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1.1	14/06/19	Draft	Sotiria Moza, Marina Polycarpou, Elena Savva (MATERIA)	Final revision and editing, final draft release for submission

EXECUTIVE SUMMARY

The present deliverable is reporting the final results of testing and evaluation WP. The introductory section provides an overview of WP7 objectives, progress, and alignment with the Medical and Technological Objectives of the FrailSafe project. A specific report is provided on WP7's schedule and different methodological approaches employed for the final evaluation.

During the second section of the report, the deliverable reports on the evaluation of the FrailSafe system through the proof of concept study performed in real-life scenarios. The rationale underlying the design of the intervention procedure and its integration in the final FrailSafe system is being described. Furthermore, detailed report on the results of the FrailSafe study, in respect to the identification of new frailty metrics, relation of frailty to comorbidities, impact of individualized interventions and rehabilitative effect of the FrailSafe system is provided.

The third section of the present deliverable is focused on describing the design, implementation and results of the final evaluation of the FrailSafe system. The section outlines the objectives of the evaluation, the different stakeholders being addressed and the retrieved sample numbers, as well as, the instruments selected and fine-tuned. Furthermore, results of the final evaluation are reported from different stakeholders' perspective, regarding the FrailSafe system's functional and non-functional characteristics. The evaluation results describe, in detail, the viewpoints of older adults, formal and informal caregivers, healthcare professionals, researchers, IT professionals, commercial stakeholders and other community members, with regards to the FrailSafe system's non-functional aspects, such as utility, acceptance, desirability, usability and exploitability.

Consequently, detailed results from the three-level socioeconomic impact analyses are reported to describe the implications of the FrailSafe system, in terms of cost, health-related life quality and societal benefits.

The report concludes by summarizing the findings of the present study and highlighting achievements, impact and success indicators, to provide evidence-based and empirical results for the effectiveness of the FrailSafe system, which could be transfered in a policy making level.

DOCUMENT INFORMATION

Contract Number:	H2020-PHC–690140	**Acronym:**	FRAILSAFE
Full title	Sensing and predictive treatment of frailty and associated co-morbidities using advanced personalized models and advanced interventions		
Project URL	http://frailsafe-project.eu/		
EU Project officer	Dr Mirela Negrean		

Deliverable number:	7.4	**Title:**	Field trials report & Socio-economic guidelines
Work package number:	7	**Title:**	Testing and Evaluation

Date of delivery	**Contractual**	**30/04/2019 (M40)**	**Actual**	TBC
Status	Draft ☒		Final ☐	
Nature	Report ☒	Demonstrator ☐	Other ☐	
Dissemination Level	Public ☒	Consortium ☐		

Abstract (for dissemination)	This deliverable reports on the results of the final evaluation analysis regarding levels of acceptance, usability, utility, desirability, exploitability and other evaluated aspects of the FrailSafe system, among multiple groups of stakeholders. Furthermore, health, economic and societal implications associated with FrailSafe system's use are presented. The deliverable concludes with an overall assessment of FrailSafe study, such as the achievement of main goals and objectives, as well as, relevant success indicators. Future implications are discussed.

Keywords	evaluation; FrailSafe; frailty; socioeconomic impact; innovation

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TABLE OF CONTENTS

List of abbreviations

ACC	Classification Accuracy
Agg	Agglomerative
AR	Augmented Reality
AUC	Area under the Receiver Operating Characteristic (ROC) curve
BAC	Balanced Accuracy
BMI	Body Mass Index
BP	Blood Pressure
CFI	Combined Frailty Index
CGA	Comprehensive Geriatric Assessment
CI	Clinical Index
CSI	Channel State Information
DAGs	Dynamic Adaptability Games
DSS	Decision Support System
DT&E	Developmental Testing and Evaluation
EC	European Conformity
EU	European Union
FI	Technical Frailty Index
FMI	Fowlkes-Mallows index
GPS	Global Positioning System
KM	k-means
MIMO	Multiple Input-Multiple Output
MO	Medical Objective
M	Month
OT&E	Operational Testing and Evaluation
QALY	Quality-adjusted life year
ROC	Receiver Operating Characteristic
Spec	Spectral clustering
SUS	System Usability Scale
TO	Technological Objective
T&E	Testing and Evaluation
UC	Use Case
UCD	User Centered Design
UI	User Interface
UoP	University of Patras
VCP	Virtual Community Platform
VPM	Virtual Patient Model
WTP	Willingness to pay
WP	Work Package
WWBS	Wearable WBan System

List of tables

List of figures

List of annexes

1. Introduction

Frailty is a clinical syndrome characterized by gradual deterioration in multiple physiological systems, and associated with weakness and low resilience to stressors. Research shows that frailty has a high prevalence among older adults affecting 15-50% of people over 85 years old (Clegg, Young, Iliffe, Rikkert, & Rockwood, 2013). If frailty is not addressed early on, it leads to increased number of falls and comorbidities, dependency, need for long-term care and high mortality rates (Fried et al., 2005; Walston et al., 2006). The syndrome constitutes a significant challenge in modern healthcare practice due to its insidious onset, progressive deterioration, multiparametric affect and high prevalence, leading to elevated health care costs and detrimental socioeconomic implications in a micro- and macro-level (Buckinx et al., 2015). There is consensus among scholars that it is an imperative for new pathways, models and protocols to be developed, in order to effectively approach, diagnose and delay frailty from an interdisciplinary perspective.

In this context, FrailSafe project's aim is to develop an innovative, multilevel system to better understand, detect and predict frailty, as well as, its relation to other health parameters. The system proposes an integrated architectural model combining sensitive electronic devices and traditional standardized instruments to collect multiparametric data from several health domains *(i.e.,* medical, physical, cognitive, social, behavioural, nutritional, psychological and functional). Advanced mining approaches, deep machine learning techniques and prediction algorithms assist in the identification of vulnerable health domains, short and long-term patient outcomes, frailty risk and generation of individualized interventions in a safe, friendly and unobtrusive manner.

1.1 Testing and evaluation overview

The FrailSafe study begun in 2016 and all efforts followed a User Centered Design (UCD) methodology. Specifically, system architecture and development were based on the analysis of user requirements and modified according to stakeholders' constant feedback. During the first years of the project, efforts were focused on the parallel development and fine-tuning of all system components and their subsequent integration in one unified system. During this process, extensive and multilevel testing of the components was conducted to ensure safety and reliability of the devices, while stakeholders continuously provided integral feedback for the development of a user-acceptable final system, which would fit their needs. During the evaluation phase, multiple user groups across three clinical centers (Cyprus, France and Greece) tested the integrated final FrailSafe system, while the results of the evaluation were continuously used as a feedback for the development, fine-tuning and construction of the final exploitation plan.

FrailSafe employed a non-pharmacological, interventional, cohort study design. In detail, 510 individuals, in total, from three clinical centres (Cyprus, France and Greece) enrolled in the study. During the development, fine-tuning and integration of the system components (M4-M30) intensive clinical studies were performed, in order to collect adequate data for the optimization of the system, quantification of the FrailSafe computational models and definition of frailty related parameters. During the testing and evaluation period (M31-M40) the clinical studies focused on evaluating and validating the FrailSafe integrated system.

Participants in the study were divided in four main groups: A-Start Group, B-Main Group, C-Evaluation Group and D-Control Group. Group C was further divided in two groups, Ci-Standard evaluation Group and Cii-Long-term evaluation Group. For consistency purposes,

groups A, B and C did not differ in terms of baseline data collection. Specifically, participants who gave their consent received a blood sampling for telomere length analysis (assessing the biological aging rhythm) (Tomiyama et al., 2012), a thorough clinical evaluation using a battery of standardised scales and paper and pencil tests (see a detailed description in *D2.1 Clinical Study Methodology*), monitoring using the FrailSafe devices and phone follow-up calls in scheduled intervals to record adverse events. However, the three groups differed in terms of methodology after the baseline assessment, in order to assess the effect of the FrailSafe system among different patterns of monitorings. Specifically, groups A, B and C differed in duration and frequency of FrailSafe monitorings, times of repeated visits for clinical evaluations and number of follow-up calls. The timeline of interventions for each group can be found in Figure 1. Scheduled timelines slightly varied among centers due to local practical modalities and depending on participants' availability to adhere the proposed timeschedule, allowing small deviations from planning for the shake of participants' convenience.

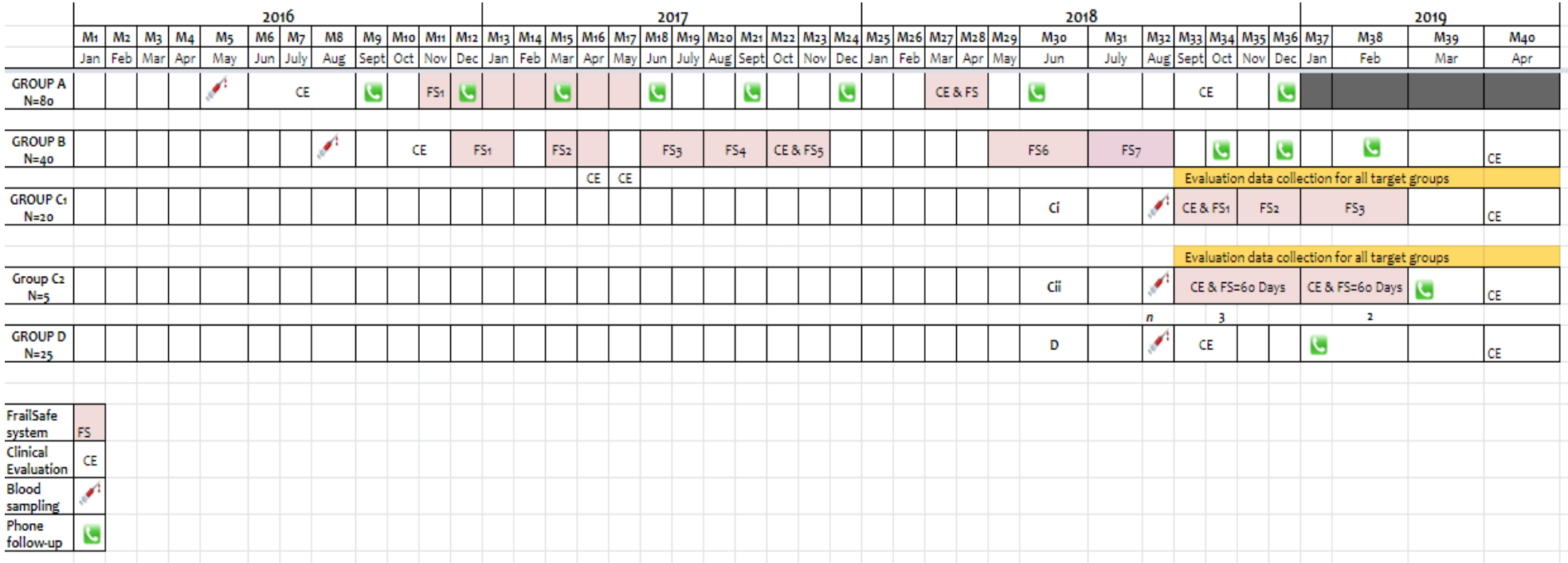


Figure 1. Interventions timeline per group

Groups A and B were mainly engaged in designing, testing and providing feedback on the developing system while participants of Group C tested and evaluated the integrated FrailSafe system and received individualized interventions based on their measurements. Finally, Group D acted as a control group. More specifically, participants of Group D received a baseline blood sampling, a thorough clinical evaluation, two phone follow-up calls and a final clinical evaluation, with no intervention or contact with the FrailSafe system in between.

1.2 Scope of D7.4 and relation to project's Medical and Technological Objectives

Testing and Evaluation (T&E), allocated in Work Package 7 (WP7), started in M18 and encompassed all research and clinical activities, as well as, the development of the final, integrated system. Evaluation process constituted an integral component of the FrailSafe study producing useful results for reconsideration of efforts, modification of systems and designing future steps for exploitation. T&E was conducted in two phases, a) the Developmental Test and Evaluation (DT&E) during M18-M30 and b) the Operational Test and Evaluation (OT&E) during M31-M40. DT&E aimed to assess and guide the development of the system, while OT&E tested the final integrated system in real-life scenarios and conditions and served as a basis to design future efforts.

In the present deliverable, the final evaluation process and results of the operational testing and evaluation are described. The results of the evaluation are closely associated with the fulfilment of the project's Medical and Technological Objectives (MOs & TOs). The relevant sections of the deliverable addressing each of the MOs and TOs can be found in the following tables (1 and 2).

Table 1. Testing & Evaluation with respect to FrailSafe's Medical Objectives

	Objective	Deliverable section addressing the objective
M01	Better understand frailty and its relation to co-morbidities	2.2.6-2.2.7
M02	Develop quantitative and qualitative measures to define frailty	2.2.1-2.2.6
M03	Use these measures to predict short and long-term outcome	2.2.1-2.2.6 & 2.1.4
M04	Develop real life tools for the assessment of physiological reserve and external challenges	Chapters 2 and 3
M05	Provide a model sensitive to change in order that pharmaceutical and nonpharmaceutical interventions which will be designed to delay, arrest or even reverse the transition to frailty, can be tested.	2.2.8 & 2.2.9
M06	Create "prevent-frailty" evidence-based recommendations for older people regarding activities of daily living, lifestyle, nutrition, etc. to strengthen the motor, cognitive, and other "anti-frailty" activities through the delivery of	2.1.3 & 2.2.8-2.2.9

	personalized treatment programs, monitoring alerts, guidance and education and estimate the influence of these interventions	
M07	Achieve all with a safe and acceptable to older people system	3.4.2

Table 2. Testing & Evaluation with respect to FrailSafe's Technological Objectives

	Objective	**Deliverable section addressing the objective**
T01	Design and development of hardware components (ambient and wearable sensors, body node coordinator (e.g., smart phone) optimised in terms of ergonomics, user-friendliness compactness, unobtrusiveness and energy consumption that can be used indoors and outdoors providing functionalities for effective yet simple and economical personalized monitoring of the individual patient's condition for purposes of detecting/alerting/averting of frailty events, merged to an integrated system, explicitly taking into account security and privacy issues.	3.4.1 & 3.4.2
T02	Design and development of efficient signal processing algorithms for low level processing including signal enhancement, activity classification, energy expenditure, and behavioural monitoring.	3.4.1 & 2.2.3-2.2.5
T03	Development of a self-adaptive Virtual Patient Model offering optimal services for managing frailty ranging from critical situation management, facilitating social integration to day-to-day self-management and health preservation based on a personalized patient profile.	2.1.3-2.1.4 & 3.4.1
TO4	Development of a generic monitoring and management infrastructure on which modular services and patient-specific applications will be built.	3.4.1
TO5	Development of novel methods for the offline management, fusion and analysis of multimodal and advanced technology data from social, behavioural, cognitive and physical activities of frail older people and application of these methods to manage and analyze the large amounts of data collected leading to integrative interpretation and better understanding of frailty, introduction of new quantitative frailty biomarkers as well as frailty metrics, correlation of comorbidities and frailty, advanced decision making capabilities (DSS) assisting diagnosis by medical professionals	2.1.4, 2.2.1-2.2.6, 3.4.1
TO6	Development of real-time data management and data mining methods effectively making decision assessing frailty levels, detecting frailty risks and triggering alarms in case of emergency situations (e.g., fall, loss of orientation, incoherent utterances or suicidal manifestations in written text) based on minimal processing of real-time multi-parametric streaming data and economical personalized monitoring guided by a minimal number of sensors and parameters (FrailSafe prediction engine and Risk Factor Evaluation).	2.2.1-2.2.6
TO7	Investigation of processing time, storage and communication trade-offs for real-time analysis at the WBAN or the phone/PDA and use of data reduction and summarization techniques for reducing raw streaming data to secondary or tertiary parameters. Effectively use Virtual Patient Models and results from the offline data mining of multi-parametric data to make real-time analysis more efficient and targeted.	3.4.1

TO8	Development of dynamically synthesized, personalized and highly innovative AR games consisting of different scenarios that measures parameters of behavioural, cognitive and physical domain while implementing various intervention strategies.	3.4.1 & 3.4.2
T09	Extensive testing of the FrailSafe integrated system in several validation scenarios while ensuring compliance with ethics standards.	3.4.1 & 3.4.2

OT&E process methodology was further divided into a two-step approach:

a) In a proof of concept study, the integrated system was tested by older adults in their home-setting and received individualized interventions based on their measurements by the FrailSafe system.

b) In a parallel manner, several stakeholder groups, who interacted directly or indirectly with the FrailSafe system, evaluated several functional and non-functional aspects, such as its utility, usability, exploitability, ease of use, etc. using a combination of quantitative and qualitative instruments.

2. Proof of concept study

A proof of concept study is an experimental method used to extract early evidence which could determine the feasibility of a tool, its viability in real-life scenarios and compliance with users' needs (Schmidt, 2006). This type of experiment offers insight that a tool can function as it was originally envisaged. In the FrailSafe study, 75 older adults participated in a real-life setting proof of concept experiment, in order to assess the impact of the FrailSafe system in their everyday life, compared to equally-sized control groups.

2.1 Design and implementation

Field trials took place from M33 till M39 (following the extension amendment) and older adults tested the integrated FrailSafe system in their home environment. The design of the field trials was employed in three levels. Firstly, 20 individuals per clinical center (60 in total) tested the FrailSafe system for three consecutive times with a two-month interval in between. Secondly, five individuals per center (15 in total) tested the FrailSafe system for 60 days while another 25 individuals per center acted as a control group (more information can be found in Figure 1 above).

Recruitment efforts for Groups C and D started early on from M20-M32 to ensure the collection of a large pool of eligible participants for randomization reasons and to avoid selection bias. Inclusion and exclusion criteria were met similarly to the previous groups, A and B. A summary of inclusion and exclusion criteria can be found in Table 3.

Table 3. Inclusion and exclusion criteria

Inclusion criteria
✓ Age ≥70 years ✓ Informed consent provided
Exclusion criteria
✓ Lack of wish to participate ✓ Consent withheld ✓ Inability to give consent because of incapacity ✓ Inability to walk ✓ Inability to speak Greek or French ✓ Diagnosis of clinically significant cognitive impairment or score less than 24 on the Mini– Mental State Examination ✓ Diagnosis of advanced malignancy, other terminal illness or an estimated life expectancy of less than 12 months ✓ Active psychiatric disorder based on medical records or clinical opinion at the time of recruitment, current substance use, or excessive alcohol use

The pre-set study methodology was followed exactly as described in *D2.1 Clinical study methodology*. Tables 4 and 5 summarize the study procedure for the Evaluation Group-C and Control Group-D.

Table 4. Study procedure summary for Group C

Standard procedure for all groups (1-5)
1. Quick first verification of inclusion and exclusion criteria 2. Randomization to groups Ci, Cii or D 3. Informed consent and attribution of a unique ID number 4. First part of clinical evaluation session: questionnaires to verify inclusion and not inclusion criteria, Fried's criteria of frailty, medical history and cognitive assessment 5. Second verification of the inclusion/exclusion criteria according to the first part of the clinical evaluation's results. If exclusion, replacement of the participant and repetition of steps 1-5 for the next candidate. The steps from this point down and their time programming will differ according to group allocation.
Group Ci- Standard evaluation group
1-5. As described above for all groups 6. Complete clinical evaluation session (M33-34) 7. First FrailSafe system home visit (M33-M34): • Blood sampling for telomeres[1] • Fill in the evaluation form regarding the participant's housing conditions • Collect any questionnaires filled in by the participant: written texts, social media and big five questionnaires • Complete any missing information of the clinical evaluation (i.e. scanning of a forgotten prescription, scanning of an older written text provided by the participant, write down dictated text) • Installation of the integrated FrailSafe system and explication of the use. Verification of its correct function. • Provide contact details and instructions, in case of any help needed. • Set the next appointment to retrieve the FrailSafe material (5th day) 8. Maintenance of the FrailSafe system at home and outdoor activities during 5 days. 9. Retrieval of systems and feedback from the participant. 10. Second FrailSafe system home visit (M35-36) • Complete any missing information of the clinical evaluation (i.e. scanning of a forgotten prescription, scanning of an older written text provided by the participant, write down dictated text). • Installation of the FrailSafe system and reminding of its use and purposes. • Verification of its correct function • Provide contact details and instructions in case of any help needed • Set the next appointment to retrieve the FrailSafe material (5th day)

[1] If not possible to be retrieved during M33, blood samplings were performed any time from M33-M39, according to participants' convenience.

11. Maintenance of the FrailSafe system at home and outdoor activities during 5 days

12. Retrieval of systems and feedback from the participant

13. Last FrailSafe system home visit (M37-38).

- Installation of the FrailSafe system and reminding of its use and purposes.
- Verification of its correct function
- Provide contact details and instructions in case of any help needed
- Set the next appointment to retrieve the FrailSafe material (5th day)

14. Maintenance of the FrailSafe system at home and outdoor activities during 5 days

15. Retrieval of systems and feedback from the participant

16. Last clinical evaluation (M39)

17. Data collection of written text after the first time (M39). The participant will either be helped to provide text by dictation or (s)he will write it down during the clinical assessment appointment.

18. Completion of FrailSafe User Satisfaction Questionnaire.

19. Explication on the completion of the FrailSafe study and cessation of their involvement as declared in the informed consent.

20. Study's completion verification. Normally at the end (M39), but could be in anytime in case of premature withdrawal.

21. Phone follow-up call during M42.

Group Cii- Long term evaluation group

1-5. As described above for all groups

6. Complete clinical evaluation session (M33, M35, M37)

7. First FrailSafe system home visit (M33-34, M35-36, M37-38[2]):

- Blood sampling for telomeres[3]
- Fill in the evaluation form regarding the participant's housing
- Collect any questionnaires filled in by the participant since the last visit: written texts, social media and big five questionnaires
- Complete any missing information of the clinical evaluation (i.e. scanning of a forgotten prescription, scanning of an older written text provided by the participant, write down dictated text)
- Installation of the integrated FrailSafe system and explication of the use and its purposes. Verification of its correct function
- Provide contact details and instructions in case of any help needed
- Set the next appointment to retrieve the FrailSafe material (61st day)

8. Maintenance of the FrailSafe system at home and outdoor activities during 60 days.

9. Phone follow-up call.

[2] The study for the 15 older adults participating in Group Cii was not performed simultaneously. Participants were split to 60-day intervals to ensure appropriate resource allocation and compliance with the methodological plan. In detail, six individuals tested the system from M33 to M34, six from M35 to M36 and three from M37 to M38.

[3] If not possible to be retrieved during M33, blood samplings were performed any time from M33-M39, according to participants' convenience.

10. Last clinical evaluation (M39)

11. Data collection of written text after the first time (M39). The participant will either be helped to provide text by dictation or (s)he will write it down during the clinical assessment appointment.

12. Completion of FrailSafe User Satisfaction Questionnaire.

13. Explication on the completion of the FrailSafe study and cessation of their involvement as declared in the informed consent.

14. Study's completion verification. Normally at the end (M39), but could be in anytime in case of premature withdrawal.

15. Phone follow-up call during M42.

In a parallel manner, participants of Group D followed a different study plan, summarized in Table 5.

Table 5. Study procedure summary for Group D

Group D– Control group
1-5. As described above for all groups
6. Complete clinical evaluation session (M33)
7. Blood sampling for telomeres[4] (M33)
8. One follow-up telephone call (M35)
9. Last clinical evaluation (M39)
10. Data collection of written text after the first time (M39). The participant will either be helped to provide text by dictation or (s)he will write it down during the clinical assessment appointment.
11. Explication on the completion of the FrailSafe study and cessation of their involvement as declared in the informed consent.
12. Study's completion verification. Normally at the end (M39), but could be in anytime in case of premature withdrawal.
13. Phone follow-up call during M42.

2.1.1 Participants characteristics in evaluation and control group

Eighty participants, in total, were recruited for the field trials in Groups Ci, Cii, and 75 for Group D among the three clinical centers (including replacements). Participant drop-offs were 17.5% for Group C and 0% for Group D. During the evaluation phase, all participants were replaced according to the methodological protocol for replacements (*D2.1 Clinical Study Methodology).* The dropouts were similar (16.7% for Group B) or smaller (26.6% for Group A) compared to previous groups. Among the users who withdrew of the study most withdrew due to emerging terminal illness or lack of wish to continue but none of them requested erasure of their data.

[4] If not possible to be retrieved during M33, blood samplings were performed any time from M33-M39, according to participants' convenience.

Gender and frailty distribution were approximately equal between groups C and D (Table 6). Most of the participants were non-frail which enabled us to study frailty transition rates. Participants were, in the majority, urban inhabitants and less among them resided in rural areas, which is logical considering that research activities were performed in big cities. However, rural residents were represented in this study, in order to obtain generalizable results. All clinical evaluations and FrailSafe sessions were performed according to schedule. Difficulties, problems, such as malfunctioning of the devices, were minimal and significantly less compared to the previous groups, which tested the developing solution.

Table 6. Gender, frailty and habitation zone distribution between Groups C and D

	% Group C	% Group D
Non-frail	70	60
Pre-frail	26	32
Frail	4	8
Male	52	44
Female	48	56
Urban	52.6	n/a
Semi-rural	32.9	n/a
Rural	14.5	n/a

2.1.2 Challenges and mitigation actions

Consortium members took appropriate measures to increase the robustness of the results in the evaluation group according to knowledge and experience gained during previous research activities [M1-M30]. This section aims to describe the risks identified early on and the mitigation strategies implemented to increase study efficacy.

During the evaluation phase, we aimed to test the impact of individualized interventions on participants of Group Ci. In the initial methodological plan (*D2.1 Clinical Study Methodology*), Group Ci was planned to be further split into two groups in order to randomize participants in one group, which would receive individualized interventions based on their measurements by the FrailSafe system and one group, which would receive generalized interventions, in order to minimize the placebo effect associated with the recommendation-receiving[5]. This plan would result into two experimental groups with 30 participants each. However, data collection, procedures and analyses in the first two clinical groups, A and B, showed that several random

[5] According to Wager and Atlas (2015, p.1) “placebo effects are beneficial effects that are attributable to the brain-mind responses to the context in which a treatment is delivered rather than to the specific actions of the drug (intervention)”.

factors and limitations (i.e., participant drop offs, absence of adverse events in such a short monitoring period, etc.) could further reduce the amount of data available for the final analyses, hence, compromising the reliability of the results. Thus, after careful planning, we implemented a mitigation strategy to ensure that we would retrieve adequate sample for the analyses. More specifically, Group C was not divided into individualized and generalized recommendation groups but received only individualized recommendations. Instead, generalized recommendations were provided to participants of Group B from their fifth session and on, while using the developed and integrated Frailsafe system. This resulted into two groups with similar methodological intervention plan (three five-day monitorings with the integrated FrailSafe system, two home visits for clinical evaluations and two phone follow-up calls) but different intervention approach (individualized versus generalized interventions). Hence, upon data analysis we expected to have 120 participants from Group B who received generalized interventions and 75 participants from Group C who received individualized recommendations. This mitigation strategy would have a two-fold advantage. Firstly, sample numbers and consequently, the reliability of our results would increase and secondly, we would avoid providing a different treatment between participants belonging to the same group (Nardini, 2014).

Finally, as stated in previous sections, OT&E was planned to begin from M31 to M36. However, a delay in completing the sessions in previous groups (A and B) according to the pre-set methodological plan, due to random factors (*i.e.,* delay in obtaining approval from ethical committees and unavailability of devices), resulted to a shift in timeline for Group C and D. Hence, instead of M31, the sessions started on M33 (see Extension Request).

2.1.3 Individualized recommendations

As mentioned in the previous section, one of the main responsibilities of OT&E was to create evidence-based, individualized recommendations for older people concerning activities of their daily living, lifestyle, nutrition, etc. which would aim to tackle frailty (MO6). A first outline of the recommendations was provided in *D2.3 Clinical Guidelines Formalized b*.

Prior to the evaluation phase, recommendation sentences, administration procedure and plan were further reviewed and optimized according to recent literature criteria and guidelines. Final recommendation sentences, from now on refered to as *guidelines* were revised to be addressed to three target groups, namely, a) older adults, b) authorized caregivers or family members and c) authorized doctors or healthcare professionals, who would be able to log in the Decision Support System (DSS) feature and view health data and notifications for their patients/relatives.

Recommendations were generated according to parameters derived from eight main health-related domains:

1) Cognitive domain
2) Medical domain
3) Nutritional domain
4) Everyday functioning domain
5) Physical domain
6) Social domain
7) Psychological domain
8) Lifestyle domain

With regard to the creation of guidelines, clinicians took under consideration three main issues. Firstly, the guidelines should be formulated in an appropriate language for each target group in order to be understandable and acceptable by all users. Secondly, we considered that "hard" results (results that could cause discomfort or stress to participants or family members) should be delivered in a careful way, in order to inform but not cause unnessecary stress. Thirdly, by default the intervention phase includes the delivery of health-related information. However, we had to keep in mind that the FrailSafe system is still under testing, it is not a medically approved instrument yet, it does not involve clinical exams and direct contact with a doctor and thus, its results may be vulnerable to errors (false-positive or -negative results). Consequently, participants should not solely rely on the recommendations received by the FrailSafe system but consult their physicians to have a valid opinion on their health status. Thus, the intergrated FrailSafe system fuctions as an assistance tool for taking medical decisions.

To address these considerations we employed three strategies. Firstly, the guidelines were individually formulated for each target group. In detail, we used simpler language (without extensive medical terminology) to address guidelines to older adults, and appropriate terms for caregivers and healthcare professionals, referencing relevant tests and devices used to acquire the results were needed. Upon formulation, the sentences were reviewed by all consortium members, including consortium physicians and healthcare professionals, who have years of experience in conveying health-related information to patients. Also, we organized focus groups with two stakeholders from each group who proposed further alterations and modifications in the way the results were conveyed. Secondly, in order to reduce the possibility for stress induction to our participants all our recommendations were attributed a soft or hard valence from consortium clinicians according to the message they conveyed. The ones that were considered as "hard" results were given specific thought on the way to be conveyed to the participants. Nevertheless, it should be stressed that all recommendations were formulated with the goal to inform the user but not cause unnesecary stress; thus, word selection was cautious for all guidelines.

In total, hard valence was attributed to eight main results which could cause stress if conveyed to older adults and family members:

1. A decline in Mini Mental State Examination (MMSE) or Montreal Cognitive Assessment (MoCA) (Cognitive domain)
2. An elevated score in Geriatric Depression Scale (GDS) (Psychological domain)
3. An irregularity in blood pressure (Medical domain)
4. A high number of comorbidities (Medical domain)
5. A high number of medications received simultaneously (Medical domain)
6. A decline in everyday functioning (Everyday functioning)
7. A decline in motor system performance and strength (Physical domain)
8. Increased risk of adverse events (Frailty Index)

Thirdly, to deliberately inform the users that the FrailSafe system is not a medical device, we included a disclaimer both to the Decision Support System's User Interface (DSS UI) and the guidelines administered to the participants (Annexes I, II, & III). The disclaimers explicitly stated that the recommendations should be considered only as an indication that a health-related parameter is out of range, that this result may have been affected by other random parameters and not correspond to an actual pathology, and that further examination from a healthcare professional is necessary to conclude regarding the importance of this finding.

After deciding on the recommendations structure and outline, we proceeded to create the cut-off scores for each variable based on well-defined clinical standards and literature review, as described in Table 7.

Table 7. Sources complementing the rationale underlying chosen thresholds

Parameter	Cut-off score	Source
Score on MMSE	24 points	Fountoulakis, Tsolaki, Chantzi, & Kazis, 2000
Score on MoCA	26 points	Nasreddine et al., 2005
Subjective memory complain	Yes	Luck et al., 2015; Schmand, Jonker, Hooijer, & Lindeboom, 1996
Smoking	Yes	Hubbard, Searle, Mitnitski, & Rockwood, 2009
Drinking alcohol	10.5 units per week	Crome et al., 2011
Physical activity	0-<2 hours/week	WHO, 2015
Raise from the chair 5 times	>15 seconds	Csuka & McCarty, 1985
Stand on single foot	<5 seconds	Vellas et al., 1997
Gait speed	Abnormal values (4.57 meters): [Men] ❖ ≥7seconds for height ≤173cm ❖ ≥6seconds for height >173cm [Women] ❖ ≥7seconds for height ≤159cm ❖ ≥6seconds for height>159cm.	Fried et al., 2001
Grip strength	Dynamometer measured grip strength (average of 3 trials, dominant hand) Normal values: [Men] ❖ >29kg for Body Mass Index (BMI) ≤24 kg/m^2 ❖ >30kg for BMI 24.1-28 kg/m^2 ❖ >32kg for BMI >28 kg/m^2 [Women] ❖ >17kg for BMI≤23 kg/m^2 ❖ >17.3kg for BMI 23.1-26 kg/m^2 ❖ >18kg for BMI 26.1-29 kg/m^2 ❖ >21kg for BMI >29 kg/m^2	Cesari, Landi, Vellas, Bernabei, & Marzetti, 2014; Cooper et al., 2013; Lee et al., 2017

GDS score	5	Pocklington, Gilbody, Manea, & McMillan, 2016
Sleep problems	Yes (occasional or permanent)	Piovezan, Poyares, & Tufik, 2013
Waist circumference	[Men] ≥103 cm [Women] ≥89 cm	Cetin & Nasr, 2014; de Hollander et al., 2012; National Heart and Blood Institute, 1998
BMI index	>30 kg/m^2 <18 kg/m^2	World Health Organization, 2016
MNA total score	≤11	Guigoz & Vellas, 1999
Body fat percentage	Abnormal values: [Men] Higher than 25% Lower than 13% [Women] Lower than 25% Higher than 36%	Tanita, 2012
Body water	Abnormal value: Lower than 50%	Tanita, 2012
Bone mass	Normal values [Men] <65kg and bone mass <2.65 g/cm^2 65-95kg and bone mass <3.29 g/cm^2 >95kg and bone mass <3.69 g/cm^2 [Women] <50kg and bone mass <1.95 g/cm^2 50-75kg and bone mass <2.40 g/cm^2 >76kg and bone mass <2.95 g/cm^2	Tanita, 2012
Muscle mass	Abnormal values: Lower than 24% and male Lower than 25% and female	Tanita, 2012
Unintentional weight loss more than 4.5 kg during the last year	Yes	Fried et al., 2001
Comorbidities	>3 comorbidities reported	Sartini et al., 2009

Polypharmacy	>4 medications received	Sartini et al., 2009
Visual acuity	Moderate or poor	Wallhagen, Strawbridge, Shema, Kurata, & Kaplan, 2001
Hearing acuity	Moderate or poor	Wallhagen, Strawbridge, Shema, Kurata, & Kaplan, 2001
Orthostatic hypotension	Test of orthostatic hypotension positive	O'Connell, Savva, Fan, & Kenny, 2015
Number of hospitalizations during the last year	>1	Hoover, Rotermann, Sanmartin, & Bernier, 2013
Number of falls during the last year	>1	Hoover et al., 2013; Joosten, Demuynck, Detroyer, & Milisen, 2014
FORA BP	Abnormal values: If average morning systolic pressure <100 mmHg or >140 mmHg If average morning diastolic pressure >90 mmHg If average evening systolic pressure <100 mmHg or >140 mmHg If average evening diastolic pressure >90 mmHg	Joint National Committee on Prevention Evaluation, and Treatment of High Blood Pressure & Committee, 1997; World Health Organization, 1999
KATZ scale score	≤1 less than normal	Dent, Chapman, Howell, Piantadosi, & Visvanathan, 2013
Lawton IADL scale score	≤1 less than normal	Dent et al., 2013
Exhaustion (Everything was an effort or Could not get going last week)	Yes	Fried et al., 2001
Living conditions	Alone	Andrew, Mitnitski, & Rockwood, 2008
Member of a social group	No	Andrew et al., 2008

More details on the tools utilized for the clinical assessment battery underlying the aforementioned parameters can be found in *D2.1 Clinical Study Methodology*. All guidelines targeted to each group, can be found in the following sections grouped by health domain and thresholds chosen per parameter.

Cognitive domain

For the construction of cognitive domain recommendations, we included participants' scores in Mini Mental State Examination-MMSE (Folstein, Robins, & Helzer, 1983), Montreal Cognitive Assessment-MoCA (Nasreddine et al., 2005) and also, participants' subjective complaints for memory difficulties. A detailed description of the recommendations according to the score obtained through the clinical evaluation can be found in Table 8.

Table 8. Recommendations for cognitive parameters per user group

		Recommendations		
Parameter	**Value**	**Older adult**	**Caregiver**	**Healthcare professional**
Score on MMSE	<24	Your score on a short cognitive test was different than usual which might be attributed to difficulties in some cognitive domain but could also be due to other factors which prevented you from performing your best at that day. Please, consider consulting your GP for further advice and/or consider visiting a professional for further cognitive assessment.	Participant's score on a cognitive screening test was outside the average range which might be attributed to difficulties in some cognitive domain but could also be due to other parameters (reduced attention, testing induced stress, etc.) which limited his/her performance on that specific day. Please, consider addressing this finding to a healthcare professional for further neuropsychological assessment and possibly participation to a cognitive enhancement programme after consulting his/her GP.	Participant had an abnormal score on a standardized cognitive screening scale (MMSE). Please, consider advising further assessment of his/her cognitive function and possibly participation to a cognitive enhancement programme according to your clinical judgement.
	24	Your score on a short cognitive test was in the lower normal range which might be attributed to difficulties in some cognitive domain but could also be due to other parameters which prevented you from performing your best at that day. Please, consider consulting your GP for further advising according to your judgement. Our team can provide a list of healthcare professionals and organizations who can further assist you in assessing your cognitive status. Engagement in cognitive exercises	Participant's score on a cognitive screening test was within the lower normal range which might be attributed to difficulties in some cognitive domain but could also be due other parameters (reduced attention, testing induced stress, etc.) which limited his/her performance on that specific day. Please, consider addressing this to a healthcare professional for further neuropsychological assessment and possibly participation to a cognitive enhancement programme (if needed), after consulting his/her GP. Our team can provide a list of healthcare professionals and organizations who can further assist in assessing his/her cognitive status.	Participant had a score in the lowest normal range on a standardized cognitive screening scale (MMSE). Please, consider advising further assessment of his/her cognitive function and possibly participation to a cognitive enhancement program, if needed, according to your clinical judgement.

		(puzzles, crosswords, etc) is highly encouraged.	Engagement in cognitive exercises (puzzles, crosswords, etc) is highly encouraged.	
	>24	Your score on a short cognitive test was within the normal range. We suggest engaging in cognitive (puzzles, sudoku, riddles) and physical exercises as regularly as possible after consulting your GP. Our team can provide a list of healthcare professionals and organizations who can further assist in assessing your cognitive status in the future. If you notice any differences in your everyday functioning please refer it to your GP.	Participant's score on a cognitive screening test was within the normal range. Regular cognitive assessment (once/year) is encouraged to identify any occuring difficulties early on. Please, do not hesitate to refer to the participant's GP or request professional help if you notice any cognitive or behavioral changes. Our team can provide a list of healthcare professionals and organizations who can further assist in assessing his/her cognitive status in the future.	Participant performed within the normal range on a standardized cognitive screening scale (MMSE). Please, consider advising him/her and/or his/her family members to arrange annual cognitive assessments, in order to detect any occuring difficulty early on.
Score on MoCA	<26	Your score on a second cognitive screening test was different than expected which might be attributed to difficulties in some cognitive domain but could also be due to other parameters which prevented you from performing your best at that day. Please, consider consulting your GP for further advising. Our team can provide a list of healthcare professionals and organizations who can further assist you in assessing your cognitive status. Engagement in cognitive exercises (puzzles, crosswords, etc) is highly encouraged.	Participant's score on a second cognitive screening test was different than expected which might be attributed to difficulties in some cognitive domain but could also be due to other parameters (reduced attention, testing induced stress, etc.) which limited his/her performance on that specific day. Please, consider addressing this to a healthcare professional for further neuropsychological assessment and possibly participation to a cognitive enhancement programme after consulting his/her GP. Our team can provide a list of healthcare professionals and organizations who can further assist in assessing his/her cognitive status. Engagement in cognitive exercises (puzzles, crosswords, etc) is highly encouraged.	Participant had an abnormal score on a standardized cognitive screening scale (MOCA). Please, consider proposing further assessment of his cognitive function and participation to a cognitive enhancement programme according to your clinical judgement.
	26	Your score on a second cognitive screening test was in the lower normal range which might be attributed to difficulties in some cognitive domain but could also be due to other parameters which prevented you from performing	Participant's score on a cognitive screening test was within the lower normal range which might be attributed to difficulties in some cognitive domain but could also be due other parameters (reduced attention, testing induced stress, etc.) which limited his/her performance on that specific day. Please,	Participant had a score within the lowest normal range (cut off point) on a standardized cognitive screening scale (MOCA). Please, consider advising further assessment of his cognitive

		your best at that day. Please, consider consulting your GP for further advising. Our team can provide a list of healthcare professionals and organizations who can further assist you in assessing your cognitive status. Engagement in cognitive exercises (puzzles, crosswords, etc) is highly encouraged.	consider addressing this to a healthcare professional for further neuropsychological assessment and possibly participation to a cognitive enhancement programme (if needed), after consulting his/her GP. Our team can provide a list of healthcare professionals and organizations who can further assist in assessing his/her cognitive status. Engagement in cognitive exercises (puzzles, crosswords, etc) is highly encouraged.	function and participation to a cognitive enhancement program, if needed.
	>26	Your score on a second cognitive screening test was within the normal range. We suggest engaging in cognitive and physical exercises as regularly as possible after consulting your GP. If you notice any differences in your everyday functioning please refer it to your physician.	Participant's score on a second cognitive screening test was within the normal range. Regular cognitive assessment (once/year) is encouraged to identify any occuring difficulties early on. Please, do not hesitate to refer to participant's GP for any cognitive or behavioral changes noticed.	Participant performed within the normal range on a standardized cognitive screening scale (MOCA). Please, consider advising him/her and/or his/her family members to arrange regular (annual) cognitive assessments in order to detect any occuring difficulty early on.
Subjective memory complaint	Yes	During the FrailSafe visit, you indicated that you notice some memory difficulties in comparison to other people of your age. Please, consider referrring to your GP or a healthcare professional for further advising if this problem seems to worsen over time or significantly affects you in your everyday life.	Participant indicated that he/she noticed having memory difficulties. Please, consider referring to his/her GP or a healthcare professional for further advising if this problem seems to significantly affect his/her everyday functioning or seems to worsen over time.	Participant had a subjective memory complain. Please, consider this parameter together with other findings of this report, as well as, your clinical jugdement to propose further neuropsychological assessment and participation to a cognitive enhancement programme, if needed.

Medical domain

For the construction of medical recommendations, we included participants' self-reported visual and hearing acuity, number of comorbidities and number of medications, performance in an orthostatic hypotension test, blood pressure measurements, as well as, self-reported number of hospitalizations and falls during the last year. A detailed description of the recommendations according to the score obtained through the clinical evaluation can be found in Table 9.

Table 9. Recommendations for medical parameters per user group

		Recommendations		
Parameter	**Value**	**Older adult**	**Caregiver**	**Healthcare professional**
Number of comorbidities	> 3	According to your reports, you have more than 3 cooccuring medical conditions which might require your attention in order to be effectively managed. Please, consider adopting a healthy lifestyle (adequate nutrition and regular exercise), perform regular examinations and follow medication and instructions provide by your GP. Do not hesitate to consult your GP if you notice anything different to your current level of functioning.	Participant has more than 3 cooccuring health problems which might adversely affect his/her health status if not addressed appropriately. He/she should adopt a healthy lifestyle (adequate nutrition and regular exercise), perform regular examinations and follow his/her medication plan and his/her GPs instructions. Please, refer to his/her GP if you notice anything different in his/her level of functioning.	Participant reported having more than 3 medical comorbidities. Please, consider proposing methods to control his health status according to your clinical judgement. Please, consider using STOPP/START criteria to regularly review his/her medication list especially if the individual presents frailty indicators (lower grip strength, slower gait speed, lower muscle mass, exhaustion, unintentional weight loss).
Number of medications	>4	According to your reports, you receive more than 4 medications daily which might collectively affect your health status. Please, try to keep record of your symptoms and possible medication side effects and refer to your GP for modifications on your medication list according to your GP's judgement.	Participant reported receiving several medications which might collectively affect his/her health status. Please, try to keep record of possible medication side effects and refer to his/her GP for modifications on the medication list according to the GP's clinical judgement.	Participant reported receiving more than 4 medications per day which might have adverse effects on his health status. Please, consider using STOPP/START criteria to regularly review his/her medication list especially if the individual presents frailty indicators (lower grip strength, slower gait speed, lower

				muscle mass, exhaustion, unintentional weight loss) or has complaints about side-effects.
Visual acuity	Moderate or poor	According to your reports you experience some visual difficutlies. Please, consider visiting your doctor to prescribe the most appropriate correction solution or aid and perform regular eye examinations to address any change in your acuity early on. Do not hesitate to report any noticed differences to your doctor.	Participant reported having vision problems. Please, consider talking to his/her GP for the appropriate correction solution or aid according to your judgement and support him/her to perform regular eye examinations to address any change early on. Do not hesitate to contact his/her GP if you notice anything different to his/her functioning.	Participant reported visual difficulties. Please, consider this finding according to your clinical judgement to propose further examinations or corrective solutions if needed
Hearing acuity	Moderate or poor	According to your reports you experience some hearing difficutlies. Please, consider visiting your doctor to prescribe the most appropriate correction solution or aid according to your judgements. It is suggested that you undertake regular examinations to address any change in your acuity early on. Do not hesitate to report any noticed differences to your doctor.	Participant reported having hearing problems. Please, consider talking to his/her GP for the appropriate correction solution or aid according to your judgement and support him/her to perform regular hearing examinations to address any change early on. Do not hesitate to contact his/her GP if you notice anything different to his/her functioning.	Participant reported hearing difficulties. Please, consider this finding according to your clinical judgement to propose further examinations or corrective solutions if needed
Orthostatic hypotension test	Positive	According to our measurements, you might experience orthostatic hypotension which can be presented with dizziness, fainting or other symptoms. Drink plenty of water throughout the day. Rise slowly when	Participant's measurements showed that he/she might experience orthostatic hypotension. Please, consult his/her GP for further assessment and instructions. Keep in mind that he/she should have	Participant's measurements showed that he/she might experience orthostatic hypotension. Please, consider this finding according to your clinical judgement, other parameters of this

		transitioning from a sitting position to a standing one and if you feel dizzy at any time point lower your head between your legs, breathe normally and ask for assistance. Please, consult your GP for further advice.	sufficient water intake throughout the day and take all necessary precautions when rising from a sitting position to a standing one.	report and patient's history to propose appropriate interventions and advice.
Number of hospitalizations (last year)	> 1	According to your reports, you were hospitalized more than 1 times during the last year. Please, consider visiting your GP for a further examination of your medical and physical status, especially if the hospitalizations were related to dizziness, falls or fractures.	Participant had more than 1 hospitalizations during the last year. He/she should consider talking to his GP for further consultation regarding his/her medical and physical status, especially if the hospitalizations were related to dizziness, falls or fractures.	Participant was hospitalized more than 1 times during the last yeart which might indicate a deterioration to his/her health status or a different underlying condition, especially if the hospitalizations were related to falls and fractures and the participant presents risk for developing frailty. Please, consider this finding according to your clinical judgement to propose further examinations and interventions.
Number of falls (last year)	> 1	According to your reports, you experienced more than 1 falls during the last year. Please, consider visiting your GP for a further examination of your medical and physical status, especially if the falls were related to dizziness, weakness or loss of orientation.	According to participant's reports, he/she experienced more than 1 falls during the last year. He/should consider visiting his/her GP for a further examination of his/her medical and physical status, especially if the falls were related to dizziness, weakness or loss of orientation.	Participant experienced more than 1 falls during the last year which might indicate a deterioration to his/her health status, an underlying condition or be an indicator of frailty. Please, consider this finding according to your clinical judgement to propose further examination.
Morning systolic pressure	<100 or >140	We noticed that at some point during the days being monitored your blood pressure pattern was different than expected which might be indicative of a health deviation but may also be attributed to a variety of not related parameters (random finding). Please, consider visiting your GP according to your judgement for further consultation if needed.	Participant had blood pressure measurements outside of the normal range during his/her monitoring which might be indicative of an underlying health problem but may also be attributed to a variety of not related parameters (random finding). Please, consider visiting his/her GP according to your judgement for further examination.	Participant had irregular blood pressure results at some points during our monitoring. Please, consider this finding according to your clinical judgement to propose further examination of his/her medical status and/or appropriate interventions.

Morning diastolic pressure	>90		same	Same	same
Evening systolic pressure	<100 >140	or	same	Same	same
Evening diastolic pressure	>90		same	Same	same

Nutritional guidelines

For the construction of nutritional recommendations, we included participants' measurements regarding their waist circumference, Body Mass Index (BMI), lean body mass and body composition measured by FORA Diamond scale, their score in Mini Nutritional Assessment scale (Guigoz & Vellas, 1999) and their self-reported unintentional weight loss during the last year. A detailed description of the recommendations according to the scores obtained through the clinical evaluation can be found in Table 10.

Table 10. Recommendations for nutritional parameters per user group

		Recommendations		
Parameter	**Value**	**Older adult**	**Caregiver**	**Healthcare professional**
Waist circumference	If men and ≥103 cm	According to your measurements your waist circumference is higher than expected which may significantly affect your health. You should follow a healthy diet and engage in regular exercise in order to maintain a healthy body weight after consulting your doctor/dietologist.	Participant's measurements showed an elevated waist circumference which can be linked to health problems and might affect his/her physical status. He/she should consider adopting a healthy diet and regular exercise after consulting his/her GP and dietologist.	Participant has a higher than normal waist circumference. Please, use this information in the context of your clinical practice and provide further examinations or lifestyle modifications according to your judgement.
	If women and ≥89 cm	same	Same	same
BMI index	Higher than 30	Your BMI index is higher than normal. You should follow a healthy diet and engage in regular exercise in order to maintain a healthy body weight after consulting your doctor/dietologist.	Participant's measurements showed an increased BMI index which is associated with health problems and might affect his/her physical status. He/she should consider adopting a healthy diet and regular exercise after consulting his/her GP and dietologist.	Participant has a higher than normal BMI index. Please, consider this finding according to your clinical judgement to propose a healthier lifestyle.

	Lower than 18	Your BMI index is lower than normal. You should follow a healthy diet, with high quality food and protein intake and engage in regular exercise in order to maintain a healthy body weight.	Participant's measurements showed a less than normal BMI index which might be due to malnutrition or other parameters and might adversely affect his physical strength and status. He/she should consider adopting a healthy diet, rich in protein and vitamins and engage in regular strengthening exercise after consulting his/her GP and dietologist.	Participant had a lower than normal BMI index which might be due to malnutrition. Please, consider this finding according to your clinical judgement to propose further examinations or lifestyle modifications.
	18-30	Your BMI index is within the normal range indicating that you maintain a healthy body weight. Make sure that you maintain a healthy diet with regular exercise (taking all necessary safety precautions) and adequate levels of hydration.	Participant's BMI index is within the normal range. He/she should make sure that he/she maintains a healthy diet with regular exercise (taking all necessary safety precautions) and adequate levels of hydration.	Participant's BMI index is within the normal range.
MNA score	If equal or less than 11	Your answers on a standardized scale showed that you have a different nutritional pattern than expected for your age. Please, consider visiting your GP in order to further examine your nutritional status.	Participant's answers on a standardized scale showed that his/her nutritional intake might be lower than expected which may affect his physical status. Please, consider consulting his/her GP for	Participant had an abnormal total score on the MNA scale (≤11) which is linked to malnutrition. Please, consider this finding according to your clinical judgement to propose further examinations and healthier lifestyle choices.

			further assessment of his/her nutritional status.	
Body fat percentage	Higher than 36% and woman OR higher than 25% and man	According to your measurements your body fat percentage exceeds the recommended guidelines which may significantly affect your health. You should follow a healthy diet and engage in regular exercise in order to maintain a healthy body weight after consulting your GP and taking all necessary safety precautions.	Participant's measurements showed that his/her body fat percentage exceeds the recommended limit which is associated with health problems and might affect his/her physical status. He/she should consider adopting a healthy diet and engage in regular exercise after consulting his/her GP and dietologist.	Participant has a higher than normal body fat percentage. Please, consider this finding according to your clinical judgement to propose healthier lifestyle choices.
	Lower than 25% and woman OR lower than 13% and man	According to our measurements, your body fat percentage is lower than normal. Body fat is necessary for all bodily functions and lower percentages are associated with nutritional deficiencies and health problems. You should follow a healthy diet, rich in high quality food and protein intake and engage in regular exercise in order to maintain a healthy body weight. Our team can provide a list of healthcare professionals and organizations who can offer support and further assist you in assessing your nutritional status. Do not hesitate to contact your GP if you notice significant discomfort.	Participant's measurements showed a less than normal body fat percentage which might be due to malnutrition or other parameters and might adversely affect his physical strength and status. He/she should consider adopting a healthy diet, rich in protein and vitamins and engage in regular strengthening exercise after consulting his/her GP and dietologist. Our team can provide a list of healthcare professionals and organizations who can offer support and further assist you in assessing your relative's nutritional status. Do not hesitate to contact his/her GP if you notice anything that alarms you in your relative's functioning..	Participant had a lower than normal body fat percentage which might be due to malnutrition. Please, consider this finding according to your clinical judgement to propose a healthier lifestyle.
Body water percentage	Lower than 50%	According to our measurements with an electronic scale, your body might need more hydration. Please, consider	Participant's measurements with an electronic scale showed that he/she might need to increase bosy	Participant's measurements on an electronic scale showed low levels of hydration. Please, consider this

		consuming more water throughout the day and maybe set a reminder on your phone, after consulting your GP.	levels of hydration. Please, consider reminding him/her to increase his water intake daily after consulting his/her GP.	finding according to your clinical judgement in order to propose increased water intake.
Bone mass index	If female weighting <50kg and bone mass <1.95	According to our measurements with an electronic scale, your bone mass is different than expected which may affect your physical strength and status. Please, consider adopting a healthy lifestyle with regular physical activity and a diet rich in minerals and vitamins, after consulting your GP/dietologist.	Participant's measurements with an electronic scale showed that his/her bone mass values were different than expected. Please, consider consulting his/her GP for further assessment of his/her nutritional status and physical status. Adoption of a healthy diet rich in vitamins and minerals and engagement in regular physical activities, after consulting his/her GP/dietologist is highly encouraged.	Participant had a lower than expected bone mass percentage on an electronic scale which might negatively affect his physical strength and status. Please, consider this finding according to your clinical jugdement to propose a healthier lifestyle.
	If female weighting 50-75kg and bone mass <2.40	same	Same	same
	If female weighting >76kg and bone mass <2.95	same	Same	same
	If male weighting <65kg and bone mass <2.65	same	Same	same
	If female weighting 65-95kg and bone mass <3.29	same	Same	same
	If female weighting >95kg and bone mass <3.69	same	Same	same

Muscle mass	Lower than 24% and male	According to our measurements with an electronic scale, your muscle mass is different than expected which may affect your physical strength. Please, consider adopting a healthy lifestyle and a diet rich in minerals, protein and vitamins, after consulting your GP. Further examination of your physical status is recommended according to your judgement.	Participant's measurements with an electronic scale showed that his/her muscle mass values were different than expected which may affect his/her physical strength. Please, consider consulting his/her GP for further assessment of his/her nutritional and physical status.	Participant had a lower than expected muscle mass percentage on an electronic scale which might negatively affect his physical strength and status and, also, be an indicator of frailty. Please, consider this finding according to your clinical jugdement to advice further examinations of his/her physical status and diet or activity modifications.
	Lower than 25% and female	same	Same	same
Unintentional weight loss	If variable equals "YES"	According to your statement, you have lost weight unintentionally during the last year. You should refer this to your GP according to your judgement in order to further assess your nutritional and medical status.	Participant stated that he/she has lost over 4.5kgs unintentionally (without modifying his nutritional intake) during the last year. He/she should consult his/her GP in order to assess his nutritional and medical status according to his/her judgement.	Participant reports unintentional weight loss of more than 4.5kgs during the last year which might be an early indicator of frailty. Please, consider further examinations according to your clinical judgement.

Everyday functioning guidelines

For the construction of everyday functioning recommendations, we included participants' scores on Katz Index of Independence in Activities of Daily Living scale (Katz, 1963), Lawton Instrumental Activities of Daily Living scale (Lawton & Brody, 1969), as well as, their self-reported exhaustion. A detailed description of the recommendations according to the score obtained through the clinical evaluation can be found in Table 11.

Table 11. Recommendations for everyday functioning parameters per user group

		Recommendations		
Parameter	**Value**	**Older adult**	**Caregiver**	**Healthcare professional**
Score on Katz ADL scale	<6	According to your answers on a questionnaire you might need assistance to perform basic everyday activities. Please, consider asking assistance from your family members or a professional if you notice that your limitations significantly affect your quality of life.	Participant reported having difficulty to perform some basic everyday activities. Please, consider providing assistance if you think that it is needed to ensure high quality of life.	Participant has difficulty performing 1 or more basic everyday activities (as assessed by KATZ scale). Please, consider this finding in the context of your clinical practice.
Score on Lawton IADL scale	<31	According to your answers on a questionnaire you can perform most of your everyday activities independently but need help in others. Please, consider requesting help by your family or a professional if you notice that your limitations significantly affect your quality of life.	Participant reported having difficulty to perform one or more complex everyday activities. Please, consider providing professional assistance if you think that it is needed to ensure high quality of life.	Participant has difficulty performing 1 or more complex everyday activities (as assessed by IADL scale). Please, consider this finding in the context of your clinical practice.
Self-reported exhaustion		According to your answers you seem to be tired lately which might indicate that you need to adopt a healthier nutrition, regular exercise or might be due to other parameters. Please, consider consulting your GP if you think that your exhaustion significantly affects you in your everyday life.	Participant reported feelings of exhaustion lately which might indicate a nutritional deficiency or be related to other parameters. Please, consider consulting his/her GP for further consultation if you think that this feeling of tireness is unjustified by his/her levels of activity or significantly affects his/her everyday functioning.	Participant reported exhaustion which might indicate an underlying condition, such as development of frailty, nutritional deficiency, medical problem or physical weakness. Please, consider this finding according to your clinical judgement in order to propose further examinations and/or interventions.

Social guidelines

For the construction of everyday functioning recommendations, we included participants' living status and if they were a member of a social group (Woo, Goggins, Sham, & Ho, 2005). A detailed description of the recommendations according to the score obtained through the clinical evaluation can be found in Table 12.

Table 12.Recommendations for social parameters per user group

		Recommendations		
Parameter	Value	Older adult	Caregiver	Healthcare professional
Living status	Living alone	Please, make sure that you maintain a rich social life and that you can have assistance if needed or in case of an emergency. Please, ask for help if you notice anything different in your regular functioning.	Please, make sure according to your judgement that he/she maintains a rich social life and that your relative can have help in case of an emergency. Do not hesitate to offer help or consult his/her doctor if you notice anything different in his/her level of functioning.	Participant reported living alone. Please, consider this information in the context of his overall health status and medical history. Please, consider advising him/her to request professional assistance according to your clinical judgement.

Member of social group	No	Make sure that you maintain a healthy and rich social life which is beneficial for your mood and stress levels. Please, consider participating in a group activity, volunteer work or be a member in an organization according to your time availabitility and capacity in order to improve your levels of activity and social life. Our team can provide a list of organizations, group activities and hobbies that might interest you.	Please, consider prompting your relative to engage more in social activities. Please, consider assisting and prompting your relative to participate in a group activity, volunteer work or be a member in an organization according to his/her time availabitility and capacity in order to improve his/her levels of activity and social life. Our team can provide a list of organizations, group activities and hobbies that might interest your relative and you. Do not hesitate to ask for help if you notice anything different in his/her level of functioning	Participant does not engage in regular group activities, such as being a member of an organization. Please, consider this information in the context of his overall social functioning and psychological status in order to propose appropriate interventions if needed.

Psychological guidelines

Psychological guidelines were based on the scores of the participants on Geriatric Depression Scale-Short form-GDS (Sheikh & Yesavage, 1986) and if they reported occasional or permanent sleep problems. A detailed description of the recommendations according to the score obtained through the clinical evaluation can be found in Table 13.

Table 13. Recommendations for psychological parameters per user group

		Recommendations		
Parameter	Value	Older adult	Caregiver	Healthcare professional
Score on GDS	≥5	According to your answers on a questionnaire you do not seem to be in a good mood lately. Physical exercise and meditation techniques can help you manage your distress after consulting your GP. Remember to be calm, rest and ask for assistance whenever you need it. Do not hesitate to refer to a healthcare professional if you experience significant psychological discomfort. Our team can provide a list of healthcare professionals and organizations who can offer support and further assist you in assessing your status.	Participant reported having a bad mood on different questions of a self-report questionnaire. Physical exercise and meditation/relaxation techniques can help him/her manage his/her levels of distress after consulting his/her GP. Remember to offer comfort and reassurance to your relative according to your judgement and remind him/her that he/she must rest and engage in recreational activities. Do not hesitate to refer to a healthcare professional if you or your relative experience significant psychological discomfort. Our team can provide a list of healthcare professionals and organizations who can offer support and further assist you in assessing your/your relative's status.	Participant had an elevated score on Geriatric Depression Scale. Please, consider advising further assessment of his/her psychological status according to your clinical judgement.
Sleep problems	Occasional or permanent sleep problems	According to your reports, sometimes you experience sleep problems. This could be attributed to high anxiety levels or some other condition. Consider maintaining a healthy weight and diet and engage in regular	Participant reported having trouble sleeping at night which might be attributed to his/her existent medical conditions, levels of anxiety or other parameters. He/she should consider maintaining a healthy body weight and diet and engage in regular exercise and	Participant reported sleeping problems. Please, use this information in the context of your clinical practice and provide further examinations or lifestyle

	exercise and relaxation techniques. Our team can provide a list of healthcare professionals and organizations who can offer support and further assist you in assessing your status. Do not hesitate to contact your GP if you notice significant discomfort.	relaxation techniques. Our team can provide a list of healthcare professionals and organizations who can offer support and further assist you in assessing your relative's status. Please, consider consulting his/her GP for further consultation if you notice that sleeping problems significantly affect his/her functioning.	modifications according to your judgement.

Physical guidelines

Physical guidelines were constucted based on the participants' scores in tests assessing physical and motor function, such as the Timed Up and Go (TUG) Test (Podsiadlo & Richardson, 1991), the Lower Extremity Muscle Strength (LEMS) Test measuring ability and speed in rising from a chair five times (Csuka & McCarty, 1985), the Single-Foot Station Test assessing balance (Vellas et al., 1997) and the Dynamometer Test assessing grip-strength (Lee et al., 2017). A detailed description of the recommendations according to the score obtained through the clinical evaluation can be found in Table 14.

Table 14. Recommendations for physical parameters per user group

		Recommendations		
Parameter	Value	Older adult	Caregiver	Healthcare professional
LEMS test	> 15 seconds	Your performance on a test assessing lower limb strength was different than expected which maybe linked to a variety of health related factors. Please, consider maintaining a healthy diet with adequate levels of protein intake and engaging in strengthening exercise and resistance training after consulting your GP/dietologist and taking all the necessary safety precautions. Our team can provide a list of healthcare professionals and organizations who can further assist you in assessing your status.	Participant had a different than expected performance on a test assessing lower limb strength that could be attributed to a variety of health related factors. He/she should consider maintaining a healthy diet with adequate protein intake and engaging in strengthening exercises and resistance training after consulting his/her GP/dietologist and taking all the necessary safety precautions. Our team can provide a list of healthcare professionals and organizations who can further assist you in assessing your relative's status.	Participant had a slower than usual performance on a lower limb strength test, which could be indicator of fraity. Please, consider this information in the context of your clinical practice and consider advising your patient to modify his diet/activity and/or undertake further examinations according to your clinical judgement.
	<15 seconds	Your performance on a test assessing lower limb strength was within the normal range. We suggest maintaining a	Participant's performance on a test assessing lower limb strength was within	Participant's performance on a lower limb strength test was within the

		healthy diet with adequate protein intake and engaging in regular strengthening exercise after consulting your GP and taking all the necessary safety precautions. In case, you or your family members notice anything different to your functioning please refer it to your GP. Our team can provide a list of healthcare professionals and organizations who can further assist you in assessing your status.	the normal range. He/she should maintain a healthy diet with adequate protein intake and consider engaging in strengthening exercises after consulting his/her GP and taking all necessary safety precautions. Regular assessment (once/year) is encouraged to identify any occuring difficulties early on. Please, do not hesitate to refer to participant's GP for any changes noticed. Our team can provide a list of healthcare professionals and organizations who can further assist you in assessing your relative's status.	normal range. Please, consider this information in conjunction with other parameters of this report.
Single-foot station	< 5 seconds	Your performance on a balance test was different than expected which could be attributed to health-related factors but could also, be a random finding. Please, visit your GP for further examination according to your judgement, especially, if you notice any differences in your balance or coordination of movements. Maintenance of a healthy diet with adequate protein intake and engagement in regular physical exercise taking all necessary safety precautions is encouraged. Our team can provide a list of healthcare professionals and organizations who can further assist you in assessing your status.	Participant had an unexpected performance on a balance test which could be attributed to health-related factors but could also, be a random finding. He/she should consider visiting his/her GP for further examination, especially, if there are any noticable differences in his/her balance or coordination of movements. Maintenance of a healthy diet with adequate protein intake and engagement in regular physical exercise taking all necessary safety precautions is encouraged. Our team can provide a list of healthcare professionals and organizations who can further assist you in assessing your relative's status.	Participant had balance difficulties according to his performance on a relevant test (single foot station) which could be an indicator of motor difficulties. Please, consider this information in the context of your clinical practice and provide your clinical advice according to your judgement, as well as, other parameters of this report.
	> 5 seconds	Your performance on a balance test was within the average range. Maintenance	Participant had a normal perfomance on a balance test. Maintenance of a healthy	Participant's performance on a balance test was within the average

		of a healthy diet with adequate protein intake and engagement in regular physical exercise after consulting your GP/dietologist is highly recommended. Do not hesitate to consult your doctor if you notice any differences to your functionality. We suggest undertaking regular physical exams to ensure that any difficulty is identified early on. Our team can provide a list of healthcare professionals and organizations who can further assist you in assessing your status.	diet with adequate protein intake and engagement in regular physical exercise after consulting his/her GP/dietologist is highly recommended. Do not hesitate to consult his/her doctor if you notice any changes in his/her functionality. We suggest undertaking regular physical exams to ensure that any difficulty is identified early on. Our team can provide a list of healthcare professionals and organizations who can further assist you in assessing your relative's status.	range. Please, consider this information in conjunction with other parameters of this report.
TUG test	Abnormal	Your performance on a gait speed test was different than normal which could be attributed to health-related factors but could also, be a random finding. Please, visit your GP for further examination according to your judgement, especially, if you notice any differences in your walking, movements or flexibility. Maintenance of a healthy diet with adequate protein intake and engagement in regular physical exercise taking all necessary safety precautions is encouraged. Our team can provide a list of healthcare professionals and organizations who can further assist you in assessing your status.	Participant had a different than expected performance on a gait speed test which could be attributed to health-related factors but could also, be a random finding. He/she should consider visiting his/her GP for further examination, especially, if there are any noticable differences in his/her balance or coordination of movements. Maintenance of a healthy diet with adequate protein intake and engagement in regular physical exercise taking all necessary safety precautions is encouraged. Our team can provide a list of healthcare professionals and organizations who can further assist you in assessing your relative's status.	Participant had slower gait speed according to his/her performance on Timed Get Up and Go Test which could be an indicator of motor difficulties or frailty. Please, consider this information in the context of your clinical practice and provide your clinical advice according to your judgement, as well as, other parameters of this report.
	Normal	Assessment of your gait speed indicates that your performance falls within the average range. Please, engage in	Participant's performance on a gait speed test was within the average range. He/she should engage in regular	Participant's gait speed was normal as assessed by Timed Get Up and Go Test. Please, consider this

		regular physical activity after consulting your doctor and taking all necessary safety precautions. Do not hesitate to consult your GP if you notice any changes to your usual level of functioning.	physical activity after consulting his/her doctor and taking all necessary safety precautions. Do not hesitate to consult his/her GP if you notice any changes to his/her usual level of functioning.	finding in conjunction with other parameters of this report, as well as, the patient's history in your clinical practice.
Grip strength assessed by dynamometer	Abnormal	Your hand strength was different than expected on a standardized test assessing hand strength which could be attributed to health-related factors but could also, be a random finding. Please, visit your GP for further examination according to your judgement, especially, if you notice any differences in your usual functioning . Maintenance of a healthy diet with adequate protein intake and engagement in regular physical exercise taking all necessary safety precautions is encouraged. Our team can provide a list of healthcare professionals and organizations who can further assist you in assessing your status.	Participant's hand strength was different than expected on a standardized test which could be attributed to health-related factors but could also, be a random finding. Please, visit your GP for further examination according to your judgement, especially, if you notice any differences in his/her usual functioning. Maintenance of a healthy diet with adequate protein intake and engagement in regular physical exercise taking all necessary safety precautions is encouraged. Our team can provide a list of healthcare professionals and organizations who can further assist you in assessing your relative's status.	Participant had a lower than average performance on a grip strength test using a dynamometer which could be an indicator of frailty. Please, consider assessing his overall physical status according to your clinical judgement.
	Normal	Assessment of your hand strength indicates that your performance falls within the average range. Please, engage in regular physical activity after consulting your doctor and taking all necessary safety precautions. Do not hesitate to consult your GP if you notice any changes to your usual level of functioning.	Participant's performance on a hand strength test was within the average range. He/she should engage in regular physical activity after consulting his/her doctor and taking all necessary safety precautions. Do not hesitate to consult his/her GP if you notice any changes to his/her usual level of functioning.	Participant's grip strength was normal as assessed by a relevant test using a dynamometer. Please, consider this finding in conjunction with other parameters of this report, as well as, the patient's history in your clinical practice.

Lifestyle guidelines

For the construction of the lifestyle guidelines, everyday habits affecting health status, such as smoking, exercising and alcohol consumption were considered (Woo et al., 2005). A detailed description of the recommendations according to the score obtained through the clinical evaluation can be found in Table 15.

Table 15. Recommendations for lifestyle parameters per user group

		Recommendations		
Parameter	Value	Older adult	Caregiver	Healthcare professional
Smoking	Yes	Smoking is related to many health problems. You should consider quiting or reducing smoking after consulting your GP. Our team can provide contact details of healthcare professionals and organizations who can assist you in your efforts.	Participant reported smoking which is related to many health problems. He/she should consider quiting or reducing smoking after consulting his/her doctor. Our team can provide contact details of healthcare professionals and organizations who can assist him/her in his/her efforts.	Participant reported smoking. Plase, consider this information in the context of your clinical practice and possibly advise him/her to quit or reduce it according to your judgement.
Alcohol consumption	>10.5 units/week	Average portion of alcohol is 1.5 unit (i.e., 1 glass of wine or 1 small bottle of beer) per day. Consumption over the recommended amount can be related to many health problems. Consider reducing the amount that you are drinking after consulting your GP. Our team can provide contact details of healthcare professionals and organizations who can assist you in your efforts.	Participant reported consumption of alcohol higher than the recommended values for older adults which can be related to many health problems. Average portion of alcohol is 1.5 unit (i.e., 1 glass of wine or 1 small bottle of beer) per day. He/she should consider reducing alcohol consumption after consulting his/her GP. Our team can provide contact details of healthcare professionals and organizations	Participant reported consuming more alcohol units than the maximum recommended ones for older adults. Please, consider this information in the context of your clinical practice and consider advising him to reduce alcohol consumption according to your clinical judgement.

			who can assist him/her in his/her efforts.	
Physical activity	0-<2 hours/week	According to your statements, your physical activity per week is lower than expected. Consider increasing your activity levels (i.e., swimming, group exercise or going for a walk every day) taking all safety precautions according to your capacity and after consulting your doctor	Participant reported engaging in less than recommended physical activity per week. He/she should consider increasing his/her activity levels taking all safety precautions according to his/her capacity and after consulting his/her GP.	Participant reported low physical activity (0 or <2h per week). Please, consider this information in the context of your clinical practice and consider advising him/her to engage in more activities according to your clinical judgement.
	>2hours/week	According to your statements, your physical activity per week is within the normal range. Make sure to maintain your activity levels by engaging in regular exercise (i.e., swimming, group exercise or going for a walk every day) taking all safety precautions according to your capacity and after consulting your doctor.	Participant reported engaging in adequate physical activity per week. He/she should maintain his/her currentbactivity levels taking all safety precautions according to his/her capacity and after consulting his/her GP.	Participant reported adequate physical activity per week. Please, consider this information in the context of your clinical practice.

After their construction, the aforementioned guidelines were incorporated in the DSS and were generated and visualized automatically on user interface depending on the participants' measurements. The layout of the interface, information conveyed and recommendations were different among the three target groups. Consortium clinicians could log in to the platform and view the participant's recommendations at any time point. In a parallel manner, log on credentials with different levels of authorization were created for all target groups: formal and informal caregivers, older users and healthcare professionals. Furthermore, a DSS mobile application was created to facilitate access to the platform for all stakeholders.

Since recommendations are generated according to each participant's measurements and stored in the system, they can be retrieved through a web service and displayed in the DSS UI, either in the web version or the mobile version. In the web version, older users have the opportunity to connect to the platform and see the recommendations which have been generated (Figure 2), as well as the ability to download the recommendations in PDF format. The clinician is also able to print the recommendations in PDF format if an older person does not wish to access to the platform (Figures 3, 4 and 5).

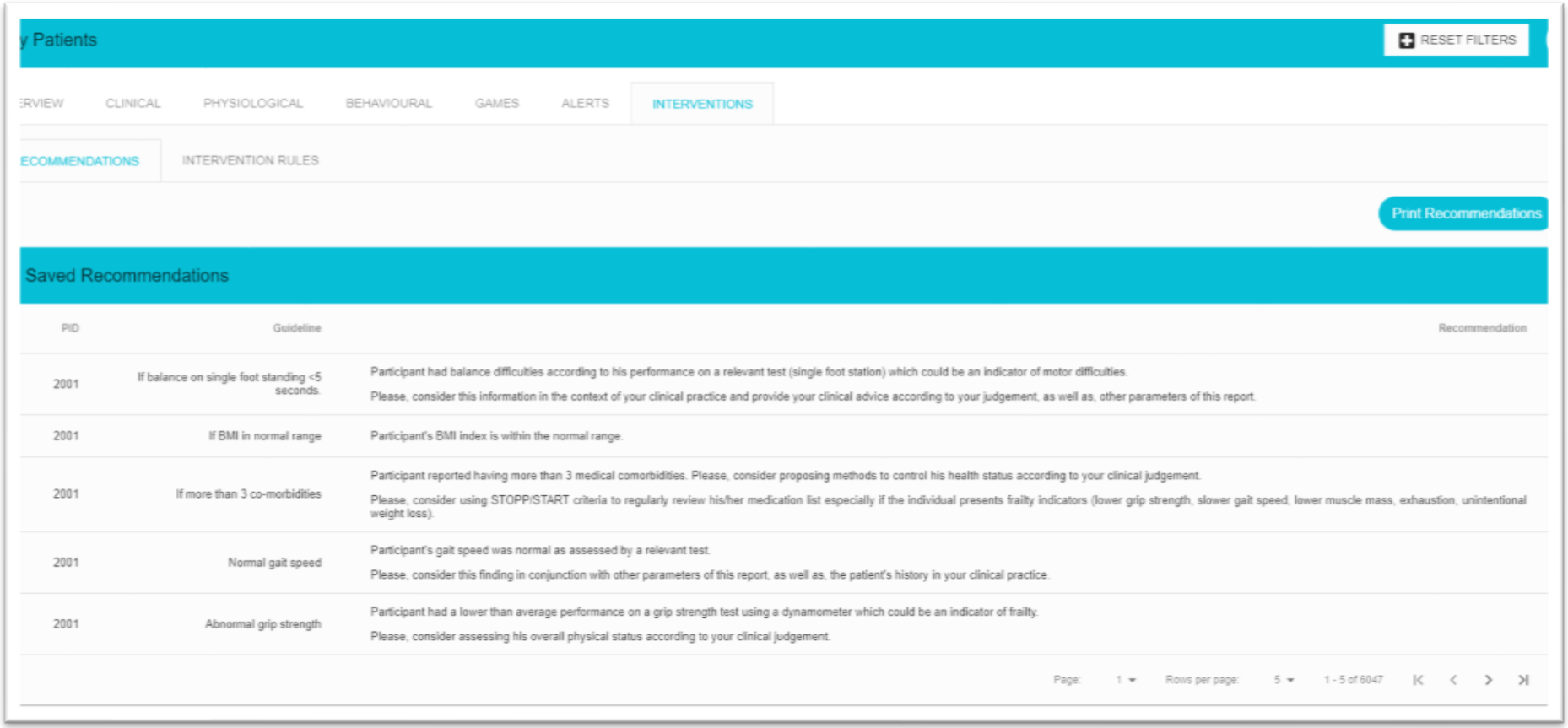


Figure 2. The recommendations view in the DSS UI

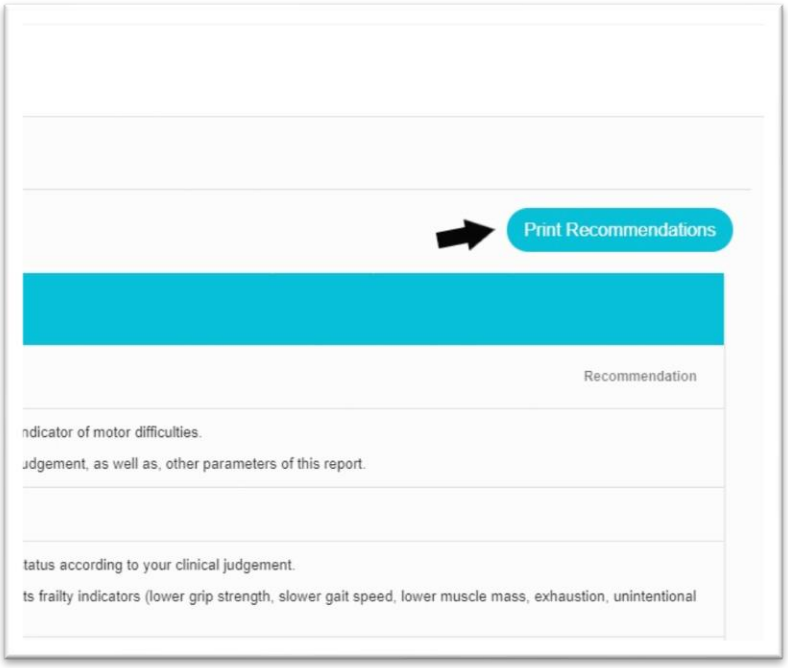


Figure 3: The user can click on the "Print Recommendations" button to download the recommendations in PDF format.

Figure 4: Example of printable recommendations, in PDF format.

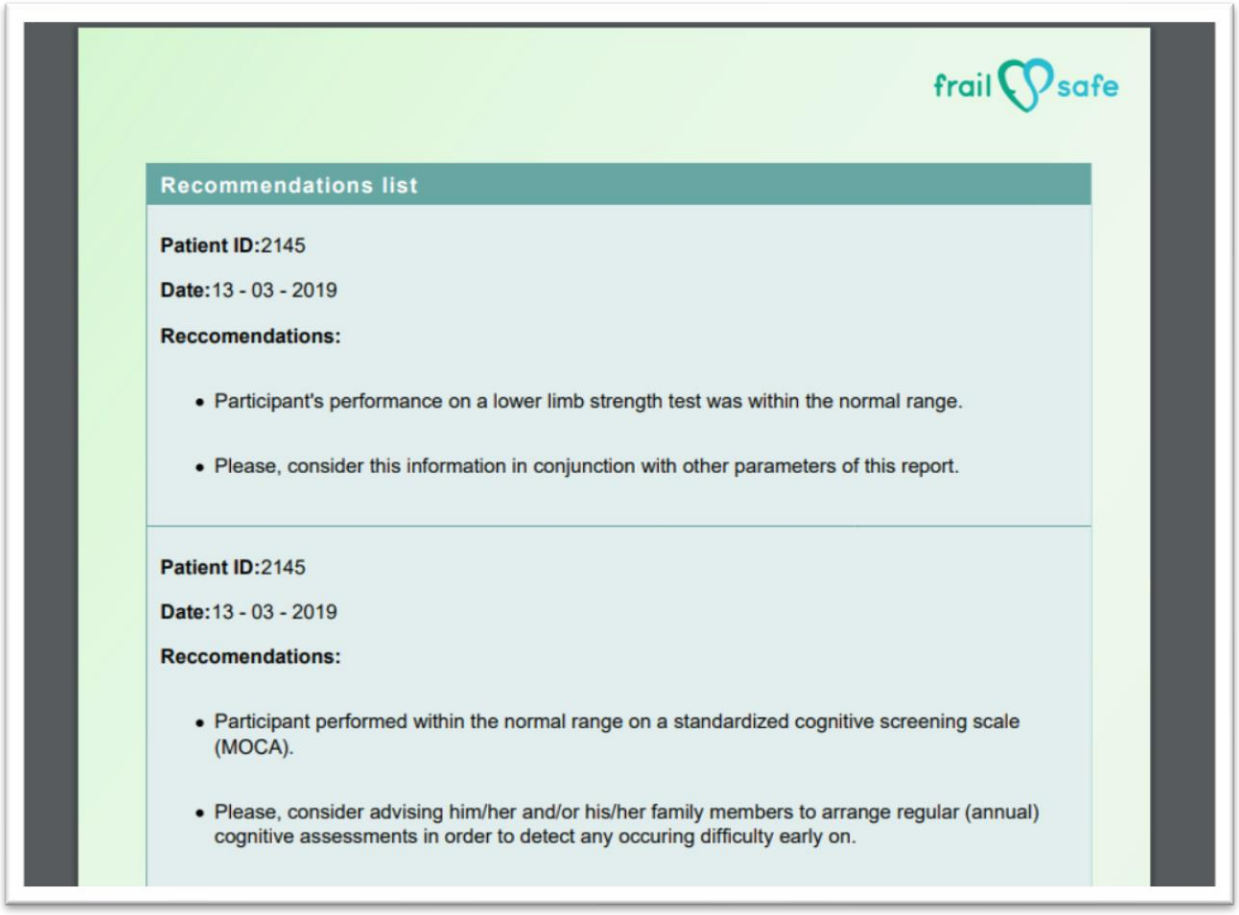


Figure 5: Example of printable recommendations, in PDF format.

In the mobile application of the DSS UI, at the clinician's interface, all the participants' recommendations are collected and displayed in order to have an overall view of their condition but they also have the option of viewing recommendations for each participant individually (Figures 6,7). At the Participant's interface, every older person can be informed about his/her recommendations so they can be aware of their health status.

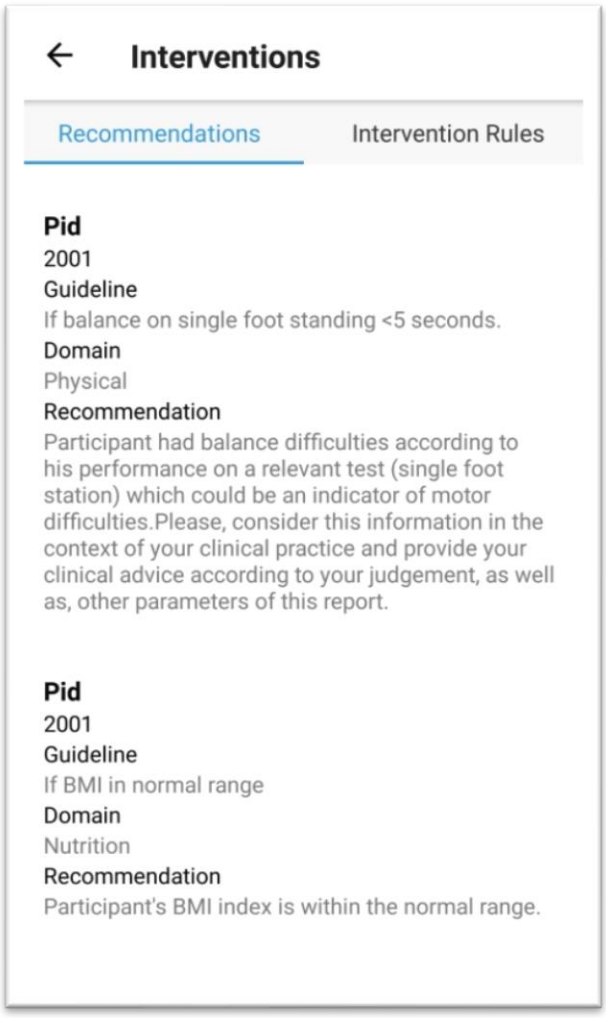


Figure 6. Recommendations for all participants, in the mobile DSS UI application

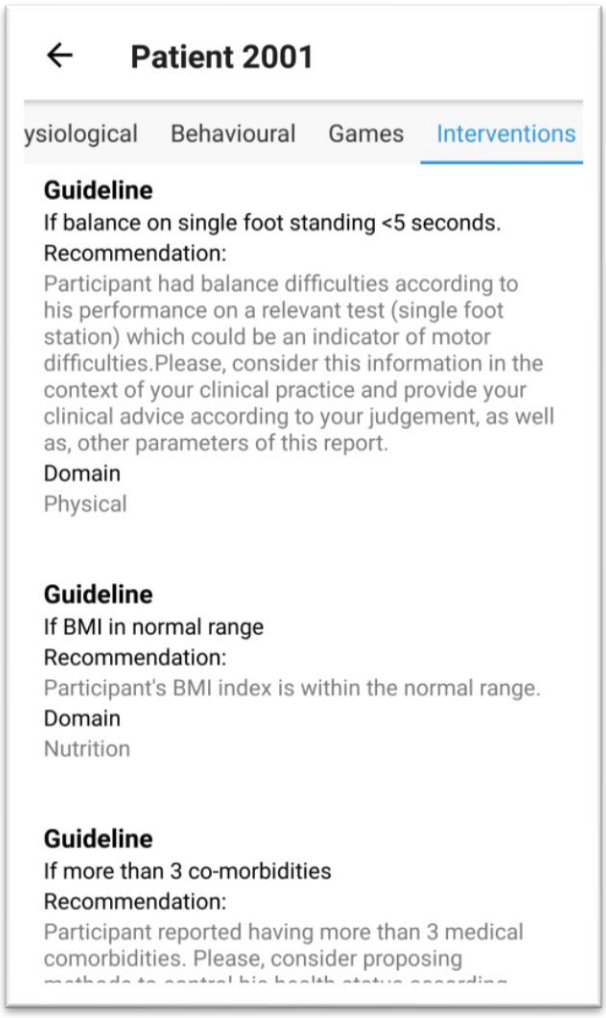


Figure 7. Recommendation for participant 2001, in the mobile DSS UI.

2.1.4 Frailty Index

As described, individualized recommendations were based on participants' scores on various scales and examinations performed during the clinical evaluation visits. Furthermore, based on each participants' measurements from the FrailSafe devices, a predictive algorithm was developed and incorporated in the FrailSafe platform to indicate the participants' risk for developing frailty. The idea was to examine whether we can extract early indicators of deterioration in the participants' health condition that might lead to adverse events.

In order to build such a metric, we have employed deep machine learning techniques which could exploit features from subjects with known outcomes and find the appropriate decision boundaries (in the original or transformed feature space) that can distinguish between profiles that are more or less prone to future adverse events, as described in the deliverable *D4.17 FrailSafe Decision Support System vers b*. The training of the prediction model was performed by examining the temporal multi-dimensional profile captured by the multiple sensing modalities (WWBS, the dynamometer, the game suite and the GPS) during a predefined time period (a year) before the adverse event. First temporal alignment of the sensor's recordings and clinical variables was performed to project all measurements acquired in different time

points into a common reference frame. The statistical features were extracted within a daily time span from the raw or secondary measurements representing physiological and cognitive state, as well as, indoor and outdoor mobility behavior. Since the devices were used on multiple days (usually a few days per month, for two to six months) prior to the adverse event, the temporal evolution of each feature could be tracked. Each time series was then modeled by a linear function whose parameters (the slope) formed the final descriptors, which we call *delta* features to differentiate them from the individual temporal measurements (*raw* features). The multi-parametric descriptors derived from all sensors were, subsequently, fused into a long feature vector and introduced to Principal Component Analysis for dimensionality reduction, such that 98% of the data variance was retained. Classification was subsequently performed on the orthogonally transformed and reduced variables using the SPEC_MIL algorithm. The classifier returns a decision score that is indicative of the risk having an adverse event in the near future and is used as FrailSafe's technical frailty index.

The construction of the frailty index was based on the main group (group B) that included 40 subjects per center that received seven FrailSafe sessions and three clinical evaluations in a 16month period. Any measurements up until six months after an adverse event were considered post-event and excluded from the analysis. Out of all participants of the main group, 79 of them had one or multiple measurements from all devices (WWBS, games, GPS, text), and had not missed the comprehensive geriatric assessment, by the time of the analysis. Evaluation was based on cross-validation, *i.e.* the subjects were split in disjoint training and test sets used for model estimation and prediction, respectively. This procedure results in subject-independent models that can be used for risk prediction for any new subject given his/her personal multi-domain profile. The evaluation of the predicitive ability of each device, as well as, combination of devices, allowed to select the final features used in the frailty index. Details on the analysis were provided in *D4.17 FrailSafe Decision Support System vers b*, and further information is provided in section 2.2.1 of this deliverable.

Frailty Risk is a multi-variable factor for which a number is calculated between 0 to 1. Once exported, this value is included in the appropriate web service and therefore can be retrieved and displayed in the DSS UI, in the web or mobile version. The specific value of the frailty index was added in the clinician's interface of the DSS UI, and in the older person’s and caregiver’s overview table. A qualitative visual indication of the frailty index was also added for the older person, as well as, for the informal caregivers presenting less verbal and more visual information. Specifically, when the Frailty Index value is up to 0.33, the risk levels are considered low, when the value is between 0.33 and 0.66, the risk levels are considered moderate and finally, when the value is greater than 0.66, the risk levels are considered high. The risk status is represented in the platform with a color indicator, green for low risk, orange for moderate risk and red for high risk. Moreover, a textual sentence of a general recommendation is presented, in order to provide a description that is more meaningful and less stressful to the individual than a numeric value.

Before the formulation of the sentences according to participants’ score on the Frailty Index, the same issues described in the previous section were considered for the conveyance of the results to user groups (margin of error, induction of stress and appropriate language). The final sentences included in the DSS according to participants’ scores can be found in the following Table and an example of visualization in DSS can be found in Figure 9.

Table 16. Frailty Index sentences per target group

Risk	Color Indicator	Older adults	Caregivers	Healthcare professionals
Low		Keep up the good work! Follow a healthy lifestyle, engage in regular exercise and consult your doctor regularly, especially if you notice anything different in your usual functioning	Prompt your relative to keep up with the good work! Assist them in maintaining a healthy lifestyle, engage in regular exercise and consult their doctor regularly, especially if you or they notice anything different in their usual functioning.	According to the data logged in the FrailSafe platform, your patient's performance is within the normative range. View the interventions tab for more details.
Moderate		Your overall measurements indicate that you could possibly improve your health status in one or more ways (either this means engaging in more regular exercise, adopting healthier nutritional habits or other). Consider consulting your GP for further instructions.	Your relative's overall measurements indicate that they could possibly improve their health status in one or more ways (either this means engaging in more regular exercise, adopting healthier nutritional habits or other). Consider consulting their GP for further instructions.	According to the data logged in the FrailSafe platform, your patient's performance in one or more health parameters is outside the normative range. View the interventions tab for more details.
High		Your overall measurements indicate that you could improve your health status in one or more ways (either this means engaging in more regular exercise, adopting healthier nutritional habits or other). Consult your GP for further assessments and instructions.	Your relative's overall measurements indicate that they could improve their health status in one or more ways (either this means engaging in more regular exercise, adopting healthier nutritional habits or other). Consult their GP for further assessment and instructions.	According to the data logged in the FrailSafe platform, your patient's performance in one or more health parameters is outside the normative range. View the interventions tab for more details.

Furthermore, healthcare professionals could have an indicator next to each of their patients, in general patient overview, in order to faciliate decision making processes (Figure 8). Especially for healthcare professionals, a disclaimer was added explaining the rationale behind the Frailty Index and its non-medical information conveyance (Figure 10).

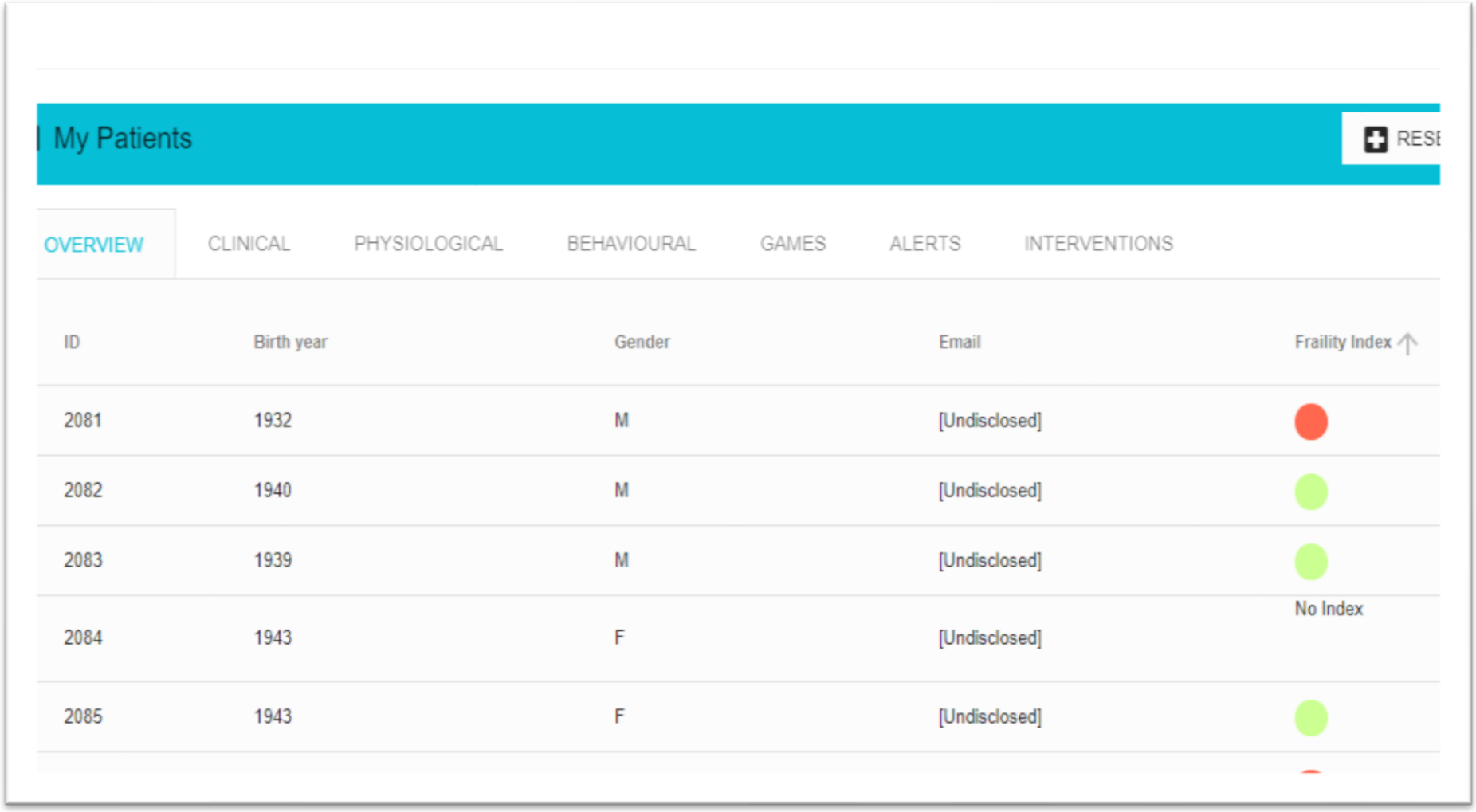


Figure 8. Frailty index in patient overview (healthcare professional authorisation)

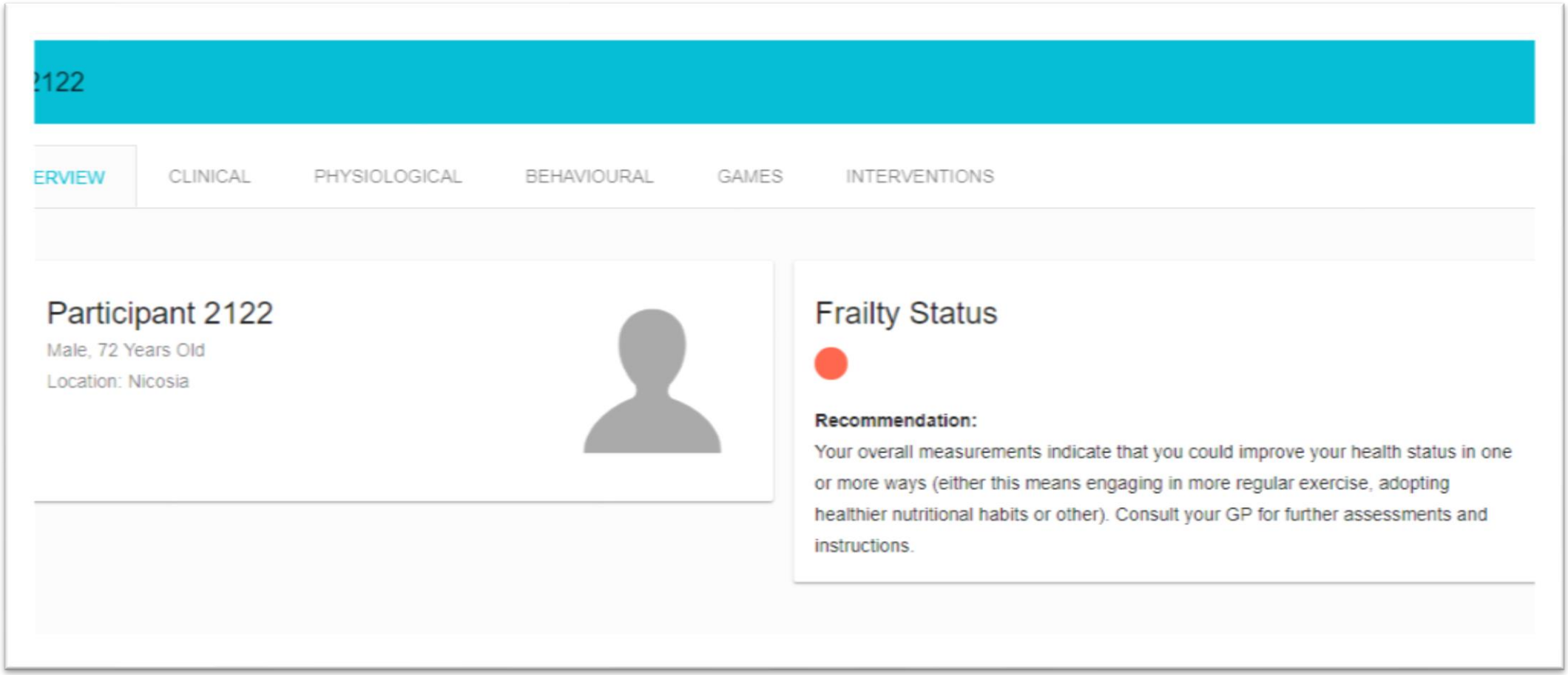


Figure 9.Frailty index in DSS (older adult authorised)

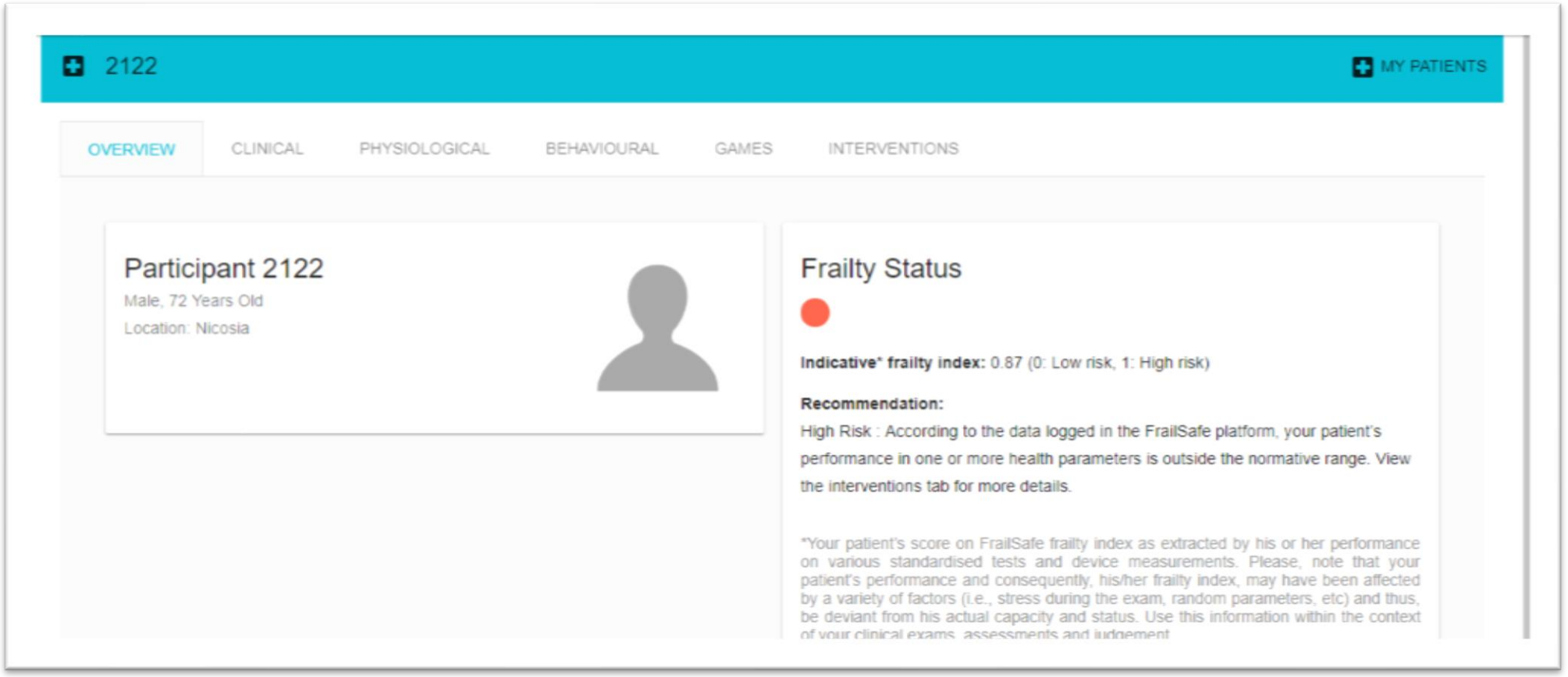


Figure 10. Frailty index in DSS (healthcare professional authorised)

2.1.5 Intervention protocol

Consortium members agreed on a common protocol for the consistent implementation of the intervention phase among clinical centers. In detail, during M38 and after at least two consecutive measurements for each participant were performed, clinicians logged in the DSS feature using each user's credentials. From the "Interventions" tab they obtained the recommendations automatically generated by the system and compiled them all in an individualized report. Consequently, a physician from each clinical centre reviewed all recommendations generated, as well as, an overview of the participants' profile based on logged data and provided an overall opinion on the results (Figure 11).

According to the domain-specific vulnerability indicated by the results (*i.e.,* recommendations indicating a vulnerability in physical or nutritional domain) a tailored intervention plan was selected for each participant. More specifically, we created leaflets with specific health, physical, nutritional, cognitive and psychosocial guidelines aimed to frailty-prevention and health improvement (Figure 12 and Annex V). Those leaflets were provided to the participants accompanying their report during a visit to their home setting on M38. Participants were given time to discuss the results and their implications, as well as, the actions they can take to improve their health. One month after the completion of recommendation administration, participants were asked to fill in a questionnaire to assess their compliance and satisfaction from this process (Annex IV).

Summary of findings and recommendations

Your FrailSafe profile shows that, compared to other people of your age, you are noticing some difficulties, especially in your memory and psychological status (i.e., elevated anxiety or mood fluctuations). According to your reports, your levels of activity seem to be within the normal range, but your hand strength falls slightly outside the normal range and you often experience tiredness and pain. Finally, you mentioned that you have more than one co-occurring health conditions (including arthralgies) and you receive over 4 medications daily. Please, consult your doctor for further instructions.

It is recommended that you:

A) Maintain a healthy diet with adequate intake of protein and vitamins and try to maintain a healthy body weight after consulting a health professional. Healthy body weight helps reduce pain in musculoskeletal disorders, reduce fat levels in your blood, improve cardiovascular function and mood. It is also recommended to do frequent physical exercise, especially muscle strengthening, after consulting your doctor, without pushing yourself beyond your limits and complying with all safety precautions.

B) The co-occurrence of more than two health conditions at the same time makes it necessary to regularly monitor your health (e.g., cardiovascular function, cholesterol levels, etc.) and strictly follow your doctor's instructions. Use reminders or a calendar to note down specific instructions and dates for follow-up exams. Reminders set on your mobile phone can also help you manage your medication. Keep in mind that taking multiple drugs at the same time, despite being unavoidable for successful health management, may have some side effects. Make sure that you observe and record any changes in your functionality or the effects of the medicines on your health, and report them to your doctor at your discretion. Keep a diary and record how your medication affects you in conjunction with other parameters (for example, "taking this medication causes me dizziness before lunchtime"). Inform your doctor about the symptoms so that he/she can modify your medication list or dosages if and when they feel it is necessary. Never attempt modifying your medications/dosages by yourself without informing your doctor. (Consult the leaflet "General recommendations: Health" attached to this report.

C) Try to reduce your anxiety and address the problems of everyday life calmly and optimistically. If you see that your bad mood affects you very much in your everyday life, consult a health professional (Consult the "General Recommendations: Psychosocial function" leaflet attached

D) You can always follow a mental enhancement program to stimulate your brain (Consult "General Recommendations: Cognitive Enhancement" leaflet attached).

You can always find your reports and recommendations at: https://ecrf.frailsafe-project.cloud

Figure 11. Example of guidelines report to an older user

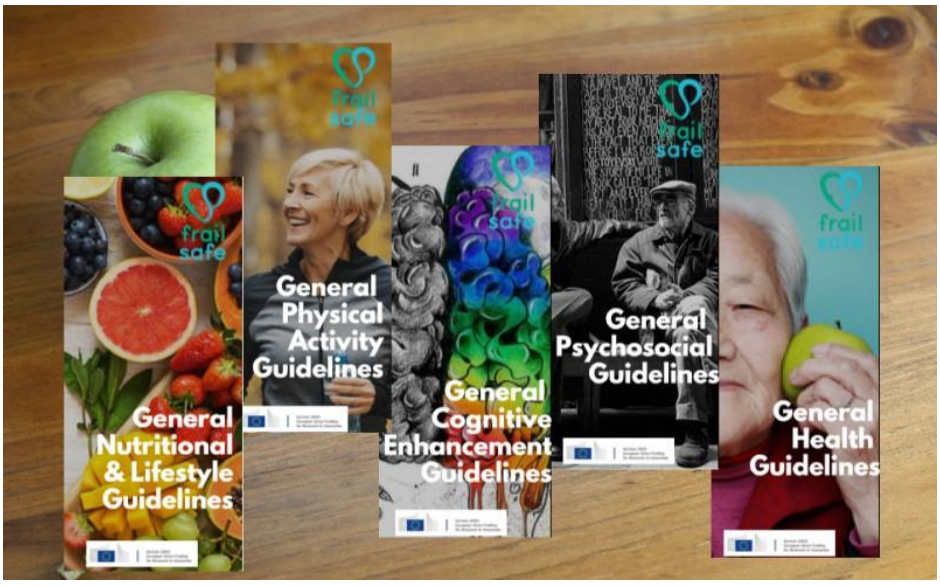


Figure 12. Leaflets: Domain health-specific guidelines

Family members and doctors were, also, included in this process, in case the participants gave them authorization to view their results on the FrailSafe study. These people were also provided with a report concerning their participant of interest and credentials to log in into the DSS platform to view the results.

2.1.6 Ethics compliance

During OT&E phase, consortium members paid special attention to the compliance with ethical standards. Participant recruitment efforts, field trials and data collection complied with all ethical standards pre-set for previous research groups (A and B) (More information is available in *D2.1 Clinical Study Methodology*). More specifically, we respected participants' anonymity by assigning a unique four-digit code to each of them upon their participation to the study and all their personal identification data were strictly confidential. Also, we did not include vulnerable people in the FrailSafe study according to specific pre-set exclusion criteria (i.e., exclusion of people with terminal illnesses, lack of ability to provide their informed consent, etc). Participants included in the study signed consent forms describing research methodology, procedure, tools and timing of visits, study goals and purposes, explicitly and in detail. Participants, also, kept a copy of the consent form including contact details of their local FrailSafe team and an independent professional related to the health sector who was assigned the role of the complaint officer, in case they had complaints related to the study. According to our methodological plan, only 25 participants per center (participants of Group C) received results generated based on their measurements by the FrailSafe system and they were informed beforehand for this process. At the same time, they were informed that the FrailSafe system is not a medically tested and approved diagnostic tool, yet, and thus, they should consult their doctors for a conclusive opinion on their health status. Furthermore, for ethical reasons, all participants (Groups A, B, C, and D) were informed to consult their doctors, in case their data indicated a health deviation that could be a medically significant finding. In this case, participants were, also, informed that the FrailSafe system is not a medically tested and approved health diagnostic tool, yet, and thus, only their doctors could provide a valid and reliable opinion on their health status.

Furthermore, researchers and medical personnel involved in field trials were experienced and received extensive training before interacting with participants. Ethical behaviours were evaluated regularly per center to ensure that every team member maintained good practices and handled participants' data responsibly and confidentially.

In addition, participants were informed explicitly that they had the right to withdraw and request their data to be erased at any time-point, without further consequences and without providing any reasons for doing so. Participants were asked if they would like to give their consent for the communication of some of their health data, either with their treating physicians or with their family members, and the respective family members and physicians were asked to provide their consent, as well, if they wished to be included in this information sharing process. Participants were explicitly informed that they could revoke this authorization at any time point without providing a reason to do so. Furthermore, we randomly selected our participants based on the larger pool of eligible people (all people had same chances to be included in the study).

During the administration of recommendations, we considered the possible impact of the availability of health-related information to the participants (i.e., stress due to a deviant health-related result) especially because these results are not accompanied by a constant, reliable professional interpretation. In this context, information on DSS platform was presented in a friendly manner avoiding strong words and accompanied by a disclaimer that every result is just an indication that a health parameter is deviant from the expected values based on normative data, but this could be a false positive or false negative result and only a doctor can decide if this indication constitutes a medically significant finding.

2.1.7 Compliance rates and impact of recommendations

At the end of the field trials, we assessed participants' compliance rates with the recommendations through the Recommendations Compliance and Satisfaction Questionnaire which was developed for study purposes (Annex IV). The questionnaire consisted of two parts. The first part captured demographic characteristics of the participants and the second consisted of several qualitative and quantitative questions assessing users' compliance with recommendations and perceived benefits from the process.

All active participants of group C (*n*=74) completed the questionnaire among the three clinical centers. A great percentage of the participants (40.6%) stated that they consulted their doctor about the recommendations provided, 51.6% stated that they partially modified their lifestyle after receiving the recommendations and 19,4% reported that they fully modified their lifestyle according to the recommendations received. Furthermore, users stated that their compliance would have increased if their doctors advised them to do so but not their family members. Differences were found between the three clinical centers with Cypriots stating that they consulted their doctor about the recommendations in greater percentages than the other countries. Also, French participants were more likely to change their lifestyle compared to the rest of the participants. This finding may be attributed to a cultural difference or the significance of the provided recommendations. The differences in recommendation adherence per country can be found in Figure 13.

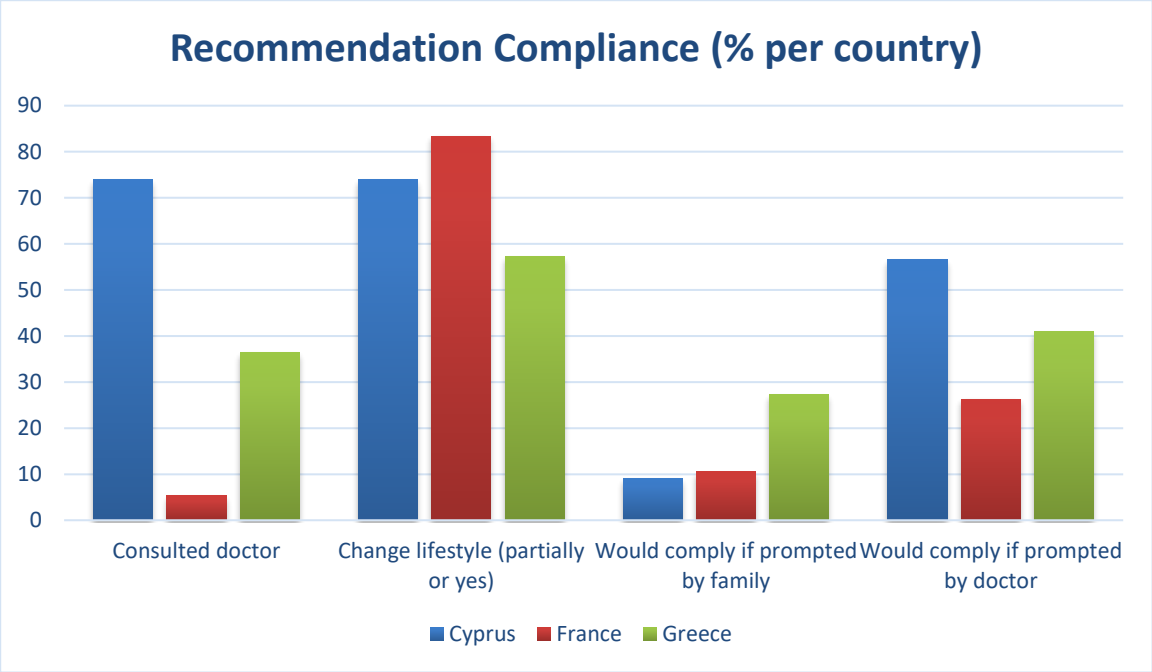


Figure 13. Recommendation compliance rates per country

The majority of the participants stated that they found the recommendations understandable, helpful and beneficial with no significant differences detected between countries. Interestingly, participants of the two sub groups of Group C differed in terms of recommendation compliance. More specifically, participants of Group Cii, who followed a two-month consecutive use of the FrailSafe system, tended to report in a greater percentage consulting their doctors or changing their lifestyle after receiving the recommendations (Figure 14). This finding is indicative that when the FrailSafe system is incorporated in older adults' everyday routine, they tend to realise more the value of recommendations, as they monitor their health status every day.

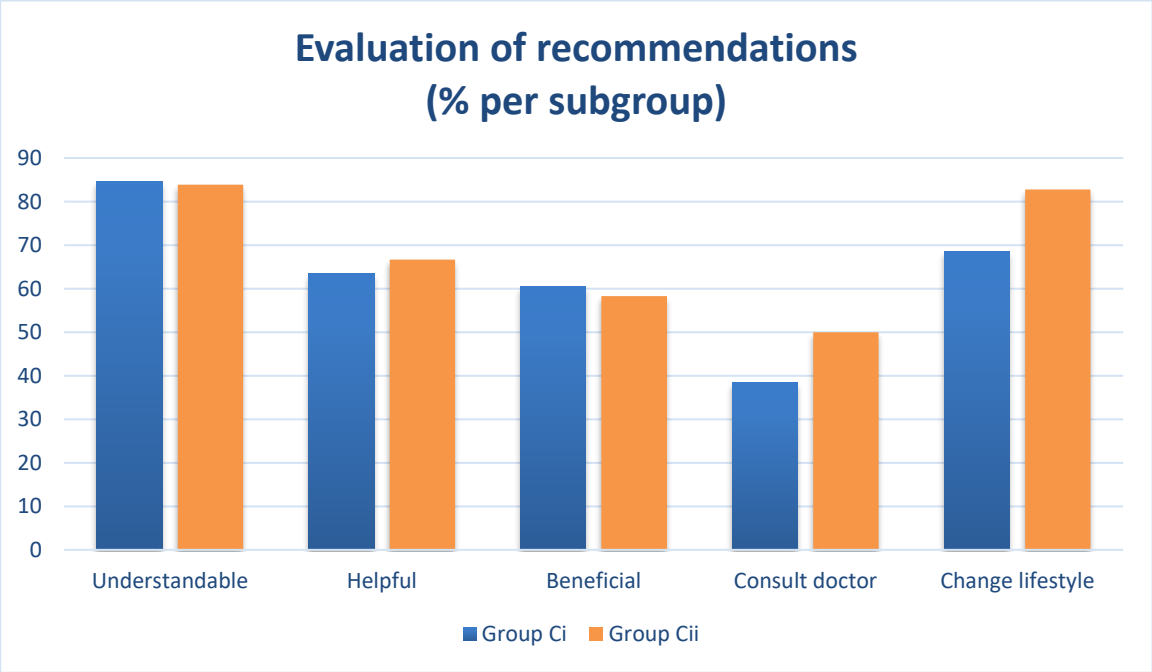


Figure 14. Evaluation of recommendations (per subgroup)

Differences were recorded, also, in terms of gender (Figure 15), with women tending to rate recommendations as more understandable than men and tending to engage more in counteractive actions, such as consulting their doctors or changing their lifestyle. This is not a surprising finding, considering that previous studies have, also, confirmed that women follow a more strict schedule considering monitoring and management of their health than men (Bertakis, Azari, Helms, Callahan, & Robbins, 2000). However, men tended to rate recommendations as more helpful than women and the two genders rated approximately equally their benefits. This might be indicative that men relied more on our reports than women, in terms of getting information on their health status but they did not tend to take actions for improving their health status.

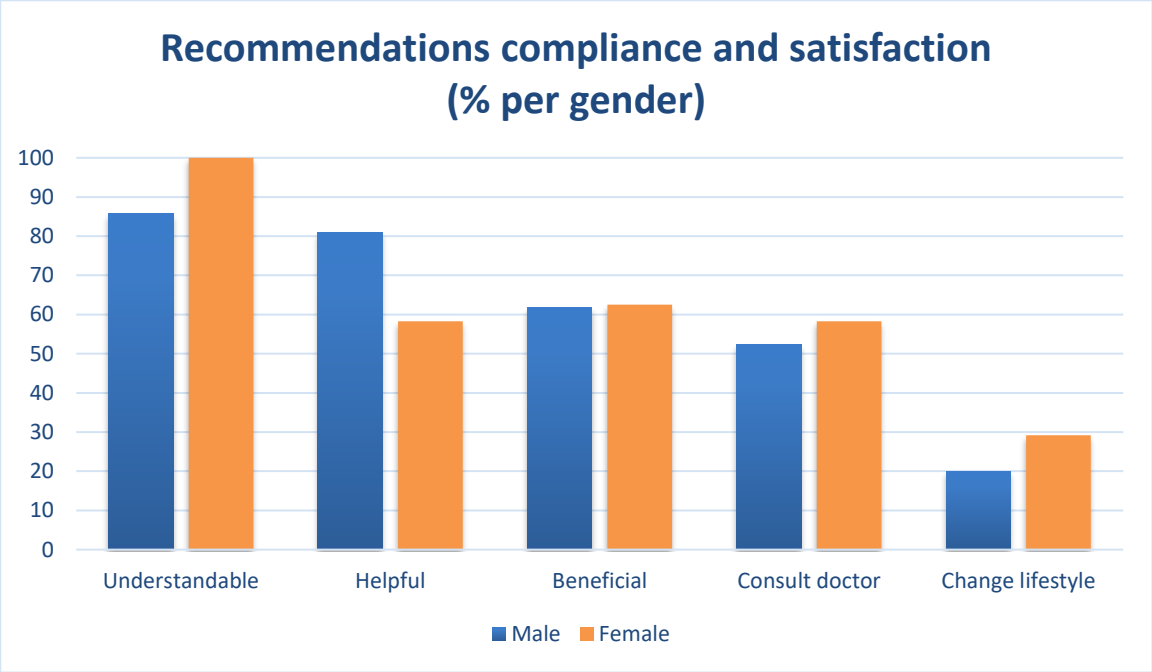


Figure 15. Recommendations compliance and satisfaction (per gender)

In general, the results showed that the recommendations were appreciated by the majority of the participants and rated as helpful and beneficial. Furthermore, the intervention increased participants' active health monitoring, as a great percentage among them reported consulting their doctors or taking precautionary measures by altering their lifestyle, which is a very optimistic finding. The impact of this attitude is discussed in the next section.

2.2 Proof of concept study results

At the end of clinical trials, the collected data logs were analysed, in order to explore the FrailSafe system's impact, identify and evaluate new frailty metrics for diagnozing, predicting and preventing frailty, define FrailSafe system's cost-effectiveness, relation to comorbidities and rehabilitative effect. The results are described, in detail, in the following sections.

2.2.1 Frailty index development and evaluation (on group B): Importance of devices

Extensive analyses were performed to identify the optimal combination of parameters which would predict hard events. We used two criteria for the assessment; the classification accuracy (ACC), i.e. the percentage of correctly classified samples, and the balanced accuracy (BAC), that expresses the average of sensitivity and specificity and that prevents the minority class to be out-weighted by the majority class. We, also, calculated the area under the receiver operating characteristic (AUC) curve, which provides an estimate of prognostic performance independently of the cut-off point or criterion value selected to discriminate between the two populations (having or having not experienced an adverse outcome.)

We examined two types of features for the calculation of FrailSafe's frailty index: the features accumulated over the multiple sessions for every participant, and the estimated temporal change of extracted features (slope). In the first case the final dataset used to train and test the classification model consisted of 1487 samples (each session is considered a sample) and 168 features, while in the second case the dataset consisted of 79 samples and 170 features. The variables were either extracted automatically from the technological devices (WWBS, games suite, GPS) or corresponded to the clinical measurements from the comprehensive geriatric assessment. In order to analyse the cost of the system, we assessed the discriminating power of every sensing modality independently, as well as in combination with each other aiming to use for the FrailSafe's frailty index the least number of sensors. The results showed that the use of text variables did not prove to be beneficial, therefore text was not used for the frailty indexes construction. The following Table shows the cross-validation performance of the device combinations using either the raw features or the slope (delta) features over the multiple sessions for every subject.

Table 17. Prediction of adverse events by temporal (raw) variables without text over multiple sessions

	AUC	Acc	BAC
all features	**0.68**	**0.69**	**0.65**
all features, no GPS	**0.69**	**0.69**	**0.65**
all features, no WWSX	0.59	0.70	0.65
all features, no Games	**0.68**	**0.70**	**0.64**
all features, no Clinical evaluations	0.62	0.61	0.51
only Fried	0.65	0.70	0.57
only GPS	0.46	0.65	0.50
only WWSX	0.63	0.65	0.55
only Games	0.45	0.61	0.47
only Clinical evaluations	0.60	0.70	0.63

Clinical Frailty Index (CI)

GPS+Games	0.49	0.59	0.46
GPS+Text	0.46	0.65	0.50
GPS+Clinical	0.60	0.69	0.62
WWSX+GPS	0.62	0.65	0.56
WWSX+Games	0.63	0.64	0.54
WWSX+Text	0.63	0.65	0.55
WWSX+Clinical	**0.71**	**0.69**	**0.65**
Games+Text	0.45	0.61	0.47
Games+Clinical	**0.64**	**0.70**	**0.65**

Combined Clinical and Technical Frailty Index (CFI)

Table 18. Prediction of adverse events by the temporal change of variables (delta features) without text

	AUC	Acc	BAC
all features	0.59	0.60	0.57
all features, no GPS	**0.71**	**0.69**	**0.68**
all features, no WWSX	0.38	0.45	0.42
all features, no Games	0.47	0.58	0.52
all features, no Clinical evaluations	0.68	0.65	0.62
only Fried	0.46	0.61	0.47
only GPS	0.49	0.67	0.58
only WWSX	0.57	0.61	0.55
only Games	0.60	0.59	0.55
only Clinical evaluations	0.29	0.47	0.39
GPS+Games	0.52	0.61	0.55
GPS+Text	0.49	0.67	0.58
GPS+Clinical	0.34	0.47	0.42
WWSX+GPS	0.56	0.60	0.55
WWSX+Games	**0.68**	**0.71**	**0.69**
WWSX+Text	0.57	0.61	0.55
WWSX+Clinical	0.52	0.58	0.54
Games+Text	0.60	0.59	0.55
Games+Clinical	0.29	0.45	0.41

Technical Frailty Index (FI)

The results showed that the inclusion of features from text analysis does not provide a significant benefit in prediction performance. In fact, this observation dictates that written text can be (at least at this stage) ignored for the construction of the frailty index in order to facilitate the analysis, since the collection of written text is more difficult. It can also be observed that the classification accuracy is similar when using raw features or slope variables (delta features), but we selected as the final prediction model (*Technical Frailty Index, FI*) of the FrailSafe platform the one based on slope variables from the WWBS and games only, because it showed to be more robust and relied on a more compact set of variables.

Also the device-related were compared against the clinical variables collected in the standard comprehensive geriatric assessment (CGA), as well as the frailty phenotype by Fried that constitutes a common reference frame. The results in Table 17 and Table 18 show that the multiple raw measurements of clinical variables and Fried status are much more informative than the temporal change of their values, whereas the variables from the FrailSafe devices show similar performance when used as raw measurements or delta features with the latter slightly outperforming the former. Since the raw values were more relevant for the clinical metrics, we defined the *Clinical Frailty Index (CI)* based on those. Finally, the best combination (considering also the minimum number of devices) of clinical and technical variables was the WWSX+Clinical raw variables, this set defined the *Combined Frailty Index (CFI)*.

2.2.2 Frailty index evaluation (on the main group): Importance of sessions

Aiming to assess the necessity for long-term monitoring we first evaluated the prediction performance of the selected model by gradually increasing the number of sessions from two, to three, till we reached eight. We used the same dataset in a cross-validation scheme in which the number of sessions for training and testing the model were the same. The AUC, accuracy and balanced accuracy are shown in the following figure. Since the analysis with delta features is a single instance problem, the results were not affected by the hyperparameter value 'frac' of the SPEC_MIL algorithm. The next graphs show the three different evaluation measures (AUC, Acc, BAC) over the maximum number of sessions in the MIL dataset in each experiment.

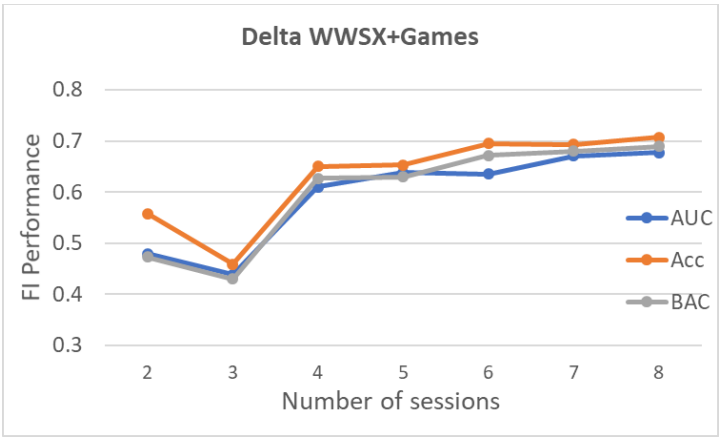


Figure 16. AUC, ACC and BAC of delta features prediction performance across consecutive sessions

On a deeper assessment, we also evaluated the performance of the raw temporal variables (not delta) by varying the number of sessions for well performing combinations of features. In this case, we also illustrate the effect of the hyper-parameter frac=0.6 (left) or frac=0.5 (right).

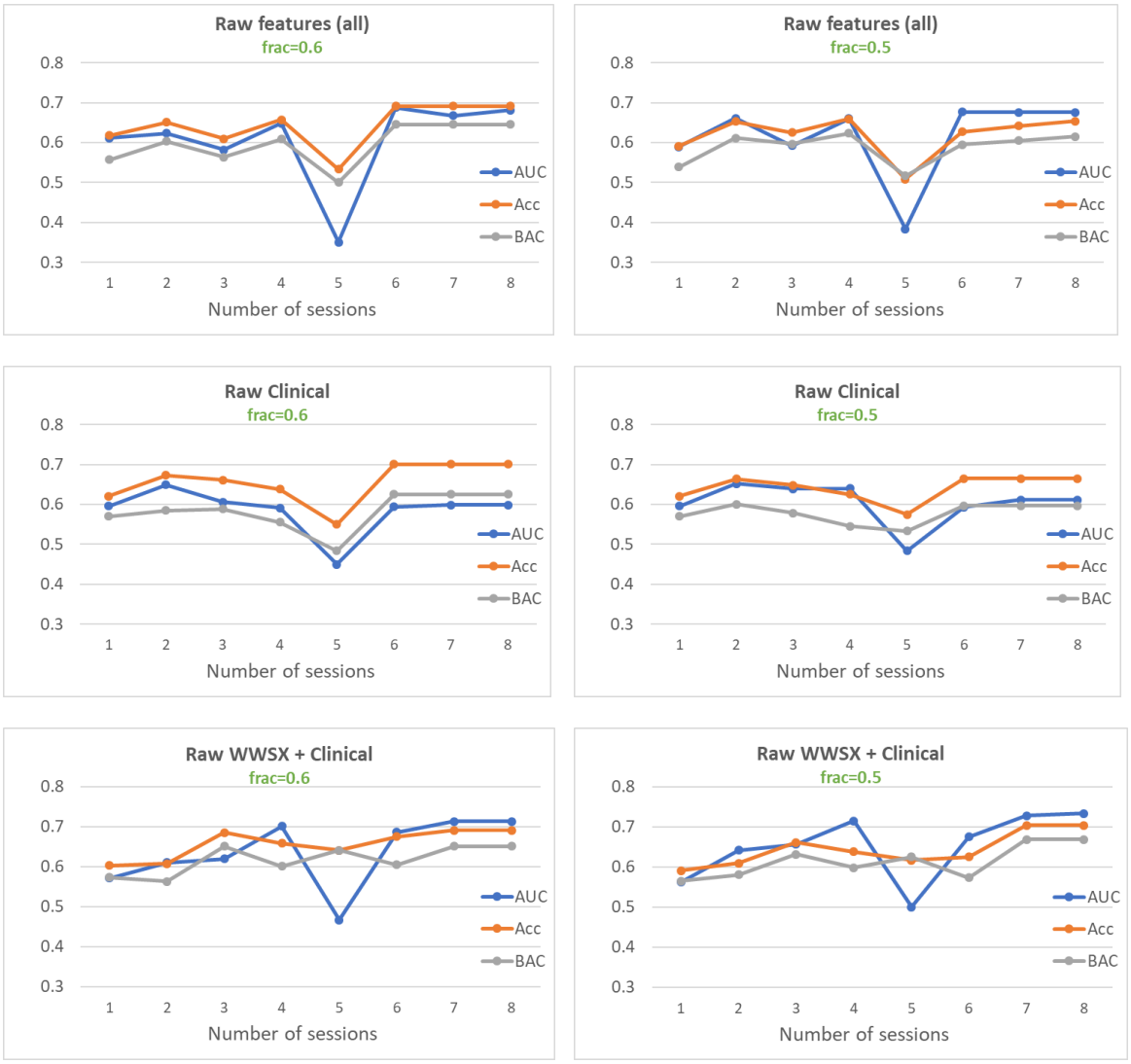


Figure 17. AUC, ACC and BAC of raw features prediction performance across consecutive sessions

From the previous graphs we observe that

(i) if delta features are used, the inclusion of more sessions tends to increase performance
(ii) if raw features are used, performance does not significantly increase by adding more sessions and also fluctuates more than for delta features
(iii) the prediction ability of raw clinical features can be slightly increased if combined with WWSX variables; this combination achieves the best results among raw features
(iv) the prediction accuracy of raw clinical (only) features increases by 13% (for Acc) and 10% (for BAC) when 6 or more sessions are used instead of only one
(v) the results are not very sensitive to the selection of hyperparameter *frac* and show similar trends.

2.2.3 Clinical index development and evaluation (on all participants): Importance of sessions

The clinical index (CI) was produced by training a multiple instance classification model on the clinical variables (raw values) aiming to predict the incidence of future hard outcomes. As

shown from the results of the previous section, when the model is trained and tested by cross-validation on the main group of participants the BAC reaches a value of 0.63. In order to evaluate more thoroughly the predictive power of CI we repeated the procedure for all the participants. Since the clinical variables had not to be combined with the ones from the FrailSafe sessions, the sampling points were the clinical evaluation. The maximum number of clinical evaluations was four and therefore, four experiments were performed with participants having maximum one clinical evaluation, maximum two clinical evaluations, etc. For consistency in the visualization, we use here the term 'session', as well, in the horizontal axes of the graphs. The **total number of participants is 542**, and the number of remaining participants after the exclusion of the ones with missing variables in shown for each experiment.

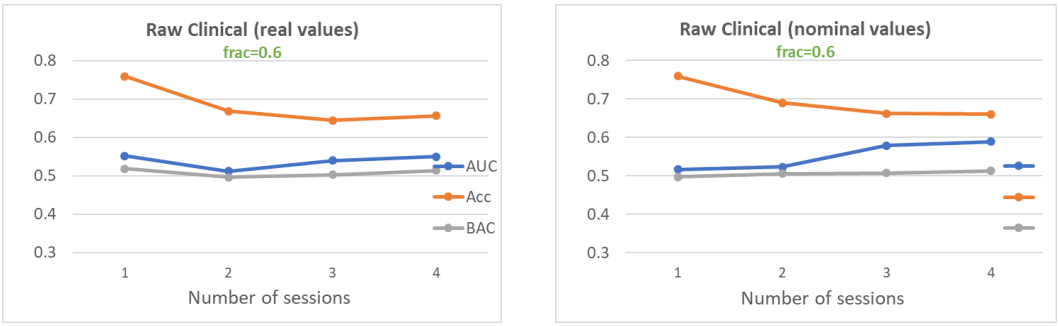


Figure 18. AUC, ACC and BAC of raw clinical features prediction performance across consecutive sessions

2.2.4 Assessment of the three indices in the short evaluation group

The predictive performance of the three indices (FI, CI, CFI) has been assessed on the short evaluation group. Out of all participants 26 remained having at least two measurements from the required Frailsafe devices and having not missed the comprehensive geriatric assessment. The following boxplots show the distribution of the values for each index for the participants who did not have an adverse event in a time period after the measurements (boxplot on the left) indicated with the **label 0**, and for the participants who experienced an adverse event (boxplot on the right) indicated with the **label 1**.

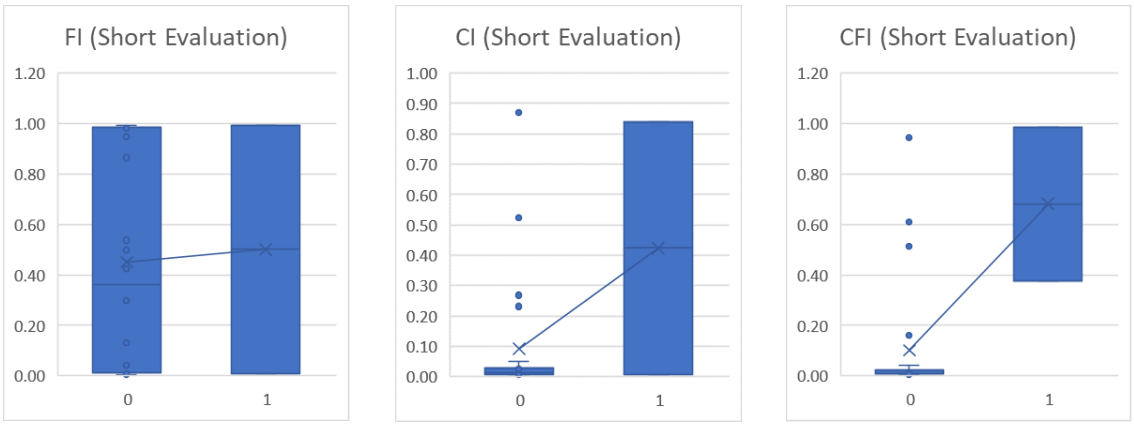


Figure 19. Predictive performance of FI, CI and CFI

The above boxplots indicate that all three indices have a potential in differentiating the two groups with the combined frailty index (CFI) displaying of the highest difference in the risk of an adverse event between the two groups.

2.2.5 Prediction of the decline of the Proxy Variables

In order to demonstrate the predictive ability of the collected data, we performed a series of analyses using the data collected by the FrailSafe devices (WWBS, GPS, Games) and the data from clinical assessments. The aim of the analysis was relaying on the clinical or on the devices' data to predict the temporal change in the values of the proxy variables (IADL, MNA, MMSE, MoCa, GDS, Gait Speed and health rate self-assessment) as well as the temporal change in the Fried status of the participants, in a period of the next three months.

In the case of the clinical assessments' data, we considered 60 participants for whom at least 4 clinical assessments where available. We computed the change of the proxy variables in the first and the last assessment and we use it as the training labels. We grouped the temporal changes of the variables on two groups: the negative scores, indicating a decline of the participant's status concerning the proxy variable, and the non-negative scores, indicating a stagnancy or an improvement of the participant's health status. In order to train our models, we discarded the clinical values of the fourth clinical assessment, since the temporal change of the proxy variables (i.e. the target of the prediction), refer to exactly this time point. In order to compute individualized features for each participant, we arranged the clinical measurements in time order to produce a 2-D matrix for each participant. We arranged the matrices to a 3D tensor of which the first dimension referred to the participants, the second dimension to the clinical measurements and the third to the temporal factor (i.e. the different clinical assessments). In a next step, we computed the individual features using tensor decomposition techniques (PARAFAC) and trained different Logistic Regression models to predict the change of the health status of the participant in the next three months (the consecutive clinical assessments where held approximately in a time period of three months).

In the case of the FrailSafe devices' data, we exploited features computed from the GPS, the WWBS and the games. In order to label the data, we exploited the nearest clinical assessment and we used the temporal change of the proxy variables as described previously. As previously, we exploited only participants having at least 4 clinical assessments and at least 4 sessions (in a temporal proximity to the 4 clinical assessments) using the FrailSafe devices and discarded the measurements of the session proximal to the fourth clinical assessment, since this is the target of the prediction. As previously described, we computed individualized features for each participant and trained different Logistic Regression models to predict the change of the health status of each participant in the next three months.

Table 19. Accuracy and Balanced accuracy with the corresponding std of 5-fold Cross Validation of the prediction of change in the health status of the participants in the next three months using the clinical scores

Clinical Scores	Acc	BAcc	% of participants with a decline	model
Fried	0.68 (0.16)	0.61 (0.20)	0.25	linear

IADL	0.55 (0.10)	0.54 (0.19)	0.23	pure quadratic
MNA	0.62 (0.07)	**0.60 (0.12)**	0.22	pure quadratic
MMSE	0.65 (0.09)	**0.65 (0.09)**	0.40	interactions
MoCa	0.62 (0.13)	0.59 (0.13)	0.63	pure quadratic
GDS	0.58 (0.22)	0.55 (0.20)	0.28	pure quadratic
GaitSpeed	0.68 (0.21)	0.68 (0.21)	0.49	pure quadratic
Self-rated health	0.72 (0.10)	**0.80 (0.10)**	0.13	pure quadratic

Table 20. Accuracy and Balanced accuracy with the corresponding std of 5-fold Cross Validation of the prediction of change in the health status of the participants in the next three months using the FrailSafe devices

FS Devices	Acc	BAcc	% of patients with a decline	model
Fried	0.65 (0.22)	**0.76 (0.11)**	0.15	interactions
IADL	0.58 (0.11)	0.58 (0.19)	0.28	interactions
MNA	0.68 (0.11)	0.57 (0.13)	0.23	quadratic
MMSE	0.55 (0.14)	0.55 (0.14)	0.50	linear
MoCa	0.68 (0.13)	**0.67 (0.12)**	0.56	linear
GDS	0.68 (0.11)	**0.67 (0.12)**	0.35	linear
GaitSpeed	0.78 (0.16)	**0.75 (0.19)**	0.63	linear
Self-rated health rate	0.60 (0.14)	0.69 (0.23)	0.13	pure quadratic

We report the results of the predictions using only the clinical assessments (Table 19) and only the FrailSafe devices (Table 20). We report the 5-fold Cross Validation Accuracy, as well as

the Balanced Accuracy (since the dataset is highly unbalanced) with the corresponding Standard Deviations (std). We report also the percentage of the participants who had a decline in their health status regarding the corresponding proxy variable (i.e. the percentage of the participants labelled by 0). Finally, we report the Logistic Regression model employed: linear, interactions (employing linear terms and all products of the linear terms), pure quadratic (employing the linear terms and squared linear terms), and full quadratic (combining all the previous terms).

We see, from Tables 19 and 20, that over all the Balanced Accuracy prediction of the Fried status, MoCa, GDS and Gait Speed are about 70% using only the devices of FrailSafe, and the Health Rate self-assessment preciction's Balanced Accuracy is 80% using the clinical scores. Furthermore, the IADL, MNA and MMSE variables have a BACC about 55%-58% using the devices and 54%-65% using the clinical assessments.

2.2.6 Clustering (qualitative metrics)

The clustering methodology provide a qualitative profiling method for assessing the decline in multiple clinical domains (physiological, behavioral, cognitive, etc.) by fusing data from different devices. Data dimensionality was reduced by manifold learning (based on PCA and LLE), which intrinsically takes into consideration the inherent geometry representation, and allows relevant comparison of individuals to the studied population through a low-dimensional Euclidean space map. Clustering was then performed in this low dimensional embedding space in order to discover coherent and well separated groups. We investigated three popular clustering algorithms, namely the agglomerative (Agg), spectral clustering (Spec), and k-means (KM). The results were evaluated by clustering validity criteria and the identified clusters were also compared with the groups determined by CGA in respect to several clinical metrics from multiple domains. Since clustering is an unsupervised classification problem, the lack of a gold standard makes it difficult to interpret the results and assess their accuracy. There are many different measures to check if good clustering has been achieved. The internal cluster validity indices quantify the quality of clustering using criteria such as cohesion and separation (similarity of an object to its own cluster and to other clusters, respectively). One of the most common criteria is the Silhouette index.

A schematic diagram of the proposed methodology is illustrated in the figure below.

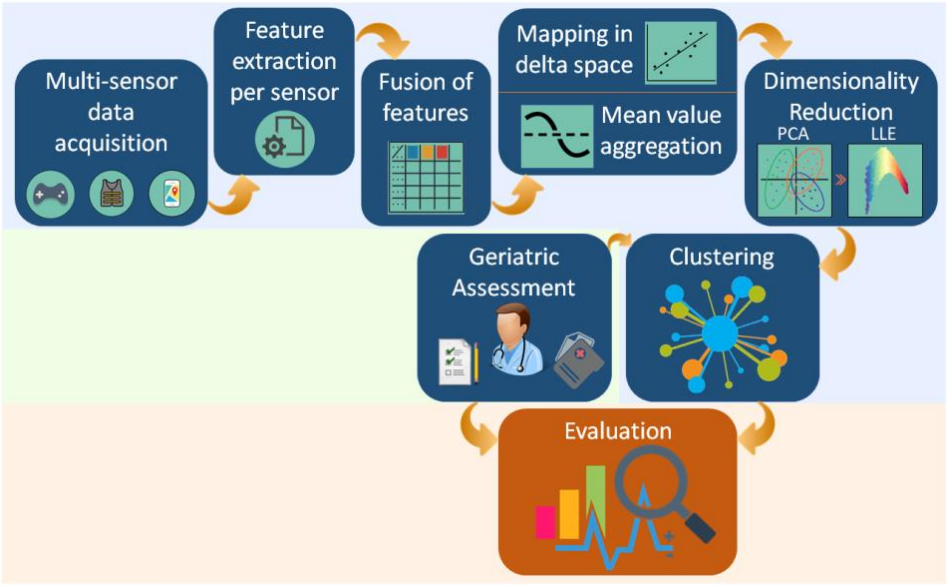


Figure 20. Illustration of clustering methodology

We performed a grid search to reveal the (1) dimensionality reduction method, (2) hyper-parameters for this method, (3) clustering algorithm, and (4) number of clusters, which result in the best clustering based on the Silhouette index. The best Silhouette index resulted from the grid search was 77.64% and it was achieved for K=3 clusters. The final representation of the initial 300 features by only 2 LLE components facilitates the exploratory analysis of the identified groups.

Clustering profiles

Additionally, to clustering validation with internal criteria, we wanted to empirically investigate what is the predictive ability of the obtained clusters. For this purpose, we used clinical metrics acquired during CGA. Those metrics are selected under the prism of their operational function to quantify frailty, and categorized into domains taking under consideration the interrelationships that run through the implication of each variable in the various aspects of frailty. Before proceeding with evaluation of the clustering based on these external criteria, we present the clinical characteristics of the participants within each of the identified clusters. The differences in the clinical profile of the participants in each cluster are presented in Figures 21-26. Figures 21, 22 and 23 illustrate the clinical profile of the participants with respect to the observed change (delta) in each of the acquired clinical metrics in the time interval between their first and last devices session. Values of clinical variables can be increased (+), unchanged (0) or decreased (-) in time, and consequently the dataset is quantized in three levels with respect to the deltas. Figures 24, 25 and 26 depict the internal structure of the identified clusters based on the values of the clinical metrics in participants' final sessions, i.e. their final clinical state. Ranges of values have been selected for the numeric metrics, to quantize the dataset according to clinicians' guidelines into two to five levels, such that all clinical variables of CGA are considered as categorical in a meaningful way. Results for all figures have been produced using the KMeans clustering algorithm the values are produced by frequency counting.

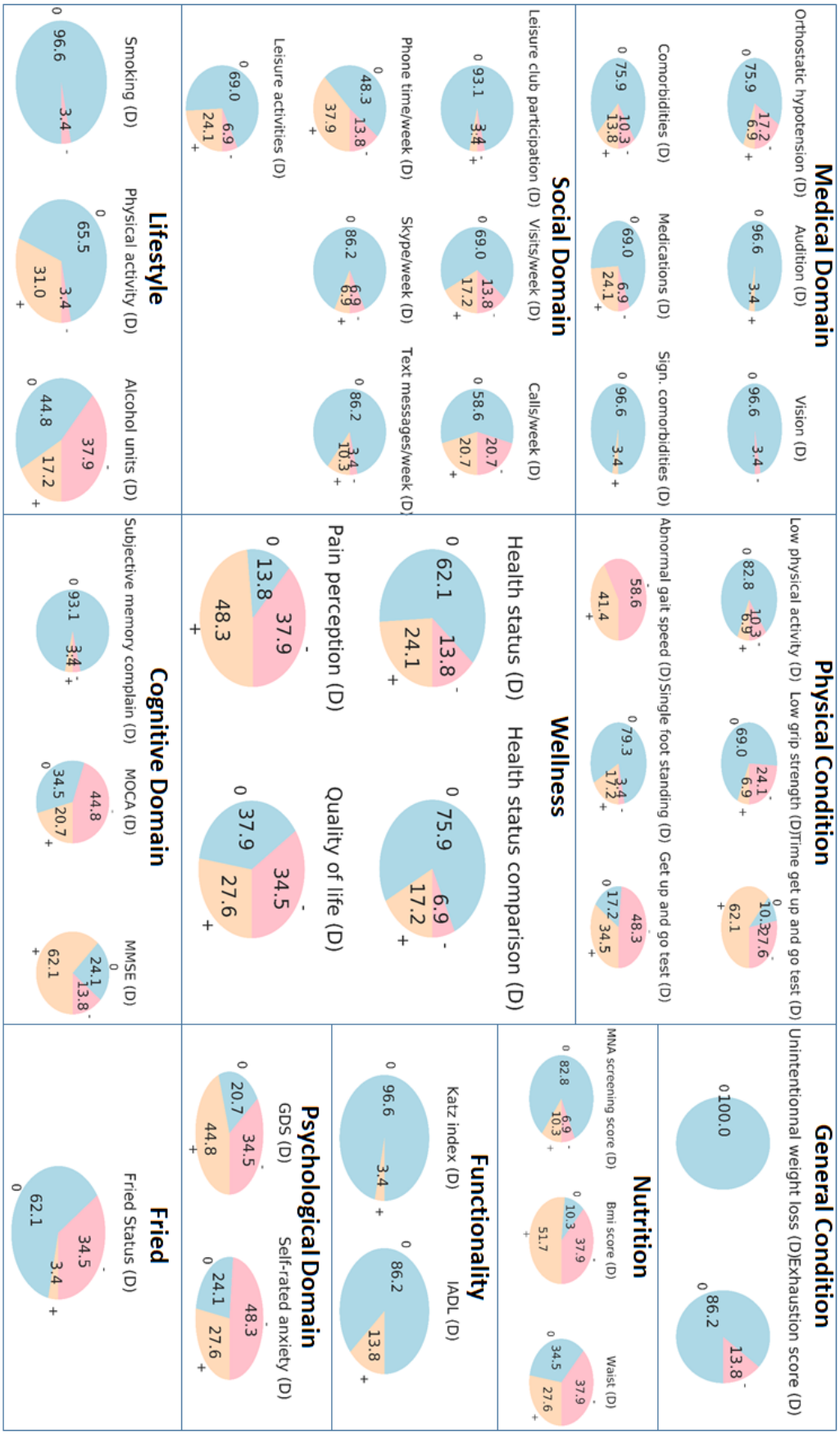


Figure 21. Cluster 1: Clinical profile with respect to change of clinical metrics

Figure 22. Cluster 2: Clinical profile with respect to change of clinical metrics

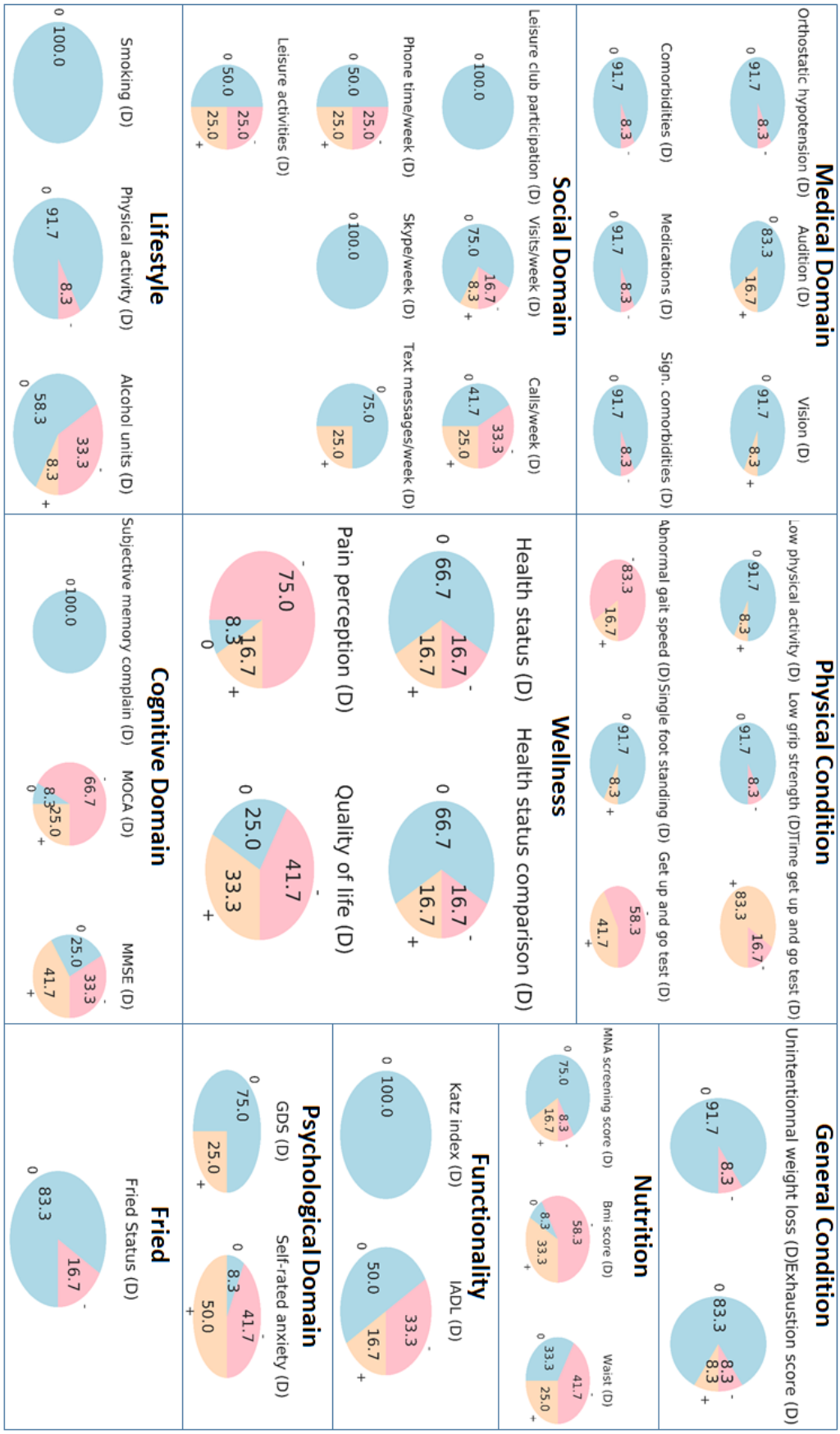


Figure 23. Cluster 3: Clinical profile with respect to change of clinical metrics

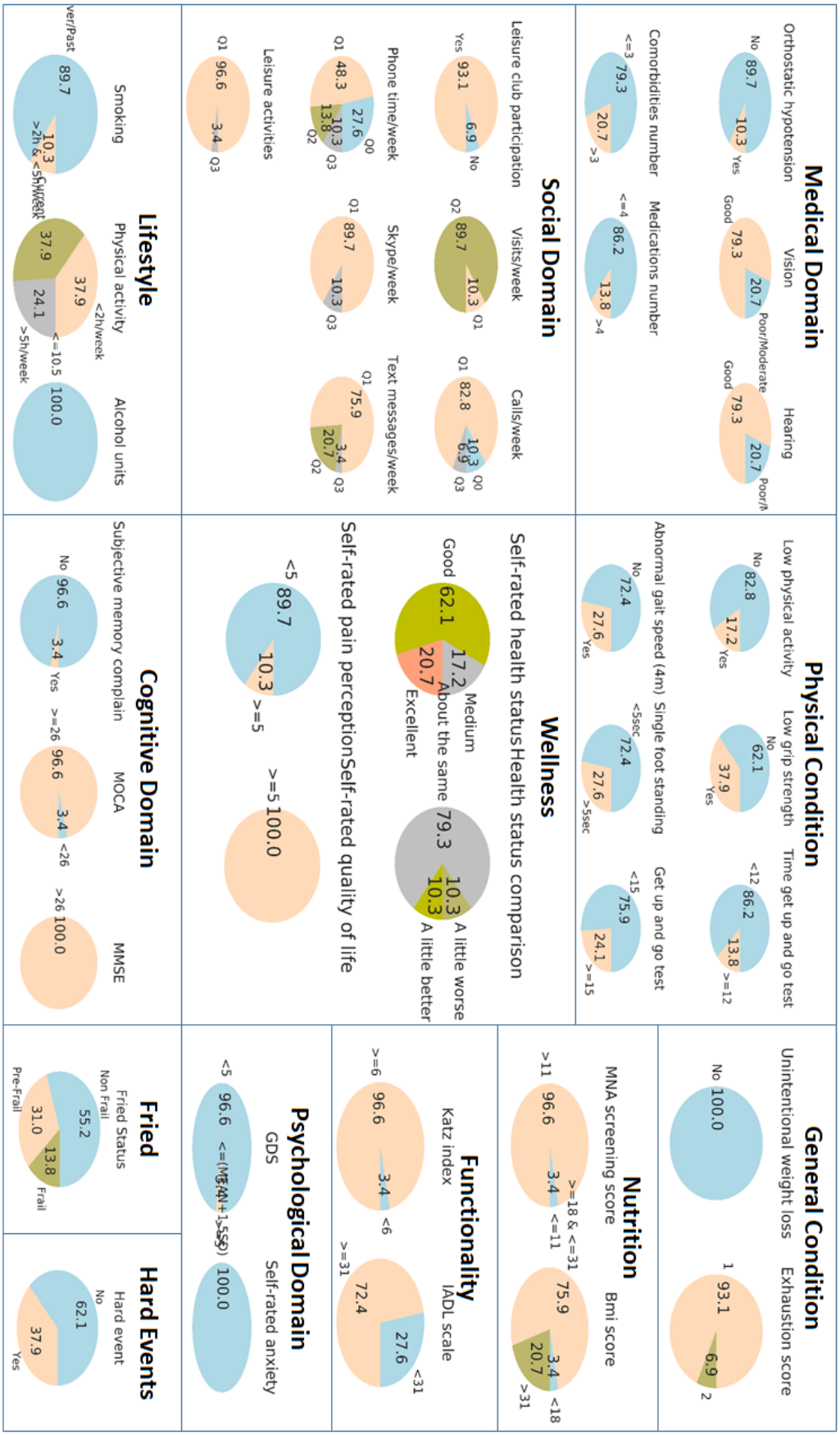


Figure 24. Cluster 1: Clinical profile with respect to last values of clinical metrics

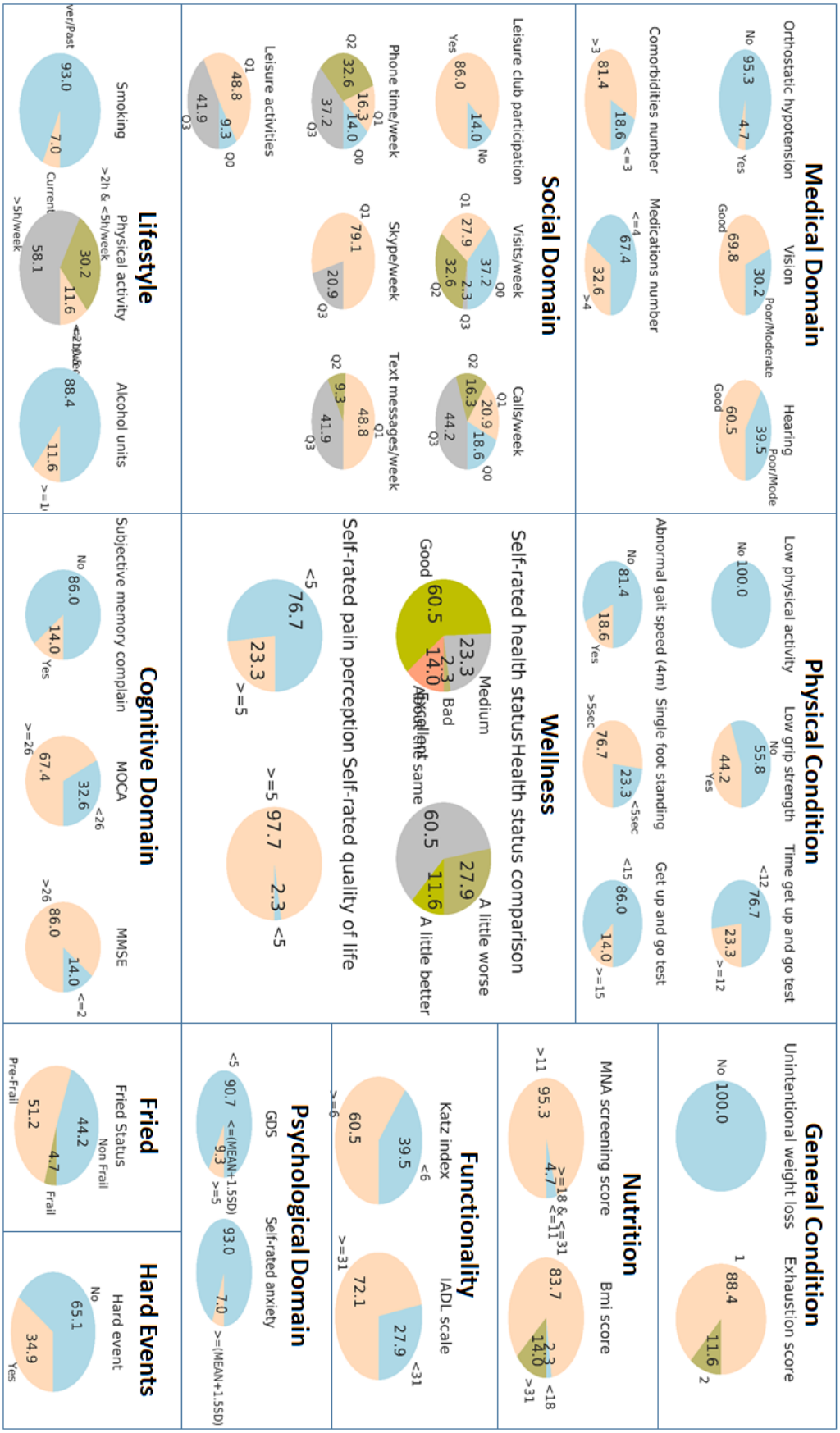


Figure 25. Cluster 2: Clinical profile with respect to last values of clinical metrics

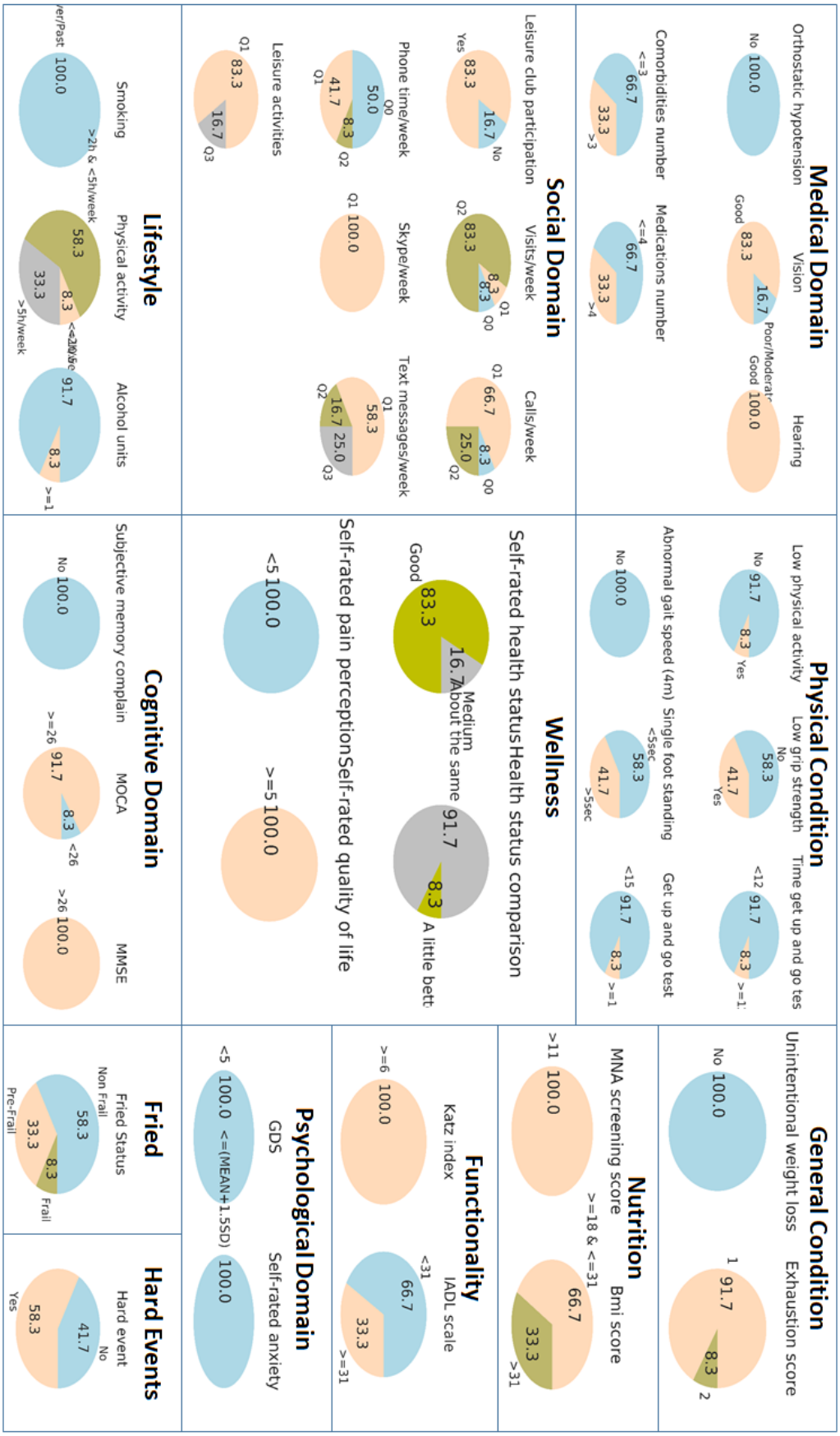


Figure 26. Cluster 3: Clinical profile with respect to last values of clinical metrics

External Evaluation

Since metrics from CGA are considered as descriptive of frailty and their operational function to quantify frailty is commonly accepted, we could trust the grouping of subjects, that results from a clustering algorithm which uses them as an input. Consequently, we selected the clustering that comes from previous clinical metrics as ground truth to assess our results. More specifically, we performed clustering of the subjects based on data from their first clinical evaluation (CE), their last clinical evaluation, as well as mean values and deltas resulted from the time points in the meanwhile. We followed the same methodology (based on PCA+LLE and KMeans) for clustering subjects based on devices data. To end up with the best possible clustering from clinical variables we tried several combinations of features and ways of features engineering, and obtained the following results in respect to investigated features and corresponding Sillhouette index (%):

- First CE, last CE, delta/mean values: 78.06
- First CE, last CE: 77.50
- Last CE, delta/mean values: 77.36
- First CE, delta/mean values: 75.66
- First CE, last CE, delta: 74.09

To evaluate the clustering that was achieved with input variables from devices we checked to what extent the subjects were grouped in the same way they are grouped when clinical variables from CGA are used as an input. We compared the labeling of the two clusterings and 75% of the subjects are grouped in the same clusters in both cases. To measure the similarity of two clusterings we also used the Fowlkes-Mallows index (FMI), which was 77.34%, indicating that our clustering method with features from monitoring devices is in high accordance with grouping achieved by taking into consideration only information from clinical evaluation sessions.

Exploratory analysis of the obtained clusters

Apart from clustering validation with internal criteria and external evaluation with clustering similarity comparison, we want to empirically investigate what is the predictive ability of the obtained clusters by using clinical metrics acquired during CGA. Hence, we explore the identified clusters trying to find out patterns in them which are in accordance with (1) the value of the geriatric indices during the last clinical evaluation of each subject and (2) the change of geriatric indices in time (delta). The first index that should be taken into account is the homogeneity of the obtained clusters with respect to (1) and (2), i.e. in what extent subjects with the same evolution or final condition in metrics from CGA, which both are not given as an input to the clustering algorithm, are grouped together. Tables 21 and 22 include all the variables for which there is complete homogeneity in some of the clusters. We consider a cluster as homogeneous if it is constituted of people with same or similar ranges of values. With respect to change of clinical metrics a cluster could have a homogeneous structure if all of its members have common transition in their clinical state or if some of them present no transition and others change in a common manner (positive or negative). The highlighted results indicate that all the subjects of a cluster have the same or similar ranges of values in all examined clinical variables of a clinical domain. For instance, all subjects of cluster 3 present a stable condition or have positive evolution in hearing, audition, orthostatic hypotension, comorbidities number, significant comorbidities number and medication number. This indicates that subjects of this cluster have the same profile regarding change in aspects of medical domain. For each of the clinical variables, positive evolution can be related either to positive

change (delta) or to negative change. For example, negative change in orthostatic hypotension means that a subject who suffered from this health problem, doesn't suffer from it anymore, hence it is considered as a positive evolution in health.

Table 21. High homogeneity cases with respect to values of the geriatric indices during last clinical evaluation (highlighted results indicate that all the subjects of a cluster have the same or similar ranges of values in all examined clinical variables of a clinical domain)

Domain	Cluster 1	Cluster 2	Cluster 3
Medical			Orthostatic hypotension (No)
			Hearing (Good)
Physical		Low physical activity (No)	Abnormal gait speed (No)
Social			Skype/week (Quartile 1)
Wellness	Self-rated quality of life (>=5)		Self-rated health status (Medium/Good)
			Health status comparison (About the same/A little better)
			Self-rated pain perception (<5)
			Self-rated quality of life (>=5)
General Condition	Unintentional weight loss (No)	Unintentional weight loss (No)	Unintentional weight loss (No)
Functionality			Katz index >=6
Psychological	Self-rated anxiety <= (mean+ 1.5 sd)		GDS < 5
			Self-rated anxiety <= (mean+ 1.5 sd)
Lifestyle	Alcohol units < 10.5		Smoking (Never/Past)
Cognitive			Subjective memory complain (No)
			MMSE >=26

Table 22. High homogeneity cases with respect to change of geriatric indices in time (delta)

Domain	Cluster 1	Cluster 2	Cluster 3
Medical	Audition (same/positive)		Audition (same/positive)
			Hearing (same/positive)
			Orthostatic hypotension (same/negative)
	Hearing (same/negative)		Comorbidities (same/negative)
			Significant comorbidities (same/negative)
			Medications (same/negative)
Physical		Low Physical Activity (same/negative)	
Social		Leisure club participation (same/positive)	Leisure club participation (same/positive)
			Skype/week (same)
			Text messages/week (same/positive)
General Condition	Exhaustion score (same/negative)	Unintentional weight loss (same/negative)	Unintentional weight loss (same/negative)
	Unintentional weight loss (same)		
Functionality	Katz index (same/positive)		Katz index (same)
	IADL (same/positive)		
Psychological			GDS (same/positive)
Lifestyle	Smoking (same/negative)	Smoking (same/positive)	Smoking(same)
			Physical activity (same/negative)
Cognitive			
Fried status			same/negative

Another factor that is taken into consideration in our exploratory analysis is that in most cases the percentage of subjects who belong to the most "interesting" ranges of the clinical variables is low. For instance, only 10 subjects of 84 (11.9%) present increase in their frailty status (e.g. from Non-Frail to Pre-Frail) and only 14 subjects of 84 (16.67%) have opposite transition (e.g. from Frail to Pre-Frail). However, one of the fundamental goals of this study is clustering to be

used as a machine learning tool which will facilitate early intervention of frailty. As a consequence, it is considered very important that subjects who present those interesting patterns to be clustered together, even if they coexist with subjects of other ranges regarding the investigated clinical variables. With this in mind, we are interested in the true positive rate (or recall) of each class of the clinical metrics, *i.e.* we explore in what extent subjects with the same condition are clustered together.

To consider a **result significant** we set the limitation, true positive rates of contradictory classes in clinical variables not to be all high (i.e. >50%), so that a clear profile of subjects in a cluster can be formed with respect to each clinical metric. For example, if true positive rate of subjects who have increase in their MoCA score in cluster 1 is 80%, while the corresponding rate of subjects who have decrease in the same score is 70%, the result cannot be accepted. Tables 23 and 24 include all cases which satisfy that constraint. The highlighted results indicate that the true positive rates of a sufficient number of variables per domain agree with each other and consequently facilitate the formation of a profile for the investigated cluster with respect to a specific clinical domain. Green color is used for good indications and orange color for negative indications.

Table 23. True positive rate with respect to values of the geriatric indices during last clinical evaluation

Domain	Cluster 1	Cluster 2
Cognitive		**MOCA < 26 ➔ 87.5%** MOCA >=26 ➔ 42.6%
		Memory complain (Yes) ➔ 85.7% Memory complain (No) ➔ 48.1%
		MMSE < 24 ➔ 100% MMSE ➔ 47.4%
Functionality		**Katz index < 6 ➔ 94.4%** Katz index >= 6 ➔ 39.4%
Lifestyle		**Alcohol units > 10.5 ➔ 83.3%** Alcohol units <= 10.5 ➔ 48.7%
Medical		**Comorbidities number > 3 ➔ 77.8%** Comorbidities number <= 3 ➔ 20.5%
		Vision (Bad/Moderate) ➔ 73.9% Vision (Good) ➔ 42.6%
Physical Condition	**Low physical activity (Yes): 83.3%** Low physical activity (No): 30.8%	**Single foot standing (>5sec) ➔ 71.7%** Single foot standing (<5sec) ➔ 26.3%
Psychological		**Self-rated anxiety > Mean + 1.5sd ➔ 100%** Self-rated anxiety <= Mean + 1.5sd ➔ 49.4%
		GDS < 5 ➔ 80% GDS >=5 ➔ 49.4%
Wellness		**Self-rated pain perception > 5 ➔ 76.9%** Self-rated pain perception > 5 ➔ 46.5%

Table 24. True positive rate with respect to change of geriatric indices in time (delta)

Domain	Cluster 1	Cluster 2
Cognitive		**MMSE negative ➔ 70.4%** MMSE positive ➔ 42.5%
Fried Status	**Negative ➔ 71.4%** **Positive ➔ 10%**	**Positive ➔ 90%** **Negative ➔ 14.3%**
General Condition		**Exhaustion score Positive ➔ 75.5%** Exhaustion score Negative ➔ 37.5%
Lifestyle	**Smoking negative ➔ 100%** Smoking positive ➔ 0%	**Smoking positive ➔ 100%** Smoking negative ➔ 0%
		Alcohol units positive ➔ 76.9% Alcohol units negative ➔ 37.5%
		Physical activity negative ➔ 81.8% Physical activity positive ➔ 30.8%
Nutrition		**Waist circumference positive ➔ 73.2%** Waist circumference negative ➔ 40.7%
Physical Condition	**Abnormal grip strength negative ➔ 77.8%** Abnormal grip strength positive ➔ 18.2%	**Abnormal grip strength positive ➔ 81.8%** Abnormal grip strength negative ➔ 11.1%
		Single foot standing negative ➔ 87.5% Single foot standing positive ➔ 25%
Social	**Participation in Leisure club negative ➔ 100%** Participation in Leisure club positive ➔ 33.3%	

Apart from what was described previously, separability of the clusters based on frequency counting is also important. Two clusters should be populated with contradictory labeled samples (relied on clinical variables), in order to be well separated based on frequency counting. However, this is difficult to be achieved in most cases, because of the unbalanced data, as it was mentioned before. More specifically, the most usual observation is that all 3 clusters constitute of subjects who belong to the normal or most common ranges of the investigated variables. Nevertheless, Table 25 presents two cases in which clusters 1 and 2 consist mainly of subjects with different profiles with respect to the investigated variables. Supposing that all subjects with less than three comorbidities should be classified in cluster 1, and those with more than 3 comorbidities should be classified in cluster 2 then the balanced accuracy of the resulted clustering would be 74.55%.

Table 25. Separability of the clusters based on overlapping with separation resulted from clinical variable classes

Domain	Cluster 1	Cluster 2
Medical	**Single foot standing (<5sec) ➔ 72.4%** Single foot standing (>5sec) ➔ 27.6%	Single foot standing (<5sec) ➔ 23.3% **Single foot standing (>5sec) ➔ 76.7%**
Physical condition	**Comorbidities number <=3 ➔ 79.3%** Comorbidities number >3 ➔ 20.7%	**Comorbidities number >3 ➔ 81.4%** Comorbidities number <=3 ➔ 18.6%

The exploratory analysis of the subjects' profiles in each of the obtained clusters revealed (a) patterns of high homogeneity, (b) cases of high true positive rate and (c) examples of high and meaningful overlap with classes defined by clinical variables. Thus, the proposed methodology could be used to predict clinical indices from CGA and as a tool to facilitate the early intervention of frailty by predicting the temporal transition of these clinical variables, which have been proved to be good descriptors of this clinical syndrome. Moreover, the proposed clustering could serve as a core tool for the high-level evaluation of subjects' condition and for making recommendations regarding selected clinical domains.

Previous analysis showed, for instance, that all subjects which are grouped in cluster 3 are characterized by a good level of life in the domains of wellness and psychology and encouraging signs of transition or a stable condition in parameters of medical domain. As an example, Figure 27 depicts how people with different ranges of values in self-rated pain perception are classified in clusters. The resulted distribution could help us conclude that subjects of clusters 1 and 2 are more likely to have increased pain. Similar conclusions could be drawn in all cases in which subjects in one cluster present a homogeneous condition regarding a clinical metric, while the same is not noticed in other clusters.

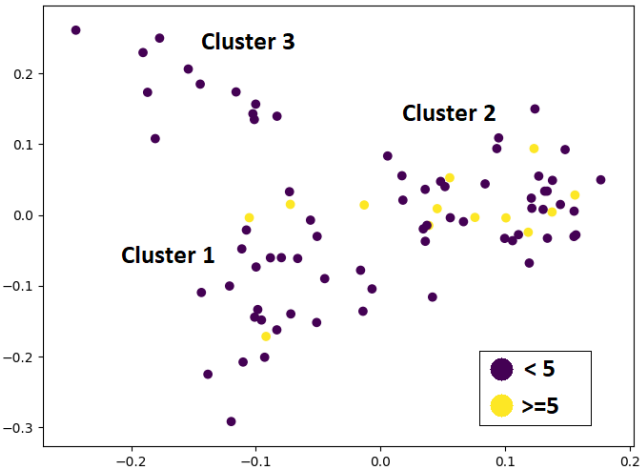


Figure 27. Clusters colored depending on self-rated pain

Sometimes visualization of the results may facilitate even more the discovering of interesting patterns. For example, in Figure 27 we observe that not only all subjects with Katz index score

>= 6 are gathered in cluster 3, but also the high majority of the ones with Katz index score < 6 are in a specific area in the two-dimensional space; in the right half of cluster 2.

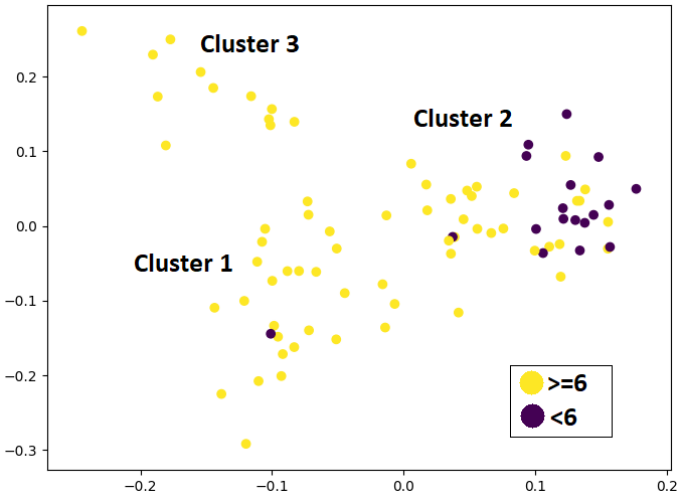


Figure 28. Clusters colored depending on Katz index score of their subjects

True positive rate analysis helped us form an opinion about the way that algorithm groups subjects which are characterized by "interesting" patterns in some clinical variables. For example, regarding the values transition in parameters of lifestyle and physical condition, most people who have a negative evolution are clustered in cluster two, while cluster 1 is characterized by opposite evolution in some of the respective variables. Figure 29 illustrates how the majority of subjects with good evolution in frailty status by Fried (e.g. from Frail to Pre-Frail) are gathered in cluster 1, and most of subjects with bad evolution are classified in cluster 2. From Figure 30 it can be noticed that it is quite possible people with MoCA score <26 (i.e. people coming under the abnormal range of values for this score) to be grouped together in cluster 2.

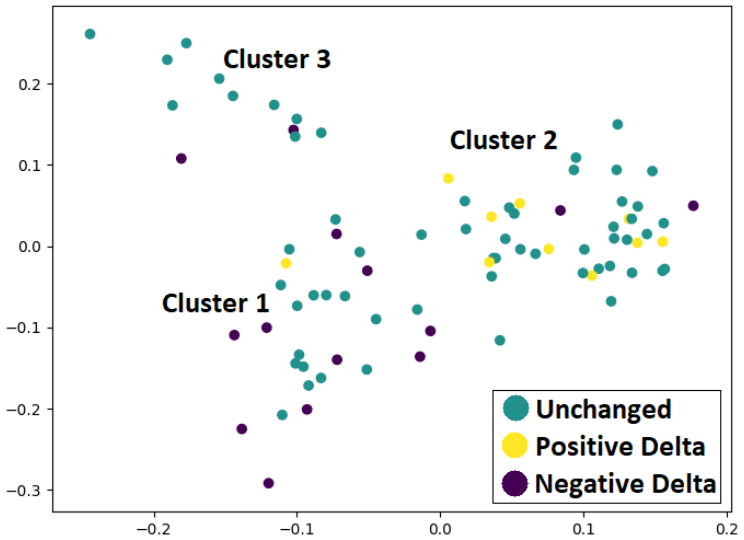


Figure 29. Clusters colored depending on delta in frailty status of their subjects

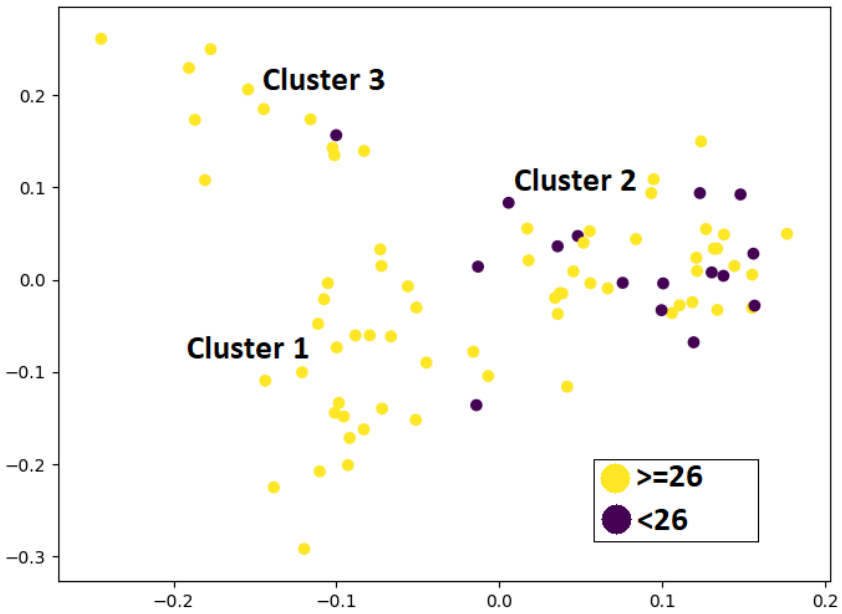


Figure 30. Clusters colored depending on MoCA score of their subjects

Consequently, the developed system could be used as a tool for personalized recommendations to subjects based on the cluster they get grouped after using the monitoring devices for a selected period of time. Since, not all people are part of a cluster for the same reason, but because of their whole clinical profile, the recommendations should not be common for everyone. For example, even though a significant percent of people in cluster 2 have low MoCA score, there are also subjects with normal values. For that reason, if someone is classified in a cluster for which there are indications that it is representative of people with abnormal values in some clinical variable or whole domain, then the respective variables obtained from the devices for this person should be examined. If they fall into abnormal ranges, a recommendation or alert should be raised. On the other hand, encouraging messages could also be raised, if the person is categorized in a cluster where most people have a positive evolution in some clinical domain or clinical variable, and that is verified from person's values in features obtained from devices. Figure 31 illustrates the proposed idea.

Figure 31. Recommendation system based on clustering

2.2.7 Frailty and relation to comorbidities

In order to explore the relation of frailty to other comorbidities we conducted three sets of correlation analyses between the generated frailty indices FI, CFI and CI and several health parameters (Table 26). Pearson correlation was calculated to explore relationships between continuous variables, Spearman to explore relations between ordinal-continuous variables and point-biserial correlation to explore relations between continuous and dichotomous variables. It should be noted that analogies in the parameters mentioned in Table 26 have different interpretations depending on their coding. For clarity, the parameters for which increased values show a health improvement are indicated with an ^{i} superscript while parameters for which increased values show a health deterioration are indicated with a ^{d} superscript. For conciseness purposes, only the statistically significant findings (p>.05) are cited in the present report.

The correlation analyses results showed that all three indices (CI, FI, CFI) were significantly correlated (in respect to p-values) with some of the health-related variables, although the correlations were not very strong (r≤.474). Specifically, the technical FI was significantly correlated only with **thyroid disease** r=.389, p=.037, indicating that when the thyroid disease prevalence increased by one point the FI tended to increase by .389 points. Furthermore, the clinical index CI was correlated with the prevalence of **arterial hypertension** r=.360, p=.043, **everyday functioning** r=-.313, p<.001, **grip strength** r=.317, p<.001, **gait speed** r=.197, p=.009 and **hearing acuity** r=.216, p=.004. Finally, several health parameters were related to the combined clinical-technical CFI index. In detail, CFI index was correlated with the prevalence of **ischemic heart disease** r=.474, p=.006, **arrythmia** r=.442, p=.011**, everyday functioning** r=-.194, p=.009, **cognitive ability** r=-.183, p=.029, **grip strength** r=.329, p<.001, **gait speed** r=.209, p=.005, **lower limb strength** r=.159, p=.034, **hearing acuity** r=.186, p=.012 and **orthostatic hypotension** r=.158, p=.034.

Since previous analyses showed that CFI index is the most robust in terms of predictive performance, we performed additional analyses to explore the most predominant associations between CFI and other comorbidities. Five multiple linear regressions were conducted with CFI as a dependent variable and other sets of health parameters (measured during the last assessment) as independent ones (Table 26). The analysis with the independent variables from the physical domain revealed a significant regression equation F(6, 168)=3.388, p=.003 with an R^2 of .076. More specifically, the only predictive factor which was found to be statistically significant was **grip strength** t=3.881, p<.001, β=.332 indicating that abnormal grip strength is associated with .332 points of increase in frailty index. The regression model with the nutritional factors did not yield statistically significant findings F(4, 171)=.532, p>.05. The model with medical factors yielded marginally significant findings F(5,174)=5.176, p=.004, R^2=.067. Significant predictors of CFI variance were **hearing acuity** t=2.720, p=.007, β=.249 and **number of medications** t=2.887, p=.004, β=.042. The results showed that an one-point decrease in hearing acuity is associated with .249 points increase in frailty index. Also, an increase of one drug in the medication list is associated with .049 points of increase in frailty index. Regarding the cognitive and psychological parameters, only **cognitive functioning** was a predictive factor of the variance of CFI t=-2.485, p=.015, β=-.281 showing that an one-point increase in MoCA score is associated with .281 points of decrease in frailty index. The regression model with the comorbidities was, also, found to be statistically significant F(16,163)=1.721, p=.047, R^2=.061. Statistically significant predictors were the prevalence of

orthostatic hypotension t=2.315, p=.022, β=.423, **stroke** t=2.626, p=.009, β=.647 and **cognitive impairment** t=2.045, p=.047, β=.776. The results showed that the prevalence of the aforementioned comorbidities increase the CFI by .423, .647 and .776 points, respectively.

It should be noted that when statistical analyses are performed towards multiple independent variables, the margin of type I error (yielding of false positive results) increases. Hence, to identify the stronger associations in terms of statistical significance, we performed a Bonferroni correction by dividing the preset level of significance a=.05 with the number of independent variables, which was 34 (Armstrong, 2014). Thus, if we consider the new and more strict level of significance (a_b=.0014), grip strength and everyday functioning have the strongest and most robust association with frailty.

The aforementioned findings indicate that frailty is a multiparametric syndrome closely dependent to other health-related parameters. Grip strength, gait speed, lower limb strength and everyday functioning were associated with frailty, as documented by numerous other research studies (see Pel-Littel, Schuurmans, Emmelot-Vonk, & Verhaar, 2009 for a review). Furthermore, this study recorded a statistically significant association of frailty with heart disorders (arrythmia, hyper- or hypotension, and ischemic disease) and especially, hypotension. This association is very important because there are studies in recent literature which have linked hypotension to frailty but results are, yet, inconclusive. For example, Rockwood, Howlett, and Rockwood (2012) found that hypotension is associated with higher mortality rates but not with frailty. Similarly, O'Connell and colleagues (2015) found that frailty is linked to orthostatic intolerance, manifested with light head feelings and dizziness but not to orthostatic hypotension. On the contrary, our study contributes to the research body which highlights the importance to monitor and manage orthostatic hypotension early on, as dizziness associated with the syndrome can increase the risk of falls and frailty prevalence (Ooi, Hossain, & Lipsitz, 2000). Furthermore, this study showed that stroke is a predictive factor of frailty which is a logical finding considering that stroke is associated with heart disease, shown in this and other studies to have a direct link to frailty. For example, a study by von Haehling, Anker, Doehner, Morley, and Vellas (2013) showed that adults with heart disease have three times higher risk to develop frailty. Furthermore, stroke incidents are linked to generalized physical and mental impairments which may increase dependency and risk for adverse outcomes. Interestingly, in our study, frailty was, also, linked to thyroid disease which association has been explored only during the last years in research. Few studies have documented such an association indicating that the hormonal disruptions present in thyroid disorders are linked to muscle weakness, dizziness and sarcopenia, all associated with frailty (Abdel-Rahman, Mansour, & Holley, 2010). In addition, frailty was linked to cognitive functioning, number of hospitalizations and polypharmacy, findings which have been recorded in previous studies, as well (Herr, Robine, Pinot, Arvieu, & Ankri, 2015; McAdams-DeMarco et al., 2013; Robertson, Savva, & Kenny, 2013). Finally, hearing acuity was found to be closely related to frailty and in fact, a predictive factor of the syndrome. Hearing acuity was listed as a frailty-marker in few other studies, as well (Panza, Solfrizzi, & Logroscino, 2015). Difficulties in hearing can decrease the environmental stimuli for older adults and thus, decrease cognitive stimulation; a disruption which may contribute to cognitive frailty and thus, constitute the mechanism underlying hearing disorders' association with the syndrome.

Table 26. Independent variables included in linear regressions: Relation of frailty to comorbidities

Physical	Nutritional	Medical	Cognitive	Comorbidities
IADL scale score[i]	MNA scale score[i]	Hearing acuity[d]	MoCA score[i]	Hypotension[d]
Exhaustion[d]	BMI*	Visual acuity[d]	GDS score[d]	Hypertension[d]
Lower limb strength test[d]	Body fat*	Falls during the last year[d]	Anxiety self-report score[d]	Arrythmia[d]
Balance[d]	Waist measurement*	Hospitalizations during the last three years[d]	Sleep[d]	Dyslipidemia[d]
TUG score[d]		Number of medications[d]		Diabetes[d]
Grip strength measurement[d]				Ischemic disease[d]
				Stroke[d]
				Renal disease[d]
				Respitory disease[d]
				Impaired cognitive function[d]
				Parkinson[d]
				Epilepsy[d]
				Osteoporosis[d]
				Thyroid disease[d]
				Lower limb disorder[d]

** Interpretation of these parameters does not denote an improvement or a deterioration per se, as increased numbers might show an improvement regarding malnutritioned adults or a deterioration regarding obese adults*

2.2.8 Impact of the FrailSafe system

To explore the impact of the FrailSafe system and individualized interventions, we performed comparative analyses between three groups of participants in the proof of concept study; the Placebo Intervention Group (Group B from the 3rd clinical evaluation and on), Actual Intervention Group (all participants of Group C) and No Intervention Group (all participants of Group D).

In order to study the evolution of frailty between the three groups after the intervention, a new three-level variable was constructed according to whether a participant remained at the same frailty status (0-steady state) and whether they progressed in a more severe frailty status (1-deterioration) or reversed to a better state (2-improvement) between their first and last assessment. A chi-square analysis showed that the distribution of frailty transition states differed significantly between the three groups $\chi^2(4)=25.971$, $p<.001$ with participants of Group C having a tendency to present higher rates of preservation of same status while participants of Group B and D tending to present higher rates of deterioration. The distribution percentages among the three groups can be found in Table 27.

Table 27. Frailty evolution distribution among Groups B, C and D

	Group B	**Group C**	**Group D**
Same state	76	92.9	85.4
Deterioration	20.8	3.6	10.1
Improvement	3.1	3.6	4.5

In order to explore the impact of individualized versus generalized recommendations we performed comparative analyses between participants of Group B and C. The Groups (group B assigned value 1 and C assigned value 2) were utilized as a dependent variable in our analyses and a set of health-related parameters (Table 28) as independent ones.

Health evolution before and after the intervention was associated with several health-related parameters was denoted by a constructed quantitative variable defined as *Delta score* which expressed the difference between a participant's performance on the first and last assessment according to the following equation:

D=Performance last assessment- Performance first assessment

It is obvious that delta scores could obtain either negative or positive values denoting an improvement or deterioration according to the health parameter. To enhance comprehensibility of the results, parameters in which positive scores show an improvement are indicated with a ^{i} superscript and parameters in which positive scores show a deterioration are indicated with a ^{d} superscript in Table 28.

A binary logistic regression with the physical parameters was statistically significant $\chi^2(7)=19.614$, $p=.006$. **Gait speed** was a predictive factor *Wald*(1)=4.572, $p=.032$, *Exp(B)*=.795, *CI*=.644-.981 indicating that people who received individualized recommendations (group C-value 2) had approximately 20% lower odds ratio to present a

deterioration of their gait speed. Also, **exhaustion** was a predictive factor *Wald*(1)=4.310, *p*=.038, *Exp(B)*=.107, *CI*=.013-.883 indicating that people who received individualized recommendations had approximately 90% less probability to report elevated signs of exhaustion. Binary logistic regressions with the set of nutritional χ^2(5)=1.435, *p*=.920, health/life related quality of life χ^2(2)=2.316, *p*=.314, lifestyle χ^2(4)=12.383, *p*=.089 and frailty variables χ^2(2)=5.418, *p*=.144 did not yield significant results. On the contrary, the set of cognitive factors was proven statistically significant χ^2(4)=18.268, *p*=.001. The only significant predictor was the delta score of **MoCA** *Wald*(1)=18.388, *p*<.001, *Exp(B)*=1.496, *CI*=1.244-1.799 showing that participants who received individualized recommendations had approximately 49% greater probability to present an improvement in their MoCA scores. Finally, the set of medical factors, also, yielded statistically significant results χ^2(4)=18.268, *p*=.001 and the only statistically significant predictor was the delta score of the **number of medications** *Wald*(1)=6.464, *p*=.011, *Exp(B)*=.798, *CI*=.670-.950, showing that participants who received generalized recommendations had approximately 20% increased number of medications across the field trials compared to those who received individualized ones.

Table 28. Independent variables in binary logistic regressions comparing groups B and C

Physical	Nutritional	Medical	Cognitive	Quality of health/life	Lifestyle	Frailty indices
IADL score[i]	Report of weight loss*	Hearing acuity[d]	MoCA score[i]	Health rate[i]	Number of social activities (going out)[i]	CFI[d]
Exhaustion self-report[d]	MNA score[i]	Visual acuity[d]	GDS score[d]	Life quality rate[i]	Smoking[d]	FI[d]
LEMS test score[d]	BMI value*	Falls during the last year[d]	Anxiety self-reported score [d]		Physical activity[i]	CI[d]
Balance[d]	Body fat*	Hospitalizations during the last three years[d]	Sleep [d]		Alcohol consumption[d]	
TUG test score[d]	Waist measurement*	Number of medications[d]				
Gait speed 4m[d]		Number of comorbidities[d]				
Grip strength[d]						
** Interpretation of these parameters does not denote an improvement or a deterioration per se, as increased numbers might show an improvement regarding malnutritioned adults or a deterioration regarding obese adults*						

A similar methodology was followed to perform comparative analyses between groups C and D. Binary logistic regressions with the set of nutritional χ^2(5)=4.918, *p*=.479, lifestyle χ^2(2)=4.007, *p*=.135, medical factors χ^2(6)=7.603, *p*=.639 or CI χ^2(1)=.222, *p*=.637 did not yield significant findings. The binary logistic regression model with the psychological-cognitive factors as independent variables was statistically significant χ^2(4)=9.501, *p*=.050. Delta scores in **MoCA** were a predictive factor *Wald*(1)=3.899, *p*=.048, *Exp(B)*=.821 indicating that participants of group C had a 17% higher odds ratio to present an improvement in their cognitive functioning. Finally, differences between groups were identified in regards to the

physical parameters $\chi^2(7)=21.502$, $p=.003$. **Gait speed** was a predictive factor *Wald*(1)=3.943, $p=.047$, *Exp(B)*=1.217 showing that people belonging in Group D had 21% increased odds ratio to present a deterioration in gait speed. A marginal significance was identified for the **IADL** score as well, *Wald*(1)=3.462, $p=.061$, *Exp(B)*=.859 indicating that participants of group C had a 15% increased tendency than participants of Group D to present an improvement in their everyday functioning.

2.2.9 Serious games impact

The present study aimed to test the rehabilitative effect of serious and augmented reality (AR) games in terms of physical and mental capacity. During the FrailSafe study, participants were administered a combined brain training paradigm with serious and AR games at multiple timepoints during the scheduled FrailSafe sessions. Training with the game suite was a self-paced task according to users' preferences and free time. The integrated paradigm included seven serious games, namely, Force Analyzer, Redwings, Railway, Simon, Memory, Reflex and Supermarket. Furthermore, three AR games were developed, namely, Memory AR and Floating Archery, played through the AR glasses, and Gravity Ball, which was played with a marker on the tablet and did not require an external device, thus facilitating the AR games' usage. All aforementioned games were different in terms of cognitive demand and designed to target different cognitive and physical domains (detailed description can be found in *D5.3 Final version of the Synthesized AR game system* (for a summary of the domains targeted by the games see Table 29).

More specifically, Force Analyzer, was played with a dynamometer and developed to assess and train strength and endurance of upper extremities. Redwings game was, also, played with a dynamometer but further targeted visuospatial ability, hand-eye coordination, attention and reaction speed. Memory and Simon were two games targeting short-term memory and visuospatial ability. Railway targeted eye-body coordination, orientation and reaction speed. Finally, Reflex targeted reaction speed and visuospatial ability and Supermarket targeted visuospatial ability and skills of everyday living. AR games, played with and without external garments to facilitate all users, targeted balance, coordination, orientation and motor skills. It should be noted that the domains described here are the most prominent to be targeted by the games' tasks, however, other skills may have also been trained during gameplay, as the tasks dictated by the games encompassed other cognitive functions, as well. For example, attention was specifically targeted in Reflex game but we expect that this domain was very important for successful gameplay in all games.

Table 29. Serious Games: Cognitive and physical skills training

	DOMAIN	DEFINITION
COGNITIVE	Short-Term Memory (Working Memory)	The capacity to hold and manipulate information "on-line" in real time.
	Visual and Spatial Ability	Ability to process incoming visual stimuli, to understand spatial relationship between objects, and to visualize images and scenarios
	Processing speed	The ability to minimize the time cycle of a repeated movement
	Motor Skills (gait speed, grip strength, etc)	Ability to mobilize our muscles and bodies, and ability to manipulate objects

	Inhibition / Attention	The ability to withstand distraction, and internal urges / Ability to sustain concentration on a particular object, action, or thought, and ability to manage competing demands in our environment.
	Orientation	Processing of spatial, temporal, and social relations relies on mental cognitive maps, on which the behaving self is oriented relative to different places, events, and people.
	Anticipation	Prediction based on pattern recognition.
	Problem solving	Defining the problem in the right way to then generate solutions and pick the right one.
	Decision Making	The ability to make decisions based on problem-solving, on incomplete information and on emotions (ours and others').
	Sequencing	The ability to break down complex actions into manageable units and prioritize them in the right order.
PHYSICAL	Strength	The ability of a muscular unit, or combination of muscular units, to apply force.
	Endurance (Muscular fatigue)	A state of exhaustion or loss of strength and/or muscle endurance following strenuous activity associated with the accumulation of lactic acid in muscles.
	Balance	The ability to control the placement of the bodies center of gravity in relation to its support base.

It should be noted that as the system was developing and new games were released at different time-points, participants of groups A and B interacted with different games at a different pattern, both between them and compared to group C, which tested the integrated serious game platform with all games available. For example, Redwings game was the first game to be released and hence, was played by more participants and in more sessions than other games resulting in a greater overall gameplay.

In the present study, participants from all groups were considered for the analyses. The total gameplay was used as a base variable, in order to explore the rehabilitative effect of the games. The variable "total gameplay" was created by summing up the gameplay logged for each individual in all sessions of the same game played per participant. Sorting the total gameplay in ascending order, we were able to identify the 20-30 users who played each game the most and peers who played the least, thus, defining two groups "Played Most" and "Played least" for each game. The sample chosen was different for each group according to the available resources. The analyses aimed to compare the groups created, in terms of their performance evolution (improvement or deterioration) in several cognitive and physical parameters between their first and last assessment with the clinical evaluation battery. For easiness in interpreting the results, delta scores were extracted for all parameters, as mentioned for previous analyses. However, in this set of analyses, a positive score in delta scores was denoted with 1, a same state with 0 and a negative score with -1. Similarly, with

the previous sections, the interpretation of positive and negative numbers was dependent on the individual parameter. For example, a positive value in MoCA score indicated that the participant obtained a higher score in their second assessment than the first, thus showing an improvement in their cognitive status. On the contrary, a positive number in delta score of gait speed, indicates that the participant needed more time to complete the task the second time compared to the first and thus, this is considered a deterioration. The list of variables used for the game-effect analyses can be found in Table 30 accompanied by superscripts indicating whether a positive number in delta scores show in improvement or a deterioration.

Table 30. Dependent variables in games' effect analyses

Dependent variables
Frailty-related
1. FrailSafe's CFI[d]
Cognitive
2. MMSE total score[i]
3. MoCA total score[i]
MoCA sub scores:
a. Visuospatial ability[i]
b. Naming[i]
c. Working memory[i]
d. Inhibition[i]
e. Attention-calculation[i]
f. Repetition[i]
g. Verbal fluency[i]
h. Abstract thinking[i]
i. Long-term memory[i]
j. Orientation[i]
Physical
4. Gait speed[d]
5. Grip strength[d]
6. Balance (binary) [d]
7. Mean systolic BP[d]
8. Mean diastolic BP[d]
9. Mean heart rate[d]
Psychological
10. GDS total score[d]
11. Anxiety self-rating (1-10)[d]

Descriptive analyses of the logged data showed that total gameplay was very diverse between different games. For example, the mean upper total gameplay duration for Redwings game was 376 hours while the same value was 1.6 hours for Force Analyzer. This can be attributed the different timepoints of game availability, game differences (*i.e.,* Redwings game is more interactive, while Force Analyzer is far simpler) and preferences of the participants, in terms of playing. The mean gameplay per group can be found in Table 31.

Table 31. Sample numbers and mean gameplay in minutes per group and game

	PLAYED MOST			PLAYED LEAST		
GAME[6]	*N*	*Mean gameplay (minutes)*	*SD*	*N*	*Mean gameplay (minutes)*	SD
Redwings	20	22574.37	7740.00	21	76.68	72.01
Memory	22	14140.40	5996.61	22	38.90	7.00
Simon	21	8881.98	2937.34	22	57.47	25.71
Reflex	22	5735.63	1610.12	22	51.27	18.62
Force Analyzer	37	100.76	71.02	30	4.97	1.32
Railway	15	2670.33	1738.81	21	43.02	18.93
Supermarket	21	987963.30	2855425.73	22	1704.49	1354.50

The total number of participants who played each game can be found in Table 32. The games of AR glasses are lower than other games, since they were incorporated in Group C [M32] and played only by participants, who did not have instability issues for safety reasons.

Table 32. Total number of sessions per game

Game	Number of sessions
Redwings	8043
Memory	4546
Simon	3281
Reflex	3840
Force Analyzer	576
Railway	1049
Supermarket	4020
Gravity ball	1405
Memory AR	46
Floating Archery AR	41

Regarding the **Redwings** game, univariate analysis of variance comparing the delta scores of all independent variables between the two groups showed that participants differed significantly in delta scores of **MoCA** $F(1,21)=5493$, $p=.029$ and **grip strength** $F(1,21)=4334$, $p=.049$. The analyses showed that the Played Most group had a more improved score in MoCA $M=.88$, $SD=1.8$ than Played Least $M=.15$, $SD=1.9$. Also, the Played Most group showed an improvement in grip strength after playing the Redwings game $M=-.59$, $SD=3.7$, whereas the Played Least group showed a deterioration $M=.09$, $SD=5.1$. Univariate analyses of variance in the aforementioned variables showed that users did not have any differences in their baseline measurements (MoCA score baseline: $F(1,21)=.074$, $p=.788$, grip strength baseline: $F(1,22)=.001$, $p=.973$).

Concerning the **Simon** game, the results showed that the two groups differed in terms of delta scores in the **MoCA sub score attention-calculation** $F(1,25)=4619$, $p=.041$. Most Played group had an elevated improvement $M=.25$, $SD=.86$ compared to the Least Played who

[6] Gameplay duration was not computed for AR games, as we followed a different procedure.

remained in same state *M*=.00, *SD*=.00. The groups did not differ in the score at baseline *F*(1,25)=3103, *p*=.090.

Similar analyses were performed for the **Memory** game. Univariate analyses of variance comparing mean delta scores between the two groups showed that they differed in terms of **MoCA subscore verbal fluency** *F*(1,24)=12784, *p*=.002 and, marginally, in terms of **MoCA abstract thinking** *F*(1,24)=4053, *p*=.055. The Played Most group achieved an improved score in verbal fluency *M*=.53, *SD*=.5 and abstract thinking *M*=.53, *SD*=.9 while Played Least had a deteriorated score in verbal fluency *M*=-.09, *SD*=.3 and abstract thinking *M*=-.09, *SD*=.5. Analysis of the same scores at baseline showed that the groups did not differ initially in terms of abstract thinking *F*(1,24)=3156, *p*=.088 but differed in verbal fluency *F*(1,24)=20308, *p*<.001. The Played Most group had obtained lower scores in verbal fluency in their first assessment *M*=.33, *SD*=.48 than Played Least *M*=1.00, *SD*=.0, which further boosts the rehabilitative effect hypothesis of Memory game.

Analyses for the Reflex game showed that groups differed in terms of **MoCA sub scores naming** *F*(1,26)=5709, *p*=.024, **working memory-attention** *F*(1,26)=4209, *p*=.050, **inhibition** *F*(1,26)=4256, *p*=.049, **language repetition** *F*(1,26)=6261, *p*=.019 and **verbal fluency** *F*(1,26)=6.244, *p*=.019. In naming the Played Most group had a more improved score *M*=3.00, *SD*=.00 compared to the Played Least *M*=1.94, *SD*=1.39. In verbal fluency, the Played Most group had an improved score *M*=.41, *SD*=.50 compared to the Played Least which showed an overall deterioration *M*=-.09, *SD*=.53. Same results were identified for language repetition were the Played Most group showed an improvement *M*=.18, *SD*=.95 while Played Least a significant deterioration *M*=-.73, *SD*=.90 and working memory-attention (Played Most: *M*=.59, *SD*=.1.0, Played Least: *M*=-.09, *SD*=.53). In terms of inhibition the Played Most group showed an improvement *M*=.29, *SD*=.47 while Played Least had a steady state *M*=.00, *SD*=.00. The groups differed in baseline in terms of language repetition *F*(1,26)=10295, *p*=.004, inhibition *F*(1,26)=4256, *p*=.049 and verbal fluency *F*(1,26)=6810, *p*=.015 with the Played Most having achieved lower scores in the three subscales (repetition: Played Most *M*=1.05, *SD*=.96, Played Least *M*=2.00, *SD*=.00 inhibition: Played Most *M*=.70, *SD*=.46, Played Least *M*=1.00, *SD*=.00, verbal fluency: Played Most *M*=.35, *SD*=.49, Played Least *M*=.81, *SD*=.40). Despite these differences, Played Most had an improvement after the intervention, even if they achieved lower scores in baseline, while Played Least exhibited a deterioration in most measures.

Similar analyses for the **Supermarket** game showed that groups differed in terms of **orientation** *F*(1,19)=5509, *p*=.030 (Played Most *M*=1.89, *SD*=3.10, Played Least *M*=-.25, *SD*=.62), **verbal fluency** *F*(1,19)=6662, *p*=.018 (Played Most *M*=.33, *SD*=.50, Played Least *M*=-.17, *SD*=.38), **attention-calculation** *F*(1,19)=9376, *p*=.006 (Played Most *M*=1.33, *SD*=1.44, Played Least *M*=--.08, *SD*=.66), **inhibition** *F*(1,19)=5297, *p*=.033 (Played Most *M*=.44, *SD*=.72, Played Least *M*=-.08, *SD*=.28), **attention-working memory** *F*(1,19)=5053, *p*=.037 (Played Most *M*=.67, *SD*=1.1, Played Least *M*=-.25, *SD*=.75), **naming** *F*(1,19)=6387, *p*=.021 (Played Most *M*=1.11, *SD*=1.45, Played Least *M*=.00, *SD*=.42) and **visuospatial ability** *F*(1,19)=5603, *p*=.029 (Played Most *M*=1.22, *SD*=2.5, Played Least *M*=-.67, *SD*=.98). In conclusion, the Played Most group showed an improvement in all domains while Played Least showed a deterioration in six out of seven domains and a steady state in one out of seven. Further analyses showed that the two groups differed in baseline in attention-calculation *F*(1,19)=6284, *p*=.021 (Played Most *M*=2.75, *SD*=.65, Played Least *M*=1.66, *SD*=1.41),

visuospatial ability *F*(1,19)=4625, *p*=.045 (Played Most *M*=2.55, *SD*=2.00, Played Least *M*=.3.91, *SD*=.79), orientation *F*(1,19)=2529, *p*=.019 (Played Most *M*=3.71, *SD*=.91, Played Least *M*=5.91, *SD*=.28) and inhibition *F*(1,19)=13571, *p*=.002 (Played Most *M*=.44, *SD*=.72, Played Least *M*=1.00, *SD*=.00). As shown, the Most Played group performed better in baseline in one out of the seven parameters and worse in visuospatial ability, inhibition and orientation. However, after the intervention the Most Played group showed a significant improvement while Played Least showed a deterioration in most parameters included in the analyses.

Concerning the Force Analyzer game, univariate analyses of variance showed that the groups Played Most and Played Least were significantly different only in terms of the mean delta scores obtained in **MoCA language repetition** *F*(1,38)=5987, *p*=.019 showing that the Played Most group had an improved score *M*=.35, *SD*=.988, while the Played Least group had a deterioration *M*=-.35, *SD*=.813. The groups did not differ in baseline language repetition performance *F*(1,38)=2726, *p*=.107. Force Analyzer did not seem to have an observed effect in our participants grip strength and physical ability.

Analyses were performed in a different manner for people who played with the AR games. The average game duration achieved by the participants in Gravity Ball game can be seen in Figure 32. The participants have been split according to their Fried-based frailty assessment. It can be observed that non-frail users achieve lower durations per game session, mostly less than 50 seconds. Pre-frail users have a wider distribution of durations, including both low durations, as well as, high durations. On the other side, frail users tend to achieve higher durations, mostly larger than 50 seconds. This is an indication that frailty level affects the game performance, which was rather expected.

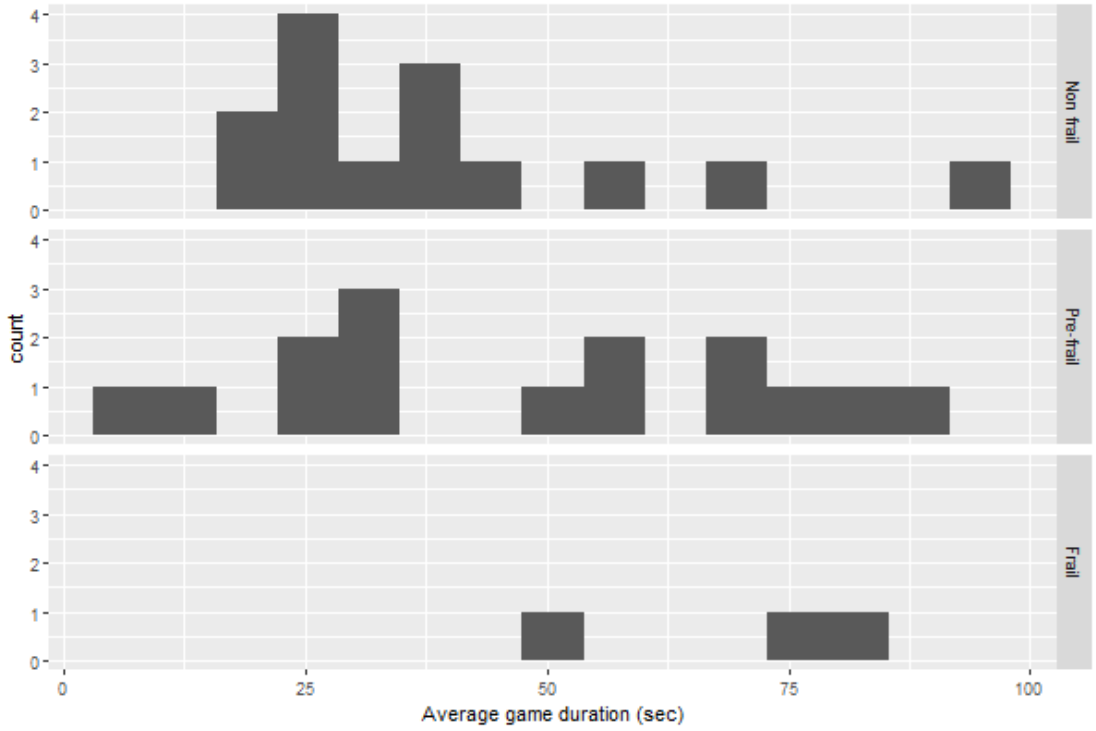


Figure 32: Average Gravity Ball duration per frailty category.

Similar results are extracted by examining the maximum difficulty level played by the participants. Figure 33 depicts the distribution of maximum achieved levels, again split according to the Fried frailty status of the participants. It can be observed that non-frail

participants stopped at a wide range of levels, both low ones and high ones. On the other hand, pre-frail and frail users mostly stopped at low levels, which is an indication of their difficulty in achieving higher performance in the game.

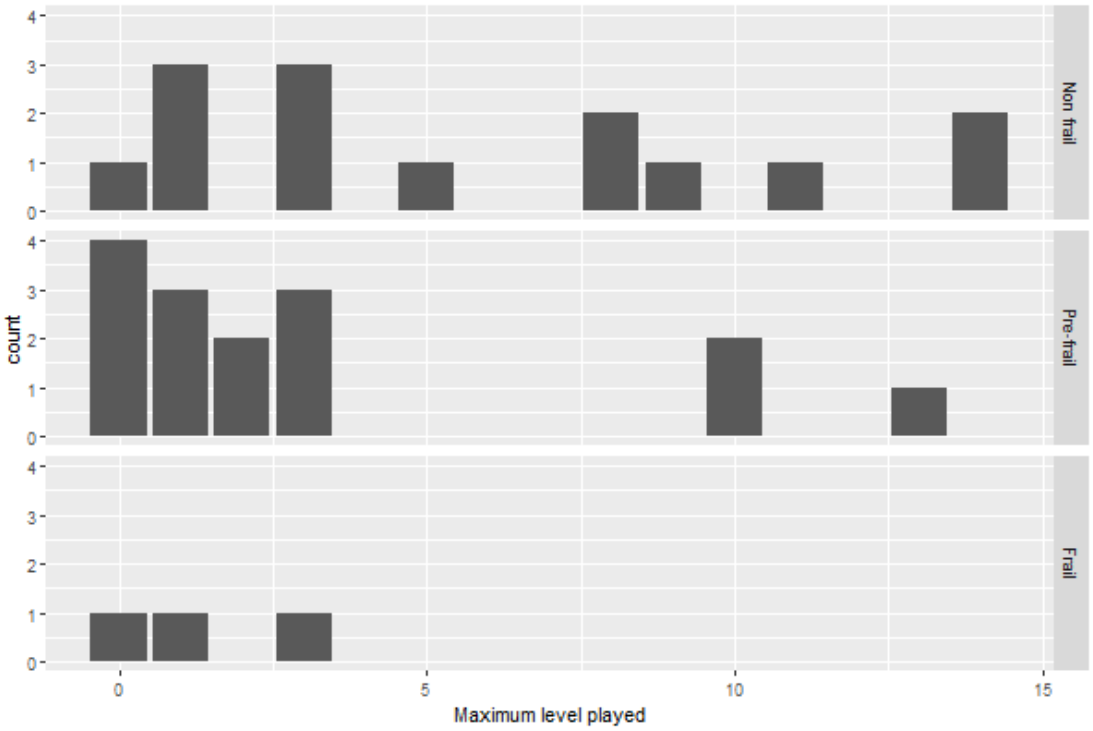


Figure 33: Maximum Gravity Ball level played by participants, per frailty category

Game-effect analyses were performed by comparing 21 individuals who played and 21 individuals who did not play the AR games in order to explore the effect of AR games overall. In particular, we randomly chose 20 individuals who played (Played group) and 20 individuals who did not play the AR games (Not Played group) and performed one-way anovas with the independent variables described in Table 30. Comparative analyses between the two groups showed that they differed in terms of delta scores in **balance** $F(1,24)=5914$, $p=.023$. In detail, the Played Most group showed an improvement in balance $M=-.30$, $SD=.48$, while Played Least did not have any differences in performance $M=0.00$, $SD=.00$. The Played Most group, also, showed an improvement in MoCA **working memory-attention** $F(1,24)=4306$, $p=.049$ (Played Most $M=.06$, $SD=.57$ Played Least $M=-.40$, $SD=.51$) and, marginally, in **gait speed** $F(1,24)=3709$, $p=.066$ (Played Most $M=-.18$, $SD=.99$, Played Least $M=.51$, $SD=.75$). In all cases, the Played group had elevated improvement compared to the Not Played group which showed a deterioration or preserved the same performance between their first and last assessment. It should be noted that the groups differed in gait speed in baseline assessment with Played Most group needing more time to perform the gait speed test than Played Least group $F(1,41)=36.076$, $p<.001$ (Played Most $M=6.05$, $SD=2.17$, Played Least $M=2.88$, $SD=1.04$) but did not differ in other measures (balance: $F(1,41)=.011$, $p=.919$, working memory-attention: $F(1,41)=.221$, $p=.641$.

To sum up, the game-effect analyses results were very optimistic with regards to the rehabilitative implications of playing FrailSafe serious and AR games. In detail, participants who played intensively with the games had improved performance in several cognitive and physical parameters after the intervention, even if, in many cases, they had achieved lower scores than the control groups in baseline. On the contrary, older adults who played very

limited time with the games presented a deterioration or a steady state in health-related parameters. However, in terms of strict research criteria and by applying the Bonferroni correction, a_b=.002, only Memory game seems to have an impact on verbal fluency.

The domains which were affected by the games were, in most cases, confirming our initial hypotheses but several surprising findings were identified, as well. For example, results showed that Redwings game can have benefits for grip strength and general cognitive function which is expected considering that it is played with an external dynamometer training strength in upper extremities and is demanding in terms of cognitive function, thus challenging multiple domains simultaneously. Also, Simon game was associated with an improvement in attention-calculation as measured by MoCA. In this particular task, participants are required to subtract the number 7 from 100, five consecutive times without reminders. Thus, it is a task challenging calculation, attention and working memory. Similarly, in Simon game participants are presented with a sequence of items and then, are requested to re-enter the sequence by memory. Hence, Simon task, also, trains working memory, attention and sequencing; the latter may have supported calculation skills.

Furthermore, in Memory game participants were required to identify pairs of rocks hiding the same item (animal picture) underneath. This game trains working memory and visuospatial attention as main functions. However, we found that participants who played intensively this game had improved performance in verbal fluency (free recall of words starting by a specific letter) and abstract thinking (identify a common characteristic between two different items). This finding can be explained, as execution of tasks can affect cognition in less obvious ways than expected. For example, abstract thinking is closely related to reasoning (“if this…, then that…” thinking) and Memory game is a game of reasoning, as performance is dictated in many cases by the reductio ad absurdum principle (i.e., if the item is not under these rocks, then it must be under the other rock). Hence, it seems plausible that Memory game affected abstract thinking. In addition, Memory game presents the users with several pictures of animals (i.e., snake, rhinoceros, etc.). These animals are not common in everyday life and thus, their memory trace (remembering the name for a specific animal) may wear off overtime in older adults (Wickelgren, 1974). Seeing the animals in Memory game might have strengthened their memory trace. Research suggests that performance in verbal fluency tasks is highly dependent on the integrity of lexical representations and relationships between words that are crystallized in long-term memory (Rohrer, Salmon, Wixted, & Paulsen, 1999) and thus, an increase in the number of strong memory stimuli present in long term memory may have, also, assisted recalling of other words.

Moreover, our study showed that Reflex game was associated with improved attention, inhibition and working memory which is explicable considering that the game requires users to be alert and pay attention to the appearing items in order to knock them off and also, remember temporarily the places where the items appear in order to complete the task effectively. Furthermore, Reflex game was linked to improved verbal fluency, and repetition. This finding is surprising considering that the game does not include a direct linguistic element. Our hypothesis with regard to this result is that improved attention may have also, benefited listening in the language repetition task. More specifically, participants may have showed improved attention after the intervention and thus, listened more carefully to the sentences expressed by the clinician, which led to an improved performance. The hypothesis regarding

the improvement observed in verbal fluency is based on searching skills. More specifically, since Reflex game has significant demands in terms of searching, vigilance and scanning, the effects of training these domains may have been also, affected the vigilance and search efficiency in free word recall.

Furthermore, results for the effects of the Supermarket game showed that playing was associated with improved performance in orientation, attention, visuospatial ability, calculation, naming, verbal fluency and inhibition. All domain benefits seem plausible considering that Supermarket game required the users to navigate through a virtual environment (visuospatial ability, orientation and sense of direction), identify and purchase only the requested items (naming, inhibition, attention, working memory) and pay the correct amount of money (attention, calculation).

Moreover, Force Analyzer game was, surprisingly, related only to benefits in language repetition and not grip strength as it was expected to. The abscess of impact in strength of upper extremities can be attributed to the limited time spend on the game by the participants (top average time 1.67 hours). This hypothesis is further supported by the finding that users who played intensively with the Redwings game showed significant improvement in grip strength. The hypothesis regarding the improvement presented in language repetition skills is that, since Force Analyzer required mental stamina, focus, attention and concentration to perform the task, the increased concentration may have also improved the performance in sentence repetition (improved concentration led to improved ability to repeat the sentences correctly).

Finally, AR games were associated with benefits in balance, gait speed and attention-working memory. The results seem plausible as AR games train hand-eye coordination, body balance and orientation, as they require the users to coordinate and balance their upper extremities (in the case of Gravity Ball) and full body (in the case of Memory AR and Floating Archery). Also, they require balanced, accurate and quick reaction to hit the assigned targets and thus, may have had a benefit in gait speed as well. Finally, games played with AR glasses, such as Memory AR tap working memory as the user has to memorize items in specific locations and recall them.

2.2.10 Follow-up study results

During M42, a phone follow-up study was performed with all participants of Group C and D in order to record individuals' health status and prevalence of adverse events three months after the completion of field trials. More than 82.6% of the participants were reached during the follow-up calls. The results (Table 33) showed that participants of Group C tended to report more adverse events than Group D. However, only 37.5% of the adverse events reported by participants of Group C were characterised by high-severity (falls, fractures, hospitalizations and deaths) as opposed to 75% of high-severity events reported by the participants of Group D. Also, a careful consideration of the events reported by the individuals shows that participants of Group C tended to report minor events (such as a myoskeletal pain or a flu) in greater percentages than individuals of Group D. The aforementioned data indicate that the intervention group (Group C) had better outcomes than the control group (Group D) three

months after the intervention and additionally, presented a more meticulous health monitoring behaviour.

Table 33. Phone follow-up study results

Group	Sample	Adverse events	Main cause	High severity
Ci	*47/60 (78.3%)*	*11 (18.3%)*	*2 falls with one fracture, 1 stroke, 3 flu/cold/virus, 2 myoskeletal pain*, 2 surgeries, 1 psychological discomfort**	*5*
Cii	*15/15 (100%)*	*5 (33.3%)*	*1 fall with fracture, 3 cold/flu/virus*, 1 myoskeletal pain*	*1*
C total	62/75 (82.6%)	16 (21.3%)	3 falls with two fractures, 1 stroke, 6 cold/flu/virus, 3 myoskeletal pain, 2 surgeries, 1 psychological discomfort	6 (37.5%)
D total	68/75 (90.6%)	8 (10.6%)	2 falls, 1 fracture and 1 dizziness, 1 death, 1 dementia & 1 amnesia, 1 pulmonary embolism	6 (75%)

2.2.11 Limitations

In conclusion, the FrailSafe proof of concept study revealed that the FrailSafe system can be a valuable, complementary tool for the prediction, management and rehabilitation of frailty. This section aims to describe the limitations of our study. To begin with, the sample of our study was adequate in order to draw indicative conclusions regarding the FrailSafe system's impact. However, a larger scale study is considered necessary to increase the robustness, replicability and generalizability of our results. Added to that, considering that the FrailSafe system was a device under testing we chose cautious language to convey results and recommendations to the participants and hence, they were not as specific as a healthcare professional's advice would be. This affected the perceived benefit of the recommendations by the participants, as many stated that they would like them to be more specific. However, taking under account ethical standards and the absence of continuous monitoring by a healthcare professional, specific results could not be conveyed in any case. Since the FrailSafe system does not opt to replace but only complement healthcare professionals in their work, we are satisfied with this outcome. Also, this finding could indicate that the expectations of users

should be redirected into the concept that the FrailSafe system is a complementary tool and cannot replace a healthcare professional, per se.

Considering the aforementioned parameters, we were not expecting to find significant impact of the interventions in the proof of concept study, though a detailed, individualized and intensive intervention plan was employed even in this short duration. However, despite the limitations, our findings showed that 71% of the participants presented compliance with individualized recommendations and took appropriate measures to improve their health, such as changing their lifestyle or consulting their doctors. Furthermore, this attitude managed to differentiate them in terms of quantifiable benefits compared to the controls, by presenting an overall significant improvement in cognitive function, gait speed, self-reported exhaustion and transition to frailty states.

Another limitation is that, several of our health data were based on participants' self-reports and hence, were subject to confounding parameters (i.e., memory difficulties introducing recall bias). However, this is a common method for acquiring patient history in every clinical setting and widely used in all epidemiological studies and also significantly cognitively impaired individuals were excluded from this study. Furthermore, in our study, data acquired through self-reports were, in many cases, further reinforced by objective measures.

Other limitations of our study concern the rates of frailty, habitation zone and gender distribution between participants. Since, older adults constitute a population with high number of drop-out rates in research (Provencher, Mortenson, Tanguay-Garneau, Bélanger, & Dagenais, 2014) it was a challenge to complete the study with exactly equal representations of each category. However, section 2.1.1 shows that approximately equal numbers, even with these challenges, were obtained.

Furthermore, as stated in section 2.1.2, Group C was not randomized in two groups as initially planned but compared against Group B. Due to this fact, the study was single-blind from the participants' perspective but not double-blind. Another challenge was proven to be the low quality of some signals due to their acquisition in a real-life home environment and not in a controlled experimental setting. These measurements were excluded from the final analyses to avoid contamination of the results, thus reducing our available data. However, after a careful examination of the issue, training manuals on wearable devices, adjustment of devices in terms of wearability and familiarization of the participants with the devices allowed us to minimize loss of data in Groups C and D.

Finally, potential bias may have been inherited in this study which is related to motivational aspects of the participants. More specifically, eligible participants in all centers were asked to participate after explaining the study procedures in detail. The ones choosing to participate were enthusiastic about the future benefits of the study, as well as the activities and interactions which would enrich their daily routine. Hence, the sample recruited may have been a priori positively biased towards the FrailSafe study.

3. FINAL EVALUATION

3.1 Evaluation through pilot trials [M18-M30]

As mentioned in section 1.2 of the present document, the second part of the OT&E procedure focused on the multiparametric evaluation of the FrailSafe system. This process begun in M18 by implementing and maintaining a constant loop between the users, clinical and technical teams to enhance the acceptability and reliability of the developing system. In progress, testing and evaluation WP laid the ground and selected the tools for the final assessment and refined them. During the final evaluation, the administration of the tools in multiple user groups according to the evaluation timeline resulted to a comprehensive data collection. One of the goals of D7.4 is to report the methods and results of the final evaluation, as well as, their implications for future activities and exploitation models.

3.2 Final evaluation objectives

The scope of the D7.4 is to evaluate the FrailSafe project according to multiple parameters, namely:

- Achievement of main project objectives and goals
- Range of impact of the FrailSafe study and system
- Safety
- Key stakeholder's satisfaction
- Acceptance
- Desirability
- Usability
- Functionality
- Utility
- Ease of use
- Ethics
- Meeting user requirements
- Multi-modality, interoperability and flexibility
- Sustainability
- Socioeconomic impact
- Cost-effectiveness
- Exploitability

3.3 Evaluation procedure and timeline

According to Evaluation protocol outlined in D7.2 and further revised and optimized, the evaluation of the FrailSafe project and system was two-fold: a) Internal, including consortium members, such as clinicians, IT professionals, researchers, etc. directly involved in the FrailSafe study or members of partner teams not directly involved into the study and b) external, involving multiple users (older users, family members, caregivers, researchers, IT professionals, healthcare professionals and commercial stakeholders).

The outline of the evaluation procedure can be summarized as follows:

1. Identification of user groups

2. Selection and fine-tuning of appropriate tools for each user group
3. Design of the evaluation timeline for all user groups
4. Administration of selected evaluation tools
5. Analysis of the collected data
6. Reporting of assessment results

The evaluation strategy was based on preset use-case (UC) scenarios (described in detail in *D1.2 User Requirements*). The first target group included primary users of the system, namely older adults. In this UC, the older user uses the integrated FS system in their home-setting and is requested to evaluate it during several time-points, with multiple tools. The second target group included secondary users of the system, such as formal and informal caregivers, researchers, healthcare professionals and IT developers. During this UC, the stakeholders have a direct and indirect interaction with the system and are requested to evaluate it with multiple tools. Thirdly, tertiary users were community members and commercial stakeholders who interacted directly or indirectly with the FrailSafe system and were requested to evaluate it, also with multiple, qualitative and quantitative, tools.

A comprehensive timeline of assessment was created, in order to optimize the evaluation reliability, efficiency and comprehensiveness of data acquired, based on four criteria:

1) The users should have acquired adequate familiarization with the system, according to the respective UC, before evaluating it.
2) The administration of tools should be in line with the available resources and simultaneously, provide a thorough and comparative view of assessments between different stakeholders.
3) The evaluation feedback should be collected in various timepoints, spanning seven-months, to serve as a continuous feedback loop for the developing exploitation strategies, business modeling and future plans.
4) The timeline of administration should ensure that an adequate sample is collected and expected sample numbers are reached (The evaluation timeline is presented briefly in Figure 34).

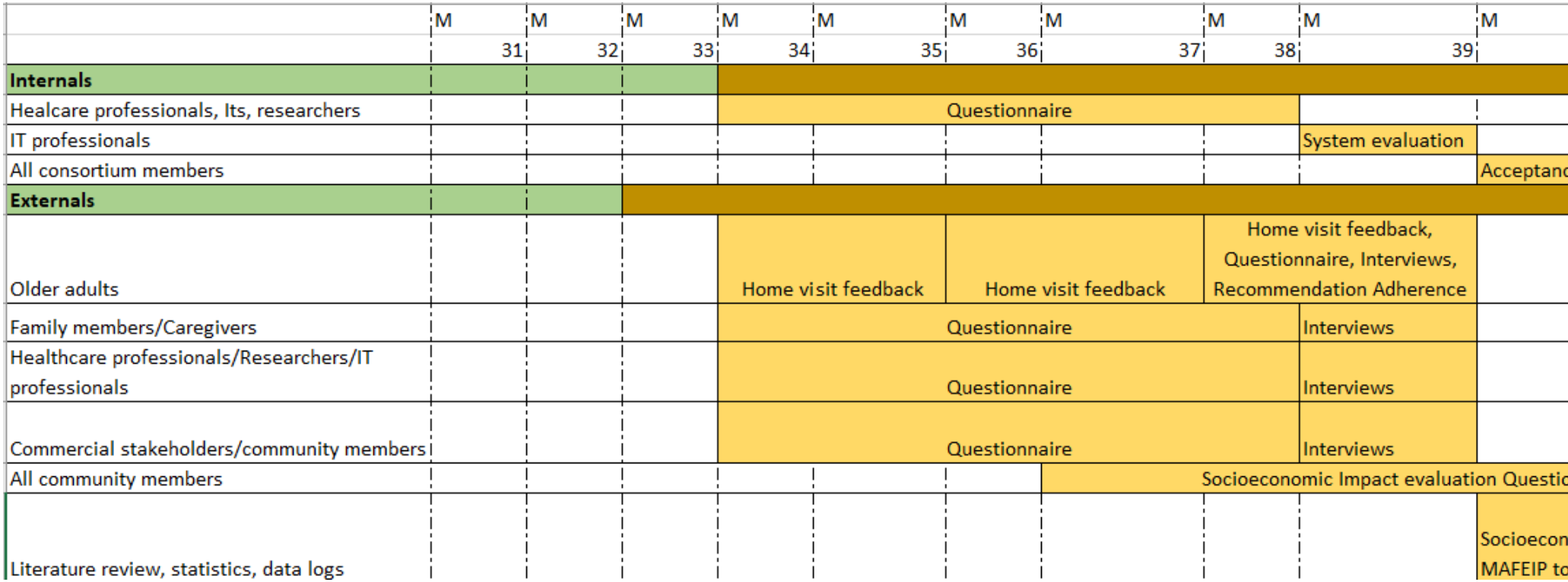


Figure 34. Evaluation timeline

According to recent literature, optimal project evaluation consists of the systematic use of mixed methodology and multiple evaluation methods to assess a product (Atkins, Odendaal, Leon, Lutge, & Lewin, 2015). Hence, the evaluation of the FrailSafe system was performed through a combination of quantitative and qualitative methods to achieve a better overview of the project outcomes. In the same manner, within-subjects, mixed assessment tools were used to collect and analyze each stakeholder's point of view.

Consortium members

Consortium members were asked to evaluate the FrailSafe system, both in terms of functional (technical) and non-functional characteristics (utility, usability, acceptability, etc.). Consortium members evaluated technically different components of the system at different timepoints from M18-M40 through multiple tools used internally, such as focus groups, questionnaires, cognitive walkthroughs and item checklists. System's reliability and sensor accuracy was cross-examined with external tools through the small-scale evaluation described in detail in *D7.3 Small-scale Evaluation Report*. Furthermore, consortium clinicians, IT professionals and researchers completed the Scale for Healthcare Professionals, IT professionals and Researchers (Annex IX) addressed, also, to external healthcare professionals, IT professionals and researchers, in order to obtain a comparative view of their opinion. The targeted sample consisted of two researchers, 10 IT professionals and 10 healthcare professionals, as internal evaluators. Also, IT professionals assessed the functional technical characteristics of the system, such as its reliability, data protection, etc. through an online survey (Annex X) and by providing an expert evaluation. Finally, all consortium members evaluated several key points of the FrailSafe system and study, such as their acceptance towards the study results and progress, as well as, future steps through a focus group performed during the last plenary meeting.

Older adults

According to the respective UC scenario, 75 older adults (Cypriots, French and Greek), who participated in the Evaluation Group (C) were requested to evaluate the FrailSafe system. The timeline and tools used included:

a) Qualitative evaluation of their experience with the FrailSafe system during and after each of the FrailSafe visits (three in total) to their home.
b) A thinking aloud protocol during their second interaction with the system
c) Administration of the User Satisfaction Questionnaire (Annex XII) after completing their participation to the study.

Users were requested to assess the system according to the aforementioned timeline and procedure. However, they were free to decline to use any of the aforementioned tools without providing a reason for that. Finally, if the participants had difficulties completing the questionnaires (i.e., due to pain in upper extremities or visual impairment) but wished to evaluate the system through a questionnaire, a clinician assisted them by reading the questions and noting down their answers.

Family members

According to the respective scenario family members and caregivers of participants in the Evaluation Group (C) and community caregivers who had directly interacted with the system otherwise (i.e., through an independent demonstration of the system) were asked to provide their feedback. The aim was to recruit 30 family members/caregivers from all three clinical centers. The stakeholders evaluated the system from M33 to M40 after their interaction with it. The evaluation tools included the administration of the FrailSafe questionnaire for Family

members/Caregivers (Annex XIII), one-to-one interviews and focus groups. The means for interaction were independently chosen for each center but generally included:

a) Being reached at the participant's home or by phone and asked to provide their feedback through a questionnaire and/or an interview.
b) Participated in workshops and demonstrations during dissemination events and were asked to provide their feedback through a questionnaire and/or an interview.
c) Being asked to participate in focus groups to evaluate the FrailSafe system.

Healthcare professionals, Researchers and IT professionals

Community members who were healthcare professionals, IT professionals and researchers were asked to evaluate the FrailSafe system after interacting directly or indirectly with it. We expected a minimum sample of five healthcare professionals, from the fields of medicine, nursing, psychology, gerontology, speech-language therapy and social work, five researchers and five ITs. The tools for evaluation included the FrailSafe questionnaire for Healthcare Professionals, Researchers and IT professionals, as well as, expert evaluations, interviews and focus groups. The experts evaluated the system independently for the three clinical centers from M33 to M40. In general, they interacted with the FrailSafe system directly or indirectly or were presented with the FrailSafe technical video and were asked to provide their feedback (questionnaire and/or expert evaluation and/or interview and/or focus group). Also, a minimal sample of two external IT professionals were expected to evaluate the functional characteristics of the system after interacting with it in a laboratory setting.

Commercial stakeholders and community members

From M33 to M40, commercial stakeholders were reached and requested to evaluate the FrailSafe system after directly or indirectly interacting with it. A broad range of stakeholders, such as policy makers, healthcare product merchandisers and insurance companies were asked to provide their feedback through completing the Commercial Stakeholder Questionnaire (Annex XIV) or providing a semi-structured interview. Expected minimal sample was 10 commercial stakeholders.

Socioeconomic impact assessment

Furthermore, a broad range of community members were reached and asked to complete the Socioeconomic Impact Evaluation Questionnaire (Annex XV) to assist us in the evaluation of the socioeconomic implications of the FrailSafe system. A minimal sample of 10 community members were expected to be reached. Except for the external evaluation of the socioeconomic implications of the FrailSafe system we performed an analysis based on a well-documented EU tool, the MAFEIP tool, in order to increase the validity of our results. The MAFEIP tool is based on the 'Monitoring and Assessment Framework for the EIP on AHA (MAFEIP) project and was constitutes a joint effort by the European Commissions' (EC) Joint Research Centre, Institute for Prospective Technological Studies (JRC IPTS), the Directorate General for Communications Networks, Content and Technology (DG CNECT), and the Directorate General for Health and Food Safety (DG SANCO). The MAFEIP tool is a web-based instrument (https://www.mafeip.eu/) assessing the socioeconomic impact of an innovation (Boehler, de Graaf, Steuten, Yang, & Abadie, 2015).

Advisory board members

FrailSafe Ethics Advisor Dr. Stefania Maggi, as well as, all advisory board members, Liz Mestheneos, Gil Goncalvez, Malena Fabregat, Jim Playfoot, Nick Guldemond and Filios Savvides, were requested to evaluate the FrailSafe integrated system in terms of ethics compliance and safety related features. The assessment was performed during M37 through an

online survey form in which several ethical issues and steps taken to ensure the achievement of ethical goals were described in detail (Annex XI).

Other sources of feedback

Except for the aforementioned measures, several other sources were used to acquire important information during the evaluation process. These sources included but were not limited to users' feedback, comments and questions obtained:

a) During and after online webinars
b) Through a short survey circulated to attendees after several dissemination events (Annex XVI)
c) Through discussions with Advisory Board members taking place throughout the study
d) Through meetings with potential investors and commercials
e) Through interactions of users on FrailSafe social media platforms.

3.3.1 Tools of evaluation

As mentioned, multiple tools were employed to serve our mixed evaluation methodology design, such as questionnaires, focus groups, interviews, expert evaluations, cognitive walkthrough, think aloud study protocols, workshops, online surveys, observation and indirect indicators of success, such as user participation in scientific events, comments, and other interactions with users. Evaluation methodology ensured that our instruments would enhance construct, convergent and criterion-based validity by including tools which are well-documented in literature for reliably measuring a theoretical construct and having good psychometric properties, and also, content validity[7] (Drost, 2011). The tools used are described in detail in the following sections.

Questionnaires and online surveys

Questionnaires were chosen as a quick and effective tool to assess user experience. The questionnaires used to evaluate the FrailSafe system employed a mixed design, as well, by combining quantitative and qualitative questions. This ensured that we could acquire quantitative results but also collect information about other aspects of user experience, which could not be assessed in a quantitative manner. During the evaluation process, different questionnaires were addressed to different users. The tools were constructed either by selecting a standardized tool either by constructing a new one based on users' characteristics. WPs 1 and 8 served as a basis for the construction of questionnaires and vice versa, the questionnaires included questions aimed to provide feedback to WP8 regarding the exploitation strategy and business models.

In general, questionnaires included a section for demographics characteristics and further questions to comprehensively assess user experience and attitudes. After their selection and fine-tuning, questionnaires were sent to all consortium members for feedback and initial modifications were implemented. Consequently, Liz Mestheneos, an Advisory Board member, who promotes the work of 50plus Hellas and the Hellenic Association of Gerontology and Geriatrics and has extensive experience in older population, assessed questionnaires from a user perspective and suggested further modifications and improvements. Lastly, a focus group, with two older adults, one family member and one doctor resulted in further modifying the questionnaires prior to their administration to the target population. During this focus group, stakeholders suggested modifications such as the inclusion of pictures of several components

[7] According to Anastasi and Urbina (1997), content validity refers to "whether (a test) covers a representative sample of the behaviour domain to be measured" (p. 114).

of the system to ensure that users could remember them and further simplification of wording. After their suggestions were incorporated, all questionnaires were circulated to consortium members before the beginning of the final evaluation phase. They were provided both as a hard-copy version (Microsoft Word document) but also, in a Google Form link, to facilitate participation of users and future analyses. Upon their creation, the FrailSafe technical video was incorporated in the online questionnaires targeted to caregivers, commercial stakeholders and community members and some of them were also administered as online surveys, disseminated through social media channels and emails.

The full set of questionnaires included the:

1) *FrailSafe: User Satisfaction Questionnaire (Annex XII)*
   This questionnaire was based on the one created to measure user requirements in WP1 as it was understandable and well-received by users. Questions were enriched to comprehensively assess user experience, ease of use, perceived benefit and consumer behavior.
2) *FrailSafe: Evaluation Questionnaire for Family members/Caregivers (Annex XIII):*
   We revised the questionnaire described in D7.2 to include a separate part for demographic characteristics. The final tool included the USE questionnaire (Lund, 2001) a standardized measure which assesses usability of a system/product with regards to four factors: usefulness, ease of use, ease of learning and satisfaction. USE questionnaire has very satisfactory psychometric properties with regards to its validity, sensitivity and reliability (Gao, Kortum, & Oswald, 2018). The questionnaire was constructed as a seven-point Likert-type scale, e.g. from -3 (disagree very strongly) to +3 (agree very strongly). Further questions were included to measure system' s utility and exploitability.
3) *Questionnaire for Healthcare professionals, IT professionals and researchers (Annex IX)*
   We revised the questionnaire described in D7.2 to include a demographics section. The revised tool included the System Usability Scale (SUS) (Brooke, 1996) which is a standardized and reliable tool according to recent literature (Tullis & Stetson, 2004). The SUS is comprised of 10 items, assessed using a five-point response scale which ranges from strongly disagree, to strongly agree. The SUS has a scoring system which delivers a single number that reflects the outcomes of the overall usability of a system. The scoring of SUS derives from the sum of score of each individual item. Each item score can range from 0 to 4. Specifically, for items 1, 3, 5, 7 & 9 the score yields from the scale value checked minus 1. For all other items the score derives from the subtracting the value checked from 5. The value of the overall usability can be found after the multiplication of the sum of each of the 10 scores with 2.5 (Brooke, 1996).
4) *FrailSafe Technical Evaluation: Functional characteristics (Annex X).* The questionnaire was created by the FrailSafe team and was addressed to internal and external IT professionals to assess functional characteristics of the FrailSafe system, such as hardware reliability, data loss prevention, etc. The questionnaire included a brief demographic section and 10 items listing the functional requirements. ITs were asked to evaluate each item with a "pass" or "fail" answer according to their level of satisfaction from the system's functional characteristics. Users could add qualitative feedback to support or enrich their answers. Consortium and external ITs had direct contact with the FrailSafe system before filling in the survey.
5) *FrailSafe: Evaluation Questionnaire for Commercial Stakeholders (Annex XIV*). The questionnaire for commercial stakeholders was constructed to assess system's

exploitability, impact, versatility, ability to be incorporated in the healthcare system and pricing.

6) *FrailSafe Ethical evaluation (Annex XI)* Ethical evaluation questionnaire was constructed to assess compliance of the FrailSafe system and study with ethical standards. Eight main ethical key-points were included in the questionnaire, such as respect for the individuals, fair treatment of participants, data anonymity, etc. The steps taken by consortium members to address each key-pointed were listed under each argument. Six members of the advisory board and the FrailSafe ethical advisor were asked to answer with a "yes", "no" or "I need more information to decide" answer whether they evaluated that each key-point was addressed appropriately. Ethical evaluators could also add further comments to justify or enrich their answers. The questionnaire was provided via Google Forms as an online survey.
7) *FrailSafe Socioeconomic Impact Questionnaire (Annex XV)* This questionnaire was constructed to assess community members opinions regarding the social, health, financial implications of the FrailSafe system. The questionnaire included positively and negatively formulated statements to avoid biased answers. The questionnaire aimed to provide a semi-quantitative assessment of the impact of the FrailSafe system and also, provide feedback for the final business modelling strategy.
8) FrailSafe Short Survey follow up
A short survey was constructed for the evaluation of users' view of the FrailSafe system regarding feasibility, acceptance and exploitability (Annex XVI). The survey consisted of five questions and was a shorter and simpler version of the FrailSafe: Evaluation Questionnaire for Commercial Stakeholders. The purpose of this instrument was to provide a short but quantifiable feedback from users attending FrailSafe dissemination events.

Cognitive walkthrough

Cognitive walkthrough (Lewis, Polson, Wharton, & Rieman, 1990) is a tool used to evaluate technical features from a user-perspective but in a laboratory setting. More specifically, during this paradigm the evaluators asked to perform predefined tasks that the end-user will be requested to perform at a later timepoint in order to identify issues and difficulties that the end-user may face and propose improvements. The cognitive walkthrough focuses on usability and easy-of-use and takes under account end-users expectations and theoretical constructs when interacting with specific features and interfaces (Mahatody, Sagar, & Kolski, 2010). Cognitive walkthrough was used by consortium professionals to evaluate several system characteristics of the system (i.e., VCP, DSS, tablet games, dynamic adaptability) and improve their usability prior to their administration to end-users.

Focus groups and workshops

Focus groups and workshops are a valuable tool for the assessment of user experience. They are defined as collaborative discussions or group interviews and can be strictly structured, semi-structured or unstructured depending on the guidance provided by the coordinator of the group. Focus groups lay the ground for free expression on a topic and thus, provide valuable insight for reserchers by offering answers to "why" and "how" questions which are difficult to be answered by other quantitative measures. In fact, usually during focus groups people express strict and honest opinions about a product and thus, are helpful for identifying aspects for improvement (Barbour, 2008; Vermeeren et al., 2010). Workshops are also a form of collaborative discussion but usually involve experts on a specific topic. During the FrailSafe study, focus groups were utilized for the assessment and improvement of system features, intervention guidelines and evaluation tools. During the final evaluation, two focus groups were performed; one involving

with healthcare professionals and one involving commercial stakeholders to assess their overall opinion on the FrailSafe system.

Key-informant interviews

From M31 to M40, consortium members performed one- to-one interviews with key-informants, such as investors, community commercials and healthcare professionals who reached us independently or were requested to provide their feedback on the FrailSafe system. The interviews were semi-structured and all feedback collected is reported in the respective sections.

Expert/Heuristic evaluation

Expert evaluation was utilized to assess system's usability and functional requirements from a technical perspective. Specifically, two external IT professionals interacted with the FrailSafe system directly and were asked to provide their feedback through an unstructured expert evaluation or by filling the FrailSafe: Technical evaluation of functional characteristics.

Observation and think aloud protocol

To obtain older adults' comprehensive feedback on their experience with the FrailSafe system we utilized a think aloud protocol. During this assessment the user was asked to interact with the FrailSafe system while explaining their thoughts and difficulties. Think aloud protocol a valuable tool for assessing otherwise non-verbalized elements of user experience (Nielsen, 1994).

Data logs

Data collected through field trials and other experimental protocols served as a basis to assess evaluation outcomes based on empirical data and quantitative analyses.

Other sources of information

Other sources of evaluation data included users' free comments and interactions obtained from dissemination events and social media platforms which are reported qualitatively in the present deliverable.

3.4 Final evaluation results

The numbers of the stakeholder groups participating in the final evaluation are summarized in Table 34. Obtained sample numbers exceeded our initially targeted numbers. This is indicative of the broader impact of dissemination and larger community interest than expected, which was also, supported by the findings of *D8.4*).

Table 34. Sample sizes of evaluation groups

Group	Targeted sample	Actual sample
Older adults	All participants of Group C	All participants of Group C
Healthcare professionals	5 internals	5 internals
	5 externals	14 externals
Family members/Caregivers	30	33
IT professionals	5 internals	20
	10 externals	12
Researchers	2 internals	6
	10 externals	16
Commercial stakeholders	10	29
Advisory board members	2	5

3.4.1 Internal evaluation results

Internal evaluation of the FrailSafe system was conducted by all consortium members. Several sub-evaluations were deployed for a thorough validation of system's functional and non-functional characteristics, as described in section 3.3. Internal evaluation results can be found in the following sections.

Evaluation of functional characteristics

Reliability and functionality

All system components were selected based on *D1.2 User requirements, use cases, UCD methodology and final protocols of evaluation studies.* Since their design and development, the components were extensively tested in a laboratory setting to ensure their reliability and safety before being administered to older users. Independent tests of reliability and safety were conducted by respective technical partners. Furthermore, once ensuring that the components were safe in a laboratory environment, they were first tested in a small sample of older adults to ensure that they are also acceptable and do not cross limits of discomfort or inconvenience for the users. Furthermore, during their development the components were continuously modified and adapted to meet users' needs till M30.

More specifically, modifications and developments were constantly performed to WWBS version 1.0 which served as a basis for the development of version 2.0. There were changes that were technology-driven, in order to optimise the performance of the wearable solution and other more oriented to the improvement of user-friendliness, for both groups of end-users and caregivers. Smartex, also, received several comments/suggestions on the design of the vest: some of them were immediately implemented (use of cotton, frontal zip) and others were taken into account for a post-project phase, in order to have a wider range of sizes, colours, different types of design to meet end users' *desiderata* (section 3.4.1). All improvements adopted for WWBS version 2.0 are described in *D.3.3 Final WWBS prototype.*

In the context of indoor localization, an unobtrusive technology for activity recognition was tested using Wi-Fi Channel State Information (CSI). The specific approach is based on the processing of CSI measurements from a MIMO (Multiple Input – Multiple Output) Wi-Fi system and consists of a Wi-Fi___33 router acting as a transmitter and a network card connected to a PC, acting as receiver. There is no need for the monitored person to carry a device. The fundamental idea is that same activities executed by a human near the area of the transmitter and the receiver cause similar reflection mechanisms to Wi-Fi___33 signals and similar channel modifications. Machine learning techniques are then able to identify activities from the processing of these measurements after a training procedure. This technology was tested regarding the accuracy of the identified activities with 2 datasets. The first one is available on-line, including 9 activities, namely walking, empty, falling, running, brushing teeth, open fridge, sitting down, boxing and pushing, while the second one was created on the premises of CERTH, including 5 activities, namely walking, empty, pushing, waving and boxing, in different positions. After the evaluation of several classifiers and features, the best accuracy for the first dataset was 95% and for the second one 80%. The results have been presented in a submitted publication[8].

[8] Tegou, Papadopoulos, Kalamaras, Votis, & Tzovaras, 2019 (submitted)

The indoor localization system was installed in the house of each subject for a number of consecutive days (1-7). After the installation, each subject was instructed to carry the mobile phone while moving around the house, performing daily activities. The mobile phone measures the RSSI values from the beacons of the house continuously; each time the subject exits a room and enters another room, a transition is recorded. This transition includes the label of the room that the subject entered and the timestamp that this change occurred. A record of room transitions is generated from each subject while moving around the house, performing his/her regular activities. The room-transitions records were processed in order to extract the time-intervals signal, which is the signal recording the time interval that the subject remained in each room. For this purpose, the interval between successive transitions is calculated, and the sequence of all time-intervals in each room-transition recorded is extracted. An example of the time-intervals signal is presented in Figure 35.

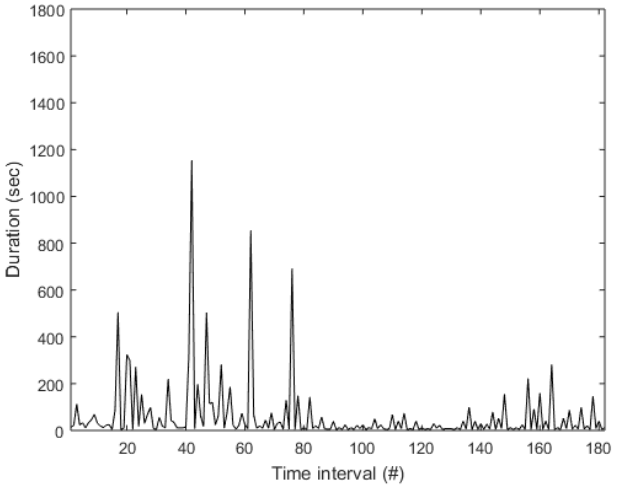


Figure 35: Time interval signal

In order to assess the frailty status, several features extracted from the time-interval segments are used for feature extraction. The extracted features are:

1. Number of room transitions
2. Room transition average time duration
3. Room transition standard deviation of time duration
4. Number of fast room transitions
5. Number of slow room transitions
6. Percentage of fast room transitions
7. Percentage of slow room transitions
8. Normalised number of fast room transitions
9. Normalised number of slow room transitions

The features extracted from the time-interval segments are used for a classification process. Two separate classification problems were addressed, being: (i) assessment of the frailty status in the non-frail/pre frail/frail scale, and (ii) identification of frail subjects, where non-frail and prefrail were considered as a single class. The obtained results using a Random Forest classifier are illustrated in Figure 36 and Figure 37. More details can be found in the related publication[9].

[9] Tegou et al., 2019

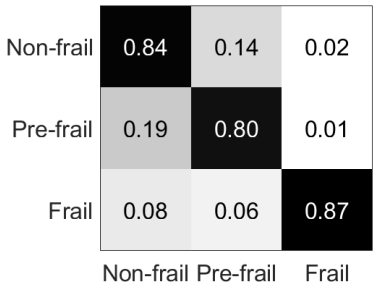


Figure 36: Percentage confusion matrix for the first classification problem

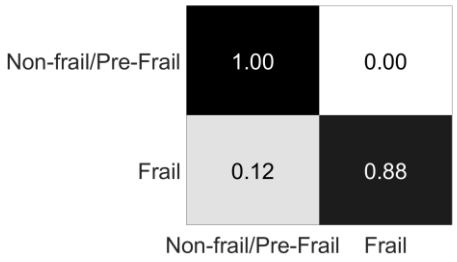


Figure 37: Percentage confusion matrix for the second classification problem

Extensive testing was employed during the development of serious games, with the use of dynamometers and augmented reality (AR) glasses, to ensure their safety, feasibility, acceptability and a seamless gameplay. For example, all games were adjusted in terms of user acceptance (i.e., enhancement of graphics and visibility, bigger images, lower accuracy required for the touch screen to function, easier beginning number of memory sequences, as well as, appropriate speed and velocity).

Modifications were also implemented in smartphone applications, in order to be compliant with users' and clinicians' requirements. For example, the information depicted on GPS application were made clearer and more concise since its initial release and indoor localization app was modified to be more user-friendly in terms of data uploading. In the same manner, extensive testing of the eCRF platform was performed both in terms of technical characteristics and compliance with user requirements in order to function seamlessly through field trials.

The language analysis tool for frailty detection was extensively tested in terms of provision of satisfactory identification of frailty transition (more information available in *D4.9 Ling Tester Test Results-Active on-line Mode vers b*). The tool was presented in two different operational modes the Offline mode where the dataset fed in the software was already collected in clinical trials and an Online mode where the tool was collecting its data constantly and almost in real time from its registered participants through multiple sources (Social Media Platforms and Emails). Although, the LingTester tool is still completely functional as it was originally designed in the deliverables, a series of events such as the strict application of the General Data Protection Regulation (GDPR) and the scandal of Social Networks user data leakages have led to the revocation of the previously granted permissions for the LingTester tool to collect and analyze user data through Facebook and Twitter. The two social networks explicitly state that they cannot allow the collection of users' data for ''Non-visible use of this data such as sentiment analysis''[10], thus making it impossible for the LingTester Online tool to anymore analyze the users' online activity

[10] https://developers.facebook.com/docs/apps/review/login-permissions/

in these networks. However, the software was designed and implemented exactly as was described in the FrailSafe proposal. It was already deployed in the previous period (before the GDPR strict application) and completed its purpose for its relative deliverables showcasing the software's abilities and test results. In case a future commercial partner is interested in using the LingTester Online tool can always request the review and signing of special contracts (as stated in the social networks permission control pages) in order to regain the permission to collect users' data for analysis purposes. Finally, it has to be mentioned that an emailing system has also been implemented in order to collect the users' data by emails (after the users consent), and also a manual mode where the administrator can add individual user's datasets of text.

Furthermore, during the FrailSafe study new frailty metrics such as the Frailty Index were developed, tested and incorporated in the integrated system. The association of frailty with other health related parameters and comorbidities was extensively explored and reported. Motion identification models and a novel Activity Classification algorithm were developed to facilitate data classification. Online analysis of data was also tested in a laboratory environment for the fall detection, instability detesction and loss of orientation tools which yielded high classification accuracy results (more information can be found in *D4.15 Signal Processing Algorithms vers b* and *D4.4 Online Analysis of Data vers b*). All data were integrated in the clouds for the final FrailSafe system to be available before M31. The results of small-scale evaluation yielded satisfactory results regarding sensors' accuracy and functionality (described in *D7.3 Small-scale evaluation results).*

Similarly, extensive testing was employed during the development of serious games, with the use of dynamometers and augmented reality (AR) glasses, to ensure their safety, feasibility, acceptability and a seamless gameplay. For example, all games were adjusted in terms of user acceptance (i.e., enhancement of graphics and visibility, bigger images, lower accuracy required for the touch screen to function, easier beginning number of memory sequences, as well as, appropriate speed and velocity).

The Virtual Supermarket game has been evaluated in a recent publication[11] in terms of its efficiency in detecting frailty-related indications with the user performance in the game. Specifically, the analysis showed that there is a statistically significant difference in game performance between the different user groups, split according to Fried frailty score. Game performance was measured in terms of game duration and errors made in the purchased items. The analysis results provide some evidence in favour of the possibility to use virtual reality games for distant self-administered evaluation of frailty status.

Internal testing of individual components not included in previous deliverables is described in the following paragraphs.

AR games

AR glasses and games were tested in a laboratory setting for their safety before being administered in real users. AR games with wearable devices are an interesting matter for research, as the scholars identify endless possibilities for older adults but several challenges for their implementation, as well (i.e., Hayhurst, 2018). After their laboratory testing, a small sample of older adults evaluated their feasibility and acceptability prior to their incorporation in field trials. The results of the evaluation with users can be found in section 3.4.2 (Primary Users).

Virtual Community Platform

[11] Paliokas et al., 2018

Furthermore, during the evaluation process, specific interest was payed to the assessment of the Virtual Community Platform (VCP) to ensure that technical partners and users endorse the VCP in terms of functionality and reliability. The internal technical evaluation of the VCP was performed by two users from each IT partner among the FrailSafe consortium partners following the cognitive walkthrough method. To avoid bias colleagues who did not work on the FrailSafe project were preferred.

During the first phase of the evaluation protocol, users received a document (Annex VI), describing a number of tasks to perform through the VCP. This step was useful in guiding the users to explore all the features of the system by mentally getting into the place of a real user. During the second phase, users received a short questionnaire to evaluate the VCP's user experience. Consortium users participating in VCP evaluation are described in Figure 38.

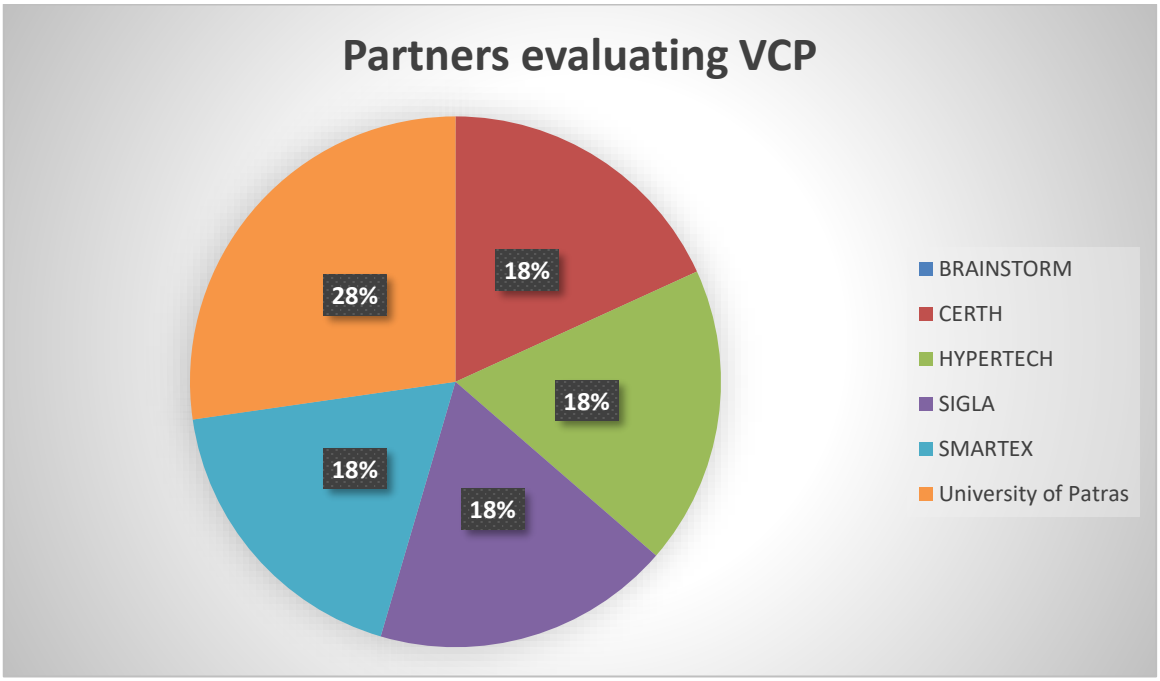


Figure 38. VCP internal evaluation: partner participation

The results showed that the majority of users rated the VCP as easy, helpful, with easy and clear navigation and simple to find information in. Additionally, free comments showed that there is room for further modifications, in terms of easiness and simplicity in navigation and exploration of information (Figure 39).

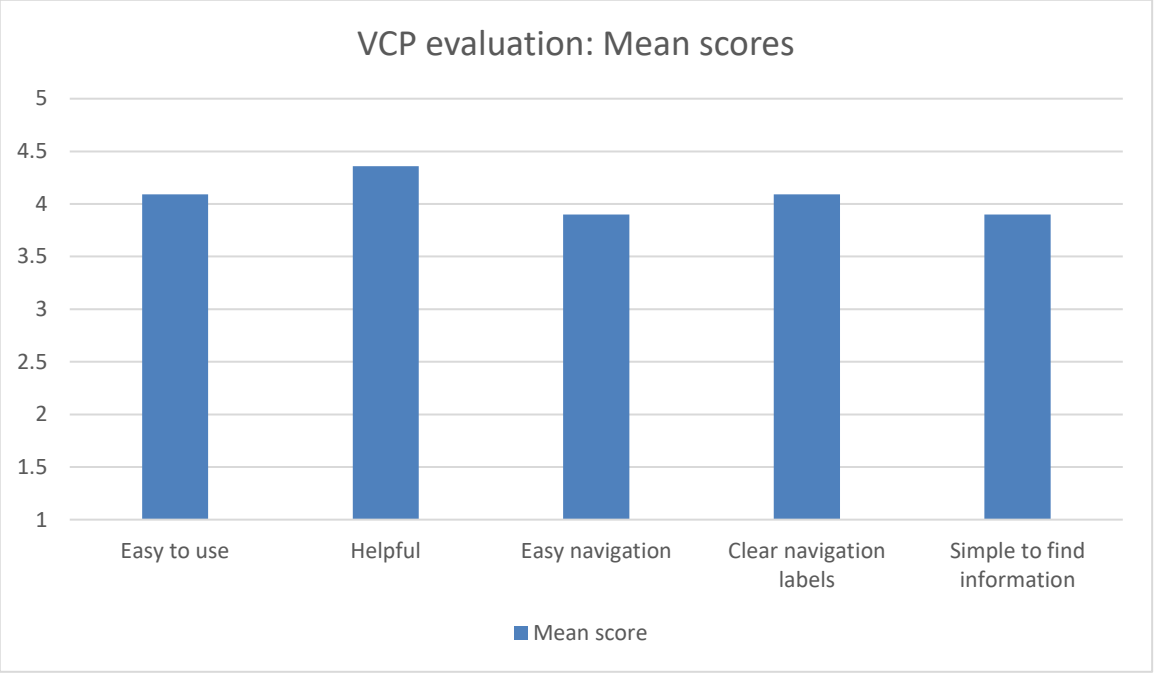


Figure 39. VCP evaluation: Mean scores on ease of use and helpfulness

The results of the questionnaires illustrate that users were satisfied in general with the capabilites provided by the platform and they consider it very helpful. Free comments showed that the details to be improved would include an even simpler design, larger font-size and bigger icons to be easier to be used by users with no or low IT literacy. One user also suggested enriching the personalization options of the user profile, i.e., include an option for adding favourite phrases, etc. Another user suggested that the notifications of the VCP could be presented as pop ups. In general, evaluators stated that the use of VCP may pose some difficulties for older adults but is "very beneficial for all stakeholders and nicely designed".

All the valuable information received by the users who followed the technical validation process, are of high importance for the completion of the platform, as user's experience in the forum is set in the core and we aim at providing a useful, easy-to-use, user-friendly tool.

Decision Support System

In addition, DSS user interface, including visualizations of various types of information, was adjusted to offer individualized interfaces for all FrailSafe users: older people and informal caregivers, healthcare professionals and researchers. In order to further comply with users' needs a mobile application of the DSS platform was also launched to facilitate usability. Appropriateness of information conveyed, visualization and data appearance on the DSS platform were evaluated and adjusted accordingly.

The Decision Support System (DSS) was designed to be used mostly by clinicians in order to view a comprehensive overview of their patient's health data, researchers to perform research activities and IT professionals. DSS is also available for older users and authorized family members to view health data and results at any given time-point. The technical functionalities of the DSS User Interface (UI) were evaluated by testing the system's basic functionalities, each time an update was incorporated:

- Overview screen
- Charts of historical data
- Alerts

- Recommendations
- Visual analytics

The above functionalities were checked in all types of interfaces, i.e. in the older person's, family member's, clinician's and researcher's interface, depending on which interface they apply to. The accuracy of the information displayed in the charts and the alert and recommendation messages was tested by comparing the information to the raw data on which they depended on, i.e. the data available in the VPM.

The DSS UI also offers the clinician with the ability to specify new rules for alert and recommendation generation. This functionality was tested as follows. A new alert rule was added for a specific user of the system. The rule was set knowing that it should produce an alert according to the user's measurements. In particular, all user measurements were checked and one type of measurement was selected to set the rule. Indeed, a new alert was generated and appeared in the DSS UI and in particular from the viewpoint of the clinician (Figure 40).

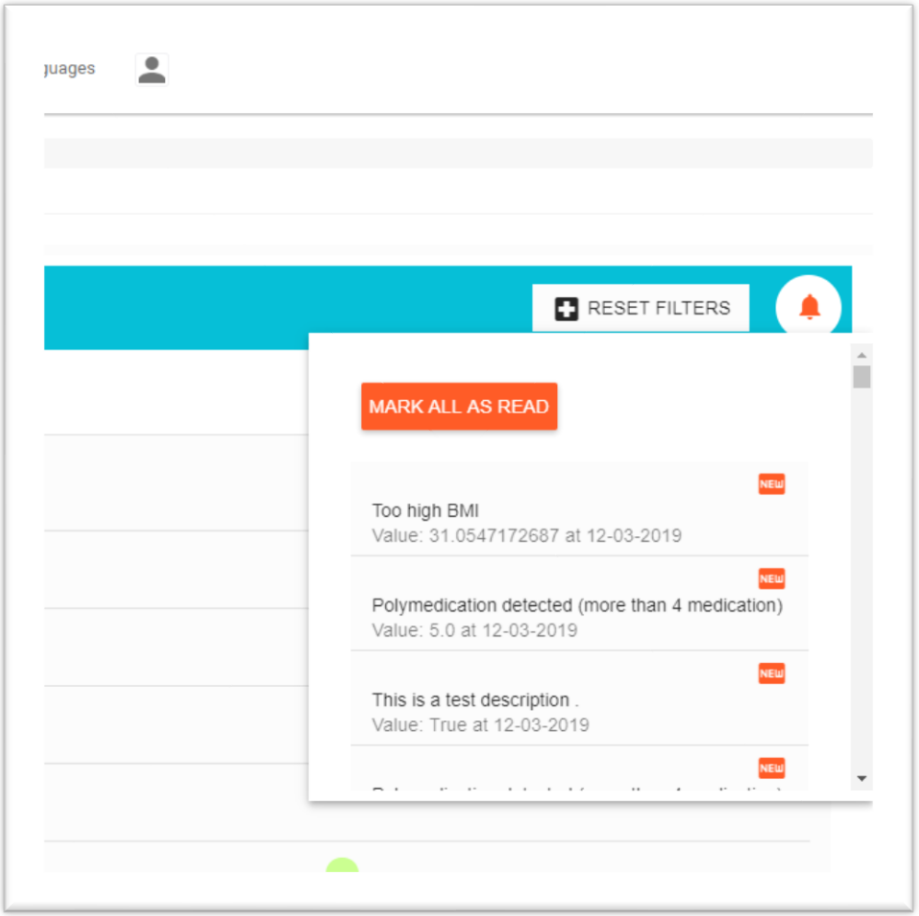


Figure 40: Generated alerts, as they appear in the DSS UI

Dynamic adaptability of serious games

Dynamic adaptable games (DAGs) were developed to offer a more personalized game play experience to users. According to recent literature, serious games are becoming increasingly attractive to older users (Theng, Teo, & Truc, 2010) while their use seems to increase their motivation and adherence to rehabilitation interventions (Sugarman, Weisel-Eichler, Burstin, & Brown, 2009). Dynamic adaptability, also, provides a better user experience to older users

especially to those presenting cognitive impairment (Bouchard, Imbeault, Bouzouane, & Menelas, 2012).

In the context of the FrailSafe study, dynamic games were developed based on a series of difficulty parameters (velocity, force, obstacles, duration, etc.) which allowed us: a) to adjust game difficulty after the first field trials and b) modify individualized difficulty after collecting information about users' capacity, performance and profile. Dynamic Adaptability (DA) is directly related to VPM function. Therefore, in its final version, DA takes into account:

- Data obtained from the VPM about the health status of the patient (cognitive status, grip strength, gait speed, etc.).
- Data obtained from previous game sessions, both from the same and other games.
- Data obtained from the active session as it is being played, so that the games can increase or decrease in difficulty in real time.

In order to better understand the dynamic adaptability and to facilitate the communication between clinicians and developers, series of tables were created, in which each difficulty parameter was related to any of the possible inputs with a specific weight (Figure 41). These tables were directly fed into the system and were designed to be open and easy to adjust even with richer graphic user interfaces.

		Force Analyzer		Red Wings			Simon		Memory			RailWay		Reflex		VPM									
		FA_MaxForce	FA_Endurance	RW_MaxDistence	RW_MeanDistance	RW_MaxForce	SM_MaxLength	SM_MeanLength	MM_LastLevel	MM_LastPairs	MM_MeanHitPercent	RR_MeanDistance	RR_MeanScore	RF_MeanReaction	RF_HitCount	MMSE	MOCA	Memory complain	Grip strength	BMI / Force	GDS Score	Polypharmacy	Visual acuity	Blood pressure	Frailty
RedWings	Maximum required force	x	x			x													x	x					x
	Plane speed													x		x	x	x		x	x	x	x	x	x
	Number of obstacles			x	x									x		x	x	x		x	x	x	x	x	x
	Starting point			x	x											x	x	x			x	x	x	x	x
Simon	Sequence speed													x											
	Starting level						x	x			x														
	Number of trees							x																	
Memo	Starting stones number							x		x	x														
	Maximum allowed moves								x		x														
RailWay	Wagon speed											x	x	x											
	Number of obstacles											x	x	x											
	Number of coins											x	x	x											
Reflex	Pineapple disappear delay													x	x	x	x	x			x	x	x	x	x
	Next pineapple time delta													x	x	x	x	x			x	x	x	x	x

Figure 41. List of dynamic adaptable parameters related to final users' feedback parameters.

DAGs were tested extensively by Brainstorm before the first version was released. These tests were mainly technical and their main objective was to check that the DA design was flexible enough to be tuned up properly, and also to verify that the system was implemented correctly and with no bugs. As a result of this process, some rules were included, such as the option not to let a parameter decrease if the patient requires to train in that specific area. The first version of DA released by Brainstorm was tested by two older participants with different patient profiles through one-to-one experiments to determine DAGs' effectiveness and desirability. The first participant had mild cognitive impairments and was pre-frail with abnormal grip strength, while the second was cognitively and physically intact. Both participants suggested modifications to dynamic adaptability (i.e., appearance rate and number of items, velocity, etc.). After the modifications were implemented by Brainstorm the second version of DAGs was released. The second version was tested by two healthcare professionals, consortium members, through a cognitive walkthrough protocol. The evaluators viewed the users' profile online and were asked to evaluate the dynamic adaptability from the perspective of the users. Evaluators did not

propose further modifications of the DAGs. Hence, the final version was released and evaluated by a sample of older users through a single- blind experiment described in section 3.4.2 (Primary Users).

Technical evaluation of the integrated system

Eight IT professionals, members of technical partners' teams and preferably not directly involved in the FrailSafe project, with a mean of 9.13 years of experience (SD=7.4, range=2-20) evaluated the FrailSafe system in terms of functional characteristics. Their answers were 100% positive that system is successful in terms of

a) data loss prevention
b) privacy of online personal data
c) network availability
d) hardware reliability
e) system security
f) ease of learning the platform
g) ease of use of the platform
h) update frequency of the platform
i) speed/responsiveness of the platform
j) ability to handle data quota

In general, the evaluators approved the FrailSafe system technically and commented that "the AI behind the project seems to be very interesting." Free comments for improvements included "integration with other platforms as iHealth or smart watches sensors, such as the FORA one you already included" or that "even though already nice, some more work could be done on the general look and feel of some of the system's components".

Five healthcare professionals members, 12 IT professionals and six researchers, members of the partners' teams and preferrably not directly involved in the FrailSafe study, evaluated the FrailSafe system by completing the same questionnaire with externals (Annex IX) in order to obtain a comparative view. The comparative results are described in section 3.4.2 (Secondary users). The individual results from the internal evaluation showed that internals rated the system with approximately 70 or more points out of 100 in SUS scale which indicates satisfactory acceptability and usability of the FrailSafe system.

Finally, during the last plennary meeting in Brussels, consortium members performed a focus group to discuss on their overall view and satisfaction from project results and the developed FrailSafe system. All members agreed that they are satisfied from the project progress and results. They also agreed that within three years the project has progressed adequately and made a significant impact, in terms of dissemination and exploitability. Regarding exploitation, members proposed that the system needs to be further tested in a large scale study to be validated and endorsed in terms of reliability and acceptability. The final conclusion was that further replication of the results in a large-scale study will boost system's exploitability, desirability and validity and will further enhance its impact and adoption perspectives in public healthcare and private sector.

3.4.2 Final external evaluation results

Primary users

Older adults evaluated the FrailSafe integrated system at several timepoints during the evaluation phase (more information is conveyed in Figure 33) and also, participated in the external evaluation of several sub-components as mentioned in section 3.4.1. All older adults of group C provided feedback for the evaluation of the system.

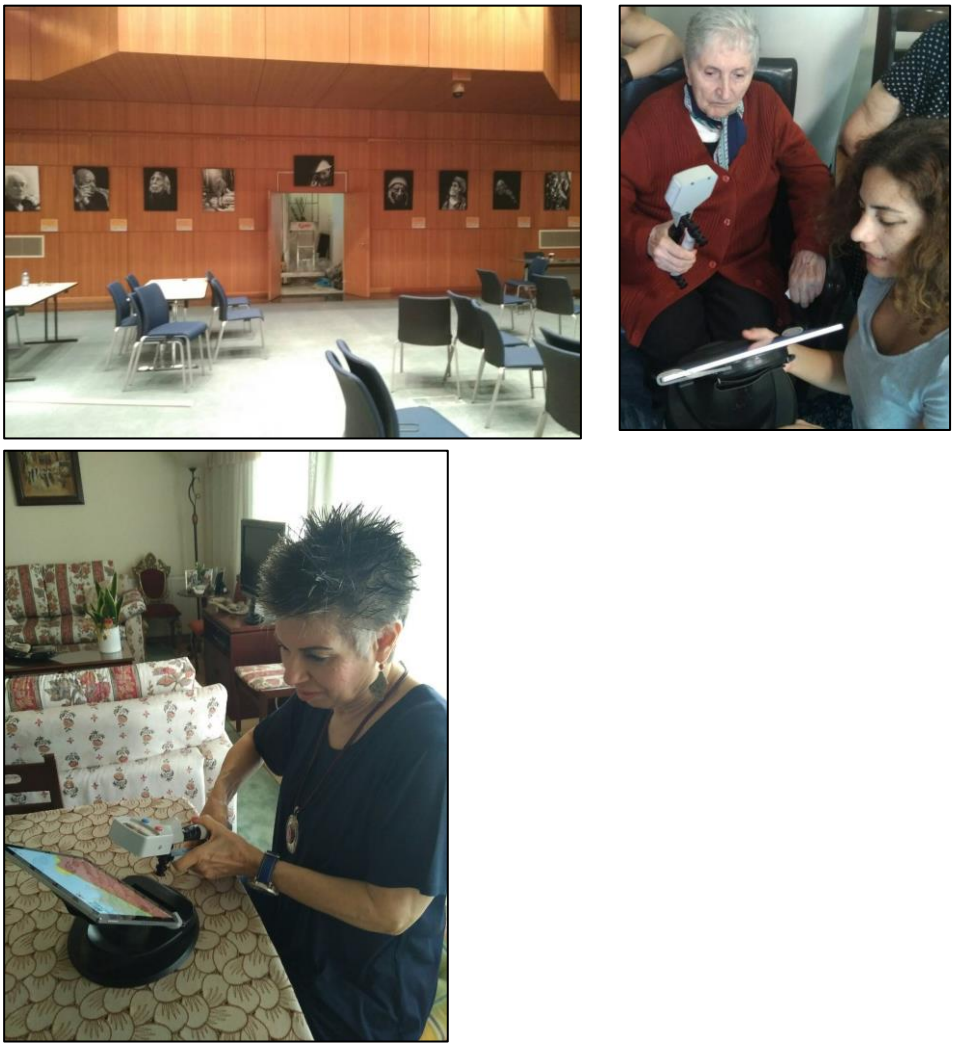
Firstly, all feedback collected by users during the visits, as well as, feedback we received through phone-calls and other interactions with them (i.e., random contacts) was reported by all three clinical centers collectively. Feedback from one-to-one interviews performed in Cyprus and Greece and the results from the think aloud protocol were also taken under consideration in the present reporting. Finally, feedback obtained through other interactions with older adults (both participants in the FrailSafe study and externals), i.e. through their participation in dissemination events, was also, compiled and analyzed. All aforementioned qualitative data were collected in written. Content analysis of the written documents yielded main thematics and conclusions which are described in the following paragraph.

The results showed that older users appreciated the fact that just wearing a vest could provide measurements of their vital signs, such as blood pressure and heart rate and for several users this was one of their motives for participating in the study. The finding suggests that older adults are especially concerned for the health of their heart and can be utilized for effective dissemination and marketing strategies. However, a great share of users suggested that the vest should be more customizable in terms of colors, textures, fabrics and sizes. Some also mentioned that they would like the device's light to be less visible to be able to hide it under their clothes. Others suggested that the light should be more obvious to facilitate the use of the system. Overall, it seems that since the WWBS is a clothing item (wearable device) it should be available in a broad range of options to fit individual users' needs. These customizations were expected but were not feasible in the context of this study, since the main goal was to test the reliability and functionality of the device and the available resources were allocated for this purpose. Thus, although the WWBS system tested was several times modified in terms of usability (D3.3) and available in three sizes, the unavailability of further individually customized options caused discomfort to the participants at some time-points (i.e., participants with larger body type felt discomfort, participants with very active social lives felt uneasy to wear the vest in public, participants with tremor in upper extremities had trouble zipping the vest, etc.).

Users also requested some modifications with regards to the RUSA device, such as waterproofing it and making it smaller, if possible. All suggested modifications have already been taken under consideration by SMARTEX and will be implemented in the commercialized WWBS versions. Other than that, participants did not experience significant problems in using the device autonomously which was a very positive and surprising finding considering older adults' general difficulties and reluctance towards technology use (Beer & Takayama, 2011; Steele, Lo, Secombe, & Wong, 2009). Significant difficulties were not detected in charging the devices, playing with the tablet serious games or using the mobile phone. Both, healthy and users with Mild Cognitive Impairment (MCI) sometimes forgot to charge the smartphone of the study. However, since most of the users were already using mobile phones of their own which they fully charged every day, this finding can be attributed to the difficulty in using and charging both devices in the same time. Future commercialization of the product will address this issue and the user will be able to download the apps in their phone or smartwatch.

Furthermore, users' evaluation of the smartphone apps showed that the apps acted as a motivation for them to keep mobile and active. In many cases, upon clinicians' visits, users were asking the number of steps they took in a day and if that was enough for improving their health

status. Added to that, users enjoyed the use of serious games and thought that several among them were very innovative. For example, one user stated that the Redwings game "is very clever, because you have fun and exercise at the same time". In fact, some participants expressed feelings of sadness when the study was completed and clinicians visited to retrieve the tablet with the serious game platform. They requested to purchase specific games (i.e., Simon and Memory) once they are commercialized. In general, participants reported being satisfied from the clinicians' visits and did not reports feelings of privacy violations while participating in the FrailSafe study. However, it should be stressed that throughout the study, participants' privacy and personal time and preferences were respected and put forward. Finally, all older adults stated that the system would enhance their self-confidence in performing day-to-day activities and that it was not intrusive or obtrusive in their everyday life. It should be noted that no participant in the present study had an official complaint about the system filed at the complaint manager.



Picture 1. Indicative interactions of evaluation stakeholders with the FrailSafe system

Upon the completion of their participation, older adults were requested to complete the FrailSafe User Satisfaction Questionnaire. Fifty-six older adults (41.1% male) participated in this process. The rest of the participants chose to provide their feedback orally and it was included in content analysis described in the previous paragraph. Among the participants who completed the questionnaires, 60.7% belonged to Group Ci. They had a mean of 74.73 years of age (SD=5.3)

and 11.48 years of education (SD=3.9). Participants were married or in a relationship in 85.5% of the cases, widowed (12.7%) and single (1.8%). The vast majority of participants reported low IT literacy skills or none at all and little prior experience with health devices. Details can be found in Table 35. Among those who currently used some type of health device, most reported using pedometers, smart calorie counters or smart blood pressure monitors. The reason for ceasing the use of those devices was either that they do not need it currently (i.e., their use was suggested for a short period by their doctors) either that they were bored of using it. Univariate analyses of variance showed that participants did not differ significantly in terms of technological skills $F(2,55)=.125$, $p>.05$ or in terms of education $F(2,51)=1.642$, $p>.05$ among the three clinical centers.

Table 35. Primary user evaluation: IT literacy and prior experience with smart health devices

Level of IT skills	% of users	Use of health device	% of users
No skills	42.9	Never used	76.8
Beginner	23.2	Used but stopped	10.7
Intermediate	21.4	Current use	12.5
Advanced	12.5		
Expert	0		

Participants rated each component in terms of satisfaction, ease of use, usability and ergonomics in a three-point scale; 1 denoting “not at all”, 2 denoting “somewhat” and 3 denoting “quite a lot”. Results showed that the BP monitor and vest were considered the components contributing the most to quality of life, further supporting the finding that older users are especially concerned about their heart function and want to be alerted accordingly. The next components rated as contributing to life quality were the tablet serious games and outdoors applications for smartphone, which indicates that the users perceive the games as beneficial for their cognitive function and they are motivated to be monitored while being alone outside. These findings were also reported during qualitative analysis of the results.

In terms of difficulty, users rated the AR games and WWBS as the most difficult components to use followed by the smartphone outdoors app (Figure 42). This might be attributed to the bigger and more specific sequence of actions they had to learn in order to use the first two components, i.e., plug the device on the vest, switch on the light, charge it at night, etc. However, no user stated that he/she needed assistance all the time with those components and all of them stated that their feelings of difficulty progressively decreased. Also, regarding this matter, our observations in Groups B and C showed that after the first training session and use of the system, participants did not have significant difficulties in recalling how to use the system, though they received a short (one page) manual for reference. This shows that devices are learnable and usable by older adults. Another support finding is that participants’ reported difficulty in Figure 42 was not correlated with the assistance they needed in using the devices. For instance, participants rated the outdoors smartphone application as somewhat difficult but they did not report needing as much assistance in using it. On the other hand, the tablet and dynamometer were rated as easy to use but users needed assistance sometimes in using them. The latter finding can be attributed to difficulties some users had in connecting the tablet and the dynamometer with Bluetooth. Similar connection difficulties may have also caused difficulties during playing the AR game with the AR glasses. Although, the connection of the dynamometer was set to automatic by default, random factors interrupted the process at times. For example, the dynamometer would need more time than expected to connect and the user might be frustrated. This finding was carefully addressed by the consortium members to, also, explore

non-wireless options for the dynamometer in the commercialized version of the FrailSafe system.

Finally, serious game platform and the outdoors application for the smartphone were rated by the older adults as the most enjoyable tools to use, followed by the BP monitor and the AR glasses. This finding is very important because it shows that despite their unfamiliarity and difficulties with technological devices older adults enjoy the use of innovative devices. Hence, health services delivered through enjoyable tools can further improve their motivation for health monitoring and adherence to health interventions a theory which has been supported by research evidence in the past (Sugarman et al., 2009).

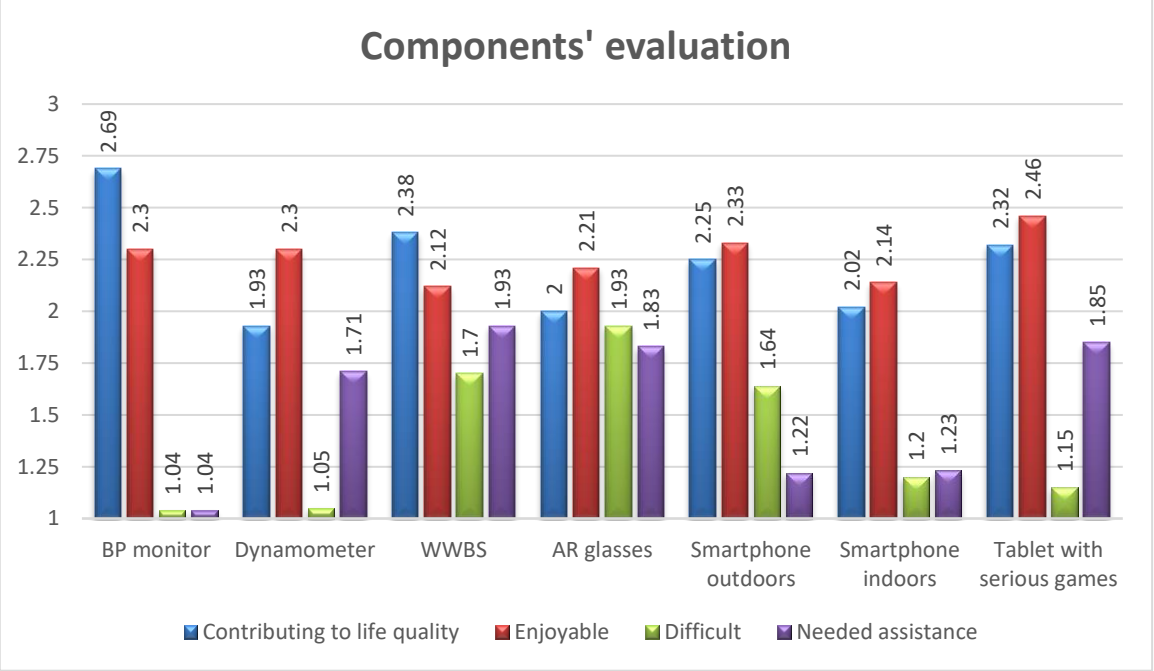


Figure 42. Primary user evaluation: components' evaluation

An overall assessment of system's contribution to life quality, enjoyability, difficulty and need for assistance can be found in Figure 43. As shown, the participants indicated that the system would contribute significantly towards a better life quality and was enjoyable, while most indicated no difficulty at all and minimal assistance needed while using it. Among the reasons they stated the system was beneficial were: "cardiac monitoring with the vest", "I take this experience as a game", "helps me monitor my health data remotely and my doctor is involved", "It reminds me to take care of myself.", "Personally, I had my own tablet and I think games help me a lot as far as it concerns my memory." However, it should be noted that some people stated that they would need a recommendation from their doctors to own and wear it consistently. This finding is in line with our observations which showed that enjoyability increases the motivation for using a health device yet, older adults need reassurance that they are using the devices for a health-related reason.

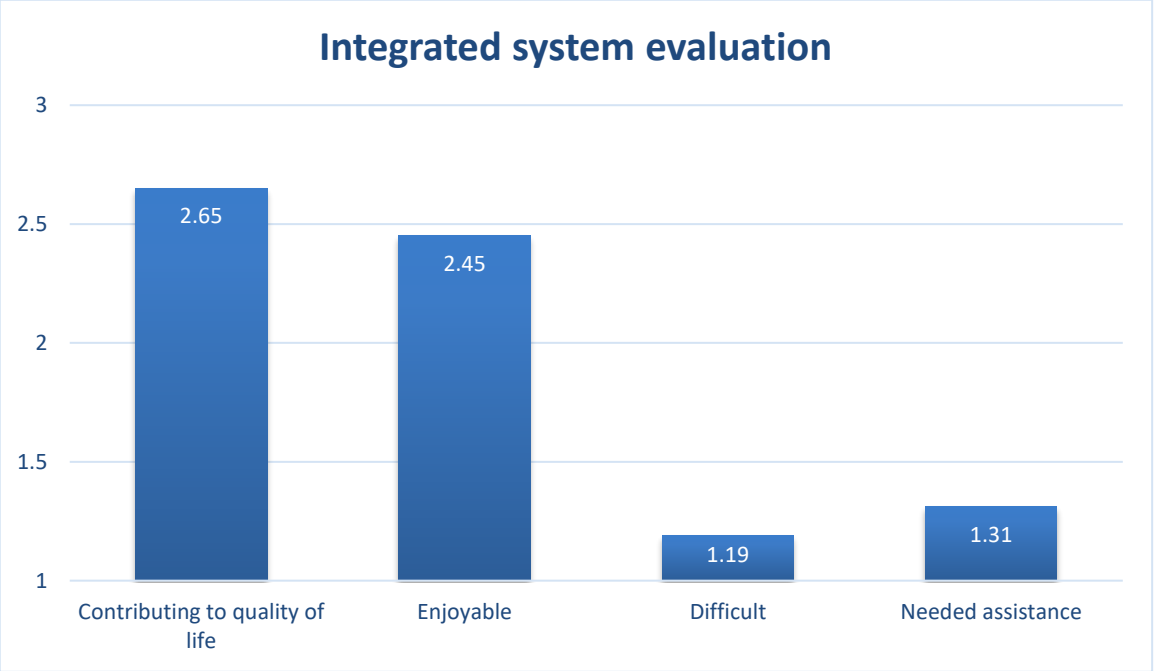


Figure 43. Primary user evaluation: system

Further analyses, showed that the majority of older adults reported that the system could contribute to an amelioration of their health status (Figure 44). The reasons supporting their answers included motivation to take care of their health and constant and individualized monitoring in an enjoyable way (Table 35). Among the users who answered "No" (14%), the reasons for their answers included the need for further testing of the system and replication of the results to be able to answer positively. Also, many answered negatively in this question because they thought that did not need an amelioration of their health status, currently, and thus the system was "not for them" or because they thought that the system was proposed as a replacement of their doctor. These findings indicate the need to market the FrailSafe system as a complementary tool and not a replacement for healthcare professionals and a preventative measure even for healthy adults.

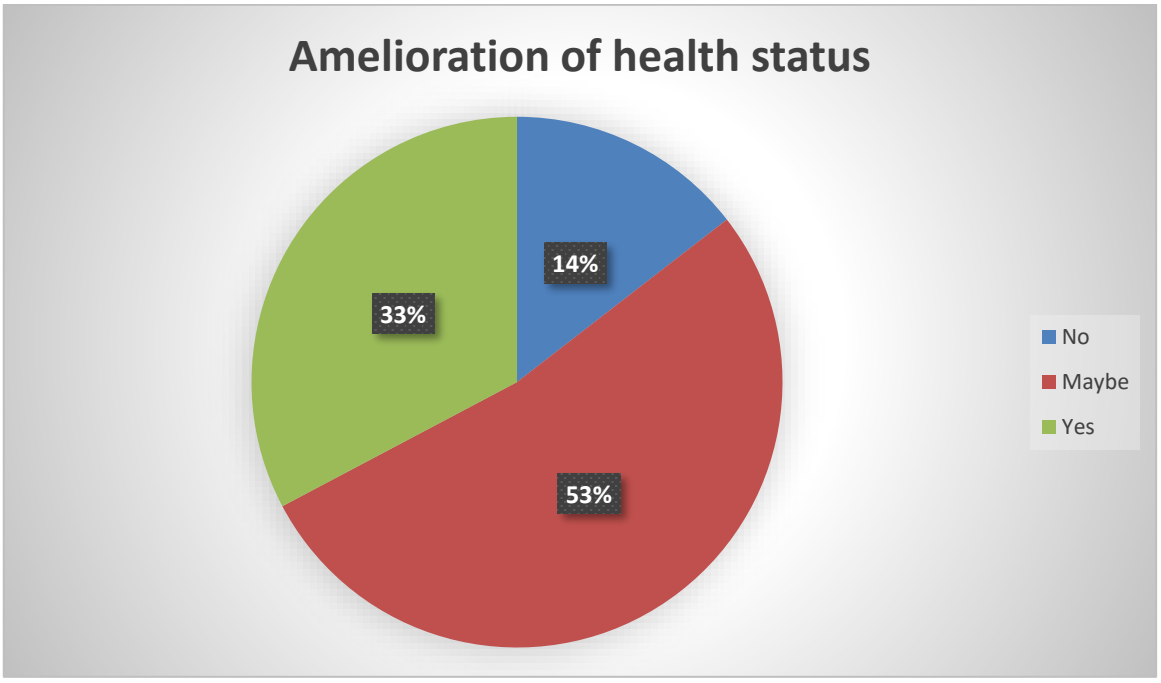


Figure 44. Primary user evaluation: amelioration of health status

Table 36. Primary user evaluation: free comments on amelioration of health status

Do you think that the system could lead to an amelioration of your health status?	**Why?**
Yes	"Can prevent health problems"
	"Constant monitoring"
Maybe	"Improves my memory, informed me about my blood pressure made me want to move more"
	"At the moment, i feel that i don't need it. But in the future its a way to control my health status and keep me and my relatives informed."
No	"I believe that every person is unique,that's why he needs to have his personal doctor."
	"I think that only a system without a doctor can't be helpful enough"

Furthermore, more than half of the participants thought that the feedback provided by the system was somewhat, much or a great deal helpful, while 37% stated that it was little or not helpful (Figure 45). Participants who rated the system as not providing helpful feedback thought that the feedback was too generic or did not need it at that timepoint because they were healthy. Our observations also, showed that participants' expectations were for the feedback provided by the system were different than intended. For example they were expecting to receive exact values, quantitative results and medical conclusions for their health status and thus, the received results did not live up to these expectations. However, this type of reporting would not be feasible or ethical in the context of the present study as the system is still under testing and not a medically accreditated instrument yet. Added to that, in any case, the system is intended to complement healthcare professionals' practise and hence, the person factor is not expected to be excluded in any case from the health monitoring process. This finding is also, supportive of the need to reorient older adults' expectations through appropriate marketting campaigns about the system's use as a preventative measure, complementary to a healthcare professional's work and monitoring, and not a replacement.

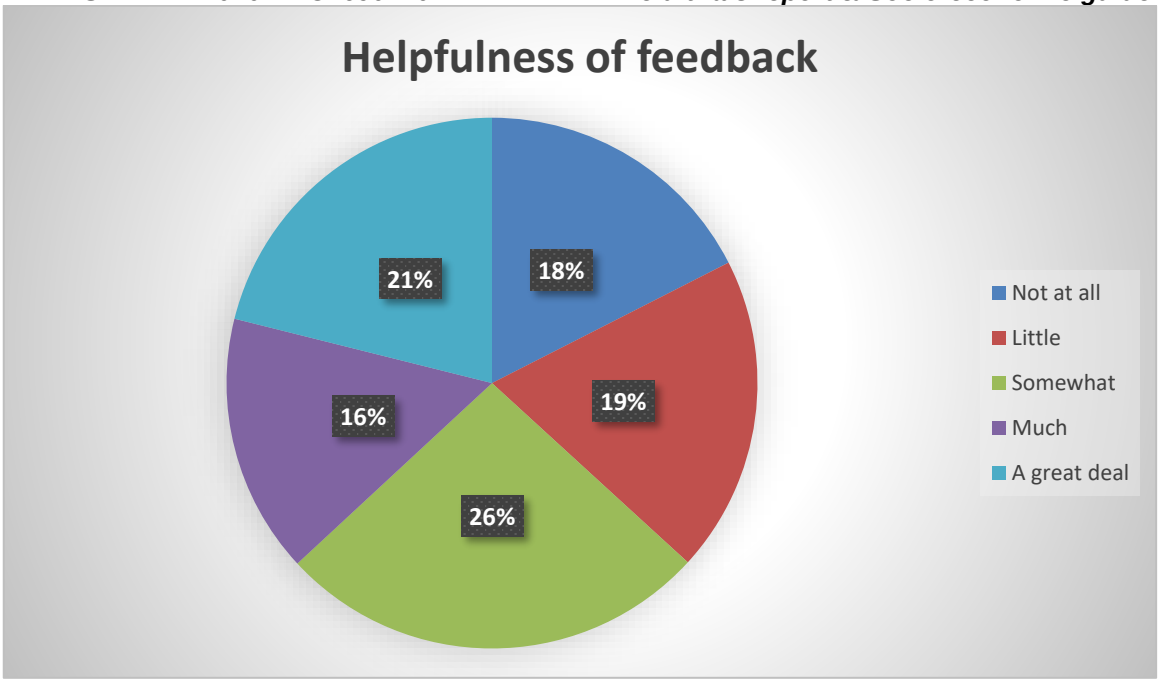


Figure 45. Primary user evaluation: Helfulness of feedback

In terms of games evaluation, Redwings was one of the top favorite games of the participants. It was rated as enjoyable, easy and interesting, they liked its visual and sound effects and stated that it helped them improve some of their skills (Figure 46). During interviews participants stated that the game is clever and innovative because “you use the dynamometer to exercise your extremities in an enjoyable manner”. Memory game was also rated as enjoyable and beneficial followed by Railway and Reflex. In terms of complexity, few users rated the games as complex or difficult and the most challenging ones were Supermarket and Gravity Ball, followed by Simon and Railway. The reasons for this, as observed through field trials, may have been related to the general difficulties some users had with tablets and little prior experience with games affecting their easiness to navigate through Supermarket and Railway, their touch accuracy in Simon and coordination in Gravity Ball. Indeed, those games are more demanding in terms of cognitive skills, as they simultaneously train working memory, balance, hand-eye coordination and visuospatial abilities. However, this multiparametric cognitive demand constitutes them also, of important value in terms of brain training. This complexity challenge for some users has been efficiently addressed by the dynamic adaptability feature which offers individualized gameplay for each user, taking under account their unique health profile, physical and cognitive status, as well as, game performance.

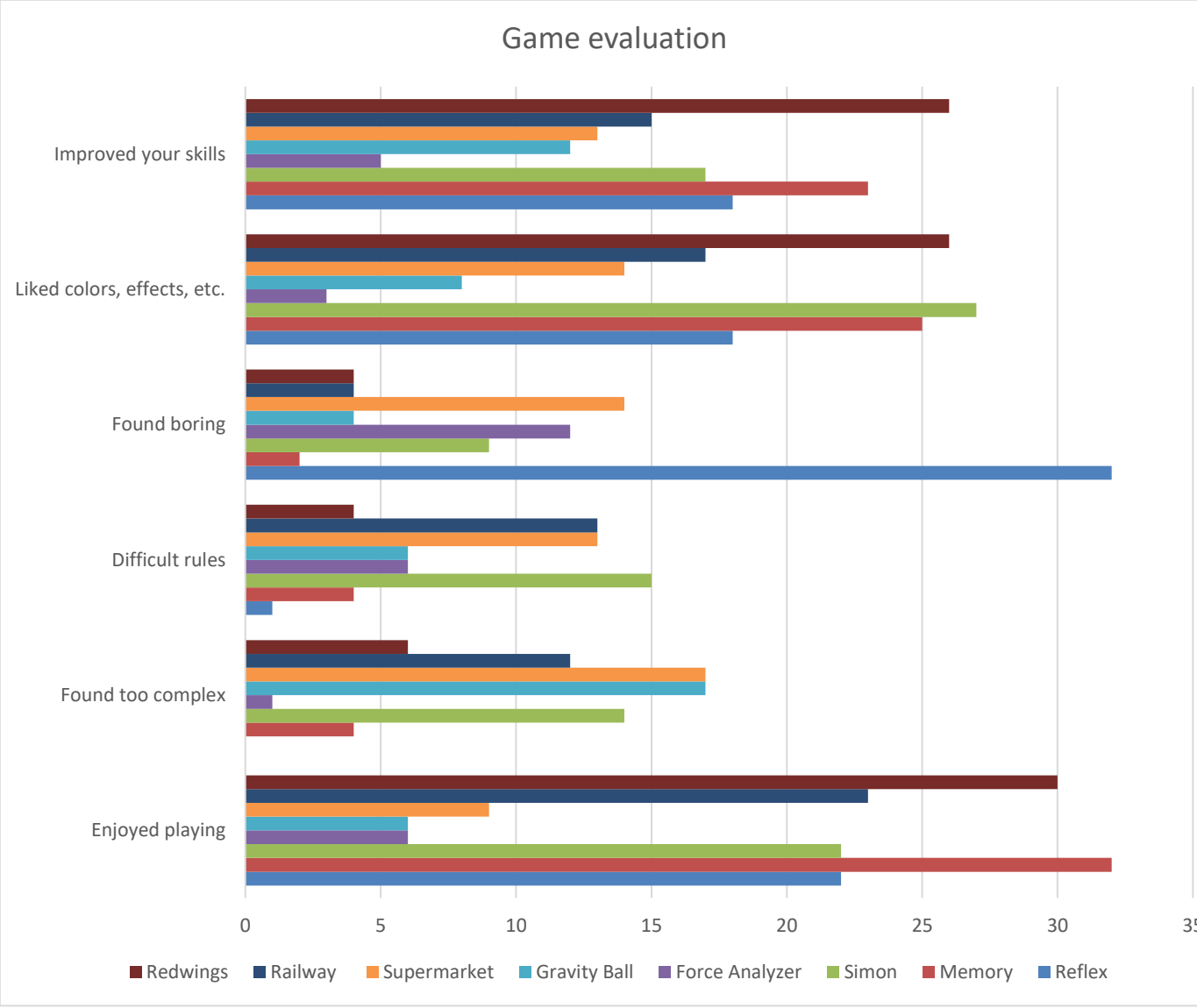


Figure 46. Primary user evaluation: game evaluation (number of users)

Older users evaluated the dynamic adaptability feature through a single-blind experiment. More specifically, 10 older participants from Greece and Cyprus (47.1% male) were asked to evaluate Reflex and Redwings games with and without the feature. The users were blind as to which game was played with the feature enabled or disabled and according to the protocol, the clinicians should alternate the sequence of enabling or disabling the feature to avoid bias. In total, five users played the Reflex game two times and five users played the Redwings game two times (one game with dynamic adaptability enabled and one game with dynamic adaptability disabled). The evaluation protocol (Annex VIII) included an informatory section in which clinicians entered information about the users' cognitive function, presence of depressive emotion and grip strength according to their last cognitive evaluation. The next section, included performance information such as users' total score achieved on each game and any observed or expressed difficulties or comments. Finally, after each session users were requested to complete the NASA Task Load Index-TLI (NASA, 1986). NASA TLI is a subjective and multidimensional measure of workload with six dimensions: mental demand, physical demand, temporal demand, performance, effort, and frustration level. This tool has been shown to have high reliability, sensitivity, simplicity and low intrusiveness in assessing workload and satisfaction (Rubio, Díaz, Martín, & Puente, 2004).

The results (Table 37) showed that players of the Redwings game rated the DA version as more physically and mentally demanding but less rushed than normal gameplay. However, they had higher feelings of successfulness and lower feelings of stress/discouragement and also, achieved better scores. Similar results were obtained for the Reflex game. Players rated the DA version of the game as more mentally demanding, more rushed and more difficult than the normal gameplay. However, they rated DA as less physically demanding, they had greater feelings of successfulness, lower feelings of discouragement and also, achieved better scores compared to normal gameplay. As seen, users rated DA features as more challenging in some cases. This finding is not negative per se, but rather indicative of a more interesting gameplay. A supportive argument for that hypothesis is that users actually achieved better scores but also, stated that games with DA enabled had "better pace, flow that keeps interest" whereas users of normal gameplay stated in many cases that the game was "boring". The satisfaction and performance in DA were not affected by cognitive function, grip strength normality and presence of depressive symptoms, as users with different graduation in these parameters had similar levels of ratings. DA evaluation, however, allowed us to detect a bug for healthy users. More specifically, DAG's for perfectly healthy older adults were too rushed-paced, which was communicated to technical partners and adjustments in level difficulty were implemented.

Table 37. Dynamic Adaptability user evaluation

	REDWINGS				REFLEX			
	Enabled DA		Disabled DA		Enabled DA		Disabled DA	
	M	SD	M	SD	M	SD	M	SD
Max score	6214.40	7728.78	3368.80	3427.37	309.22	138.44	261.00	153.55
Mentally demanding	6.00	3.31	5.80	3.34	4.33	2.34	4.00	1.22
Physically demanding	6.20	2.58	5.80	3.27	6.22	1.30	6.80	1.09
Rushed pace	6.00	1.00	6.20	3.11	6.89	1.96	3.80	1.09
Feelings of successfulness	6.40	3.05	5.20	.83	5.67	1.58	4.60	1.94
Feelings of difficulty	6.40	2.30	6.20	3.11	6.11	2.20	5.80	2.58
Feelings of insecurity, discouragement, stress	3.00	1.58	6.20	2.38	4.89	2.31	6.20	2.95

Regarding the assessment of AR glasses and games, both games released by CERTH, Memory AR and Floating Archery, were assessed with a quantitative and qualitative protocol. The first version of AR glasses (model BT-300) and Memory AR game were tested by 12 older adults from the clinical center of University of Patras. The second version of AR glasses (BT-350) were

tested by eight older adults from the clinical center of Materia Group. The protocol for testing the AR glasses was the same for both games, in order to produce comparative results. After a training session with the participants describing the scope of AR glasses and games and the steps to set up and play each game, users were asked to set up and play the game independently four consecutive times; two times in a sitting and two in a standing position (Annex VII). The purpose of this assessment was to evaluate whether any difficulties related to the use of AR glasses would decrease progressively and to compare the safety and acceptability of the games between a standing and sitting position. It should be noted that the game was simple to play and thus, participants were not expected to experience discomfort from playing the same game four consecutive times.

The results from the Memory AR game and Floating Archery games showed that users' time to setup the game reduced significantly with the progression of trials (Figure 47). Also, the successfulness of participants in setting the games up progressive increased from 60% in the first trial to 100% in the end. Similar results were obtained for participants' time (Figure 48) and successfulness in completing the games ranging from 88% in the first trial to 100% in the last. It should be noted that no significant differences were found between sitting and standing position. As observed in the following figures, Memory AR users had a spike in game setup and gameplay in the transition from a sitting to a standing position which might be attributed to the change of context but overall, this value was again lower than their baseline one, indicating familiarization with the device and game. Also, no significant differences in terms of usability and acceptance were found between the two games except for the fact that the total gameplay was greater in Memory AR than Floating Archery but this is attributed to different game characteristics and not difficulty in completing the game.

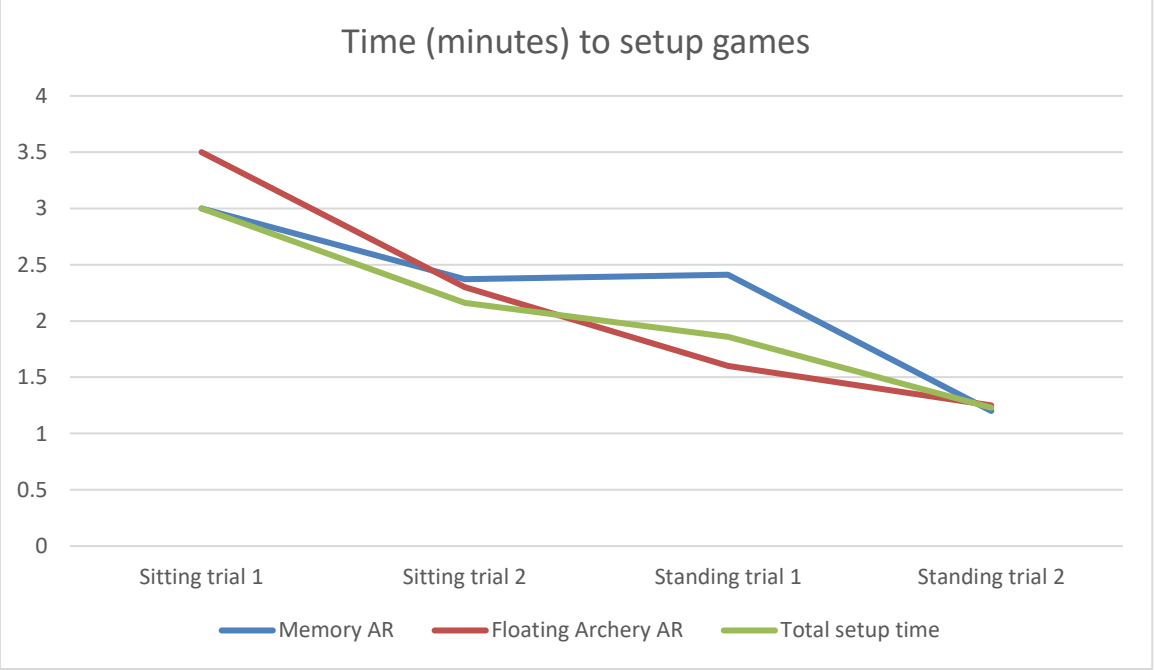


Figure 47. Primary user evaluation: Time to setup AR games

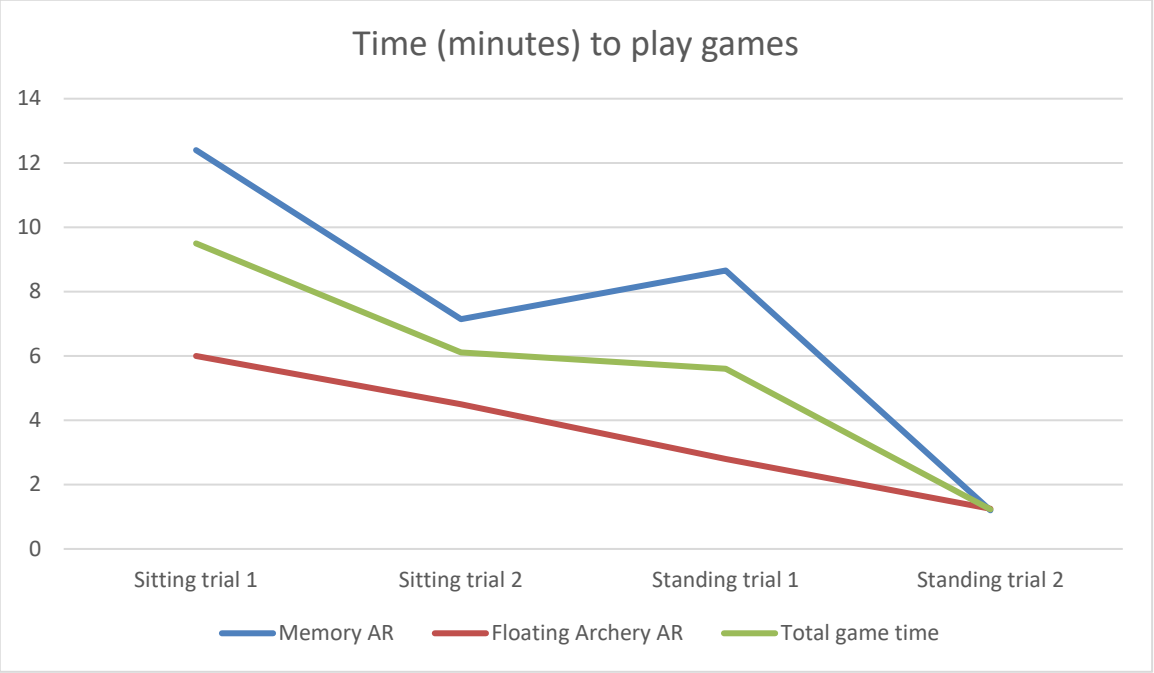


Figure 48. Primary user evaluation: Time to play AR games

In terms of self-reported feelings and adverse events, people experienced enthusiasm, surprise and pleasure with the first games (Figure 49) which feelings tending to fade with the progression of trials and as they familiarized themselves with the games. Also, some people experienced eye discomfort during the first trials and three experienced dizziness in the sitting position for the first trial only. This finding indicates that for safety purposes, introduction of users to AR games should be performed in a sitting position till they familiarize themselves with the novel visual environment. Overall, users rated the games as safe, interactive and useful. Finally, users rated the system with more than three point five points out of seven in terms easiness to control which is satisfactory considering elderly participants 'overall unfamiliarity with such devices.

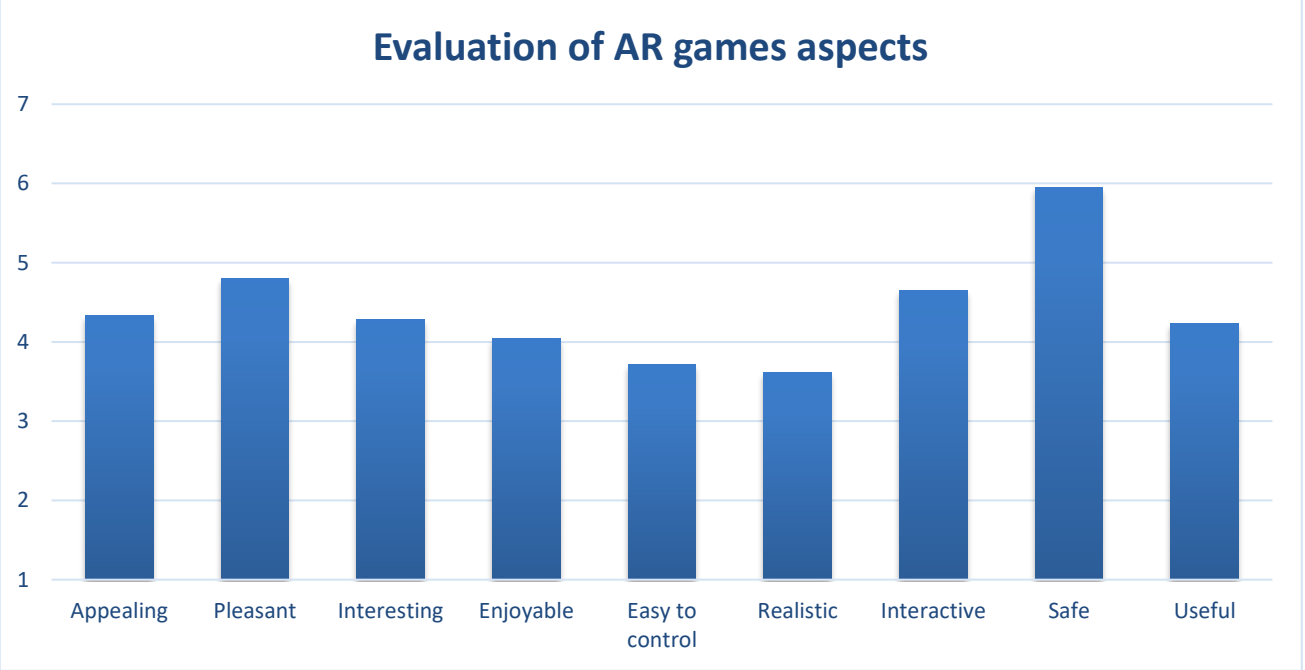


Figure 49. Primary user evaluation: AR games aspects

VCP and DSS platform were, also, evaluated by older adults. Regarding VCP evaluation, two users were requested to perform the protocol pre-tested by internal IT professionals (Annex VI) and express their thought processes and difficulties through a think aloud protocol. Older users who were English speakers and had some IT literacy were included in this assessment. Also, after interacting with the platform they were requested to fill in the short evaluation questionnaire for the VCP. In general, users agreed that VCP can be used and endorsed in terms of usability by older adults who have some familiarization with computers. This was expected as VCP is offered in an internet website similarly to other forums and thus, requires basic computer skills and internet access in order to be used. However, older users stated that they did not know such spaces exist and they found it useful to be able to share their opinions and concerns online with other users. They stated that it would be easier for them to be able to navigate and participate in the forum with a voice-based paradigm so that they would not have to use the mouse. In the non-voice-based protocol utilized in the present evaluation users were successful in performing all of the important tasks, such as posting a comment or searching for information on a specific topic. Modifications were suggested in terms of usability, such as including bigger fonts and pictures, as well as, an informative video with animated instructions. Also, users insisted on including a multilingual support on the forum as not all older adults are familiar with the English language. All suggestions will be carefully considered for future improvements of the VCP. In total, the users rated the VCP as easy (3.6/5 points), helpful (3.8/5 points), easy to navigate (3.4/5 points), with clear navigation labels (3.4/5 points) and easy to find information in (3.5/5 points).

DSS platform and mobile application were also assessed by three older adults through a think aloud protocol. Older users were English speakers but had different levels of IT literacy. All users stated that both interfaces were easy to find information in with clear labels and graphs. One user found it very difficult to read the graphs and stated that he would rely on the interventions tab to be informed about alerts regarding his health status. Older adults stated that they prefer viewing the information on a laptop or a computer screen for visibility reasons than on their mobile phone and thus, they would not be likely to download the mobile application. All in all, users were very interested to see their data collectively and were surprised by the interoperability of the devices. One user stated: “Oh! This is magnificent! I can see my measurements from the vest and tablet and my doctor can see them too?”. Finally, all users suggested offering a multilingual support for their peers who are not English speakers and were satisfied by data protection.

Regarding the integrated system’s safety, the vast majority of the participants (87.7%) stated that they did not have any unpleasant experiences or effects when interacting with the devices, which is backed up by the clinicians’ experience, observations and feedback received during field trials. Seven percent of the users (4 participants) stated that they had some trouble with the AR glasses as they were heavy or they had trouble seeing through them, one user experienced headache after one hour of gameplay with the tablet and some users had discomfort while using the WWBS device because it was too tight. The issues with the AR glasses can be attributed to the unfamiliarity of the users with the device as they are called “glasses” but due to hardware characteristics they are indeed heavier than normal glasses. Also, the vision disturbance can be attributed to difficulty adjusting the focus of the AR glasses. All individuals have different visual system in terms of genetics and thus, manual adjustment of the device’s focus is required for some users in order to have a crystal-clear picture. Lastly, the headache caused after an hour of sustained use of the tablet screen is a common side-effect of screen exposure even for young adults (Montagni, Guichard, Carpenet, Tzourio, & Kurth, 2016). This possible effect, as well as,

other potential effects will be included in our safety instructions manual, though the users of the FrailSafe system are not required to use the screens for such prolonged periods of time.

Further analyses showed that 82.5% of the users did not have any concerns regarding the use of the system and 85.5% stated that it is safe and secure to use. On the other hand, 10.5% (6 older adults) expressed worries about the system which, however, were vague and descriptive. For example, two people stated that the system is new and not tested extensively yet (4 users), some users expressed worries about data protection and some stated that they maintain a cautious attitude towards technology in general. This finding shows the need for the FrailSafe system to be extensively tested, endorsed and certified before entering the market.

Regarding the importance of training, more than half of the participants stated that it is important (40.4%) or very important (33.3%) to undertake a training programme before getting to use the system but only 14% of users rated it as absolutely important and the rest thought that it was not necessary.

Regarding purchase and use intentions (Figure 50), more than half of the users stated that they would like to use the system again in their home setting. Also, more than half stated “maybe” or “yes” in the question “Would you like to purchase the system?” and the vast majority answered “maybe” or “yes” in the question “Would you like to purchase specific components of the system?”. The components rated as more preferable for purchase can be found in Figure 51. In general, people’s ratings in this item support previous findings that older users are interesting in purchasing components which they find both enjoyable and contributing to their life quality.

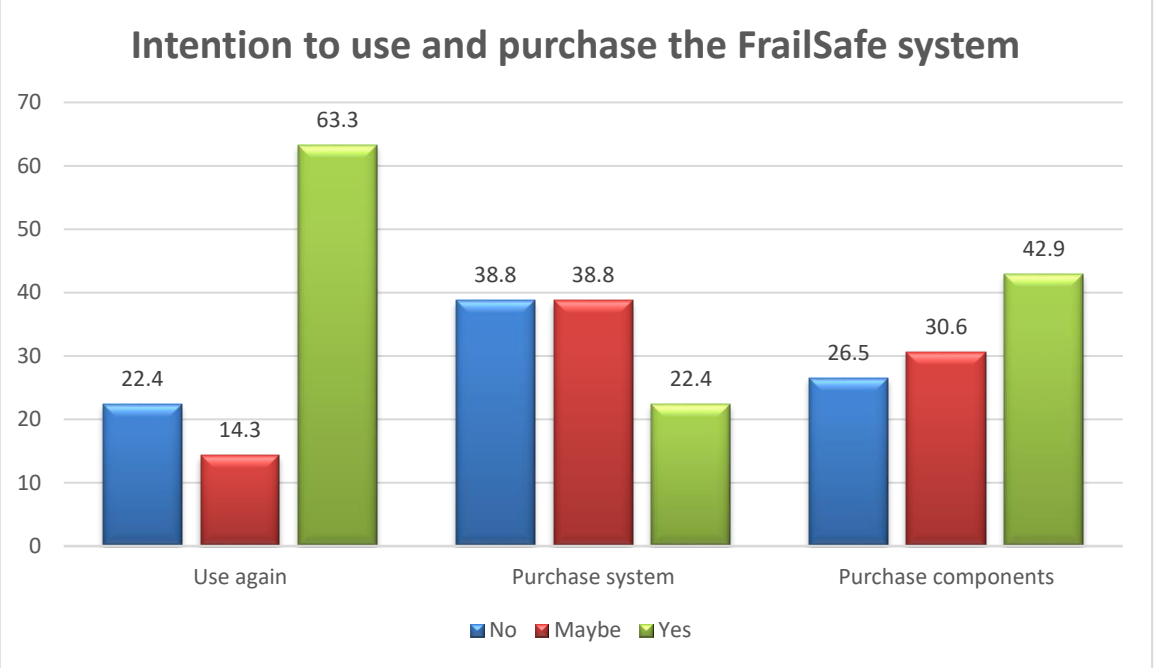


Figure 50. Primary user evaluation: Intention to use and purchase the FrailSafe system

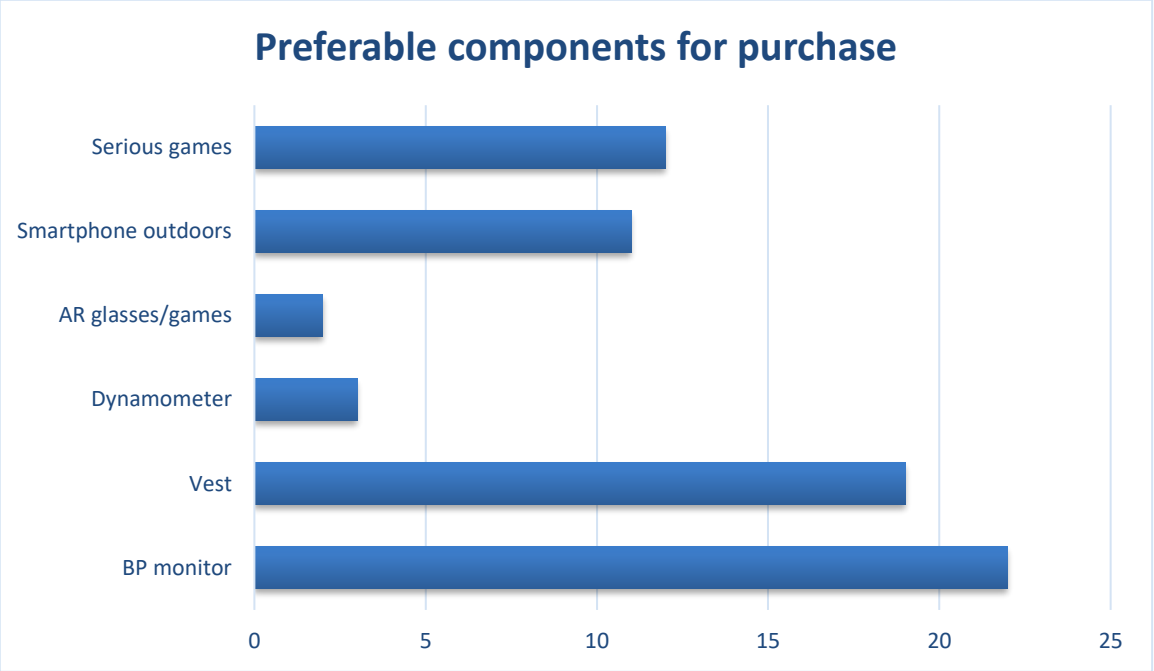


Figure 51. Primary user evaluation: Preferable components for purchase

Regarding the pricing system, 67.9% of the users stated that they would purchase the integrated system for less than 500 euros in an one-off payment. Also, they stated that they would pay less than 50 euros (25%), less than 25 euros (25%) or less than 10 euros (30.3%) per month to have a monthly subscription in the MonitorMe full package, though several of the users rated it in a low price because they thought they did not need it in the present. Fourty two-point one percent of the participants rated the MonitorMe person-living-alone package as the package they would be willing to pay less than 20 euros per month to subscribe to and they also rated it as very important. The vast majority (79.6%) of the participants stated that they would purchase a subscription to the MonitorMe physical-evaluation package and stated that they would pay from less than 10 euros (32.1%) to 20 euros per month (17.4%). Regarding the MonitorMe psychological and behavioral evaluation package, 37% of the participants stated that they would purchase it only for free. Twenty two point five percent of the participants stated that they would pay less than 15 euros monthly and 18.5% stated that they would pay less than 10 euros monthly for a subscription to this package. The rest of the users rated it at higher prices. The results indicate that there is a need among elder users for continuous monitoring of their health status and more importantly for alerts for adverse events to be delivered to trusted parties which guides their purchase intentions. Also, most users rated low the purchase intention for a psychological and behavioral monitoring which is might be indicative of older adults' anachronistic attitude towards mental health. For example, previous studies have shown that older adults are less likely to present help-seeking attitudes compared to younger peers (i.e., (Wetherell et al., 2004). However, there were users who rated psychological monitoring highly and this might be attributed to their current needs. For example, older adults who suffered from psychological discomfort may have rated higher the maximum price they would be willing to pay for a subscription to the MonitorMe psychological and behavioral evaluation package. Finally, pricing evaluation indicates that older adults were typically willing to spend the lowest possible amount of money for a service. This cannot be attributed to a difficulty in estimating a service's price per se but is rather reflective of income and spending restrictions, a theory supported by European statistics (Casey, 2002).

Further analyses showed that purchase behavior and evaluation of the system were associated with caregivers' age and technological level of competency. More specifically, the older the participants were the greater they tended to rate the contribution of the integrated system to their quality of life $r(55)=.750$, $p=.032$, which is understandable considering that needs for health monitoring and effective health management increase with age. Secondly, it seems that more technologically competent older adults were more willing to use the system again in their home-setting for free $r(55)=.281$, $p=.038$ or expressed greater intention to purchase it $r(55)=.267$, $p=.049$ which indicates the importance of assisting older adults in familiarizing with technological products, in general.

All in all, the results showed that older users were interested in the system and felt safety and confidence by the constant monitoring in their home-setting and while performing their everyday activities. Similar results were obtained through interviews available in https://frailsafe-project.eu/frailsafe-media and focus groups. Several older users stated that the use of such systems is more difficult for the people who are not familiar at all with technology but they, also, stated that the benefits of using them are more important than the effort needed. They also agreed that it is learnable after the first training sessions and that the learning curve is decreasing overtime. Also, several users claimed that the system would be very useful for them but they would need a specific motivation to adhere to its use. This finding explains why older users who considered themselves healthy and active and voluntarily participated in the FrailSafe study, felt bored during the consecutive FrailSafe trials. Finally, as mentioned in previous paragraphs, users participating in focus groups and interviews also suggested offering a more customizable vest and applications operating in several devices and operating systems which have all been considered by consortium members and will be implemented in the final commercialized product.

Family members/Informal caregivers

In total, 33 family members and informal caregivers (72.7% males) who interacted directly or indirectly with the FrailSafe system participated in the final evaluation. Approximately half of them (45.5%) were related to people participating in the evaluation Group C and the rest were caregivers who interacted with the FrailSafe system otherwise (through workshops, focus groups, online surveys, etc.). Family members participating in the evaluation were from Cyprus, Denmark, France, Greece and Spain. Their age-groups can be found in Figure 52. Most of the caregivers stated their relative/patient was completely autonomous (33.3%), in 37.5% of the cases they claimed providing some assistance with everyday tasks or that their relative had a housekeeper assistance on a permanent basis (37.5%). Twelve point five percent reported providing intensive assistance to their relative and 4.2% of the cases reported providing assistance only with laborious tasks. Approximately half of the caregivers stated that have never used a smart health device before (45.5%), while 33.3% reported currently using one and 21.2% having used one in the past but having ceased its use. The most commonly reported smart health devices were pedometers, smart bands, smartwatches or smart assistants. The reasons reported by users for ceasing their use concerned the complexity of the devices or lack of interest. Users' level of technological competency can be found in Figure 53.

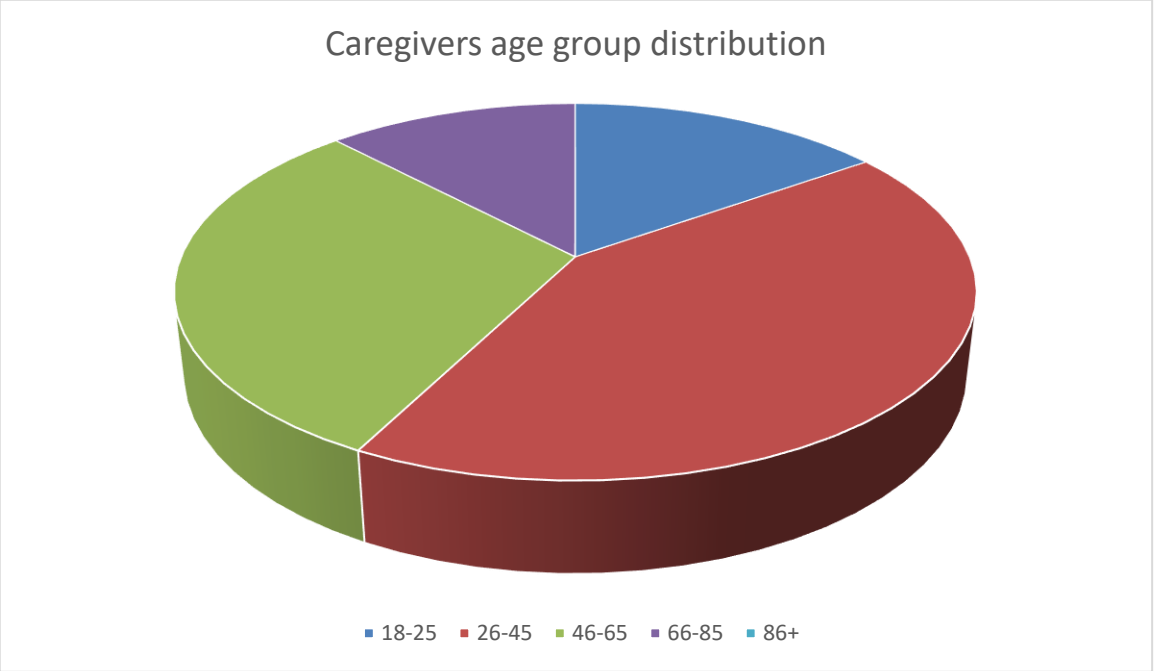


Figure 52. Secondary user evaluation: Caregivers' age group

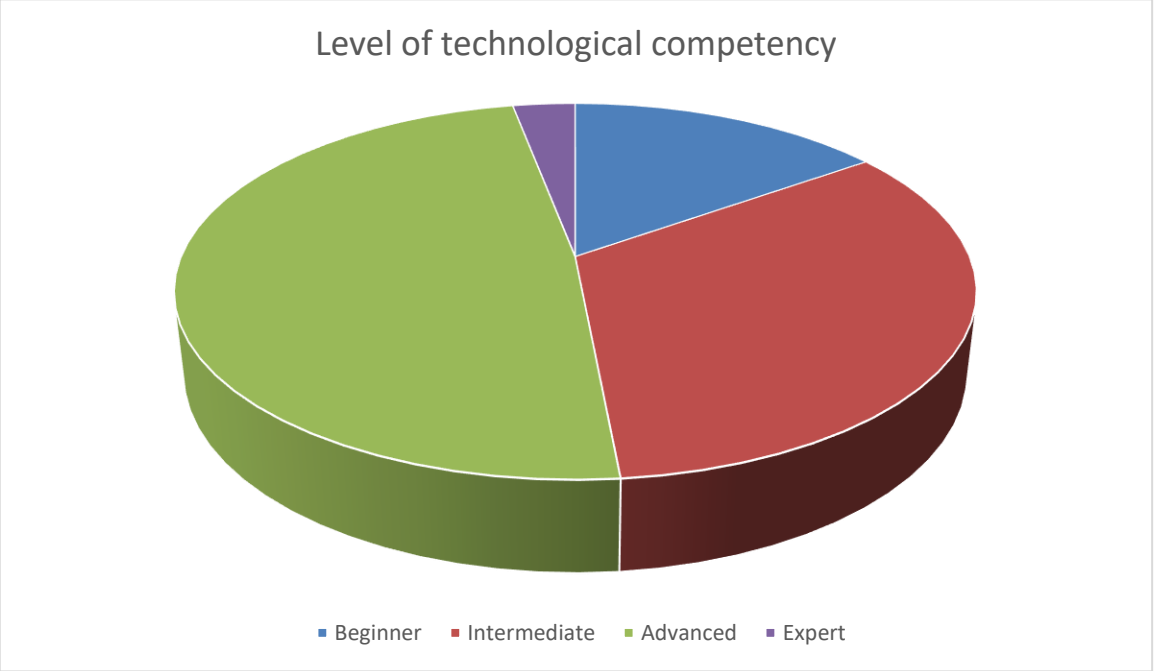


Figure 53. Secondary user evaluation: Caregivers technological competency

As a reliable measure for usability, we used the USE questionnaire (Lund, 2001). USE questionnaire measures 4 dimensions, namely, usability, ease of use, ease of learning and satisfaction. Total scores for each dimension range from -15 to 15 for usability, -12 to 12 for ease of use, -9 to 9 for ease of learning and -15 to 15 for satisfaction. The scores obtained for each dimension can be found in Figure 54.

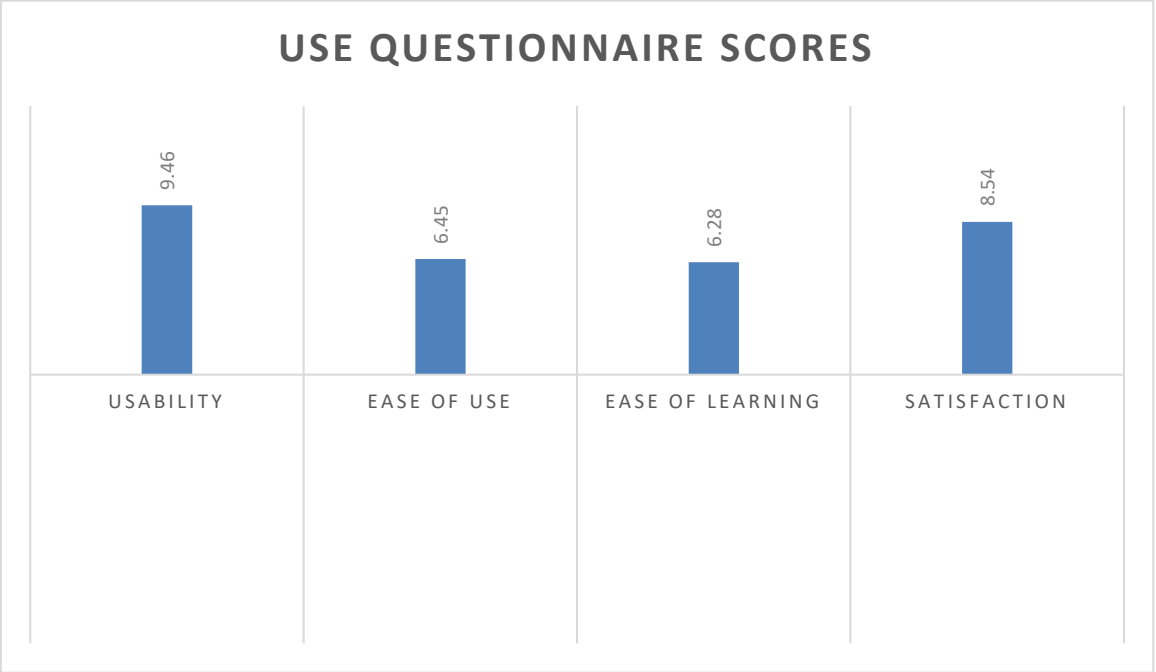


Figure 54. Secondary users' evaluation: USE questionnaire scores

On average, users evaluated positively the FrailSafe integrated system in terms of usability, ease of use and learning and satisfaction. Regarding other aspects of the system, such as helpfulness and cost-effectiveness, results showed that on average users rated all aspects with more than three point five out of five points which is a very satisfactory score (Figure 54). Caregivers agreed that the system would improve a great deal the autonomy of their family member and their confidence (Figure 56). Also, they stated that it provides helpful feedback, it would be cost-effective, offer protection of personal data and they would be willing to try it. Caregivers rated lower than other items the ease of learning and adherence, which is understandable considering older adults challenges in using technological devices. However, users' evaluation showed that they are more effective than they and their family members think in using technology and there are ways to further increase their adherence to such interventions. This finding is supported by numerous previous studies, which show that older adults' perceived difficulty is higher than their actual competency and in fact, their perceived difficulty can determine their actual difficulty (Barnard, Bradley, Hodgson, & Lloyd, 2013). This is an extremely important finding which shows that our efforts should focus in empowering older adults to use new devices and increase their IT literacy through a supportive family context.

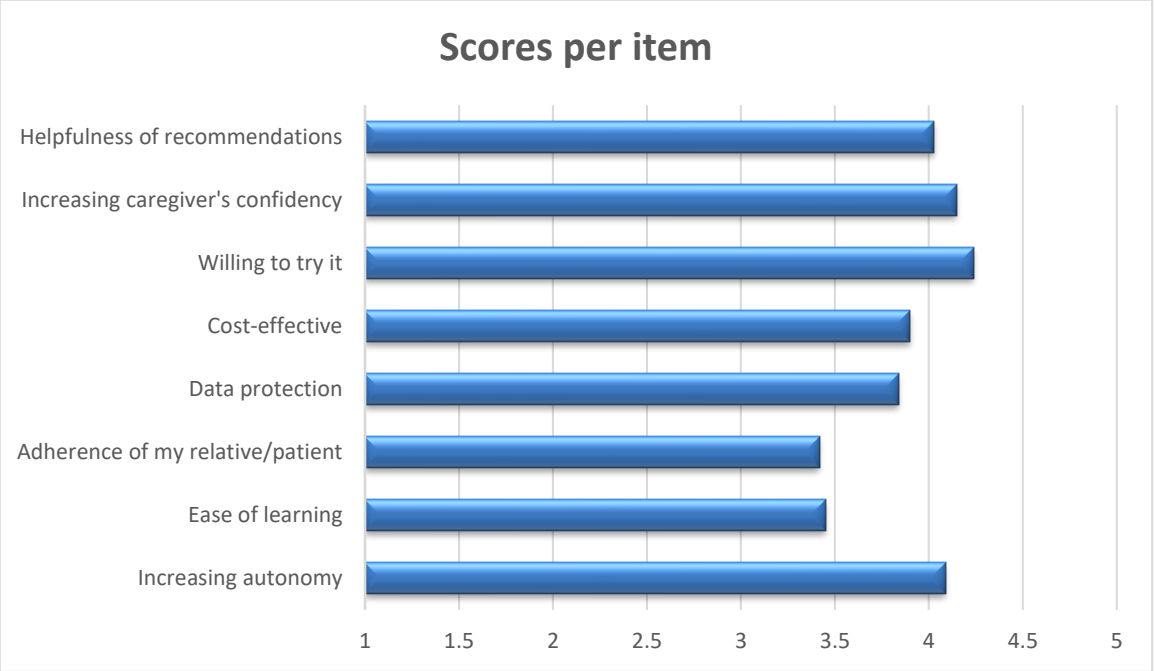


Figure 56. Secondary users' evaluation: Other evaluation items

Regarding suggestions for modifications of individual components, caregivers' comments were similar to the ones obtained from older users. Specifically, some caregivers stated that the mobile phone was too heavy for some users to carry with them along with their own mobile phone, the vest should be more customizable and the dynamometer was too stiff sometimes.

VCP and DSS were also evaluated by caregivers as system components. More specifically, three family members evaluated the VCP through a think aloud protocol. Regarding the VCP, all caregivers stated that they appreciated the establishment of an open space in which they would share experiences and opinions about health issues that pose challenges in their everyday life. They stated that the forum is important to, also, have emotional support from other people with similar experiences. Two out of three users reported having prior experiences with health forums but they were not actively participating in one. Overall, they liked the design of VCP and all of them could perform the tasks described in Annex VI. Detailed rating can be found in Figure 57. Some of the users worried about the ability of older adults with MCI or no technological competency to use the forum but overall stated that it would be very beneficial for those who are competent to participate. Finally, all users stated that the VCP should be supporting multiple languages to be friendly to many users.

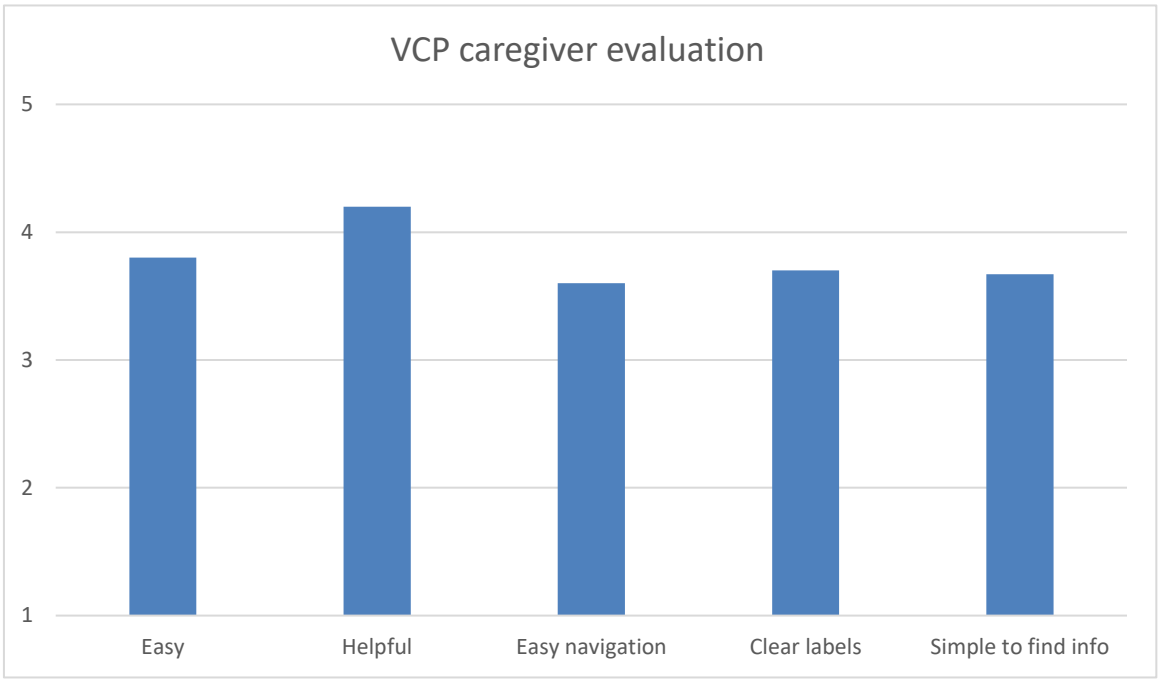


Figure 57. Secondary users' evaluation: VCP

Furthermore, three caregivers evaluated the DSS feature through a focus group. All found it very helpful and easy to use and stated that it would increase their feelings of safety and confidence in caring about their relative or patient. Caregivers, in contrast to older adults, preferred the use of the mobile application compared to the computer interface as it would fit their busy lifestyle. Some expressed worries beforehand about data protection but their worries faded when they saw that users were denoted with four-digit numbers and no personal identification data were available online.

As seen in Figure 58 the vast majority of caregivers stated that they would recommend the integrated system to their friends, purchase the integrated system or purchase individual components.

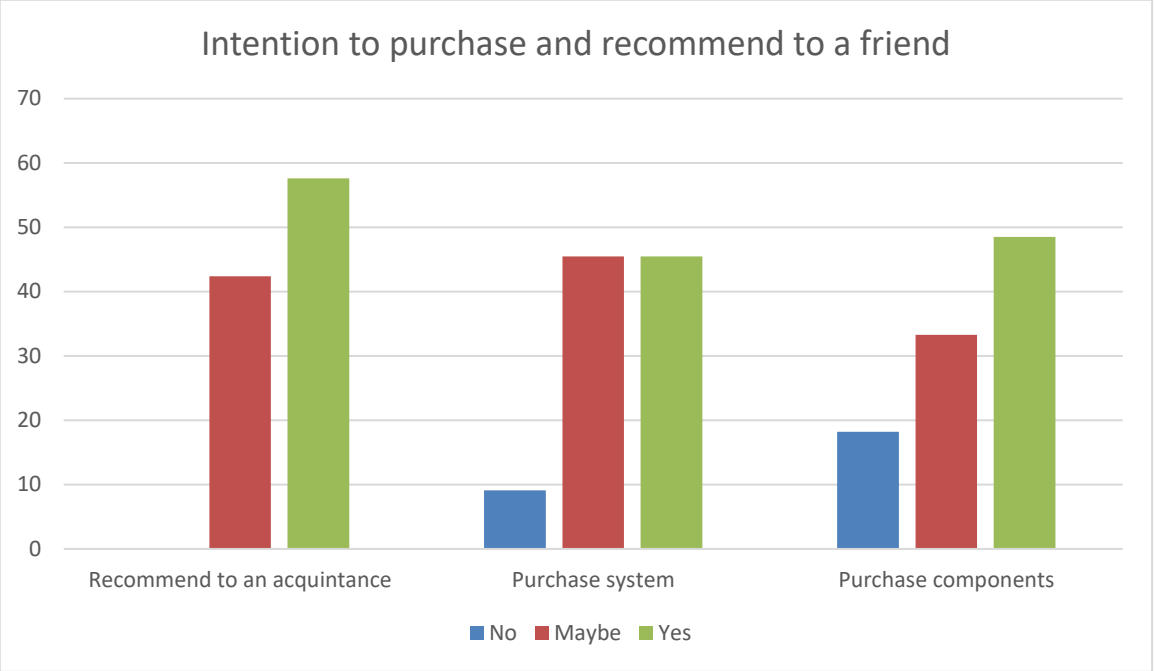


Figure 58. Secondary users' evaluation: Purchase intention

Similar to the older adults' evaluation, the components rated as most desirable to be purchased were the WWBS and serious games followed by the BP monitor and the smartphone apps (Figure 59). Caregivers rated the indoor localization app as equally important in contrast to older users' evaluation of this component. This finding may be attributed to older users' difficulty to understand the value of localizing oneself in a small environment. On the other hand, this feature offers valuable information for caregivers as they can have an overview of the person's indoor activity patterns (i.e., time spend in bedroom inactive).

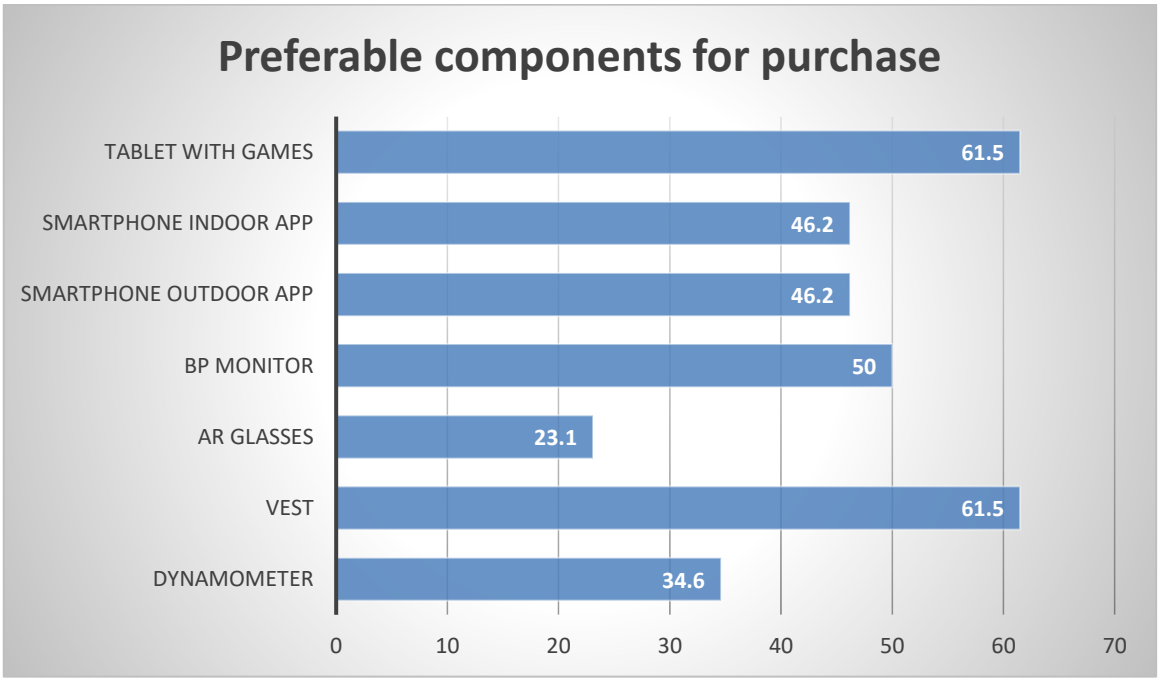


Figure 59. Secondary users' evaluation: Preferable components for purchase

In terms of pricing, 52.9% of caregivers stated that they would purchase the integrated system for less than 500 euros and 29.4% for less than 1000. The majority of users stated that they would pay less than 25 euros per month for the subscription to MonitorMe full package (32.4%) and in smaller percentages chose different prices. Also, most users (33.3%) reported that they

would be willing to spend less than 30 euros monthly for the MonitorMe person- living-alone package, 40% stated that they would be willing to pay less than 10 euros for the package offering reports on physical evaluation and 30% reported that they would spend less than 10 euros for the package offering psychological and behavioral evaluation reports. These ratings indicate that family members value higher the packages offering total evaluations of health status or alerts for adverse events which was expected considering that the information provided by these packages is more important for their relative's vitality than a psychological evaluation. However, the prices chosen in this evaluation can be only considered as vaguely indicative of what a stakeholder would be willing to pay for the commercialized product as desirability and value are expected to grow with further certification and obtaining of further evidence-based utility of the FrailSafe system.

Regarding system's safety, nearly, one out of four users (26.5%) had some type of concern towards the system. Most concerns were related again to older adults' ability to use or adhere to such innovative devices and data protection. Also, several people stated that they need more testing, certifications and endorsements from doctors to trust the system. Similarly, concerning the importance of training, 45.5% of family members rated that a training on how to use the system is absolutely important and the rest of people rated different options in smaller percentages. The latter rating contradicts the ratings of older users who rated the training as important or very important but did not rate it as mandatory. The aforementioned findings are very interesting because they show that older adults' experience with technology and overall competency (perceived or actual) is different, and possibly higher than expected by other parties.

Similar results were obtained through the focus groups, interviews and other interactions with caregivers. They all thought that the system is very useful for them and would reduce their anxiety or uncertainty associated with a fragile parent living alone. Many provided their contact details to be informed as soon as the first product is released on the market. Also, several requested to prebook a position for their parents to participate in a next similar study to test this product for free. Family members who participated in the recommendations phase stated that it is very useful to get reports on their parents' health status but some stated that they would like the reports to be more specific. This finding is aligned with older adults' comments described in the previous section. However, in the context of the present study and in order to comply with ethical standards it was not possible to explicitly inform an older adult or his/her family member for a specific score. All in all, the system aims to be a valuable, effective complementary tool for healthcare professionals to empower but not diminish their role.

Healthcare professionals, Researchers and ITs

Twenty nine healthcare professionals, 22 researchers and 22 IT professionals evaluated the FrailSafe system with the respective questionnaire (Annex IX). Most of the professionals (52.2%) listed Greece as their country, 19.4% listed France and the rest were people from Cyprus, Italy, Spain and United Kingdom. SUS scale yielded satisfactory levels of acceptance for healthcare professionals M=68.55, SD=11.2, IT professionals M=71.75, SD=8.16 and researchers M=78.85, SD=12.1. Externals generally reported higher levels of acceptance for the system than internals (Figure 60) which is understandable considering that consortium members have higher standards and are stricter towards the evaluation of their product. Either way, all scores were approximately 70 or greater which indicates that the system is acceptable for all stakeholders.

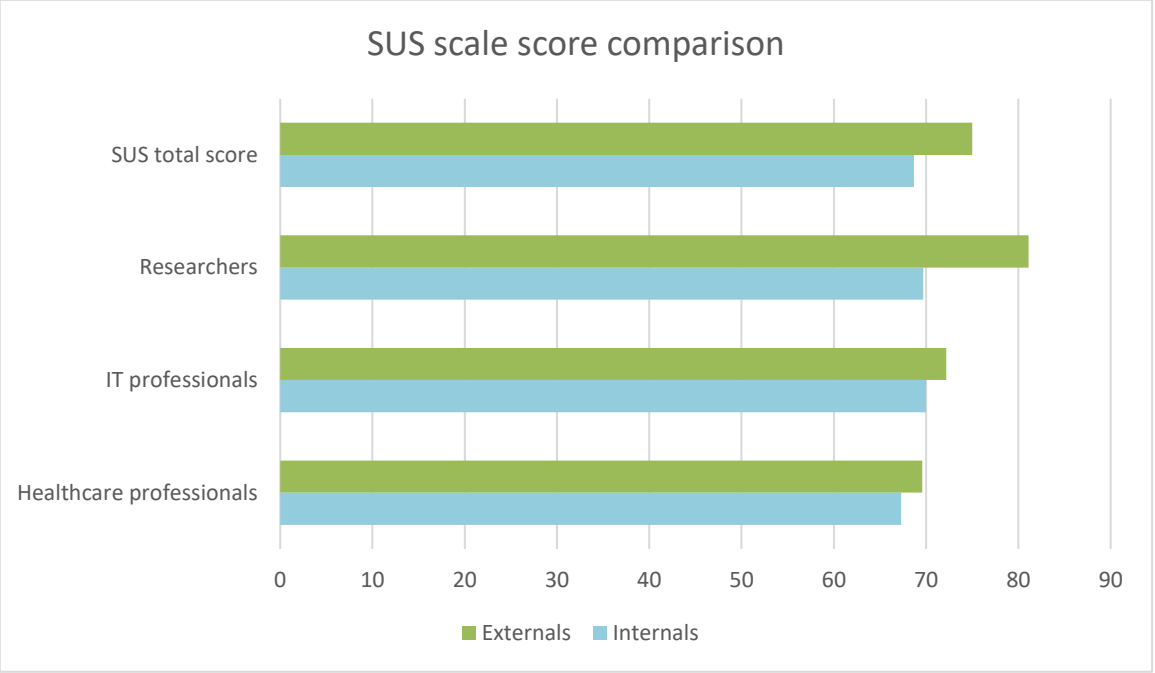


Figure 60. Secondary users' evaluation: SUS scores for professionals

Users' scores concerning other aspects of the system, such as difficulty, ease of use and complexity can be found in the following figure (Figure 61). Overall, professionals rated high positive aspects of the system, such as easiness to use, likelyhood of integration to their practise, enhancement of their confidency and quick learning. Similarly, negative aspects such as, difficulty, inconsistency and complexity were rated low. Similarly to the SUS scale scores, internals evaluated the system more strictly in all aspects assessed which we consider a positive finding.

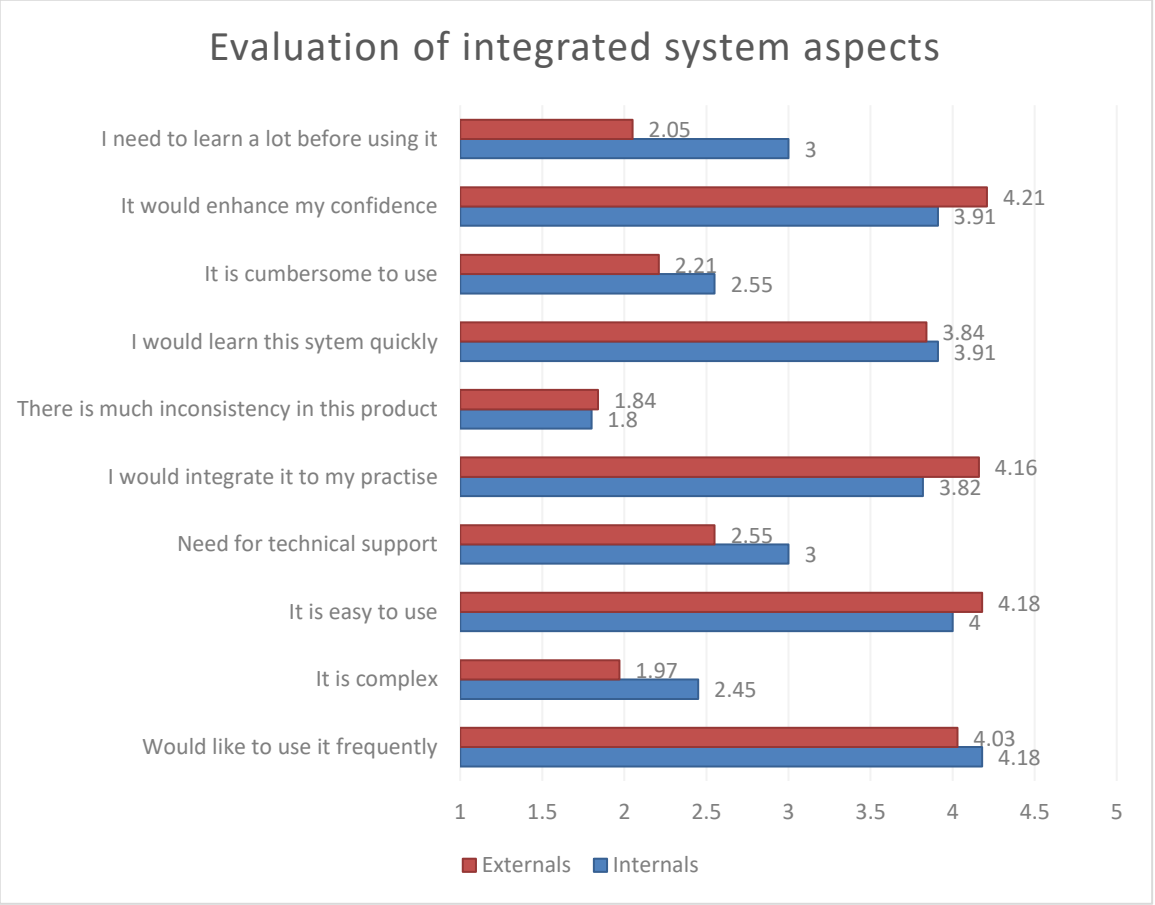


Figure 61. Secondary users' evaluation: Evaluation of integrated system aspects

DSS questionnaire (Annex IX) included 7 questions with answers based on a Likert scale from 1 to 5 with 5 denoting the greatest possible agreement with each statement. Regarding the evaluation of DSS by professionals, the results yielded high scores both in total and in individual items, such as ease of use, understandability, cost-effectiveness, etc. (Figure 62 and 63).

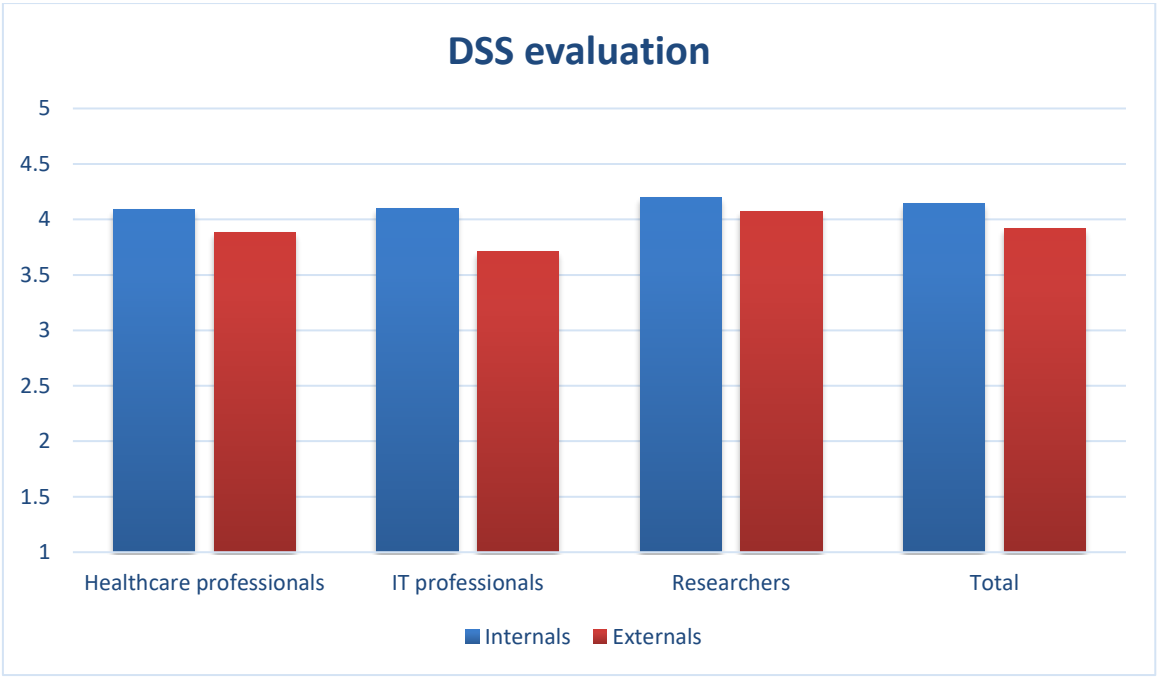


Figure 62. Secondary users' evaluation: DSS

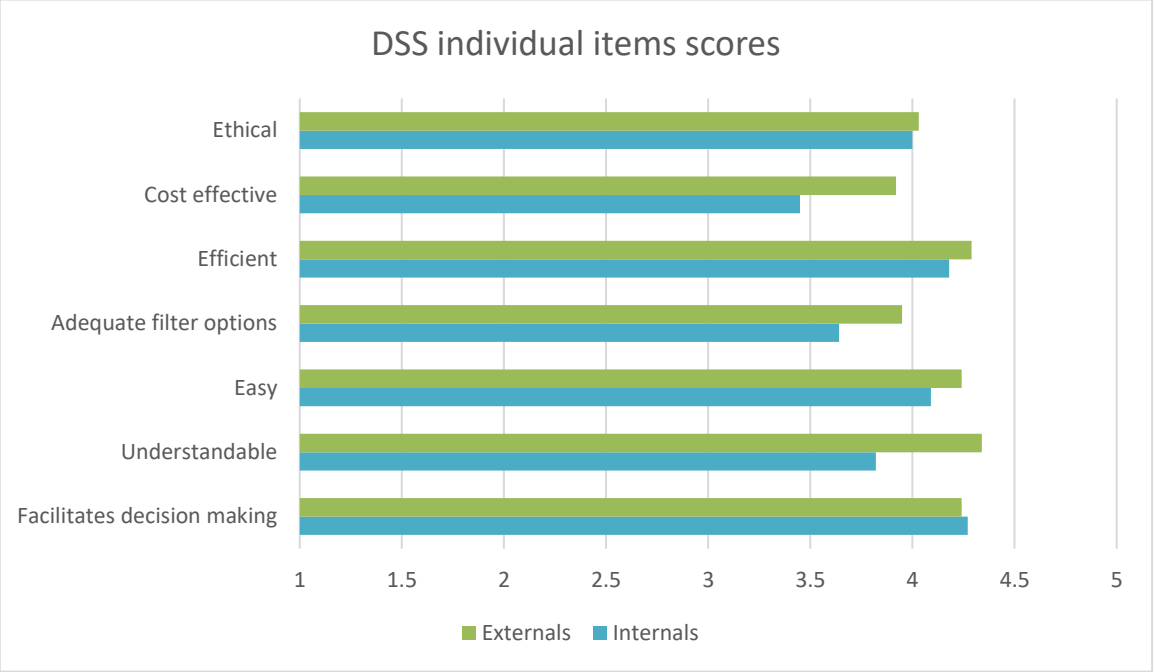


Figure 63. Secondary users' evaluation: DSS individual items scores

A focus group performed in Cyprus with one doctor, two psychologists and one physiotherapist yielded similar results. All stakeholders stated that they would be interested to try the FrailSafe system in their practice and that it would cover several inefficiencies of the traditional healthcare delivery practice. Some professionals expressed concerns about data protection of the online information and the need for further testing and certifications.

Finally, one external IT professional, a mechanical engineer with 20 years of experience in the sector, accepted to perform an expert evaluation of the functional characteristics of the FrailSafe system. The IT professional endorsed the system, in terms of offering multimodality, covering multiple areas of interest, offering high levels of integration, data security and covering an intensive market need. He congratulated the consortium for achieving so much in three years, “considering that in several areas you had to start from the beginning” and that “older adults constitute a very difficult population group to test technology products”. Then, the evaluator focused in providing suggestions for further and optimal improvement of the system in future efforts. These suggestions were:

- Offering a smaller, more durable (in terms of cleaning) and waterproof RUSA device
- Offering customizable vest options
- Providing the option for wireless charging of devices
- Ensure that there is a back-up system to avoid disruptions in communications (i.e., send a signal in a call center if the system does not get a signal from a specific user for a specific time period)
- Incorporate fingerprint or face recognition to access DSS mobile app.

Commercial stakeholders

Twenty six commercial stakeholders from various fields assessed the FrailSafe system with the commercial evaluation questionnaire (Annex XIV). The stakeholders were related to the health sector and had a mean of 12.76 of experience (SD=8.3). The countries listed included the

Cyprus, Spain, Poland, Austria, and United Kingdom The profession distribution of the commercials who participated in the present evaluation can be found in Table 38.

Table 38. Commercial stakeholders professions

Profession	Number of participants
Business consultants	3
Health product suppliers/vendors	3
Health professionals	3
Healthcare provider	2
Health-related IT professional	4
Insurance company	2
Public authority	2
Researcher	7

Results of commercial stakeholders' evaluation of the FrailSafe system showed that on average all people rated positively the system, as it fills a current need in the market, would increase the efficacy of their practice, increase their current number of customers and have an added value for their products or services. Commercials rated lower than other items the cost-effectiveness of the system and their likelihood to incorporate it in their practice, though the likelihood of purchase yielded a high score (Figure 64). This finding may be attributed to conceptual differences between the three items, as purchase does not necessarily guarantee the ultimate value of the product in terms of cost-effectiveness. Hence, commercials in this evaluation rated high the likelihood to purchase a promising system but its cost-effectiveness and incorporation in their practice will depend on the system's behavior and functionality overtime.

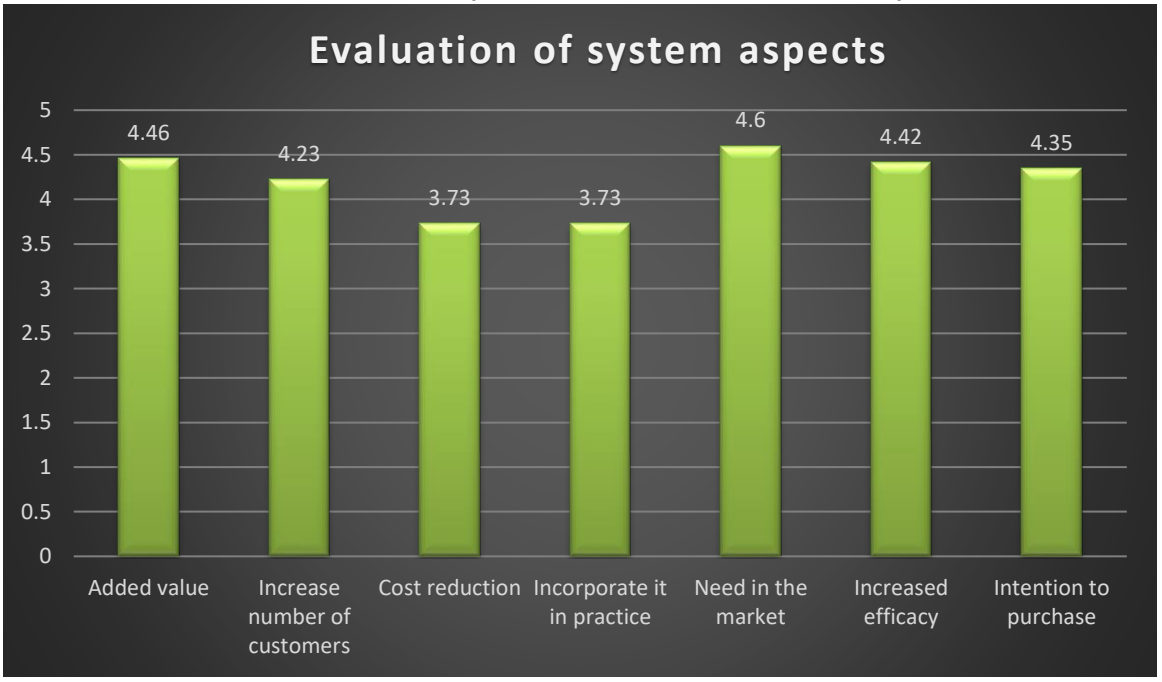


Figure 64. Tertiary users' evaluation: Evaluation of system aspects

In general, most stakeholders were conservative about the likelihood of incorporation of the FrailSafe system in their countries healthcare system with 15. 3% answering "yes", 46.2% "maybe" and 38.5% "no". This finding is disappointing as it is in direct contrast with the reported need for such a tool. The reported obstacles for the implementation of the FrailSafe system in public policies were the costs, the very traditional and inflexible frameworks and the need for extensive testing and evidence-based, high impact results to persuade policy makers.

Regarding purchase intention, 70.6% of people stated that they would be willing to adopt the FrailSafe system in their practice and 29.4% stated “maybe”. No user answered negatively. Also, commercial stakeholders stated that the vast majority of their customers would use the FraiSafe system, which depending on the sector and share of older users as patients, ranged from 5-75%. Responses in pricing items can be found in detail in Figures 65-71. The overall results of pricing evaluation showed that the majority of tertiary users would be willing to buy the system for less than 1000 euros. With regards to the subscription services, most users reported that they would pay less than 80 euros for the DoctorMe (full plan), more than 30 euros for receiving notifications only, less than 40 euros for periodical physical evaluations and suggestions, less than 40 euros for suggestions and recommendations only, and less than 20 euros for psychological and behavioral periodical evaluations. The interesting finding was that among users who participated in pricing evaluation no one listed the suggestions and recommendations or the psychological/behavioral evaluation packages as a feature they are not interested in. Finally, most users stated that they would be willing to pay less than 150 euros monthly for a subscription to the ProData package. Due to the wide diversity of evaluators of the pricing system the present results are only indicative of the users’ optimal maximum amount ratings per service. However, they provide a general basis for exploitation strategies.

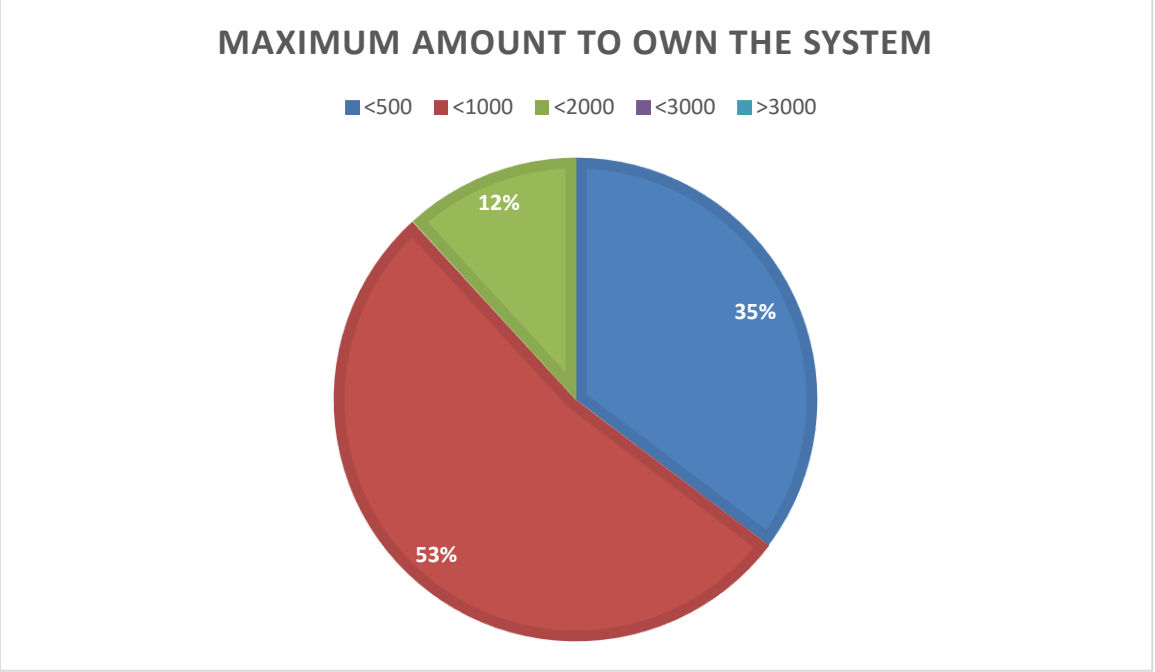


Figure 65. Tertiary users' evaluation: Maximum amount to own the system

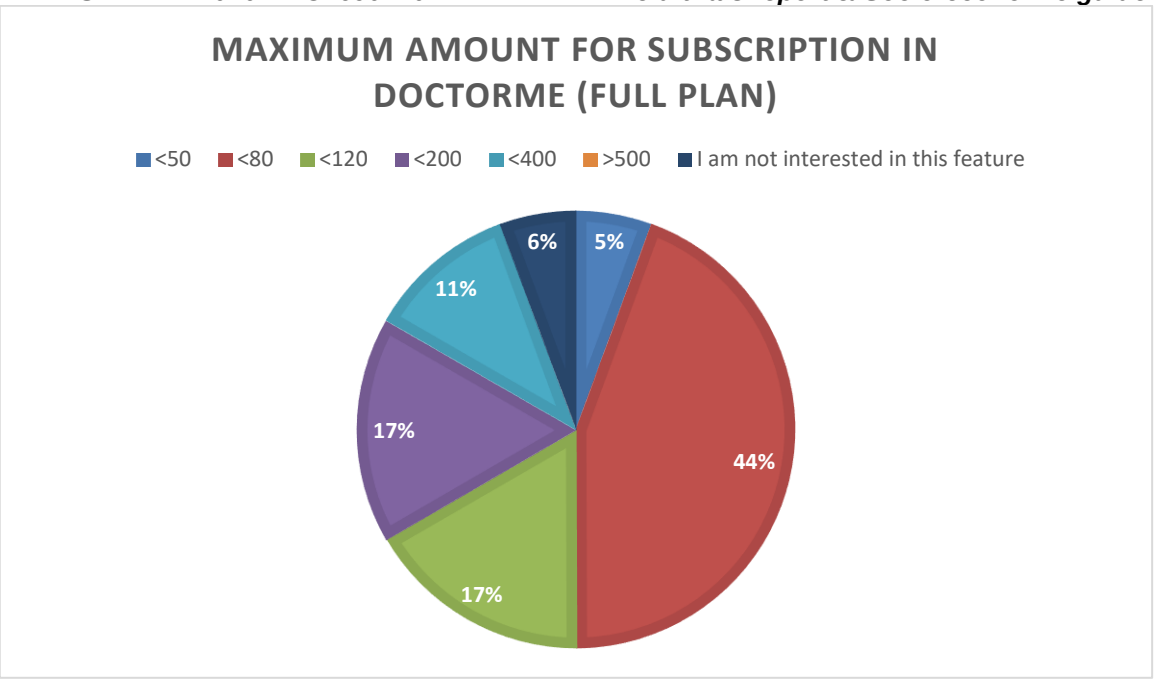


Figure 66. Tertiary users' evaluation: Maximum amount to subscribe to DoctorMe (full plan)

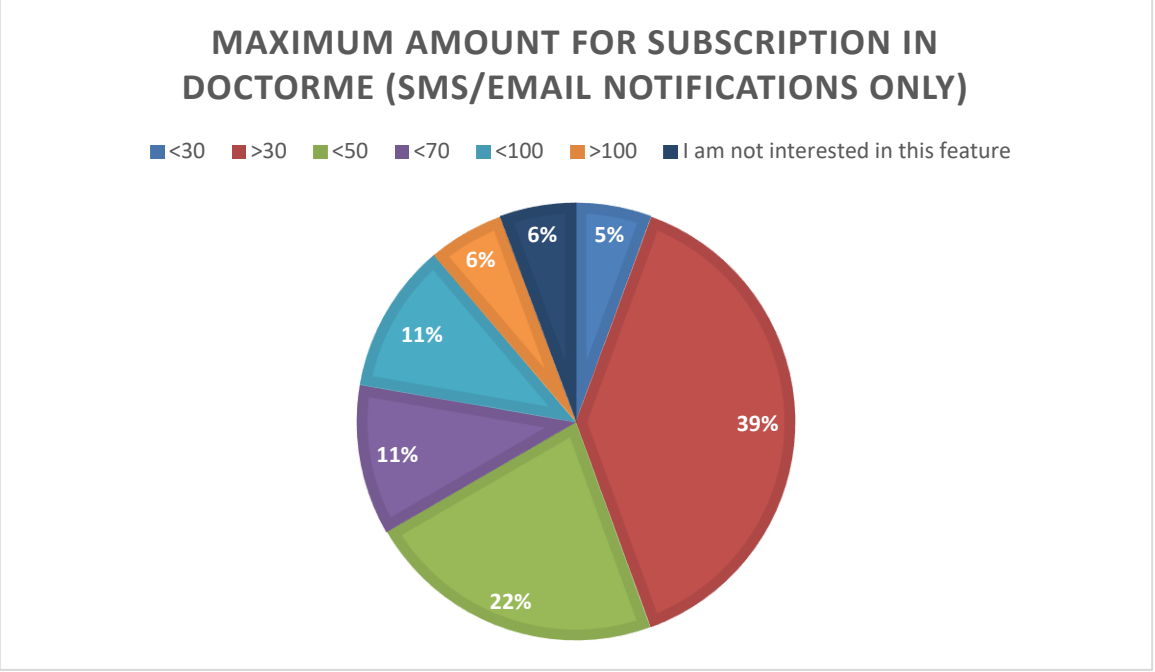


Figure 67. Tertiary users' evaluation: Maximum amount to subscribe to DoctorMe (sms/email notifications only)

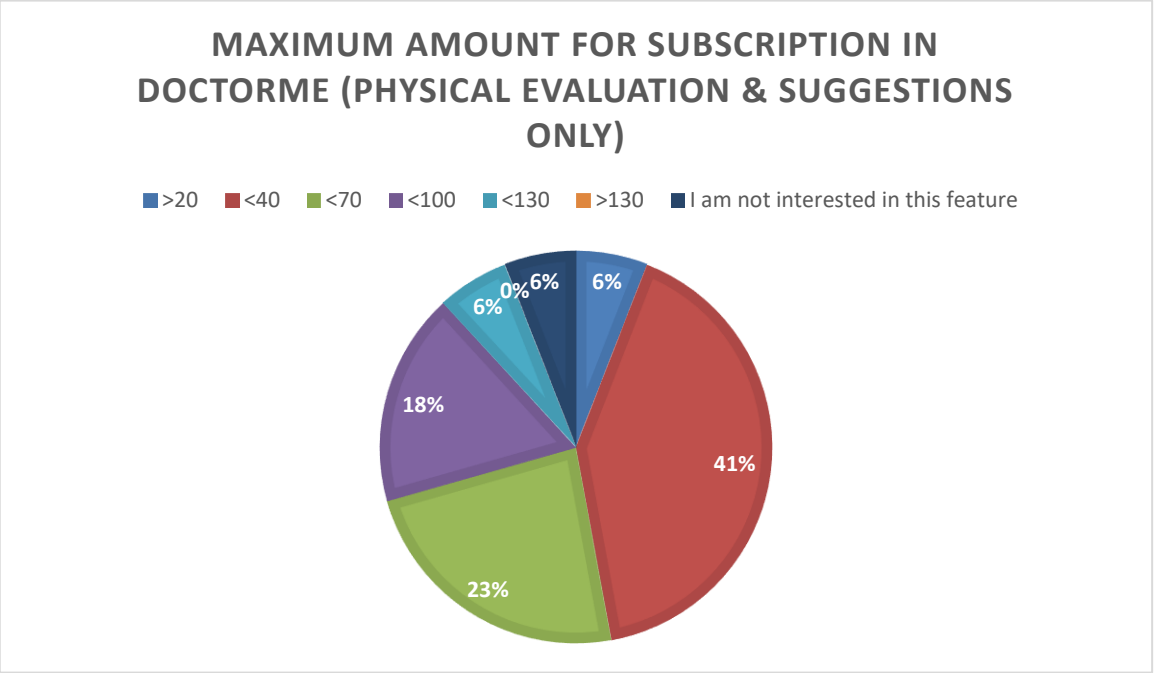


Figure 68. Tertiary users' evaluation: Maximum amount to subscribe to DoctorMe (physical evaluation and suggestions only)

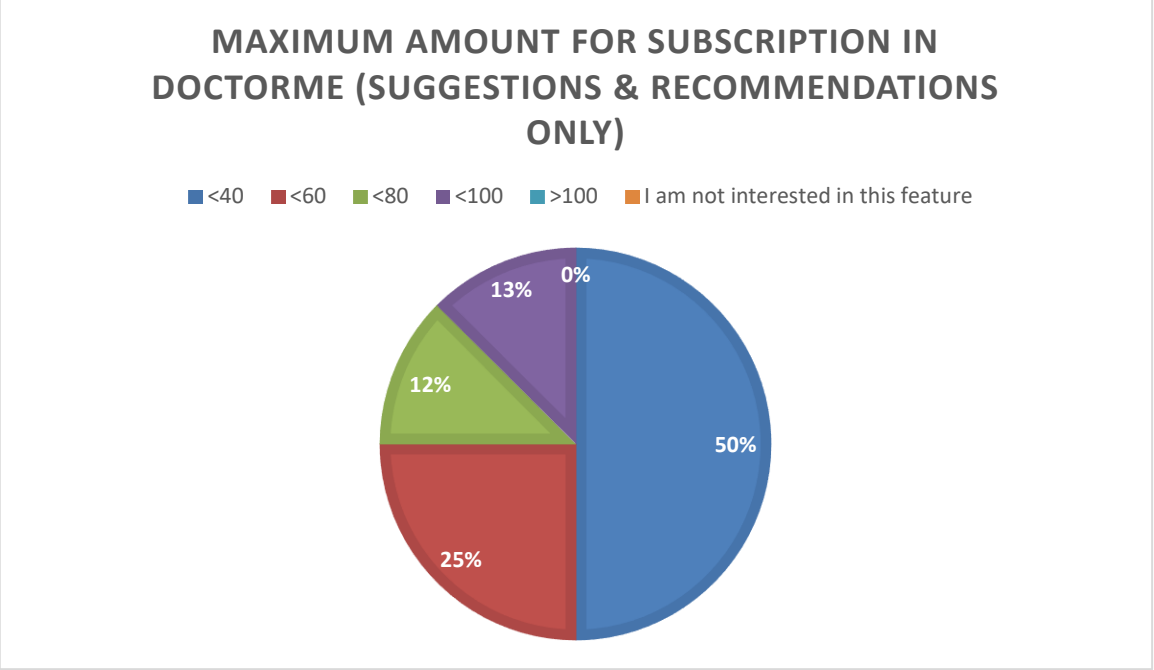


Figure 69. Tertiary users' evaluation: Maximum amount to subscribe to DoctorMe (suggestions and recommendations only)

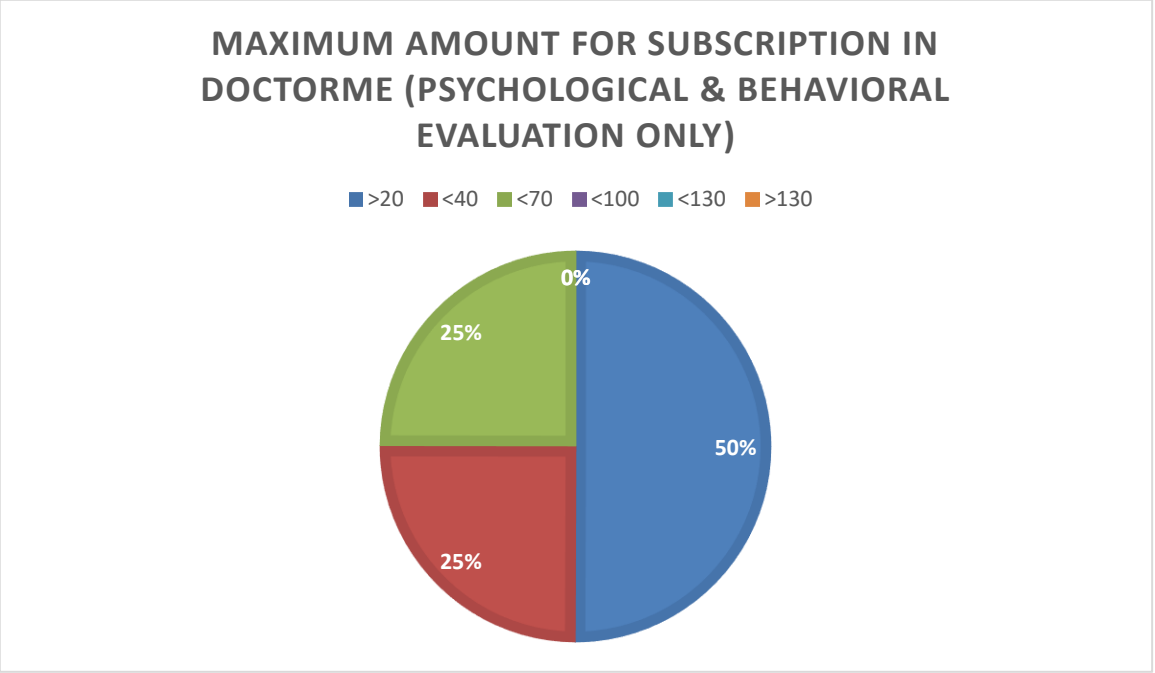


Figure 70. Tertiary users' evaluation: Maximum amount to subscribe to DoctorMe (psychological and behavioral evaluation only)

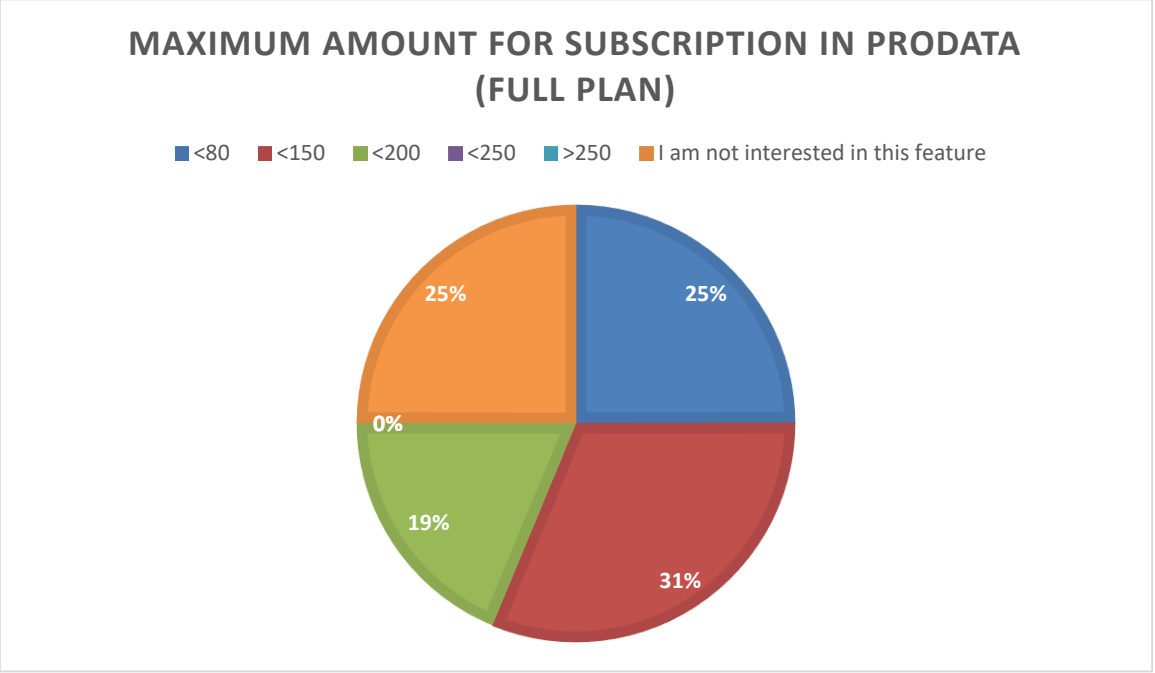


Figure 71. Tertiary users' evaluation: Maximum amount to subscribe to ProData (full plan)

In total, commercials congratulated the rationale underlying the current product, stressed the need for its implementation in modern healthcare but also described obstacles in existing frameworks which could hinder its seamless exploitation. Interviews conducted with several stakeholders (available at https://frailsafe-project.eu) yielded similar results. One policy maker stressed the importance of conducting intense awareness strategies to inform policy makers about the results of this study and also, implementing empowering training sessions with older adults with regards to their IT literacy skills. Two insurance brokers rated the FrailSafe system as a powerful product having benefits for both customers and insurance companies. Finally, a healthcare product supplier suggested that the FrailSafe system is an innovative solution which

is missing from the current market and would be a product of great value for vendors who are premium-seekers.

Ethical evaluation
The results from the ethical evaluation of the FrailSafe system, performed in M37 showed that all advisory board members rated 100% positively the achievement of ethical goals.

Advisory board meetings
All feedback obtained from AB members was utilized for evaluation purposes. Advisory Board members provided overall evaluations of the system, dissemination and exploitation strategies, as well as, their suggestions for future steps. Qualitative analyses of data showed that advisory board members embraced the FrailSafe solution as an innovative tool which covers an important need in the market.

Malena Fabregat suggested distinguishing exploitation strategies for different packages, stakeholders and countries, as healthcare systems vary significantly across Europe. Also, she suggested adopting a more modular approach to tackle the obstacles of cost for the implementation of the healthcare system. Mrs. Fabregat also, advocated the need for the system to be on the public side and endorsed by key opinion leaders.

According to Fillios Savvides the main advantage of the FrailSafe system is its holistic approach compared to other competitive products currently available on the market. Mr. Savvides stated that the healthcare systems in Europe work towards adopting innovative technological tools to increase the efficacy and cost-effectiveness of the provided services and thus, there is a market opportunity for the FrailSafe system. Mr. Savvides also suggested that the two most exploitable qualities of the system are its affordability and cost-saving.

Liz Mestheneos endorsed the overall project progress and suggested modifications of the system from a user perspective, such as offering a more customizable vest and multiplayer options for games. She stressed the need for a large-scale evaluation of the FrailSafe system and application for a patent. She referred to the increasing need for active aging and IT literacy among older adults and stressed the usefulness of using computers and tablets. Mrs. Mestheneos also mentioned that older people isolated from technological advances often feel isolated from their families, as well, and that FrailSafe system has a high advantage in this matter as it can be incorporated in everyday life and increase IT literacy. Finally, Mrs. Mestheneos proposed that there are older adults who are early-adopters of innovative products, as a quality of their character, and thus our marketing strategies should begin from those adults. Furthermore, according to her, getting grandchildren attracted to the FrailSafe system would further enhance older adults' willingness to adopt and adhere to the solution.

Finally, Jim Playfoot also offered his suggestions on exploitation and dissemination strategies focused on the effectiveness of the direct promoting of the product through our website and high-impact dissemination strategies, through intensive campaigns utilizing modern tools (i.e., social media).

After event surveys
Surveys circulated after major dissemination events, such as the AGE General Assembly, webinars, the FrailSafe Final Conference, the "Frail Trail" photography exhibition and others (details on events available at https://frailsafe-project.eu/ and D8.4) yielded important

information regarding system evaluation and impact from the general public and scientific community.

Fourty five users in total from various age-groups, professions and countries evaluated the FrailSafe system through the short survey (Annex XVI). All in all, 93.3% of the users stated that they were satisfied by the topics covered throughout our events and the quality of the presented data. Many users stressed the need in the market for a system like the FrailSafe system and a great portion of users stated that they would be likely to purchase the FrailSafe system instead of other competing products available (more information in Figures 72 and 73).

Free comments of users included that the FrailSafe system covers an important gap in the approach of frailty. They stressed the need for policy makers and governmental institutions to learn and adopt the solution. They also stressed the need to be accessible by the vast majority of people by being offered at an affordable price and covered by healthcare insurances. Attendees, in line with other users, suggested several modifications to the vest (enlarge the zip or provide a version with a scratch, make it more customizable and easier to be worn in formal events, etc.). Several users appreciated the need for some components to be available as standalone devices, such as the games. A user said “I would be interested in a stand-alone app to optimize cognitive reserve. I am still in my 50s so don’t anticipate frailty for some time but would love to play the various games”. Family members were, also, interested in the commercialization of the FrailSafe system and many expressed the need to purchase it for their parents. Some expressed that a training scheme should be kept in mind with refreshment sessions for all groups but especially for the older adult with memory difficulties. Others expressed worries about the cost of maintenance. All in all, they rated the system as “a good system, well integrated and complete”. Finally, regarding data exploitation, attendees expressed the need to provide the users with the right to decline sharing of their anonymized data or at least be reimbursed for this offer.

Stakeholders’ opinion was that it would be desirable but difficult to implement such an innovative service to the healthcare system of their country. The reasons mentioned in descending order of frequency were: costs of implementation, need for further testing and certifications and bureaucracy. Attendees also suggested addressing the marketing campaigns to younger people as well, i.e., people in their 50s, in order to obtain a maximized preventative effect.

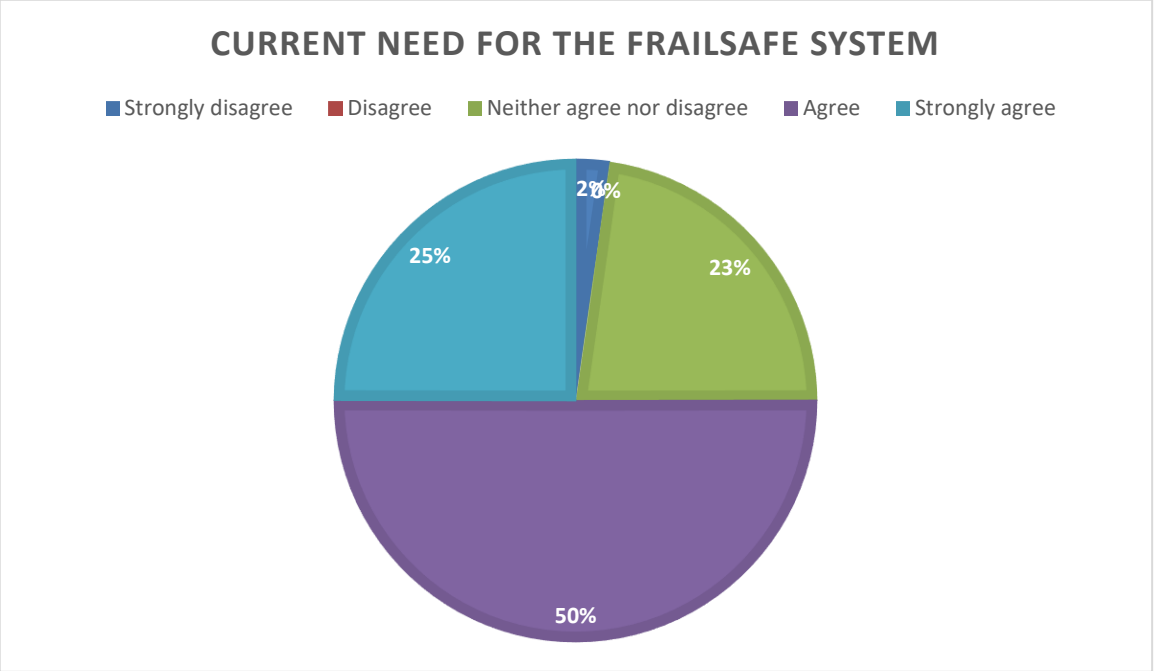


Figure 72. Tertiary users' evaluation: Need for the FrailSafe system

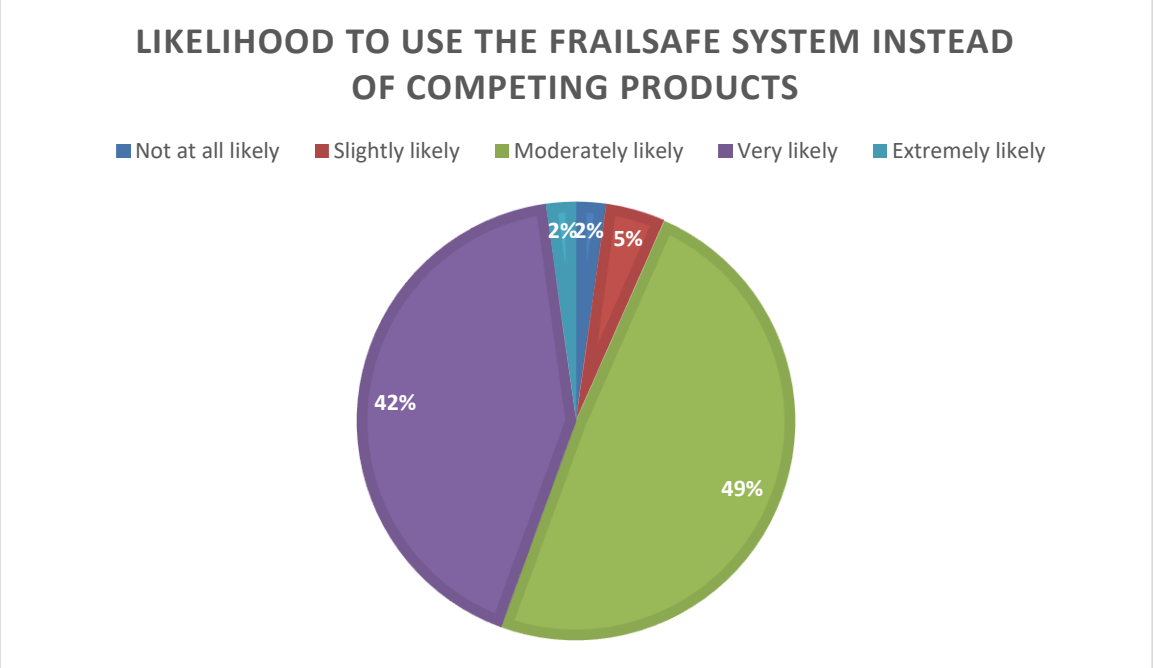


Figure 73. Tertiary users' evaluation: FrailSafe instead of other competing products

3.5 Success indicators

Successfulness in project completion is closely dependent to the achievement of project goals as stated in the Grant Agreement. With this prerequisite in mind, this section aims to analyze the achievements of the FrailSafe study in relation to initial goals and objectives.

With regards, to MOs, the FrailSafe study contributed in the recent body of literature aiming to better understand frailty and its relation to co-morbidities and other health parameters. Our analyses shed light to domains which should be further explored and valued with regard to frailty, such as hypotension, hearing acuity and thyroid disease (2.2.7). In addition, throughout the study, quantitative (CI, FI and CFI) and qualitative (cluster profiling) measures were developed and evaluated, in order to define and detect frailty and predict long- and short-term outcomes

(2.2.1-2.2.6). The study, also, showed that the instruments developed constitute real-life tools as they are used in home-settings and serve users through multiple and popular gateways (tablets, smartphones, pcs) (3.4.1). The FrailSafe system can assess both intrinsic reserve of the user (i.e., cognitive capacity) and external challenges (i.e., polypharmacy). Furthermore, the results showed that the FrailSafe system is sensitive to change as it was found to detect more accurately than traditional measures changes in health-status over a short-time and also, its impact in terms of health improvement could be quantified even in a six-month experiment (2.2.8 & 2.2.9). This shows that over longer monitoring periods the impact could possibly be even greater. Also, in the FrailSafe study we created "prevent-frailty" evidence-based recommendations for older people regarding activities of daily living, lifestyle, nutrition, etc. to strengthen the motor, cognitive, and other "anti-frailty" activities through the delivery of personalized treatment programs, monitoring alerts, guidance and education (2.1.3) and estimated the influence of these interventions (2.2.8 & 2.2.10). Furthermore, the external evaluation results showed that the system is acceptable and desirable not only by older adults, but also, by informal and formal caregivers, researchers, IT professionals and commercial stakeholders (3.4.2).

With regard to TOs, the FrailSafe system is operated by software and hardware components which were optimized multiple times during the study and will be also, improved in future efforts in order to comply with user needs and newest technological advances (3.4.1). The components operate together to offer a simple, acceptable and ethically compliant system (3.4.2). In addition, the system is monitoring multiple health parameters, such as nutritional, medical, cognitive, behavioral, psychological, social and physical at the same time assisting healthcare professionals in decision making processes via the DSS feature (2.1.4). Furthermore, deep learning machine technics contributed in the development of efficient algorithms for activity classification, risk detection and signal management (3.4.1, 2.2.1-2.2.6). Also, an individual user profiling was incorporated in the FrailSafe system, the VPM, which can feed data to dynamic adaptable games and guide interventions and alerts. Based on the personalized profiling, users can receive individually fitted health improvement suggestions (2.1.3 & 3.4.1). The VPM and DSS features accompanied by the Frailty Index are able assess frailty levels, detect frailty risks and trigger alarms in case of emergency situations (e.g., fall, loss of orientation, incoherent utterances or suicidal manifestations in written text) based on minimal processing of real-time multi-parametric streaming data and economical personalized monitoring (2.2.1-2.2.6). Furthermore, frailty detection and prediction can be based on a minimal number of sensors and parameters (2.2.1-2.2.6) to ensure cost-effectiveness and adherence to system usage. Added to that, dynamic adaptable games (3.4.1) were developed in the context of the FrailSafe study which feed on information on behavioral, cognitive and physical status of users while implementing various intervention strategies (2.2.8). AR games are part of the integrated FS system and were evaluated along with all other components in the testing and evaluation tasks (3.4.1 & 3.4.2). Also, the FrailSafe integrated system was evaluated in several validation scenarios while ensuring compliance with ethics standards (3.4.1 & 3.4.2).

Finally, D7.4 shows that we achieved the success indicators of WP7 as set in Grant Agreement. More specifically, we identified four novel biomarkers and frailty metrics (2.2.1-2.2.6) and the majority of users gave positive feedback on the FrailSafe system regarding its innovativeness acceptability and helpfulness (3.4.2). Also, the participation of users to events, social media, evaluation procedure and other dissemination activities outreached our initial expectations which shows that the impact of the system was greater than initially expected.

4. SOCIOECONOMIC IMPACT EVALUATION

The socioeconomic impact evaluation was a three-step approach in order to obtain a comprehensive perspective of outcomes. At first, we performed an extensive literature review to describe the background of frailty in Europe and FrailSafe system's position in it, as well as, its potential health, social and economic benefits. The second part refers to the results of the socioeconomic impact ratings of the FrailSafe system by community members to explore if community opinions are in line with the potential identified by literature review. Lastly, an empirical analysis via the MAFEIP tool was performed to further support the cost-effectiveness and impact of the FrailSafe system.

4.1 Background study

Frailty is a clinical syndrome associated with limitations in multiple health domains, such as malnutrition, muscle weakness, instability and inability to perform activities of daily living. Many scholars have proposed that frailty is linked to the functional reserve of an individual, usually refered to as intrinsic capacity (WHO, 2017). This theory stems from the observation that minor adverse events (i.e., a fall) have disproportionate affects in certain individuals (Clegg et al., 2013). Finally, frailty is linked to increased levels of dependency and high mortality rates (Fried et al., 2001).

To date, early diagnosis of frailty is challenging in modern clinical settings. Firstly, due to its multiparametric and insidious affect, early detection of frailty can only be performed through the frequent evaluation of multiple health parameters, i.e., nutritional, cognitive, physical and medical (Fulop et al., 2010) which poses a significant financial burden for the older person and family members, as well as, public healthcare. Secondly, clinicians have not yet reached a consensus on the absolut clinical determinants of frailty (Ensrud et al., 2009; Wick, 2011) or the most appropriate tools to assess it, which further hinders its early detection and effective management. Lastly, there are only few available instruments available to assess the frailty phenotype which are, usually, administered when the syndrome has significantly progressed and its clinical manifestations are eminently obvious. The most popular among those tools is the five criteria scale proposed by Fried and coworkers (2001) which is considered a reliable measure to assess frailty and is being widely used in many countries.

According to European statistics, the increasing percentage of people aged 65, which is expected to double till 2060 (Lanzieri, 2011) and the high prevalence of frailty are associated with significant health, social and economic costs both at personal and public level. This makes it is an imperative for new measures to be developed utilizing cutting-edge technology to address this medical and societal challenge. The FrailSafe system proposes an effective, innovative, multiparametric and acceptable solution for older adults and healthcare professionals to predict, assess, prevent and manage effectively frailty, thus filling a gap in clinical practice.

Also, according to recent literature, disability and frailty in people aged 65+ constitute a public health issue. In fact, 22% of people aged 65 and over report that their health is fair or poor (Sawyer & Sroczynski, 2017), 40% among them report limitations in performing household activities, and more than two thirds report having moderate or severe functional limitations (Eurostat, 2018). Added to that, frailty is associated with increased costs for acute and long-term care. For example, research shows that falls affect one out of three people 65+ years old and nearly one out of two people over 80 years old (Stalenhoef, Crebolder, Knottnerus, & van der Horst, 1997). Studies also support the fact of reduced life quality and higher mortality rates after fall-related injuries (Muscedere et al., 2017). Except for the cost of acute treatments, research shows that frail patients are more likely to become institutionalized thus increasing the costs

for residential and long-term care (Muscedere et al., 2017). According to the 2009 Ageing report, healthcare and long-term care expenditure is expected to increase by about 2.4 percentage points of GDP by 2060 (European Commission, 2009). Added to that, curative and rehabilitative care costs are accounting to more than half of the total health expeditures for most member states and long-term care nearly to one fourth of many member states (i.e., Belgium, Netherlands, Luxemburg) (Eurostat, 2018). However, research shows that the expediture for long-term care is underestimated as informal caregivers usually provide care services for older adults in an unpaid manner, which of course has also adverse implications for the economy, as well. For example, research suggests that if informal care costs were estimated, care for older adults would add up to a great share of total GDP (Mayhew, 2000). Added to that, research shows that informal care is not a service public care should continue to count on, as 32% of older adults and 45% of the very old population live alone (Casey, 2002); a percentage subject to increases considering the modern changes in families and the increased rates of mobility recorded in the EU. The impact is also observable in pensioning systems (as people retire earlier) and healthcare provision, because they are in need of more and pricier healthcare services.

Considering the aforementioned pressing facts, there is an imperative need for healthcare products which would prevent, predict and delay the progression of disability and frailty. In fact, a report by European Commission suggests that expediture for healthcare is closely dependant to technological progress as new devices can suggest more efficient, innovative and cheaper in the long term methods to prevent health deterioration (Casey, 2002).

In addition, it is undoubtable that, except for the public cost, increased needs for healthcare services pose a significant burden for older adults, as well. Research shows that spending for care services, skilled nurses, medication and residential care tends to increase rapidly by age and peaking around 92 years (Sawyer & Sroczynski, 2017). Consequently, increasing needs for doctor visits, medications and examinations bear a considerable cost and thus, people may avoid expenses deemed unnecessary by them. Hence, in many cases frailty remains undiagnosed and so are significant other health diseases. In fact, according to statistics, people 65+ have average less income than younger people and this tends to further decrease with age (Casey, 2002). Only in 2008, approximately 17% of older adults in Europe lived below the threshold of poverty (Wolff, 2010). The difficulty of communication between healthcare professionals and institutions in modern healthcare and the absence of interoperability of services, further hinders effective diagnosis and treatment of diseases and increases the personal costs. In fact, data indicates that 20-50% of older adults in the EU have never had a blood cholesterol measurement and approximately 500000 deaths could be preventable if there were better healthcare systems (Eurostat, 2018). Heart diseases, cancer, hypertension and pneumonia are the lead causes for preventable deaths (77% of the total amenable mortality rates) which could be prevented by more intensive and effective monitoring (Eurostat, 2018). For example, circulatory diseases are still the main causes of death and hospitalizations among people aged 65+ in the EU (Buchow, Cayotte, & Agafitei, 2012). Circulatory diseases commonly stem from accumulating preventable health deviations, such as a high BMI, smoking, undiagnosed hypertension, etc. Providing continuous monitoring would enable older adults to get recommendations about such deviations and prevent them from accumulating. FrailSafe system can provide early identification of health related disorders and frailty transition thus, prevent health deterioration early on, preserving independency and reducing mortality rates.

It seems logical that older adults' quality of life is significantly affected by the health deterioration and uneffective treatment, as well. The prevention of decline early on promotes independence and inclusion in social activities for further time. Added to that, the use of the FrailSafe system

does not prohibit older adults from performing their everyday activities and hence, it does not interfere with their social interactions. On the contrary, several users stated that throught their participation they gained IT literacy and familiarized with technological devices. This enabled them to be included in conversations with younger members of their family and perform activities together. Using a technological device which can take care of them individually offers feelings of confidence, reassurance and safety while promoting activity and healthy lifestyle choices. Except for the aforementioned advantages of identifying and managing health disorders early on, there is a significant employment benefit for the society resulting from active and healthy aging. According to the EU Labour Force Survey, 23% of people aged 60-64 years old and 10% of people aged 65+ are still in the workforce (Casey, 2002). This implies that aged population contributes to employment and financial competitiveness of the EU which is significantly compromised by disability and frailty prevalence later in life. Older people must be active and autonomous to participate in labour and be socially engaged. Keeping older adults active for as long as possible is one of the pillars of the EUs agenda. However, till new solutions are adopted instead of traditional and obsolete measures disability will still continue to increase at a higher pace than in the past.

A Eurobarometer study (European Commission, 2011) revealed that 70% of the European citizens aged 15+ belive that older adults have a major role in society and efforts should be focused on promoting their active and healthy aging. Similarly, 71% of the responders stated that people aged 55+ play a significant role in politics by voting and participating in political activities. Being socially active except for boosting older adults sense of self-worth and competence has great benefits for the society at large. For instance, in modern society the vast majority of active older adults offer great support in families by participating in child caring and housekeeping. Furthermore, a great share of older adults participate actively in charity organizations, business associations and clubs which promotes growth, connection of generations and knowledge sharing. Participation in social activities increase feelings of social inclusion and decreases isolation and depression among older adults. A survey conducted in 2007 showed that approximately one out of ten elderly responders felt being left out of the society. Also, recent research shows that frailty is associated with low mental and physical health-related quality of life (Chang et al., 2012)

Except for the person, the FrailSafe system is expected to promote psychological well-being for family members as well. Family caregivers bear significant emotional burden as they observe their parents health deterioration and decline. Also, they have feelings of uncertainty when their parents live far or alone. The FrailSafe system offers continuous monitoring and alerts in case of adverse events promoting feelings of confidence and safety among caregivers. The financial consequences to families of providing informal care are substantial. An important cause of these financial consequences is lost or reduced employment of caregivers (Covinsky et al., 2001)

Benefits can be seen for healthcare professionals and formal caregivers as their practice can become more efficient and quick. Professionals can record at any time their patients' vital signs and can avoid unnesecary visits for examinations and, also make effective prescribing and alterations in medication list which has benefits for the patients themselves. Reseach shows that prescription of multiple drugs can have undesirable adverse events such as dizziness which are associated with falls thus contributing to the problem of hard outcomes associated with frailty (Stockl, Le, Zhang, & Harada, 2010). Researchers can also identify new frailty patterns further promoting research activities and ability to tackle frailty.

4.2 Results from questionnaires

Significant socioeconomic benefits of the FrailSafe system were identified by all community members (including university students, family members, healthcare professionals, researchers, commercial stakeholders and caregivers) who participated in the socioeconomic evaluation. Responders stated that the FrailSafe system could promote a healthier lifestyle for older adults and give the patient a more central role in health management. Furthermore, on average users stated that the FrailSafe system would contribute significantly in improving current healthcare systems by enhancing care for remote or critically ill patients, reduce waiting times and inefficiences and promote intracommunication between healthcare professionals. Further details on the health benefits of the FrailSafe system vcan be found in Figure 74.

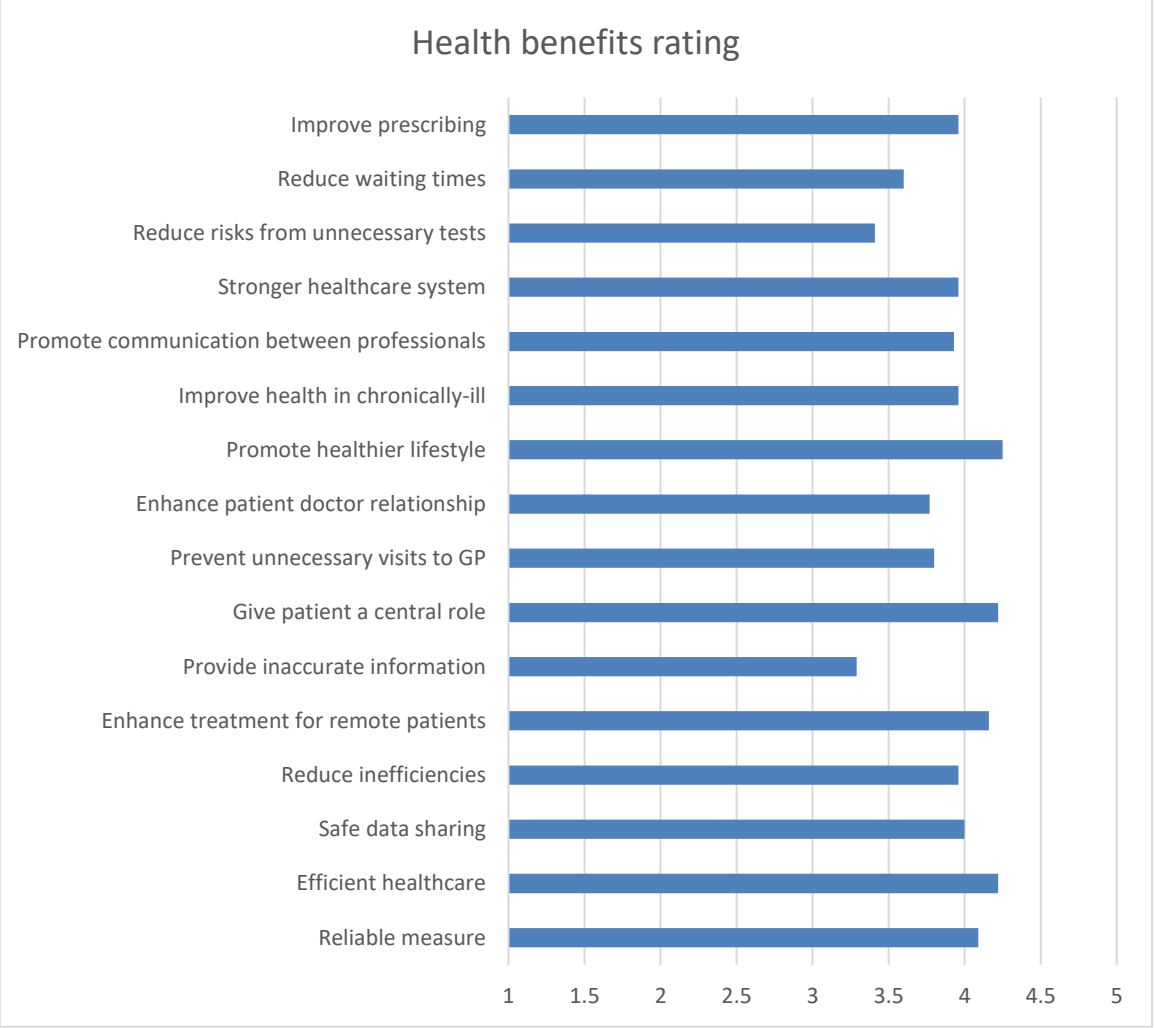


Figure 74. Socioeconomic impact analysis: Health

Participants also reported significant financial benefits stemming from the use of the FrailSafe system, such as reduction of private and public cost, the enhancement of revenues in healthcare and the contribution in job creation and growth of certain industries. More information can be found in Figure 75.

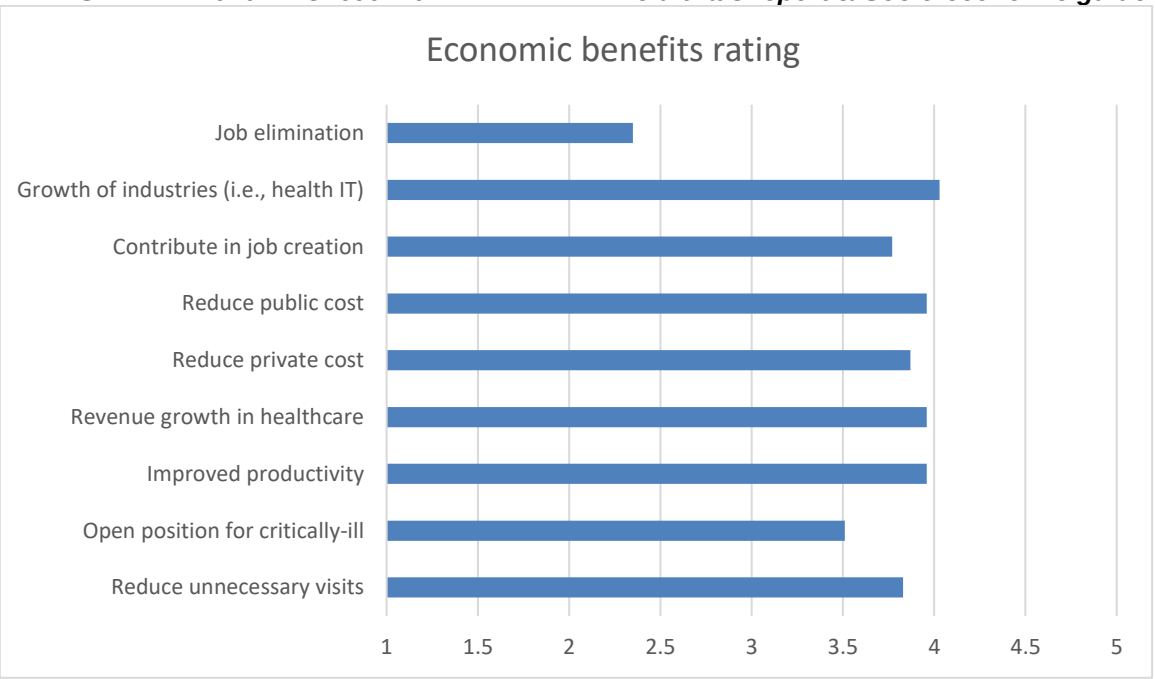


Figure 75. Socioeconomic impact analysis: Economy

Finally, responders rated highly the potential impact of the FrailSafe system in society. In detail, they rated highly the contribution of the system in innovation promotion, social inclusion and boosting of IT literacy skills among older adults and keeping older adults active. More information can be found in Figure 76.

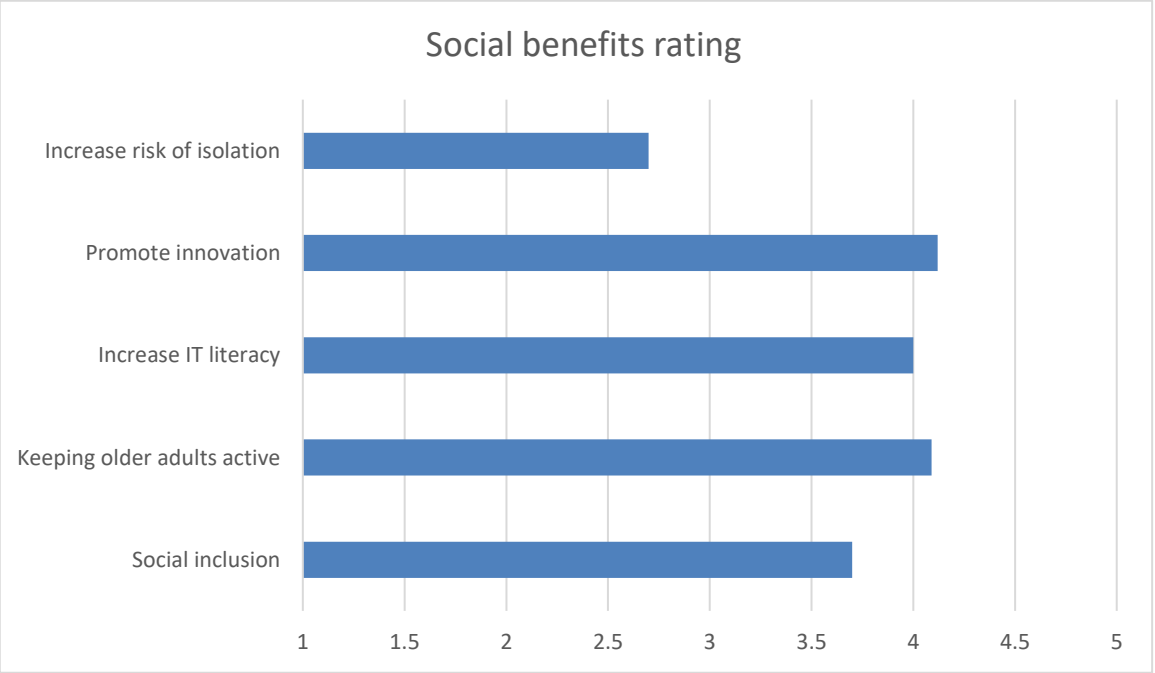


Figure 76. Socioeconomic impact analysis: Society

To sum up ,analysis of the results shows that users rated highly the impact of the FrailSafe system in health, economy and society at large, with health and financial benefits being the central focus of their views. A comparative view of the results can be found in Figure 77.

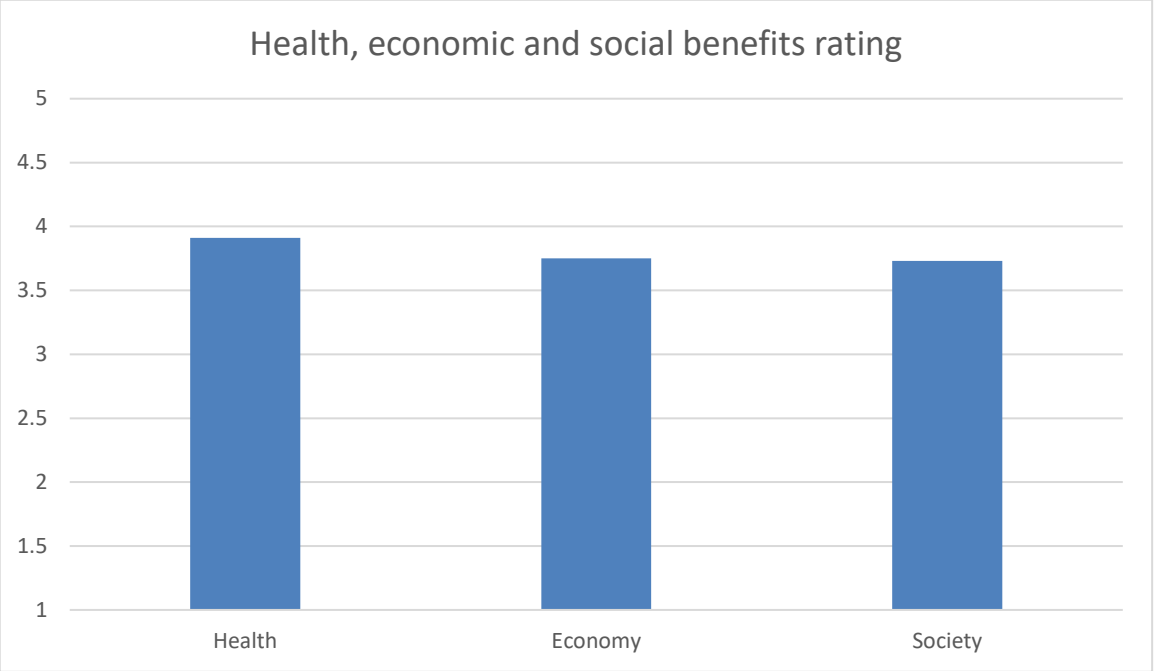


Figure 77. Socioeconomic impact analysis: Total rating

4.3 MAFEIP tool

For the calculation of cost-effectiveness of the FrailSafe system in short and long-term we adopted a health and a societal perspective analysis through the MAFEIP tool. The methodology underlying this calculation was a three-step approach: a) defining relevant cost categories, b) estimating frequency and resources devoted to each category per person, annually, depending on frailty state. For the health sector, the cost categories considered were annual GP visits, outpatient visits, surgeries, medication costs, etc. The societal cost was considered by adding additional societal expenses to the total expenses for the health sector, such as environmental costs and costs for informal caregivers.

The estimation of healthcosts associated with frailty was challenging as there are very few studies and data available in relation to the evolution of costs with the progression of frailty. Two of the very few (Bock et al., 2016; Sawyer & Sroczynski, 2017) showed that healthcare costs increase 12.41-50.32% from non-frail to pre-frail while the increase amounts to 60.27-82.45% from non frails to frails. Pricing of components was based on Cypriot-Greek data obtained by the general knowledge on pricing system and Materia Group' s and its strategic partner's in Greece, Aktios, available databases. The prices were cross-validated with regards to application to other European countries as well, i.e., the Netherlads (Ruikes et al., 2018; Simpson et al., 2018), in order to obtain more representative and generalizable results.

Hence, we estimated the costs per year at baseline from our databases and using the average rate of cost increase derived from literature review, we increased these costs for 31.36% for the transition to pre-frail status and 71.36% for the transition to frail status (utilizing the average cost increase stemming from literature data described above). The quantifiable effect of the Frailsafe system in percentage of benefits for the intervention group was based in the analyses described in section 2.2.8. In particular we estimated that since the FrailSafe system has a 17% estimated benefit in cognitive ability, 21% estimated benefit with regards to gait speed and 15% marginal estimated benefit with regards to everyday functioning, it has an overall 18% estimated average health benefit, which was used as a criterion for our calculations.

Guided by this methodology, the costs in baseline were calculated for standard care and for care with the integrated FrailSafe system (Table 39).

Table 39. Socioeconomic impact analysis: Health cost calculation per patient at baseline-non frail state (intervention/control)

	Health costs							
NON-FRAIL	**CONTROL GROUP**	**FREQUENCY**	**COST/ITEM**	**TOTAL**	**INTERVENTION GROUP**	**FREQUENCY**	**COST/ITEM**	**TOTAL**
	Emergency department visits	0.25	7	1.75	Emergency department visits	0.20	7	1.43
	GP visits private	5.00	50	250.00	GP visits private*	5.00	50	250.00
	Hospital admissions	0.12	2000	240.00	Hospital admissions	0.09	2000	196.80
	Medications	3.00	16	48.00	Medications	2.46	16	39.36
	Occupational therapy	0.00	30	0.00	Occupational therapy	0.00	30	0.00
	Chiropody	2.77	20	55.40	Chiropody	2.27	20	45.42
	Physiotherapy	2.04	30	61.20	Physiotherapy	1.67	30	50.18
	Speech therapy	0.00	30	0.00	Speech therapy	0.00	30	0.00
	Social work (post retirement support loss of prof role)	0.19	30	5.70	Social work	0.15	30	4.67
	Psychological/cognitive therapy	0.28	40	11.20	Psychological/cognitive therapy	0.22	40	9.18
	Daycare center	0.00	30	0.00	Daycare center	0.00	30	0.00
	Optician	1.00	40	40.00	Optician*	1.00	40	40.00
	Dental	4.00	40	160.00	Dental*	4.00	40	160.00
	Hearing	0.50	40	20.00	Hearing*	0.50	40	20.00
	Dietician	1.80	40	72.00	Dietician	1.47	40	59.04
	Homecare	0.00	30	0.00	Homecare	0.00	30	0.00
	Respite	0.00	100	0.00	Respite	0.00	100	0.00
	Surgeries	0.30	3000	900.00	Surgeries	0.24	3000	738.00
	Assistive (wheelchairs, hearing aids, glasses)	0.80	500	400.00	Assistive (wheelchairs, hearing aids, glasses)	0.65	500	328.00
					Purchase of FrailSafe system	1.00	250	250.00[12]

[12] 250 euros is the estimated cost for the purchase of the basic FrailSafe package with at least a three-year useful life. However, it should be noted that considering depreciation the annual cost of owning the FrailSafe system is even lower; estimated at 250:3=83.33 euros annually.

					Annual subscription	12	20	240.00
Total cost/year				**2265.25**				**2432.10**
*No decrease is expected on indicated cost components as the notifications of the FrailSafe system might increase visits for consultation.								
ESTIMATED COSTS FOR OTHER FRAILTY STATES								
	PRE-FRAIL	2975.30		**2591.74**				
	FRAIL	3881.73		**3448.95**				

The costs are calculated at an individual level but are estimated to be much higher in terms of public healthcare expediture, considering working hours, costs for equipment, etc. Hence, at baseline the costs are estimated at 2265.25 euros for standard care and 2432.10 for care with the FrailSafe system. Hence, innovative model of care will have an added cost of 167 euros for the first year which is affordable considering the future benefits in health monitoring and improvement of health status for the patients.

Based on our data, the costs for standard care in baseline were expected to increase by 31.36% (cost increase rate) with the transition to pre-frail state and 71.36% (cost increase rate) with the transition to frail state. Hence, for standard care the costs are expected to be raised at 2975.30 euros for prefrail and 3881.73 euros for frail adults. However, in the innovative care model we are expecting a 18% improvement of health status on average annually (based on the proof of concept study results). Hence, the progression of disease and costs is expected to be delayed and the frequency of consumption of most cost components to decrease.

Thus, including the improvement parameter, the costs for healthcare in the intervention group with the transition to pre-frail status were calculated according to the following equation.

costs of innovative care in other frailty statuses = [baseline costs of innovative care-baseline costs * improvement rate] * [1+ cost increase rate per frailty status] + cost of subscription in the FrailSafe system.

It should be noted that the cost of purchase and cost of subscription in the FrailSafe system were subtracted from the baseline costs before the analysis with the equation mentioned above. Only the costs for subscription were added in the calculated number, amounting to an estimate of 20 euros per month in baseline, 40 euros per month in pre-frail and 60 euros per month in frail status.

Hence, the costs of the innovative model in the prefrail status are estimated at [(1942.10-349.57)] + [(1942.10-349.57)* 31.36%] + 600=1592.53 + 499.41 + 480= 2571.94 euros. The analysis showed that in pre-frail status the use of FrailSafe system can reduce the healthcare costs by 403.36 euros compared to standard care. Similar results were obtained for the frail state using 18% improvement rate and 71.36% increase of costs rate. The results showed that the FrailSafe system solution is cheaper than standard care for the transition to frail status, as well (3448.95 euros) and in fact, costing 432.78 euros less than standard care.

Consequently, the societal costs were calculated by adding the additional social expenses (Table 40) to the baseline costs for each group, as calculated in Table 39. For standard care the costs for each frailty status were calculated according to the following equation

Societal costs for standard care = (social costs+health costs)* cost increase rate per state

and were amounting to 6402.35 euros for pre-frail state and 8351.91 euros for frail state annually. Similarly, with the previously stated methodology, costs for the FrailSafe solution were calculated according to the equation described above, thus, amounting to 2985.99 for the pre-frail and 4049.08 for the frail state. The results show that the FrailSafe system is a cost-effective tool, especially, from a societal perspective.

Table 40. Socioeconomic impact analysis: Additional social costs (intervention/control)

SOCIAL COSTS							
CONTROL GROUP	**FREQUENCY**	**COST/ITEM**	**TOTAL**	**INTERVENTION GROUP**	**FREQUENCY**	**COST/ITEM**	**TOTAL**
Mental support for caregivers/family members	0	60	0	Mental support for caregivers/family members	0	60	0
Medical bills for caregivers/family members	0	40	0	Medical bills for caregivers/family members	0	40	0
Social security benefits	0.25	250	62.5	Social security benefits	0.205	250	51.25
Housekeeper costs	52	20	1040	Housekeeper costs	52	20	1040
Environmental cost of medical waste	0	50	0	Environmental cost of medical waste	0	50	0
Special diet products	0.4	16	6.4	Special diet products	0.328	16	5.248
Transportation	300	5	1500	Transportation**	300	4.1	1230
				Purchase of FrailSafe system	1	250	250
				Annual subscription	12	20	240
			2608.90				**2816.49**

** Transportation costs are not expected to decrease in frequency in the intervention group but in terms of cost since more active adults tend to use more affordable transportation (walking, taking the bus, etc.)
*The indicated components are considered to have a benefit for the society since older adults' employment and spending on leisure activities benefit the society

All aforementioned results were fed into the MAFEIP tool using the 3-state Markov model. Three types of outputs[13] were generated from the tool and incorporated in this report to interpret the socioeconomic analysis results. The first output described the incremental costs and health-related quality of life effects of the FrailSafe solution per age-gender combination. The second output described the average incremental gains per person with regards to economic and health outcomes (incremental cost and effects) and the third, the FrailSafe system's impact in a population-level

The incremental costs output is generated by calculating the costs of a person of a specific age and gender following the FrailSafe solution minus the costs of the same person if they followed the standard healthcare. The undiscounted results show that the FrailSafe system is a significantly cost-saving solution, especially, till the age of 80 for women and 77 for men (Figure 78).

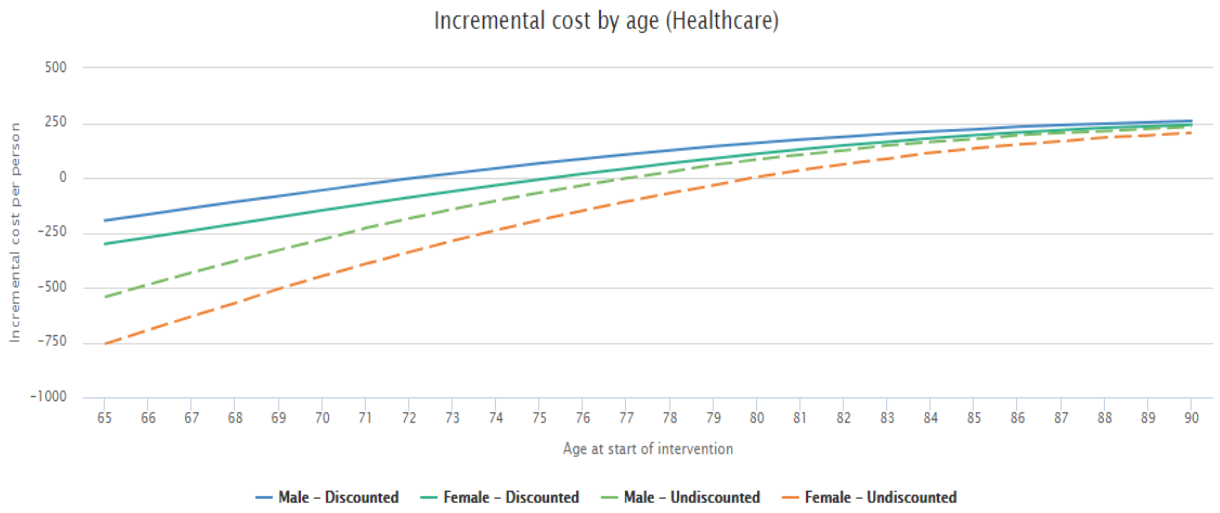


Figure 78. Socioeconomic analysis: Incremental cost by age

Similarly, the incremental effects output describes how much quality of life is gained when the FrailSafe system is used instead of the standard care. Figure 79 shows that older adults have a gain in health-related life quality by using the FrailSafe solution compared to standard care, especially till the age of 74 for males and 77 for females (undiscounted values).

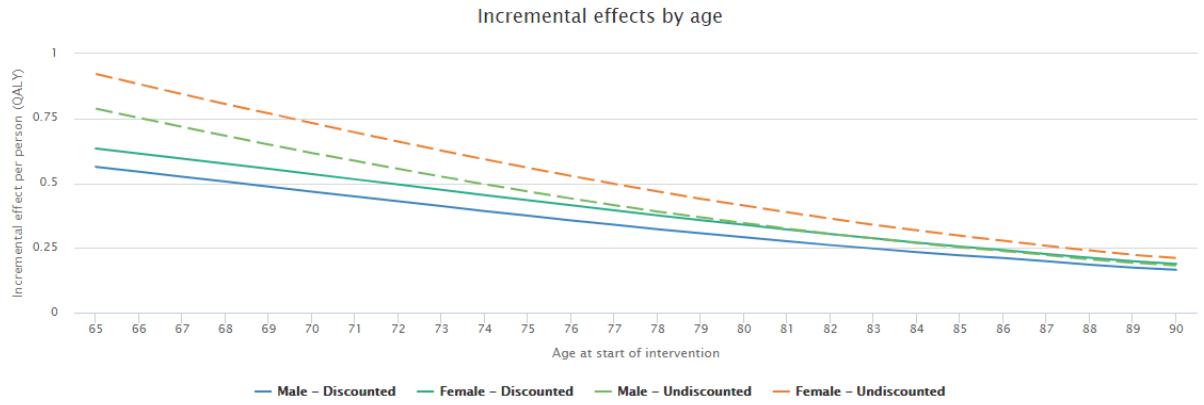


Figure 79. Socioeconomic impact analysis: Incremental effects by age

[13] https://tool.mafeip.eu/assets/files/MAFEIP_User_Guide_v2_Website.pdf

The next output refers to the overall impact of the intervention on healthcare/societal cost and quality-adjusted life years (QALYs) for the total target population. The results represent the average outcome per patient across all age-gender combinations. The interpretation of Figure 80 shows that the FrailSafe system's benefits in terms of costs and QALYs categorise it as a dominant product (see Figure 81 for the interpretation legend) in market. Regarding healthcare, the quadrant interpretation shows that the FrailSafe system is better than current practice but are inconclusive regarding its cost-effectiveness (if it is better and cheaper or better but more expensive). On the contrary, taking under account the total costs for care (health and societal), the analysis showed that the FrailSafe system is significantly cheaper than standard care (Figure 82). Willingness to Pay (WTP) denotes the maximum amount of money that a patient would be willing to pay to achieve a better quality of life. In both plots (healthcare and societal) the FrailSafe system stands in the affordable side (below the threshold) indicating that patients would purchase it to achieve a better quality of life.

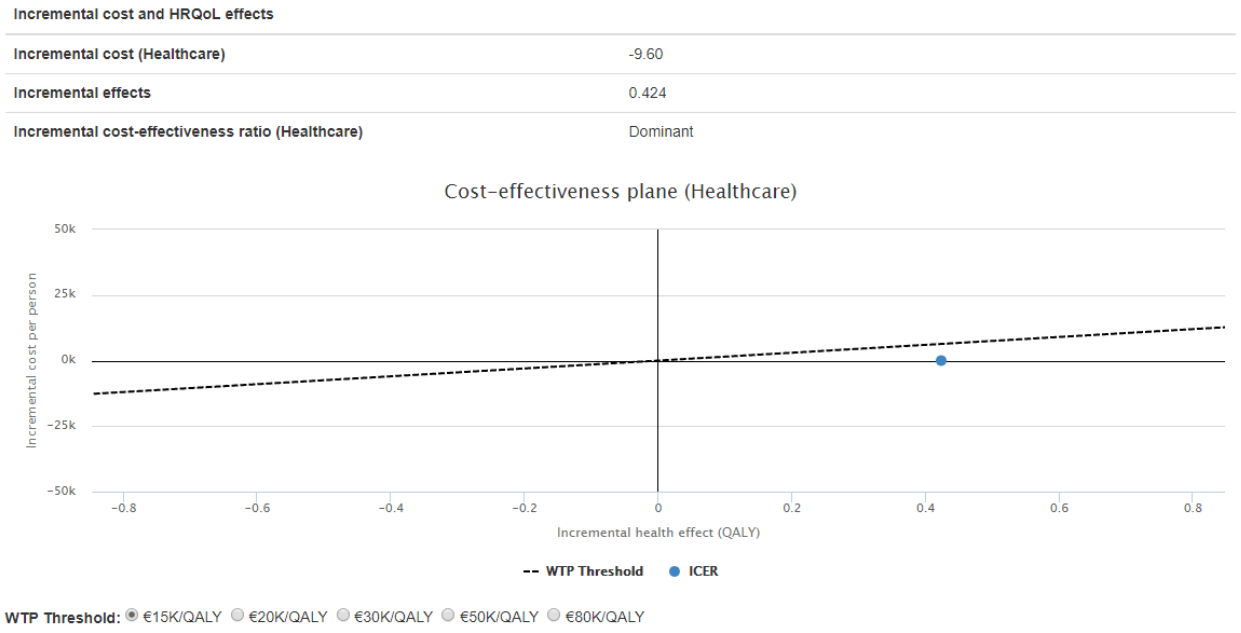


Figure 80. Socioeconomic impact analysis: Cost-effectiveness plane (healthcare)

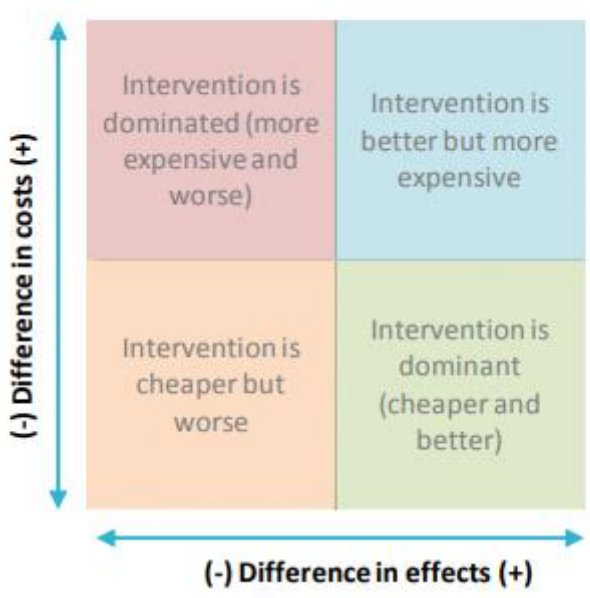


Figure 81. Socioeconomic impact analysis: Interpretation of quadrants

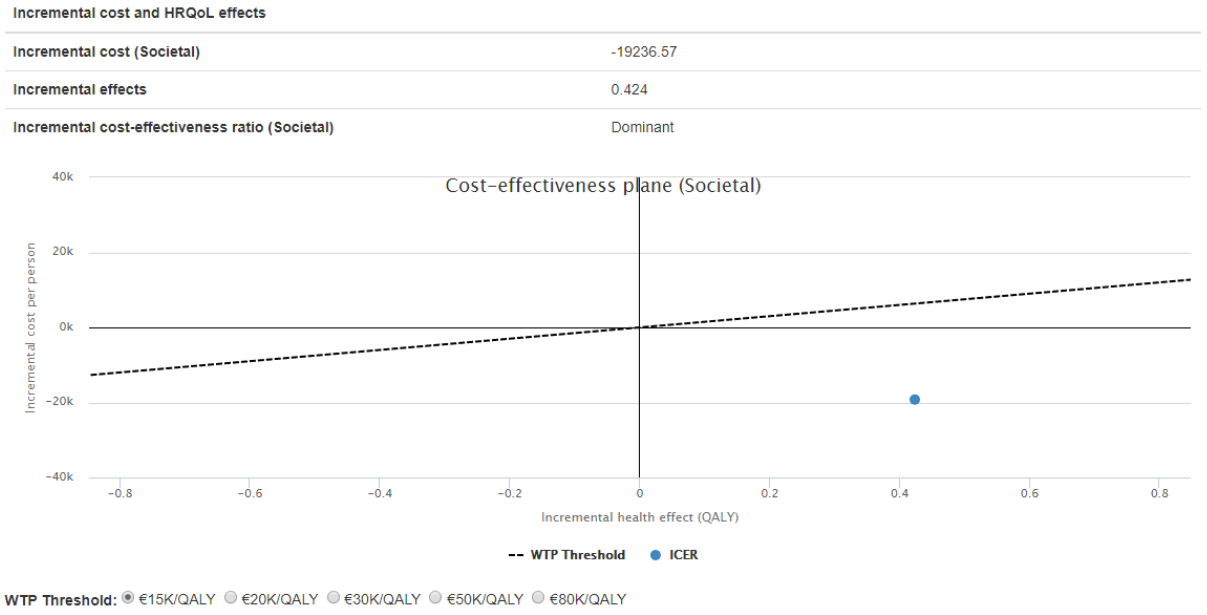


Figure 82. Socioeconomic impact analysis: Cost-effectiveness plane (societal)

Finally, the last outputs show how the incremental costs and effects (QALYs) are accumulated over the model time horizon (50 years) for the whole population. Hence, interpretation of Figure 83 shows that regarding healthcare costs, the FrailSafe system starts with a minor peak in costs for the person which, however, decrease progressively and continuously over the course of 35 years. After this timepoint the costs remain steady but are still significantly lower than the initial cost.

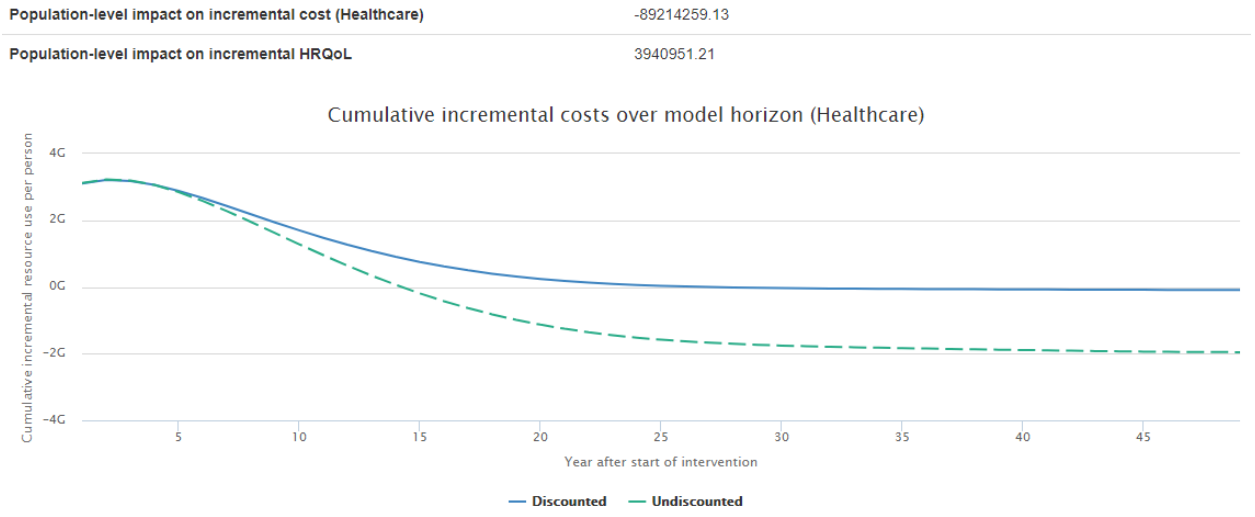


Figure 83. Socioeconomic impact analysis: Cumulative incremental costs

Finally, positive results were identified for the incremental effects of the FrailSafe study, as well, over the course of 50 years. In detail, the use of FrailSafe system instead of standard care has a continuously increasing benefit on QALYs for 25 years for undiscounted values and 22 years for discounted values. After that timepoint, the benefits on QALYs remain steady but are still significantly higher than the initial benefit (Figure 84).

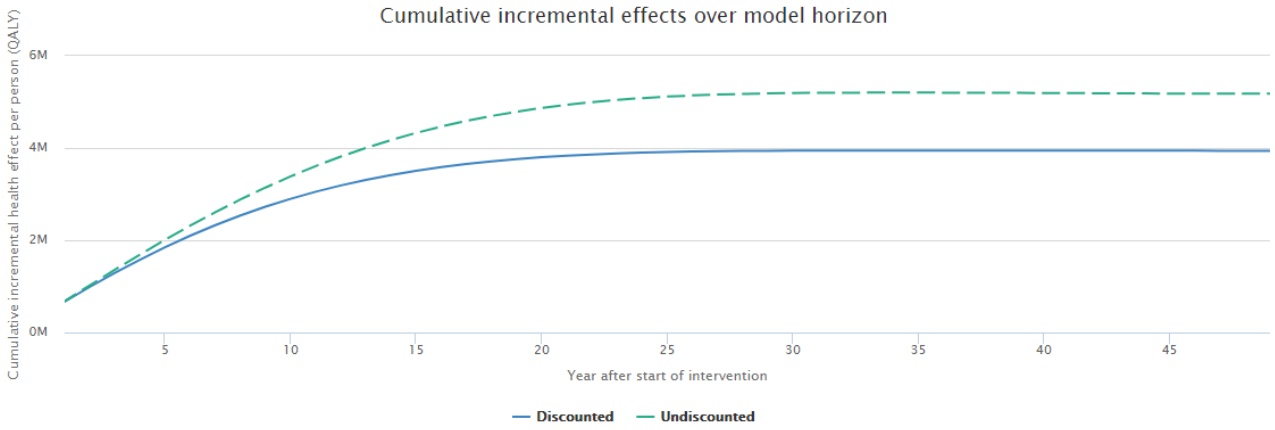


Figure 84. Socioeconomic impact analysis: Cumulative incremental effects

In conclusion, the socioeconomic impact analyses showed that there is an imperative in current healthcare to tackle frailty and enhance active aging and health quality in old age. Addressing this challenge would result in a significant benefit for healthcare, society and economy, as it would increase efficiency in health practises, decrease costs at a personal and public level, enhance life quality, social inclusion, feelings of confidence among older adults and also, relieve caregivers from a significant financial and psychological burden. The results of our analyses showed that the aforementioned benefits of the FrailSafe system are supported by community members. Finally, the socioeconomic analysis through the MAFEIP tool showed that FrailSafe is a cost-effective and dominant solution which is better and cheaper than standard care, especially, taking under account both health and societal costs of aging and disability. The benefits of the FrailSafe system in cost-saving and QALYs are further increased if viewed from a 50-year course perspective, when the solution seems to result in a significant and continuous decrease in costs for up to 35 years and a continuous increase in life-quality for up to 25 years.

5. DISCUSSION

WP7 performed a comprehensive assessment of the FrailSafe system, an innovative solution to tackle the immense challenge of frailty in modern healthcare. The evaluation aimed to explore the acceptability, utility, reliability and desirability of the FrailSafe system, identify the challenges in the implementation and exploitation of the solution, as well, as feed the exploitation models and boost their efficacy in the future.

Despite the difficulties in epidemiological studies with older adults, the FrailSafe study managed to include approximately equally distributed participants between groups in terms of frailty and gender. Also, many non-frails were recruited, in order to study the course of the syndrome. Minimal problems were detected with devices in this phase while all system components were fully developed, integrated and evaluated in multiple validation scenarios, both internally and externally. Also, new, quantitative and qualitative, frailty indicators were developed which have an adequate performance accuracy and frailty's relation with comorbidities was extensively explored. Furthermore, the analyses provided evidence that the FrailSafe system can function and provide alerts with a minimal set of components thus, increasing cost-effectiveness and usability. Ultimately, the project met its initial goals, objectives and success indicators.

The six-month proof of concept study revealed that despite the short course of frailty monitoring and implementation of interventions, the FrailSafe system has promising results. The FrailSafe system resulted in significant impact on older adults, as a significant percentage of them stated

that they took health-improvement measures (40.6% consulted their doctors and 71% partially or fully modified their lifestyle) after receiving individualized recommendations. This attitude had an impact in their health status as we observed benefits in frailty transition, gait speed, grip strength, cognitive function and self-reported exhaustion and social activities. A particular effect was identified by playing FrailSafe serious and AR games in several cognitive and physical parameters associated with frailty.

The general view of the results showed that the FrailSafe system is deemed very promising and desirable by all target groups involved in this evaluation. All stakeholders rated that the system provides a holistic solution that would address a significant challenge and a gap in current healthcare. Its social, financial and health implications, extensively discussed throughout the present report, show that the solution could indeed provide a solution profitable for all parties and thus, benefit the society as a whole.

Our study is considered succesful given that in a relatively small period of time (40 months) we developed a holistic health ICT solution, tested it thoroughly and observed impact. However, future challenges in system acceptance are the sample numbers and duration of interventions tested in this study which are inevitably small to provide robust conslusions on the health value of the FrailSafe system. Its effectiveness, reliability and rehabilitative effect have to be extensively tested in real-scenarios and a larger population sample to boost commercialization success and appeal. Robust results and a large-scale study will boost our opportunities for a medical certification, and influence policy makers and other commercial stakeholders into adopting the solution. Of course, several modifications are already envisaged by consortium members to customize the solution and make it more appealing to users and further testing activities are currently performed at Materia, Cyprus.

6. FUTURE IMPLICATIONS

The results of the present deliverable offered valuable insight on future activities and strategies to be employed by the FrailSafe consortium. The future implications are related both to optimization of the system and to exploitation, dissemination and further validation strategies.

Firstly, users highlighted the need for the availability of more customised options for the vest equipment and enhancement of durability (i.e., water resistance) of RUSA devices. Also, users highlighted the importance of providing applications (GPS app, serious games) which would be compatible with multiple gateways and operating systems. Furthermore, an issue was, also, detected with the wireless dynamometer provided in the context of the present study, due to connectivity difficulties. Lastly, other improvement suggestions included the provision of back-up strategies to ensure continuous and reliable monitoring for older adults and the optimization of platforms, in terms of visibility and acceptability (i.e., font-size, picture-size and multilingual options).

All aforementioned improvement suggestions are feasible and are taken under careful consideration by technical teams and are, already, or will be implemented in the near future. Apart from that, the system is a priori designed to have high levels of interoperability, in order to be sustainable with the progression of technological advances. For example, GPS and indoor localization apps can be used both with the users' smartphones and other devices, such as smartwatches. The same applies for the game suite which can be modified to be used with tablets, smartphones or other gateways. This shows that the system can be adaptable and adjustable, so that its use will be sustainable in the light of future technological advances.

Another finding that will be utilized in future efforts is the intense need for launching IT literacy awareness campaigns for older adults and family members, in order to empower and enhance their and their family members attitudes towards technology use. The results of our study showed that older adults have amore increased perceived difficulty in using technological devices compared to their actual difficulty, which further supports the need to enhance technology use among older population. Comments provided by Mrs. Mestheneos, such as the engagement of early-adopters and grandchildren in this process, may further boost changes in this direction.

Furthermore, our research showed that elderly adults are motivated to monitor their health status with the FrailSafe system and are compliant with health-improvement suggestions. However, the results showed that their expectations should be redirected to think about the solution only as a complementary tool and not a replacement for healthcare professionals.

Finally, the aforementioned findings, as well as, all stakeholders highlighted the need for further testing and replication of the results of this study in a large-scale experiment. This finding is in line with the consortium's viewpoint as it will allow endorsement of the system by key-opinion leaders and community members, provide robust and replicated results and boost the system's potential to be incorporated both in private and public healthcare settings.

References

Abdel-Rahman, E. M., Mansour, W., & Holley, J. L. (2010). Hypothesis: Thyroid Hormone Abnormalities and Frailty in Elderly Patients with Chronic Kidney Disease: A Hypothesis. *Seminars in Dialysis*, *23*(3), 317–323. https://doi.org/10.1111/j.1525-139X.2010.00736.x

Anastasi, A., & Urbina, S. (1997). *Psychological testing*. Prentice Hall/Pearson Education.

Andrew, M. K., Mitnitski, A. B., & Rockwood, K. (2008). Social vulnerability, frailty and mortality in elderly people. *PloS One*, *3*(5), e2232.

Armstrong, R. A. (2014). When to use the Bonferroni correction. *Ophthalmic & Physiological Optics : The Journal of the British College of Ophthalmic Opticians (Optometrists)*, *34*(5), 502–508. https://doi.org/10.1111/opo.12131

Atkins, S., Odendaal, W., Leon, N., Lutge, E., & Lewin, S. (2015). Qualitative process evaluation for complex interventions BT - Complex interventions in health: An overview of research methods. In D. A. Richards & I. Rahm-Hallberg (Eds.). London: Routledge.

Barbour, R. (2008). *Doing focus groups*. Sage.

Barnard, Y., Bradley, M. D., Hodgson, F., & Lloyd, A. D. (2013). Learning to use new technologies by older adults: Perceived difficulties, experimentation behaviour and usability. *Computers in Human Behavior*, *29*(4), 1715–1724.

Beer, J. M., & Takayama, L. (2011). Mobile remote presence systems for older adults: acceptance, benefits, and concerns. In *2011 6th ACM/IEEE International Conference on Human-Robot Interaction (HRI)* (pp. 19–26). IEEE.

Bertakis, K. D., Azari, R., Helms, L. J., Callahan, E. J., & Robbins, J. A. (2000). Gender differences in the utilization of health care services. *The Journal of Family Practice*, *49*(2), 147–152.

Bock, J.-O., König, H.-H., Brenner, H., Haefeli, W. E., Quinzler, R., Matschinger, H., … Heider, D. (2016). Associations of frailty with health care costs--results of the ESTHER cohort study. *BMC Health Services Research*, *16*, 128. https://doi.org/10.1186/s12913-016-1360-3

Boehler, C. E. H., de Graaf, G., Steuten, L., Yang, Y., & Abadie, F. (2015). Development of a web-based tool for the assessment of health and economic outcomes of the European Innovation Partnership on Active and Healthy Ageing (EIP on AHA). *BMC Medical Informatics and Decision Making*, *15*(3), S4. https://doi.org/10.1186/1472-6947-15-S3-S4

Bouchard, B., Imbeault, F., Bouzouane, A., & Menelas, B.-A. J. (2012). Developing serious games specifically adapted to people suffering from Alzheimer. In *International Conference on Serious Games Development and Applications* (pp. 243–254). Springer.

Brooke, J. (1996). SUS-A quick and dirty usability scale. *Usability Evaluation in Industry*, *189*(194), 4–7.

Buchow, H., Cayotte, E., & Agafitei, L. (2012). Circulatory Diseases–Main Causes of Death for Persons Aged 65 and More in Europe, 2009. *Eurostat Statistics in Focus 7/2012*.

Buckinx, F., Rolland, Y., Reginster, J.-Y., Ricour, C., Petermans, J., & Bruyère, O. (2015). Burden of frailty in the elderly population: perspectives for a public health challenge. *Archives of Public Health*, *73*(1), 19.

Casey, B. (2002). Conditions for Active Ageing at International Level. In *18th CEIES Seminar: Active Ageing Statistics*.

Cesari, M., Landi, F., Vellas, B., Bernabei, R., & Marzetti, E. (2014). Sarcopenia and physical frailty: two sides of the same coin. *Frontiers in Aging Neuroscience*, *6*, 192.

Chang, Y.-W., Chen, W.-L., Lin, F.-G., Fang, W.-H., Yen, M.-Y., Hsieh, C.-C., & Kao, T.-W.

(2012). Frailty and Its Impact on Health-Related Quality of Life: A Cross-Sectional Study on Elder Community-Dwelling Preventive Health Service Users. *PLOS ONE*, *7*(5), e38079. Retrieved from https://doi.org/10.1371/journal.pone.0038079

Clegg, A., Young, J., Iliffe, S., Rikkert, M. O., & Rockwood, K. (2013). Frailty in elderly people. *The Lancet*, *381*(9868), 752–762.

Cooper, C., Fielding, R., Visser, M. V, Van Loon, L. J., Rolland, Y., Orwoll, E., … Epstein, S. (2013). Tools in the assessment of sarcopenia. *Calcified Tissue International*, *93*(3), 201–210.

Covinsky, K. E., Eng, C., Lui, L.-Y., Sands, L. P., Sehgal, A. R., Walter, L. C., … Yaffe, K. (2001). Reduced employment in caregivers of frail elders: impact of ethnicity, patient clinical characteristics, and caregiver characteristics. *The Journals of Gerontology Series A: Biological Sciences and Medical Sciences*, *56*(11), M707–M713.

Crome, I., Brown, A., Dar, K., Harris, L., Janikiewicz, S., Rao, T., … Tarbuck, A. (2011). Our invisible addicts: First report of the older persons' substance misuse working group of the Royal College of Psychiatrists. *London: Royal College of Psychiatrists*, *1*.

Csuka, M., & McCarty, D. J. (1985). Simple method for measurement of lower extremity muscle strength. *The American Journal of Medicine*, *78*(1), 77–81.

D.C., Cetin & G., N. (2014). Obesity in the elderly: more complicated than you think. *Cleveland Clinic Journal of Medicine*, *81*(1), 51.

de Hollander, E. L., Bemelmans, W. J., Boshuizen, H. C., Friedrich, N., Wallaschofski, H., Guallar-Castillón, P., … collaborators, W. C. elderly. (2012). The association between waist circumference and risk of mortality considering body mass index in 65- to 74-year-olds: a meta-analysis of 29 cohorts involving more than 58 000 elderly persons. *International Journal of Epidemiology*, *41*(3), 805–817. https://doi.org/10.1093/ije/dys008

Dent, E., Chapman, I., Howell, S., Piantadosi, C., & Visvanathan, R. (2013). Frailty and functional decline indices predict poor outcomes in hospitalised older people. *Age and Ageing*, *43*(4), 477–484.

Drost, E. A. (2011). Validity and reliability in social science research. *Education Research and Perspectives*, *38*(1), 105.

Ensrud, K. E., Ewing, S. K., Cawthon, P. M., Fink, H. A., Taylor, B. C., Cauley, J. A., … Cummings, S. R. (2009). A comparison of frailty indexes for the prediction of falls, disability, fractures, and mortality in older men. *Journal of the American Geriatrics Society*, *57*(3), 492–498.

Folstein, M. F., Robins, L. N., & Helzer, J. E. (1983). The mini-mental state examination. *Archives of General Psychiatry*, *40*(7), 812.

Fountoulakis, K. N., Tsolaki, M., Chantzi, H., & Kazis, A. (2000). Mini mental state examination (MMSE): a validation study in Greece. *American Journal of Alzheimer's Disease*, *15*(6), 342–345.

Fried, L. P., Hadley, E. C., Walston, J. D., Newman, A. B., Guralnik, J. M., Studenski, S., … Ferrucci, L. (2005). From bedside to bench: research agenda for frailty. *Science's SAGE KE*, *2005*(31), pe24.

Fried, L. P., Tangen, C. M., Walston, J., Newman, A. B., Hirsch, C., Gottdiener, J., … Burke, G. (2001). Frailty in older adults: evidence for a phenotype. *The Journals of Gerontology Series A: Biological Sciences and Medical Sciences*, *56*(3), M146–M157.

Fulop, T., Larbi, A., Witkowski, J. M., McElhaney, J., Loeb, M., Mitnitski, A., & Pawelec, G. (2010). Aging, frailty and age-related diseases. *Biogerontology*, *11*(5), 547–563.

Gao, M., Kortum, P., & Oswald, F. (2018). Psychometric Evaluation of the USE (Usefulness, Satisfaction, and Ease of use) Questionnaire for Reliability and Validity. In *Proceedings of the Human Factors and Ergonomics Society Annual Meeting* (Vol. 62, pp. 1414–1418).

SAGE Publications Sage CA: Los Angeles, CA.

Guigoz, Y., & Vellas, B. (1999). The Mini Nutritional Assessment (MNA) for grading the nutritional state of elderly patients: presentation of the MNA, history and validation. In *Nestle Nutr Workshop Ser Clin Perform Programme* (Vol. 1, pp. 3–11).

Hayhurst, J. (2018). How augmented reality and virtual reality is being used to support people living with dementia—Design challenges and future directions. In *Augmented Reality and Virtual Reality* (pp. 295–305). Springer.

Herr, M., Robine, J., Pinot, J., Arvieu, J., & Ankri, J. (2015). Polypharmacy and frailty: prevalence, relationship, and impact on mortality in a French sample of 2350 old people. *Pharmacoepidemiology and Drug Safety*, *24*(6), 637–646.

Hoover, M., Rotermann, M., Sanmartin, C., & Bernier, J. (2013). Validation of an index to estimate the prevalence of frailty among community-dwelling seniors. *Health Rep*, *24*(9), 10–17.

Hubbard, R. E., Searle, S. D., Mitnitski, A., & Rockwood, K. (2009). Effect of smoking on the accumulation of deficits, frailty and survival in older adults: a secondary analysis from the Canadian Study of Health and Aging. *JNHA-The Journal of Nutrition, Health and Aging*, *13*(5), 468–472.

Joint National Committee on Prevention Evaluation, and Treatment of High Blood Pressure, D., & Committee, N. H. B. P. E. P. C. (1997). The sixth report of the Joint National Committee on Prevention. Detection, Evaluation, and Treatment of High Blood Pressure. *Arch Intern Med*, *157*, 2413–2446.

Joosten, E., Demuynck, M., Detroyer, E., & Milisen, K. (2014). Prevalence of frailty and its ability to predict in hospital delirium, falls, and 6-month mortality in hospitalized older patients. *BMC Geriatrics*, *14*(1), 1.

Katz, S. (1963). Studies of illness in the aged. The index of ADL: a standardized measure of biologic and psychologic function. *JaMa*, *185*, 94–99.

Lanzieri, G. (2011). The greying of the baby boomers. *A Century-Long View of Ageing in European Populations. Stat Focus*, *23*, 1–12.

Lawton, M. P., & Brody, E. M. (1969). Assessment of older people: self-maintaining and instrumental activities of daily living. *The Gerontologist*, *9*(3_Part_1), 179–186.

Lee, L., Patel, T., Costa, A., Bryce, E., Hillier, L. M., Slonim, K., … Molnar, F. (2017). Screening for frailty in primary care: Accuracy of gait speed and hand-grip strength. *Canadian Family Physician*, *63*(1), e51–e57.

Lewis, C., Polson, P. G., Wharton, C., & Rieman, J. (1990). Testing a walkthrough methodology for theory-based design of walk-up-and-use interfaces. In *Proceedings of the SIGCHI conference on Human factors in computing systems* (pp. 235–242). ACM.

Luck, T., Luppa, M., Matschinger, H., Jessen, F., Angermeyer, M. C., & Riedel-Heller, S. G. (2015). Incident subjective memory complaints and the risk of subsequent dementia. *Acta Psychiatrica Scandinavica*, *131*(4), 290–296. https://doi.org/10.1111/acps.12328

Lund, A. M. (2001). Measuring usability with the use questionnaire12. *Usability Interface*, *8*(2), 3–6.

Mahatody, T., Sagar, M., & Kolski, C. (2010). State of the art on the cognitive walkthrough method, its variants and evolutions. *Intl. Journal of Human–Computer Interaction*, *26*(8), 741–785.

Mayhew, L. D. (2000). Health and elderly care expenditure in an aging world.

McAdams-DeMarco, M. A., Law, A., Salter, M. L., Boyarsky, B., Gimenez, L., Jaar, B. G., … Segev, D. L. (2013). Frailty as a novel predictor of mortality and hospitalization in individuals of all ages undergoing hemodialysis. *Journal of the American Geriatrics Society*, *61*(6), 896–901.

Montagni, I., Guichard, E., Carpenet, C., Tzourio, C., & Kurth, T. (2016). Screen time exposure and reporting of headaches in young adults: A cross-sectional study. *Cephalalgia*, *36*(11), 1020–1027.

Muscedere, J., Waters, B., Varambally, A., Bagshaw, S. M., Boyd, J. G., Maslove, D., … Rockwood, K. (2017). The impact of frailty on intensive care unit outcomes: a systematic review and meta-analysis. *Intensive Care Medicine*, *43*(8), 1105–1122. https://doi.org/10.1007/s00134-017-4867-0

Nardini, C. (2014). The ethics of clinical trials. *Ecancermedicalscience*, *8*, 387. https://doi.org/10.3332/ecancer.2014.387

Nasreddine, Z. S., Phillips, N. A., Bédirian, V., Charbonneau, S., Whitehead, V., Collin, I., … Chertkow, H. (2005). The Montreal Cognitive Assessment, MoCA: a brief screening tool for mild cognitive impairment. *Journal of the American Geriatrics Society*, *53*(4), 695–699.

National Heart and Blood Institute, L. (1998). Clinical guidelines on the identification, evaluation, and treatment of overweight and obesity in adults: the evidence report. *Obes Res*, *6*, 51S–210S.

Nielsen, J. (1994). *Usability engineering*. Elsevier.

O'Connell, M. D. L., Savva, G. M., Fan, C. W., & Kenny, R. A. (2015). Orthostatic hypotension, orthostatic intolerance and frailty: The Irish Longitudinal Study on Aging-TILDA. *Archives of Gerontology and Geriatrics*, *60*(3), 507–513.

Ooi, W. L., Hossain, M., & Lipsitz, L. A. (2000). The association between orthostatic hypotension and recurrent falls in nursing home residents. *The American Journal of Medicine*, *108*(2), 106–111.

Organization, W. H. (1999). 1999 World Health Organization-International Society of Hypertension guidelines for the management of hypertension: guidelines subcommittee. *J Hypertens*, *17*, 151–183.

Organization, W. H. (2016). Global database on body mass index. 2006. *Global Database on Body Mass Index*.

Organization, W. H. (2017). *WHO clinical consortium on healthy ageing: topic focus: frailty and intrinsic capacity: report of consortium meeting, 1–2 December 2016 in Geneva, Switzerland*. World Health Organization.

Panza, F., Solfrizzi, V., & Logroscino, G. (2015). Age-related hearing impairment—a risk factor and frailty marker for dementia and AD. *Nature Reviews Neurology*, *11*(3), 166.

Pel-Littel, R. E., Schuurmans, M. J., Emmelot-Vonk, M. H., & Verhaar, H. J. J. (2009). Frailty: defining and measuring of a concept. *JNHA-The Journal of Nutrition, Health and Aging*, *13*(4), 390–394.

Piovezan, R. D., Poyares, D., & Tufik, S. (2013). Frailty and sleep disturbances in the elderly: possible connections and clinical implications. *Sleep Science*, *6*(4), 175–179.

Pocklington, C., Gilbody, S., Manea, L., & McMillan, D. (2016). The diagnostic accuracy of brief versions of the Geriatric Depression Scale: a systematic review and meta-analysis. *International Journal of Geriatric Psychiatry*, *31*(8), 837–857.

Podsiadlo, D., & Richardson, S. (1991). The timed "Up & Go": a test of basic functional mobility for frail elderly persons. *Journal of the American Geriatrics Society*, *39*(2), 142–148.

Provencher, V., Mortenson, W. Ben, Tanguay-Garneau, L., Bélanger, K., & Dagenais, M. (2014). Challenges and strategies pertaining to recruitment and retention of frail elderly in research studies: a systematic review. *Archives of Gerontology and Geriatrics*, *59*(1), 18–24.

Robertson, D. A., Savva, G. M., & Kenny, R. A. (2013). Frailty and cognitive impairment—a review of the evidence and causal mechanisms. *Ageing Research Reviews*, *12*(4), 840–851.

Rockwood, M. R. H., Howlett, S. E., & Rockwood, K. (2012). Orthostatic hypotension (OH) and mortality in relation to age, blood pressure and frailty. *Archives of Gerontology and Geriatrics*, *54*(3), e255–e260.

Rohrer, D., Salmon, D. P., Wixted, J. T., & Paulsen, J. S. (1999). The disparate effects of Alzheimer's disease and Huntington's disease on semantic memory. *Neuropsychology*, *13*(3), 381.

Rubio, S., Díaz, E., Martín, J., & Puente, J. M. (2004). Evaluation of subjective mental workload: A comparison of SWAT, NASA-TLX, and workload profile methods. *Applied Psychology*, *53*(1), 61–86.

Ruikes, F. G. H., Adang, E. M., Assendelft, W. J. J., Schers, H. J., Koopmans, R. T. C. M., & Zuidema, S. U. (2018). Cost-effectiveness of a multicomponent primary care program targeting frail elderly people. *BMC Family Practice*, *19*(1), 62.

Sartini, M., Cristina, M. L., Spagnolo, A. M., Cremonesi, P., Costaguta, C., Monacelli, F., … Odetti, P. (2009). The epidemiology of domestic injurious falls in a community dwelling elderly population: an outgrowing economic burden. *European Journal of Public Health*, *20*(5), 604–606.

Sawyer, B., & Sroczynski, N. (2017). How do health expenditures vary across the population. *Kaiser Family Foundation*.

Schmand, B., Jonker, C., Hooijer, C., & Lindeboom, J. (1996). Subjective memory complaints may announce dementia. *Neurology*, *46*(1), 121 LP-125. https://doi.org/10.1212/WNL.46.1.121

Schmidt, B. (2006). Proof of principle studies. *Epilepsy Research*, *68*(1), 48–52.

Sheikh, J. I., & Yesavage, J. A. (1986). Geriatric Depression Scale (GDS): recent evidence and development of a shorter version. *Clinical Gerontologist: The Journal of Aging and Mental Health*.

Simpson, K. N., Seamon, B. A., Hand, B. N., Roldan, C. O., Taber, D. J., Moran, W. P., & Simpson, A. N. (2018). Effect of frailty on resource use and cost for Medicare patients. *Journal of Comparative Effectiveness Research*, (0).

Stalenhoef, P. A., Crebolder, H. F. J. M., Knottnerus, J. A., & van der Horst, F. G. (1997). Incidence, risk factors and consequences of falls among elderly subjects living in the community: a criteria-based analysis. *The European Journal of Public Health*, *7*(3), 328–334.

Steele, R., Lo, A., Secombe, C., & Wong, Y. K. (2009). Elderly persons' perception and acceptance of using wireless sensor networks to assist healthcare. *International Journal of Medical Informatics*, *78*(12), 788–801.

Stockl, K. M., Le, L., Zhang, S., & Harada, A. S. (2010). Clinical and economic outcomes associated with potentially inappropriate prescribing in the elderly. *The American Journal of Managed Care*, *16*(1), e1-10.

Sugarman, H., Weisel-Eichler, A., Burstin, A., & Brown, R. (2009). Use of the Wii Fit system for the treatment of balance problems in the elderly: A feasibility study. In *2009 Virtual Rehabilitation International Conference* (pp. 111–116). Ieee.

Tegou, T., Kalamaras, I., Tsipouras, M., Giannakeas, N., Votis, K., & Tzovaras, D. (2019). A Low-Cost Indoor Activity Monitoring System for Detecting Frailty in Older Adults. *Sensors*, *19*(3), 452.

Theng, Y.-L., Teo, P. F., & Truc, P. H. (2010). Investigating sociability and affective responses of elderly users through digitally-mediated exercises: a case of the Nintendo Wii. In *IFIP Human-Computer Interaction Symposium* (pp. 152–162). Springer.

Theou, O., Stathokostas, L., Roland, K. P., Jakobi, J. M., Patterson, C., Vandervoort, A. A., & Jones, G. R. (2011). The effectiveness of exercise interventions for the management of

frailty: a systematic review. *Journal of Aging Research*, *2011*.

Tomiyama, A. J., O'Donovan, A., Lin, J., Puterman, E., Lazaro, A., Chan, J., … Blackburn, E. (2012). Does cellular aging relate to patterns of allostasis?: An examination of basal and stress reactive HPA axis activity and telomere length. *Physiology & Behavior*, *106*(1), 40–45.

Tullis, T. S., & Stetson, J. N. (2004). A comparison of questionnaires for assessing website usability. In *Usability professional association conference* (Vol. 1). Minneapolis, USA.

Vellas, B. J., Wayne, S. J., Romero, L., Baumgartner, R. N., Rubenstein, L. Z., & Garry, P. J. (1997). One-leg balance is an important predictor of injurious falls in older persons. *Journal of the American Geriatrics Society*, *45*(6), 735–738.

Vermeeren, A. P. O. S., Law, E. L.-C., Roto, V., Obrist, M., Hoonhout, J., & Väänänen-Vainio-Mattila, K. (2010). User experience evaluation methods: current state and development needs. In *Proceedings of the 6th Nordic conference on human-computer interaction: Extending boundaries* (pp. 521–530). ACM.

von Haehling, S., Anker, S. D., Doehner, W., Morley, J. E., & Vellas, B. (2013). Frailty and heart disease. *International Journal of Cardiology*, *168*(3), 1745–1747. https://doi.org/https://doi.org/10.1016/j.ijcard.2013.07.068

Wager, T. D., & Atlas, L. Y. (2015). The neuroscience of placebo effects: connecting context, learning and health. *Nature Reviews Neuroscience*, *16*(7), 403.

Wallhagen, M. I., Strawbridge, W. J., Shema, S. J., Kurata, J., & Kaplan, G. A. (2001). Comparative impact of hearing and vision impairment on subsequent functioning. *Journal of the American Geriatrics Society*, *49*(8), 1086–1092.

Walston, J., Hadley, E. C., Ferrucci, L., Guralnik, J. M., Newman, A. B., Studenski, S. A., … Fried, L. P. (2006). Research agenda for frailty in older adults: toward a better understanding of physiology and etiology: summary from the American Geriatrics Society/National Institute on Aging Research Conference on Frailty in Older Adults. *Journal of the American Geriatrics Society*, *54*(6), 991–1001.

Wetherell, J. L., Kaplan, R. M., Kallenberg, G., Dresselhaus, T. R., Sieber, W. J., & Lang, A. J. (2004). Mental health treatment preferences of older and younger primary care patients. *The International Journal of Psychiatry in Medicine*, *34*(3), 219–233.

WHO. (2015). Physical Activity and Older Adults. Retrieved from https://www.who.int/dietphysicalactivity/factsheet_olderadults/en/

Wick, J. (2011). Understanding frailty in the geriatric population. *The Consultant Pharmacist®*, *26*(9), 634–645.

Wickelgren, W. A. (1974). Single-trace fragility theory of memory dynamics. *Memory & Cognition*, *2*(4), 775–780.

Wolff, P. (2010). 17% of EU citizens were at-risk-of-poverty in 2008. *Statistics in Focus*, 8.

Woo, J., Goggins, W., Sham, A., & Ho, S. C. (2005). Social determinants of frailty. *Gerontology*, *51*(6), 402–408.

Annex I. Individualized recommendations template (Participant Form)

Individualized Recommendations

Participant Form

Important Note: *Present recommendations are provided only in indicative title and do not constitute medical recommendations. Please, keep in mind that the recommendations provided here may have been affected by several other parameters (i.e., stress during the examination, random factors, etc.) and may not necessarily reflect a change in your health status. More specifically, the recommendations aim to serve just as an indication that one or more health-related aspects may be out of range and should be further examined by a healthcare professional, in order to determine if this finding is medically significant or not. Thus, you and your family members should utilize our suggestions taking under consideration your own judgement. Our team can provide contact details for professionals and organizations who can assist you in any domain if needed.*

Participant's name:

Date:

Recommendations list per domain

Research team doctor's conclusion

Contact the FrailSafe team in your country:

(Provide details here)

Annex II. Individualized recommendations (Caregiver Form)

Individualized Recommendations

Caregiver Form

Important Note: *Present recommendations are provided only in indicative title and do not constitute medical recommendations. Please, keep in mind that the recommendations provided here may have been affected by several other parameters (i.e., stress during the examination, random factors, etc.) and may not necessarily reflect a change in your patient's health status. More specifically, the recommendations aim to serve just as an indication that one or more health-related aspects may be out of range and should be further examined by a healthcare professional, in order to determine if this finding is medically significant or not. Thus, you and your patient should utilize our suggestions taking under consideration your own judgement. Our team can provide contact details for professionals and organizations who can assist you in any domain if needed.*

Participant's name:

Date:

Recommendations list per domain

Research team doctor's conclusion

Contact the FrailSafe team in your country:

(Provide details here)

Annex III. Individualized recommendations (Healthcare professional Form)

Individualized Recommendations

Doctor Form

Important Note: *Please, treat the information below with confidentiality. Your patient participates in the EU funded project FrailSafe which assesses frailty and several health-related domains and factors with clinical evaluations, comprehensive geriatric assessments, standardized scales, clinical examinations and, both standardized (i.e., BP monitor) and unstandardized (i.e., vest developed to monitor activity signals, platform "serious games", etc.) devices. According to the participant's results, his/her reports, measurements and performance on various tests and games, several recommendations are proposed to improve his/her health status by our automatic system. Your patient gave us his/her permission to share the results with you. Please, consider these recommendations in the context of your clinical practice only as indicators for further examinations and actions subject to your clinical judgement. Please, note that the integrated system proposed by the FrailSafe project is currently under testing, which is the main objective of the FrailSafe research project itself. If needed, please, reach us on the contact details provided at the end of this document.*

Participant's name:

Date:

Recommendations list

Research team's doctor's conclusion

Contact the FrailSafe team in your country:

(Provide details here)

Annex IV. Recommendations Compliance and Satisfaction Questionnaire

RECOMMENDATION COMPLIANCE AND SATISFACTION QUESTIONNAIRE

As a participant of the FrailSafe study, during the last months you have been given a summary of recommendations according to our health-related measurements. Now, we would like you to tell us your opinion regarding these recommendations by answering to the following questions.

PART A. DEMOGRAPHICS

Year of birth	
Gender	☐ Male ☐ Female
Years of education **(do not count vocational training)**	

PART B. RECOMMENDATION EVALUATION & ADHERENCE

Did you find the recommendations understandable?

☐ **Yes** ☐ **No** ☐ **I am not sure**

Did you find the recommendations helpful?

☐ **Yes** ☐ **No** ☐ **I am not sure**

Did you consult your doctor about any of the recommendations provided?

☐ **Yes** ☐ **No**

Did you change your lifestyle according to the recommendations you received (engage in more physical exercise, alter your dietary habits, try to lose weight, etc.)

☐ **Yes** ☐ **No** ☐ **Partially**

If you did not adhere to some or any of the recommendations provided, could you please indicate the reasons for that (choose all that represent you)?

I did not find the recommendations important or alarming enough to take actions

I did not understand the recommendations provided

I did not read the recommendations provided thoroughly

I have planned to follow some or all of them to the near future

I had financial restrictions to follow the recommendations provided

I felt too stressed to engage in further examinations

I did not have the time to take actions

My personal physician did not encourage me to do so

I do not think that the recommendations were corresponding to my actual health status

Other. Please, specify _____

Would you have been more motivated to consult your doctor or alter your lifestyle if someone else (i.e., a close family member) urged you to?
☐ Yes ☐ No ☐ I am not sure

Would you have been more motivated if your doctor had, also, recommended you to alter your lifestyle or take further exams?
☐ Yes ☐ No ☐ I am not sure

In general, how beneficial do you think it is to receive health-related notifications from the FrailSafe system?			
1	2	3	4
Not at all	Somewhat	A lot	I am not sure

Is there something you would like to change in the procedure of the recommendations provision by the FrailSafe system?
Text:

Annex V. Individualized recommendations: domain-specific guidelines

A. Nutritional Guidelines

Food groups, servings and nutrients

Eat well by including a variety of nutritious foods from each of the four major food groups.

Eat at least 5 servings of fruit and vegetables. They can be fresh, frozen or canned. Eat more dark green vegetables such as leafy greens or broccoli, and orange vegetables such as carrots and sweet potatoes.

Include at least one serving of protein including fish, seafood, chicken, beans and peas and lean meat.

Eat at least 3 servings of cereals, breads, crackers, rice or pasta every day, preferably whole-grain.

Have 3 servings of low-fat or fat-free dairy (milk, yogurt or cheese) that are fortified with vitamin D to help keep your bones healthy.

Take opportunities to eat meals with other people.

Control your portions. Many of the times people tend to overestimate one serving size. Examples of 1 serving are: 1 medium banana, 1 cup of pasta (150gr), 1 medium potato (136gr),

Eat three meals every day and nutritious snacks in between.

Prepare foods or choose pre-prepared foods, drinks and snacks with:

- **minimal added fat**, especially saturated fat
- **low in salt** (if using salt, choose iodized salt)
- **little added sugar**.

Consider food safety when purchasing, preparing, cooking and storing food.

Explore more at https://www.nia.nih.gov/ and https://www.choosemyplate.gov/ where you can find many tools to assess your body mass index and calorie needs per day.

Example of a healthy meal

Octopus with pasta, salad with boiled vegetables, seasonal fruit and water

Keep hydrated

Aim to drink around 8 glasses of water a day, even if you don't feel thirsty.

Take sips from a glass of water, milk, or juice between bites during meals.

Have a cup of low-fat soup as an afternoon snack.

Drink a full glass of water if you need to take a pill.

Don't stop drinking liquids if you have a urinary control problem. Talk with your doctor about treatment.

Keep active

Aim for 150 min of physical activity per week

Limit alcohol and quit smoking

Men should not drink more than 2 drinks per day and women no more than 1 drink per day: one drink is equal to about 2/3 of a can of beer, 1 small glass of wine or 30 ml of liquor (about 1 shot).

No matter your age, quitting smoking improves your health. If you quit smoking, you are likely to add years to your life, breathe more easily, have more energy, and save money.

Reading food labels

NUTRITIONAL FACTS			
Per serving (80gr) Package includes 2 servings		**% Daily value	A package might include more than one servings. Pay attention to the nutrients you take by one serving.
Calories	360	12%	Nutrients to eat in moderation
Total Fat	13gr	7%	Nutrients to include in your daily diet.
Saturated	4.5gr	-	**If a food has 5% of the Daily Value or less, it is low in that nutrient. If it has 20% or more, it is high in that nutrient. Low or high can be either good or bad—it depends on whether you need more of a nutrient (like fiber), or less (like fat).
Trans	0gr	-	
Cholesterol	0gr	-	
Sodium	180mg	7%	
Total carbohydrates	17gr	6%	
Dietary fiber	1gr		
Sugars	1gr		
Protein	2gr		
Vitamin A		0%	

Calcium		2%

Make sure you take enough:

Vitamin D: Fish are a great source of Vitamin D. Make sure to take walks on sunny days because Vitamin D is produced by your body when exposed to sunlight.

Protein: For strong muscles. A great source is chicken and brown rice

Iron: Provides oxygen to cells. A great source are lentils with fresh lemon juice

Vitamin B12 & Omega 3, 6 fatty acids: Healthy brain and nervous system. Greta sources are beef liver, Solomon and walnuts

Calcium: For strong bones. Except for dairy, almonds, sardines and sesame seeds are great sources of protein.

Healthy eating on a budget

1. Buy fresh produce when it's in season and freeze it.

2. Look for sales, and plan meals accordingly.

3. Try less expensive cuts of meat.

4. Beans and whole grains, like quinoa and brown rice, are an inexpensive and tasty way to eat more protein.

5. Go to the farmers market at the end of the day.

Supplements

What if I want to take (or am already taking) supplements?

Vitamin and mineral supplements do not replace a healthy diet, but as you get older, some supplements may boost your nutritional intake. For your safety, always consult your doctor, pharmacist or dietitian before taking any vitamin and mineral supplements. Unnecessary health supplements may do more harm than good. For example, some supplements can change the way your medicine works.

Refer to a healthcare professional immediately if you notice:

Swallowing problems

Fatigue

Chronic pain

Mobility problems

Dental problems

They can lead to malnutrition if not properly addressed.

Always, consult your doctor before implementing any changes to your nutritional plan.

Learn more: (each clinical center inserted their national sources here)

https://www.diatrofi.gr/

https://www.mednutrition.gr/

https://logodiatrofis.gr/

http://www.diatrofikoiodigoi.gr/

Sources: (each clinical center inserted their national sources here)

http://www.who.int/nutrition/topics/ageing/en/index1.html

https://www.nia.nih.gov/health/sample-menus-healthy-eating-older-adults

https://www.healthhub.sg/live-healthy/456/Dietary%20Guidelines%20for%20Older%20Adults

https://www.health.govt.nz/system/files/documents/publications/food-nutrition-guidelines-healthy-older-people-background-paper-v2.pdf

B. Physical Activity Guidelines

Exercise improves cardiorespiratory and muscular fitness, bone and functional health, reduces the risk of depression and cognitive decline and reduces risk of falling.

Adults 65+ years old should do at least 150 minutes of moderate-intensity aerobic physical activity throughout the week or do at least 75 minutes of vigorous-intensity aerobic physical activity throughout the week or an equivalent combination of moderate- and vigorous-intensity activity.

There are a number of ways to accumulate the total of 150 minutes per week. You can perform activities in multiple shorter bouts, of at least 10 minutes each, spread throughout the week then adding together the time spent during each of these bouts: e.g. 30 minutes of moderate-intensity activity 5 times per week.

Physical activity includes:

Leisure time activities: walking, dancing, gardening, hiking, swimming

Transportation activities: walking or cycling

Occupational activities

Household chores

Playing games, sports or any planned exercise, in the context of daily, family, and community activities.

Essential parts of physical activity

Warm-up and Cool-down It is important to incorporate lower intensity activities at the beginning and end of your routine to properly warm up and cool down your body. This helps to prevent injuries and reduce muscle soreness. Examples of warming-up would be to walk briskly before aerobic exercise.

Aerobic Activity Aerobic activity includes: jogging, biking, dancing, brisk walking and swimming. When chronic conditions make it hard to achieve the 150 minutes each week, older adults should be physically active as their abilities and conditions allow. The intensity of the activity depends upon the older adult's level of fitness.

Muscle-Strengthening Activities Older adults should participate in muscle-strengthening activities at least 2 days a week while including all major muscle groups: legs, hips, back, chest, abdomen, shoulders, and arms. One set of 8 to 12 repetitions of each exercise is effective. Muscle strengthening activities include: using of exercise bands, weight machines, hand-held weights, digging, lifting, and carrying as part of gardening and carrying groceries.

Balance Activities for Older Adults Older adults at risk of falling should concentrate on exercises that maintain or improve balance. Increased risk of falling occurs when older adults have trouble walking or have had falls in the recent past. The guidelines recommend older adults to do balance training 3 or more days a week and do standardized exercises from a program demonstrated to reduce falls. Examples of balance exercises are: backward walking, sideways walking, heel walking, toe walking, standing from a sitting position

Flexibility Activities Even though flexibility does not have recommended guidelines, it is an important part of physical fitness. Flexibility plays an integral part in some types of physical activities such as dancing. Adults should perform stretching exercises to help increase flexibility.

Keep safe

Talk to your doctor before engaging in any physical activity program, especially if you have a chronic health condition (such as heart disease, arthritis, or diabetes) or symptoms (such as chest pain or pressure, dizziness, or joint pain, hernia). If you cannot do the recommended amounts of physical activity due to health conditions, you should be as physically active as your abilities and conditions allow. For example, exercises performed on a chair (i.e., hand lifting) are also beneficial for your health.

Remember to start slowly!

Aim for light or moderate intensity activity for short periods of time.

Make sure to spread out the physical activity sessions throughout the week.

Increase physical activity gradually over a period of weeks to months.

Wear loose, comfortable clothing and well-fitting, sturdy shoes specifically designed for the activity you perform.

Wait to exercise until you feel better if you have a cold, the flu or another illness. If you miss exercise for more than 2 weeks, be sure to start slowly again.

Set small daily goals and aim for daily consistency rather than perfect workouts.

Find forms of exercise that are fun or enjoyable, like dance classes and group activities.

Distract yourself with an iPod or other portable media player to download audiobooks, podcasts, or music.

Recruit an “exercise buddy.” It's often easier to stick to your exercise routine when you have to stay committed to a friend.

Be patient when you start a new exercise program. Most sedentary people require about four to eight weeks to feel coordinated and sufficiently in shape so that exercise feels easier.

How can I reduce risk of falls?

Strengthen your muscles: exercise to strengthen your muscles, especially your legs, and improve your balance. There are many programs or activities that will help you achieve this.

Optimize your eyesight: have your vision assessed regularly by an optometrist. Correct problems (myopia, presbyopia, cataracts, etc.) as needed.

Create a safe environment: limit carpets that slide easily over floors and over which you may slip and fall, remove furniture that obstructs passageways, use adequate lighting.

Do not stop any medication without talking to your doctor, nurse or pharmacist.

Learn more: (each clinical center inserted their national sources here)

https://www.healthline.com/health/everyday-fitness/senior-workouts#minute-strength-routine

Sources: (each clinical center inserted their national sources here)

http://www.who.int/dietphysicalactivity/factsheet_olderadults/en/

https://www.nhs.uk/live-well/exercise/physical-activity-guidelines-older-adults/

C. Psychosocial Guidelines

Everyday life challenges us in many ways but positive thinking can be a powerful ally. Positive emotions can improve your cardiovascular function, your immune system and overall health.

You can learn to think positive. It just takes time and practice. Things you can do include:

Smile! It can help lower stress.

Reframe. Spin your thoughts to the good things instead of dwelling on the bad.

Keep a gratitude journal.

Do good things for others.

Surround yourself with people who boost your spirits.

Accept things you can't change.

Improve your well-being by:

Keeping active: Go for a daily walk or join a senior exercise class at a nearby gym or senior center. If you have physical limitations, try chair exercises.

Socialising: Senior centers offer a variety of classes, from crafts and hobbies to computer classes. Some also offer transportation to those who need it.

Staying involved in family gatherings: Engage frequently in family meetings and spend time with your grandchildren.

Calling on friends: Stay connected with your peers. Get your hair done together, go on a shopping trip, or have them over for coffee.

Staying in touch with technology: Catch up with loved ones through phone and send email letters, cards and photos. Try making a video call. Younger family members can help you familiarize yourself with technology and several sites offer free computer lessons.

Learning new things and hobbies: Try taking a class at your local community college. Many are free or offered at a very low cost.

Adopting a pet: Caring for an animal can keep you socially engaged, happier and calmer.

Playing games: Word puzzles, crosswords, Sudoku and online games keep your brain stimulated. You can also start a bridge club with your friends.

Stimulating your spiritual world: Religious activities can offer meaningful things to do and support. Try volunteering to your local church.

Participate in research projects offered in your country. You can help research activities and benefit from new experiences.

It is not too late to make a difference: Offer your help and knowledge to local associations and centers which need volunteers.

Coping with stress and anxiety

Stress is a common feeling among modern people, but there is no need to add further strain to your everyday life. Try these techniques when you're feeling anxious or stressed:

Take some relaxation time: practice yoga, listen to music, meditate, get a massage. Stepping back from the problem helps clear your head.

Eat well-balanced meals. Do not skip any meals.

Limit alcohol and caffeine.

Get enough sleep.

Exercise daily.

Take deep breaths when feeling pressure. Inhale and exhale slowly 10 times.

Count to 10 slowly. Repeat, and count to 20 if necessary.

Do your best. Instead of aiming for perfection, which isn't possible, be proud of however close you get.

Accept that you cannot control everything.

Welcome humor to your life. A good laugh goes a long way.

Learn what triggers your anxiety. Is it your health, family or something else you can identify? Write in a journal when you're feeling stressed or anxious, and look for a pattern.

Talk to someone. Tell friends and family you're feeling overwhelmed, and let them know how they can help you. Talk to a physician or therapist for professional help.

Dealing with sleep difficulties

· Follow a regular sleep schedule. Go to sleep and get up at the same time each day, even on weekends or when you are traveling.

· Avoid napping in the late afternoon or evening. Naps may keep you awake at night.

Develop a bedtime routine. Take time to relax before bedtime each night. Some people read a book, listen to soothing music, or soak in a warm bath.

Try not to watch television or use your computer, cell phone, or tablet in the bedroom. The light from these devices may make it difficult for you to fall asleep.

Keep your bedroom at a comfortable temperature, not too hot or too cold, and as quiet as possible.

Use low lighting in the evenings and as you prepare for bed.

Exercise at regular times each day but not within 3 hours of your bedtime.

Avoid eating large meals close to bedtime. They can keep you awake.

Stay away from caffeine late in the day, found in coffee, tea, soda, and chocolate.

Remember that even small amounts of alcohol can make it harder to stay asleep.

Get plenty of sunlight in the morning to improve your sleep quality.

Talk to your doctor for professional help

Keep your bedroom safe

Before going to bed, lock all windows and doors.

Keep a telephone with emergency phone numbers by your bed.

Have a lamp within reach that is easy to turn on.

Put a glass of water next to the bed in case you wake up thirsty.

Don't smoke, especially in bed.

Remove area rugs so you won't trip if you get out of bed during the night.

Sexual life

People tend to forget about their sexual needs as they grow older. However, an active sexual life can have major benefits:

1) It is stimulating for the brain
2) Can reduce feelings of anxiety and derpression
3) Decreases blood pressure and risk of stroke and prostate cancer.
4) Releases endorphins, which have been shown to act as natural painkillers.
5) Boosts the bond with your partner and makes you feel self-confident and happy

If you do seem to have a problem that affects your sex life, talk to your doctor. He or she can suggest a treatment depending on the type of problem and its cause.

Learn more: (each clinical center inserted their national sources here)

https://www.nia.nih.gov/health/cognitive-health-resources

Sources: (each clinical center inserted their national sources here)

https://www.nia.nih.gov/health/cognitive-health-resources

http://www.who.int/bulletin/volumes/91/9/13-119230/en/

https://www.nia.nih.gov/health/good-nights-sleep

https://www.sleepfoundation.org/sleep-tools-tips/healthy-sleep-tips

https://www.aging.com/the-way-of-living-being-happy-and-healthy-at-an-old-age/

http://apps.who.int/healthinfo/systems/surveydata/index.php/catalog/10/download/48

D. Cognitive Guidelines

Aging affects our brain as much as it affects the rest of our bodies. However, brain is an extremely adaptive organ and cognitive exercises can help you maintain and even improve its function and feel happier and healthier.

Keep in mind that cognitive exercises should be challenging for you in order to work out your brain like a muscle. Very easy exercises do not train the brain as they do not stimulate it enough.

Examples of cognitive exercises are:

Learning new skills, such as quilting, dance or digital photography.

Reading books and magazines. Try reading a book written in a foreign language to further exercise your brain.

Play games, like crosswords, riddles, online games. Learn how to use new technological devices

Spread your knowledge to younger people or peers and teach a class or offer consultation services.

Work or volunteer to a local center or shelter.

Invest in a formal cognitive training program with a healthcare professional.

Connect with other people through social activities and visit with family and friends.

Use memory tools such as big calendars, to-do lists, reminders in your phone and notes to yourself.

Use your memory as regularly as possible. For example, memorize the shopping list instead of writing it down.

Put your wallet or purse, keys, and glasses in the same place each day.

Get lots of rest.

Do things differently. Brain is challenged when you perform everyday routines in a different way. For example, if you regularly brush your teeth with your right hand, start brushing them with the left one. The same applies for all routines. A good exercise is to try and read a newspaper article, holding the newspaper upside down.

Travel and gain new experiences. Participate in an excursion with your local senior center or join a sports team, i.e. hiking team.

Participate in research projects offered in your country. You can help research activities and benefit from new experiences.

Other important things for brain health are:

Engaging in regular physical exercise

Eating healthy, nutritional foods, especially foods containing vitamin B12 and omega fatty acids, such as milk and milk products, lean meat, fish and nuts.

I often forget things, is it serious?

As we age we may not be as quick and efficient thinking compared to younger people. Many people are worried about memory loss and cognitive changes. Keep in mind that not all difficulties are indicative of a serious condition. For example, it is normal to make a bad decision once in a while, miss a payment, forget what day it is and remember it later, or losing things from time to time.

You should visit your doctor if you notice making poor judgements frequently, have trouble taking care of your bills, house and hygiene, lose track of the date or time of the year, get lost in places you know well or notice any changes in your function that make you feel worried or stressed.

Keep in mind that certain medical conditions can cause temporary memory problems which go away once a person gets treatment. Refer to your doctor for consultation.

People with some forgetfulness can use a variety of techniques, called “mnemonics” that may help them deal with memory difficulties. Our memory can hold approximately 3-7 pieces of information and mnemonics help us reduce the information we want to remember in order to “fit” to our memory capacity. Some techniques are described below:

1) Acronyms: Creating an acronym from the first letter of each word you want to remember. For example, if you want to go shopping for Milk, Eggs, Salt, Bread and Olives, creating the acronym **MESBO**, can help you remember this list.

2) Create meaningful connections: When you first meet someone it is difficult to memorize his/her name as it does not mean something to your brain, but adding meaning to it makes the memory stronger. For example, if you meet a person called Kathrin you can make a mental image of her with a cat (Cat-Kathrin). You can even combine information. For example if a person is called Mike and is a singer you can just make the mental image of a microphone.

3) Animate information mentally: Mental images or stories strengthen the memories. Here is an example of this technique: If you have to go shopping for chicken, milk, carrots and socks, you can make a mental imagery of a pig in socks eating carrots and drinking milk. Sounds funny but works.

4) Recall frequently: Memories wear out if we do not recall them from time to time. If you want to retain and enhance a memory recall it frequently (either it is a phone number or a fact). Rereading it also works but recall is the most efficient method to boost your memory.

Online cognitive training programs

There are many companies who offer personalized brain training exercises online for a small fee or a free trial. Among them are Lumosity, NeuroNation, CogniFit, BrainMetrix and Brainhq.

Sources: (each clinical center inserted their national sources here)

Amiryousefi, M., & Ketabi, S. (2011). Mnemonic instruction: A way to boost vocabulary learning and recall. *Journal of Language Teaching and Research*, *2*(1), 178.

https://www.ttk.ee/public/Handbook-EN.pdf

E. General Health Guidelines

As people age their medical needs tend to increase. In this leaflet you will find useful information to assist you in keeping healthy and active.

There are several measures you can take to improve the quality of your life.

These include:

Regular visits to your doctor for examinations and following of their recommendations and instructions (yearly flu shot, screening for breast, cervical cancer, checking blood pressure, etc).

Paying attention to your body and alerting your doctor immediately if something feels unusual. For instance, if you start to feel dizzy or unsteady it's important to follow up on this with your doctor to avoid a fall.

Keep your home safe by making sure that all the rooms are well lit, moving furniture that can be an obstruction, checking to see that the electrical and gas appliances are safe and up to date, looking out for wiring that's loose or rugs or carpets that would cause a fall. It is also advisable to ensure that your home is properly insulated.

Recommended examinations

Blood pressure check: One in every three adults has elevated blood pressure, which is known as hypertension. It increases the risk for cardiovascular problems. This is why it's essential to have your blood pressure checked at least once a year

Blood tests for lipids: Healthy cholesterol and triglyceride levels decrease your risk of cardiorespiratory diseases. If test results show high levels of either, your doctor may recommend an improved diet, lifestyle changes, or medications to reduce them.

Colorectal cancer exam: A colonoscopy is a test where a doctor uses a camera to scan your colon for cancerous polyps. A polyp is an abnormal growth of tissue. After the age of 50, you should get a colonoscopy every 10 years. And you should get them more frequently if polyps are found, or if you have a family history of colorectal cancer. Colorectal cancer is highly treatable if caught early.

Vaccinations: Get a tetanus booster every 10 years and if your doctor recommends it get a yearly flu shot.

Eye exams: The American Academy of Ophthalmology suggests adults get a baseline screening at age 40. Your eye doctor will then decide when follow-ups are needed. This may mean annual vision screenings if you wear contacts or glasses, and every other year if you don't.

Periodontal exam: Oral health becomes more important as you age. Many older Americans also may take medications that can have a negative effect on dental health.

Hearing test: Hearing loss is often a natural part of aging. Sometimes it can be caused by an infection or other medical condition. Every two to three years you should get an audiogram.

Bone density scan: Both women and men are at risk for this condition, however women are affected more often. A bone density scan measures bone mass, which is a key indicator of bone strength. Regular bone scans are recommended after age 65, especially for women.

Vitamin D test: This vitamin helps protect your bones. It may also defend against heart disease, diabetes, and some cancers. You may need this test performed annually. As you get older your body has a harder time synthesizing vitamin

Thyroid-stimulating hormone screening: Sometimes the thyroid, a gland in your neck that regulates your body's metabolic rate, may not produce enough hormones. This may lead to sluggishness, weight gain, or achiness.

Skin check: Check regularly for new or suspicious moles, and see a dermatologist once a year for a full-body exam.

Diabetes test: Everyone should be screened beginning at age 45 for the condition. This is done with a fasting blood sugar test.

Mammogram: Women over 55 should have an exam every 2 years or every year if they choose. If your risk for breast cancer is high because of family history, your doctor may suggest an annual screening.

Pap smear: Pap smears can detect cervical or vaginal cancer. A pelvic exam helps with health issues like incontinence or pelvic pain.

Prostate cancer screening: Possible prostate cancer can be detected either by a digital rectal exam or by measuring prostate-specific antigen (PSA) levels in your blood.

Taking more than 3 medications

People 65+ years old may need to take 3 or more prescription drugs daily. However, many medications or their combination may cause side effects with adverse implications for health. This phenomenon is known as polypharmacy and can be prevented by

Monitoring your status and noticing any changes or symptoms related to medication. Once you start taking a drug, mention any unexpected symptoms to your doctor or pharmacist as soon as possible. This includes changes in your sex life.

Referring to your doctor for a regular revision of your medication list

Never commence or cease medication without consulting your doctor

Side effects often associated with prescription drugs include nausea, diarrhea, constipation, dizziness, drowsiness and irritability. Some side effects go away over time as your body gets used to a new drug, so your doctor may recommend you stick with your current plan for a little longer. In other cases, you may be able to lower your dose, try a different drug, or add another one, like an anti-nausea medicine, to your routine.nBut never stop a medicine or change your dosage without your doctor's approval -- especially if you're being treated for a serious health condition. You need to take some medicines, like antibiotics, for a full course to avoid getting sick again. Others don't work as well if you skip a dose, cut it in half, or take it with or without food.

Safety tips for medication

Tell the pharmacist if you have trouble swallowing pills.

Make sure you can read and understand the name of the medicine as well as the directions on the container.

Check that you can open the container.

Ask about special instructions on where to store a medicine.

Check the label on your medicine before leaving the pharmacy.

Make a list. Write down all medicines you take, including over-the-counter drugs and dietary supplements.

Check expiration dates on bottles

Follow instructions.

Use the right amount. Don't take a larger dose of a medicine thinking it will help you more. It can be very dangerous, even deadly. And, don't skip or take half doses of a prescription drug to save money

Take medicine on time. Some people use meals or bedtime as reminders to take their medicine. Other people use charts, calendars, or weekly pill boxes. You can also set timers and write reminders to take your medication.

Turn on a light. Don't take medicine in the dark; otherwise, you might make a mistake.

Avoid drinking alcohol.

Check before stopping. Take prescription medicine until it's finished or until your doctor says it's all right to stop.

Do not take medicines prescribed for another person or give yours to someone else.

Technology for health monitoring

Today there are many technological devices available to assist you in health monitoring such as digital watches with heart rate monitors and alarm buttons in case of emergencies, applications for smartphones and digital pillboxes for efficient medication distribution with reminders.

Learn more: (each clinical center inserted their national sources here)

Assistive devices

https://frailsafe-project.eu/

https://www.ageukmobility.co.uk/mobility-news/article/life-changing-technology-for-the-elderly

https://medicalfuturist.com/the-greatest-technological-developments-for-the-elderly

Annex VI. Virtual Community Platform: Evaluation procedure and questionnaire

VCP Evaluation Protocol

Here below the protocol to be applied by the users, divided into functional tasks.

Each user will be assigned a credentials couple (i.e. username and password).

User Login & Navigation to VCP

- Access http://frailsafe-project.eu/cb-login
- Login to the VCP with your credentials.
- Click the item “TASKS” at the navigation bar.
- Select the “VCP” item on the list.
- Edit profile
- When you redirect to the VCP, at the navigation bar of the VCP select the “Profile” item.
- When you are redirected to the Profile, click the “Edit” icon on the right.
- Select the “Edit” item at the navigation bar of the profile and then the “Update profile” item.
- Add number 2 to your username and click the “Update” button.
- You should see the message “Your settings have been saved”.
- Turn back to the forum by selecting the item “TASKS” at the navigation bar of the webpage and selecting the “VCP” item on the list.
- Add a new topic & Navigation
- At the navigation bar of the forum click the “New Topic” item.
- In the new page, choose a “Category” from the list and specifically from the list of “Comorbidities”.
- In the Subject write the word “Discussion”.
- Select the “Topic icon” with the question mark.
- If you have chosen for example the category “Arterial Hypertension”, write in the “Message”: “Is there anyone else here with Arterial Hypertension”?
- Click the “Submit” button.
- At the top of the new page check the success message that says “You have been subscribed to this topic. Your message has been successfully posted”.
- Below, see that the new topic has been created.
- Under the subject Discussion, click on the “Action” button and then click “Favorite” to add the topic to the favorites. After, check the success message “This topic has been added to your favorites” at the top of the page.
- Under the icon of your account check that you are the topic author and online and click the button “MORE” and see how many posts you have done.
- After, under the new topic you created click the “Action” button and then click “Quote”.
- When you are redirected, in the textbox under the quoted message write: “No one?” and click the “Submit” button.
- When you are redirected, check the success message “Your message has been successfully posted.” at the top of the page and check that your new post appears along with the quoted first post.
- Find the text box for Search in the topic, write “no one” and click the icon of Search. Check that in the new page appears the latest post that you wrote “No one?” along with the quoted first post.
- Select the “Index” item from the navigation bar of the forum.

Search topic & Reply

- Select the “Search” item at the navigation bar of the forum.
- In “Search by Keyword” division, write the keyword “frail” in the text box Keywords and click the “Search” button at the bottom of the page.
- Check that the result is one post with the Subject “Discussion about frailty” and the message contains the word “frail” that you searched.
- Click on the Subject of the post and redirect to the post.
- Click the “Action” button under the post and then click “Reply”.
- When you are redirected, in the textbox write: “Hi! Also me!” and click the “Submit” button.
- Check that reply has been posted.
- Click the “Search” item at the navigation bar of the forum to go back to the initial search page.
- This time execute a Search by User Name. Write “sigla” in the text box User Name and click the “Search” button at the bottom of the page.
- Check that the result of the search is 5 posts of the user “sigla”.
- Select the “Index” item from the navigation bar of the forum.

Subscribe, Change Status & Check Subscriptions and Favorites

- Go to category Frailty Status and click on the Frail subcategory.
- Click the “SUBSCRIBE” button to subscribe to this subcategory.
- Check the success message “You have been subscribed to this category and will get notified by email about new posts.” at the top of the page.
- At the navigation bar of the forum at the right corner click the icon of your profile. At the drop-down list click “AWAY”. Check the success message “Successfully Saved Status” at the top of the page.
- At the same list click the user icon.
- When you are redirected to your profile, at the navigation bar click “VCP”.
- There you can see your posts.
- Click on “FAVORITES” and you can see the topic that you have marked above as favourite.
- After, click on “SUBSCRIPTIONS” and you are able to see the subcategory to which you have subscribed.
- Click the delete icon on the right of the Frail category. Check the success message “Category subscription deleted successfully!” at the top of the page.

Check Inbox & Send message to user

- At the navigation bar click the “INBOX” item. See that the “Empty Inbox” message appears.
- Click the item “TASKS” at the navigation bar.
- Select the “VCP” item on the list.
- Go to the Frailty category and click at the Frail subcategory.
- At the “Discussion about frailty” click the user “sigla” that started the topic.
- At the top you will see an indication that you have no established connection with this user. Click the “REQUEST CONNECTION” button and check the success message “Connection Pending Acceptance!” at the top of the page.
- In the navigation bar below click the “BLOGS” item and see that user sigla has one blog.
- Click on the title of the blog and see one post.
- Press the back button and click the “QUICK MESSAGE” at the bottom navigation bar.
- In the textbox write “Hi” and click the “SEND MESSAGE” button.
- At the top navigation bar click hover the mouse to the “MESSAGES” button and click “Send private message”.

- Click the “Show users” item on the right and select “adminv” from the list to send the message to two users.
- Write “Hello” to the text box, check “Copy to me” and click Send.
- Then you will see your inbox and the message you just sent because you requested a copy.
- Click the outbox and you will see the same message sent by you.
- Click the item “TASKS” at the navigation bar.
- Select the “Profile” item on the list.

Create blog

- In your profile click the “BLOGS” item at the navigation bar.
- Click the “New Blog” button.
- On the Access list, click the “VCP User”.
- As Title write your username.
- As Blog write also your username.
- Click the “CREATE BLOG” button.
- Check the success message “Blog saved successfully” at the top of the page.
- Hover on the “Settings” icon on the right corner of your Blog and click “Edit”.
- Add number 2 to the title and click the “UPDATE BLOG” button.
- Check the success message “Blog saved successfully” at the top of the page.
- Hover on the “Settings” icon on the right corner of your Blog and click “Delete”.
- Then click “Cancel” at the window message.

Manage Connections

- At the top navigation bar click “CONNECTIONS” item and then “Manage Connections”.
- The message “There are currently no users connected with you” appears.
- Click the “CANCEL” button.

Questionnaire

Here below the set of questions to be replied by users.

Question
How easy to use do you find the forum? (1-5, lowest to highest)
How helpful is the forum in your opinion? (1-5, lowest to highest)
What do you like least about the forum?
Do you find it easy to navigate inside the forum? (1-5, lowest to highest)
Are the navigation labels clear & concise? (1-5, lowest to highest)
How simple it is to find the information you need? (1-5, lowest to highest)
Is there anything else you would like to be different?
Have you got any free comment on the forum? (any topic)

Annex VII. AR games and glasses evaluation protocol

AR glasses games evaluation protocol

Participant ID

_____

1) Indicate participant's relationship with technology and games:

Mark only one oval.

- ☐ Not familiar at all
- ☐ Beginner
- ☐ Familiar
- ☐ Advanced

SITTING POSITION: TRIAL 1

Start set-up time

_____

Example: 8:30 AM

End set-up time

_____

Example: 8:30 AM

Successful independent set-up?

Mark only one oval.

- ☐ Yes
- ☐ No

Start game time

_____

Example: 8:30 AM

End game time

_____

Example: 8:30 AM

Completed game successfully?

Mark only one oval.

- ☐ Yes
- ☐ No

Did participant experience:

Check all that apply.

- ☐ Fear
- ☐ Pleasure
- ☐ Surprise

- ☐ Anxiety
- ☐ Calmness
- ☐ Enthusiasm
- ☐ Other:

Did participant experience:

Check all that apply.

- ☐ Motion sickness
- ☐ Headache
- ☐ Dizziness
- ☐ Faint
- ☐ Double vision
- ☐ Other:

SITTING POSITION: TRIAL 2

Start set-up time

Example: 8:30 AM

End set-up time

Example: 8:30 AM

Successful independent set-up?

Mark only one oval.

- ☐ Yes
- ☐ No

Start game time

Example: 8:30 AM

End game time

Example: 8:30 AM

Completed game successfully?

Mark only one oval.

- ☐ Yes
- ☐ No

Did participant experience:

Check all that apply.

- ☐ Fear
- ☐ Pleasure
- ☐ Surprise
- ☐ Anxiety

- ☐ Calmness
- ☐ Enthusiasm
- ☐ Other:

Did participant experience:

Check all that apply.

- ☐ Motion sickness
- ☐ Headache
- ☐ Dizziness
- ☐ Faint
- ☐ Double vision
- ☐ Other:

STANDING POSITION: TRIAL 1

Start set-up time

Example: 8:30 AM

End set-up time

Example: 8:30 AM

Successful independent set-up?

Mark only one oval.

- ☐ Yes
- ☐ No

Start game time

Example: 8:30 AM

End game time

Example: 8:30 AM

Completed game successfully?

Mark only one oval.

- ☐ Yes
- ☐ No

Did participant experience:

Check all that apply.

- ☐ Fear
- ☐ Pleasure
- ☐ Surprise
- ☐ Anxiety
- ☐ Calmness

- ☐ Enthusiasm
- ☐ Other:

Did participant experience:

Check all that apply.

- ☐ Motion sickness
- ☐ Headache
- ☐ Dizziness
- ☐ Faint
- ☐ Double vision
- ☐ Other:

STANDING POSITION: TRIAL 2

Start set-up time

Example: 8:30 AM

End set-up time

Example: 8:30 AM

Successful independent set-up?

Mark only one oval.

- ☐ Yes
- ☐ No

Start game time

Example: 8:30 AM

End game time

Example: 8:30 AM

Completed game successfully?

Mark only one oval.

- ☐ Yes
- ☐ No

Did participant experience:

Check all that apply.

- ☐ Fear
- ☐ Pleasure
- ☐ Surprise
- ☐ Anxiety

- ☐ Calmness
- ☐ Enthusiasm
- ☐ Other:

Did participant experience:

Check all that apply.

- ☐ Motion sickness
- ☐ Headache
- ☐ Dizziness
- ☐ Faint
- ☐ Double vision
- ☐ Other:

Part B. Technical issues

Explain any technical difficulties using the AR glasses or playing the game as reported by the participant or noticed by the examiner:

Part C. User satisfaction

Rate the game in terms of each adjective with 1 denoting “not at all” and 7 denoting “as much as it can be”. So, is the AR game:

Appealing

Mark only one oval.

1 2 3 4 5 6 7

Pleasant

Mark only one oval.

1 2 3 4 5 6 7

Interesting

Mark only one oval.

1 2 3 4 5 6 7

Enjoyable

Mark only one oval.

1 2 3 4 5 6 7

Easy to control

Mark only one oval.

1 2 3 4 5 6 7

Realistic

Mark only one oval.

1 2 3 4 5 6 7

Interactive

Mark only one oval.

1 2 3 4 5 6 7

Safe

Mark only one oval.

1 2 3 4 5 6 7

Useful

Mark only one oval.

1 2 3 4 5 6 7

Annex VIII. Dynamic Adaptability Evaluation Protocol

Dynamic Adaptability Evaluation

Section A. Participant details

Clinical center

- ☐ Cyprus
- ☐ France
- ☐ Greece

Participant ID

_____

Gender

- ☐ Female
- ☐ Male

Cognitive status (last MoCA score)

Mark only one oval.

- ☐ >26
- ☐ 26
- ☐ <26

Presence of depressive symptoms (last GDS score)

- ☐ Depression symptoms absent
- ☐ Depressive symptoms present

Grip strength (last CE measurement)

- ☐ Normal
- ☐ Abnormal

IT user (self evaluation)

- ☐ Do not use computer technologies at all
- ☐ Beginner, I can use a computer or smartphone with help
- ☐ Intermediate user, I can use independently a computer or smartphone
- ☐ Advanced user, I use several apps and configure them

Section B. Information by the clinician

Game

- ☐ Redwings
- ☐ Reflex

Dynamic adaptability

- ☐ Enabled
- ☐ Disabled

Max score (meters for Redwings and score in upper left corner for Reflex)

Difficulties detected

Section C. NASA Task Load Index (TLX)

How mentally demanding was the game?

Mark only one oval.

1	2	3	4	5	6	7	8	9	10
Vey low	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯ Very high

How physically demanding was the game?

Mark only one oval.

1	2	3	4	5	6	7	8	9	10
Vey low	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯ Very high

How hurried or rushed was the pace of the task?

Mark only one oval.

1	2	3	4	5	6	7	8	9	10
Vey low	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯ Very high

How succesful were you in accomplishing what you were asked to do?

Mark only one oval.

1	2	3	4	5	6	7	8	9	10
Vey low	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯ Very high

How hard did you have to work to accomplish your level of performance?

Mark only one oval.

1	2	3	4	5	6	7	8	9	10
Vey low	◯	◯	◯	◯	◯	◯	◯	◯	◯	Very high

How insecure, discouraged, irritated, stressed and annoyed were you?

Mark only one oval.

1	2	3	4	5	6	7	8	9	10
Vey low	◯	◯	◯	◯	◯	◯	◯	◯	◯	Very high

Annex IX. Scale for Healthcare Professionals, IT professionals and Researchers

Scale for Healthcare Professionals, IT professionals and Researchers

Take a moment to tell us your opinion about the FrailSafe system. Please, choose the answer that best represents you on each of the following statements. The following video explains how the FrailSafe system works.

The FrailSafe System

PART A. GENERAL INFORMATION

1. Please, choose the category that best describes your profession

Mark only one oval.

- ☐ Healthcare professional Researcher
- ☐ IT professional

2. Please, indicate your work position

_____

3. Are you a member of the FrailSafe consortium?

Mark only one oval.

- ☐ Yes
- ☐ No

4. Please, indicate your years of experience

_____

5. Please, indicate your country

Mark only one oval.

- ☐ Cyprus
- ☐ France
- ☐ Greece

Other:

Part B. SUS Scale

The System Usability Scale (SUS) provides a quick, standardized and reliable tool for measuring the usability of the FrailSafe system.

1. I think that I would like to use this system frequently

Strongly disagree	1	2	3	4	5	Strongly agree

2. I think that the system is unnecessarily complex

Strongly disagree	1	2	3	4	5	Strongly agree

3. I think that the system is easy to use

Strongly disagree	1	2	3	4	5	Strongly agree

4. I think that I would need the support of a technical person to be able to use this system

Strongly disagree	1	2	3	4	5	Strongly agree

5. I think that the various functions in this system are well integrated

Strongly disagree	1	2	3	4	5	Strongly agree

6. I think that there is too much inconsistency in this system

Strongly disagree	1	2	3	4	5	Strongly agree

7. I would imagine that most people would learn to use this system very quickly

Strongly disagree	1	2	3	4	5	Strongly agree

8.I find that the system is very cumbersome to use

Strongly disagree	1	2	3	4	5	Strongly agree

9. I feel very confident in using the system

Strongly disagree	1	2	3	4	5	Strongly agree

10. I need to learn a lot of things before I could get going with this system

Strongly disagree	1	2	3	4	5	Strongly agree

Part C. DSS platform

The DSS platform, refers to the Decision Support System which is offered by the FrailSafe system. It is an online platform which stores, handles and processes multiple health data and automatically generates alerts and recommendations based on those parameters. It can be used by doctors, older adults and family members to assist them in health management and prevention of diseases. It is depicted in the FrailSafe video (minute 02:03:00).

I think that FrailSafe DSS platform could facilitate decision making processes

Strongly disagree	1	2	3	4	5	Strongly agree

I think that data outputs are depicted in a comprehensive and understandable manner

Strongly disagree	1	2	3	4	5	Strongly agree

I think that the platform is easy to use

Strongly disagree	1	2	3	4	5	Strongly agree

I think that the platform offers adequate filter options

Strongly disagree	1	2	3	4	5	Strongly agree

I think that FrailSafe DSS platform will be cost-effective

Strongly disagree	1	2	3	4	5	Strongly agree

I think that FrailSafe DSS platform is compliant with ethical requirements

Strongly disagree	1	2	3	4	5	Strongly agree

Please, share with us any further comments

Thank you for your time!

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Annex X. Technical evaluation: Functional characteristics

Technical Evaluation: Functional characteristics

Tell us your opinion regarding the IT characteristics of the FrailSafe platform.

Are you a consortium member?

- ☐ Yes
- ☐ No, I am an external evaluator

Please, indicate your work position.

Please, indicate your years of experience.

According to your opinion does the FrailSafe system “pass” or “fail” in terms of:

Data loss prevention

- ☐ Pass
- ☐ Fail
- ☐ Other:

Privacy of online personal data

- ☐ Pass
- ☐ Fail
- ☐ Other:

Network availability

- ☐ Pass
- ☐ Fail
- ☐ Other:

Hardware reliability

- ☐ Pass
- ☐ Fail
- ☐ Other:

System security

- ☐ Pass
- ☐ Fail

- ☐ Other:

Ease of learning the platform

- ☐ Pass
- ☐ Fail
- ☐ Other:

Ease of use of the platform

- ☐ Pass
- ☐ Fail
- ☐ Other:

Thank you for your time!

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FrailSafe: Ethical Evaluation questionnaire

Ethics constitute a vital quality in every research. In FrailSafe, we considered all aspects of our study, in order to ensure that our research methods adhere to the principles and legal requirements of biomedical research and Information and Communications Technology (ICT). Individual actions taken to address eight main ethical issues in the FrailSafe study are being described in this protocol.

Please, review the actions described below and evaluate if we achieved each point with a "Yes", "No", or "I need more information to decide" answer. You can add further comments in the respective fields.

Ethical point (1): Anonymity of data

Description of actions

- Participants' anonymity was one of the most important responsibilities of the FrailSafe consortium towards ensuring the ethicality of the study. The study included 510 healthy, older participants in total, from Cyprus, France and Greece (170 per clinical center). The processes for ensuring the anonymity of data were followed in every clinical center.

In detail:

- Each participant was assigned a unique four-digit code upon his/her participation to the study. His/her personal demographic data (name, address, telephone numbers, emails) were known only to the nurses and researchers who were directly involved to data collection and entry. No other member of the consortium had access to this information.
- When reporting a technical difficulty to the partners concerning one or more participants, researchers of the clinical centers stated the participant's code and never reported the participant’s name or gender in the correspondence.
- Each clinical center ensured that participants' protocols were securely stored and accesible only to the directly involved researchers. No electronic/cloud-based documents included participants' personal identification data.
- Blood sampling processes, also, took place using only the participants' four-digit codes to tag their blood specimens.
- All data collected by the FrailSafe devices could not be associated with any personal details and no information such as images, video or voice data were recorded.
- We collected data that would serve solely the specific research goals and no other.
- While collecting old and recent text samples for natural language analysis purposes, any words that could possibly be considered identifiable elements were masked.
- As standard approach, in any case, all data treated and managed by the project reference to anonymous subjects and by no mean anagraphical data are stored in digital format by the project.

1.a In your opinion and according to the information provided, has FrailSafe project employed adequate actions to preserve the anonymity of data where necessary?

- ☐ Yes
- ☐ No
- ☐ I need more information to decide

1.b Further comments

Ethical point (2): Respect for participants' rights

Description of actions

- In alignment with ethical research methods, the FrailSafe study followed specific principles to ensure that participants' rights were fully respected. In particular:
- Each clinical center applied and obtained their national Bioethics committee's approval before applying research protocols. The respective Bioethics Committees also reviewed and approved consent forms, as well as, the material that was disseminated to the participants.
- We did not include vulnerable people in the FrailSafe study according to specific preset exclusion criteria (i.e., exclusion of people with terminal illnesses, lack of ability to provide their informed consent, etc.).
- Participants were given consent forms describing research methodology, procedure, tools and timing of visits, study goals and purposes, in detail.
- Participants were also informed orally (through open-discussions) about all the details included in the aforementioned forms, in case they had any further questions to be resolved.
- Participants were given a consent form copy including contact details of their local FrailSafe team and an independent professional related to health sector who was assigned the role of the complaint officer.
- Participants were explicitly informed that they would not receive compensation for their participation to the FrailSafe study.
- According to our methodological plan, only 25 participants per center (Group C) received results generated from the FrailSafe project's measurements and they were informed beforehand for this process. At the same time, they were informed that the FrailSafe system is not a medically tested and approved health diagnostic tool, yet and thus, should consult their doctors for a conclusive opinion on their health status.
- However, all participants (all groups) were informed to consult their doctors, in case their data showed an indication for a health deviation that could be a medically significant finding. Again, participants were informed that the FrailSafe system is not a medically tested and approved health diagnostic tool, yet and thus, only their doctors could provide a valid and reliable opinion on their health status.
- All researchers were experienced and received training before getting involved in the study. Ethical behaviors were evaluated regularly per center to ensure that every team member interacted with the participants and handled data responsibly and confidentially.
- Participants were informed explicitly that they had the right to withdraw and request their data to be erased at any time-point, without further consequences and without providing any reasons for doing so.
- In some cases, for dissemination purposes, participants were asked if they wished to share their photos or opinions in public (i.e., FrailSafe photo exhibition) and those who agreed signed informed consent documents. Before providing the consent forms, participants were explicitly informed about the possible impact of these actions, the means of dissemination (i.e., newspaper, internet, etc) and that they could refuse to participate without any further consequences. Before providing their consent, participants were also informed that if they wished to withdraw from the study and erase these published data we could delete all published photos and not disseminate further material. However, due to the way the internet works we would be unable to ensure that all their previously published data could be restricted.
- In all processes, we included only participants who could and would provide their written consent.
- Participants were asked to give their consent for communication of some of their data either with their treating physicians or with their family members (if they wished so) and we asked the respective family members and physicians to provide their consent, as well, in order to be included in this information sharing process.
- The participants have the right to obtain information as to whether or not personal data concerning him or her are being processed, as well as the right to the following information according to art. 15 GDPR: i.e., the purposes of the processing; the time

that data will be stored or if not possible the criteria used to determine this period. The information sheet given to the participants clearly states this right and the way to obtain this information.

2.a In your opinion and according to the information provided, has FrailSafe project employed adequate actions to respect participants' rights to consent/withdraw/be informed

- ☐ Yes
- ☐ No
- ☐ I need more information to decide

2.b Further comments

Ethical point (3): Transparency

Description of actions

- ❖ Complying with research standards FrailSafe consortium took actions to ensure transparency in every aspect of our study. In particular:
- ❖ Throughout the study, our deliverables included detailed description of data collection methods, analyses, results, as well as, obstacles, limitations of our study and mitigation strategies.
- ❖ Published manuscripts in scientific journals included detailed description of data collection methods and tools, results, study limitations, acknowledgements and conflicts of interest.
- ❖ Consortium members signed an IPR contract for the exploitation of the products of the study.
- ❖ Partners had full transparency in their communication. Results, obstacles and problems were publicly discussed the soonest possible and solutions were decided and implemented collaboratively
- ❖ Consortium members constructed a complete data management plan and concluded to share collected datasets with the community, after ensuring the protection of IPR and patents.

3.a In your opinion and according to the information provided, has FrailSafe project employed adequate actions to preserve transparency?

- ☐ Yes
- ☐ No
- ☐ I need more information to decide

3.b Further comments

Ethical point (4): Erasure of data

Description of actions

- FrailSafe consortium took under consideration the fact that the users should be given the right to decide if they wanted to fully or partially erase data at any timepoint. Thus, we ensured that:
- Users data can be manually deleted from all devices before the upload in the FrailSafe server.
- Any user of the platform can request the erasure/modification of their data through the specific contact point provided, at any timepoint. This function was not provided through an automatic deletion button to protect users from accidentally deleting important health data.
- Through a specific feature, the users can choose to temporarily cease the system's monitoring activities, at any timepoint. These activities can restart only after the user chooses to enable them again.

4.a In your opinion and according to the information provided, has FrailSafe project employed adequate actions to provide an erasure function?

- ☐ Yes
- ☐ No
- ☐ I need more information to decide

4.b Further comments

Ethical point (5): Accountability

Description of actions

- To be accountable for the FrailSafe study we:
- Provided participants and their authorized family members with contact details of the researchers' team per country, in case more information was needed.
- Assigned the role of the complaint manager to an independent professional related to the health sector.
- Engaged personnel (nurses/researchers) who were familiar with ethics and good research practices.
- Provided training to all staff members before their contact with the participants and evaluated researchers' behavior regularly.
- Reported conflicts of interest in research papers submitted to scientific journals.
- Provided participants with detailed descriptions of study purposes, methodologies, data management and handling, as well as, the risks related to their participation (if any).

5.a In your opinion and according to the information provided, has FrailSafe project employed adequate actions to ensure accountability?

- ☐ Yes
- ☐ No
- ☐ I need more information to decide

5.b Further comments

Ethical point (6): Fair treatment and ensuring no harm was caused to participants

Description of actions

- To ensure fair and harmless treatment of participants we:
- Randomly selected our participants based on the larger pool of eligible people (all people had same chances to be included in the study).
- Ensured that the devices were safe for older adults:
- All devices were evaluated for their safety/discomfort in a lab environment and then, in a small sample of participants (both quantitatively and qualitatively) before being administered to the whole sample
- We performed daily phone calls while the users were using the devices in order to record any technical difficulties and evaluate safety of the devices for those participants who consented to be called daily.
- We gave participants the right and freedom to call their local research team at any time to report discomfort, difficulties and adverse events related to the FrailSafe system or if they wished to discontinue their participation or usage of the FrailSafe devices.
- Made sure that users were informed beforehand for any inconvenience or discomfort that might arise during their participation to the FrailSafe study.
- Did not put pressure to participants to use a device if they were not willing to do so.
- Did not put pressure to participants for the intensive phone follow-up and monitoring described in our methodological plan.
- Respected their wish to sparse interventions.
- Considered the psychological impact of availability of health-related information to the participants (i.e., stress due to a deviant health-related result) especially because these results are not accompanied by a constant, reliable professional interpretation. In this context, information on our platform is presented in a friendly manner avoiding frightening words and phrases and accompanied by a disclaimer that every result is just an indication that a parameter is deviant than expected based on normative data but this could be a false positive or false negative result and only a doctor can decide if this indication constitutes a medically significant finding as the FrailSafe system is not a medically tested and approved diagnostic tool yet.
- Respected confidentiality of data.
- Informed participants about possible “intimacy violation” issues, for example while home visits where bedrooms and bathrooms should be access for the installation of devices and respected their wish to share or not such spaces.
- Respected personal dignity (including treating the individual with respect)
- Respected physical and mental health and emotional wellbeing by preventing and minimizing risks associated with the study.
- Protected users from harm by explicitly informing them about any risks identified.
- Ensured that users agreement to participate in the project must be entirely voluntary and participants should be able to withdraw their consent or request erasure of their data at any point in the project without requirement to explain the reason behind their decision to withdraw.

6.a In your opinion and according to the information provided, has FrailSafe project employed adequate actions to ensure fair treatment of users and not causing harm?

- ☐ Yes
- ☐ No
- ☐ I need more information to decide

6.b Further comments

Ethical point (7): Collegiality

Description of actions

- The FrailSafe consortium recognized the need to preserve collegiality and well-intended relationships to promote and achieve research objectives and maintain good research practices. Hence, partners:
- Showed each other respect and promoted constructive criticism.
- Maintained transparency of their work.
- Promoted team-work.
- Engaged in frequent and transparent communication.
- Discussed, agreed on and complied with good practices for data ownership and sharing, authorship, publication and peer review.

7.a In your opinion and according to the information provided, has FrailSafe project employed adequate actions to preserve collegiality?

- ☐ Yes
- ☐ No
- ☐ I need more information to decide

7.b Further comments

Ethical point (8): Data security and cookies

Description of actions

- One of our priorities was the preservation of data security online. Thus, we employed several methods to:
- Prevent data loss:
- All the data stored within the system are backed up on a regular basis according to their sensitivity
- All the data can be restored from the backups
- All the components of the system can be restored if the system unlikely goes out of service for any reason
- All the data are securely stored on a network portion completely separated from the rest of the system's modules
- Encryption of data at rest and in transmission is applied whenever possible
- Employ up-to-date security protocols:
- Encryption of data in transit is always used (i.e. adoption of secure transfer protocols as HTTPS)
- We provide appropriate levels of authorization per user
- Each user is provided of anonymized credentials (i.e. with no reference to an existing individual or personal email)
- The criterion of the least privilege is adopted in giving authorization to the system resources, meaning that each user can view/manage only the data he/she owns/inserted and the portion of the system he/she strictly needs
- The same applies for the technical partners, meaning that each partner is the only one that can access the resources they manage and need to access for their work, each partner can work only on the data processing systems they implemented and each partner can only work with the databases they own and maintain

- The system is designed to keep resources isolated to prevent both external and internal unauthorized accesses
- Avoid cookies were possible
- Generally, we do not use cookies. Cookies are only used in the official website of the project, for the purpose of hosting the Virtual Community Platform. In the latter case, users are notified of cookies usage and are given the option to accept, reject or learn more about it before engaging in any website activities.
- Comply with GDPR
- The system is designed and implemented to fully comply with the General Data Protection Regulation (GDPR Regulation 2016/679) . First of all, the data managed by the system are completely anonymized before their input into the system. Added to that, as a default approach the maximum level of technical security possible has been implemented and applied by design.

8.a In your opinion and according to the information provided, has FrailSafe project employed adequate actions to ensure data security and avoidance of cookies?

- ☐ Yes
- ☐ No
- ☐ I need more information to decide

8. b Further comments

Thank you for your time!

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Annex XII. User Satisfaction Questionnaire

User Satisfaction Questionnaire

Evaluation questionnaire for participants in Group C

Information from clinicians

Please, enter the details below.

1. Please, indicate your clinical center *

- ☐ Cyprus
- ☐ France
- ☐ Greece

2. Please, indicate the participant's group *

- ☐ Ci
- ☐ Cii

Part A. General Questions

We will ask you to provide some general information for yourself.

1. Please, indicate your year of birth

_____

2. Please, indicate your total years of education (do not count vocational training)

_____

3. Please, indicate your civil status

- ☐ Married/ in couple
- ☐ Widow/er/divorced
- ☐ Single

4. Please, indicate your gender

- ☐ Female
- ☐ Male

5. How would you generally assess your technological skills and competency?

- ☐ Do not use computer technologies at all
- ☐ Beginner, I can use a computer or smartphone with help
- ☐ Intermediate user, I can use independently a computer or smartphone

- ☐ Advanced user, I use several apps and configure them
- ☐ Expert user, I am able to configure complex settings or develop new features myself

6. Please, indicate your familiarity with smart health apps or devices in general (i.e., calorie tracker, GPS tracker, smartwatch measuring heart rate, etc.)

- ☐ I have never used a smart health app or device *Skip to question 11.*
- ☐ I used a smart health app or device in the past but I do not use it now
- ☐ I currently use a smart health app or device other than the FrailSafe system

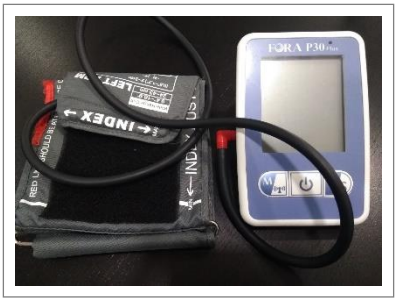
7. What smart health app or device do you/have you used?

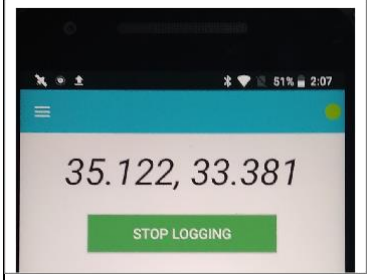
8. If you stopped using it, why did you do so?

Part B. User Experience Evaluation: Components

Please, help us evaluate FrailSafe components by answering to the following questions.

Please, use the pictures below as a guide to answer to the questions that follow.

Blood pressure measuring device	Vest
	
Dynamometer with tablet games	AR Glasses & Games

	
Smartphone indoor localization (Beacons)	Smartphone outdoor monitoring (GPS tracker, pedometer)
	
Tablet with serious game platform	
	

1. Which components of the FrailSafe system have you used?

- ☐ Blood pressure measuring device
- ☐ Vest
- ☐ Dynamometer with tablet games
- ☐ AR Glasses
- ☐ Smartphone indoor localization (Beacons)
- ☐ Smartphone outdoor monitoring (GPS tracker, pedometer)
- ☐ Tablet with serious game platform

2. How much do you think that the use each of the following components could assist you in achieving a better quality of life (i.e., improved health monitoring, social life, cognitive function)?

Mark only one box per row.

	Not at all	Somewhat	Quite a lot	I don't know
Blood pressure measuring device				
Vest				
Dynamometer with tablet games				
AR Glasses				
Smartphone indoor localization (Beacons)				
Smartphone outdoor monitoring (GPS tracker, pedometer)				
Tablet with serious game platform				

3. How do you think that the components you indicated in Q.2 as somewhat/quite a lot assistive contribute to a better quality of life?

4. Why do you think the components you indicated in Q.2 DO NOT contribute to a better quality of life?

5. How much did you enjoy using each of the following components?

Mark only one box per row.

	Not at all	Somewhat	Quite a lot	I don't know
Blood pressure measuring device				
Vest				

Dynamometer with tablet games				
AR Glasses				
Smartphone indoor localization (Beacons)				
Smartphone outdoor monitoring (GPS tracker, pedometer)				
Tablet with serious game platform				

6. Briefly explain the reasons you DID NOT enjoy the components you indicated in Q.5

7. How difficult did you find it to use each of the following components?

Mark only one box per row.

	Not at all	Somewhat	Nearly impossible to use	I don't know
Blood pressure measuring device				
Vest				
Dynamometer with tablet games				
AR Glasses				
Smartphone indoor localization (Beacons)				
Smartphone outdoor monitoring (GPS tracker, pedometer)				

Tablet with serious game platform				

8. Briefly explain what kind of difficulties you had while using the components indicated in Q.7

9. Indicate if you needed any assistance with each of the components

Mark only one oval per row.

	Not at all	Sometimes	All the time	I don't know
Blood pressure measuring device				
Vest				
Dynamometer with tablet games				
AR Glasses				
Smartphone indoor localization (Beacons)				
Smartphone outdoor monitoring (GPS tracker, pedometer)				
Tablet with serious game platform				

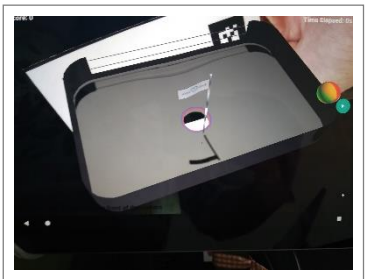
Please, use the following images as a guide to answer to the next question

REFLEX

MEMORY

SIMON

FORCE ANALYZER



GRAVITY BALL

SUPERMARKET

RAILWAY

REDWINGS

10. Indicate all of the following games that you:

Check all that apply.

	Reflex	*Simon*	*Memory*	*Force Analyzer*	*Gravity Ball*	*Supermarket*	*Railway*	*Redwings*
Enjoyed playing								
Found too complex								
Found boring								
Liked colors, background,								

music, effects, etc								
Thought rules were difficult to understand								
Thought that helped you improve some of your skills								

Part C: User Experience Evaluation: Integrated System

Please, take a moment to help us evaluate the integrated FrailSafe system by answering to the following questions.

Did you experience any unpleasant situation while using the system?

- ☐ Yes
- ☐ No
- ☐ Maybe

What kind of unpleasant situation did you experience?

- ☐ Loss of balance/fall
- ☐ Pain
- ☐ Stress
- ☐ Palpitations
- ☐ Headache
- ☐ Dizziness
- ☐ Blurred vision
- ☐ Other:_____

3. Did you have unpleasant experiences with any component in particular? If yes, please, explain.

4. Do you think that this system contributes to an amelioration of your health status?

Mark only one oval.

- ☐ Yes
- ☐ No
- ☐ Maybe

5. Please, briefly provide 1-2 reasons explaining your answer

6. Do you feel that the FrailSafe System is safe and secure to use?

Mark only one oval.

- ☐ Yes
- ☐ No
- ☐ Maybe

7. Please, briefly provide 1-2 reasons explaining your answer

8. Would you be willing to use this system again in your home setting?

- ☐ Yes
- ☐ No
- ☐ Maybe

9. Would you be willing to pay a certain amount of money to own this system?

- ☐ Yes
- ☐ No
- ☐ Maybe

When available as a product, the FrailSafe system will include hardware equipment and full or partial subscription to monitoring services which could provide alerts in case of emergencies. Please, take a moment to tell us your opinion on our pricing system.

10. What is the maximum amount that you would be willing to spend on an one-off payment in order to own the FrailSafe system (hardware-equipment)?

- ☐ less than 500€
- ☐ less than 1.000€
- ☐ less than 2.000€
- ☐ less than 3.000€
- ☐ more than 3.000€

11. Please, indicate the maximum amount that you would be willing to pay on a permanent subscription basis in order to benefit from the different FrailSafe plans described below.

a) MonitorMe (full package): including all the services provided by the FrailSafe system (training and technical assistance, self-monitoring of your vital signs, notifications and alerts in case of emergency etc.)

- ☐ only for free
- ☐ less than 10€ monthly
- ☐ less than 25€ monthly
- ☐ less than 50€ monthly
- ☐ more than 50€ monthly

b) MonitorMe (person living alone): including notifications and alerts messages in case of falls, loss of balance or loss of orientation

- ☐ only for free
- ☐ less than 10€ monthly
- ☐ less than 20€ monthly
- ☐ less than 30€ monthly
- ☐ more than 30€ monthly

c) MonitorMe (physical evaluation): including periodic evaluations on your physical conditions based on your real-life data

- ☐ only for free
- ☐ less than 10€ monthly
- ☐ less than 15€ monthly
- ☐ less than 20€ monthly
- ☐ more than 20€ monthly

d) MonitorMe (psychological & behavioral evaluation): including periodic evaluations on your psychological/behavioral condition and instant alerts in case of extreme events, which are all measured and analyzed using your real-life data

- ☐ only for free
- ☐ less than 10€ monthly
- ☐ less than 15€ monthly
- ☐ less than 20€ monthly
- ☐ more than 20€ monthly

12. FrailSafe system is designed to function and provide alerts with all of its components integrated. However, if there was an option, would you prefer to buy some of its components only?

- ☐ Yes
- ☐ No
- ☐ Maybe

13. Which component/s would you prefer to purchase?

- ☐ Blood pressure monitor
- ☐ Vest
- ☐ AR Glasses
- ☐ Smartphone outdoors (GPS tracker, pedometer)
- ☐ Smartphone indoor localization (Beacons)
- ☐ Tablet with Serious Games Platform
- ☐ Dynamometer with Tablet Games

14. Do you think the feedback provided by the system is helpful for you?

Mark only one oval.

- ☐ A great deal
- ☐ Much
- ☐ Somewhat
- ☐ Little
- ☐ Not much

15. Do you have any concerns/worries about using the system (i.e., data protection, etc)?

Mark only one oval.

- ☐ Yes
- ☐ No
- ☐ Maybe

16. Please, briefly explain your concerns

17. How important do you think it is to undertake a training program before using the FrailSafe system?

- ☐ Not at all
- ☐ Somewhat important
- ☐ I don't know
- ☐ Very important
- ☐ Absolutely important

Thank you for your time!

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Annex XIII. FrailSafe: Evaluation Questionnaire for Family Members/Caregivers

Questionnaire for Family Members/Caregivers

Tell us your opinion about the FrailSafe system as a family member or a caregiver who interacted directly with the system or learned about it otherwise. The following video can inform you how the system works from a user-perspective.

The FrailSafe system

http://youtube.com/watch?v=3pF89h6fbrI

Information for clinicians

Please, enter the details below.

1. Please, indicate your country

- ☐ Cyprus
- ☐ France
- ☐ Greece
- ☐ Other:_____

2. Please, indicate the Group that your family members belonged to during his/her FrailSafe study participation

- ☐ Ci
- ☐ Cii
- ☐ Not related to clinical groups
- ☐ I do not know

PART A: General Questions

1. Please, indicate your age group below

- ☐ Between 18 and 25 years old
- ☐ Between 26 and 45 years old
- ☐ Between 46 and 65 years old
- ☐ Between 66 and 85 years old
- ☐ 86 years or older

2. Please, indicate your years of education (do not count vocational training)

3. Please, indicate your gender

- ☐ Female
- ☐ Male

4. How did you learn about the FrailSafe system?

- ☐ I am a caregiver/an acquaintance/related to a participant to the FrailSafe study
- ☐ I am a member of the community/caregiver and interacted with the FrailSafe system otherwise.

5. Please, indicate the degree to which you provide assistance to your relative who used the FrailSafe system

- ☐ He/she is completely autonomous
- ☐ Sometimes I provide assistance with everyday tasks (i.e., cooking, cleaning, shopping) or help him/her monitor his/her health
- ☐ He/she has a housekeeper/informal caregiver to assist him/her with everyday tasks
- ☐ I provide intensive assistance to him/her approximately everyday
- ☐ Not applicable

6. How would you generally assess your technological skills and competency?

- ☐ Do not use computer technologies at all
- ☐ Beginner, I can use a computer or smartphone with help
- ☐ Intermediate user, I can use independently a computer or smartphone
- ☐ Advanced user, I use several apps and configure them
- ☐ Expert user, I am able to configure complex settings or develop new features myself

7. Indicate your familiarity with smart health apps or devices in general (i.e., calorie tracker, GPS tracker, smartwatch measuring heart rate, etc.)

- ☐ I have never used a smart health app or device
- ☐ I used a smart health app or device in the past but I do not use it now
- ☐ I currently use a smart health app or device other than the FrailSafe system

8. What smart health app or device do you/have you used?

9. If you stopped using this app/device, why did you do so?

Part B. USE questionnaire

Please, take a moment to tell us your opinion about the FrailSafe system as a means to monitor your relative's health or support his/her health self-monitoring.

Choose the answer that best represents you on each of the following statements assessing the degree to which the FrailSafe system would be useful, easy to use, easy to learn and satisfactory in terms of caring for your relative/monitoring his/her health.

Usefulness

1. It would help me be more effective in caring about my patient/relative

Strongly disagree	-3	-2	-1	0	1	2	3	Strongly agree

2. It would help me be more productive

Strongly disagree	-3	-2	-1	0	1	2	3	Strongly agree

3. It would be useful in my everyday tasks

Strongly disagree	-3	-2	-1	0	1	2	3	Strongly agree

4. It would give me more control in health monitoring of my patient/relative

Strongly disagree	-3	-2	-1	0	1	2	3	Strongly agree

5. It would make the things I want to accomplish easier to get done

Strongly disagree	-3	-2	-1	0	1	2	3	Strongly agree

Ease of use

6. I believe that it is easy to use

Strongly disagree	-3	-2	-1	0	1	2	3	Strongly agree

7. I believe that it is simple to use

Strongly disagree	-3	-2	-1	0	1	2	3	Strongly agree

8. I believe that it is user friendly

Strongly disagree	-3	-2	-1	0	1	2	3	Strongly agree

9. I believe that it requires the fewest steps possible to accomplish what I want to do

Strongly disagree	-3	-2	-1	0	1	2	3	Strongly agree

Ease of learning

10. I believe I would learn to use it quickly

Strongly disagree	-3	-2	-1	0	1	2	3	Strongly agree

11. I believe that I would easily remember how to use it

Strongly disagree	-3	-2	-1	0	1	2	3	Strongly agree

12. I believe that it would be easy to learn to use it

Strongly disagree	-3	-2	-1	0	1	2	3	Strongly agree

Satisfaction

13. I am satisfied with it

Strongly disagree	-3	-2	-1	0	1	2	3	Strongly agree

14. I would recommend it to a friend

Strongly disagree	-3	-2	-1	0	1	2	3	Strongly agree

15. It is fun to use

Strongly disagree	-3	-2	-1	0	1	2	3	Strongly agree

16. It works the way I want it to work

Strongly disagree	-3	-2	-1	0	1	2	3	Strongly agree

17. It is wonderful

Strongly disagree	-3	-2	-1	0	1	2	3	Strongly agree

Part C. Further points

1. I believe that the FrailSafe system would increase my relative's/patient's autonomy

Strongly disagree	1	2	3	4	5	Strongly agree

2. I think that my relative/patient would learn easily how to use it

Strongly disagree	1	2	3	4	5	Strongly agree

3. I believe that my relative/patient would adhere to the procedure required by the FrailSafe system

Strongly disagree	1	2	3	4	5	Strongly agree

4. I believe that the FrailSafe system offers protection of personal data

Strongly disagree	1	2	3	4	5	Strongly agree

5. I believe that the FrailSafe system could be a cost-effective health monitoring aid

Strongly disagree	1	2	3	4	5	Strongly agree

6. I would be willing to try the FrailSafe system along with other available care services for my relative (day-care, nursing care, etc)

Strongly disagree	1	2	3	4	5	Strongly agree

7. I would feel more confident or secure if my relative was using the FrailSafe system

Strongly disagree	1	2	3	4	5	Strongly agree

8. Please, tick the components of the FrailSafe system that you DID NOT like

- ☐ Blood pressure measuring device
- ☐ Vest
- ☐ Dynamometer with tablet games
- ☐ AR Glasses
- ☐ Smartphone outdoors (GPS tracker, pedometer)
- ☐ Smartphone indoor localization (Beacons)
- ☐ Tablet with Serious Games Platform

9. Please, explain your answer in Q.8

10. Would you recommend FrailSafe system to a friend/relative/acquaintance?

- ☐ Yes
- ☐ No
- ☐ Maybe

11. Are you willing to pay a certain amount of money to own this system?

- ☐ Yes
- ☐ No
- ☐ Maybe

When available as a product, the FrailSafe system will include hardware equipment and full or partial subscription to monitoring services which could provide alerts in case of emergencies. Please, take a moment to tell us your opinion on our pricing system.

12. What is the maximum amount that you would be willing to spend on an one-off payment in order to own the FrailSafe system (hardware-equipment)?

- ☐ less than 500€
- ☐ less than 1.000€
- ☐ less than 2.000€

- ☐ less than 3.000€
- ☐ more than 3.000€

13. Please, indicate the maximum amount that you would be willing to pay on a permanent subscription basis in order to benefit from the different FrailSafe plans described below.

a) MonitorMe (full package): including all the services provided by the FrailSafe system (training and technical assistance, self-monitoring of your vital signs, notifications and alerts in case of emergency etc.)

Mark only one oval.

- ☐ only for free
- ☐ less than 10€ monthly
- ☐ less than 25€ monthly
- ☐ less than 50€ monthly
- ☐ more than 50€ monthly

b) MonitorMe (person living alone): including notifications and alerts messages in case of falls, loss of balance or loss of orientation

- ☐ only for free
- ☐ less than 10€ monthly
- ☐ less than 20€ monthly
- ☐ less than 30€ monthly
- ☐ more than 30€ monthly

c) MonitorMe (physical evaluation): including periodic evaluations on your physical conditions based on your real-life data

- ☐ only for free
- ☐ less than 10€ monthly
- ☐ less than 15€ monthly
- ☐ less than 20€ monthly
- ☐ more than 20€ monthly

d) MonitorMe (psychological & behavioral evaluation): including periodic evaluations on your psychological/behavioral condition and instant alerts in case of extreme events, which are all measured and analyzed using your real-life data

- ☐ only for free
- ☐ less than 10€ monthly
- ☐ less than 15€ monthly
- ☐ less than 20€ monthly
- ☐ more than 20€ monthly

14. FrailSafe system is designed to function and provide alerts with all of its components integrated. However, if there was an option, would you prefer to buy some of its components only?

- ☐ Yes
- ☐ No
- ☐ Maybe

15. Which ones would you prefer to purchase?

- ☐ Blood pressure measuring device
- ☐ Vest
- ☐ Dynamometer with tablet games
- ☐ AR Glasses
- ☐ Smartphone outdoors (GPS tracker, pedometer)
- ☐ Smartphone indoor localization (Beacons)
- ☐ Tablet with Serious Games Platform

16. Do you think the feedback provided by the system is helpful for you?

Not much	1	2	3	4	5	A great deal

17. Do you have any concerns/worries about using the system?

- ☐ Yes
- ☐ No
- ☐ Maybe

18. Briefly explain your concerns

19. How important do you think it is to undertake a training program before using the FrailSafe system?

Not at all	1	2	3	4	5	Absolutely important

20. Please, share any further thoughts

Thank you for your time!

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Annex XIV. FrailSafe Questionnaire for Commercial Stakeholders

FrailSafe Questionnaire

We would appreciate your opinion regarding the utility and exploitability of the FrailSafe system. The following video explains how the FrailSafe system works.

The FrailSafe System

Part A. General Questions

1. Please, indicate what best describes your profession

- ☐ Researcher on computer sciences, health sciences and/or social sciences Health related IT developer/enterprise
- ☐ Health professional (nurse, psychologist, speech therapist, etc.)
- ☐ Health provider institution (hospital, long-term care centre, day-centre, etc.) Business consultant
- ☐ Insurance company
- ☐ Health products supplier/vendor Public authority
- ☐ Other:

2. Please, indicate your work position

3. Please, indicate your years of experience in the health sector

4. Please, state 1-3 main advantages that an app/mHealth device should have in order to be competitive according to your opinion

5. Which is your country?

Part B. Utility/usability

Please, indicate your level of agreement with each of the following statements. Leave unanswered any items that are not applicable to your work position/sector.

1. I think that FrailSafe system could have an added value for the quality of my services/work/sector.

Strongly disagree	1	2	3	4	5	Strongly agree

2. I think that FrailSafe system could increase the number of my current customers.

Strongly disagree	1	2	3	4	5	Strongly agree

3. I believe that FrailSafe system could reduce the costs of my business

Strongly disagree	1	2	3	4	5	Strongly agree

4. I believe that there is currently a need in the market for a product such as FrailSafe system

Strongly disagree	1	2	3	4	5	Strongly agree

5. I believe that FrailSafe system could increase the efficacy of my practice/services/sector

Strongly disagree	1	2	3	4	5	Strongly agree

6. If the FrailSafe system was available today, how likely would you be to use it instead of competing products currently available?

Strongly disagree	1	2	3	4	5	Strongly agree

Part C. Exploitability

1. Please, mention 1-2 groups that you think would be most likely to adopt the FrailSafe system (i.e., older adults, policy makers, etc)

2. Do you think that the FrailSafe system could be easily integrated to the healthcare system of your country?

- ☐ Yes
- ☐ No
- ☐ Maybe

3. What would be the obstacles in the implementation of the FrailSafe system in your healthcare system?

4. Would you be willing to adopt the FrailSafe system in your practice?

- ☐ Yes
- ☐ No
- ☐ Maybe

5. What is the maximum amount that you would be willing to spend on an one-off payment in order to own the FrailSafe system, which you could lease/rent to clients in order to remote monitor them?

- ☐ less than 500€
- ☐ less than 1.000€
- ☐ less than 2.000€
- ☐ less than 3.000€
- ☐ more than 3.000€

6. What is the maximum amount that you would be willing to pay on a permanent subscription basis in order to benefit from the different FrailSafe plans described below?

a) DoctorMe (full plan): including 24/7 remote monitoring of person's status, view history of exams, tests and daily-life data, insert and view clinical results (eCRF), receive system-generated suggestions which you can propose/apply to your patients, provide personalized feedback through the system, receive SMS/email notifications and alerts in case of emergency, exchange information with your clients in a forum-like environment, system training and technical assistance by the FrailSafe team

- ☐ less than 80€ monthly
- ☐ less than 120€ monthly
- ☐ less than 200€ monthly
- ☐ less than 400€ monthly
- ☐ more than 500€ monthly
- ☐ I am not interested in this feature

b) DoctorMe (SMS/email notifications only): including notifications and alert messages for your patients in case of falls, loss of balance or loss of orientation

- ☐ less than 30€ monthly
- ☐ less than 50€ monthly

- ☐ less than 70€ monthly
- ☐ less than 100€ monthly
- ☐ more than 100€ monthly
- ☐ I am not interested in this feature

c) DoctorMe (physical evaluation & suggestions only): including periodic evaluations on your patients' physical conditions/status based on your patients' real-life data

- ☐ less than 40€ monthly
- ☐ less than 70€ monthly
- ☐ less than 100€ monthly
- ☐ less than 130€ monthly
- ☐ more than 130€ monthly
- ☐ I am not interested in this feature

d) DoctorMe (suggestions & recommendations only): including periodic suggestions on the treatments to be applied to your patients based on data analysis conducted using your patients' real-life data

- ☐ less than 50€ monthly
- ☐ less than 70€ monthly
- ☐ less than 100€ monthly
- ☐ less than 130€ monthly
- ☐ more than 130€ monthly
- ☐ I am not interested in this feature

e) DoctorMe (psychological & behavioral evaluation only): including periodic evaluations on your patients' psychological/behavioral condition and instant alerts in case of extreme events, which are all measured and analyzed using your patients' real-life data

- ☐ less than 40€ monthly
- ☐ less than 60€ monthly
- ☐ less than 80€ monthly
- ☐ less than 100€ monthly
- ☐ more than 100€ monthly
- ☐ I am not interested in this feature

f) ProData (full plan): including access to anonymized diverse historical medical data of older people collected during their real-life activities and/or insertion of your own data for comparison or further analysis

- ☐ less than 80€ monthly
- ☐ less than 150€ monthly
- ☐ less than 200€ monthly
- ☐ less than 250€ monthly
- ☐ more than 250€ monthly
- ☐ I am not interested in this feature

7. Please, indicate the estimated percentage of your current clients/target groups who would adopt the FrailSafe system

8. List briefly a few reasons that would lead you to NOT adopt the FrailSafe system and/or your concerns about this solution

9. Please, express any further thoughts

Thank you for your time!

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Annex XV. FrailSafe: Socioeconomic Evaluation Questionnaire

FrailSafe Socioeconomic impact

We would appreciate your opinion regarding the socioeconomic impact of the FrailSafe system. The following video explains how the FrailSafe system works.

The FrailSafe System

http://youtube.com/watch?v=3pF89h6fbrI

Part A. General Questions

1. Please, indicate your years of education (do not count vocational training)

2. Please, indicate your year of birth

3. Please, indicate your gender

- ☐ Male
- ☐ Female

5. Which is your country?

Part B. Impact in health

Please, indicate your level of agreement with each of the following statements. Leave unanswered any items that are not applicable to your work position/sector.

1. I think that the FrailSafe system could be a reliable measure of a person's healthcare status

Strongly disagree	1	2	3	4	5	Strongly agree

2. I believe that the FrailSafe system can help make the process in healthcare more efficient

Strongly disagree	1	2	3	4	5	Strongly agree

3. I believe that sharing patient data electronically through the FrailSafe system is safe

Strongly disagree	1	2	3	4	5	Strongly agree

4. I believe that the FrailSafe system would reduce inefficiencies in healthcare delivery

Strongly disagree	1	2	3	4	5	Strongly agree

5. I believe that the FrailSafe system could enhance medical treatment for remote patients.

Strongly disagree	1	2	3	4	5	Strongly agree

6. I believe that the FrailSafe system could provide inaccurate information diagnostically

Strongly disagree	1	2	3	4	5	Strongly agree

7. I believe that the FrailSafe system gives patients a more central role in the management of their health

Strongly disagree	1	2	3	4	5	Strongly agree

8. I believe that the FrailSafe system could contribute to decrease unstructured, ad hoc, emergency interactions between care staff and patients for no emergency reasons

Strongly disagree	1	2	3	4	5	Strongly agree

9. I believe that the FrailSafe system could enhance patient-doctor relationship

Strongly disagree	1	2	3	4	5	Strongly agree

10. I believe that the FrailSafe system can help promote a healthier lifestyle

Strongly disagree	1	2	3	4	5	Strongly agree

11. I believe that the FrailSafe system can improve health in chronically ill patients

Strongly disagree	1	2	3	4	5	Strongly agree

12. I believe that the FrailSafe system can provide easiness and effectiveness of data communication between professionals

Strongly disagree	1	2	3	4	5	Strongly agree

13. I believe that the FrailSafe system can contribute to a stronger healthcare system

Strongly disagree	1	2	3	4	5	Strongly agree

14. I believe that the FrailSafe system can reduce risks associated with repeated diagnostic tests

Strongly disagree	1	2	3	4	5	Strongly agree

15. I believe that the FrailSafe system can reduce patients' waiting times

Strongly disagree	1	2	3	4	5	Strongly agree

16. I believe that the FrailSafe system can improve prescribing practices by allowing healthcare professionals to take more factors into account during the process of prescribing

Strongly disagree	1	2	3	4	5	Strongly agree

17. Do you have any concerns about FrailSafe system's use in the healthcare system?

18. Further comments

Part C. Impact on Economy

1. I think that the FrailSafe system could reduce unnecessary visits to the doctor

Strongly disagree	1	2	3	4	5	Strongly agree

2. I believe that the use of the FrailSafe system could open more positions in healthcare delivery for critically ill patients

Strongly disagree	1	2	3	4	5	Strongly agree

3. I believe that the FrailSafe system could result to improved productivity through the introduction of more efficient business processes

Strongly disagree	1	2	3	4	5	Strongly agree

4. I believe that the FrailSafe system could result to revenue growth for the healthcare industry resulting from extended market coverage

Strongly disagree	1	2	3	4	5	Strongly agree

5. I believe that the FrailSafe system could reduce private cost for healthcare services

Strongly disagree	1	2	3	4	5	Strongly agree

6. I believe that the FrailSafe system could reduce public cost for healthcare services

Strongly disagree	1	2	3	4	5	Strongly agree

7. I believe that the FrailSafe system could contribute to job creation

Strongly disagree	1	2	3	4	5	Strongly agree

8. I believe that the FrailSafe system could contribute to the growth of certain industries within the healthcare system (i.e, healthcare IT)

Strongly disagree	1	2	3	4	5	Strongly agree

9. I believe that the FrailSafe system could result to job elimination

Strongly disagree	1	2	3	4	5	Strongly agree

10. Do you have any concerns with regard to the economic impact of the FrailSafe system?

11. Further comments

Part D. Social impact

1. I think that the FrailSafe system could contribute to social inclusion of older adults

Strongly disagree	1	2	3	4	5	Strongly agree

2. I believe that the use of the FrailSafe system could contribute in keeping older adults active

Strongly disagree	1	2	3	4	5	Strongly agree

3. I believe that the use of the FrailSafe system could increase IT literacy among older adults

Strongly disagree	1	2	3	4	5	Strongly agree

4. I believe that the FrailSafe system could promote innovation

Strongly disagree	1	2	3	4	5	Strongly agree

5. I believe that the FrailSafe system could increase the risk of isolation for older adults

Strongly disagree	1	2	3	4	5	Strongly agree

6. Do you have any concerns with regard to the social impact of the FrailSafe system?

7. Further comments

Thank you for your time!

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Annex XVI. FrailSafe Short Survey

EU FrailSafe event follow-up survey

Thank you for participating at the EU FrailSafe (event) on (date).

In order to improve future activities and collect your feedback about the presented solution, the team would be grateful if you could fill in the present survey.

Were you satisfied with the overall content of the event? *

- ☐ Yes
- ☐ No
- ☐ Other:

Were you satisfied with the discussions? *

- ☐ Yes
- ☐ No
- ☐ Other:

FrailSafe Digital Health Solution

Our team would like to hear more about your opinion about the presented solution.

I believe that there is currently a need in the market for a product such as the FrailSafe system *

- ☐ Strongly disagree
- ☐ Disagree
- ☐ Neither agree nor disagree
- ☐ Agree
- ☐ Strongly agree

If the FrailSafe system was available today, how likely would you use it instead of currently products currently available? *

- ☐ Not at all likely
- ☐ Slightly likely
- ☐ Moderately likely
- ☐ Very likely
- ☐ Extremely likely

Do you think that the FrailSafe system could be easily integrated into your country's healthcare system? *

- ☐ Yes
- ☐ No
- ☐ Other:

What would be the obstacles for implementation of the FrailSafe system into your healthcare system?

What is the maximum amount that you would be willing to spend on an one-off payment in order to own the FrailSafe system? *

- ☐ less than 500€
- ☐ less than 1.000€
- ☐ less than 2.000€
- ☐ less than 3.000€
- ☐ more than 3.000€

Any comment that would enable us to improve our activities?

Thank you for your time!

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