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"CARELINK for Dementia suffers and their community"

Deliverable D4.3

Final Trial Evaluation Report

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Partner	Country	National Funding Body	Logo
WATERFORD INSTITUTE OF TECHNOLOGY (WIT)	IRELAND	ENTERPRISE IRELAND	ENTERPRISE IRELAND
INSTITUTO DE DESENVOLVIMENTO DE NOVAS TECNOLOGIAS (UNINOVA)	PORTUGAL	FUNDAÇÃO PARA A CIÊNCIA E A TECNOLOGIA	FCT Fundação para a Ciência e a Tecnologia MINISTÉRIO DA CIÊNCIA, TECNOLOGIA E ENSINO SUPERIOR
U-SENTRIC	BELGIUM	IWT AGENTSCHAP VOOR INNOVATIE DOOR WETENSCHAP EN TECHNOLOGIE	iwt
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CARELINK Project Profile

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Twitter	@Carelink_AAL
LinkedIn Group	Carelink
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Partners

TSSG	WATERFORD INSTITUTE OF TECHNOLOGY (WIT) - [COORDINATOR]	IRELAND
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CREAGY	CREAGY AG (CRE)	SWITZERLAND

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Document Control

This deliverable is the responsibility of the Work Package Leader. It is subject to internal review and formal authorisation procedures in line with ISO 9001 international quality standard procedures.

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Executive Summary

Objectives

This deliverable presents the planning for the field trials as well as an evaluation report including recommendations for the further development of the Carelink solution before exploitation.

The field testing of the Carelink system by potential end-users is an integral aspect of the co-designing approach in the project. In general, the document defines the scope of the pilot studies by first identifying key research objectives, secondly describing the methodology for gaining user insights, thirdly the participants the consortium has participated in the pilot studies, and fourthly, the test results per country to show whether there are country-specific differences, and finally a summary.

Results

This document addresses various questions related to ethical issues, to the test procedure and particular user experiences and data security.

The step-by-step three step test approach was very helpful and supportive. Important insights came from the first two test levels. They made it possible for project developers to continuously improve the product and the platform towards market maturity so that the solution could be tested with field trial participants.

Thanks to UNINOVA who provided two different boards offering different technologies for the devices, the project was able to successfully carry out the field tests, as there was a back-up connectivity solution in places with geographical connection problems.

The results are published in detail in this report together with suggestions and recommendations for improvements which were compiled from the feedback of the end users and the project team.

The overall solution based on latest technology and the idea of using everyday end user devices and end-user tools like mobile phones and internet is operational, usable and unique.

Enhancements are necessary in the area of GPS data tracking (tracking per time slot). Battery lifetime between two charging cycles is the critical point to make progress in the further product development. Due to the fact that we were trialling with new network technologies we came across some connectivity and coverage issues, but it is expected that as these network technologies will mature and become more stable, powerful and readily available.

The platform could make the interface available to other devices and open up new business opportunities with this next step.

Only the last route and the current position of the Person with Dementia (PwD) are important information for the Caregiver (CG).

Overall the solution was very well received by the participants in the field trial. With regards to the platform and interfaces the majority liked the ease of setup and use, which is based on non-proprietary technology (internet application instead of mobile app download, cell phone, SMS, link

to an internet map). There was general acceptance of the devices, however there was a consensus that some fine-tuning and miniaturising of devices would be better for a marketable product

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1 INTRODUCTION

Well-planned user trials are key for successful product development and ultimately also for market launch. Special pilot trials help to identify current flaws of the system, benefits and creative ideas for additional aspects to be implemented in the technology. The user trials of Carelink will explore the proper usability and the accessibility of the system from a point of view of caregivers and People with Dementia (PwD).

This document presents the approach of the field trials. The results are examined and summarized and provided to the product developers.

This deliverable is structured as follows; in the next section scope of the studies will be elaborated upon in detail. The main research objectives, aspects of methodology to efficiently assess end-user feedback, and the system components available for the field trial are described and the results and feedbacks of the test participants are evaluated. Quantitative and qualitative results as well as recommendations and proposals for enhancements are part of the evaluation section.

2 ABBREVIATIONS AND ACRONYMS

Abbreviation	Description
PwD	People with Dementia
CG	Care Giver
SUS	System Usability Scale
UTAUT	Unified Theory of Acceptance and Use of Technology
MMSE	Mini-Mental State Examination
EKOS	Ethikkommission Ostschweiz (Ethic Commission Switzerland East)
HRA	Federal Act on Research involving Human Beings
FADP	Federal Act on Data Protection
GDPR	General Data Protection Regulation
eurec	European Network of Research Ehtics Committees

3 SCOPE OF THE FIELD TRIALS AND RESEARCH DESIGN

3.1 Time, duration and place

The consortium had made a clear distinction between software and hardware testing and field trials. The software and hardware testing had been carried out at the development sites with specific software and hardware test teams before it was tested by the users. Software and hardware testing ensured that the system worked according to the documented requirements and specifications (D2.1 and D4.1). The pre-tests ensured that all the specified functionalities had been available and no technical defects and bugs as well as no performance and speed problems had been detected. Successful software and hardware testing exercises were a prerequisite for any field trials, because end users time and goodwill are very precious - there is no value to let real end users find obvious problems and bugs in the service. Software and hardware testing focused on the functionality whereas the field trials focused on usability, accessibility and user satisfaction. Nevertheless, technical problems couldn´t be excluded during the execution of the field trials and had been reported to the technical side for further improvement of the offered solution.

The testing was split into two study circles, which allowed concrete recommendations for improvement of Carelink to the consortium and which was flexible enough to react to unforeseen circumstances in terms of technology handling and usability.

The first test trial had been executed in two countries (Switzerland and Ireland) in September/October 2019. At this point, a group of caregivers had been involved in order to test the features, the characteristics and the interface of the devices and the platform. Five end-user households (five couples / 10 persons) in each country for a fixed time span of one week had tested the devices in interaction with the software platform. The goal was to gather meaningful insights on the platform's usability and user satisfaction. The participants' feedback had been used to further advance the development of the platform system especially the wearable devices for the field trials.

The second set of trials were expected to be executed in three countries (Switzerland, Ireland, Portugal) from October until December 2019. At this point, we planned to involve caregivers together with their care participants for a fixed time span of six weeks in order to test the modified features, the characteristics and the interface of the platform as well as its interaction with the sensor tag suite. Due to delays in hardware development the solution was not available to fully carry out these tests until early 2020, after which the Covid-19 situation began arising in Europe. As there were different approaches taken by each country's government it was not possible to carry out these user trials with PwD in either Ireland or Portugal. However, we did manage to trial with users in Switzerland. The system was evaluated in ten end-user households and/or care institutions in Switzerland and was demonstrated to carers in Portugal and Ireland in order to get their feedback. After the testing phase, feedback had been gathered for the final evaluation of the system. The goal

was to gather meaningful insights on the system's' usability and user satisfaction. The participants' feedback was then used to make recommendations and proposals how to further advance the development of the platform system.

3.2 Research objectives

3.2.1 Purpose

The central research objective of the trials focused on usability, accessibility, and user satisfaction. The pilot studies allowed us to receive direct inputs from the end users in order to analyse the ease of use, the general satisfaction with the system and to detect real errors and hints in the developed components and prototypes of the Carelink solution or misunderstandings in the product or interface design.

Consequently, concrete recommendations for improvement of the Carelink system had been the output of these test phases.

The full evaluation results with all details are published in chapter 4 in order to gain insights on user experience, product adoption, usability and accessibility, market relevance etc. and conclusions and recommendations will be given in chapter 5 so that the prototype can be further improved to become a market ready product.

3.2.2 Outcomes

Primary outcomes of the field trials were:

- Acceptability of the system by the (cared) – PwD - and the informal/formal caregivers
- Usability of the system by the (cared – PwD - and the informal/formal caregivers
- User satisfaction of the system by the (cared – PwD - and the informal/formal caregivers

Results of qualitative terms of the field trials were:

- Reduction of caregiver burden through the use of the electronic attendants
- Improvement of the quality of work, and stress reduction, of the formal caregivers as workload may be reduced given that they are now getting a warning if their PwD wanders
- Improvement/stability of the quality of life of the cared person

3.3 Methodology

3.3.1 General research design

The field trials were conducted as an exploratory study as user-centred interaction design to evaluate the Carelink system by testing it on users, with a before and after design. The field trials had been small-scale studies, conducted mainly to control whether and how the developed services are perceived useful and useable. It was out of the scope of this study to afford in-depth evaluations of the efficacy of the system due to: (a) the small sample size, linked to the resources available in the project (b) the same study was conceived as merely a pilot study of components and prototypes of the offered solution. To reach the objectives of the field trials, both quantitative and qualitative methods were used to have clear and comparable information on the usability, accessibility and user satisfaction of the Carelink system.

For the first pilot study, insights and feedback from the participants had been collected between and after the trial using a combination of standardized and individualized questionnaires. The participants had been contacted once a week in order to receive constant feedback. A couple of interposed questions had been asked and it gave the test teams the opportunity to support the user test community. The focus of the evaluation was on preliminary satisfaction with the platform and potential problems of usage. With this focus we showed our continued availability and problems identified by the study participants, which were linked to the usability and accessibility of the system, could be analysed easily.

Separate questionnaires had been elaborated for caregivers and assisted people. All questionnaires ensured the data collection of all relevant aspects and made it possible to analyse changes during the test period. All questionnaires were created by the end user group in collaboration with the technical side. In addition to other especially designed questions, all questionnaires received the validated System Usability Scale (SUS) (Brooke 1996) as well as the Questionnaire on Technology Acceptance based on the Unified Theory of Acceptance and Use of Technology (UTAUT) (Venkatesh et al., 2003).

The System Usability Scale (SUS) is a reliable tool for measuring usability. It consists of at least a 10-item questionnaire with five response options for respondents, from "Strongly agree" to "Strongly disagree". It allows for evaluation of a wide variety of products and services, including hardware, software, mobile devices, websites and applications. It is easy to administer to participants and can be used on small sample sizes with reliable results and can effectively differentiate between usable and unusable systems.

The Questionnaire on Technology Acceptance is based on the Unified Theory of Acceptance and Use of Technology (UTAUT, Venkatesh et al., 2003). The aim of the authors was to build a reliable instrument for the measurement of technology acceptance starting from UTAUT model and constructs. The 41-items of the questionnaire derived from the UTAUT core constructs, such as anxiety, attitude, facilitating condition, intention to use, perceived adaptability, perceived enjoyment, perceived ease of use, perceived sociability, perceived usefulness, social influence, social presence, trust, use/usage.

The findings from the pilot studies had been used to suggest changes and improvements for the service that the development partners can implement in the next development iterations. Due to the delays in receiving hardware from chip manufacturers, which then had to be optimised for the Carelink solution we were behind in our schedule for the initial trials. These delays squeezed the timeframe between trials and unfortunately due to the high time pressure for testing there was not sufficient time to fully implement new features, such as route prediction, between the pre-test and field test. While we did build route prediction, and tested it with synthetic data, it was not fully implemented enough to standard suitable for use in user trials.

As described in deliverable D4.2 different test scenarios had been used in the test task. To ensure that the system is properly working when the project goes into field tests with PwDs two different phases has been run upfront. The results and findings of these phases showed the project the level of usability and functionality of the whole system (software, hardware, user interface) and had been very useful to guarantee an acceptable level of quality for the field test.

3.3.2 Inhouse test

Each development partner ran their own inhouse tests to be sure that their part of the overall solution will run properly as an independent system. In a second step the interfaces had been tested between the independent systems and as final inhouse test phase the end-to-end connectivity was executed.

Already at this stage, the project realized that the major challenge will be the wireless communication in all countries involved in the project. The usage of the state of art technology limited the communication coverage in the different countries and led to the decision to develop a new device board based on different (older) broadband technology in order to ensure field tests in areas which had not been covered with the latest LTE-NB network technology. Addressing these mobile network issues took time as we had, in some cases, to deal with the network providers (Vodafone) to debug communication issues and the fact that we were not the priority business of the carrier meant we were always in a holding pattern. This type of problem resolution was not factored into our schedule and ate into our deliver schedule.

3.3.3 Pre test

Before running the field tests with PwDs it was essential to gain experience with the stability and the handling of the solution outside the lab environment. It gave us the chance to test the whole setup and execution procedure including all necessary documentation i.e. consent form and the case report form.

Each country ran such tests with five couples/pairs for at least one week. The main benefit of this stage was to get first feedbacks from elderly users of the Carelink solution which had not been involved in the whole project development in either phase before (including specifications of user requirements).

It also gave us a first impression whether the project would achieve viable and valuable results for the expected outcomes (see 3.2.2). The results showed that the quality of the prepared trace-documents is sufficient and doesn't need changes for the field test phase.

3.3.4 Field test

After successful desk-, inhouse- and pre-tests the field tests had been launched in two countries in parallel: Switzerland and Ireland. Portugal as third test country could only start with their tests after completion of the field tests in Switzerland or Ireland because not enough devices had been available for all three countries in parallel. Due to the availability of devices from the manufacturer, the lead time involved in sourcing and then the adapting of the hardware to suit the Carelink solution it was decided to take this parallel trial approach. That was no problem in general the only disadvantage was the extended test period which affected the overall project deadline.

Due to the Corona pandemic and the governmental lockdown the field test in Ireland and Portugal had to be interrupted. Within Ireland and Portugal the severity of the restrictions prohibited engagement with elder citizens or visits to care homes, and as such we were in no position to trial in these countries. Switzerland was lucky to close the field test just in time as planned. Only the final task 'interview with CG and PwD' had to be cancelled. This task was replaced by an interview with the CG by phone. In Ireland and Portugal, we delayed as long as possible, and when the opportunity arose, we were able to carry out demonstrations of the Carelink solution to carers and medical practitioners. This is not the full trials that we desired, but felt it was a good alternative as we were speaking with people that are close to the problem.

3.4 Participants

3.4.1 Inclusion and exclusion criteria

For the first set of trials, participants in two countries had been recruited who were willing to test the features, characters and the interface of the first prototype of the platform.

The consortium targeted caregivers with at least minor technological affinity to be able to use the system. It was no problem to handle the system and didn't require major exclusion criteria. Voluntary participants who took on the role of caregivers, however, must fulfil the following inclusion criteria to test the system at home:

- living independently in a private household or in a care home
- (former, current or potential) formal or informal caregiver
- some technological affinity
- availability of time for the evaluation

Exclusion criteria:

- lack of informed consent
- unavailability of time

For the second set of trials (field test), participants in three countries had to be recruited who were willing to test the features, characters and the interface of the modified prototype of the platform as well as its interaction with the device.

The trial plans for each country involved ten caregivers together with people who need assistance. The consortium targets caregivers with at least minor technological affinity to be able to use the system. It was expected that handling of the system will not require major exclusion criteria. Voluntary participants who took on the role of caregivers, however, must fulfil the following inclusion criteria to test the system at home or in a care institution:

- living independently in a private household or work in a care home
- formal or informal caregiver
- some technological affinity
- currently or potentially taking care of one or more person(s) who needs assistance involved in the trail
- availability of time for the evaluation

Exclusion criteria:

- lack of informed consent
- unavailability of time

The (cared) person must fulfil the following inclusion criteria to test the system at home or in a care institution:

- needs assistance from Carelink solution
- living in ordinary housing; and caregiver involved in the trial cohabiting or living close by; or living in a care home
- stable medical condition
- availability of time for the evaluation

Exclusion criteria:

- lack of informed consent
- unstable medical condition
- unavailability of time

3.4.2 Recruitment and participants Switzerland

Akademie Berlingen recruited the participants through elderly homes, memory clinics, Alzheimer Associations, "Alzheimer Cafè" groups, care organisations as well as through personal contacts. In Switzerland, participants had mainly been recruited from Akademie Berlingen's network among older adults living independently as well as from its network of care institutions. The Academy has access to a huge network of private households (more than 2000 affiliated addresses) with people in the age group 60+ as well as to more than 600 care institutions all over Switzerland. Concretely, people were recruited by newsletter publications, phone calls, emails and onsite recruiting talks.

Finally, we carried out the trials in Switzerland in the following PwD composition:

Sex		**MMSE score**				**Age**	
F	*M*	*Questionably significant*	*Mild*	*Moderate*	*Severe*	*60-80 years*	*81 – 100 years*
5	**5**		**5**	**5**		**5**	**5**

3.4.3 Recruitment and participants Ireland

In Ireland, recruitment of participants was made through expressions of interest and publicising the results of the project, with an invite for collaborators to get in touch.

Expressions of interest were received from carers both at an informal and formal level, as well as elderly care homes of the general kind and specific to Alzheimer's.

Due to the situation that arose out of covid-19 and the restrictions of external people engaging with elderly care homes, we were not in a position to carry out the desired field trials. As an alternative to this we again approached individuals to give demonstrations of the overall system, setting up users, PwD and then creating locally based restricted safe zones, and gave a demo of the use of the platform if a device was brought outside such a safe zone. This gave the overview of actually using the system, without engaging with the vulnerable community.

3.4.4 Recruitment and participants Portugal

In Portugal, the recruitment of participants was made with a collaboration with *Associação Alzheimer Portugal*, the major institution operating in the country.

Through *Alzheimer Portugal*, a communication was distributed to multiple regional and local branches, in order to maximize the outreach for interested participants. One of these local branches was *Casa do Alecrim*, a care home for elderly Alzheimer's patients, which initially produced 4 interested pairs of participants, and also from the institution personnel as well. Unfortunately, 3 pairs where rejected due to low mobility and the 4th declined to participate after being informed about the trial processes, due to the added difficulty of the carer with the daily task of charging the insole. The institution personnel were interested in testing a solution for indoor localization since they have restricted areas that some patients are not allowed to enter. However, since all the patients are already in an advanced state of dementia, have very limited mobility and are confined to the facility grounds, none were in a position that could be fit for the tests.

Additionally, an elderly care home serving 2000+ beneficiaries, *Santa Casa da Misericórdia de Alenquer*, was also in the process of collaborating with interested participants for the trials, but on the week that the in person meeting was going to take place, restriction rules due to covid-19 forbid any and all access to care homes across the country, followed by movement restrictions for non-emergency personnel.

Due to covid-19 imposed restrictions (such as the declaration of the state of emergency) all attempts to carry out the trials were invalidated and therefore suspended.

In order to obtain further validation of the feedback, received from the specialist during the aforementioned meetings (with Alzheimer Portugal and Casa do Alecrim), an additional online interview was conducted, with a Specialist involved with carers and Alzheimer's Café.

3.5 Available System Components and Features

3.5.1 Deployed Equipment Switzerland

There had been five devices available for inhouse tests; three Pycom boards and two Sodaq Boards. The first connection tests with the Swisscom LTE-NB network out of Berlingen (close to lake of Constance) showed the insufficient coverage of this technology in this region. At the initial stages when setting out the technologies we were informed by Swisscom that there would be no issues, but we subsequently found out that there was indeed a coverage issue and we had to work around this. After much to-and-fro and clarification with the network specialists from Swisscom, Uninova decided to redevelop new Pycom boards with access to LoRa as fall back technology. After reassembling all devices, the inhouse tests started with all ten devices.

Database and user interface functionalities had been tested inhouse as well. After some minor adjustments to address any errors the in-house testing identified, the process tests could be initialized. The results achieved led to enhancements of optimized PC/user interaction. Additionally, this phase gave us our first real-time results for battery usage and battery time available between charging cycles. We knew from discussions with test prospects that battery usage time is a key factor for the acceptance of the whole system, and not only the devices.

Another unforeseen task/service was to lend mobile phones to the care givers together with the devices because we didn't know at the start of the project that quite a lot of homes for elderly people have banned their employees to use private mobile phones at the workplace due to an incident in a senior home in Switzerland about two years ago.

3.5.2 Deployed Equipment Ireland

In Ireland we had the same devices as Switzerland and Portugal (5 Pycom boards and 5 Sodaq boards). We arranged IoT-Narrowband network coverage with Vodafone-Ireland for the duration of the trials, free of charge, as Vodafone-Ireland are interested in building relationships with research groups in Ireland to assist in the trials of such services for the community.

3.5.3 Deployed Equipment Portugal

The equipment to be deployed in Portugal consisted in the same number of devices as Switzerland and Ireland (10 total), with 5 composed by Pycom boards and 5 by Sodaq boards. The IoT-Narrowband network coverage was provided by a protocol with Altice Portugal (for the 10 devices). Additionally a LoRa node was also implemented at the research site, providing access to *The Things Network (TTN)*, an open collaborative LoRaWAN community, that enabled the use of the *TTN* services and APIs.

3.5.4 Installation procedure

With the web-based approach for CG and PwD administration it was a big advantage compared to other solutions on the market that there was no software distribution or app download onto the mobile phone necessary. This made the whole setup procedure very easy to handle. The trickiest thing was to implement the micro SIM card into the devices, but this should be simplified until market maturity of the device.

Only a few PwD and CG data had to be entered on the platform once before the system was ready to use. Our Carelink solution User Manual can be used to guide the users on how to navigate through this process.

Screens in local language (multilingual) had been very supportive and made it easy for the user to navigate on the screen.

3.6 Ethical issues

Ethical issues had been addressed nationally by each project partner with their corresponding organization. Basis for all parties were the eurec statute and the national legislation and regulations. All project partners who carried out the field test in their country met the legal requirements with regard to medical questions and the handling and protection of personal data.

3.6.1 Informed consent and involvement of the ethics committees

3.6.1.1 Switzerland

The Federal Act on Research involving Human Beings (HRA) does not need to be applied for this AAL project, according to ECOS. Therefore, there was no need to go through a complete ethics approval process for Switzerland. According to EKOS, the planned field trials are part of an early stage of knowledge acquisition that cannot be summarized under the term "science" of the HRA. The Federal Act on Data Protection (FADP) had to be taken into account.

The formal approval for pre-test and field test was granted by EKOS based on submitted documents which were 'informed consent' and 'case report form'. These documents served as a template for the other test partners to get the approval from their national bodies. This approach saved time and ensured comparability of the test results between the three countries.

3.6.1.2 Ireland

In Ireland, due to the approach we were taking and that these trials were seen as functional, as opposed to medical we were given approval to carry on. In order to achieve this approval, the project had to be presented to an ethical board of directors who then make a decision based on the application and submission of documents – which included the Consent Form as prepared for the project by Akademie-Berlingen. It has to be noted that 'consent forms' were a pre-condition of this approval, and the appropriate data security measures were being enforced.

3.6.1.1 Portugal

In Portugal, *Associação Alzheimer Portugal* helped review the legal requirements and concluded that the trials don't require approval of an ethics board due to the non-medical nature of the procedures. The previous acceptance of the Swiss trials helped confirming that the appropriate measures were in place to safeguard the participants, the caregivers and the partners. Both the people with dementia and their carers are required to read, understand and consent with the Participant Information and Informed Consent documents before being admitted in the trial.

3.6.2. Monitoring and support during the trials

Regular communication and monitoring of participants were key during the trial period; special attention had been put on informing the users upfront that they are testing a prototype and not a market-ready product. This ensured highly qualitative feedback and reduced the potentially too high expectations of trial participants. In each country, there was one project team member to assist in queries and support the CGs and PwDs in daily usage/operation.

3.6.1.1 Switzerland

Main initial and support services to participants of field trials in Switzerland were :

- We talked to potential participants a few weeks before starting the field trial and informed them of the aim and procedure of the test. We explained how important their contribution to this test is and what they can benefit from.
- A personal conversation with potential trail participants (not over the phone) had been key to participation
- A clear and simple information about start, duration, tasks/duties during test phase and completion of trial period was important and gave confidence
- Regular call/support for care givers the feeling of not being left alone
- We also eexplained in detail what personal data will be used for, how will it be stored and what will happen with this data after finishing the trial period
- At the end of the field trial, we took time for the interview and the questionnaire. Unfortunately, due to the Corona Pandemic we only could have an interview with the CGs via telephone

- In this interview, we promised the CGs to inform them of final test results, findings and further steps

3.6.1.2 Ireland

Due to covid-19 emergency situation in Ireland and the protective measures put in place by the government no trials were able to take place with vulnerable patients. Due to restrictions from covid-19, no personal communication/monitoring with the Alzheimer's, or even elderly, participants could take place. As an alternative, and as agreed with the Irish funding organization and the AAL board, we demonstrated the Carelink solution, including the front-end application, devices and safety zones to a smaller set of carers and practitioners.

3.6.1.3 Portugal

Due to covid-19 emergency situation no trials were able to take place. Due to restrictions from covid-19, no personal communication/monitoring with the participants would have been possible.

3.6.2 Data storage and data protection

All information relating to the participants had been collected with the proper measure to guarantee their confidentiality and with respect to the data protection laws. All personal data was kept separated from the results from questionnaires. The informed consent was kept locked in a safe place at the test partners offices. The consortium took into consideration the Helsinki Declaration for research and the legal regulations for privacy and personal data protection. All gathered data was anonymized. No names or personal documents had been shared between the partners. Only the research team of each organisation had access to this data in order to secure participants' identification. Before a participant took part in the field trial, she or he got informed about the data protection and the anonymity of his data. Based on the current EU GDPR (General Data Protection Regulation) in force, each organisation complied with its national legislation on privacy issues and data protection.

3.6.3 Expected and effective risks

We didn't expect any negative effect on the users from use of Carelink services. The researchers provided clear and detailed information about the terms of use of Carelink services offered during the pilot studies. We did not expect any negative effect on the health of users, social participation or other personal dimensions for use of Carelink services. Users who took part in the studies would have no direct costs related to the use of Carelink services.

None of these fears occurred and also no unforeseen risks occurred either.

3.6.4 Exits during test phase

The users had been informed about the duration of the studies in order to ensure that they were aware of the timeframe availability of our system. This ensured that participants were fully aware that this is a trial period, and not a system that is available to them long-term. After the end of the trial period, the users had been asked to return the Carelink devices. All organizations involved in the trials got in touch with the participants sufficiently prior to the de-installation of the system to make the users aware of the removal. This procedure ensured that the end of the trial and the removal of devices/solution was not a surprise to the participants, and they had the chance to mentally adapt to the upcoming situation of the trial close. The length of the trial was also communicated in the recruitment phase. Problems linked to the removal of the system had been considered carefully. In cases, where the end-user participant was uncomfortable with the system, the trail was ended immediately.

In Switzerland two couple (CG and PwD) exited after four weeks. In both cases CGs asked to exit from field trial and return the devices because their PwDs always refused to wear the device even they had signed the informed consent. Learnings and suggestions for future developments will be explained in chapter 4 Evaluation.

4 EVALUATION

The field trials were severely impacted by the corona pandemic. In Switzerland the field trials started at the end of January 2020 and could be completed at the start of the state pandemic campaigns 'stay at home' and 'social distancing'; this was exactly the period of six weeks field trial.

In Portugal and Ireland, the project teams planned to start their field trials by mid of March 2020. Due to the pandemic state campaigns in their countries they had to stop the field trial task with no end user engagement permitted. In the second week of March, European countries were in the early stages of their first implementations of lockdown.

Most of our findings and outcomes are based on feedbacks and comments from the CGs. It was difficult to get useful and detailed feedbacks and comments from the PwDs. It would not be expedient for the project if marketable services would be further developed on basis of the feedback from PwDs with mild or moderate MMSE scores. All CGs said their PwDs are unable to respond to our questions in meaningful way, nor would they have a self-determined opinion on how to use the device. We are relying on the informed decision of the caregiver to give their opinions and how the solution is perceived and will work in their situation.

4.1 Person with Dementia (PwD)

4.1.1 Devices and general impression Switzerland

Due to the fact that five of the field trial PwDs were rated MMSE 'moderate' it was hardly possible to have questionnaire rated by them and to conduct a discussion to deepen the ratings. So, the findings and comments below is the outcome and feedback of the other five field test participants.

The overall satisfaction with the device was rated 'neutral'. For the PwDs is it difficult to understand why they should wear such a device. They listen to all the explanations but forget everything in the next minute. Normally they signed the letter of acceptance in the presence of their legal assistant or the legal assistant signed for them.

To evaluate the device was as well quite complex for them; one PwD destroyed the device because after a few test days he didn't remember why it should be worn and he threw it away. One of the insole devices was broken after about four weeks of testing. This PwD went for a walk every day and had always the insole in his shoes. In summary, due to the nature of the participants, there was limited feedback about the form or material of the device, and we have to rely on the feedback from the caregiver in this situation.

None of the PwDs had been able to charge the device independently; they always had forgotten to charge them if the CG hadn't done the job. Therefore, there was no feedback from the PwDs about handling of device charging or the battery lifetime between two charging circles. However, it is an issue that needs to be considered in further development towards a marketable solution

Overall the outcome of these questionnaires and interviews was very modest but the CGs told me that all assessments or answers to the questions are very spontaneous and arbitrary.

4.1.2 Devices and general impression Ireland

Due to covid-19 rules in Ireland, and the cohort of participants that we wished to trial with, no persons with dementia were allowed to trial the devices.

4.1.3 Devices and general impression Portugal

Due to covid-19 no people with dementia were able to trial the devices.

4.2 Care Giver (CG)

4.2.1 Platform

Under the term 'platform' the project covered all aspects of setup functions to open and enter the base data for new carelink users (PwD and CG). Entering and maintaining the user data is key for the acceptance of the overall system before the devices and the carelink functionality can be used. Especially considering that the platform user interface is not often used by the CG, it has to be simple and self-explanatory.

4.2.1.1 Switzerland

All CGs evaluated registration and data entering as very simple and self-explanatory. Some had difficulties to draw and specify or to change the safe/unsafe zone of the PwD but all of them could enter the data and specify the zones finally.

Sequence and process of entering PwD data could be optimized as well. Even full address is already entered the system is not able to display the correct location in the map. CG has to enter the location name once again and scroll up and down on the screen map until he can click the position.

If he wants to specify the zones afterwards the system doesn't display the map of the already entered location. CG has to type in the location name once again. This process/functionality must be designed and implemented more user-friendly.

The alerting service was evaluated as very helpful and supportive, but at times was hampered by network issues causing the message to be delayed or in some cases not being received

The application in general and its functionalities as well as the UIs had been evaluated as user-friendly, self-explanatory and as clear.

Font size, font colour, font type as well as buttons are well readable. Dialogs, user guidance, interactions and process designs seem to be intuitive and self-explanatory for the CGs.

4.2.1.2 Ireland

In Ireland caregivers were given demonstrations of the Carelink solution and asked to comment based on this demo. Overall impressions were that the caregivers were very impressed with the solution and the service that it provides. The Carelink interface was generally found to be simple and easy to use and carers could not have difficulties using the interface. It was however pointed out by one of the caregivers that a user manual was a big help with setting up the PwD and linking to devices, due to their current technology knowledge limitations. Another point that raised interesting questions was that of data security and following GDPR guidelines. While it was understood that rules would need to be followed, there was also a general feeling that at certain stages the safety of the individual would surpass the need for GDPR compliance. When dealing with relatives or PwD under their care that may have a wandering problem, then they are of the opinion that the safety of the individual must be the primary concern, and in these cases the data privacy is a secondary concern.

4.2.1.1 Portugal

One caregiver that was interested in participating (but that ended up withdrawing) commented on the absence of enabling more than one telephone number, responsible for the same person with dementia, on the platform. Therefore, only one caregiver could be responsible for the PwD. Additionally, there was a second point that was the fact that as the primary caregiver did not have access to a Smartphone, the alert system issued by the platform would not bring him any advantage.

4.2.2 Devices and general impression Switzerland

User satisfaction had a wide spread of ratings. The satisfaction ratings had a regular distribution between unsatisfied and very satisfied. These unsatisfactory votes may have been a result of the problems that occurred on devices coming from a certain manufacturer, and this would have influenced their decision However, it has to be noted that no CG was very unsatisfied with the PwD device.

User-friendliness of the device was perceived average to rather high by all CGs. That's quite remarkable because we have to consider that even though some of the devices did not work properly the CGs rated them positive and appropriate. They like the idea of the technical setup for the Carelink solution using common general technology like mobile phones, local sim cards, SMS , internet links and internet maps as well as base data collection via common user interface with well recognised tools, such as maps. From their viewpoint this is a big advantage compared to other services available in the market which normally are based on proprietary platforms.

It was quite useful to have two different types of devices. At the initial meetings for the field test most of the CGs and PwDs wanted to use the insole device. They found the idea quite interesting and had never seen or experienced such a device type for similar solutions or products. It was tricky to convince test persons that a belt clip offers the same services and are suitable as well.

Feedbacks after the test cycle were somewhat sobering. The insole device didn't disturb emotionally too much or made walking difficult, but the device is, as currently designed, still too tall at the heel. The test participants mentioned that they would prefer no taller insole than a normal insole, which would mean

that the board and the battery had to be built-in the insole. There are ongoing discussions with a shoe manufacturer to implement this solution into their brand. Several feedbacks mentioned that they would need two or more devices for the same PwD because it could happen that the insole is in a pair of shoes but the PwD runs off in slippers.

Belt clips had been rated much higher after the test. It took more time to convince the PwD to wear the device because they very often they don't want to wear something if they don't know or understand why they should do this. But once they accepted wearing the device always it got good acceptance by all PwDs and CGs. Several participants recommended to have a changeable clip system which allows them to clip the device at a rollator in instead clipping to the belt.

The plug-in connection to charge the battery was not a problem but all the CGs lacked a visual charge indicator, as everyone knows from their cell phone. Important for all CGs was the autonomy of the battery. Daylight duration (approx. 10 hours) is the minimum for them (charging overnight) some mentioned in the feedback that they would prefer a 4-5 days charging interval. But the visual charge indicator is much more important for the user of such a device.

Material quality and form (look and feel) of the device were not rated very enthusiastic. Everybody took into consideration that these are prototype devices and they know that marketable products will look totally different but nevertheless their feedbacks gave additional input to the project team. The market product (belt clip) should be designed softer and also smaller and also its colour and haptic could be enhanced. The material should be more robust (one insole and one clip had broken during the test period). The device should be able to withstand 100 kg pressure or more (especially for insoles). The insole device perhaps would need a new design idea to have a product which one could somehow 'built-in' in any insole on the market. As part of the follow-on from this project, we are investigating this option with a shoe manufacturer to build such a solution into their shoe brand.

Overall there had been no problems using the tracking devices and the only difficulty reported had been the irregular tracking message sent by the device. This was a result of our GPS chips from one manufacturer failing to lock on to the global positioning satellites and as such not being able to report a breach of safety zone rules. This is something that we will need to address with chip providers for future versions of the product and will need rectifying for a market solution. The whole process confirming the latest SMS message should be reviewed once again and checked if a more user-friendly confirmation process could be designed.

4.2.3 Devices and general impression Ireland

Of the two devices there was an interest in both, with some preferring the shoe insole and others preferring the belt clip. It was felt that the belt clip was more suited to males, and one carer pointed out that a unified sex-agnostic approach might work better (e.g. a watch). All agreed that a more finished product would be desired, and that in the current format (functional prototypes) a lot of change or downsizing would be required (e.g. jewellery). However, they were more appealing than ankle bracelets that carry

out similar tasks but would add a level of stigmatisation to the wearer. Another point that was made related to charging is that a second backup device may be required as the primary one gets charged.

It was also pointed out that even though the insole is a good way of getting the users to have it when they are going out, that night-time wandering may occur barefooted.

In one of the demonstrations there was an issue receiving the GPS signal, but the carer was cognisant of the fact that this was a demonstration and would expect all these types of issues to be resolved for a marketable product.

4.2.4 Devices and general impression Portugal

The *Casa do Alecrim* care home personnel commented on the format of the two prototypes, with respect to the insole revealed interest that was lower, as well as it would be interesting not to be necessary to be removed to charge the device, this can be solved in future iterations of the prototype with different hardware, or by embedding the hardware in the shoe itself. As far as the belt box, they revealed that they would also like it to be smaller in size.

One caregiver demonstrated preference for the device with the insole format, since the PwD does not wear a belt, thus excluding the belt box format. It was also pointed out that anything that was not "fixed" to the person would increase the high probability that the PwD would forget where he/she had left it, or even not want to use it.

The received feedback pointed out the overall difficulty in smoothing the acceptability, of the insole and belt box devices, by the PwDs, and also the complex maintenance requirements the caregiver is subjected to. A fully integrated shoe as a device, was perceived as a more viable, comfortable and desirable solution for both the carer and the PwD, due to the fact that it is much more natural a scenario in which the PwD can just go to a store and select the pair of shoes that suits him/her best, without the discomfort of having to switch the insoles for larger ones, or removing the insoles for charging.

In the final interview (conducted online due to covid restrictions) with a caregiver specialist, Dr.a Catarina Alvarez, the conclusions from the project were presented and valuable feedback was provided, with more emphasis in the ethical aspects of such types of solutions.

Some wearable device's integrations may not be suited for all genders (e.g. the belt box is more difficult to wear by females), although the value of having these types of devices is, without a question, an important need for wandering detection.

However, some terms, used in the project communication, need to take into account the stigmatization that they cause, to the persons they refer to, such as the "Person with Dementia" or "wandering event". This terms involuntarily brand these persons, with the negative connotations and judgements that are associated with lower cognitive function, and often encourage misunderstandings of dementia. To circumvent this issue, it is proposed that a reorientation of the terms takes place, using lesser diminutive terms to describe or address the people that suffer from these conditions.

Another point raised by the specialist was the ethical/juridical question, posed with forcing someone (who is unfit to give informed consent) to wear a tracking device, which can have different consensus in different

countries, as well as different legal procedures that need to be respected. Also, as a service provider we should ensure that the buyer of these solutions is informed of the fundamental rights of the PwD.

In conclusion, the Carelink solution should be rebranded to ensure that the devices empower people with dementia and their carers and avoid stigmatizing stereotypes.

4.3 Overall evaluation

All findings from all test phases in Ireland, Portugal and Switzerland were included in the overall assessment. Because of the Covid-19 restrictive measures that were implemented across the EU the field trials couldn't carried out in Ireland and Portugal. However, we are convinced that the most important knowledge could be gained from the remaining tests, so that an assessment of the marketability of this system can be made. We do not believe that the cultural differences of the PwDs would be significant and would have a strong impact for the decision of further developments.

4.3.1 Devices

The devices were accepted pretty well by all PwDs and CGs. We used two different types of boards and unfortunately only one product type worked more or less perfect, and there were issues with the second board stemming from the chip manufacturer. Even taking it upon ourselves to attempt at reprogramming these boards were not a complete success, and it required buy in from the manufacturer to address this issue, and therefore beyond our control and capabilities.

As mentioned above, the most problematic service was obtaining the GPS signals. This is also related to the selected signal sequence. And the selected signal sequence has consequences to the battery lifetime between two charging processes. And one of the most important points for CGs is the battery lifetime between two charging processes. This battery lifetime should be at least 10 hours so that it can be charged overnight. A battery lifetime of 4 or 5 days would be even more desirable.

A visual battery charge indicator as mobile phones use it is a must. All CGs explained that they accepted this missing function for a test sequence, but they never would purchase such a product without visual battery charge indicator.

To enter a micro sim card into the device should be as easy as with a mobile phone. Anyway, CGs and PwDs compare the handling as well as the functionality and user friendliness always with a cell phone. That is quite important to know because Carelink is a product for a population of users which are not tech enthusiasts. Therefore, all services, handling, UI, etc. should follow the already known mobile phone features. It is not needed to develop everything from scratch. It is more successful to use available market components on latest technology, assemble them in an intelligent manner and add a minimum of self-developed services this will lead to the highest possible success.

In addition to the challenges described above there was a strong user requirement from the test participants to further minimize the device. In particular the insole must be thinner than the current one but also the belt clip should have a smaller and nicer design. Shape and colour should look more appealing.

There popped up other ideas as well like watches or necklaces as alternatives to the tested products. For the insole they brought up the idea to place the shoes on an induction mat to allow for wireless charging.

4.3.2 Platform

The platform is more or less ready for use. There are only a few things which should be built in the functionality and the processes to make the whole application more user-friendly.

A wizard type guide through the setup, whereby a user is brought through the screens using a series of prompts for the first time they use the system, which can be switched off in subsequent uses of the system. After entering the CG data, the system should lead to the 'add PwD' screen and from there to 'location' screen which displays as next screen the 'add/edit zones' screen which has already filled in the location name and displays the correspondent map. It is not so important like the process just described but some of the CGs evaluated it as supportive if the platform would fill in the telephone country code automatically if the platform knows the pc position.

The latest or current route should always be displayed on the 'routes' screen. All historical data can be deleted as soon as the device sends the GPS location of 'location home'.

After sending an alarm-SMS to the mobile phone of the CG a simple button 'resolved' should appear on the display. As soon as the message is reported as 'solved' the CG should still be able to press the link of the SMS and the platform shows the current route and position of the PwD.

4.3.3 General impression

The overall idea of the solution is still fantastic, outstanding and unique. All involved persons like the idea to have a product available which is based and developed on standard recognisable, but which does however use propriety hardware. They like the idea to buy a device, install a micro sim card, enter a few data over an internet application without downloading an application from a webstore and to start immediately accompanying a person in a simple and secure manner.

As long as they can use nicknames for the platform registration, they do not mind having this proprietary component as part of the overall solution.

More or less everything is available with the Carelink solution, but minimizing the devices and enhancing the battery lifetime with a higher clocked GPS signal will enhance the offering, and be required for a market ready product

The Carelink solution could also be used and of interest to other populations i.e. people with other disabilities or child supervision. The risk of walking away is also important for these two groups.

5 CONCLUSIONS

No field trial participant had any ethical or data protection concerns, everyone was amazed at the simple approach of the Carelink solution. The majority of them liked the ease of setup and use, which is based on non-proprietary technology. (internet application instead of mobile app download, cell phone, SMS, link to an internet map).

The step-by-step three step test approach was very helpful and supportive for the project. Important insights came from the first two test levels. They made it possible for project developers to continuously improve the product and the platform towards market maturity so that the solution could be tested with field trial participants.

Thanks to UNINOVA which used two different boards for the devices the project was able to successfully carry out the field tests. Unfortunately, there were issues with boards from one manufacturer, which were acknowledged as a problem and beyond the remit of the Carelink team to fix.

The overall solution based on latest technologies and the idea of using everyday end-user devices and end-user tools like mobile phones and internet gives a comfort factor to the users which encourages usage

Further enhancements are necessary from the chip manufacturers in the area of GPS data tracking (tracking per time slot) and coupled with battery duration between two charging cycles - these are two of the critical technical points to further progress the product development. Both of these technologies are progressing fast, with chip releases on a regular basis, so even though there were circumstances whereby there were issues, further development should stay on track as the technologies become more established, powerful and minimized, their availability and stability will rise.

The platform also makes the interface available to other devices and thus allows us to open up new business opportunities with this next steps.

APPENDICES

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