to overcome perceived or real memory losses. (F1) The External scale contains eight items regarding the use of external aids and devices for supporting remembering (e.g., shopping lists, notes, putting things in a specific place). (F2) The Internal scale contains ten items regarding the use of strategic mnemonic strategies to facilitate or improve memory efficiency. (F3) The Reliance (or Recruitment) scale contains five items related to the recruitment of other people for memory assistance. These first three scales relate to the Substitution mechanism of compensation theory (Dixon et al., 2008), which is replacing a declining technique by a new one or doing something in a different way. (F4) The Time scale contains four items regarding the extent to which the respondent invests more time in performing memory tasks. (F5) The Effort scale contains six items regarding the investment of more effort when performing a memory task such as rehearsing or retrieving information. The Time and Effort scales relate to Remediation mechanisms which require investing more time and effort to adapt and overcome losses. Finally, two scales investigate general aspect of memory compensation. (FG1) The Success scale contains five items regarding the use of Accommodation strategies which aim to reduce the mismatch between environmental demands and personal skills by adjusting one's goal. It assesses the extent of commitment to memory performance and the motivation to maintain a given memory competence. The higher the commitment, the less a person will tend to accommodate to his/her losses as he/she will maintain the same criterion of success and sense of control. Finally, (FG2) the Change scale contains five items regarding the extent to which the respondent is aware of changes in the need of compensation (i.e. external, internal, reliance, time and effort) over the 5–10 years prior to testing. This last scale reflects personal insight and beliefs regarding memory losses. Participants respond to each item (except for the change scale) on a 5-point scale (0 = *never*, 1 = *seldom*, 2 = *sometimes*, 3 = *often*, and 4 = *always*.) The Change scale has the following scale: 0 = *much less often*, 1 = *less often*, 2 = *no difference*, 3 = *more often*, and 4 = *much more often*; except for the item "Do you spend more or less time learning important things today compared with 5–10 years ago (e.g., reading things more slowly or reading them more than once" which had the choice options: 0 = *much less time*, 1 = *less time*, 2 = *no difference*, 3 = *more time*, and 4 = *much more time*). This scale is administrated twice times, i.e. before the HA installation (baseline assessment), and at 12 months after the HA installation, and optionally at 24 months after the HA installation.
	Risk profile of Frailty	SEGAm scale [55, 56]	*The SEGAm instrument* (modified Short Emergency Geriatric Assessment) assesses multi-dimensionally the frailty. It is composed of two parts (A and B). The part A comprises 13 items (age, living space, medication, mood, perception of own health, fall in the last 6 months, nutrition, associated diseases, IADL, mobility, continence, meals, cognitive function, especially orientation and memory), coded from 0 (most favorable situation) to 2 (least

			favorable situation), giving an overall score of 26 points. Subjects are considered as not very frail (score <8), frail (score between 8 and 12), or very frail (score >12). The part B called « complementary data » comprises 11 items [hospitalization in the last 6 months, vision, audition, family support, home service, natural caregiver need, (natural) caregiver burden perception, subject's life project, life project according to caregiver),), coded from 0 (most favorable situation) to 2 (least favorable situation), giving an overall score of 22 points ; the higher the score, the greater the fragility. This scale is administrated three times, i.e. before the HA installation (baseline assessment), and at 6 and 12 months after the HA installation, and optionally at 18 and 24 months after the HA installation
		PSQI [58]	*The Pittsburgh Sleep Quality Index (PSQI).* is a self-rated 19 item-questionnaire which assesses sleep quality and disturbances over a 1-month time interval. It provides 7 component scores, i.e., subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication and daytime dysfunction, each weighted equally on a 0-3 scale. The 7 component scores are summed for providing a global PSQI score ranging from 0 to 21; higher score indicate worse sleep quality. Participants underwent this questionnaire tests twice times, i.e. before the HA installation (baseline measurement), and at 12 months after the HA installation, and optionally at 24 months after the HA installation.
		LSN Scale [60]	*Lubben Social Network (LSN) Scale.* assesses isolation by providing an assessment of person's social connections in terms of both family interactions and interactions with friends. Precisely, this scale assesses structural (e.g., network size), interactional (e.g., frequency of contact) and functional components (e.g., purpose of support) of an individual's family and friendship ties. Scores range from 0 and 60, with a higher score indicating more social engagement and better networks. This scale is administrated twice times, i.e. before the HA installation (baseline assessment), and at 12 months after the HA installation, and optionally at 24 months after the HA installation
HA perceptions	**User Satisfaction**	QUEST 2.0 [63]	*The QUEST 2.0 questionnaire.* is a measure of user satisfaction with assistive technologies with two components, Device and Services. The questionnaire consists of 12 items and each item is evaluated on a scale ranging from 1 to 5. A value 1 corresponds to 'not satisfied at all' and a value 5 to 'very satisfied'. The total score is on a scale of 5. A high score denotes a high user satisfaction with the technology. HA Participants underwent this questionnaire twice (6 and 12 months after the HA installation) and optionally two additional times, i.e. 18 and 24 months after the HA installation.
	User experience	Attrakdiff questionnaire [62]	*The Attrakdiff questionnaire.* decomposes user experience into five dimensions: ergonomic quality, hedonic quality, appealingness, anxiety and safety perception, and social influence. Answers to the questionnaire range over a scale of 7 points, from −3 to 3, including two antonyms (e.g., nervous/relaxed). Each dimension of the questionnaire consists of 6 items. Participants underwent this questionnaire tests three times, i.e. before the HA installation (baseline for participant's Perceptions regarding Assistive technologies), at 6 and 12 months after the HA installation, and optionally at 18 and 24 months after the HA installation.
	Caregiver's usefulness perception	IADLSupport scale [27]	*The IADL support scale.* is an adaptation of the Lawton scale presented earlier, to assess burden for IADL support. Answers varied from 0 (very easy to assist), to 4 (very hard to assist), in reference to the assistance given to the participant in particular. For instance, an item of this scale is: "For you, the support that you provide for eating is: Very hard–Very easy." Caregivers underwent this questionnaire tests two times, i.e. before the HA installation (baseline for participant's Perceptions regarding Assistive technologies) and 12 months after the HA installation, and optionally at 18 and 24 months after the HA installation.
HA-related measures	**Actimetric data**	Level of Activity at home	*Level of activity at home.* is measured with three indicators: 1) Quantity and duration of daytime activity; 2) Quantity and Duration of night activity and then 3) Cumulative activity. Quantity and Duration of activity are approximated by averaging all movements (detected and registered by HA system) over a period of 30 consecutive days starting at the time of installation, then 6 months and 12 months after installation (optionally at 18 and 24 months).
		Specific located activities	*Specific located activities* refer to movement activity located in a specific room of the home, namely bedroom, bathroom, living room, and kitchen. Nutrition-related activities are specifically approximated by the detection of

			opening/closing of fridge each day.
		Level of Activities out of home	*Level of Activities out of home* is approximated by the number of exits from the home each day and their duration.
	HA Use and Usage	Primary tablet-based Assistive services Uses	*The use* of *HA assistive services* is quantified by the following measures across periods of 6 months: -Total number of notifications on the primary Tablet then separately the number of non-critical and critical notifications -Number of responses to critical notifications -Number of consultation of notifications -Number of pauses of HA system
		Secondary tablet-based uses and usages	*The uses and usages of the secondary tablet* are quantified thanks to the following indicators across periods of 6 months: - Number of browser openings - Number of openings of simplified mailer - Nb of mail received vs. nb of mail sent - Number of applications opened - Number of opening app according to the need targeted classification by Olson et al., 2011, i.e., "communication", "financial management", "health services", "home equipment"; "leisure", "shopping" and "transport".

Treatment fidelity and Data Collecting

An external trial monitoring board has been specially set up and met once yearly or as needed. It included 12 members gathering multiple expertise (gerontology and geriatrics, clinical trials for behavioral interventions, home services; public services for older adults; user-centered gerontechnology; Internet of things and software orchestration; epidemiology and statistics, and innovation transfer). This board provided trial oversight and monitored participant safety and well-being during all the trial duration.

A detailed manual of operations has been developed for all study protocols and the HA-related implementation and training protocols have been scripted. All study activities are discussed at weekly HA coordinating team meetings with the project coordinators, the data management team and technical staff around issues related to data collection, transfer or the HA technology.

Constitution of the control group

The best way to assess the efficacy of an AAL, is to compare the individual evolution over time of the equipped persons compared to non-equipped ones. To do so, a control group has been constituted from two existing epidemiological population-based cohorts on aging, the Three-City (3C) study [32] and the AMI cohort [69]. Briefly 9,294 participants of the 3C study, aged 65 and older, initially noninstitutionalized, were selected from the electoral rolls in three French cities (Bordeaux, Dijon, and Montpellier) and included from 1999 to 2000.

The AMI cohort included 1002 retired farmers, aged 65 and older, randomly selected from the Farmer Health Insurance System and followed-up since 2007. In each cohort, several follow-up examinations have been performed every two to three years with visits conducted at home by trained psychologists. The two cohorts rely on similar design that allows pooled analyses. For each cohort, an ethics committee approved the research according to the principles embodied in the Declaration of Helsinki: for 3C the Ethical Committee of the University Hospital of Kremlin-Bicêtre (Paris, France) and Sud-Méditerranée 3 (Nîmes, France) and for AMI the committee of the University Hospital of Bordeaux (France).All participants gave written informed consent.

The control group of the present trial has been constituted from the sample of 3C-participants living in the Bordeaux site (N=2104), not equipped by the HA solution and interviewed at both the 10-year and the T12 follow-ups and from the AMI sample, using the baseline and the T2 follow-ups. Following the HA eligibility criteria, the control group included 70+ older persons, living alone, in an independent community setting. Comparisons between the two groups (intervention vs. control) are possible thanks to similar assessment tools between studies regarding the main outcomes: Instrumental ADL (IADL scale), cognitive performances (MMSE, IST, BVRT TMT and FCSRT), depressive symptomology (CES-D scale),, hospitalization and institutionalization. The twelve-month follow-up data being not available in the control sample, imputations have been performed according to a linear hypothesis of evolution of the scores between T0 and T24.

Baseline description of HA and control groups

As indicated in **Figure 5**, a total of 490 individuals received the pre-screening visit for the HA condition. Of these, 261 people were excluded due to ineligibility (n = 18) or lack of interest in participating (n= 242). A total of 230 older adults received the baseline assessment and of these 99 were excluded (16 ineligible, 83 refusals).

In addition, a total of 547 participants were enrolled in the trial, 474 in control condition and 73 in HA condition, with available follow-up data at M12.

The **figure 5** illustrates the recruitment flowchart throughout the 24 months-duration of the HA condition.

The HA sample is primarily female (79.2%) and ranges in age from 70 to 93 years (M = 82.2, SD = 4.3). The participants in HA condition have varied living spaces (37.0% living in rural areas) , 47.8% do not have a senior highschool degree and 43,6% do not have a junior highschool degree. From the 3C and AMI cohorts, we selected 474 control participants according to the eligibility criteria.

When comparing characteristics at baseline between the HA sample and the control group, we observed no differences by age, education, living condition (all living alone), IADL-disability, depressive symptoms and cognition. Noted that for the MMSE test, the control group tended to have higher mean score, but this difference was not significant (p=0.0816). However, as indicated in **Table 4**, participants in the HA condition were more often women (87.7% vs. 77.8%, p=0.0538)

Table 4. Sample description and group comparisons for baseline measures of primary and secondary outcomes

	DomAssist N=73		**Controls N=474**		
	N	mean (SD) / n (%)	N	mean (SD) / n (%)	p
Mean age (SD)	73	81.2 (5.1)	474	81.3 (4.3)	0.8483
Age80+ (%)	73	43 (58.9%)	474	303 (63.4%)	0.4603
Female gender (%)	73	64 (87.7%)	474	372 (77.8%)	0.0538
Lower level of education	62	27 (43.5%)	474	229 (48.3%)	0.4800
Living alone	73	73 (100.0%)	474	478 (100.0%)	-
IADL-disability (%)	67	21 (31.3%)	473	137 (29.0%)	0.6887
IADL mean score (SD)	64	6.4 (2.2)	473	6.4 (2.5)	0.9267
CESD mean score (SD)	73	10.0 (6.7)	427	9.1 (8.9)	0.3810
MMSE mean score (SD)	66	26.0 (2.4)	474	26.6 (2.6)	0.0816
Benton mean score (SD)*	68	10.8 (2.2)	318	11.2 (2.3)	0.1281
Isaac 15s mean score (SD)	72	26.3 (6.1)	459	26.2 (6.4)	0.9435
Isaac 30s mean score (SD)	72	40.6 (8.5)	459	40.1 (10.4)	0.6801

**the Benton test was not available in the AMI cohort*

Regarding our two primary outcomes, the sample size provides a reliable statistical power of 0.80 with a significant level set at 0.05 attesting of a significant difference in means of IADL score between the two groups for a difference above 0.87 units.

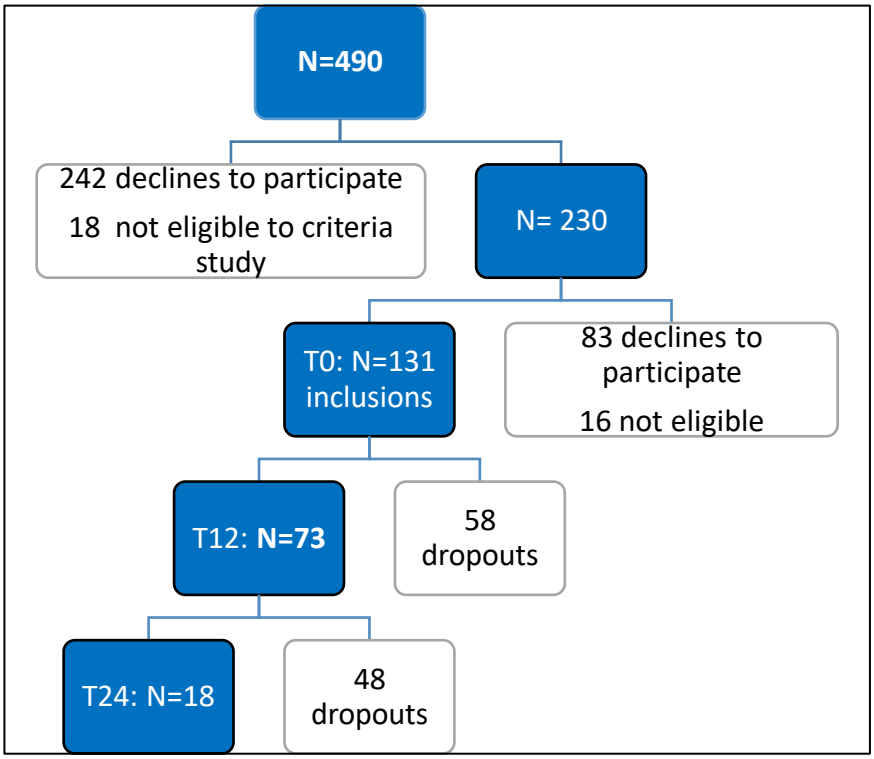

Figure 4 *: Recruitment Diagram* for *HomeAssist condition*

Statistical treatments

All measures of the study will be tested based on an intention-to-treat approach using a two-tailed level of significance set at alpha = .05.

Descriptive analyses were conducted to characterize the recruited sample compared to the others (excluded and refusals) on the data available at the eligibility visit, to describe the characteristics of the recruited sample at baseline and also of the drop outs.

We also describe the evolution of the primary and secondary efficacy outcomes over 12 months of HA utilization and conducted comparisons by age, gender, initial level of technology acceptance and user satisfaction with HA technology (collected after 6 months of utilization).

Finally, the CT approach allows to compare primary and secondary efficacy outcomes in the HA and control conditions. The two groups compared being initially comparable (except for sex ratio and the MMSE score), we compared, for each outcome, the mean score at T12 in the HA and the control groups. In addition, in order to control for confounders, three successive linear regression models were conducted, as follows: i) Model 1 : $Y_{(at\ T12)}$ = DomAssist (vs. control) + age + gender ; ii) Model 2 : $Y_{(at\ T12)}$ = Model 1 + dependant variable at T0 ($Y_{(à\ T0)}$) ; iii) Model 3 : $Y_{(at\ T12)}$ = Model 2 + MMSE T0.

Discussion

The HomeAssist project proposes a *ecosystemic human-centered* approach to introducing a personalized AAL platform dedicated to frailty individuals and their caregivers. One of the major consequences of frailty is the threat of progressive loss of the capability to perform activities of daily living. Hence, our main outcome is to evaluate the benefit of our approach on this capability. A total of 131 users and their family or formal caregivers participated to our proposed field study and 73 accepted to continue the experience until 12 months. Such a clinical validation study is rare in the field of technology-based interventions in terms of experimental design quality, as most studies in the AAL- field remain at the prototyping level (due to technological challenges) or at best pilot studies (due to the challenges of a field study) with small samples that do not really provide the onset of ground of truth of AAL –based interventions.

Furthermore, we have included evaluations that cover more broadly other critical indicators for home care, such as the rate of institutionalization in nursing homes, the impact on mental and physical health, and data reported by HA (actimetrics, use and usages of services). For equipped group, we are also gathering data on factors that influence usability, technology acceptance and use. These multiple secondary indicators aim to respond to the needs expressed by all the project's stakeholders (aging policy makers, home service organizations, caregivers, older adults and researchers from different domains) for successful participatory achievements while also to move on to more daring, innovative plans, to move into new research areas, rather than mere collaboration between various research areas. Indeed, the field and participatory nature of the present study implies to combine a traditional top-down approach (i.e. expectation relative to specific primary criteria for a prescriptive purpose) with a bottom-up approach definitively driven by stakeholder's problem whose the common concern is the healthy aging in place. The growing of citizen science supports that this combining approach (albeit risked) is a successful way for bridging science and practices with the result of quick societal impact for targeted people and for emerging new research issues [66].

From our combined approaches, the study consortium encountered a few issues that reinforced the study-related challenges, especially with older adults, and with technology-based intervention. First, major challenges are related to the study design where the HA condition is compared to a control condition of subsample of an existing population-based cohort on aging. We paid great attention to match as well as possible the two groups in respect of the factors known for influencing the IADL score (main criteria outcome) such as demographic factors, frailty score, cognitive status, etc. Despite of this, we are aware that a such matching method does not neutralize possible biases related to differences in recruitment methods, in the number of home visits on one year-deployment, or in the minimal level of technology acceptance that is probably shared by the participants of HA condition. It should be remembered that out of almost 500 older adults contacted, only 47% met our selection criteria, and only 27% agreed to participate in the study, and half of the participants dropped-out after 12 months of experimentation, notably regarding technology-related challenges. A second study challenge is the great variability of participants' technological skills in HA condition. We set up a standardized training phase for the use of HA, and each participant was guaranteed to keep the two tablets provided for the study after the experiment in order to prolong the interest of such a technology training. Additionally, the interoperability of HA with a variety of technologies (Bluetooth, UPnP, ZWave, Web

services, *etc.*); and its unique point of user interaction are major assets for ensuring the acceptance of HomeAssist at the organizational level (bypassing the technical disparities across territories) and the individual level (reducing the demand on cognitive or learning resources for using the assistive services). Another study challenge is to provide 24/7 technology-intervention requiring uninterrupted Internet access and good quality bandwidth in territories with disparate digital infrastructure. Technologically, any elaborated assistance service is based on the Internet and it is impossible to guarantee its continuous operation. To minimize service interruptions, we have made sure to use a single Internet operator to avoid multiple service interruptions due to operator-dependent updates. Covering a wide spectrum of needs and their evolution critically relies on the ability to populate the HA service catalog with a range of applications that match these needs. To do so, the HA leverages a dedicated Integrated Development Environment while relying on needs analysis and human centered design. This strategy is of paramount importance to ensure that the proposed assistive support is personalized for fulfilling the requirements of participants and caregivers and then while promoting their autonomy and self-determination.

Despite all these challenges, the outcomes of the HA study will yield significant insight on the benefits of AAL for frail older adults. It will also yield some insights on factors influencing technology acceptance, use and usages in frails individuals. Indeed, it will be possible to explore how they vary according to participant characteristics such as gender, age, cognitive abilities and the frailty level. The study will also inform on the feasibility of technology-based personalizing of assistive services and will probably bring some useful learnt lessons for future technology-based field studies.

To honestly conclude the presentation of this study, limitations must be mentioned. First, as mentioned above, differences in recruitment between the two study groups will have to be taken into account in the analysis of the results. And, if the results remain convincing, then it will be necessary to go further and consider conducting a trial using strict RCT methods. In the same vein, there is the question of scaling up for a large-scale intervention. As also mentioned, our ecosystemic and participatory approach has led us to work directly with the stakeholders in frailty and home care for the elderly in a given territory, in order to both design upstream HA and evaluate it downstream. Consequently, a scaling up on other territories for the evaluation of HA will be required thereafter for a better proof of the interest of an AAL system such as HA.

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Conflicts of interest

The authors declare that they have no conflicts of interest.

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Author statements

H. Amieva : Conceptualization, methodology, validation, investigation, data curation, paper writing. A. Edjolo: Formal analysis, data curation, writing paper; C. Consel : Software, resources, project administration and funding acquisition ; K. Pérès : Conceptualization, methodology, formal analysis, data curation, writing paper; H. Sauzéon : Conceptualization, methodology, validation, investigation, resources, data curation, supervision, project administration, funding acquisition, paper writing.

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