AAL Programme





AAL-CP-2018-5-149-SAVE 01/09/2019 - 31/08/2022

AAL Programme

Project - SAfety of elderly people and Vicinity Ensuring - "SAVE"

Deliverable 2.6: Services Validation Actions

Version: 2.0

Main editor: INRCA

Contributing partners: UnitBv, VS, NIMR, ISS, Labidee

Table of Contents

CONTENT	4
Summary	4
1. Sensor network	4
1.1. Aqara Home kit and smartwatch	5
2. The Validation Study Plan	7
2.1 Recruitment Strategy in each site	
Italy	
Romania	
Hungary	11
2.2 Trial Description in each site	
Italy	
Romania	
Hungary	24
2.3 Problematic aspects faced during validation	26
3. Wellbeing device	29
REFERENCES	33

CONTENT

Summary

D2.6 Services Validation Actions is aimed at 1) presenting the different SAVE services: the Aqara Home kit, the smartwatch, and the Wellbeing device; 2) describing how each country (Italy, Romania, and Hungary) validated these systems: recruitment, installation, data collection and data analysis.

1. Sensor network

The concept of the SAVE system is that of a multicomponent platform based on works with multiple smart-home and wearable sensors streamed directly to a cloud-based platform, where algorithms detect any behavioral and physiological information about the older adults' well-being and security in their habitat.

Figure 1 presents an overview of the SAVE solution highlighting the actors and some technical aspects.

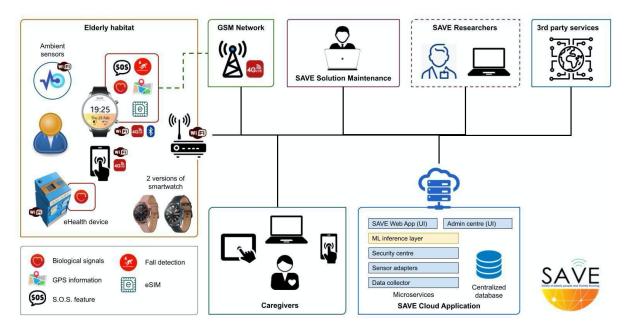


Figure 1. SAVE solution overview

The SAVE solution consists of a kit of sensors (Aqara Home) and a smartwatch (Samsung Galaxy Watch3) with the SAVE software pre-installed. All tools are connected to the SAVE cloud application.

1.1. Agara Home kit and smartwatch

The SAVE system was implemented in end users' homes. The Aquara Home kit (Figure 2) consisted of: 1 control unit, 1 smoke sensor (kitchen), 2 flood sensors (kitchen and bathroom), 1 contact sensor (entrance door) and 2 presence sensors. In addition, the user was provided with a Galaxy smartwatch 3 (Figure 3), which could connect directly to the Internet, using either the GSM network or a smartphone.

Flood sensors will be installed in the bathroom (preferably next to the washing machine) and kitchen (preferably next to the dishwasher), presence sensors in the living room and bed-room, and the contact sensor will be installed at the entrance door. The sensors are powered by button batteries, with very low energy consumption; the producer of the sensors advertises an autonomy of 2 years with a standard CR2032 button battery. Only the sensors' hub and the SAVE Sensors Adapter (Figure 4) are powered from a socket (the SAVE Sensor Adapter is actually powered by the USB connector on the sensors' hub). For the best user experience, the required software (for the sensor kit and the smartwatch) will be installed on the users' smartphones in Romania and Italy. On the Hungarian side, users are provided with a separate mobile phone to receive data and transmit it to the cloud system. The sensor set and the smartwatch software are only downloaded to the user's mobile phone at the user's request. The sensors have been located in places where they do not affect the daily activity of the users, these being easy to move according to preferences and small enough to blend in the background.

The other devices can be used as long as they are charged (the smartwatch and the smartphone). Thus, the responsibility of the end user is to charge their smartwatch and not to unplug the sensors' hub (and the smartphone from the charger - in Hungary). It is planned to place the central unit in the bedroom, where the user can easily charge the smartwatch in the evening.

The smartwatch included a wide range of sensors, which could be used to measure physical activity (number of steps and their frequency, speed of movement), obtain some basic biological signals (e.g., pulse beat), provide an SOS service (call to the caregiver) and detect possible falls. This information was then used to assess the well-being of users.

Thus, at the end of the installation, users will have the Aqara Home System in their homes (5 sensors and a sensor hub), a Samsung smartwatch, and a SAVE sensors adapter, all of which are connected to a router with unlimited internet access. After installing the system, there will be a brief instruction training session on the use and purpose of these devices and the services they offer. This will ensure that the end users are encouraged to use them, performing some tests:

- Heart rate testing in association with the frequency indicated on the smartwatch;
- Testing the emergency system by pressing the power button 3 times;
- Testing of the flood and door sensors by visualizing the values received by the SAVE cloud app through the SAVE Web App;
- Calling a friend/relative from their smartwatch.

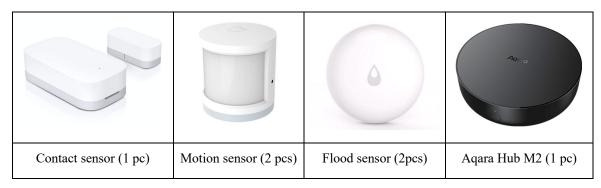


Figure 2. Aqara Home kit



Figure 3. SAVE smartwatch face



Figure 4. SAVE sensors adapter

2. The Validation Study Plan

The SAVE study involved primary, secondary and tertiary users. The validation phase of the study has been successfully performed by all three countries (Italy, Romania, and Hungary) with 80 subjects that used the SAVE system for 21 consecutive days in their homes during daily life.

The primary users who meet the following study inclusion/exclusion criteria have been recruited to demonstrate the usability of the system in the three pilot sites.

Inclusion and exclusion criteria for each end user group are described in Table 1.

Table 1. Eligibility criteria for primary, secondary and tertiary users

End user Type	Inclusion Criteria	Exclusion Criteria
Primary users-	 Age => 65 years Mini Mental State Evaluation (MMSE) between 21 and 27 Healthy or mild to moderate chronic illness or musculoskeletal disease Feel physically fit to participate in the study (assessment with FAC and Barthel Index): sufficiently capable of moving, able to maintain and change their position, manipulate and move objects, move in their place of residence, experience the surrounding environment, move by means of transport Live alone Interest in the project Willingness to sign the written informed consent Able to perform the tasks suggested by the caregiver Able to use smartphone, smartwatch Presence of a caregiver 	 Age < 65 years MMSE <21, subjects diagnosed with dementia or with MMSE ≥ 28 or ≤20 Participants suffer from severe chronic disease (e.g., symptomatic cardiovascular or respiratory disease, myocardial infarction or stroke in the last 6 months, presence of significant visual and/or auditory impairment, severe metabolic dysfunction, oncological pathologies) or severe disability No agreement on written informed consent Participants are carriers of cardiac pacemakers or implantable defibrillators Presence of conditions that make it difficult to use a smart device (e.g., moderate/severe dementia, aphasia, etc.) A person placed under guardianship Nickel allergy
Secondary users	- Willingness to sign the written informed consent	- A person without professional experience in the field of aging care

	 Lay caregiver helping the involved older adults (family members, helping volunteers) Professional assistant to their involved older adults (social worker, nurse, physiotherapist, doctor) 	
Tertiary users	 Willingness to sign the written informed consent Persons who are related to home care and social assistance in municipal care, research field, decision-makers in financing and management 	- Less than half a year of experience

The study involved the use of the SAVE platform by the user for a total of 21 consecutive days, at the end of which the system was validated. The research staff ensured both the administration of tests by specialists, and the supervision of the interaction between user and prototype system by technicians. The study involved the use of a mixed-methods approach, in which both qualitative (open questions) and quantitative (standardized tests) data were collected. The standardized tests assessed cognitive status, walking ability, activities of daily living, health and well-being, and emotional state; also, usability, user experience and acceptance of technology. On the other hand, the open-ended questions investigated the experience with technology and with the Save system and the concept of privacy and stigma.

The validation protocol for primary users consists of four dimensions sections, which include a series of scales, as follows:

A) Health and Wellness Condition:

- Mini-Mental State Examination (MMSE) [1];
- Functional Ambulation Category (FAC) [2];
- Barthel Index [3];
- SF-12v2 TM Health Survey [4];
- Five Well-Being (WHO-5) Index [5];
- EuroQol 5 Dimension 5 Level (EQ-5D-5L) [6].

B) Self-efficacy:

- General Self-Efficacy Scale (GSE) [7].
- C) Usability and Acceptance:
- System Usability Scale (SUS) [8];

- User Experience Questionnaire (UEQ-S) [9];
- Quebec User Evaluation of Satisfaction with assistive Technology (QUEST 2.0) [10].

D) Privacy and Stigmatization

• Open questions.

Table 2 summarizes the dimensions and measures of the evaluation study for all the users.

Table 2. Dimensions and measures of the evaluation study for all the users

Type of end users	Dimensions	Scales	Timing	g of data co	ollection
			T0	T1	T2
		MMSE	X		
		FAC	x		
	Health and Wellness	Barthel Index	X		
Primary users	Condition	SF-12v2	X	x	X
		WHO-5 Index	X	X	X
		EQ-5D-5L	X	X	X
	Self-efficacy Usability and Acceptance	GSE	Х	Х	х
		SUS		X	Х
	•	UEQ-S		X	X
	1	QUEST 2.0		X	X
	Privacy and Stigma	Open questions	х	х	х
Secondary	Usefulness		х	х	Х
users	Reliability		Х	х	х
Tertiary	Reduction of time		x	X	х
users	Reduction of cost		х	х	х
	Reduction of workload		х	х	х

The data collection sheet for secondary users consists of a sequence of 5-Likert scale questions on the following dimensions (Table 2):

- Usefulness of the system;
- Reliability of the system,

and some free comments about the satisfaction with the system.

The data collection sheet for tertiary users consists of a sequence of 5-Likert scale questions on the following dimensions (Table 2):

- Impact of the system on the reduction of time spent in caregiving activities;
- Impact of the system on the reduction of the cost of caregiving activities;
- Impact of the system on the reduction of the workload.

Each instrument will be administered, if possible, in a face-to-face session in the presence, otherwise remotely by a trained interviewer who will report the answers on a paper version of the data collection card.

During the period of use of the system, three different measurements were made (T0, T1, T2): before the start of the trial, after 10 days, and at the end of the trial. During the trial, the user could call the researcher and/or technical staff in case of problems with the system or related services.

The following log data is continuously recorded: usage time /used ser-vices (time/number), number of interactions, participation in social events (web conference, phone call, video call), tracked daily activities, number of errors, number of aids required for the tasks, recognized user commands, used input modality, captured touch screen data/activity, number of services used in the given period, number of tasks solved by using the SAVE system (for example, did the user get an answer to a question, did the user manage to call/inform the caregiver, was the user able to perform recreational activities with the help of the device, did the user manage to send the alarm to the caregiver, whether the caregiver was informed about the user's fell, could not sleep, decreased activity, be deteriorated, etc.).

The data were then analyzed at both national and cross-national levels.

2.1 Recruitment Strategy in each site

The primary users were 80 older adults: 30 participants were enrolled in Romania, 25 in Italy and the remaining 25 in Hungary. Their caregivers (30 enrolled in Romania, 25 in Italy and 25 in Hungary) as secondary users and at least 5 tertiary users for the site were involved.

Italy

In 2022, all the necessary procedures were initiated to obtain the approval of the study by the Ethics Committee. After obtaining ethical approval in April 2022, the recruitment of the 25 subjects for the trial of the study began.

Participants were selected on the basis of free participation and effective adherence to the inclusion criteria. The staff involved in the study solicited their networks (associations, leisure centers, trade unions, etc.), which, after verifying the inclusion criteria, provided the names of potential participants. The research staff then contacted them by phone describing the objectives, methods, procedures and timing of the project. Once compliance with the inclusion and exclusion criteria of the study is verified and informed consent is obtained, the staff members proceed with the baseline evaluation.

Romania

In Romania, user recruitment was carried out after receiving the ethics agreement in April 2022. User recruitment was done through two organizations, the Social Assistance Directorate Brasov (DAS – http://www.dasbv.ro) and the organization "Hand to Hand". For both organizations, the SAVE team organized a meeting with the management and the elderly groups. Among the older people who attended these meetings, some of them showed interest in being involved in the project on a voluntary basis. From the two organizations we managed to recruit 30 users who were part of the project from June 2022 to July 2023. The challenge of this project was to convince the users to be involved in the project, taking into account the Covid-19 pandemic. At each installation a member from DAS or Hand to Hand was present to offer support and assistance. The involvement of users and caregivers was of real support in the completion of the data collection.

Hungary

In Hungary, when the SAVE pilot was authorized, we were faced with a complete transformation of the national authorization paths and procedures due to the MDR. The ethical approval of the Hungarian SAVE pilot test was obtained much later, in October 2022, than that of the Romanian and Italian pilots, which was ultimately an essential reason for the 2nd project extension. Recruitment of the participants began in November 2022.

OMINT-NIMR designed a two-track recruitment strategy for the Hungarian pilot test. OMINT-NIMR is a healthcare organization, so we used the convenient recruitment strategy from the beginning of the pilot test. The second way was to demonstrate the SAVE remote care services to professional elderly care organizations, elderly associations and clubs. We held demonstrations at the National Associations of Disabled People (MEOSZ) of 6th, 7th and 13th district of Budapest, in the pensioner club of 1st district of Budapest, and the Elderly Care Services of the 7th and 11th districts of Budapest. OMINT-NIMR's SAVE research team visited the participants who expressed interest in taking part in the pilot test, verified their compliance with the inclusion criteria, discussed the procedure with them and set up a waiting list. The waiting list usually consisted of three to four applicants, and only twice during the seven-month pilot test was it emptied due to unexpected medical treatments, travel or other personal reasons.

The Hungarian primary users included in the pilot testing were a total of 27 people, of which two primary users dropped out earlier than the planned 21-day test period. With the convenient recruitment strategy, 20 primary users were involved from the pensioners' club of Budapest 1st. district and the Elderly Care Service 11th district, and only five primary users were included, 2 from 1st district and 3 from 11th district. It should be noted that seven interested primary users on the waiting list who met the selection criteria, the OMINT-OORI SAVE team spent considerable time convincing them, but after getting to know the system, they did not agree to participate in the testing. The proportion of secondary and tertiary users recruited according to the convenience/controlled recruitment strategy was the same as that of primary users. The poor performance of the controlled recruitment strategy can be explained by the fact that in Hungary the state-sponsored elderly care smartwatch program (https://gondosora.hu/) has already been introduced in many professional organizations.

2.2 Trial Description in each site

The pilot sites from Italy and Budapest had at its disposal 5 sensor kits each and the pilot site from Romania had 10 sensor kits, that could be installed from time to time at the recruited users' homes.

Italy

The trial began on August 26, 2022 and ended on June 20, 2023.

Table 3 illustrates the collected data in the Italian pilot site. Specifically, the IT_F code refers to the tests carried out in Fabriano by LabIdee.

Table 3. Data of the recruited users in Italy (INRCA and LabIdee)

User Code	Age	Gen- der	Smart devices used	Sen- sors used	Health measu- ring devices	Apps used		Date of installa- tion	trial	Planned date of trial end	date of	T0 data collec- tion	T1 data collec- tion		Pre- sence of caregi- ver
IT_P 01	81	F	only phone (no smart)	none	heart rate monit or	none	not inter ested	28/09 /2022	28/09 /2022	19/10 /2022	19/10 /2022	28/09 /2022	11/10 /2022	19/10 /2022	yes

IT_P 02	78	F	Smart- phone, tablet	none	1	1	4	06/10 /2022	06/10 /2022	27/10 /2022	27/10 /2022	06/10 /2022	17/10 /2022	27/10 /2022	yes
IT_P 03	88	F	only phone (no smart)	none	1	none	not inter ested	19/10 /2022	19/10 /2022	9/11/2022	10/11 /2022	19/10 /2022	28/10 /2022	10/11 /2022	yes
IT_P 04	86	F	Smart- phone	none	1,4	1,2	vide ocall	20/10 /2022	20/11 /2022	10/11 /2022	11/11 /2022	20/10 /2022	02/11 /2022	11/11 /2022	yes
IT_P 05	81	F	Smart- phone, Alexa	none	blood press ure monit or	none	not inter ested	25/10 /2022	25/10 /2022	15/11 /2022	15/11 /2022	25/10 /2022	04/11 /2022	15/11 /2022	yes

IT_P 06	84	F	Smart- phone	none	blood press ure	none	not inter ested	02/11 /2022	02/11 /2022	23/11 /2022	24/11 /2022	2/11/ 2022	14/11 /2022	24/11 /2022	yes
IT_P 07	84	F	phone	none	blood press ure	none	not inter ested	14/11 /2022	14/11 /2022	05/12 /2022	06/12 /2022	14/11 /2022	24/11 /2022	06/12 /2022	yes
IT_P 08	81	M	Smart- phone, compu ter	none	blood press ure, oxyge n levels	1,2,3,	not inter ested	24/11 /2022	24/11 /2022	15/12 /2022	15/12 /2022	24/11 /2022	05/12 /2022	15/12 /2022	no
IT_P 09	90	F	phone	none	1,2	none	not inter ested	18/01 /2023	18/01 /2023	08/02 /2023	08/02 /2023	18/01 /2023	18/01 /2023	08/02 /2023	yes

IT_10	74	F	smartp hone	none	none	none	not inter ested	30/11 /2022	30/11 /2022	21/12 /2022	21/12 /2022	30/11 /2022	10/12 /2022	21/12 /2022	yes
IT_11	78	M	Smart- phone, compu ter	none	1,2	4,6	5	06/02 /2023	06/02 /2023	27/02 /2023	27/02 /2023	06/02 /2023	16/02 /2023	27/02 /2023	no
IT_12	83	F	Smart- phone	none	1,4	1,2	4	12/01 /2023	12/01 /2023	02/02 /2023	02/02 /2023	12/01 /2023	23/01 /2023	02/02 /2023	yes
IT_13	81	F	phone, compu ter	2	1,2,4	none	4	08/3/ 2023	08/3/ 2023	29/03 /2023	30/03 /2023	08/3/ 2023	20/03 /2023	30/03 /2023	yes

IT_14	96	M	Smart- phone compu ter	none	1,3,4	5,6	not inter ested	05/4/ 2023	05/4/ 2023	26/4/ 2023	28/04 /2023	05/4/ 2023	14/04 /2023	26/04 /2023	yes
IT_15	73	M	Smart- phone, smart watch, compu ter and tablet	2	1	4,5, 6	not inter ested	06/4/ 2023	06/4/ 2023	27/4/ 2023	28/04 /2023	06/4/ 2023	14/04 /2023	26/04 /2023	yes
IT_16	82	F	Smart- phone, compu ter	none	1,4	1,4,5,	not inter ested	17/5/ 2023	17/5/ 2023	07/06 /2023	06/06 /2023	17/05 /2023	26/05 /2023	26/05 /2023	yes
IT_17	65	F	Smart- phone, compu ter	none	1	1,5,6	not inter ested	17/05 /2023	17/05 /2023	31/05 /2023	31/05 /2023	17/05 /2023	24/05 /2023	01/06 /2023	yes

IT_18	80	F	Smart- phone, tablet	none	1	1,3,4,	1,3,4	23/05 /2023	23/05 /2023	06/06 /2023	06/06 /2023	23/05 /2023	30/05 /2023	06/06 /2023	yes
IT_19	72	M	Smart- phone	none	1	none	none	23/05 /2023	23/05 /2023	13/06 /2023	13/06 /2023	23/05 /2023	01/06 /2023	13/06 /2023	yes
IT_20	80	M	Smart- phone, compu ter, tablet	vi- deo ca- mera	1,3,4	1,4,6	1,4,6	06/06 /2023	06/06 /2023	20/06 /2023	20/06 /2023	06/06 /2023	13/06 /2023	20/06 /2023	yes
IT_F 01	81	M	mobile phone	none	heart rate monit or	none	not inter ested	26/08 /2022	26/08 /2022	15/09 /2022	13/09 /2022	26/08 /2022	14/09 /2022	20/09 /2022	no

IT_F 02	77	F	mobile phone	none	blood press ure, heart rate monit or	none	not inter ested	21/09 /2022	21/09 /2022	08/10 /2022	12/10 /2022	21/09 /2022	03/10 /2022	14/10 /2022	yes
IT_F 03	85	М	mobile phone, compu ter	none	blood press ure, heart rate monit or	1,2,4	not inter ested	28/10 /2022	28/10 /2022	20/11 /2022	20/11 /2022	28/10 /2022	08/11 /2022	18/10 /2022	yes
IT_F 04	94	F	Smart- phone	none	blood press ure, heart rate monit or	none	not inter ested	21/11 /2022	21/11 /2022	02/12 /2022	02/12 /2022	21/11 /2022	02/12 /2022	14/12 /2022	yes

IT_F	75	M	mobile	none	none	1,4,5,	not	28/04	28/04	18/05	26/05	28/04	16/05	26/05	yes
05			phone,			6	inter	/2023	/2023	/2023	/2023	/2023	/2023	/2023	
			compu				ested								
			ter												

Services and devices in Italy

This section provides an overview of the services and devices used during the 21-day pilot testing period in Italy. The aim of this section is to highlight the usage percentage of each service among the older participants. All services and devices were installed within end users' homes ensuring a comprehensive evaluation of their effectiveness and usability.

- 1) Movement Sensors: during the pilot test, movement sensors were installed in all the users' homes, and they were used 100% of the time. These sensors effectively captured movement data, providing insights into the users' activity levels and patterns, even if only in two rooms of the house.
- 2) Door Sensor: similarly, door sensors were installed in the homes of the end users and were utilized 100% of the time. The door sensors proved valuable in monitoring the opening and closing of doors, ensuring the safety and security of the users, although some PUs and SUs reported that sometimes the sensor did not work perfectly.
- 3) Flood Sensors: the installation of flood sensors in bathrooms and kitchens of the end users' homes resulted in their usage of 100%. Notably, one user experienced an actual flood warning alarm during the testing period, demonstrating the effectiveness of these sensors in detecting potential water damage incidents.
- 4) Blood Pressure Monitoring: after calibrating the smartwatches, consistent blood pressure measurements were successfully obtained for all end users. The blood pressure monitoring feature was utilized consistently and reliably.
- 5) Heartbeats per minute: using the smartwatches, heartbeats per minute were monitored for all end users 100% of the time. This provided valuable information on heart rate trends and abnormalities.
- 6) Steps per Day Monitoring: steps per day were monitored every day for all end users. This feature enabled the tracking of their daily activity levels, promoting awareness of physical movement and encouraging a healthy lifestyle.
- 7) GPS Location: the GPS location service only worked if the end user went out with the smartphone. In Italy, the smartphone worked as a router, so it was left at home and remained connected together with the Aquara hub and sensor adapter. For this reason, the GPS location could not work outside. More than one user and caregiver reports the desire to have a smartwatch that tracks physical activity, for example when cycling, and detects emergency situations even outside, without having to carry the smartwatch with you. End users and caregivers have recognized this lack as a limitation and an important function to be integrated into the system in the future.

- 8) Fall Detection: in Italy, only one user experienced the fall twice, but unfortunately the smartwatch was not able to detect these events.
- 9) Data Monitoring for End Users: apart from a short system interruption, data monitoring for end users was consistently maintained throughout the pilot testing period. This allowed for continuous tracking of their activities and health metrics.
- 10) Data Monitoring for Caregiver: data monitoring for caregivers was successfully conducted. However, three end users did not have a caregiver, resulting in the absence of data monitoring for these specific individuals. Many caregivers agreed that an event notification system on their smartphone would be more useful, as would being able to see the trend of data from week to week, rather than from day to day.

Overall, all the services have been effectively tested with positive results with respect to their functioning and usefulness. Blood pressure and heart rate monitoring services have been actively used by users and in one case, blood pressure monitoring proved to be particularly useful in highlighting a situation worthy of clinical investigation.

Romania

The trial began on June 16, 2022 and ended on July 1, 2023.

Table 4 illustrates the collected data in the Romanian pilot site.

Table 4. Data of the recruited users in Romania

User	Α	G	Smart	Sen-	Health	Apps	Apps	Date	Date	Plann	Real	T0	T1	T2	Pres
	g	e		sors	measu	used	in	of	of	ed	date	data	data	data	ence
	e	n		used	ring		future	install	trial	date	of	collec	collec	collec	of
					device			ation	start	of	trial	tion	tion	tion	care
					S					trial	end				giver
										end					
RO_01	67	F	Smart	Gas	2	5	none	16.06.	16.06.	07.07.	13.02.	16.06.	28.06.	07.07.	yes
								2022	2022	2022	2023	2022	2022	2022	
RO_02	73	M	Smart	Gas	0	all	none	16.06.	16.06.	07.07.	23.02.	16.06.	28.06.	07.07.	yes
								2022	2022	2022	2023	2022	2022	2022	
RO_03	75	F	Smart	Gas	5	all		17.06.	17.06.	08.07.	10.02.	17.06.	26.06.	08.07.	yes
								2022	2022	2022	2023	2022	2022	2022	
RO_04	70	F	Smart	none	0	all		21.06.	21.06.	12.07.	03.02.	21.06.	30.06.	12.07.	yes
								2022	2022	2022	2023	2022	2022	2022	_
RO_05	78	M	Smart	Gas	2	all		05.07.	05.07.	26.07.	13.02.	05.07.	15.07.	26.07.	yes
			Comp					2022	2022	2022	2023	2022	2022	2022	
			uter												
RO 06	77	F	Smart	Gas	1	5		06.07.	06.07.	27.07.	13.02.	06.07.	18.07.	27.07.	yes
								2022	2022	2022	2023	2022	2022	2022	
RO 07	80	M	Smart	Gas	1	5		18.10.	18.10.	08.11.	08.02.	18.10.	28.10.	08.11.	yes
								2022	2022	2022	2023	2022	2022	2022	_

RO_08	77	F	Smart	Ga	2	5	21.10. 2022	21.10. 2022	11.11. 2022	09.02. 2023	21.10. 2022	01.11. 2022	11.11. 2022	yes
RO_09	83	F	Smart	Non e	0	2	03.11.	03.11. 2022	24.11. 2022	08.02. 2023	03.11. 2022	13.11. 2022	24.11. 2022	yes
RO_10	72	F	Smart	Non	2	5	22.11. 2022	22.11. 2022	13.12. 2022	08.02. 2023	22.11. 2022	02.12. 2022	13.12. 2022	yes
RO_11	66	M	Smart	Gas	2	5	13.02.	13.02.	06.03.	19.05.	13.02.	27.02.	06.03.	yes
RO_12	83	F	Smart	Gas	2	5	2023 10.02.	2023 10.02.	2023 03.03.	2023 09.05.	2023 10.02.	022 20.02.	2023 03.03.	yes
RO_13	84	F	Smart	Gas	2	5	03.04.	2023 03.04.	2023 25.04.	2023 13.04.	2023 03.04.	2022 15.04.	2023 25.04.	yes
RO_14	92	F	Smart	Gas	5	5	2023 03.04.	2023 03.04.	2023 25.04.	2023 26.05.	2023 03.04.	2023 15.04.	2023 25.04.	yes
RO_15	80	F	Smart	Non	0	5	2023 21.02.	2023 21.02.	2023 14.03.	2023 13.04.	2023 21.02.	2023 02.03.	2023 14.03.	yes
RO_16	74	F	Smart	e Gas	5	5	2023 16.03.	2023 16.03.	2023 06.04.	2023 19.05.	2023 16.03.	2022 26.03.	2023 06.04.	yes
_							2023	2023	2023	2023	2023	2023	2023	
RO_17	82	F	Smart	Gas	5	5	24.02. 2023	24.02. 2023	17.03. 2023	09.05. 2023	24.02. 2023	06.03. 2023	17.03. 2023	yes
RO_18	77	M	Smart	Gas	5	5	13.04. 2023	13.04. 2023	04.05. 2023	09.05. 2023	13.04. 2023	23.04. 2023	04.05. 2023	yes
RO_19	73	F	Smart	Gas	1	5	13.04. 2023	13.04. 2023	04.05. 2023	11.05. 2023	13.04. 2023	23.04. 2023	04.05. 2023	yes
RO_20	65	F	Smart	Gas	1	5	16.04.	16.04.	07.05.	08.05.	16.04.	27.04.	07.05.	yes
RO_21	67	F	Smart	Gas	1	5	2023 13.04.	2023 13.04.	2023 03.05.	2023 09.05.	2023 13.04.	2023	2023 03.05.	yes
RO_22	69	M	Smart	Gas	5	5	2023 13.04.	2023 13.04.	03.05.	2023 11.05.	2023 13.04.	2023	2023 03.05.	yes
RO_23	67	F	Smart	Gas	5	5	2023 16.04.	2023 16.04.	2023 07.05.	2023 08.05.	2023 16.04.	2023 27.04.	2023 07.05.	
RO_24	66	F	Smart	Gas	0	5	2023 08.05.	2023 08.05.	2023 29.05.	2023 30.05.	2023 08.05.	2023 19.05.	2023 29.05.	
RO_25	74	F	Smart	Gas	5	5	2023 09.05.	2023 09.05.	2023 30.05.	2023 08.07.	2023 09.05.	2023	2023 30.05.	
RO_26	80	F	Smart	Non	0	5	2023 09.05.	2023 09.05.	2023 30.05.	2023 14.07.	2023 09.05.	2023 20.05.	2023 30.05.	
RO_27	66	M	Smart	e Gas	5	5	2023 09.05.	2023 09.05.	2023 30.05.	2023 08.07.	2023 09.05.	2023	2023 30.05.	
RO_28	72	M	Smart	Gas	5	5	2023 08.05.	2023 08.05.	2023 29.05.	2023 19.06.	2023 08.05.	2023 19.05.	2023 29.05.	
RO_29	83	M	No	Gas	1	5	2023 11.05.	2023 11.05.	2023	2023 19.06.	2023 11.05.	2023 22.05.	2023 1.07.2	
RO_30	69	F	phone Smart	Gas	2	5	2023 11.05.	2023 11.05.	023	2023 06.07.	2023 11.05.	2023 22.05.	023 1.07.2	
							2023	2023	03	2023	2023	2023	03	

Hungary

The trial began on November 30, 2022 and ended on July 7, 2023.

Table 5 illustrates the collected data in the Hungarian pilot site.

Table 5. Data of the recruited users in Hungary (OMINT-NIMR)

Primary User	Secondary User	Tertiary User	Sampling	T0	T1	T2	
PU01	SU01	T01	convenient sampling	2022.11.30	2022.12.10	2022.12.21	SAVE kit #1
PU02	SU02	T01	convenient sampling	2022.12.28	2023.01.06	2023.01.20	SAVE kit #2
PU03	SU03	T01	convenient sampling	2023.01.06	2023.01.19	2023.01.27	SAVE kit #3
PU04	SU04	T01	convenient sampling	2023.01.10	2023.01.23	2023.02.01	SAVE kit #4
PU05	SU05	T01	convenient sampling	2023.01.18	01.31-02.01	2023.02.08	SAVE kit #5
PU06	SU06	T01	convenient sampling	2023.01.23	2023.02.03	2023.02.17	
PU07	SU07	T01	convenient sampling	2023.02.01	drop out		
PU08	SU08	T01	1st district club	2023.02.03	2023.02.14	2023.03.01	
PU09	SU09	T01	convenient sampling	2023.02.08	2023.02.20	2023.03.01	
PU10	SU10	T01	convenient sampling	2023.02.09	2023.02.20	2023.03.06	
PU11	SU11	T01	convenient sampling	2023.02.21	2023.03.02	2023.03.14	
PU12	SU12	T01	1st district club	2023.03.03	2023.03.13	2023.03.27	
PU13	SU13	T01	convenient sampling	2023.03.08	2023.03.20	2023.03.29	
PU14	SU14	T02	11th district dub	2023.03.21	2023.04.03	2023.04.13	
PU15	SU15		convenient sampling	2023.03.27	2023.04.05	2023.04.17	
PU16	SU16		11th district club	2023.03.30	2023.04.12		
PU17	SU17	T01	convenient sampling	2023.03.31	2023.04.12	2023.05.05	
PU18	SU18	T01	convenient sampling	2023.04.05	2023.04.17	2023.04.27	
PU19	SU19		convenient sampling	2023.04.16	2023.04.27	2023.05.08	
PU20	SU20		11th district club	2023.04.21	2023.05.02	2023.05.15	
PU21	SU21	T01	convenient sampling	2023.05.03	2023.05.15	2023.06.01	
PU22	SU22	T01	convenient sampling	2023.05.10	2023.05.19	2023.05.31	
PU23	SU23		convenient sampling	2023.05.22	2023.06.05	2023.06.12	
PU24	SU 24		convenient sampling	2023.06.03	2023.06.13	2023.06.26	
PU25	SU25		convenient sampling	2023.06.08	2023.06.19	2023.06.28	
PU26	SU26		convenient sampling	2023.06.14	2023.06.22	2023.07.06	

Figure 5 shows the locations of the Hungarian primary users' residences.

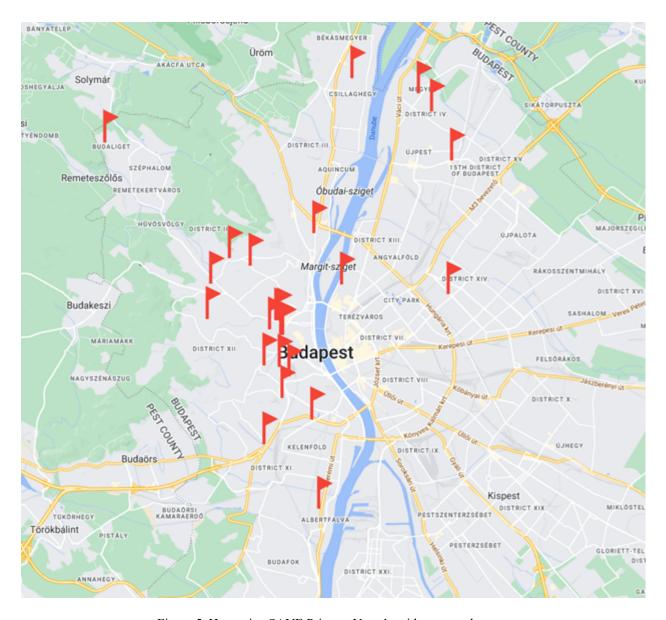


Figure 5. Hungarian SAVE Primary Users' residences on the map

2.3 Problematic aspects faced during validation

In this paragraph a summary of the most frequent problematic aspects faced during the validation is reported.

Table 6 describes a list of macro-problems based on feedback of primary and secondary users involved in the validation phase.

Table 6. Description of problem faced and exit strategy

Problem faced	Description	Exit strategy
Connection problems		These are inherent issues with any IT system. However, the availability of the systems was over 99% over the whole period of the pilot phase.
		Most of the connection problems were on pilot sites and support was offered to solve them individually.
Problems with transmission and visualization of data on the cloud	Some caregivers reported that sometimes the web portal was unclear, the graphics were difficult to read, the detected times were wrong, and some sentences were not translated in the requested language	The user experience was improved and evolved all the way through the piloting phase and the raised issues were solved.
Problems with detection of seniors' falls	In some cases, the smartwatch did not detect older adults' falls	In the SAVE system the fall detection relies on the algorithm implemented by Samsung in their smartwatches. There are several levels of sensibility offered.
		A better wearable device can be employed in the future and/or an own algorithm can be implemented.

Stressful situations related to smartwatch and sensors	Many end users reported experiencing a feeling of control, not so much from the SAVE system itself, but from caregivers through the system	
Poor user experience with technology	Many end users reported that they have been helped by their caregivers in putting on, taking off, using and charging the smartwatch	
Problems with the hub (Dominic box)	During one of the trials the power connector (mini usb) broke off while the user disconnected it	The hubs were reused during the pilot phase and were stressed more than in a typical scenario (just connect and forget about it). However, a more user-friendly and sturdier connector should be employed for newer versions (USB type C).
Problems with smartwatch battery life	Some users complained that the charge in the smartwatch lasted less than 12 hours	This situation is not a general one; some of the smartwatches were more power-hungry than others. This can be related to several causes: application installed on the smartwatch, setting of some healthmonitoring applications, number of notifications received, always on visibility setting for the watch face, physical activity of the user, the correctness of wearing the watch (it must be tight on the wrist), connectivity settings, quality of the battery, version of the operating system, etc The normal battery life of the smartwatch employed in SAVE is about 24 hours for normal use.

		The employment of newer, more efficient smartwatches can solve this problem.
Some users prefer apps instead of accessing web pages	Some users asked why there is no app? It is not convenient to use web pages (on the phone).	The web pages are always up to date (no need to update an app) and are built on the mobile-first philosophy. Also, for the web pages there are no hardware or software compatibility issues even with older or newer devices. The webpages can be placed as shortcuts on the main screen of the mobile device (looking like an app). Apps can be developed for the users that prefer them.
No GPS signal inside apartments	Some users complained the GPS signal is weak inside the home.	This is a known problem for GPS. It only works well outside. However, in SAVE the GPS is only useful if the user is outside the house.
Different time zones in the SAVE web applications	Some users noticed the SAVE web application uses another time zone.	The web applications use the GMT time (so is independent of the user's location). A user preference can be added to shift the time zone to a preferred one.
The smartwatch does not detect walking with crutches		In the SAVE system the fall detection relies on the algorithm implemented by Samsung in their smartwatches. There are several levels of sensibility offered.
		A better wearable device can be employed in the future and/or an own algorithm can be implemented.

There are few options only on the SAVE online interface	Most of the data can only be seen for the last two days, the data cannot be downloaded	
The activity of secondary users is only visible for the current month on the SAVE interface		This is the current behavior of the SAVE interface. In the pilot phase, the focus of the user interfaces was on the end and secondary users. For the tertiary user, only the bare necessary features were implemented. The data is available, and the user interface can be extended to offer more log data.

3. Wellbeing device

The Wellbeing device (Figure 6) is also part of the SAVE project. Its scope consists in assessing

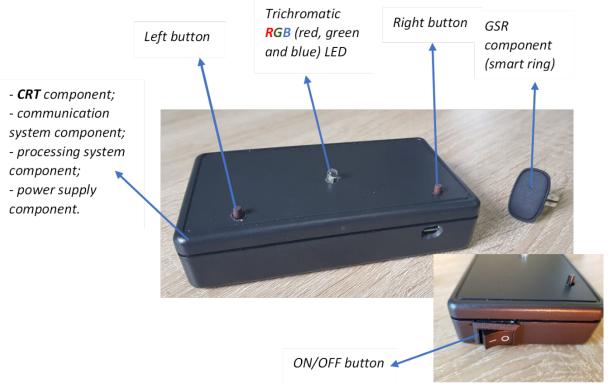


Figure 6. Wellbeing device

intraindividual variability across reaction time (RT) tasks performance and the corresponding galvanic skin response (GSR). Intraindividual variability, according to the literature, is considered a risk factor predictive of successful aging, implicitly well-being, and it is significant in assessing individuals whose disorders are mild. Visual choice reaction time tasks performance has been widely analyzed to measure age-related declines in processing speed.

The proposed well-being assessment system consists of two major components, as Choice Reaction Time (CRT) and Galvanic Skin Response (GSR) system components. Stress Assessment Technologies are based on wearable devices measuring galvanic skin response (GSR) in order to evaluate specific changes and detect stress level and phase (excitement, stress and recovery).

Choice Reaction Time (CRT) methodology is based on several visual stimuli and two response buttons. In the Figure 5, a trichromatic RGB (red, green, and blue) light-emitting diode (LED) is emitting a stimulus with respect to the following procedure:

- The blue LED color represents the target, and when the blue stimulus lights up, the older adult has to discriminate, select, and execute the right button (R);
- The red or green LED colors represent distractors and when the red or green stimulus lights up, the older adult has to discriminate, select, and execute the left button (L).

The Wellbeing system is using wireless and built-in sensor data acquisition, together with a cloud-based platform for both remote and on-site data monitoring.

In the 2022-2023 period, the Technology Club hosted the first trial of the Wellbeing device based on Choice Reaction Time (CRT) both in Italy and Romania.

The data collection in Italy took place from 22 March to 7 June 2022 at the Neurology Unit of the IRCCS INRCA of Ancona. A total of 20 patients were recruited, including 12 women aged between 61 and 85 (mean 74 and standard deviation +/-6.26) and 8 men aged between 72 and 80 (mean 78 and standard deviation +/-2.53)

In Romania, a total of 24 older adults participated in the Technology Club of Braşov, including 16 women aged between 63 and 80 (mean 72.8 and standard deviation +/-4.82) and 8 men aged between 66 and 85 (mean 76 and standard deviation +/-6.32).

In Italy, with the help of neuropsychologists, it was decided to involve all the patients who turned to the Neurology Department of INRCA for a neuropsychological evaluation and who gave their consent to the study. So, a pre-selection was not made, but initially it was decided to randomly collect data based on the turnout at the department.

At the end of the data collection, based on the latest neuropsychological evaluation and cognitive diagnosis, neuropsychologists suggested dividing the 20 patients into 3 categories: 1. Dementias;

- 2. Amnestic mild cognitive impairment (a-MCI) and multi-domain aMCI (a-MCI-MD);
- 3. Subjective cognitive decline (SCD) and Non-amnestic mild cognitive impairment (na-MCI).

In Romania, out of the 24 subjects, 21 were divided into categories 2 and 3, as follows: 10 seniors - Amnestic mild cognitive impairment (a-MCI) and multi-domain aMCI (a-MCI-MD) and 11 seniors - Subjective cognitive decline (SCD) and Non-amnestic mild cognitive impairment (na-MCI).

A first cross-national statistical analysis will be made considering the reaction times, correct answers and errors made, personal data, MMSE and cognitive diagnosis useful to reveal the possible correlation of these data in the dementia diagnosis process.

Regarding the processing and analysis of the data obtained from the Wellbeing systems used within the Technology Club of Ancona and Braşov, Machine Learning methods, neural networks can be used, and in situations where the available data is insufficient for the development of the networks, transfer learning methods will be used.

Considering the data collected in the Technology Club, it is of interest to create a cognitive diagnosis tool using transfer learning (deep learning) that can be compared to traditional machine learning methods. The existing data, presented in Table 7, allow the automatic recognition of three categories of cognitive disorders.

The identification of a pre-trained similar neural network, data preprocessing, data set augmentation methods (i.e., for balancing the number of examples per class) are considered for the development of a cognitive diagnostic tool using transfer learning.

Multiple machine learning methods are considered to evaluate the collected data, already implemented through the MATLAB tool - Classification Learner.

Table 7. Data collected through the Wellbeing device in Italy and Romania and divided by cognitive categories

Categories	Technology Club					
	Ancona	Brașov	Total			
Dementias	6	0	6			
a-MCI + a-MCI-MD	8	10	18			
SCD + na-MCI	6	11	17			

Transfer learning is achieved by using an existing network, trained for a similar task. A new structure of upper layers is trained, with the aim of performing another task. For training the upper layers a much smaller number of data can be used than the one used to develop the existing neural network, considering the fact that the rest of the intermediate layers are already trained. The procedure is described in Figure 7, where the Neural Network - Task 2 represents the cognitive diagnosis tool to be developed.

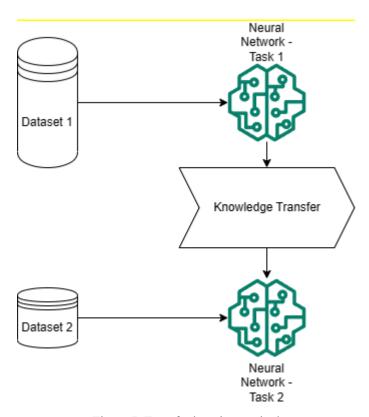


Figure 7. Transfer learning method

REFERENCES

- 1. Folstein, M.F.; Folstein, S.E.; McHugh, P.R. "Mini-Mental State": A practical method for grading the cognitive state of patients for the clinician. J. Psychiatr. Res. 1975, 12, 189–198.
- 2. Mehrholz, J.; Wagner, K.; Rutte, K.; Meiner, D.; Pohl, M. Predictive validity and responsiveness of the functional ambulation category in hemiparetic patients after stroke. Arch. Phys. Med. Rehabil. 2007, 88, 1314–1319.
- 3. Collin, C.; Wade, D.T.; Davies, S.; Horne, V. The Barthel ADL Index: A reliability study. Int. Disabil. 1988, 10, 61–63.
- 4. Ware, J.E.; Kosinski, M.; Keller, S.D. A 12-item short-form health survey: Construction of scale and preliminary tests of reliability and validity. Med. Care 1996, 34, 220–233.
- 5. Bech, P. Measuring the dimension of psychological general well-being by the WHO-5. QoL Newsletter 2004, 15–16.
- 6. Group, The EuroQol. EuroQol-A new facility for the measurement of health-related quality of life. Health Policy 1990, 16, 199–208.
- 7. Schwarzer, R.; Jerusalem, M. Generalized Self-efficacy Scale. In Measures in Health Psychology: A User's Portfolio. Causal and Control Beliefs; Weinman, J., Wright, S., Johnston, M., Eds.; NFER-Nelson: Windsor, Berkshire, UK, 1995; pp. 35–37.
- 8. Brooke, J. SUS: A 'Quick and Dirty' Usability Scale. In Usability Evaluation in Industry, 1st ed.; Jordan, W.P., Thomas, B., McClelland, I.L., Weerdmeester, B., Eds.; CRC Press: London, UK, 1996; ISBN 9780429157011.
- 9. Schrepp, M.; Hinderks, A.; Thomaschewski, J. Design and evaluation of a short version of the user experience questionnaire (UEQ-S). IJIMAI 2017, 4, 103–108.
- 10. Demers, L.; Weiss-Lambrou, R.; Ska, B. The Quebec User Evaluation of Satisfaction with assistive Technology (QUEST 2.0): An overview and recent progress. Technol. Disabil. 2002, 14, 101–105.