





DELIVERABLE

D 3.1. PRE-PILOT TESTING REPORT

			TV-based ASSistive
		Droject name	Integrated Service to
Editor(S)		Project name	SupporT European Adults
			living with Dementia
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v.3.	19.02.19	Spanish Phase II results	IBIMA
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v.2.	15.05.19	Romanian Phase II results	ILD

Deliverable Summary

D3.1 Pre-pilot testing report. This report results of the feasibility study and serves for possible system refinement.

T3.1 Pre-Testing (Leader IBIMA): Based upon the first version of the system prototype of TV-AssistDem, the objective of this task was to confirm that the system was suitable for use in the clinical setting, before committing to the full pilot. During the pre-testing phase, 15 patients were provided with the system. They received the same explanation of the pilot objectives as in the main pilot; they were also asked to provide the same data on their well-being. Data provided during the feasibility study was not stored to avoid statistically insignificant aberrations. Patients were contacted weekly to solicit their feedback on use of the application. The pre-testing phase was considered successfully completed when at least 12 of the 15 patients were comfortable with its use. Moreover, these efforts have served for possible system refinements.





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1 INTRODUCTION

The pre-pilot study involved all consortium partners. Clinical researchers were responsible for clinical recruitment, data collection, technology installation, follow up and issue reporting. Reported issues could be stated by the users concerning the STB services and interface or encountered by the researcher regarding the frontend interface and the backend services. Based on the reported issues, developers were responsible for updating the technology. Analysis of clinical and technological data was responsibility of the statistician (Table 1. Consortium tasks during the pre-pilot.).

GENERAL TASK	SPECIFIC TASK	CONSORTIUM PARTNER	
CLINICAL ASSESSMENT	Recruitment	IBIMA	
	Feasibility study	ILD	
	Set-Top-Box updates	SHTV	
	Frontend updates	MEDEA	
	Backend updates	CNR-ISTC	
	Clinical analysis	IMSD	
	Usage analysis		

Table 1. Consortium tasks during the pre-pilot.

2 PRE-PILOT

The pre-pilot compromised six processes (Figure 1. Pre-pilot processes.)

RECRUITMENT	DATA COLLECTION	PREPARATION FOR INSTALLATION	INSTALLATION	FOLLOW-UP	END OF STUDY
CONTACT RECRUITMENT CENTRES REFERRAL PROCESS TELEPHONE CALL PROTOCOL VISIT 0 - SCREENING PARTICIPANT INFORMATION SHEET PARTICIPANT	VISIT 1 ASSESSMENT OF CAPACITY TO CONSENT PATIENT AND CAREGIVER CONSENT FORMS PATIENT AND CAREGIVER CASE REPORT FORMS CLINICAL RECORDS CHEFCK-LIP	INSTALLATION REQUIREMENTS PRE-INSTALLATION CHECK-LIST	• AGREEMENT FORM • FEASIBILITY STUDY: PHASE I	• VIDEOCONFERENCE CALLS	 FEASIBILITY STUDY: PHASE II PATIENT AND CAREGIVER CASE REPORT FORMS RETURN FORM

Figure 1. Pre-pilot processes.





2.1 RECRUITMENT PROCESS

2.1.1 SPAIN

The recruitment process, which started during the month of July, faced delays due to several circumstances and challenges. In Spain, users and professionals were less available during the summer months due to holidays.

74 candidates were recruited for the pre-pilot. The referral centres were a public hospital (University Regional Hospital), primary health care centres (Unidad de Gestión Clínica Costa del Sol) and a private therapeutic centre for Alzheimer (NEURODEMFA). The remaining candidates contacted the IBIMA research team requesting a memory check-up after receiving the information of TV-AssistDem via the local dissemination events in newspapers and radio, as well as, social media (Figure 2. Spanish recruitment.).



Figure 2. Spanish recruitment.

The recruited candidates by centres were as follows: 39 patients from public hospital, 14 patients from primary health care centre, 1 patient from private therapeutic centre for Alzheimer and 20 patients via local dissemination (Figure 3. Recruited candidates by referral centres.).



Figure 3. Recruited candidates by referral centres.

Out of the 35 recruited candidates 15 were men and 20 women (Figure 4. Sex of recruited candidates.).



Figure 4. Sex of recruited candidates.

Following the recruitment telephone call protocol, 34 candidates were scheduled a screening interview, 23 candidates were found not eligible for the screening interview during the telephone call and 17 candidates refused to be scheduled for a screening interview (Figure 5. Telephone call protocol.)



Figure 5. Telephone call protocol.

The reasons for not finding the candidates eligible for the screening interview were: 1 candidate was not living independently, 1 candidate had no prescribed medication, and 1 candidate had a condition which may compromise the use of TV-AssistDem.





Initially, the only technological requirement for inclusion was having a TV. However, the developers found the system not to be compatible with cable TV. Internet connectivity was recommended but not an exclusion criterion since IBIMA would provide it for those patients who didn't have it. However, as the feasibility study started IBIMA faced internal problems to provide the routers for those patients without WIFI (Figure 6. Candidates not eligible for screening interview.).



Figure 6. Candidates not eligible for screening interview.

34 candidates were interviewed for screening following the Researchers Manual. 20 were clinically excluded during the interview, 12 were eligible for participation but 5 refused to participate (Figure 7. Screening interview.).



Figure 7. Screening interview.

The reasons for clinical exclusion were: 7 candidates MMSE over 27, 10 candidates MMSE under 23, 3 candidates GDS over 11 and 2 candidates had conditions which may compromise the use of TV-AssistDem (Figure 8. Clinical exclusion criteria.).



The recruitment process concluded when enough patients met eligible criteria for the feasibility study (Figure 9. Recruitment flow chart.).



Figure 9. Recruitment flow chart.





2.1.2 ROMANIA

In Romania, the recruitment process started in December 2018 but given the winter holidays we had to postpone the process for the beginning of January when the patients and their caregivers were available.

At the beginning of the process, 35 candidates were recruited for the pre-pilot. Most of the subjects were home care recipients, elderly people that are receiving a form of medical home assistance from the INGRIJIRI LA DOMICILIU team. They were referred to the researchers involved in the project by the field medical team at ILD. The remaining candidates contacted the research team requesting a memory check-up after receiving the information of TV-AssistDem via the local dissemination events in newspapers and social media (Facebook) (Figure 2. Spanish recruitment.).







Figure10. Romanian recruitment.

Analyzing the source of recruitment, 23 candidates are current patients of SC Îngrijiri la Domiciliu SRL (66%) and the others 12 candidates (34%) are the result of the local newspapers and social media campaigns (Facebook) (Figure 11. Recruited candidates by referral centers (RO).



Figure 11. Recruited candidates by referral centers (RO).

Regarding the gender proportion, out of the 35 recruited candidates 15 were men and 20 women (Figure 4. Sex of recruited candidates.).



Figure 12. Sex of recruited candidates (RO).





Following the recruitment telephone call protocol from all 35 recruited candidates, 13 were scheduled for the screening interview, 12 candidates were found not eligible for it and 10 candidates refused to be scheduled for a screening interview (Figure 5. Telephone call protocol.)



Figure13. Telephone call protocol (RO)

After the screening interview the results showed that 3 candidates were not living independently, 2 candidates had no prescribed medication, 4 candidates had a condition which may compromise the use of TV-AssistDem, 1 candidate didn't had an informal caregiver, and 2 of them didn't had Wi-Fi or antenna cable. (Figure 6. Candidates not eligible for screening interview.)

As for the installation issues in Romania, like in Spain, we were confronted with the lack of internet connection, the lack of Wi-Fi router or the patient's television has only one HDMI jack even if the only technological requirement was having a functional TV. Also, another technical issue encountered was the length of the HDMI cord, which turned out to be very short so we had to buy 2 HDMI longer cables. Regarding the lack of HDMI jack, we had to buy a splitter. The internet problem was resolved with a wireless router installed for the feasibility period.







Figure14. Candidates not eligible for screening interview (RO).

13 candidates were called for the screening interview using the Researcher Manual as guideline. 4 patients were excluded out of clinical issues (they did not get the score on the MMSE and GDS testing), 2 had conditions that can compromise the use of the TV-ASSISTDEM, 7 were eligible for participation at the study but 2 of them refused to participate. (Figure 15. Screening interview (RO))



Figure 15. Screening interview (RO).





There were four main reasons for clinical exclusion: 2 candidates scored MMSE over 27 (25%), 2 candidates had a score of under 23 at the MMSE test (25%) and for 2 candidates the GDS was over 11 (25%). 2 candidates refused to participate (25%)

(Figure 8. Clinical exclusion criteria.).



Figure16. Clinical exclusion criteria (RO).





In Romania the recruitment process ended when we reached the target number of patients with all the eligible criteria fulfilled for the feasibility study (Figure 9. Recruitment flow chart.).



Figure17. Recruitment flow chart in Romania

2.2 DATA COLLECTION PROCESS

Following the Researchers Manual, after receiving the Participant Information Sheet, patients were assessed their capacity to consent, the patient and caregiver signed the Consent Forms and the Case Report Forms were completed. They were given the Installation Requirements Sheet and were scheduled for an installation visit.





2.3 PREPARATION FOR INSTALLATION PROCESS

2.3.1 CLINICAL RECORDS

2.3.1.1 SPAIN

The clinical records were checked in the Diraya platform from the public health service records from the Sistema Andaluz de Salud (SAS) (Figure18. Diraya platform.) The figure is an example provided by the SAS and does not include data from a real patient.

listoria de Salud Unica				CONSILIERA DE SA
			JUANES ESPAÑOL ESPAÑOL NUMSA: AN0841736796	NUSS: 280000000293 Pecha Nac: 08/06/1967
Historia Única \		Hoja de resu	men Integral	Imprim
Datos de salud generales	-	Antecedentes familia	275	
Hergias (16/02/1996)		Anteredentes menos	ra las	
 Contraindicaciones (12/02/2006) 		Enfermedad actual y	evolución	
Prescripciones (05/11/2009)		Terrahar disantetion		
3. Antecedentes (15/01/2008)		a naroar angiovitica		
Episodios de Urgencias	•	Diagnósticos de la er	opecialidad	Works
Urgencias (12/02/2009 - 15/02/2009)		resfriado	(786.52) RESPIRACION DOLOROSA	26/04/10
Estudios Radiológicos	•	HEDRE	(700.0) FIEDRE	25/04/10
RX brazo (15/02/2009)		Tratamiento		
TAC de Torax (21/03/2008)		Plan de actuación		
Consultas Externas	•			
Consultas (14/02/2010)				
Episodios de Hospitalización	•			
Hospitalizado (20/03/2008 - 25/03/2008)	0			
💦 Estudios Radiológicos	•			
TAC de Torax (21/03/2008)	_			
🗋 Atención Primaria Desa	+			
AREA HOSPITALARIA CENTRO	•			
📕 A. Hospitalaria de Valme	Ξ			
diagnosticos al alta del are	a 📊			



2.3.1.2 ROMANIA

In Romania, the clinical records check was not possible because there isn't a national data base available for private units. The only medical information we had access to were the patient's personal medical documentation.







Figure.19. Personal medical documentation in Romania.

2.3.2 FRONTEND

The patient and caregiver profiles were created in the frontend (Figure 20. Frontend feasibility patients. And Figure 21. Frontend feasibility patients in Romania)

Gestionar Cuidadores	ID 🕸	AVATAR 1	NOMBRE I	EDAD 🕼	ESPACIO	EQUIPO 1	MOSTRAR DATOS	EDITAR 🗍	ELIMINAR 1
O Gestionar pacientes	42	۲	DOLORES VILLATORO LAVADO	62	Spanish Site	PRE-PILOT		O	Θ
Gestionar equipos	43	A	MARIA ROSARIO RUIZ MORENO	70	Spanish Site	PRE-PILOT		C ,	Θ
Q Gestionar Stimulus	48	.	ÁNGELES RIVAS SEGOVIA	79	Spanish Site	PRE-PILOT		C	\bigcirc
Gestionar videoconferencia	94	6	ISABEL LÓPEZ RAMBLA	80	Spanish Site	PRE-PILOT		C +	Θ
Gestionar VOD	95		ROSARIO GALÁN DIAZ	65	Spanish Site	PRE-PILOT		C ,	Θ
	96	3	MARÍA BERMÚDEZ MATEO	71	Spanish Site	PRE-PILOT		(C)	Θ
	97	4	CAMELIA PÉREZ HERNÁNDEZ	78	Spanish Site	PRE-PILOT		C	Θ
	Mostranc	lo registros del	1 al 7 de un total de 7 registros (filtrado de un to	otal de 38 reg	istros)			Anterior	Siguiente

Figure 20. Frontend feasibility patients.





Assist Dem	TVASSIST	DEM - Web	Server					v. 1.1.0
	≣ Ɗ							ro-site - Site Manager
Acasa								
Gestioneaza Locatii	Lista Pacie	enti Introducere	e pacient nou					
Sestioneaza Specialisti	Afișează 1	0 v înregistrări pe	pagină				Caută:	
Gestioneaza pacienti	ID IA	AVATAR	NUME	STB 11	LOCATIE	ARATA DATELE	EDITEAZA	STERGE II
Gestioneaza Stimulus	73	۲	Familie Patient F-Patient-11		Romanina Site	Ê	C +	Θ
	126	14	ENE MANDICA	2989	Romanina Site		C +	\bigcirc
	138	8	CAREGIVER CAREGIVER		Romanina Site		C ,	\bigcirc
	140	۲	office romania	2987	Romanina Site		©,	Θ
	145		GHIU CORNEL	2992	Romanina Site		C	\bigcirc
	160	۲	Chelaru Doru	2986	Romanina Site		©.	\bigcirc
	168	۲	Stiubei Elena	2985	Romanina Site		©.	\bigcirc
	169	۲	STANCIU Elena	2994	Romanina Site		C +	Θ
	170		TEST-SHTVS RO Name SHTVS RO Sur		Romanina Site	after	~	-

Figure 21. Frontend feasibility patients in Romania

2.3.3 STIMULUS©

The data and profile picture of the patients was introduced in Stimulus© (Figure 22. Stimulus feasibility patients. And Figure 23. Stimulus feasibility patients in Romania)



Figure 22. Stimulus feasibility patients.







Figure 2310. Stimulus feasibility patients in Romania.

2.3.4 LINPHONE

One Linphone account was created per caregiver, however, some patients demanded more caregiver accounts (Figure 24 Linphone caregiver account.).

linphene	Products	Solutions	Licensing & services	Technical corner	About us	News	» 🛯 ⊠ d
c	Create an account						
U	Jsername *						
	Caregiver						
(t	this will be your SIP usernam	ne)					
P	Password *						
c	Confirm *						
E	i-mail *						
	soporte.tvassistdem@gm	ail.com					

Figure 24 Linphone caregiver account.





2.4 INSTALLATION PROCESS

2.4.1 SPAIN

Technical issues delayed the installation process and were found during follow-up (Table2. Technical issues during follow-up process.)



Table2. Technical issues during follow-up process.

The first two installations found TV tunning problems which were later solved by developers creating a TV tunning file to install in the STB.

Antenna low signal was found during one installation and developers had to provide an antenna amplifier to solve this issue.

Two home's were found to have a low WI-FI signal which prevented the STB to work properly and developers had to provide a WIF-FI signal amplifier to solve this issue.





During the first installations, the system was found not to be compatible with all WI-FI services disabling the videoconference functionality. Developers took some weeks to solve this issue using VPN, for this reason, some patients who had the STB installed and had been trained for its use, could not use it until this issue was solved. However, the VPN solution also led to problems preventing the videoconference follow-up calls.

IBIMA recruited patients with no WI-FI since routers were to be installed when needed, however, internal problems prevented this to happen and only one router was installed. The recruited patient had to wait for the router to be available which delayed the installation and led to the exclusion of other recruited patients.

Linphone services crashed during a videoconference follow-up day, and none of the scheduled videoconference took place.

2.4.2 ROMANIA

In Romania, some technical issues delayed the installation process, as presented in the following table.



Table. Technical issues during follow-up process in Romania.





The most common problem in the installation process was the lack of 2 HDMI jacks so HDMI jack splitters had to be bought. The second most common problem was the length of the HDMI cord so the installation process was postponed at least for a couple of days, time in which we had to search for suitable alternatives. Also, for one of the subjects a wireless internet router was bought to ensure the connectivity during the feasibility study.

After installing the STB, some delays were encountered because of back-and registration issues, such as the subjects couldn't log in on the STB. This technical issue determined one patient to not use the system at full capcacity.

As in Spain, Sc. Îngrijiri la Domiciliu recruited patients with no WI-FI so we had to extend the time allocated for installation.

2.5 FOLLOW-UP PROCESS

2.5.1 SPAIN

Patients were scheduled videoconference calls to do a follow-up on the system usage, to resolve problems and to encourage the use of the different functionalities. Two patients signed an Image Rights Consent Form to allow researchers to take screenshots during the videoconference calls (Screenshot 1. Videoconference follow-up call.)



Screenshot 1. Videoconference follow-up call.

2.5.2 ROMANIA

Also in Romania patients were scheduled videoconference calls to do a follow-up on the system usage, to resolve problems and to encourage the use of the different functionalities but





none of them took pictures during this process. Related to this STB functionality-interactive videoconference, our patients manifested a lack of interest in using it at full capacity.

2.6 END OF STUDY PROCESS

The patients were scheduled a final visit for Phase II one month after the installation visit and Phase I. The patients were interviewed following the Researcher Manual for the Case Report Forms. All patients were offered to keep TV-AssistDem for longer and 4/7 patients in Spain and 2/5 in Romania decided to continue using it once the feasibility study had concluded.

3 FEASIBILITY STUDY

The feasibility study methodology was based on Sheehan & Lucero (2015). PHASE I consisted on a usability evaluation of a one-time introduction to the TV-AssistDem functionalities with professional observation and evaluation for analysis. PHASE II gathered the usage of the system in the participants' home environment during a period of four weeks in the backend and was followed by analysis. Assessment of user satisfaction via interview and completion of the System Usability Scale was carried out to conclude PHASE II of the feasibility study.

The tool "Mantis" was used to report any issues gathered during the pre-pilot study (Figure 11. Reporting issues process.).



Figure 11. Reporting issues process.





Main menu	Patients reported it was user-friendly overall but suggested several changes regarding icons and names of the functionalities Patients specially liked their profile picture				
	1. COGNITIVE STIMULATION				
Name and icon	Change name to "Memory games", patients found it unfamiliar and complex				
Appearance	Include the Stimulus user name Increase the size of the fonts, patients found it too small TRAINING: No issues FREE ACCESS: No issues STATISTICS: Increase the size of the fonts				
Functionality	Simplify the display, patients found it too complex Raise the time limit to perform the exercises, patients reported enjoying the exercises from the "Free access menu" when they selected the option "No time limit", otherwise they felt discomfort and frustration because they did not have enough time to perform the exercise				
	2. VIDEOCONFERENCE				
Name and icon	Change name to "Videocall", patients found it unfamiliar Change icon to a "Telephone", patients found it complex Patients liked the contact list and appreciated having a pre-view of				
Appearance	their camera Include a screen to display when waiting for the videoconference to start				
Functionality	Change ringtone, patients found it disturbing Patients reported to enjoy videoconferencing with their caregivers and the health professional, however there were many connectivity and VPN problems which have prevented the use of this functionality VPN Did not work properly and needed repeatedly remote assistance AUDIO Echo was reported during videoconferences by the professional and user INCOMING CALL The screen would not show the incoming call message but the user could hear the ring tone				
	3. MEASUREMENTS				
Name and icon	Change name to "Health data" and icon to "sphygmomanometer", patients reported them to be unfamiliar and complex				
Appearance	Include data graphically, patients reported they would like to see this type of information displayed in graphs				





Functionality	Readjust minimum/maximum levels of some measurements, patients couldn't insert values out of the pre-set levels Include a "Delete/Edit" option for the measurement inserted Display more than three previous measurements, patients and caregivers reported they would like to view at least the last week or month				
	4. MY HEALTH				
Name and icon Appearance Functionality	Not available during testing time				
Researcher feedback	Patients were asked what information this functionality and researched Image: Distribution of the second	eation they would like to see displayed ers created a possible layout. Patient 13:22 Wednesday, 21 – november - 2018 Contraindications: Unknown. Active prescriptions: • Amitriptiline, 10mg, capsules, oral, 0-0-1 • Diacepam, 5mg, tablets, oral • Tramadol, 50mg, capsules, oral, 1-0-1			

5. HEALTHCARE EDUCATION

Name and icon	No issues			
Appearance	Include infographics with bigger size fonts			
	Patients reported different opinions			
Functionality	Some found depressive the videos of dementia patients			
-	Others found interesting all videos, specially the physical activity one's			
Researcher feedback	Remote management for new content			
6. MY MEMORIES				
Name and icon	No issues			
Appearance	No issues			
Functionality	Patients reported to enjoy viewing the family photographs and videos Remote update of this content was requested by caregivers			
7. CALENDAR AND REMINDERES				
Name and icon	Change the "physical activity" icon to "sport shoes", patients found the baseball player icon unfamiliar			
Appearance	Add event: The default option for the last step should be the "okay" one, not the "cancel" one. Event reminder: Include option of how many minutes/hours/days you want the reminder to appear before the event takes place. Event reminder: Include option daily/weekly reminder.			





	Enable the use of the numbers in the remote control When selecting the day and time on the calendar Patients reported interest in using it for events and caregivers for mood/action tracking		
Functionality	Include when creating an event how many minutes/hours/days the patient wants the reminder to appear before the event takes place Increase the time reminders are displayed on screen		
Reseracher	When creating a "Medication event" enable the selection of the		
feedback	medication available on the frontend/backend		
8. GENERAL INFORMATION			
Name and icon	No issues		
Appearance	No issues		
Functionality	Patients reported this information should be updated frequently with health campaigns		
Reseracher feedback	Remote management for new content		

	SET-TOP-BOX SERVICES		
	REMOTE CONTROL		
	The HOME and BACK button are small and visually difficult		
	to see (black and blue).		
	The OKAY button being blue is confusing since the BLUE		
RED	button on the bottom right of the remote is blue and there is a		
	blue INTERNET button.		
	The option of using the RED button on the remote to go		
	back to the TV is confusing with the red TV button.		
	The QWERTY KEYBOARD buttons are small.		
	1 ran out of batteries and another one desynchronized with the		
	dongle		
	ANTENNA SIGNAL		
	TV tunning problems during first installations		
	1 STB gave a bad TV signal, the patient reported the image		
IBIMA	and audio of the TV was poor and disconnected the STB		
	watching the TV without the STB service.		
	MEDIA STORAGE		
	When uploading picture files an error due to "FULL MEMORY"		
	appeared and the "My memories" functionality would not work		
STB – BACKEND - FRONTEND			
	Measures recorded in the STB interface by one caregiver were		
	not be displayed in the frontend.		
	Events recorded in the frontend were not displayed in the STB		
IBIMA	interface.		
	The connection between STB and backend services crashed		
	and there was information not being displayed in the STB		
	interface		





	Contacts inserted in a patient contact list in the frontend were not displayed in the STB interface
ILD	Measures and events recorded in the STB interface by caregiver or patient were not being displayed in the frontend.
	Error in inserting new patients information and caregivers contact
	The application interactive videoconference crushed several times during the usage

FRONTEND INTERFACE			
	Translations in Spanish needed		
	Include in Home menu "STB usage statistics" so that the researcher can do a follow up and detect users which may need encouragement videoconference calls.		
IBIMA	Combine the process of "insert a patient", "insert a medication" "insert measures", "insert a caregiver" and "manage videoconference".		
	Include "STB number"		
	Include "Edit" option for medications and events created.		
	Errors reported: "500 Internal Server Error", "404 Not Found"		
	Several translations in Romanian needed		
	Errors reported: "500 Internal Server Error", "404 Not Found"		
ILD	Include "Edit" option for medications and events created.		
	Include a password in section "Log In" and "Log out"		

EXTERNAL SERVICES

STIMULUS

Two different management sites were requested for each research site **LINPHONE** Services crashed "fail to register" and "error I/O"

Table 3. Functionality access.





4 CONCLUSIONS

The pre-pilot has allowed researchers to identify the tasks needed during the clinical trial and estimate the effort in hours per research site (Table 4. Effort in hours estimated for the clinical trial per research site.)

TASK	DETAILS	HOURS/PATIENT	CONTROL GROUP	INTERVENTION GROUP	TOTAL
TELEPHONE CALL	Check inclusion/exclusion criteria Schedule Visit 0	0,05	60	60	6
VISIT 0 + VISIT 1	Screening, Participant information sheet, Assessment of capacity to consent, Patient and caregiver consent forms, Patient and caregiver case report forms	1	60	60	120
MEDICAL RECORDS	Comprobar datos clínicos: comorbilidades, medicación y uso de recursos	0,25	60	60	30
FRONTEND	Register patient and caregiver information and photographs	0,25	0	60	15
EXCEL DATA	Transcribe data from visit 0 and visit 1	0,25	60	60	30
STIMULUS	Register user and upload patient photograph	0,10	0	60	6
TEST STB	Check installation material Check STB inferface: user name and photograph, Stimulus account, videoconference contact list, welcome message on calendar and test functionalities	0,5	0	60	30
INSTALLATION	Go to patient's home, STB installation and training session	3	0	60	180
	TOTAL	5,4	60	60	417

Table 4. Effort in hours estimated for the clinical trial per research site.

The pre-pilot results allow the consortium to foresee anticipated challenges for the clinical trial: technological exclusion during recruitment, high effort of hours/patient for the processes needed, connectivity problems and poor engagement.

The extensive penetration of cable TV in Spain and Romania will restrict the clinical setup. Developers have not been able to offer cable TV compatible STB due to financial budget restrictions. In order to face this limitation, Spain has broadened the recruitment centres (Figure 12. Spanish recruitment reinforcement.).







Figure 12. Spanish recruitment reinforcement.

Also, the internal problem faced by IBIMA during the pre-pilot to provide the routers for those patients without WIFI needs to be solved for the clinical trial.

Taking into consideration the due date of the project and the delay the clinical trial faces, the researcher sites must consider the effort in hours estimated per patient and assure enough researchers to meet the recruitment needs in the expected time.

Wireless or phone network connectivity problems will limit the TV-AssistDem use on a daily basis. Developers will have to handle connectivity problems to guarantee the system offers a continuous and high-quality experience.

Out of the four barriers for engagement expected; patient sensorial and/or psychomotor impairment, patient illiteracy, patient cognitive and functional decline and patient negative attitudes and views towards ICTs, the most frequent one's during the pre-pilot have been the two latter ones. Researchers will face poor engagement by guaranteeing videoconferencing solutions for guidance, support, and encouragement for each participating home, however, the videoconference functionality must be stable so that connectivity problems do not result in further disengagement.

Patients have not reported perceiving the platform as too intrusive or invasive, however, socially and physically active patients have reported the system as time-consuming.





