frail safe

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Behavioral Monitoring

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Change History

Ver.	Date	Status	Author (Beneficiary)	Description
2.6.1	21/6/17	Draft	Marina Kotsani (INSERM)	First Draft
2.6.2	23/6/17	Draft	Konstantinos Deltouzos (UoP) Dimitrios Vlachakis (UoP)	Statistical data and diagrams provided
2.6.3	28/6/17	Draft	Marina Kotsani (INSERM)	Incorporation of statistical data in the report, clinical comments
2.6.4	29/6/17	Draft	Athanase Benetos(INSERM)	Several Revisions
2.6.5	30/6/17	Final	Marina Kotsani (INSERM) Athanase Benetos (INSERM)	Final revision
2.6.6	20/11/17	Draft	Konstantinos Deltouzos (UoP) Eva Zacharaki (UoP) Emilia Papagiannaki (UoP)	New statistical data and diagrams provided
2.6.7	22/11/17	Draft	Konstantinos Moustakas (UoP)	Contribution of some paragraphs
2.6.8	22/11/17	Draft	Marina Kotsani (INSERM)	Integration of new data in the draft
2.6.9	25/11/17	Draft	Athanase Benetos (INSERM)	Several Revisions
2.6.10	27/11/17	Draft	Sibora-Rafaella Tsela (UoP) Marina Polycarpou (MATERIA) Konstantinos Deltouzos (UoP) Anne Freminet (INSERM)	Input about updated data related to clinical studies
2.6.11	28/11/17	Final	Marina Kotsani (INSERM)	Integration of final revisions and pagination

TRACK CHANGES

Some adaptations have taken place according to the Reviewer's comments after the Review Meeting in Patras on the 28th and 29th of September 2017.

In the introduction section forthcoming deliverables that will treat multiple data derived from the FrailSafe system are mentioned (page 21).

In page 23, additional explanations on data presentation is offered.

In several parts of section 2, new data from the second clinical evaluation of group B regarding behaviour are presented. In section 2.1_medical domain (pages 27-28 and 31-33), in section 2.3_lifestyle domain (pages 40 and 43-45), in section 2.4_functional capacity domain (page 47), in section 2.5_physical domain (pages 59-60 and 62-66), in section 2.6_nutritional domain (page 71) and in section 2.7_cognitive domain (page 73).

Section 2.12 is devoted to basic data derived from devices used during home visits. Its introductory part mentions deliverables treating the Virtual Patient Model in more detail, the final D9.8 deliverable that will present the added value of the FrailSafe integrated system, and also briefly refers to the VERITAS project (pages 92-93).

In section 2.12.1 data from the WWS and WWBS monitoring are presented (pages 93-96), whereas section 2.12.2 refers to data from the GPS monitoring (pages 96-101) and section 2.12.5 presents data from the redwings-dynamometer game (pages 102-109).

Sections 4.Undesirable events monitoring (pages 112-113), 5.Drop-offs (pages 113-114) and follow up by regular phone calls (pages 115), are also updated to 20/11/2017.

Finally, in the revised version of this deliverable, the paragraph referring to the WWBS updated system has been deleted, because relevant data are presented together with the WWS version in section 2.12.1.

EXECUTIVE SUMMARY

This report enters the context of tasks 2.4 Behavioral monitoring and 2.2 Clinical monitoring of older people, of Work Package 2.

The main objective of the present deliverable is to present the first data obtained from the field studies that run simultaneously in the three clinical centers. These first outputs will enter the integrated FrailSafe database, will undergo complex analysis so as to finally emerge the most performant ones in terms of early frailty identification and outcomes' prediction, as described more thoroughly in the deliverable 2.4 Completion of quantification campaign. These final results will be presented in the D9.8_Project Final Report, while this deliverable presents mostly descriptive results. Along with the presentation of each variable's measurements, some elements about feasibility and acceptability issues will also be mentioned.

In the present revised version, data collected up to now from the devices during home visits are presented. Moreover, whereas in the initial version we presented data derived from the first clinical evaluation of all participants of the Start up (A) and the Main group (B), in this revised version, selected data, mostly related to the behavioral monitoring, coming from the second (in six months' interval) clinical evaluation of group B are presented.

As a secondary objective, this deliverable also refers to undesirable events occurring during the follow up phase of the study, either potentially relevant with the study's interventions or not, the drop-off rates and their reasoning.

The last session expands to new perspectives and the actions to come in order to ameliorate behavioral monitoring. New devices and applications, in the phase of integration currently or in the near future, will be briefly introduced.

DOCUMENT INFORMATION

Contract Number:	H2020-PHC–690140	**Acronym:**	FRAILSAFE
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Work package number:	2	**Title:**	Clinical studies, measurements, clinical analysis

Date of delivery	**Contractual**	**27/11/2017 (M23)**	**Actual**	29/11/2017
Status	Draft ☐		Final ☒	
Nature	Report ☒	Demonstrator ☐	Other ☒ (data)	
Dissemination Level	Public ☒	Consortium ☐		
Abstract (for dissemination)	This is the revised version of a deliverable that reports on the preliminary data collected at the recruitment phase of group A and B of the FrailSafe clinical study. These data come both from the clinical evaluation visits and the FrailSafe home sessions and have been fed in the eCRF platform and extracted to a central database in order to be integrated with the data coming from the rest of the FrailSafe devices. Initial descriptive statistics are presented, along with current and forthcoming strategies for the behavioural monitoring.			
Keywords	Behaviour, data, descriptive statistics, monitoring.			

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List of figures

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List of abbreviations and acronyms

(*in alphabetic order*)

BMI	Body Mass Index
bpm	beats per minute
cm	centimeters
eCRF	Electronic Case Report Form
GDS	Geriatric Depression Scale
GPS	Global Possitioning System
IMU	Inertial Measurement Unit
MCI	Mild Cognitive Impairment
MMSE	Mini Mental State Examination
MNA	Mini Nutritional Assessment
MoCA	Montreal Cognitive Assessment
QoL	Quality of Life
sec	seconds
TUG	Timed get Up and Go
VAS	Visual Analogue Scale
vs	versus
VPM	Virtual Patient Model
VSM	Virtual Super Market
WP	Work Package
WWBS	Wearable WBAN System
WWS	Wearable Wellness System

1. Introduction

The FrailSafe project aspires at revealing new indicators that will prove to be descriptive of frailty and predictive of its evolution and adverse events. In order to develop a kind of novel frailty biomarkers, series of parameters and variables are about to be tested. These variables correspond to "objective" measurements of performance and descriptives of people's behavior, both in an intermittent and a continuous unobstructive way, during the FrailSafe home session.

At this point of the study a sufficient number of information, though not all data collected, are fed in the central database and have started providing outputs for analysis. Being still in an early phase of the study, when hard and proxy outcomes (as defined in the revised version of D 2.1, M23) have not yet occurred in a sufficient incidence to draw conclusions, the several metrics are still being seen from a descriptive point of view. More descriptive, as well some analytical statistics related to specific frailty metrics will be presented in forthcoming deliverables (D 2.5 - Completion of quantification campaign (vers b), D 4.2 - Offline analysis of data (vers b), D 4.4 - Online analysis of data (vers b), D 4.15 - Signal processing algorithms for extraction of frailty related indicators (vers b), D 4.16 - FrailSafe Decision Support System (vers a), D 4.17- FrailSafe Decision Support System (vers b) and D 7.3 - Small-scale evaluation report). However, the project's main medical objective, which is the investigation of the added value of the FrailSafe integrated system on the early detection, evaluation and prediction and prevention of frailty evolution cannot be accomplished before the latest phase of the project, when the participants' follow up and data collection will have progressed enough. These core results will be presented in D9.8_Project's Final Report (M36).

This report aims to give a first view of the data that has been collected through the eCRF platform. Since the nature of the data is complex, it has been considered that the appropriate representation of the data should be visually-friendly, with histograms and boxplots in order to make the evaluation an easy process.

The distributions of the measured variables are split in Domains, (as defined in the D2.4, M18), while the participants are grouped according to their frailty status, as it has been measured by Fried's criteria of frailty, and when appropriate, according to sex. Thus, each histogram represents three different distributions, one for each of the groups *Frail, PreFrail NonFrail.* This representation makes it easy to recognize different behaviors among the groups, and decide if a specific variable is proper for separating the groups or not.

A similar analysis per frailty status will be performed in the course of the study, according to the new frailty metrics and frailty categories that will emerge from the project's long-time data and outcomes analysis.

Figure 1 depicts the age distribution of our study population so far (group A and B).

The actual number of participants in the database is 378 and not 360 as we would expect if 120 participants were recruited for group A and B from each centre. This happens because in the eCRF were also included people that dropped off later on, who have later on been replaced. We judged it appropriate to also include them in the present time-shot analysis, since the purpose of the present report is not the follow up monitoring, but rather the description of the initial data obtained by the first clinical and devices'-based evaluations. In a next stage of the study, individuals that dropped off will be analysed separately to identify any relevant special characteristics related to their withdrawal.

Table 1. Frailty status repartition of the participants of groups A and B.

Total_records	Total_Frail	Total_PreFrail	Total_NonFrail
378	100	158	120

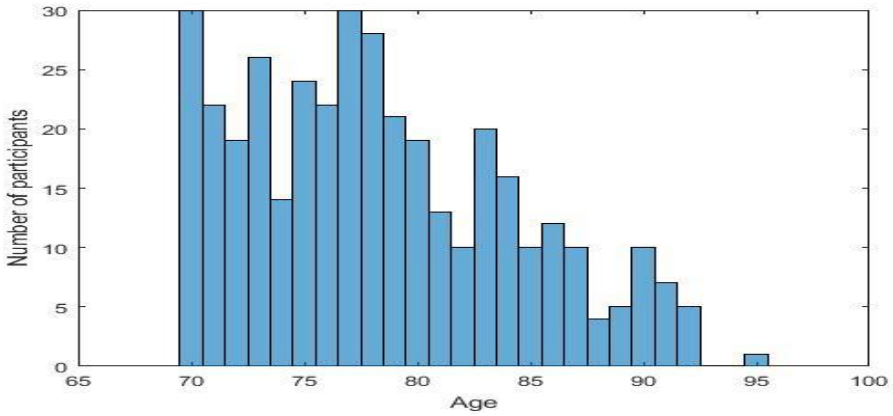
Table 2. Sex repartition of the participants of groups A and B.

Total_records	Total_Male	Total_Female
378	142	236

Table 3. Age range repartition of the participants of groups A and B, per frailty group.

Age	Frail	Pre-frail	Non-frail	Total N
70-75	20	47	68	135
76-80	29	60	31	120
>80	51	51	21	123
	100	158	120	378

Figure 1. Distribution of ages in our study population of group A and B.



Finally, all throughout the tables of data presentation, there might be small deviations between the total number of participants studied and the number of values available for each parameter, due to some missing values.

1.1 Explanations on data presentation

The present report presents descriptive data. All collected data from the initial evaluation of the participants of group A and B are presented, along with data related to objective behavioural monitoring from the second clinical evaluation of group B. Data derived from devices during all FrailSafe home sessions up until 20/11/17 are also presented.

Regarding the data presentation by histograms, since the number of the participants of each group (Frail, NonFrail, PreFrail) is not the same, normalization has been applied so that one can compare the three groups' behavior. Thus, on y-axis one doesn't see the actual number of participants that fall in each bin, but values from 0 to 100 maximum, showing the percentage of the participants falling in a specific bin. It should be noted here that even if there are missing values, the bars for each frailty group sum up to 100. This way all groups are normalized while the actual number of each group (as well as the number of missing values) is depicted on a table for each domain. For all numerical variables, the x-axis is split in clinically meaningful range categories, and on each space one can see a triplet of bars representing each of the three frail-related categories. In the case of nominal variables, the spaces on x-axis are split by default according to the number of classes, but the bars are also presented in triplets.

When appropriate, the analysis per sex is presented.

2. eCRF data description

The present report follows the clinical domains' repartition presented in D2.4 (M18), and will be completed by presenting centralized data extracted from the FrailSafe system devices.

2.1 Data derived from parameters of the medical domain

2.1.1 Clinical questionnaire-derived data

Even though the reporting of medical co-morbidities does not exactly enter the "behavioral" monitoring concept, the actual medical and health condition can influence a person's behavior and functional status.

Table 4 presents the minimum, maximum and mean values of the continuous variables that compose this domain of evaluation, followed by tables describing categorical variables and by figures displaying available data.

Table 4. Basic descriptive statistics of continuous variables corresponding to the questionnaire-derived data of the medical domain

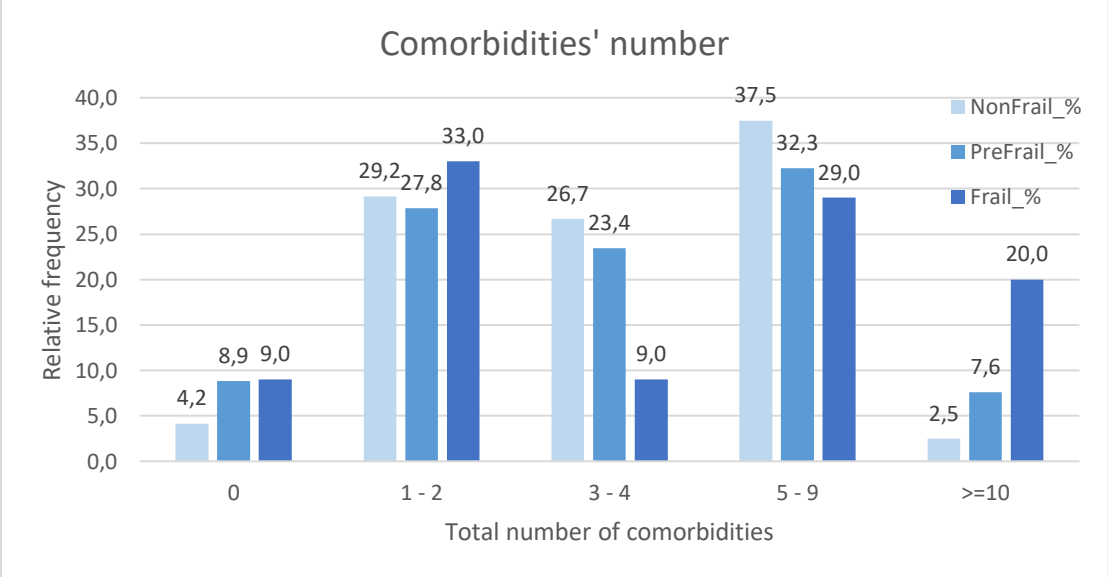
	Minimum	Maximum	Mean
Number of comorbidities	0	17	4,5
Number of significant comorbidities	0	5	0,3
Number of medication taken	0	17	3,9
Hospitalisation in the last year	0	15	0,4
Hospitalisation in the last three years	0	30	0,7

The tables and figures below present the repartition of the study's participants according to categories of number of comorbidities, number of significant comorbidities accumulated on a person and number of drug active substances' categories taken per day. By "significant comorbidity" we defined those that, according to the clinical investigator's evaluation play an important role in the functional status of the person.

Table 5. Repartition of participants in each category of number of comorbidities according to frailty group.

Number of comorbidities	NonFrail	PreFrail	Frail	Total N
0	5	14	9	28
1 - 2	35	44	33	112
3 - 4	32	37	9	78
5 - 9	45	51	29	125
>=10	3	12	20	35
	120	158	100	378

Figure 2. Repartition of percentages in each category of number of comorbidities, according to frailty group.

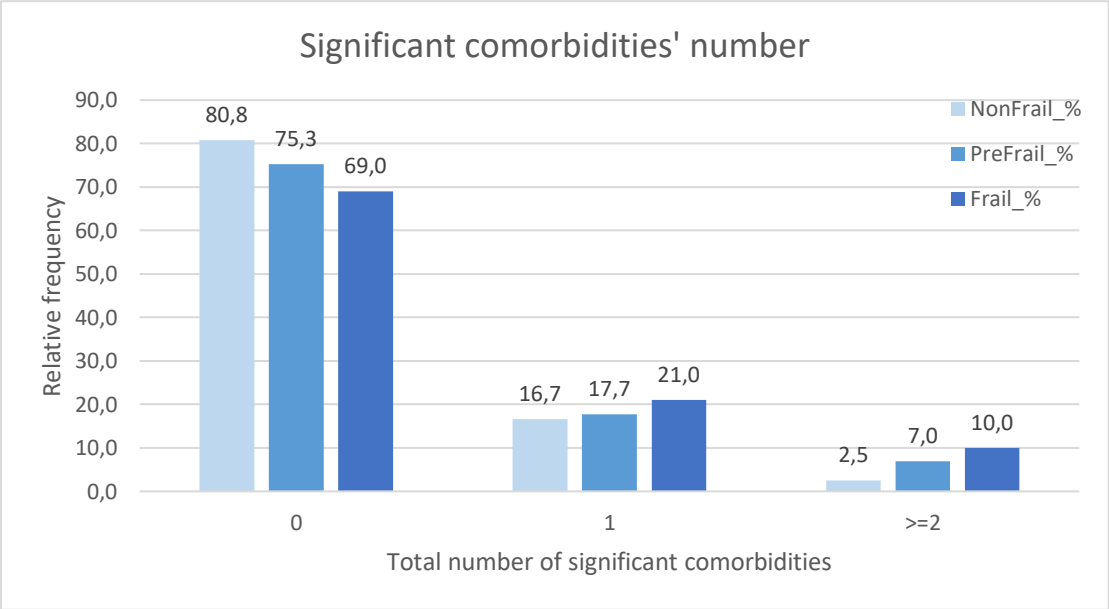


We observe that the repartition of multimorbidity in all categories bellow 10 comorbidities is quite random regarding the frailty level of the participants. However, frail individuals predominate in the group of 10 or more comorbidities (20%), in which the percentage of non-frail subjects is very limited (2.5%).

Table 6. Repartition of participants in each category of number of significant comorbidities, according to frailty group.

Significant comorbidities' number	NonFrail	PreFrail	Frail	Total N
0	97	119	69	285
1	20	28	21	69
>=2	3	11	10	24
	120	158	100	378

Figure 3. Repartition of percentages in each category of number of significant comorbidities, according to frailty group.

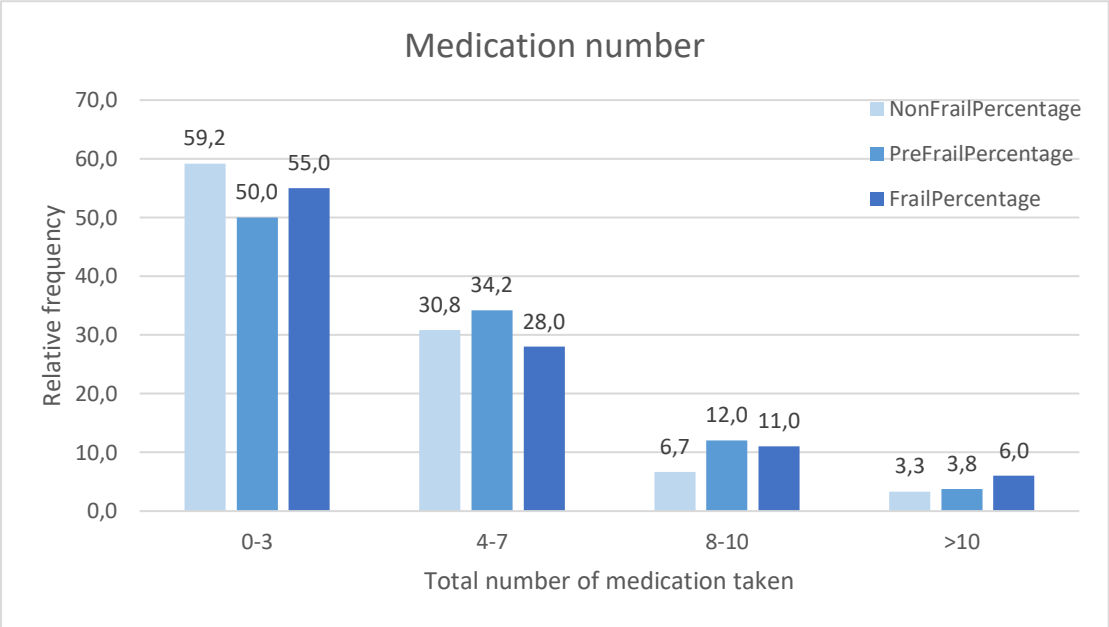


The majority of participants do not present a comorbidity that significantly effects their functional level, according to the clinician's evaluation, even though in the category of no significant comorbidity, those that outnumber are the non-frail (80.8% vs 69% for frails). As significant comorbidities start to accumulate, mainly as they reach the level of 2 or more significant comorbidity per person, the frailty group outweighs both the pre- and the non-frails. Very few non-frail people are encountered in the category of 2 or more comorbidities significant for the functional status (2.5%), perhaps reflecting the clinical significance of functional status and multimorbidity in the frailty phenotype.

Table 7a. Repartition of participants in each category of number of medication taken per day, according to frailty group (initial evaluation).

Number of medication taken per day	NonFrail	PreFrail	Frail	Total N
0-3	71	79	55	205
4-7	37	54	28	119
8-10	8	19	11	38
>10	4	6	6	16
	120	158	100	378

Figure 4a. Repartition of percentages in each category of number of medication taken per day, according to frailty group (initial evaluation).



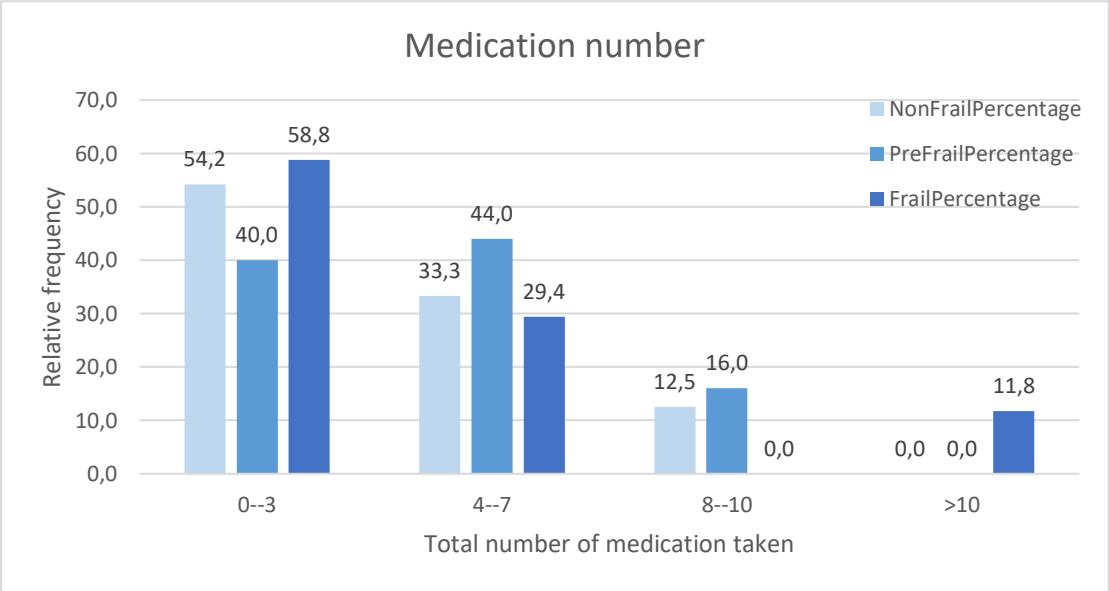
More than half of our study population take three or less medication per day. The repartition of frailty status is almost equally distributed across number of medication categories.

Similar results we observe in the second evaluation of group B, with the only difference that people that take more than 10 medication per day, belong only to the frailty group.

Table 7b. Repartition of participants in each category of number of medication taken per day, according to frailty group (second evaluation).

Number of medication taken per day	NonFrail	PreFrail	Frail	Total N
0--3	26	20	10	56
4--7	16	22	5	43
8--10	6	8	0	14
>10	0	0	2	2
	48	50	17	115

Figure 4b. Repartition of percentages in each category of number of medication taken per day, according to frailty group (second evaluation).



Regarding the frequency of the most common comorbidities (Annex 1), arterial hypertension is by far the most prevalent comorbidity in all three frailty groups (64% in frails, 51% in pre-frails and 55% in non-frails), followed by arthralgias in about 40% of participants of all groups. Dyslipidemia, anxiety disorder, eye disease and urinary incontinence closely follow. The prevalence of dyslipidemia seems to be higher in the non-frail group (42.5 vs 27 and 32% in frail and pre-frail group), but we believe that this could be a bias referring to the lack of sufficient evidence of screening and treating dyslipidemia in frail and perhaps pre-frail older populations. Otherwise, not surprisingly, most co-morbidities seem to generally present a higher prevalence in the frailty group.

About the nature of the significant comorbidities (Annex 2) most commonly we observe arthralgias (presenting as significant in about 8, 10.1 and 4.2% of frails, pre-frails and non-frails respectively), arterial hypertension (presenting as significant in about 7, 2.5 and 3.3% of frails, pre-frails and non-frails respectively), depression and anxiety disorders, osteoporosis and lower limp disability as an aftereffect of surgery or traumatism. Comorbidities presenting as significant exclusively in the frailty group are heart and respiratory insufficiency, stroke, Parkinson's disease and impaired cognitive function.

Tables and figures below present the prevalence of residual non-compensated sensory impairment by frailty group.

Table 8. Repartition of participants in each category of hearing impairment, according to frailty group.

Hearing impairment	NonFrail	PreFrail	Frail	Total N
Hears moderately	23	40	24	87
Hears poorly	1	6	12	19
Hears well	96	112	64	272
	120	158	100	378

Figure 5. Repartition of percentages in each category of hearing impairment, according to frailty group.

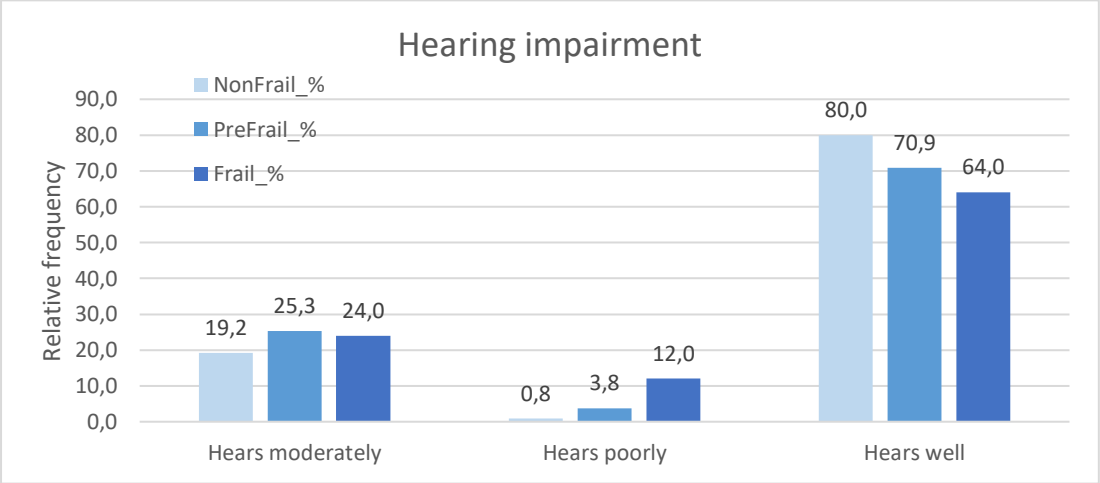
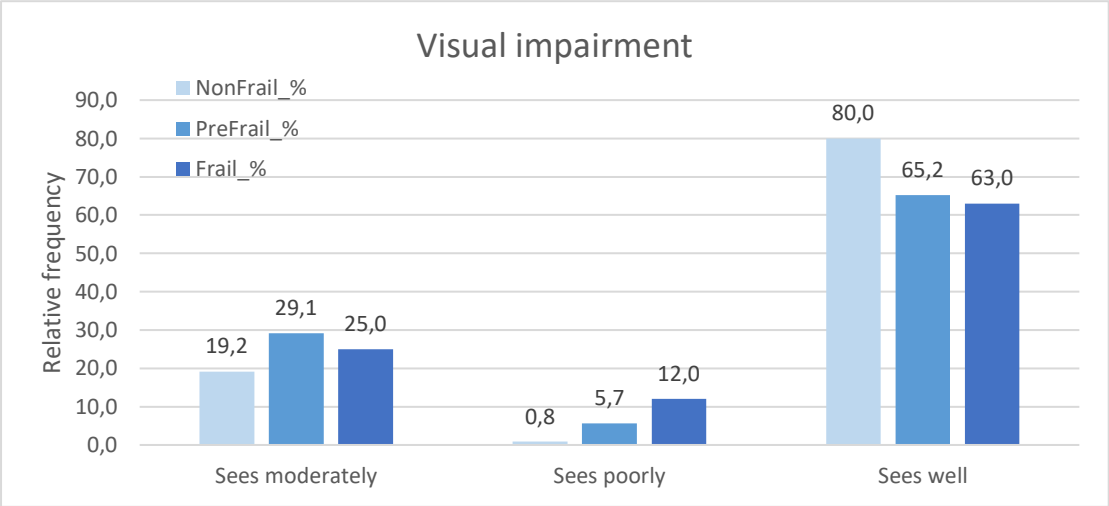


Table 9. Repartition of participants in each category of visual impairment, according to frailty group.

Visual impairment	NonFrail	PreFrail	Frail	Total N
Sees moderately	23	46	25	94
Sees poorly	1	9	12	22
Sees well	96	103	63	262
	120	158	100	378

Figure 6. Repartition of percentages in each category of visual impairment, according to frailty group.



In the intermediate category of hearing performance, all frailty groups show similar prevalence. On the other hand, poor audition is more prevalent in the frailty group, and almost inexistent for the non-frails, while normal audition is dominated by the non-frail group. A similar phenomenon is observed about visual impairment, implying that sensory organs' deficiencies could be an important contributor to frailty.

Another parameter to be monitored in the medical domain is the number of hospitalizations in one and three years' time.

Table 10a. Repartition of participants in each category of number of hospitalizations in last year, according to frailty group (initial evaluation).

Number of hospitalisations in last year	NonFrail	PreFrail	Frail	Total N
0	105	121	76	302
1	13	27	13	53
>=2	1	10	8	19
	119	158	97	374

Figure 7a. Repartition of percentages in each category of number of hospitalizations in last year, according to frailty group (initial evaluation).

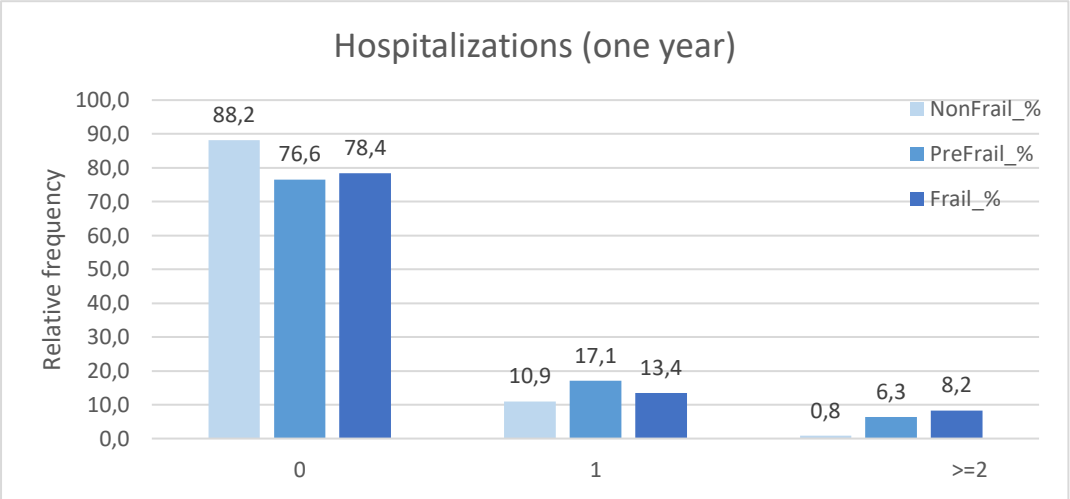


Table 10b. Repartition of participants in each category of number of hospitalizations in last year, according to frailty group (second evaluation).

Number of hospitalisations in last year	NonFrail	PreFrail	Frail	Total N
0	37	41	13	91
1	8	7	2	17
>=2	2	2	2	6
	47	50	17	114

Figure 7b. Repartition of percentages in each category of number of hospitalizations in last year, according to frailty group (second evaluation).

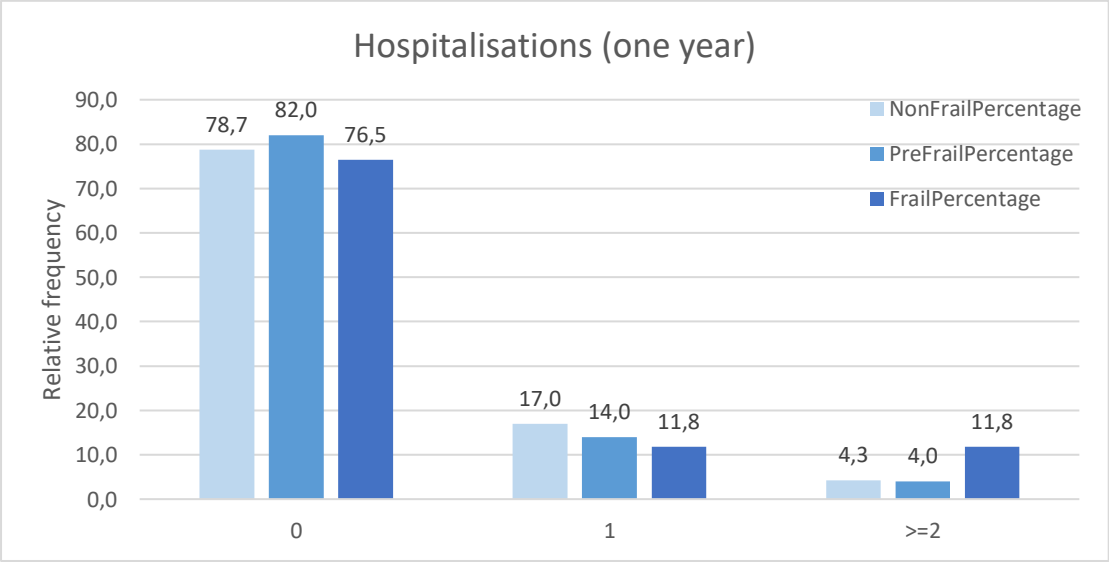


Table 11a. Repartition of participants in each category of number of hospitalizations in last 3 years, according to frailty group (initial evaluation).

Number of hospitalisations in 3 years	NonFrail	PreFrail	Frail	Total N
0	90	95	57	242
1	26	44	21	91
>=2	4	19	20	43
	120	158	98	376

Figure 8a. Repartition of percentages in each category of number of hospitalizations in last 3 years, according to frailty group (initial evaluation).

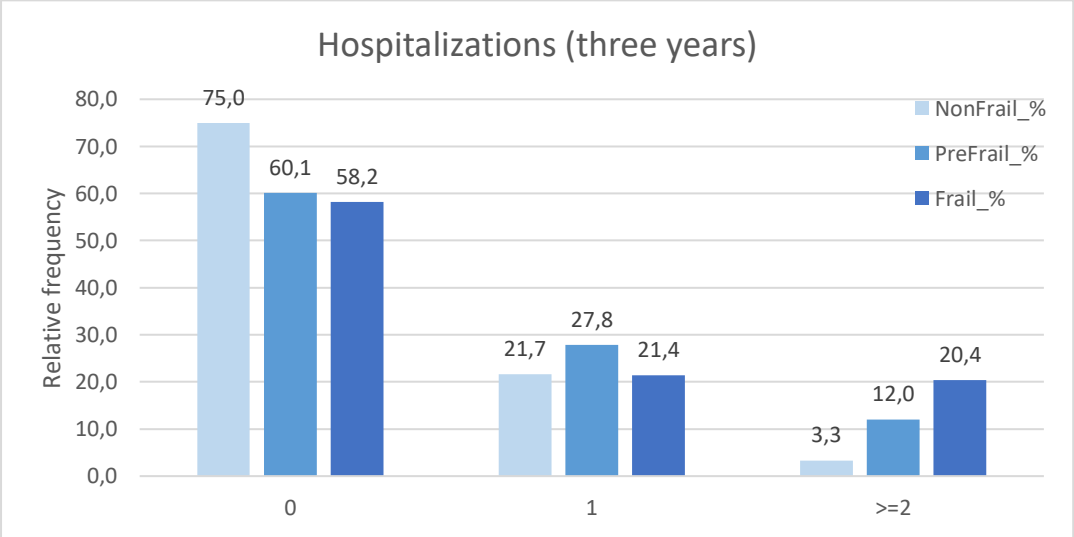
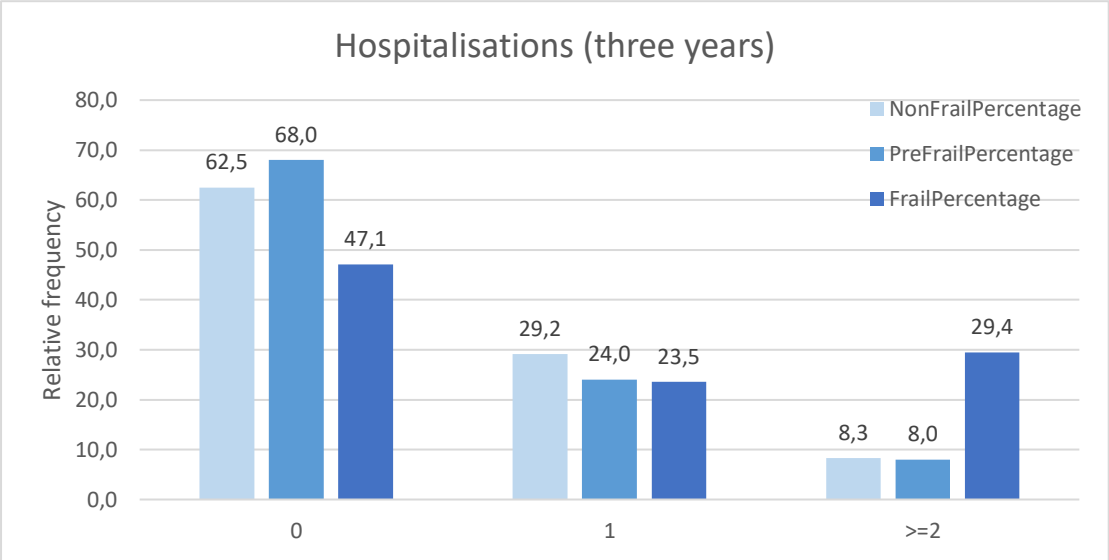


Table 11b. Repartition of participants in each category of number of hospitalizations in last 3 years, according to frailty group (second evaluation).

Number of hospitalisations in 3 years	NonFrail	PreFrail	Frail	Total N
0	30	34	8	72
1	14	12	4	30
>=2	4	4	5	13
	48	50	17	115

Figure 8b. Repartition of percentages in each category of number of hospitalizations in last 3 years, according to frailty group (second evaluation).



Regarding hospitalizations both in one and three years' time, the group of non-frails is more prevalent in the no hospitalization category during the first evaluation, phenomenon that is not reproduced in the second evaluation. On the other hand, the frails, predominate in the category of 2 or more hospitalizations in one but mostly in three years' time in both time spot's evaluations.

2.1.2 Instrumental measurements'-derived data

Data presented in this sub-session are derived from instrumental measurements during the initial clinical evaluation visit.

Table 12 presents the minimum, maximum and mean values of the systolic and diastolic blood pressure, the heart frequency and the arterial stiffness evaluated by the pulse wave velocity.

Blood pressure and heart rate values correspond to the mean obtained by the two lasts out of three semi-automated measurements by an electronic device, with one minutes' interval.

Table 12. Basic descriptive statistics of continuous variables corresponding to the instrumental measurements'-derived data of the medical domain

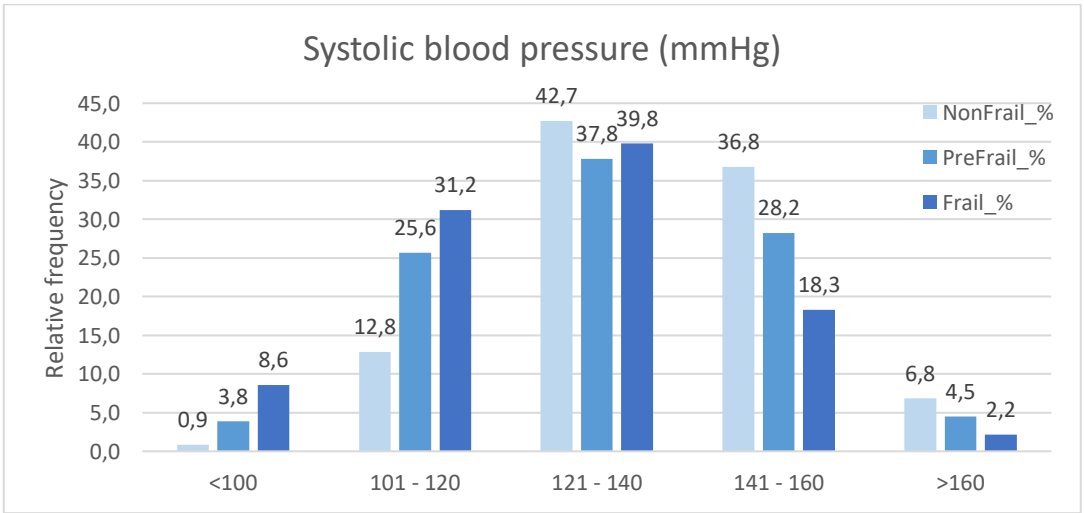
Instrumental measurements	Minimum	Maximum	Mean
Systolic blood pressure	80	180	133,1
Diastolic blood pressure	52	150	79,8
Heart frequency	46	102	71,9
Pulse Wave Velocity	9,5	15,8	12,0

The tables and figures below present the repartition of the study's participants according to categories of systolic, diastolic blood pressure, heart frequency and pulse wave velocity, followed by table 17, describing the prevalence of orthostatic hypotension and by figures displaying available data.

Table 13. Repartition of participants in each category of systolic blood pressure, according to frailty group.

Systolic blood pressure (mmHg)	NonFrail	PreFrail	Frail	Total N
<100	1	6	8	15
101 - 120	15	40	29	84
121 - 140	50	59	37	146
141 - 160	43	44	17	104
>160	8	7	2	17
	117	156	93	366

Figure 9. Repartition of percentages in each category of systolic blood pressure, according to frailty group.

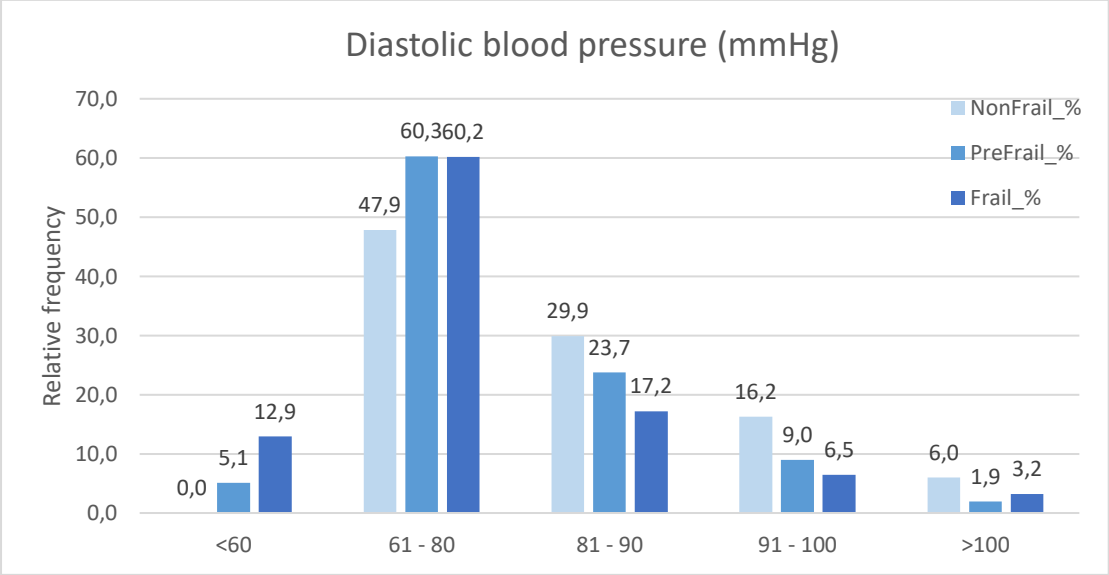


An interesting observation is that the ranks of low systolic blood pressure are mainly dominated by frail participants, while higher systolic blood pressure ranges are mostly observed in non-frail individuals. This could imply either an arterial hypertension overtreatment effect, less well compensated in the frailty group, or a bidirectional impact of low systolic blood pressure levels, that could also bear frailty themselves. "Normal" systolic blood pressure ranges, even though their actual values are highly questionable regarding older adults, show almost equal distributions between 3 frailty groups.

Table 14. Repartition of participants in each category of diastolic blood pressure, according to frailty group.

Diastolic Blood Pressure (mmHg)	NonFrail	PreFrail	Frail	Total N
<60	0	8	12	20
61 - 80	56	94	56	206
81 - 90	35	37	16	88
91 - 100	19	14	6	39
>100	7	3	3	13
	117	156	93	366

Figure 10. Repartition of percentages in each category of diastolic blood pressure, according to frailty group.

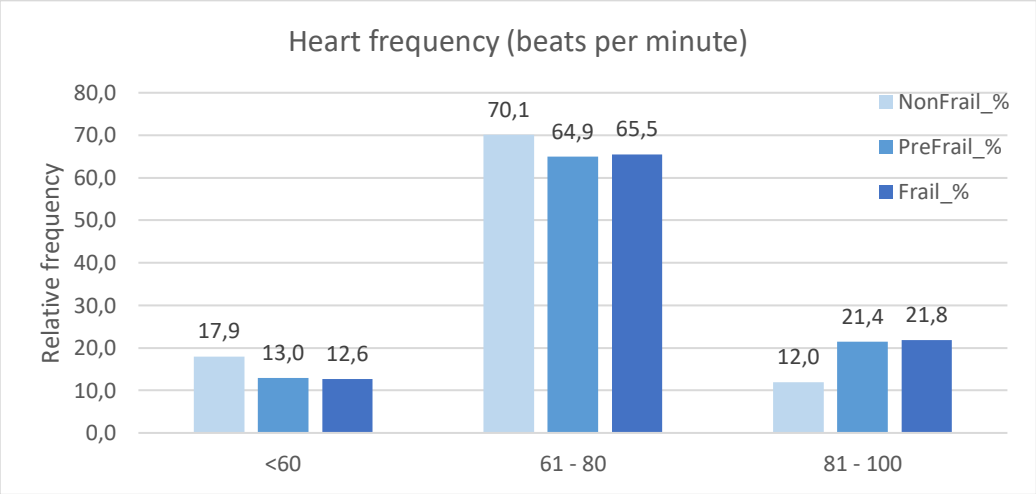


Similarly to systolic, low diastolic blood pressure levels are most prevalent among frail individuals.

Table 15. Repartition of participants in each category of heart frequency, according to frailty group.

Heart Frequency (beats per minutes)	NonFrail	PreFrail	Frail	Total N
<60	21	20	11	52
61 – 80	82	100	57	239
81 – 100	14	33	19	66
	117	153	87	357

Figure 11. Repartition of percentages in each category of heart frequency, according to frailty group.

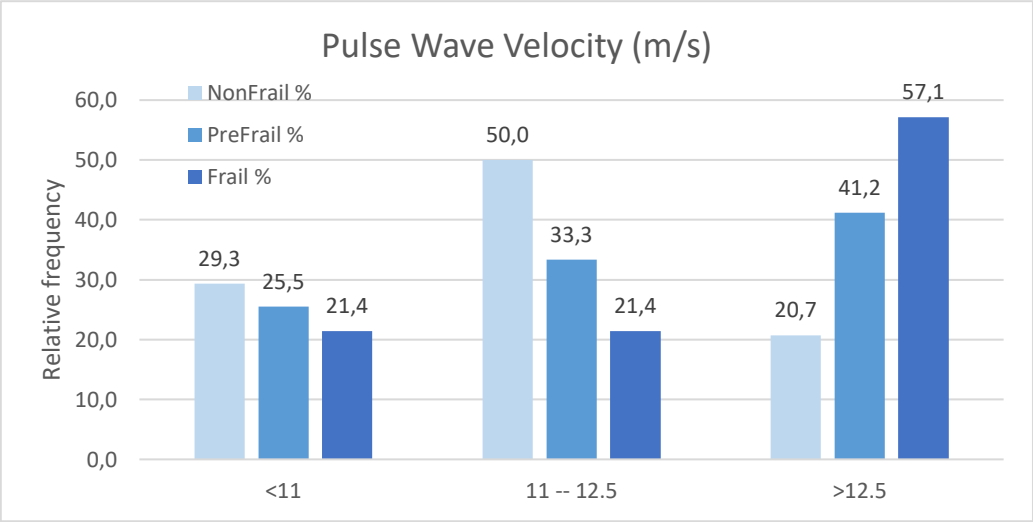


In the case of heart frequency ranges, frail and pre-frail individuals seem to present similar values, with the majority of them in the mean category of 61-80 beats per minute(bpm). Non-frails slightly outweigh others in the lower ranges of <80 bpm and also in the <60 bpm category.

Table 16. Repartition of participants in each category of pulse wave velocity, according to frailty group.

Pulse Wave Velocity (m/s)	NonFrail	PreFrail	Frail	Total N
<11	17	13	3	33
11 - 12.5	29	17	3	49
>12.5	12	21	8	41
	58	51	14	123

Figure 12. Repartition of percentages in each category of pulse wave velocity, according to frailty group.

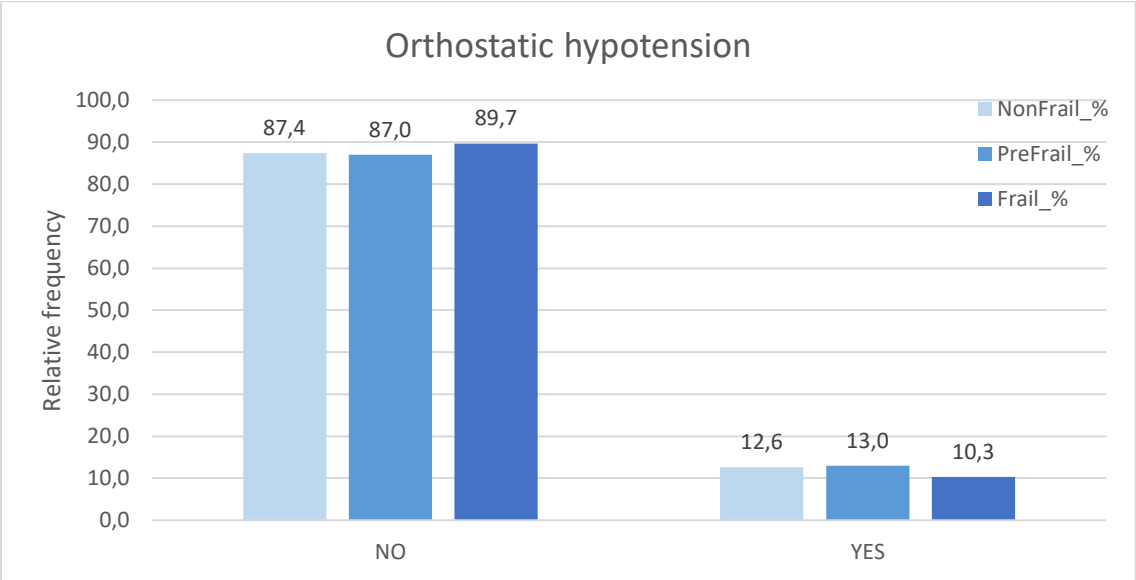


Pulse Wave Velocity (PWV) expresses arterial stiffness, a classical index of vascular aging. In the lower categories of PWV, expressing less arterial stiffness and therefore arterial condition resembling more to younger individuals, the dominant group are the non-frails (29.3% for PWV<11m/s and 50% for PWV between 11 and 12.5), while the frailty group shares a 21.4% of its individuals for each category. The resting majority of the frails (57.1%) belongs to the high PWV category >12.5m/s, implying stiffer and therefore "older" arteries. Non-frail individuals enter this category of PWV with a percentage of no more than 21%.

Table 17. Repartition of participants according to the presence or absence of orthostatic hypotension, per frailty group.

Orthostatic hypotension	NonFrail	PreFrail	Frail	N total
No	104	134	87	325
Yes	15	20	10	45
	119	154	97	370

Figure 13. Prevalence of orthostatic hypotension, per frailty group.



The prevalence of orthostatic hypotension in our study population, is nearly 10% for all frailty categories.

2.2 Data derived from parameters of the general condition domain

Data presented in this sub-session are derived from clinical questionnaires during the initial clinical evaluation.

The general condition domain is composed by two categorical questions, both making part of Fried's criteria of frailty, the unintentional weight loss and the self-reported fatigue and exhaustion.

Tables 18 and 19 present the frequencies of each response to these questions and figures 14 and 15 the corresponding percentages per frailty group.

Table 18. Repartition of participants according to the presence or absence of unintentional weight loss, per frailty group.

Unintentional Weight Loss	NonFrail	PreFrail	Frail	Total N
No	118	144	67	329
Yes	0	12	31	43
	118	156	98	372

Figure 14. Prevalence of unintentional weight loss, per frailty group.

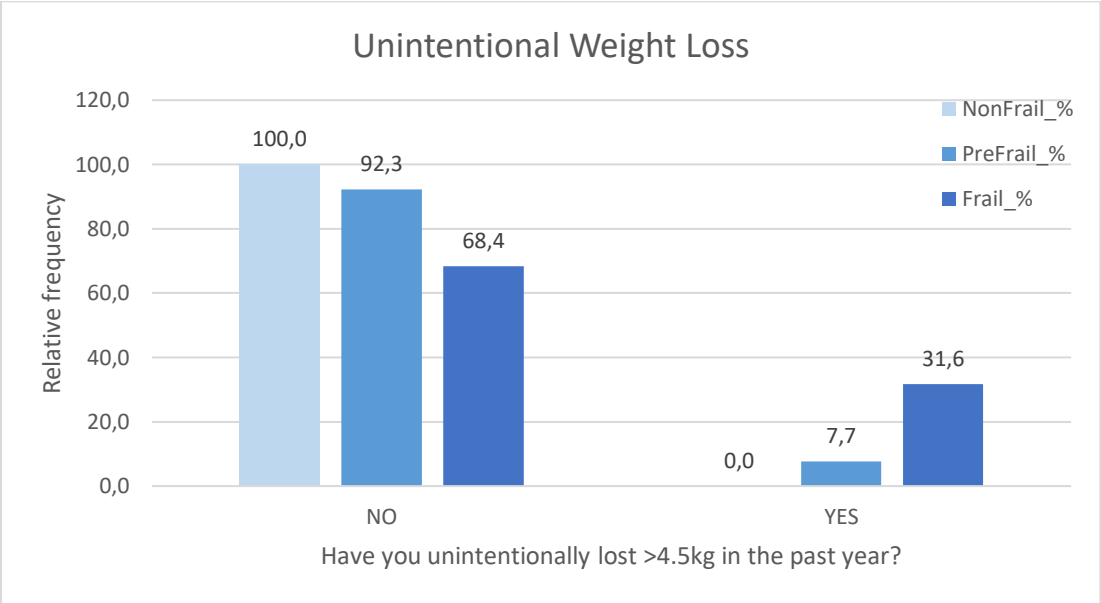
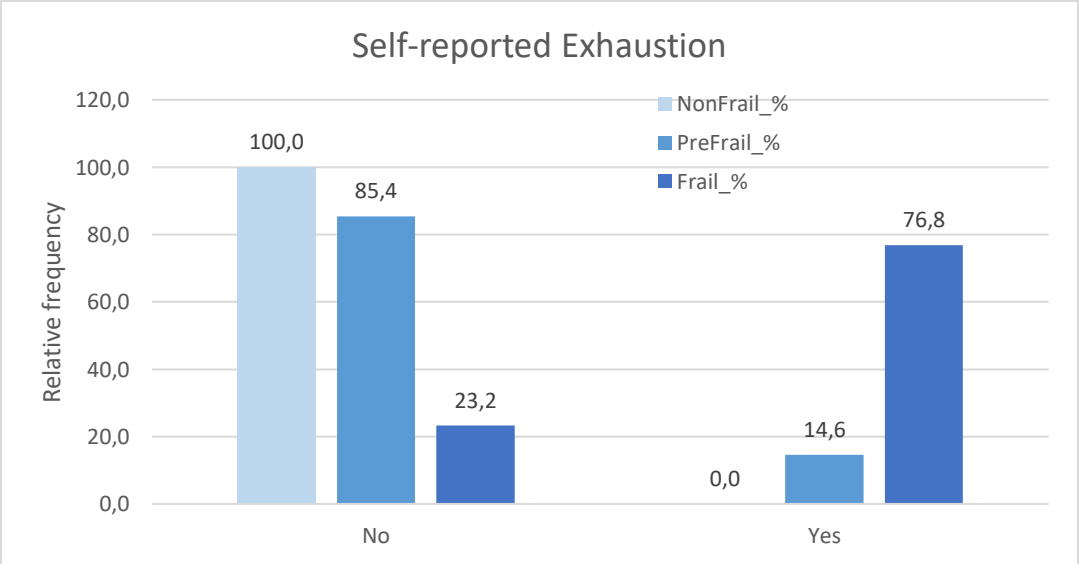


Table 19. Repartition of participants according to the self-reported exhaustion, per frailty group.

Self-reported Exhaustion	NonFrail	PreFrail	Frail	Total N%
No	119	135	23	277
Yes	0	23	76	99
	119	158	99	376

Figure 15. Prevalence of self-reported exhaustion, per frailty group.



For both questions of this domain, it is not a surprise that 100% of non-frail participants give a negative answer, since they represent frailty criteria according to Fried. However, in regards of the frequency by which each criterion is presented, 31.6% of frail and 7.7% of pre-frail participants report an unintentional weight loss, while more than double (76.8%) is the percentage of frails and pre-frails (14.6%) who report exhaustion.

2.3 Data derived from parameters of the lifestyle domain

Data presented in this sub-session are derived from questionnaires performed during the clinical evaluation visit.

They refer to smoking and alcohol consumption status and physical activity. The alcohol consumption is expressed both by ordinal categories and by alcohol units consumed per week. Since this reference values are different for men and women, table 20 presents the minimum, maximum and mean values of alcohol units consumed per week for each sex. Tables and figures that follow present categorical data.

About categories of alcohol consumption, cut off values were chosen based on recommended consumption of 2-3 units per day for women, (taking into account the 2 units' threshold and calculating the analogue of 14 units per week) and 3-4 units per day for men (taking into account the 3 units' threshold and calculating the analogue of 21 units per week).

Table 20a. Basic descriptive statistics about alcohol consumption (initial evaluation).

	Minimum	**Maximum**	**Mean All**	**Mean for women**	**Mean for men**
Alcohol consumption (alcohol units per week)	0	63	3,54	2,33	5,58

Table 20b. Basic descriptive statistics about alcohol consumption (second evaluation).

	Minimum	**Maximum**	**Mean All**	**Mean for women**	**Mean for men**
Alcohol consumption (alcohol units per week)	0	25	3,7	2,7	5,5

Table 21. Repartition of participants according to the alcohol consumption by women, per frailty group.

Alcohol units consumed per week by women	NonFrail	PreFrail	Frail	Total N
<=14	74	93	60	227
>14	1	1	2	4
	75	94	62	231

Figure 16. Prevalence of alcohol consumption beyond the recommended quantity by women, per frailty group.

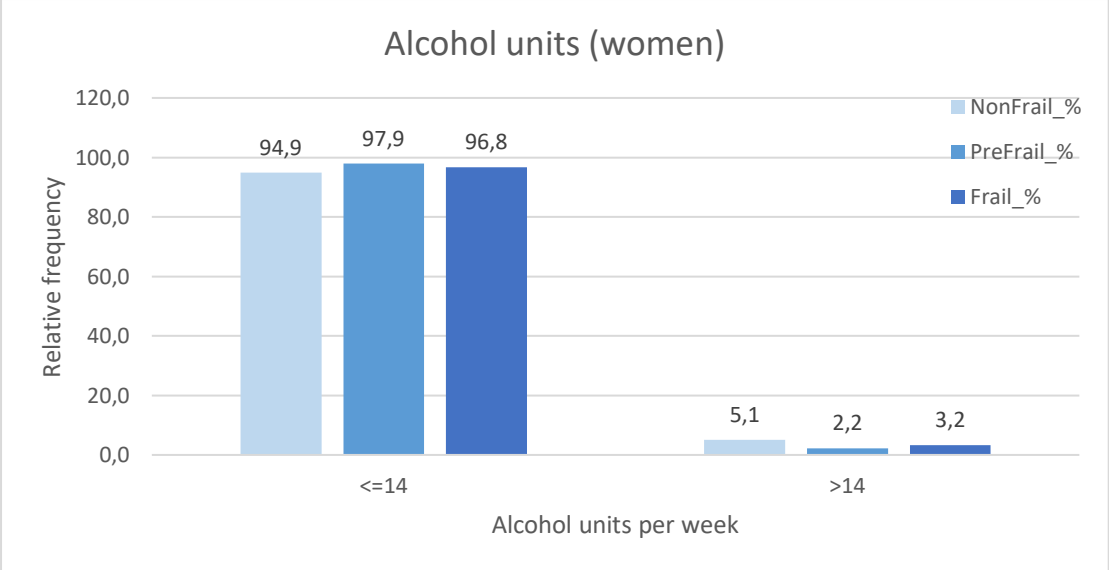
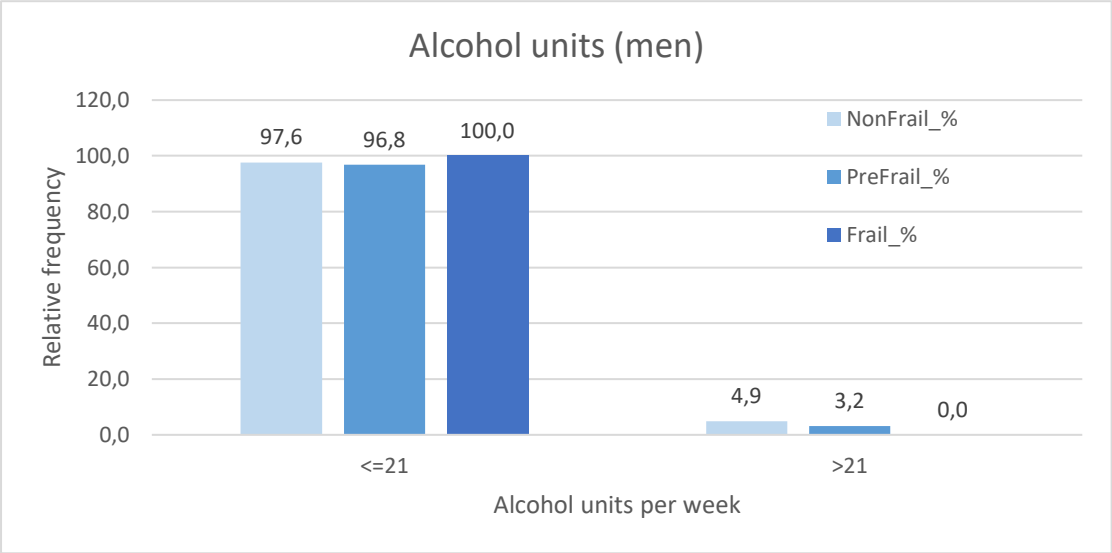


Table 22. Repartition of participants according to the alcohol consumption by men, per frailty group.

Alcohol units consumed per week by men	NonFrail	PreFrail	Frail	Total N
<=21	40	60	37	137
>21	1	2	0	3
	41	62	37	140

Figure 17. Prevalence of alcohol consumption beyond the recommended quantity by men, per frailty group.



Very few people, men and women, across all frailty categories excess recommended alcohol consumption.

Table 23a. Repartition of participants according to the smoking status, per frailty group (initial evaluation).

Smoking status	NonFrail	PreFrail	Frail	Total N
Current smoker	7	11	8	26
Never smoked	71	98	59	228
Past smoker (stopped at least 6 months)	40	49	33	122
	118	158	100	376

Figure 18a. Prevalence of each category of smoking status, per frailty group (initial evaluation).

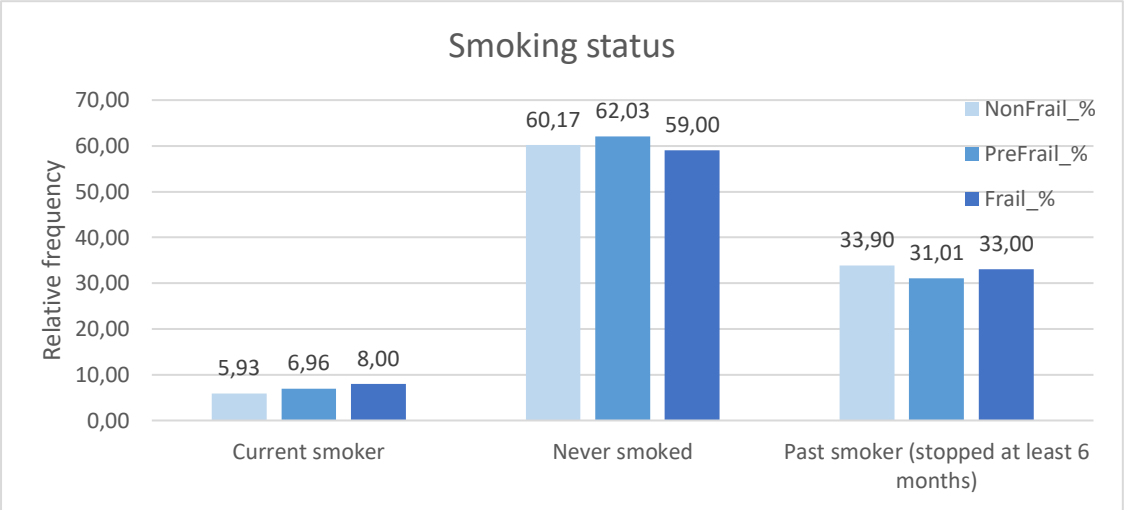
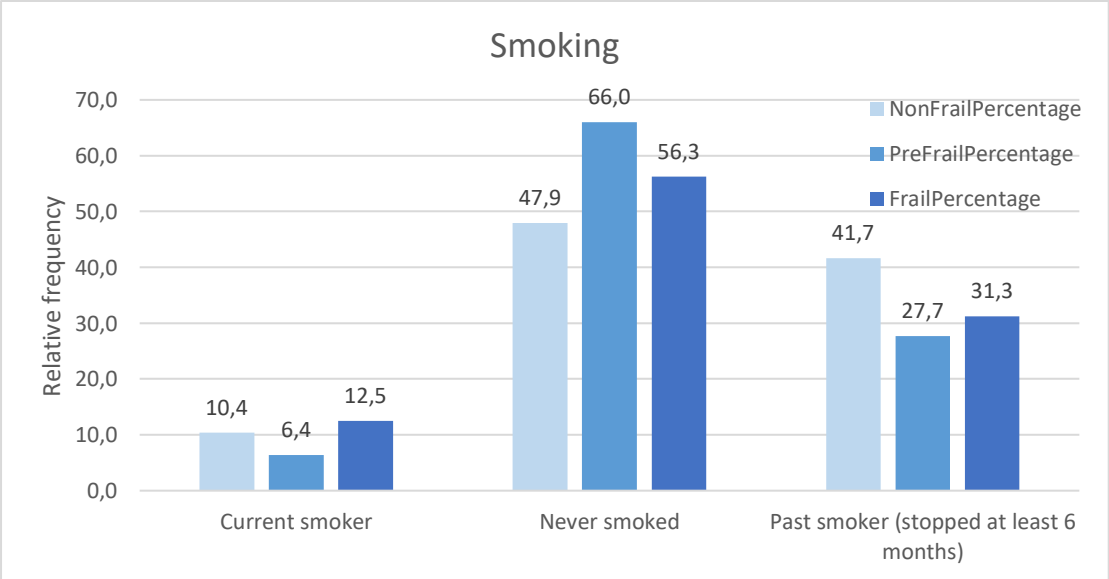


Table 23b. Repartition of participants according to the smoking status, per frailty group (second evaluation).

Smoking status	NonFrail	PreFrail	Frail	Total N
Current smoker	5	3	2	10
Never smoked	23	31	9	63
Past smoker (stopped at least 6 months)	20	13	5	38
	48	47	16	111

Figure 18b. Prevalence of each category of smoking status, per frailty group (second evaluation).



Most participants report that they had never smoked and almost one third of them that they have quitted smoking at least 6 months ago. Smoking status is similar across all frailty categories The same pattern is observed in both evaluation time spots.

Table 24a. Repartition of participants according to categories of physical activity, per frailty group (initial evaluation).

Duration of physical activity	NonFrail	PreFrail	Frail	Total N
< 2 h per week	13	51	51	115
> 2 h and < 5 h per week	34	57	17	108
> 5 h per week	67	39	7	113
No	4	11	24	39
	118	158	99	375

Figure 19a. Prevalence of each category of physical activity, per frailty group (initial evaluation).

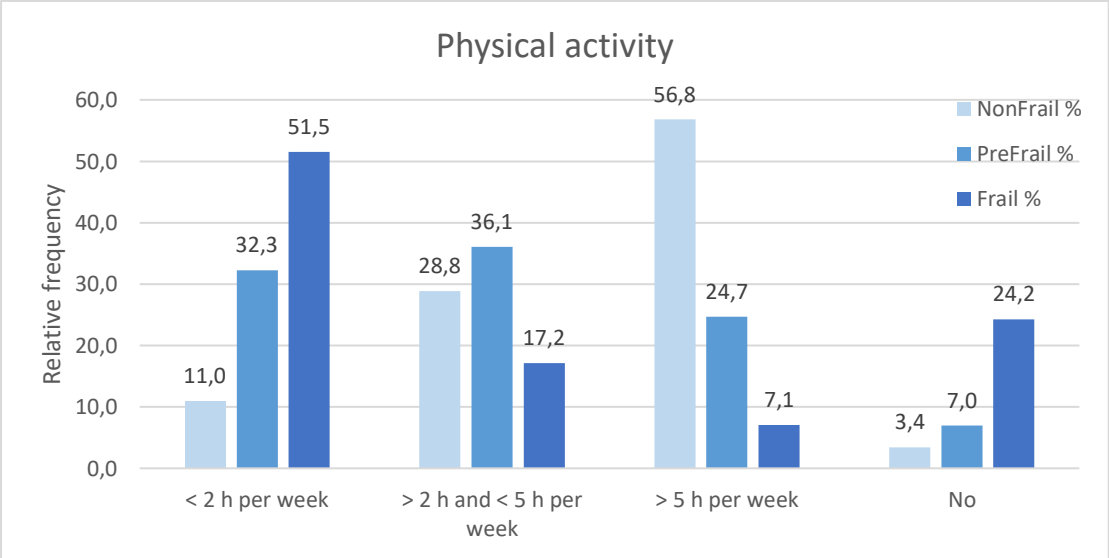
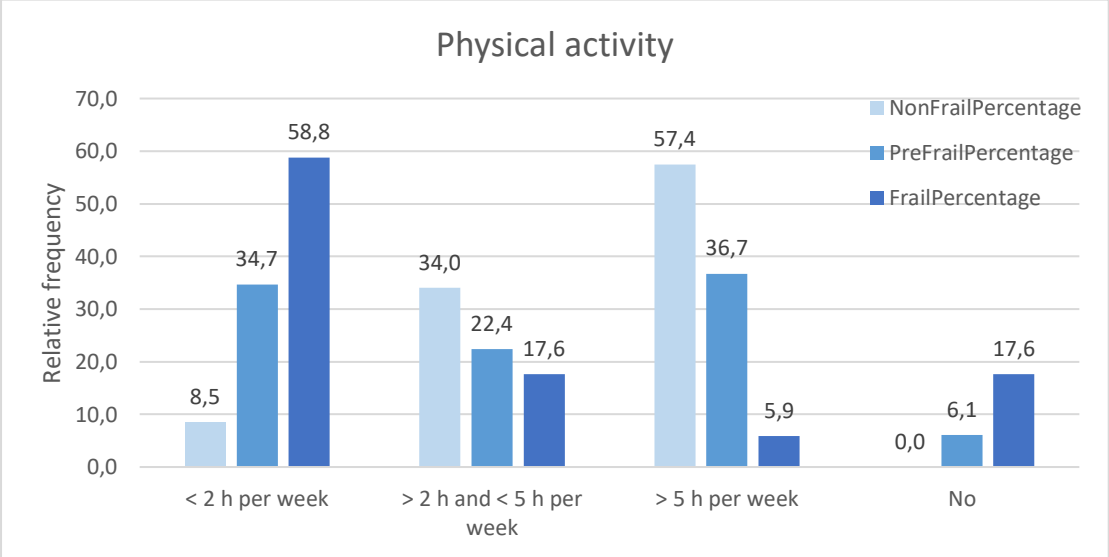


Table 24b. Repartition of participants according to categories of physical activity, per frailty group (second evaluation).

Duration of physical activity	NonFrail	PreFrail	Frail	Total N
< 2 h per week	4	17	10	31
> 2 h and < 5 h per week	16	11	3	30
> 5 h per week	27	18	1	46
No	0	3	3	6
	47	49	17	113

Figure 19b. Prevalence of each category of physical activity, per frailty group (second evaluation).



The lower the physical activity is, the most prevalent the group of frail participants. The exact opposite applies for the non-frail individuals; more than half of them (56.8% in the first and 57,4% in the second evaluation) report a physical activity for more than 5 hours per week, even of mild intensity, 28.8% an activity between 2 and 5 hours (34% in the second evaluation), 11% an activity of less than 2 hours per week (8,5% in the second evaluation) and only 3.4% no physical activity at all in the first evaluation, percentage the turned to zero in the second time spot. For frail individuals, on the contrary, no physical activity is reported by 24.2% of them in the first and 17,6% in the second evaluation. Physical activity, even when self-reported, may be a reliable indicator of frailty status.

2.4 Data derived from parameters of the functional capacity domain

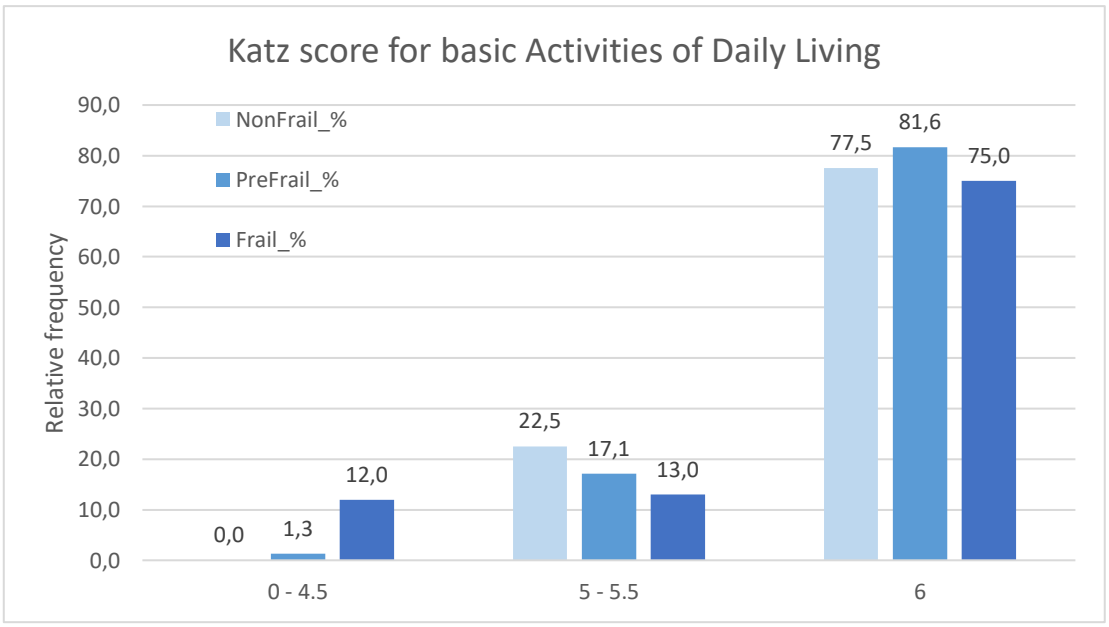
Data presented in this sub-session are derived from questionnaires performed during the clinical evaluation visit.

This domain consists of two largely used scales to evaluate autonomy in activities of daily living (ADL), the Katz's score for basic ADL and the Lawton's score for instrumental ADL (IADL). The grading system of the latter has been largely debated, since all items don't apply equally to men and women, mainly because of cultural differences in older generations. Therefore, apart from an additive total score (the higher the score the more autonomous the person) and we also present results per item.

Table 25. Repartition of participants according to categories of basic ADL, per frailty group.

Katz's score for basic Activities of Daily Living	NonFrail	PreFrail	Frail	Total N
0 - 4.5	0	2	12	14
5 - 5.5	27	27	13	67
6	93	129	75	297
	120	158	100	378

Figure 20. Prevalence of each category of basic ADL, per frailty group.



In the high functionality groups, the great proportion of individuals belong either to the non- or to the pre-frail group. Low basic ADL scores are quite rare and are almost exclusively dominated by frail individuals (12%).

Tables 26 presents the total additive IADL score per frailty category in the initial and in the second clinical evaluation.

Table 26a. Mean IADL additive score for men and women, per frailty group (initial evaluation).

Mean IADL scores	**Non-frail**	**Pre-Frail**	**Frail**
Men	6,2	6,1	4,6
Women	6,7	6,5	5,5

Table 26b. Mean IADL additive score for men and women, per frailty group (second evaluation).

Mean IADL scores	**Non-frail**	**Pre-Frail**	**Frail**
Men	6,4	6,5	6,0
Women	6,9	6,8	6,4

As expected, IADL score, expressing level of autonomy is highly correlated to the frailty status. The frailer the person, the lower the total score of autonomy in the Activities of Daily Living.

The tables that follow show similar results for all of the separate items of the IADL scale. In the answers that express the higher level of autonomy, the prevalence of the frailty group is constantly lower than that of the pre- and non-frailty group. On the contrary, the frailty group almost universally outweighs the other two in the answers expressing various levels of reduced autonomy.

Table 27. Repartition of participants according to performance in the telephone usage item of IADL, per frailty group.

IADL-telephone usage	NonFrail	PreFrail	Frail	Total N
Answers telephone; but does not dial	1	1	4	6
Dials a few well - known numbers	3	5	8	16
Operates telephone on own initiative; looks up and dials numbers	116	150	83	349
I don 't know	0	1	0	1
Does not use telephone at all	0	0	5	5
	120	157	100	377

Figure 21. Prevalence of each category of performance in the telephone usage item of IADL, per frailty group.

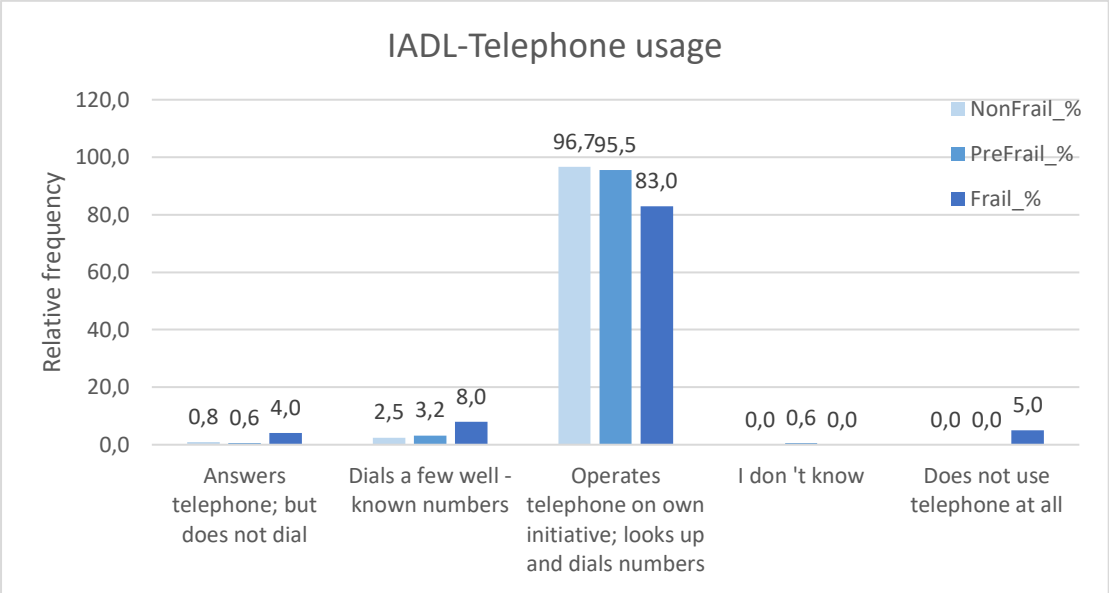


Table 28. Repartition of participants according to performance in the shopping item of IADL, per frailty group.

IADL-shopping	NonFrail	PreFrail	Frail	Total N
I don 't know	1	0	0	1
Completely unable to shop	0	0	16	16
Needs to be accompanied on any shopping trip	0	6	16	22
Shops independently for small purchases	5	15	9	29
Takes care of all shopping needs independently	114	136	59	309
	120	157	100	377

Figure 22. Prevalence of each category of performance in the shopping usage item of IADL, per frailty group.

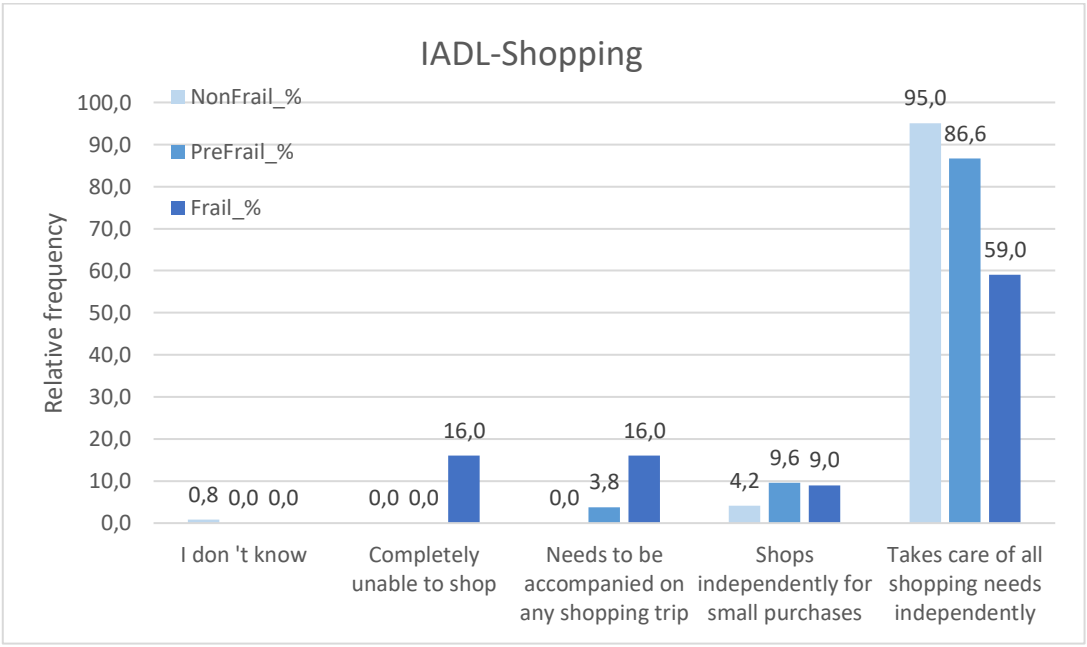


Table 29. Repartition of participants according to performance in the meals' preparation item of IADL, per frailty group.

IADL-Meals' preparation	NonFrail	PreFrail	Frail	Total N
Heats and serves prepared meals or prepares meals but does not maintain adequate diet	2	12	6	20
Needs to have meals prepared and served	1	6	19	26
Non applicable - never used to do this	8	13	3	24
Plans; prepares; and serves adequate meals independently	102	124	64	290
Prepares adequate meals if supplied with ingredients	7	2	8	17
	120	157	100	377

Figure 23. Prevalence of each category of performance in the meals' preparation item of IADL, per frailty group.

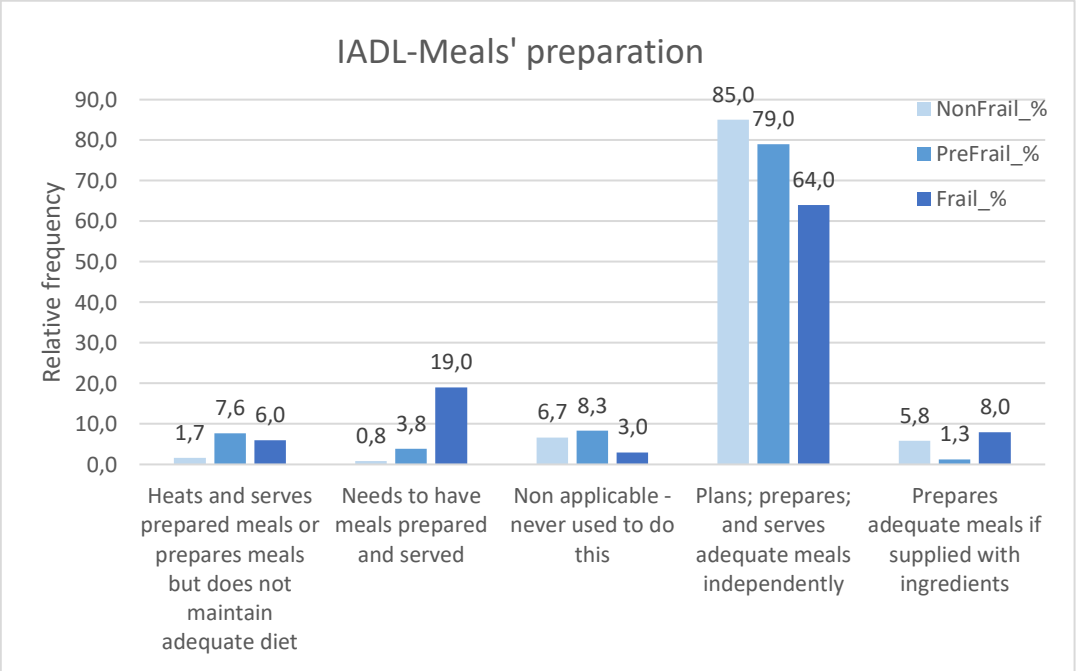


Table 30. Repartition of participants according to performance in the housekeeping item of IADL, per frailty group.

IADL-housekeeping	NonFrail	PreFrail	Frail	Total N
Does not participate in any housekeeping tasks	1	7	12	20
Maintains house alone with occasion assistance (heavy work)	96	110	46	252
Needs help with all home maintenance tasks	0	2	10	12
Non applicable - never used to do this	4	11	7	22
Performs light daily tasks such as dishwashing; bed making	14	22	17	53
Performs light daily tasks; but cannot maintain acceptable level of cleanliness	5	5	8	18
	120	157	100	377

Figure 24. Prevalence of each category of performance in the housekeeping item of IADL, per frailty group.

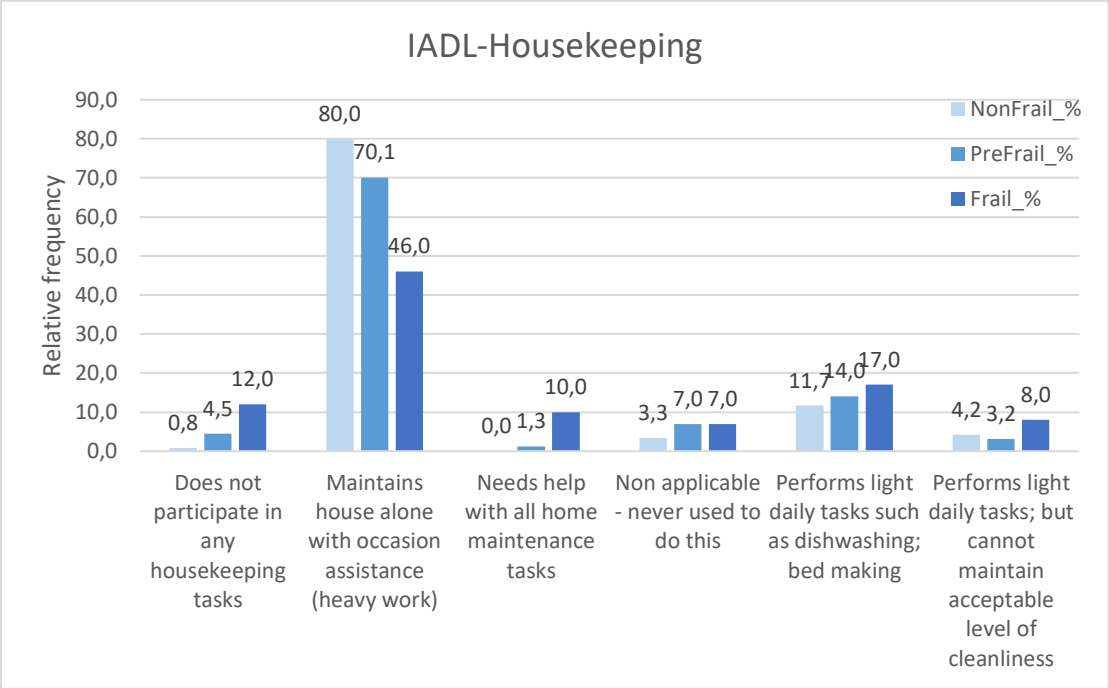


Table 31. Repartition of participants according to performance in the laundry item of IADL, per frailty group.

IADL-Laundry	NonFrail	PreFrail	Frail	Total N
All laundry must be done by others	15	16	27	58
Does personal laundry completely	94	120	59	273
I don 't know	0	1	0	1
Launders small items; rinses socks; stockings; etc	3	6	5	14
Non applicable - never used to do this	8	14	9	31
	120	157	100	377

Figure 25. Prevalence of each category of performance in the laundry item of IADL, per frailty group.

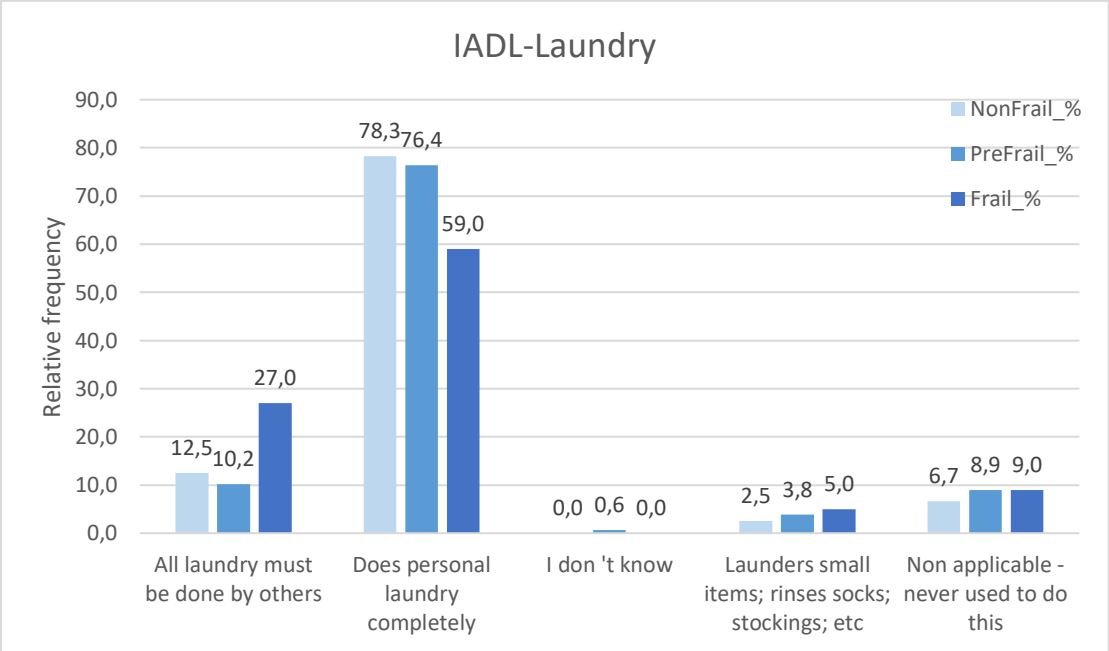


Table 32. Repartition of participants according to performance in the mode of transportation item of IADL, per frailty group.

IADL-Transportation	NonFrail	PreFrail	Frail	Total N
Arranges own travel via taxi; but does not otherwise use public transportation	4	12	12	28
Does not travel at all	2	1	8	11
I don 't know	0	1	0	1
Travel limited to taxi or automobile with assistance of another	1	4	26	31
Travels independently on public transportation or drives own car	111	131	51	293
Travels on public transportation when assisted or accompanied by another	2	8	3	13
	120	157	100	377

Figure 26. Prevalence of each category of performance in the mode of transportation item of IADL, per frailty group.

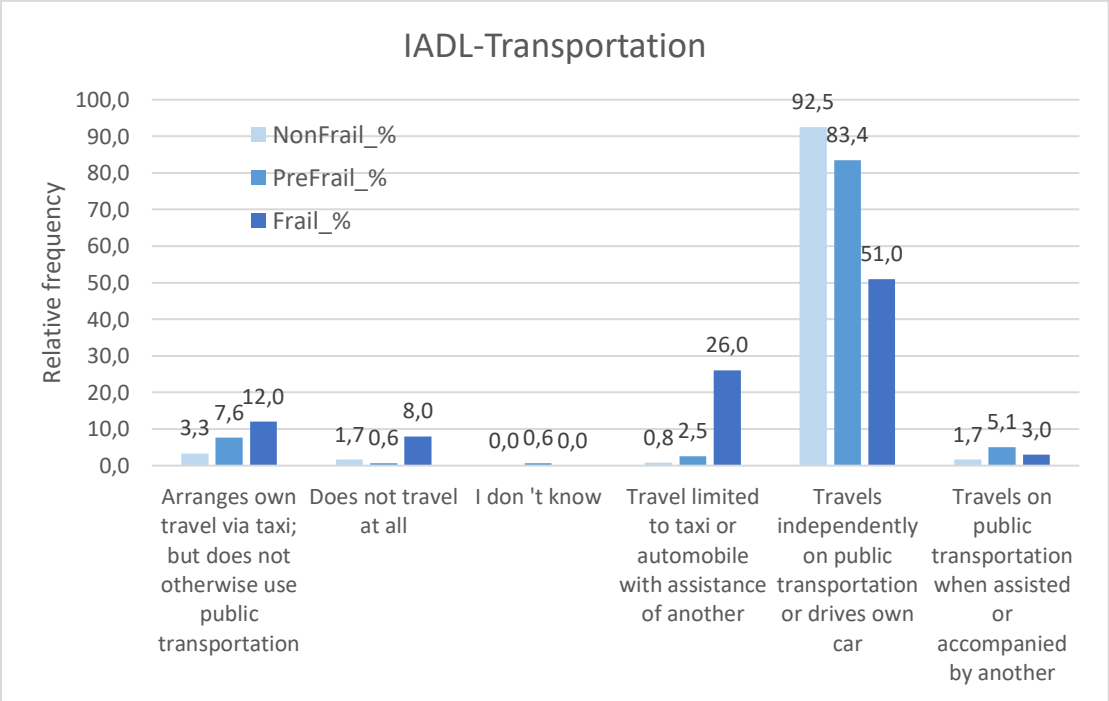


Table 33. Repartition of participants according to performance in the responsibility of taking their own medication item of IADL, per frailty group.

IADL-Responsibility in managing medication	NonFrail	PreFrail	Frail	Total N
Is not capable of dispensing own medication	1	3	16	20
Is responsible for taking medication in correct dosages at correct time	113	144	72	329
Not applicable; does not take any medication	3	6	0	9
Takes responsibility if medication is prepared in advance in separate dosages	3	4	12	19
	120	157	100	377

Figure 27. Prevalence of each category of performance in the responsibility of taking their own medication item of IADL, per frailty group.

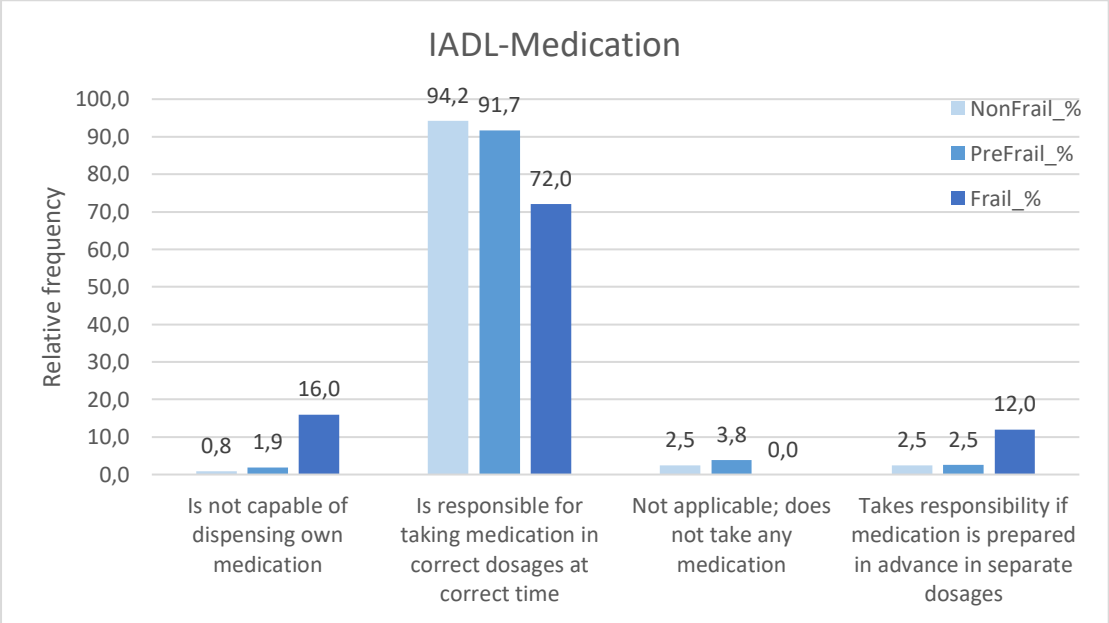
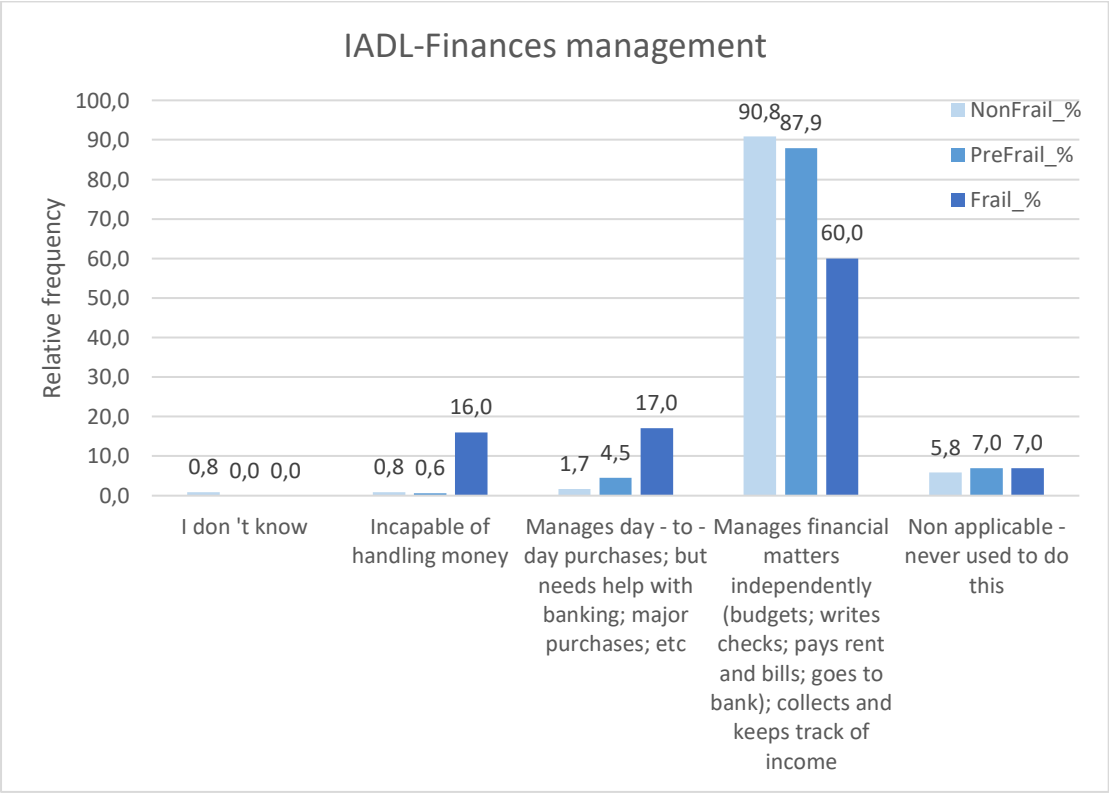


Table 34. Repartition of participants according to performance in the finances' management item of IADL, per frailty group.

IADL-Finances' management	NonFrail	PreFrail	Frail	Total N
I don 't know	1	0	0	1
Incapable of handling money	1	1	16	18
Manages day - to - day purchases; but needs help with banking; major purchases; etc	2	7	17	26
Manages financial matters independently (budgets; writes checks; pays rent and bills; goes to bank); collects and keeps track of income	109	138	60	307
Non applicable - never used to do this	7	11	7	25
	120	157	100	377

Figure 28. Prevalence of each category of performance in the finances' management item of IADL, per frailty group.



2.5 Data derived from parameters of the physical condition domain

Data presented in this sub-session are derived from instrumental measurements, tests and clinical questionnaires performed during the clinical evaluation visit.

Table 35 presents minimum, maximum and mean values of physical performance tests, followed by tables describing the repartition of participants in each physical performance category, according to frailty status, and by histograms depicting the same data in the form of percentages.

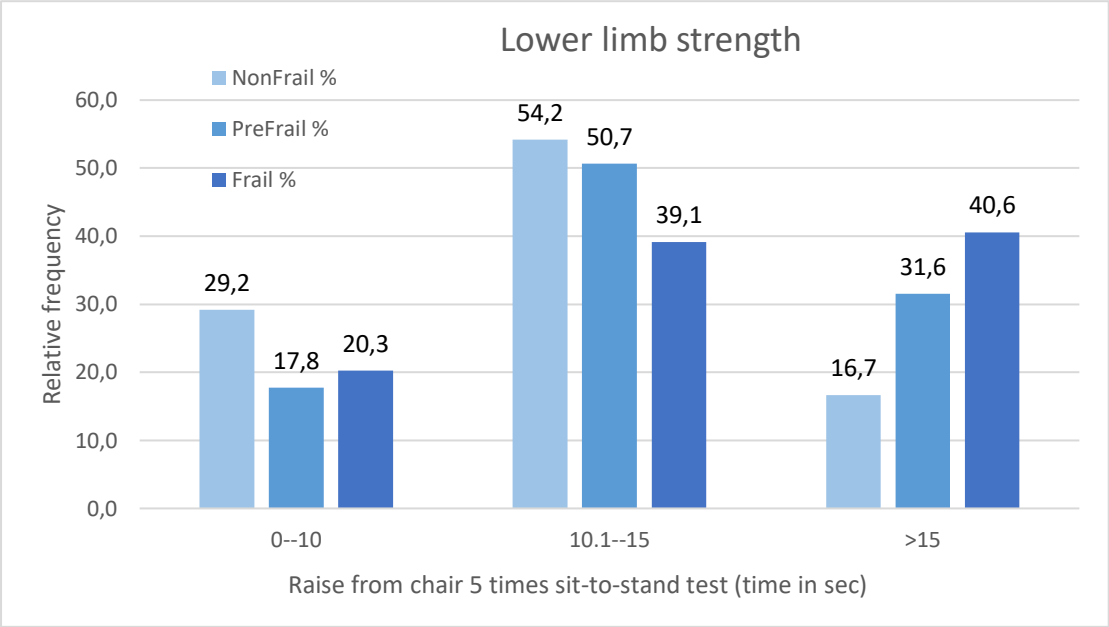
Table 35. Basic descriptive statistics about physical tests' performance.

	Minimum	**Maximum**	**Mean**
5 times sit up and stand test (sec)	5,7	50,2	14,2
Timed get Up and Go test (sec)	3,1	60,0	11,5
Gait speed (m/s)	0,13	2,7	0,8
Number of falls in last year	0,0	40,0	0,6
Number of fractures in adult lifetime	0,0	4,0	0,2

Table 36. Repartition of participants according to performance in the 5-times sit-and-stand test, expressing lower limb strength, per frailty group.

Time for 5 times sit-and-stand test from a chair (seconds)	**NonFrail**	**PreFrail**	**Frail**	**Total N**
<=10	35	27	14	76
10.1 -15	65	77	27	169
>15	20	48	28	96
	120	152	69	341

Figure 29. Prevalence of each category of performance in the 5-times sit-and-stand test, expressing lower limb strength, per frailty group.

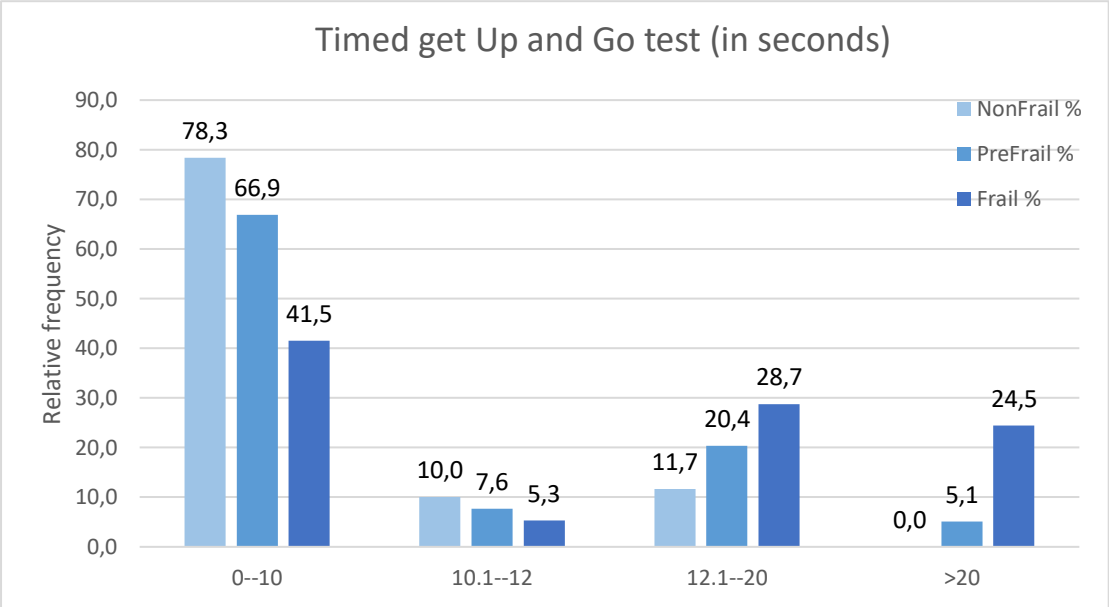


The predominant group in the category with the worst performance in the 5-times sit-and-stand test (time >15seconds) is the frail one. An almost equal percentage of them (39.1%) find themselves in the intermediate category of 10-15 seconds, while only 20.3%of them can perform the test in less than 10 seconds. In best performance categories, <10 seconds and 10.1-15 seconds, we find the majority of non-frail and pre-frail individuals. However, most of both pre-frail and non-frail participants perform in the middle range category, between 10.1 and 15 seconds.

Table 37. Repartition of participants according to performance in the Timed get Up and Go test, per frailty group.

Timed get Up and Go test (seconds)	NonFrail	PreFrail	Frail	Total N
<=10	94	105	39	238
10.1 -12	12	12	5	29
12.1 -20	14	32	27	73
>20	0	8	23	31
	120	157	94	371

Figure 30. Prevalence of each category of performance in the Timed get Up and Go test, per frailty group.



Most of the study's participants perform the Timed get Up and Go test (TUG) in less than 10 seconds. Still, in this category the predominant groups are the non-frail and the pre-frail ones, and less than half frail people (41.5%) belong in this category. While few non-frails and pre-frails perform the TUG test in more than 10 seconds, the frails outweigh those categories. There is no non-frail person needing more than 20 seconds for the TUG task.

Table 38a. Repartition of participants according to gait speed (4 meters' straight walk), per frailty group (initial evaluation).

Gait speed (m/s)	NonFrail	PreFrail	Frail	Total N
<=0.8	44	103	85	232
0.81 -1	17	19	10	46
>1	59	36	5	100
	120	158	100	378

Figure 31a. Prevalence of each category of gait speed (4 meters' straight walk), per frailty group (initial evaluation).

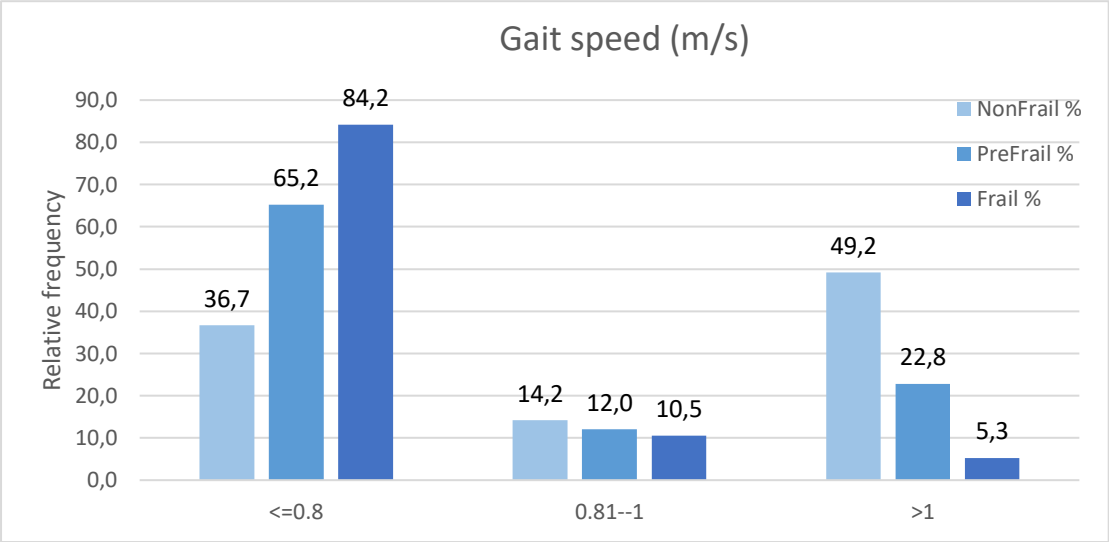
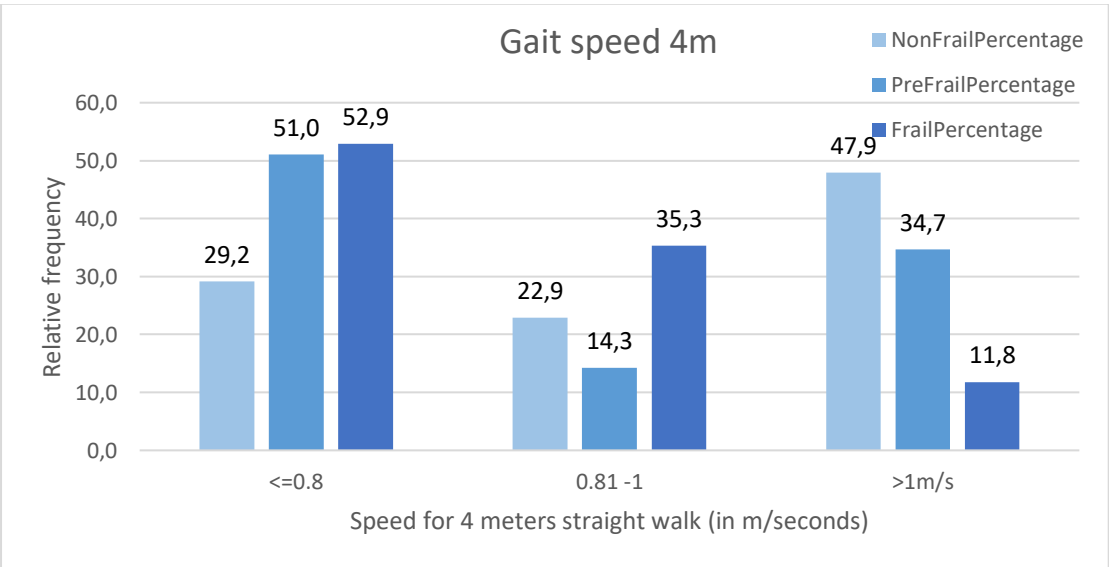


Table 38b. Repartition of participants according to gait speed (4 meters' straight walk), per frailty group (second evaluation).

Gait speed (m/s)	NonFrail	PreFrail	Frail	Total N
<=0.8	14	25	9	48
0.81 -1	11	7	6	24
>1	23	17	2	42
	48	49	17	114

Figure 31b. Prevalence of each category of gait speed (4 meters' straight walk), per frailty group (second evaluation).

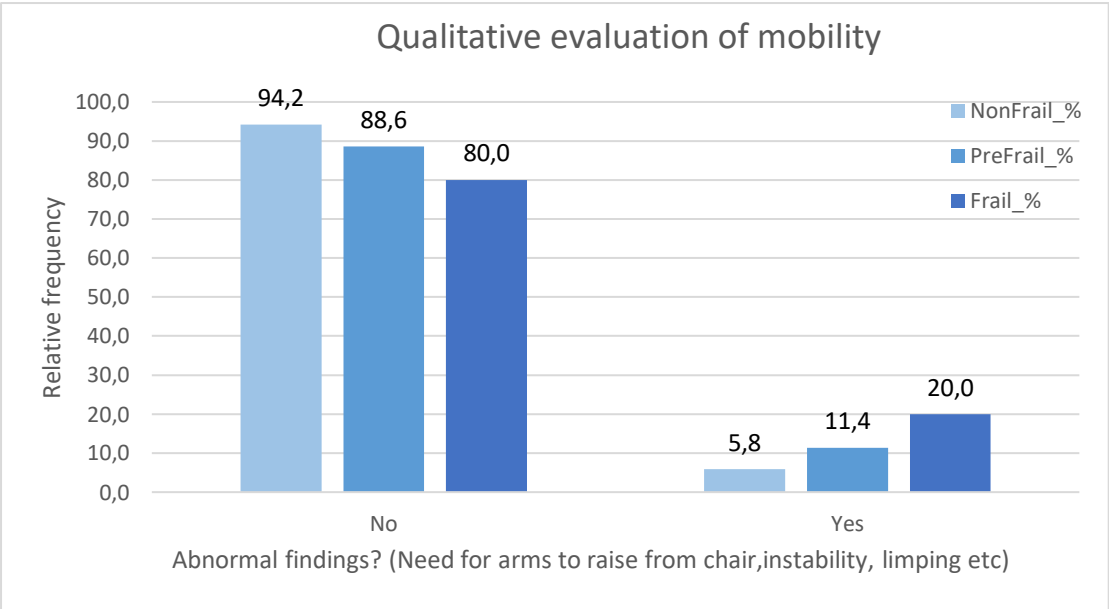


Although in the intermediate category of medium gait speed the results are not very indicative, the extreme categories reveal a clear relation between the slow gait speed and frailty. In the first evaluation (figure 31a), 84% percent of frail people had a gait speed of less than 0.8m/s, while their percentage in the high speed category (>1m/s) is only 5.3%. The non-frails perform mostly >1m/s (49.2%), a 14% of them perform between 0.81 and 1m/s and 36.7% in the low speed category of ≤0.8m/s. The pre-frail group shows intermediate performances between the frails and the non-frails. Almost the same pattern is observed in the second evaluation, though percentages differ slightly, and the repartition of frail individuals is important (35.3%) also in the intermediate performance range (0,81-1m/s).

Table 39. Repartition of participants according to the presence of abnormal findings in the qualitative evaluation of the mobility, per frailty group.

Abnormal finding in qualitative evaluation of mobility	NonFrail	PreFrail	Frail	Total N
No	113	140	80	333
Yes	7	18	20	45
	120	158	100	378

Figure 32. Prevalence of the presence of abnormal findings in the qualitative evaluation of the mobility, per frailty group.

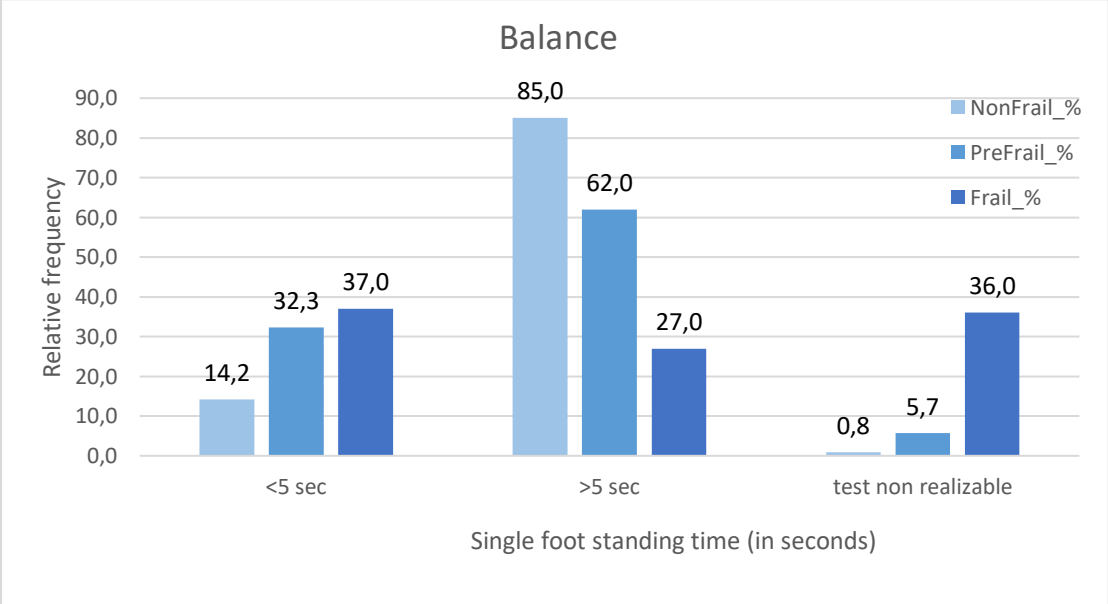


In terms of the qualitative evaluation of gait, most people with normal finding belong to the non-frail group (94.2%), followed by pre-frails and frails (88.6 and 80% respectively), whilst the opposite is observed in the group with abnormal qualitative gait findings: the majority are frail (20%), followed by pre-frails (11.4%) and only a small percentage (5.8%) of non-frails present qualitatively abnormal gait finding.

Table 40. Repartition of participants according to performance in the single foot standing time test, expressing balance, per frailty group.

Balance (single foot standing time in seconds)	NonFrail	PreFrail	Frail	Total N
<5 sec	17	51	37	105
>5 sec	102	98	27	227
test non realizable	1	9	36	46
	120	158	100	378

Figure 33. Prevalence of each category of performance in the single foot standing time test, expressing balance, per frailty group.



Not surprisingly, most of the people performing well in the balance test belong to the non-frail group, while most people with poor balance are frail. Also, frail ones outstand in the category of the inability to perform the test, usually due to important mobility restriction reasons.

Table 41a. Repartition of participants according to performance in the grip strength measurement, per frailty group (initial evaluation).

Abnormal grip strength (dymanometer measurement)	NonFrail	PreFrail	Frail	Total N
No	119	45	5	169
Yes	0	113	94	207
	119	158	99	376

Figure 34a. Prevalence of abnormal performance in the grip strength measurement, per frailty group (initial evaluation).

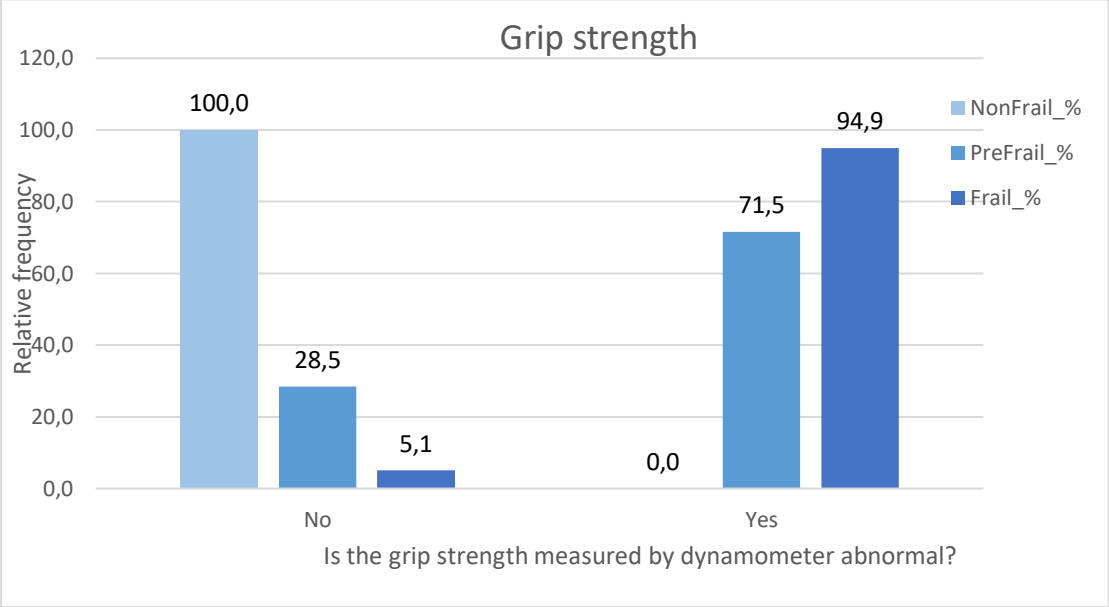
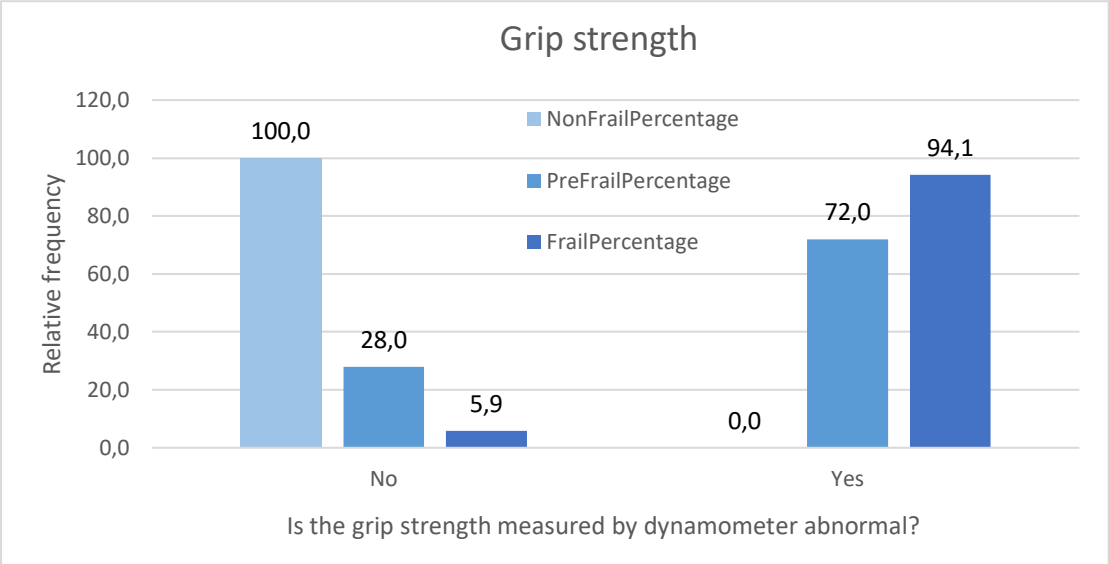


Table 41b. Repartition of participants according to performance in the grip strength measurement, per frailty group (second evaluation).

Abnormal grip strength (dymanometer measurement)	NonFrail	PreFrail	Frail	Total N
No	48	14	1	63
Yes	0	36	16	52
	48	50	17	115

Figure 34b. Prevalence of abnormal performance in the grip strength measurement, per frailty group (second evaluation).



As abnormal grip strength is a frailty criterion, according to the presently employed Fried's frailty categorization, it is normal that all non-frail people belong to the normal grip strength category. Very few frail people show normal grip strength performance, while the majority of them (95% in the first and 94,1% in the second evaluation), have this criterion positive. The prevalence of abnormal grip strength is rather prevalent also in the pre-frail group, were 1-2 frailty criteria need to be fulfilled. It seems that this specific criterion positivity is the case in almost 72% of pre-frail cases.

Table 42a. Repartition of participants according to the presence of low physical activity, as defined by Fried's criterion, per frailty group (initial evaluation).

Low physical activity according to Fried's criterion	NonFrail	PreFrail	Frail	Total N
No	119	143	43	305
Yes	0	15	56	71
	119	158	99	376

Figure 35a. Prevalence of low physical activity, as defined by Fried's criterion, per frailty group (initial evaluation).

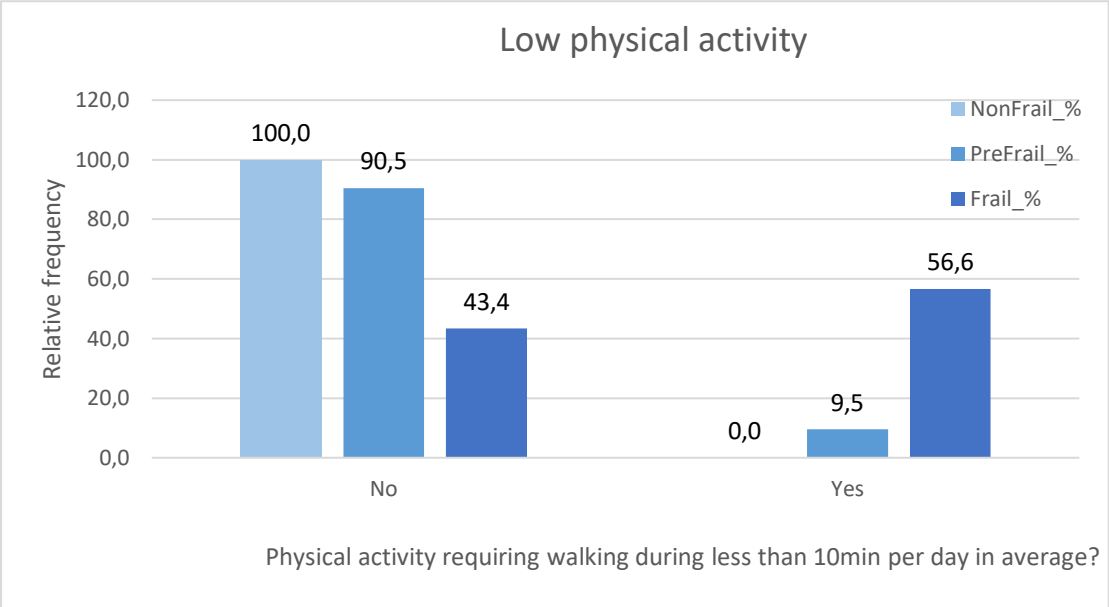
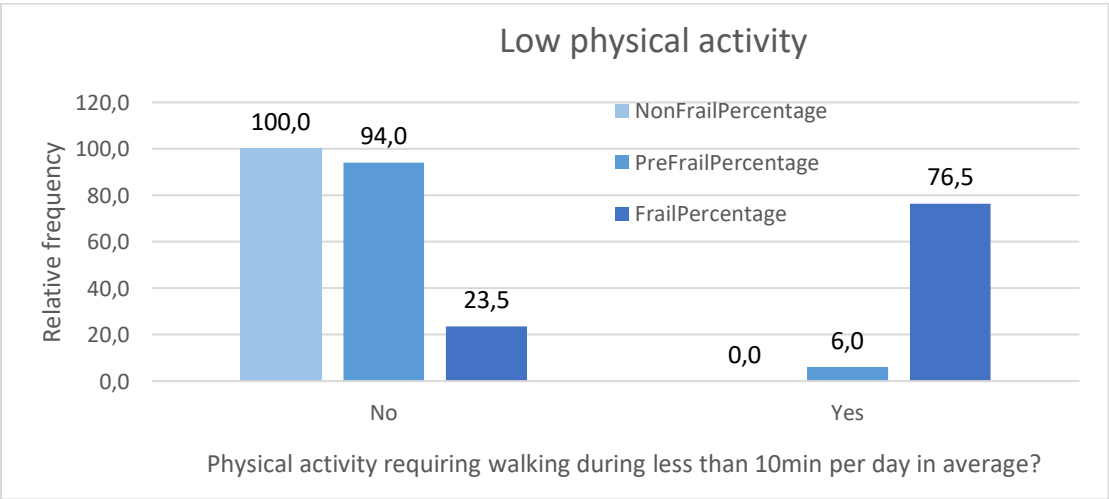


Table 42b. Repartition of participants according to the presence of low physical activity, as defined by Fried's criterion, per frailty group (second evaluation).

Low physical activity according to Fried's criterion	NonFrail	PreFrail	Frail	Total N
No	48	47	4	99
Yes	0	3	13	16
	48	50	17	115

Figure 35b. Prevalence of low physical activity, as defined by Fried's criterion, per frailty group (second evaluation).



Similarly to grip strength, low physical activity, defined as mobile activity for less than 10 minutes per day, is another Fried's frailty criterion, employed in the present categorization into frailty groups. Thus, there are no non-frails in the low physical category group, while those who dominate this category are the frails (56.6% in the first and 76,5 in the second evaluation), followed by a small percentage of pre-frail individuals. However, the prevalence of pre-frails with this criterion positive is far less important than the prevalence of pre-frails with low grip strength (9.5 vs 71.5% respectively for the first and 6 vs 72% for the second evaluation).

Table 43a. Repartition of participants according to category of number of falls in the last 12 months, per frailty group (initial evaluation).

Number of falls in last year	NonFrail	PreFrail	Frail	Total N
0	96	114	60	270
1	15	30	16	61
>=2	9	13	21	43
	120	157	97	374

Figure 36a. Prevalence of each category of number of falls in the last 12 months, per frailty group (initial evaluation).

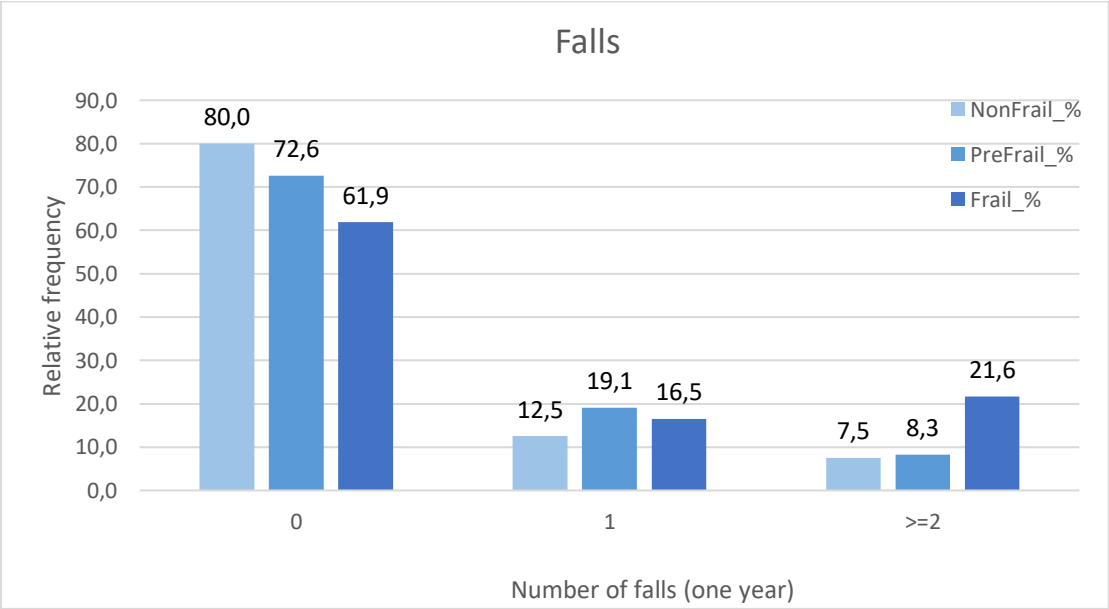
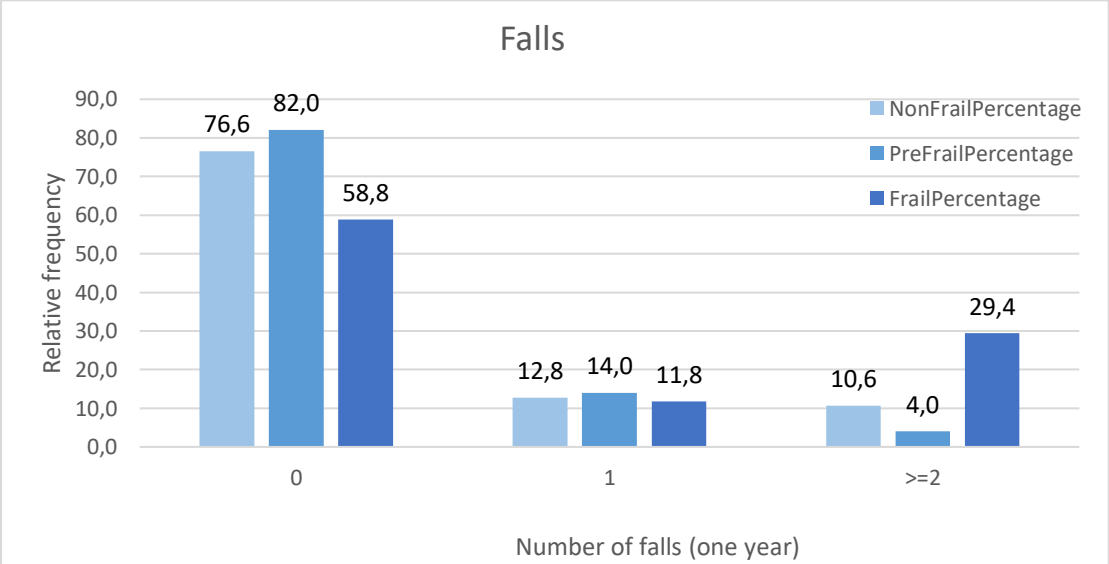


Table 43b. Repartition of participants according to category of number of falls in the last 12 months, per frailty group (second evaluation).

Number of falls in last year	NonFrail	PreFrail	Frail	Total N
0	36	41	10	87
1	6	7	2	15
>=2	5	2	5	12
	47	50	17	114

Figure 36b. Prevalence of each category of number of falls in the last 12 months, per frailty group (second evaluation).

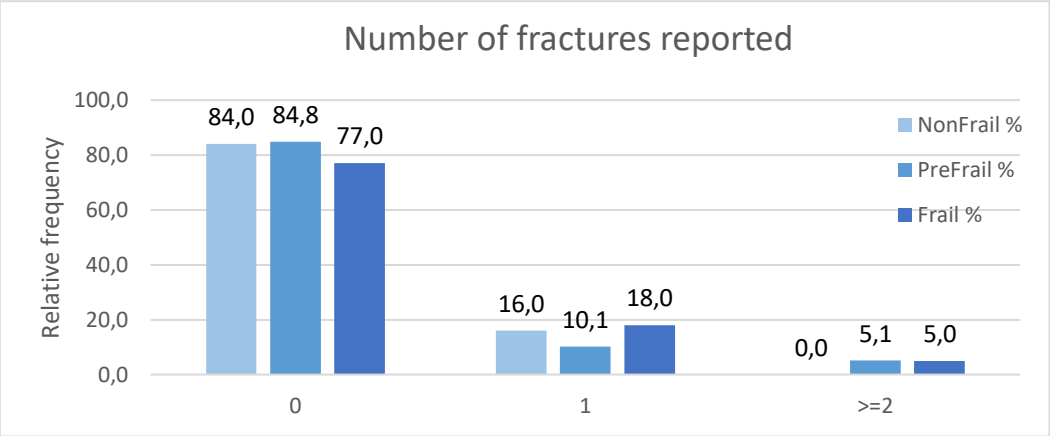


The dominant frailty group in the no falls category is the non-frails in the first and the prefrails in the second evaluation, while the frails predominate in the category of 2 or more falls in the last year in both time spots. An incidence of one fall per year is equally observed in the three frailty categories.

Table 44. Repartition of participants according to the number of fractures in their adult lifetime, per frailty group.

Number of fractures in the last 3 years' time	NonFrail	PreFrail	Frail	Total N
0	100	134	77	311
1	19	16	18	53
>=2	0	8	5	13
	119	158	100	377

Figure 37. Prevalence of each category of number of fractures in the adult lifetime, per frailty group.



Due to the small number of factures, it is difficult to extract conclusions for their repartition among frailty groups.

2.6 Data derived from parameters of the nutritional domain

Data presented in this sub-session are derived from clinical questionnaires and instrumental measurements performed during the clinical evaluation visit.

Table 45 presents basic descriptive statistics about minimum, maximum and mean values of continues variables evaluated in this domain, followed by tables describing the distribution of the study's participants to each category of these variables, according to their frailty status, as well as by histograms depicting the same data in the form of percentages.

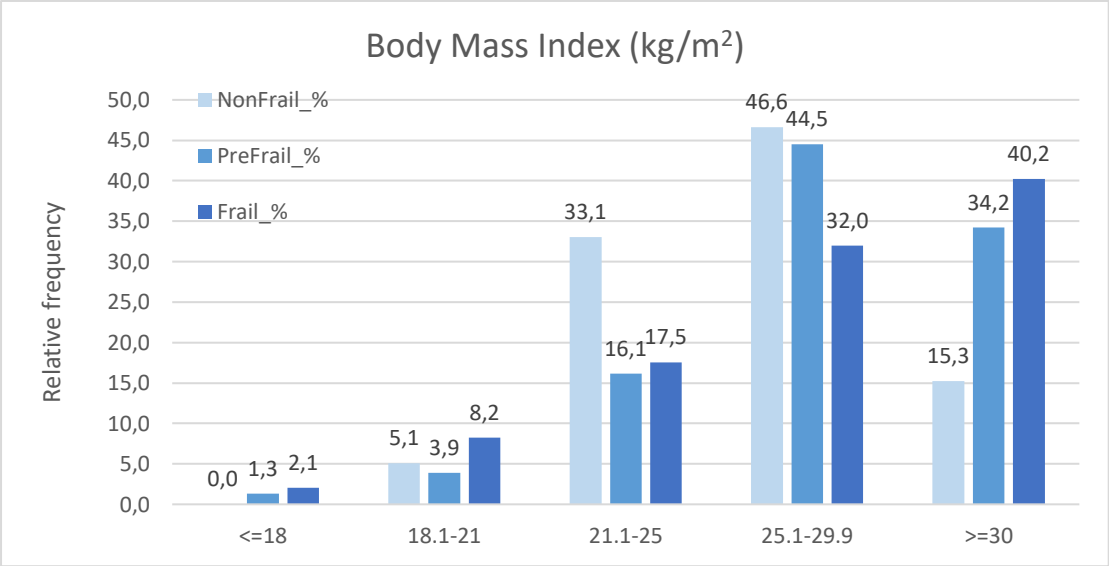
Table 45. Basic descriptive statistics about parameters of the nutritional domain.

	Minimum	**Maximum**	**Mean**
BMI score	16,4	44,1	27,8
Waist circumference	55,0	141,0	99,2
MNA screening score	6,0	14,0	13,0
MNA total score	11,5	27,0	21,4
BMI: Body Mass Index, MNA: Mini Nutritional Assessment			

Table 46. Repartition of participants according to the category of body mass index (BMI), per frailty group.

Body Mass Index	NonFrail	PreFrail	Frail	Total N
<=18	0	2	2	4
18.1-21	6	6	8	20
21.1-25	39	25	17	81
25.1-29.9	55	69	31	155
>=30	18	53	39	110
	118	155	97	370

Figure 38. Prevalence of each category of body mass index (BMI), per frailty group.



We observe that non-frail participants are mostly found in the intermediate categories of body mass index (BMI), between 21 and 30 kg/m^2. Almost 10% of frail individuals present a BMI of 21 or less, but most of them (40.2%) have a BMI of 30 or more, outweighing all other frailty groups in this BMI category.

Table 47. Repartition of participants according to waist circumference category for women, per frailty group.

Waist Circumference for women (cm)	NonFrail	PreFrail	Frail	Total N
<88	25	16	11	52
>=88	52	77	51	180
	77	93	62	232

Figure 39. Prevalence of each category of waist circumference for women, per frailty group.

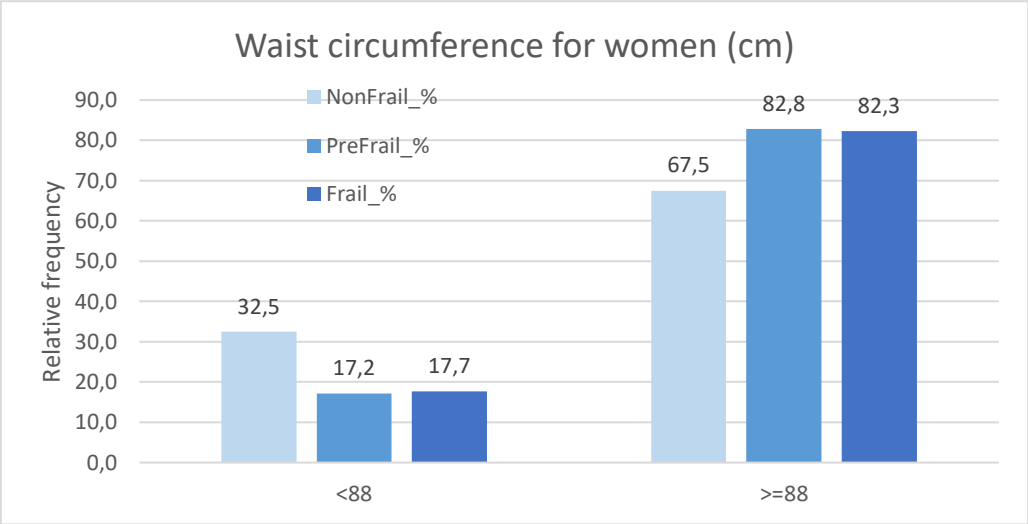
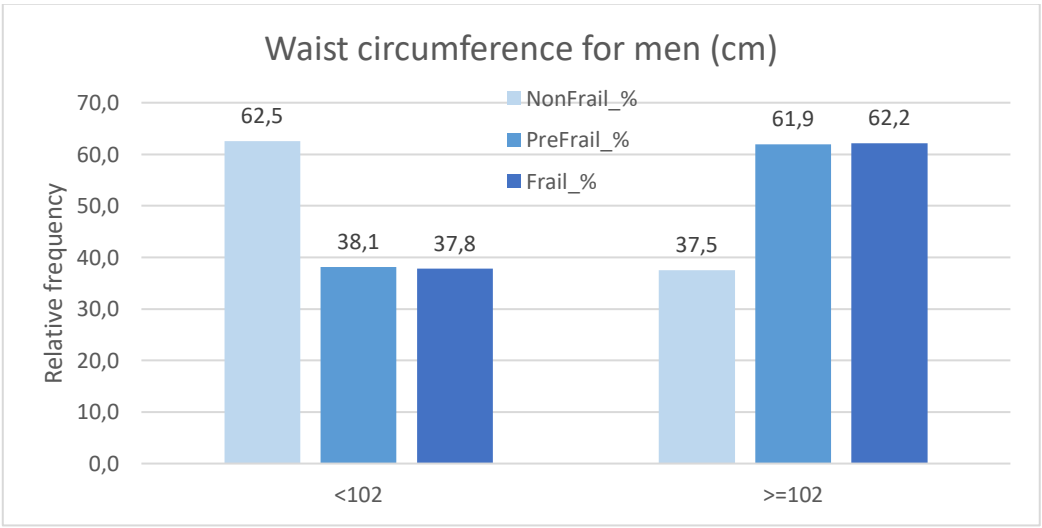


Table 48. Repartition of participants according to waist circumference category for men, per frailty group.

Waist Circumference for men (cm)	NonFrail	PreFrail	Frail	Total N
<102	25	24	14	63
>=102	15	39	23	77
	40	63	37	140

Figure 40. Prevalence of each category of waist circumference for men, per frailty group.

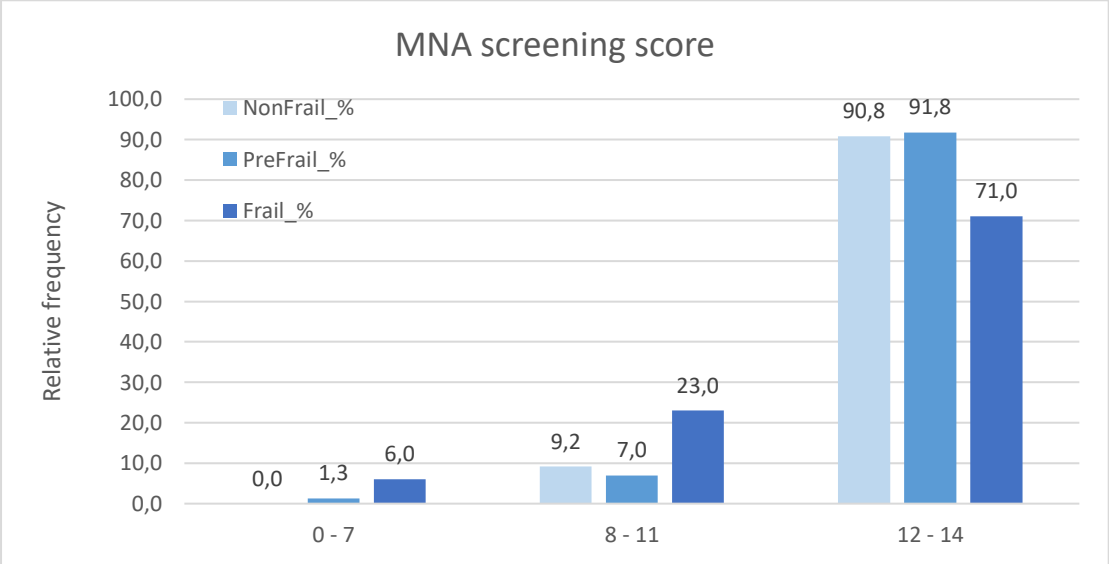


The majority of women of all frailty groups have a waist circumference superior than 88 centimeters, but the percentage of non-frails in this category is lower in comparison to the percentages of frails and pre-frails. The same pattern goes also for men, in whom, however, the non-frail group mostly belong to the slim waist circumference category of <102 centimeters.

Table 49a. Repartition of participants according to categories in the Mini Nutritional Assessment (MNA) screening test score, per frailty group (initial evaluation).

MNA screening score	NonFrail	PreFrail	Frail	Total N
<12	11	13	29	53
12 - 14	109	145	71	325
	120	158	100	378

Figure 41a. Prevalence of each category of the Mini Nutritional Assessment (MNA) screening test score, per frailty group (initial evaluation).



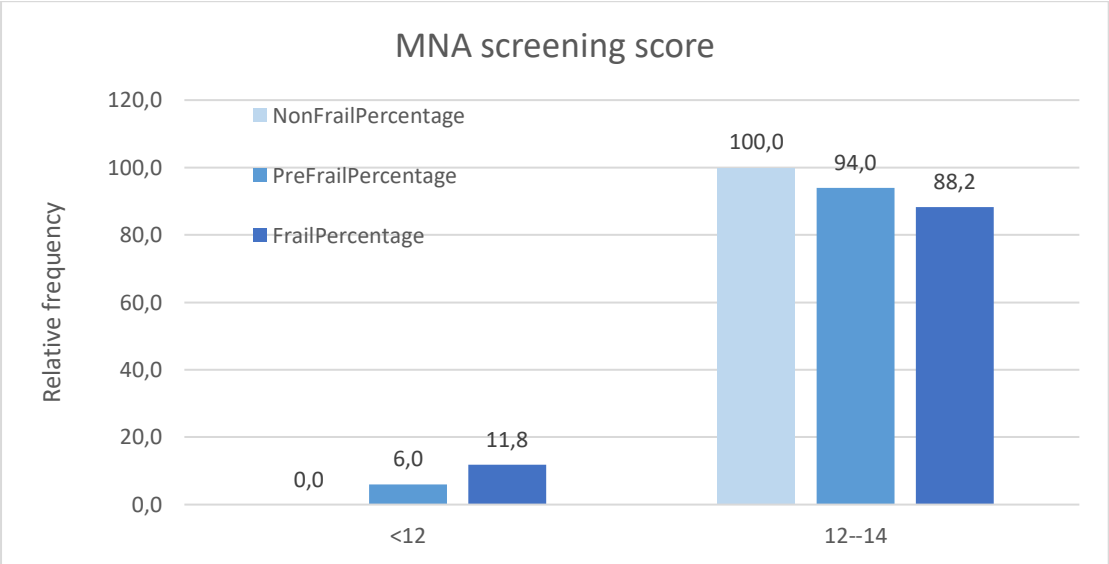
The Mini Nutritional Assessment (MNA) screening score, works as a discriminator for those who need to undergo the MNA total score, who are those who have a score <12 in the screening test. The vast majority of non-frail and pre-frail participants (90.8 and 91.8% respectively), have MNA screening scores in the normal range and therefore do not require further evaluation. The same applies of 71% of frail individuals, while 23 and 6% of them have a MNA screening score in the range of 8-11 and <8 respectively, with this last category implies an almost certain nutritional

problem. No non-frail person and very few pre-frail ones (1.3%, 2 individuals) rank to this category.

Table 49b. Repartition of participants according to categories in the Mini Nutritional Assessment (MNA) screening test score, per frailty group (second evaluation).

MNA screening score	NonFrail	PreFrail	Frail	Total N
<12	0	3	2	5
12 - 14	48	47	15	110
	48	50	17	115

Figure 41b. Prevalence of each category of the Mini Nutritional Assessment (MNA) screening test score, per frailty group (second evaluation).

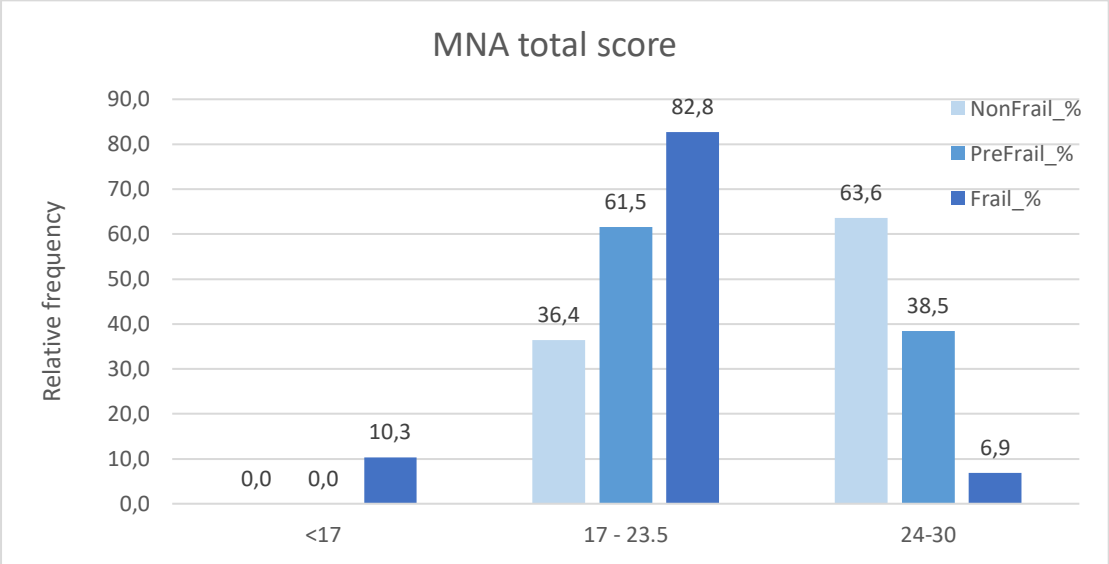


The pattern stays coherent also in the second evaluation. All non-frail people's nutritional status is found satisfactory by the screening score, whereas a considerable percentage of frail people (11,8%) scores low in the MNA screening score and requires further evaluation of the risk of malnutrition.

Table 50. Repartition of participants according to categories in the Mini Nutritional Assessment (MNA) total test score, per frailty group (initial evaluation).

MNA total score	NonFrail	PreFrail	Frail	Total N
<17	0	0	3	3
17 - 23.5	4	8	24	36
24-30	7	5	2	14
	11	13	29	53

Figure 42. Prevalence of each category of the Mini Nutritional Assessment (MNA) total test score, per frailty group (initial evaluation).



A MNA total score <17 is indicative of bad nutritional status and at this category we only find people characterized as frail. In the intermediate category, expressing risk of malnutrition, lies the majority of frail people (82.8%), followed by 61.5% of pre-frails and 36.4% of non-frails. The prevalence of those latter is dominating the normal nutrition category (MNA total score 24-30), followed by the 38.5% of pre-frails. Only 6.9% of frail individuals reach the category of normal nutritional status.

In the second clinical evaluation few people underwent the MNA full test (n=5), due to high performance in the prerequisite screening test.

2.7 Data derived from parameters of the cognitive domain

Data presented in this sub-session are derived from clinical questionnaires performed during the clinical evaluation visit.

Tables 51a and b present the minimum, maximum and mean values of the two cognitive scores that we employ in order to evaluate cognitive function, the Mini Mental State Examination (MMSE) score and the Montreal Cognitive Assessment (MoCA) score, followed by tables showing the repartition of our study's participants to scoring categories of these tests, as well as to the presence of a subjective memory complaint, accompanied by the corresponding histograms.

It is worth reminding that a score inferior at 24 in the MMSE test is an exclusion criterion for the study, and therefore, normally, it's minimum value is 24. The same does not apply for the MoCA score, which contributes to the diagnosis of Mild Cognitive Impairment (MCI) when inferior at 26.

Table 51a. Basic descriptive statistics of cognitive tests performed (initial evaluation).

	Minimum	**Maximum**	**Mean**
MMSE score	24	30	27,6
MoCA score	10	30	25,5

Table 51b. Basic descriptive statistics of cognitive tests performed (second evaluation).

	Minimum	**Maximum**	**Mean**
MMSE score	24	30	28,1
MoCA score	17	30	26,8

Table 52. Repartition of participants according to categories in the Mini Mental State Examination (MMSE) score, per frailty group (initial evaluation).

MMSE score	**NonFrail**	**PreFrail**	**Frail**	**Total N**
24-26	14	42	47	103
27-30	106	116	53	275
	120	158	100	378

Figure 43. Prevalence of each category of the Mini Mental State Examination (MMSE) score, per frailty group (initial evaluation).

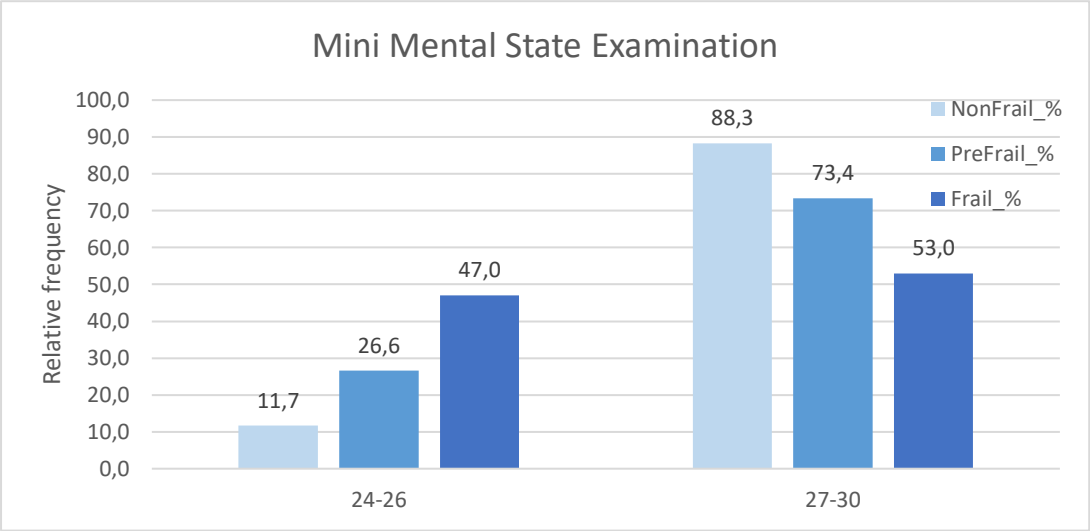
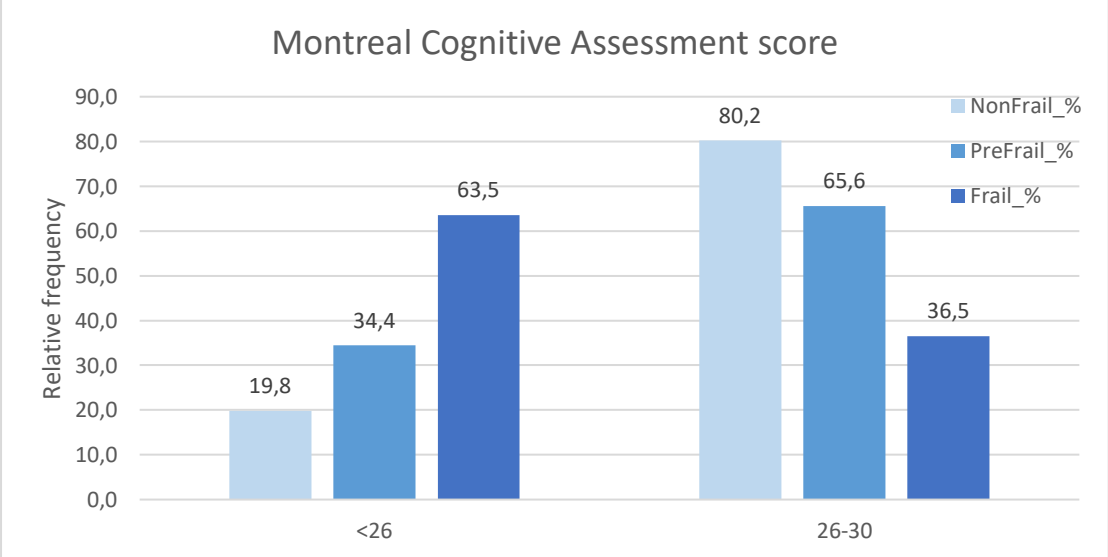


Table 53. Repartition of participants according to categories in the Montreal Cognitive Assessment (MoCA) score, per frailty group (initial evaluation).

MoCA score	NonFrail	PreFrail	Frail	Total N
<26	22	42	47	111
26-30	89	80	27	196
	111	122	74	307

Figure 44. Prevalence of each category of the Montreal Cognitive Assessment (MoCA) score, per frailty group (initial evaluation).

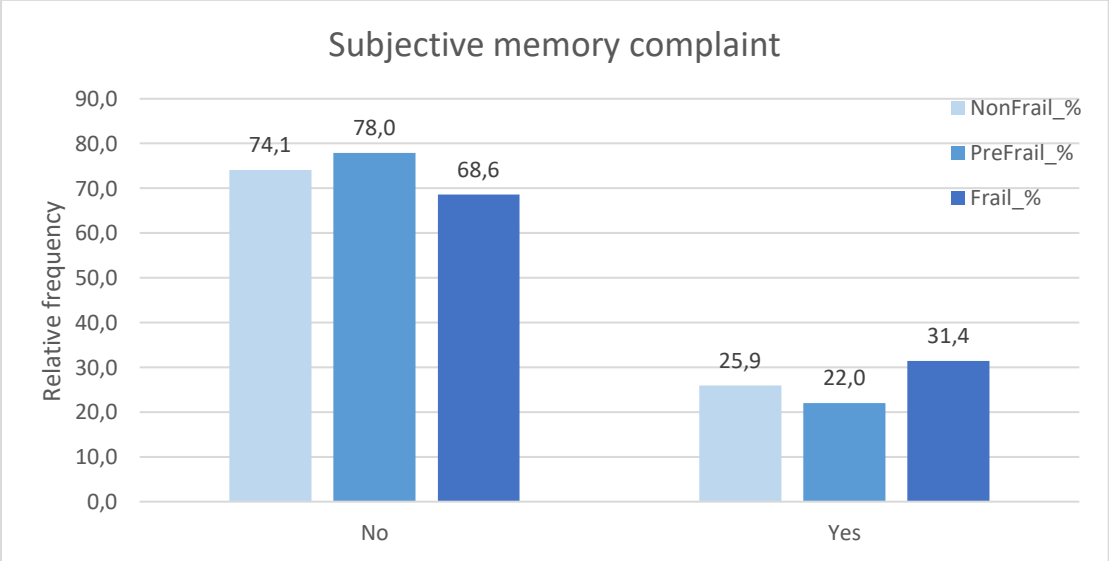


Performance in both MMSE and MoCA scores follow the same pattern of values' distribution. The dominant group in the lower cognitive performance category is the frail group, both for MMSE (47%) and for MoCA (63.5%). Only 11.7% of non-frail people have a MMSE <27, while 88.3% of them have a MMSE between 27 and 30, as do also the 73.4% of pre-frails and the 53% of frails. Similarly, for MoCA, 80.2% of non-frails, 65.5% of pre-frails and 36.5% of frails perform highly, between 26-30. The lower performance category (MoCA<26), representing also a high probability of Mild Cognitive Impairment (MCI), is dominated by frail individuals (63.5% of them), followed by 34.4% of pre- and 19.8% of non-frails. These observations could be an index of a bidirectional relation between cognitive and physical frailty, even if Fried's criteria, currently employed for the frailty status distinction, do not take under account the cognitive aspect of frailty.

Table 54. Repartition of participants according to the presence of a subjective memory complaint, per frailty group.

Subjective memory complaint	NonFrail	PreFrail	Frail	Total N
No	80	92	48	220
Yes	28	26	22	76
	108	118	70	296

Figure 45. Prevalence of subjective memory complaint, per frailty group.



Results regarding subjective memory complaint are not yet conclusive in this initial descriptive data presentation. However, the group that expresses more frequently memory complaints seems to be the frail one.

2.8 Data derived from parameters of the psychological domain

Data presented in this sub-session are derived from the questionnaire for the detection of depression GDS-15 items (Geriatric Depression Scale-15 items) and the visual analogue scale (VAS) about anxiety self-rating, performed during the initial clinical evaluation visit. Their minimum, maximum and mean values are presented in table 55.

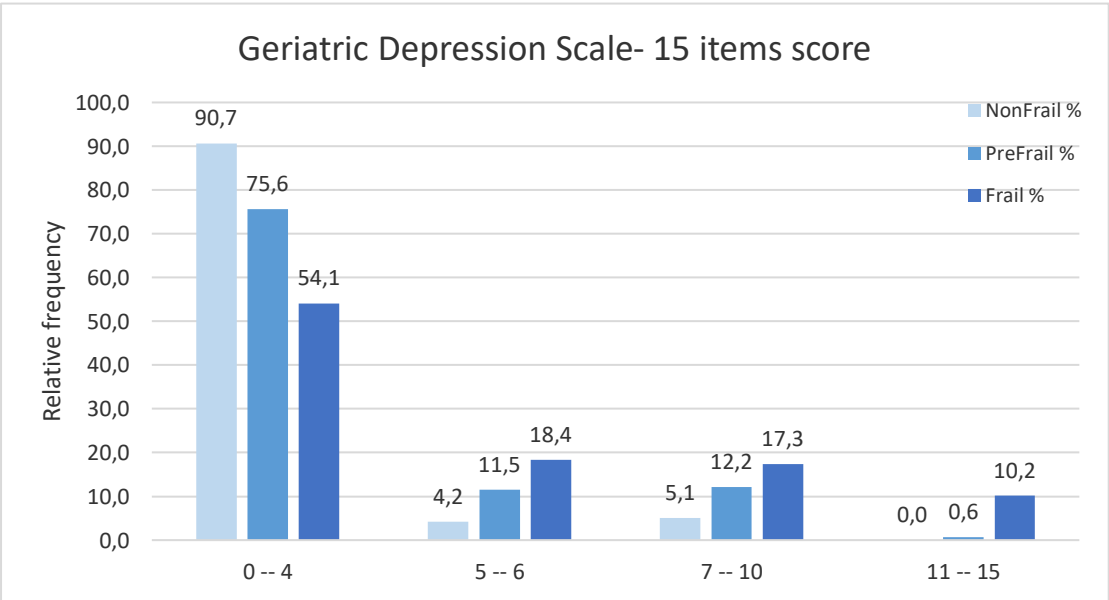
Table 55. Basic descriptive statistics about GDS (Geriatric Depression Scale) -15 items score and the VAS (Visual Analogue Scale) for the anxiety self-rating.

	Minimum	Maximum	Mean
GDS score	0	13	3,2
Self-rated anxiety (VAS)	0	10	4,2

Table 56. Repartition of participants according to categories in the GDS-15items' score, per frailty group.

GDS-15 items' score	NonFrail	PreFrail	Frail	Total N
0 - 4	107	118	53	278
5 - 6	5	18	18	41
7 - 10	6	19	17	42
11 - 15	0	1	10	11
	118	156	98	372

Figure 46. Prevalence of each category of the GDS-15 items' score, per frailty group.

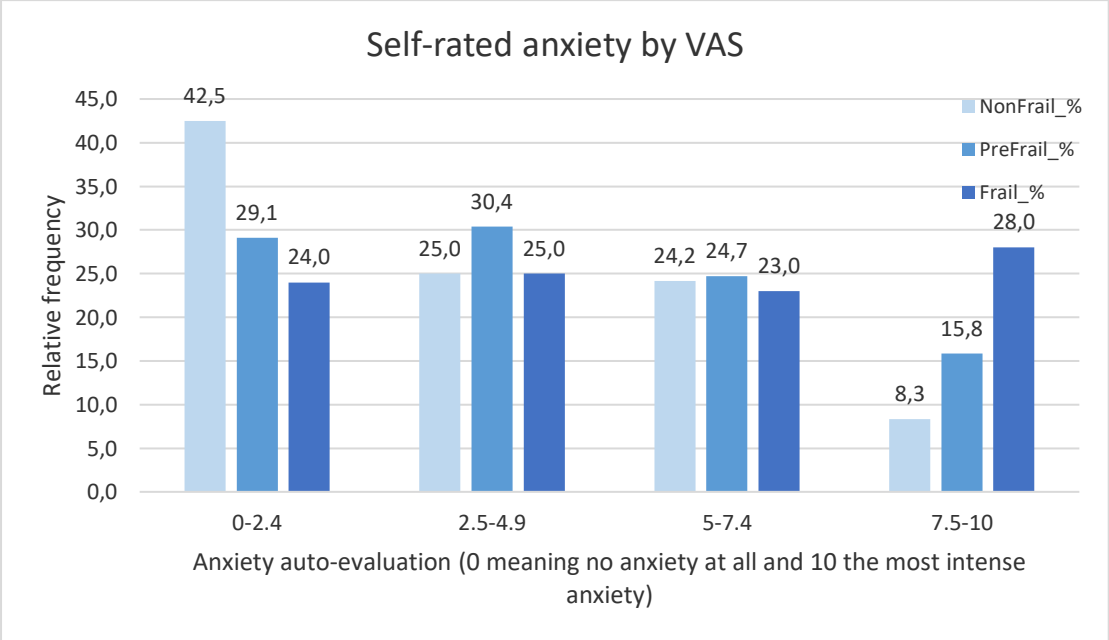


It is clear, observing this diagram, that most of non-frail participants (90.7%) belong to the lowest scores of depression (GDS<5). In this category also enter the majority of pre-frail (75.6%) and frail individuals (54.1%), with descending prevalences. On the other hand, the dominant group in all GDS categories, except for the lowest, is the frail group, followed by pre-frails. In the highest depression level scores (GDS>10), we encounter almost exclusively frail individuals (10.2%).

Table 57. Repartition of participants according to categories of the level of anxiety, self-evaluated by a Visual Analogue Scale, per frailty group.

Self-rated anxiety (VAS)	NonFrail	PreFrail	Frail	Total N
0-2.4	51	46	24	121
2.5-4.9	30	48	25	103
5-7.4	29	39	23	91
7.5-10	10	25	28	63
	120	158	100	378

Figure 47. Prevalence of each category of the level of anxiety, self-evaluated by a Visual Analogue Scale, per frailty group.



Intermediate categories of self-rate anxiety by VAS are not very indicative of the repartition of frailty groups. The high-rated category (augmented levels of anxiety, VAS 7.5-10) is dominated by the frailty group; 28% of frails, 15.8% of pre-frails and 8.3% of non-frails report a high rate of anxiety. On the contrary, the majority of non-frail individuals report a very low anxiety level (VAS 0-2.5), followed by 29.1% of pre-frails and 24% of frails.

2.9 Data derived from parameters of the social domain

Data presented in this sub-session are derived from questionnaires performed during the initial clinical evaluation visit. Although social relations-related data enter the score of "behavioral monitoring", data from the second evaluation's time spot are not presented in this report, because of the assuming lack of objectivity due to the absence of a standardized questionnaire to collect this kind of information.

This domain consists of exploring the living conditions and the various forms of social interactions the study's participants have, by qualitative and mostly quantitative means and is mainly based on self-reporting. There are two categorical variables (living conditions and membership to a club or association) and six quantitative variables referring leisure activities' and social contacts' frequency and duration.

Table 58 provides the minimum, maximum and mean values of the quantitative variables, followed by tables and figures displaying both qualitative and quantitative variables, relevant to the social domain description.

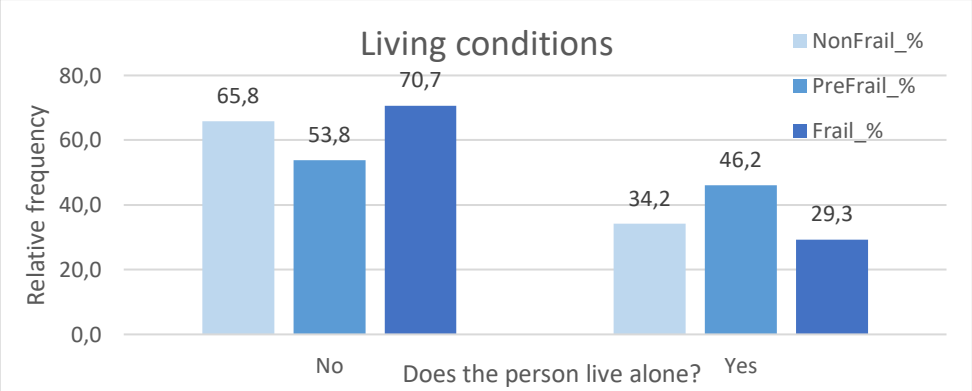
Table 58. Basic descriptive statistics describing the quantitative variables that compose the social domain.

All measurements refer to a week's time	**Minimum**	**Maximum**	**Mean**
Leisure activities (how many times they go out for a leisure activity)	0	28	5,8
Visits (how many visits and social contacts they exchange)	0	1	0,6
Calls (how many telephone calls they exchange)	0	70	9,5
Phonecall duration (how many minutes they spend on phone)	0	1200	156,9
Videocalls (how many time in minutes)	0	180	4,0
Text messages (how many sms or email they write)	0	161	6,4

Table 59. Repartition of participants according to their living conditions, per frailty group.

Living conditions (does he/she live alone?)	NonFrail	PreFrail	Frail	Total N
No	79	84	70	233
Yes	41	72	29	142
	120	156	99	375

Figure 48. Prevalence of each category of living conditions, per frailty group.

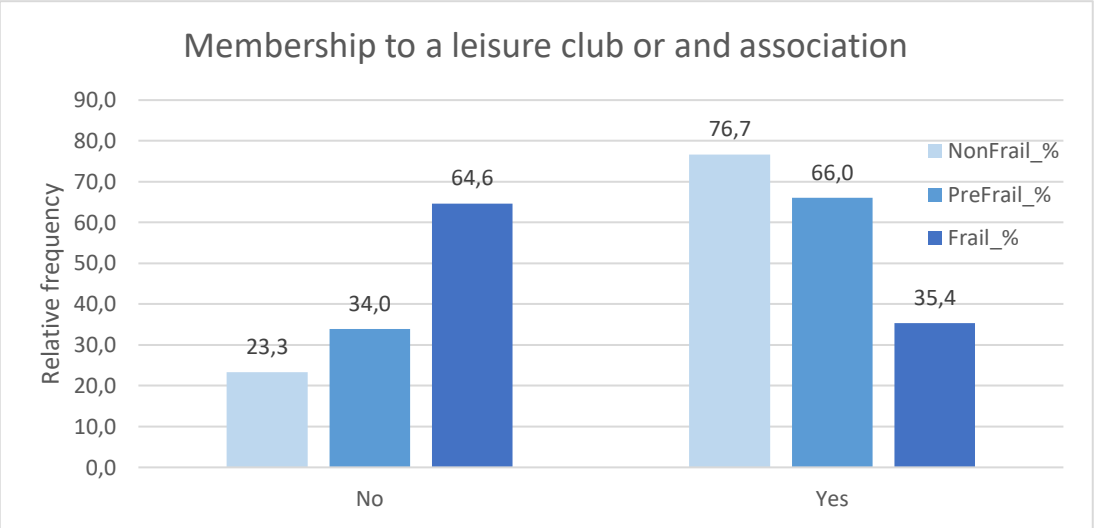


Most of the study's participants do not live alone, regardless of frailty status. However, frail people are more prevalent in the category of accompanied living (70.7% vs 53.8 of pre-frails and 65.8% of frails). The majority of people who live alone belong to the pre-frail group.

Table 60. Repartition of participants according to membership to a leisure club or association, per frailty group.

Membership to a leisure club or an association	NonFrail	PreFrail	Frail	Total N
No	28	53	64	145
Yes	92	103	35	230
	120	156	99	375

Figure 49. Prevalence of membership to a leisure club or association, per frailty group.

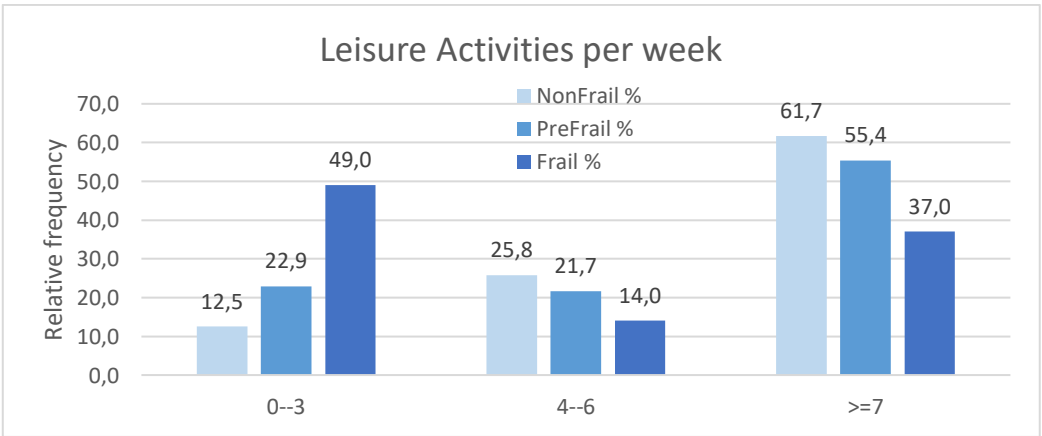


Only 35.4% of frail people are members to a leisure club or association, while the percentage for pre-frails and non-frails is 66 and 76.7% respectively.

Table 61. Repartition of participants according to categories of number of leisure activities per week, per frailty group.

Number of leisure activities per week	NonFrail	PreFrail	Frail	Total N
0--3	15	36	49	100
4--6	31	34	14	79
>=7	74	87	37	198
	120	157	100	377

Figure 50. Prevalence of each category of number of leisure activities per week, per frailty group.



The more the number of leisure activities per week, the less the prevalence of frail individuals. On the other hand, 49% of frail people report 3 or less leisure activities per week, while the percentage for pre-frail and non-frail participants is 22.9 and 12.5% respectively.

Table 62. Repartition of participants according to number of visits and social interactions exchanged per week, per frailty group.

Number of visits and social contacts per week	NonFrail	PreFrail	Frail	Total N
0--1	22	27	24	73
2	30	20	12	62
3--6	47	57	30	134
>=7	20	51	32	103
	119	155	98	372

Figure 51. Prevalence of each category of the number of visits and social interactions exchanged per week, per frailty group.

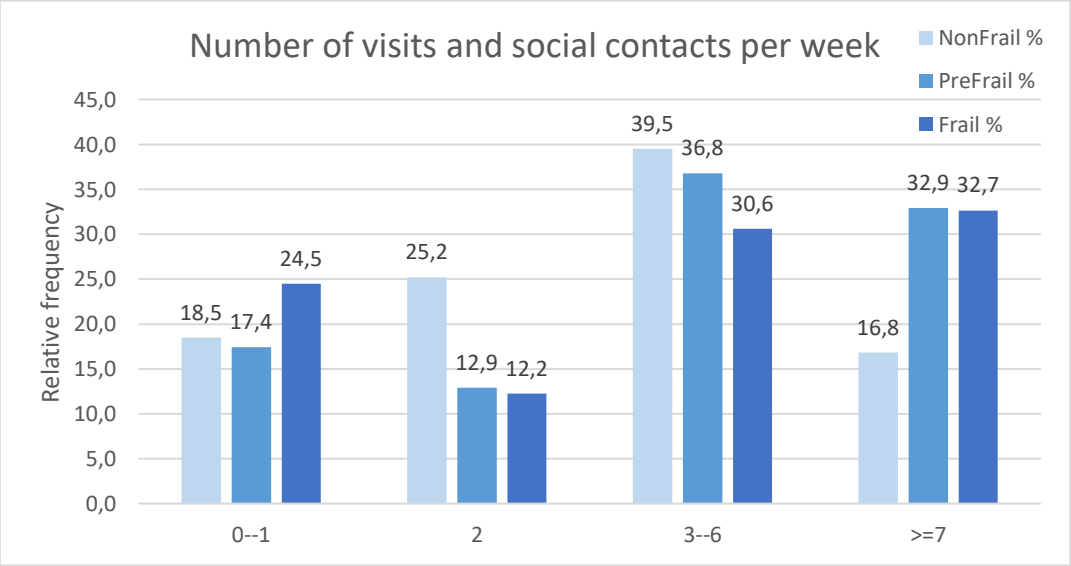
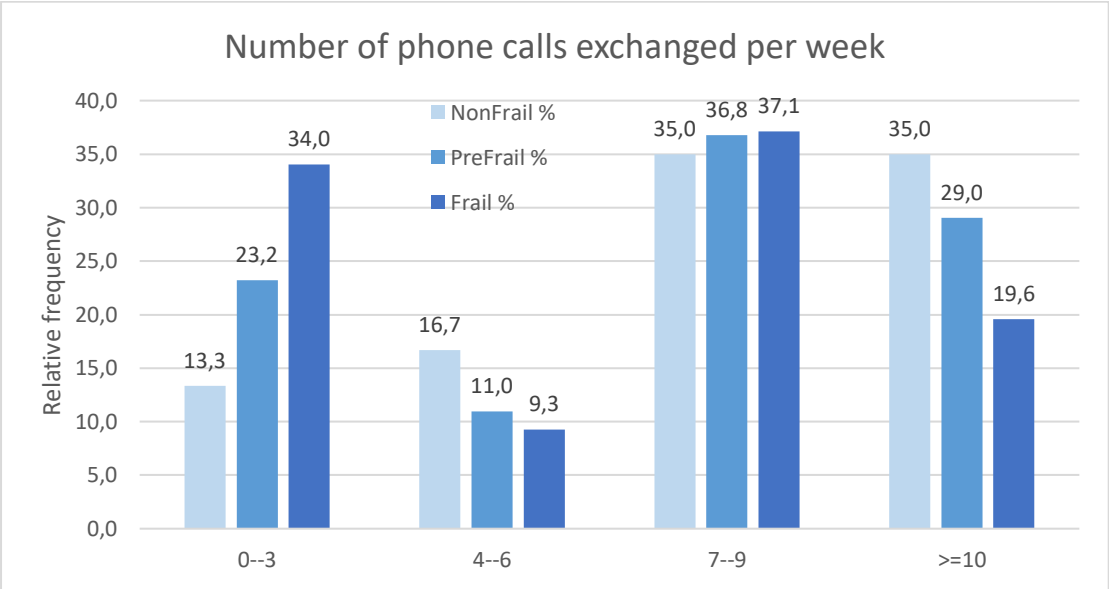


Table 63. Repartition of participants according to categories of number of phone calls exchanged per week, per frailty group.

Number of phone calls exchanged per week	NonFrail	PreFrail	Frail	Total N
0--3	16	36	33	85
4--6	20	17	9	46
7--9	42	57	36	135
>=10	42	45	19	106
	120	155	97	372

Figure 52. Prevalence of each category of number of phone calls exchanged per week, per frailty group.

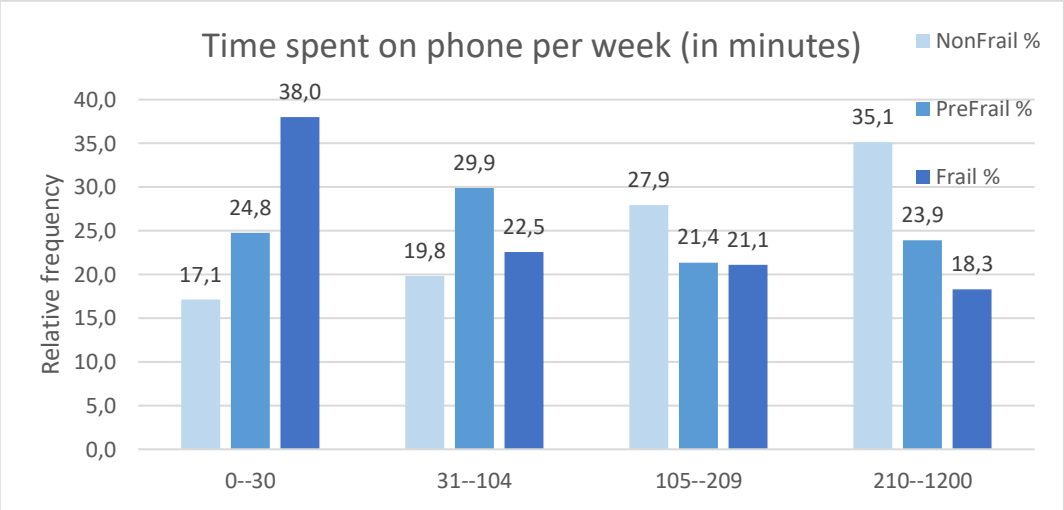


Both for the number of social interactions and phone calls exchanged per week, it's hard to identify a pattern between according to frailty status, although the frail group outweighs the rest in the less frequent phone call communication.

Table 64. Repartition of participants according to categories of the time (in minutes) spent on phone per week, per frailty group.

Time spent on phone calls per week (minutes)	NonFrail	PreFrail	Frail	Total N
0--30	19	29	27	75
31--104	22	35	16	73
105--209	31	25	15	71
210--1200	39	28	13	80
	111	117	71	299

Figure 53. Prevalence of each category of the time (in minutes) spent on phone per week, per frailty group.

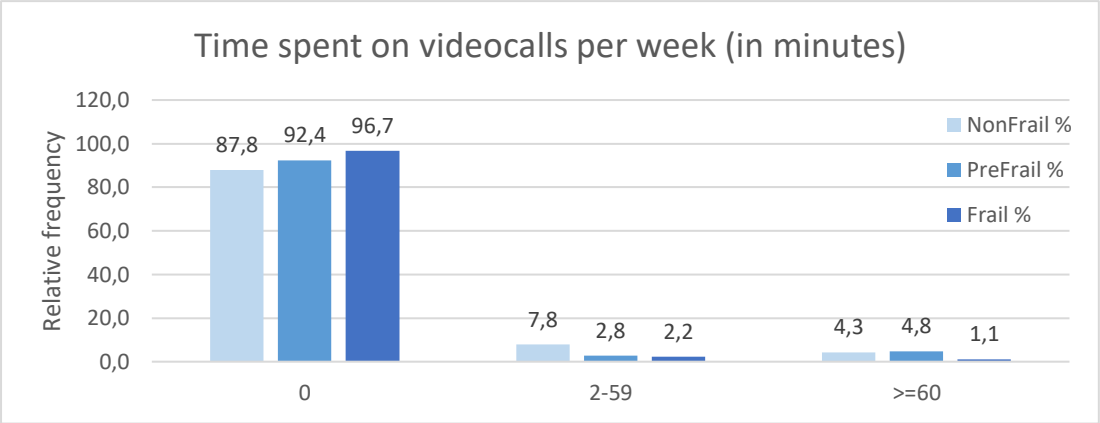


Regarding the time spent on the phone per week, it seems that frail participants are more prevalent in the less-time-spent-on phone categories, while non-frails ones, tend to spent more time on telephone.

Table 65. Repartition of participants according to categories of the time (in minutes) spent on videocalls per week, per frailty group.

Time spent on videocalls per week	NonFrail	PreFrail	Frail	Total N
0	101	134	88	323
2-59	8	4	2	14
>=60	5	7	1	13
	114	145	91	350

Figure 54. Prevalence of each category of the time (in minutes) spent on videocalls per week, per frailty group.

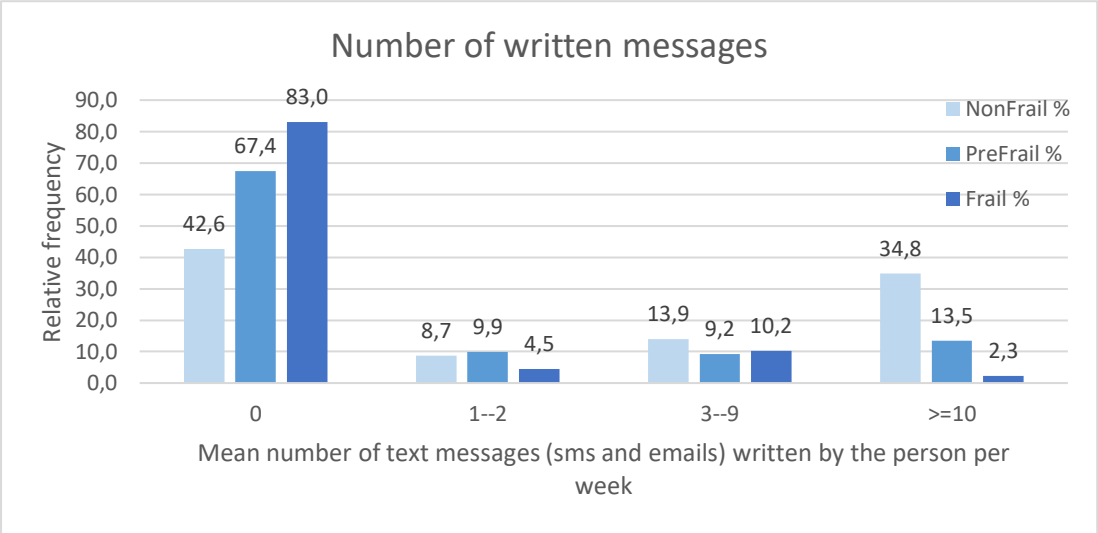


Very few of our study participants use distance video-communication means (like skype®), revealing also their limited familiarity with computers' and internet usage.

Table 66. Repartition of participants according to categories of the number of messages (sms and emails) written by the person per week, per frailty group.

Number of sms+emails written per week	NonFrail	PreFrail	Frail	Total N
0	49	95	73	217
1--2	10	14	4	28
3--9	16	13	9	38
>=10	40	19	2	61
	115	141	88	344

Figure 55. Prevalence of each category of the number of messages (sms and emails) written by the person per week, per frailty group.



The frailty group outweighs the rest in the less frequent written texts' communication (sms or emails produced and sent by themselves). In the high number of sms and emails category, non-frail participants largely outweigh others.

2.10 Data derived from parameters of the environmental domain

Data presented in this sub-session are derived from questionnaires performed during the first home visit for the FrailSafe session. In this way, the investigator can form an opinion of the participant's environment.

Table 67. Repartition of participants according to their own evaluation of their housings' suitability to their needs, per frailty group.

Housing environment suitable according to participant's evaluation	NonFrail	PreFrail	Frail	Total N
No	6	4	4	14
Yes	92	123	90	305
	98	127	94	319

Figure 56. Prevalence of housing's suitability to their needs, according to participants themselves, per frailty group.

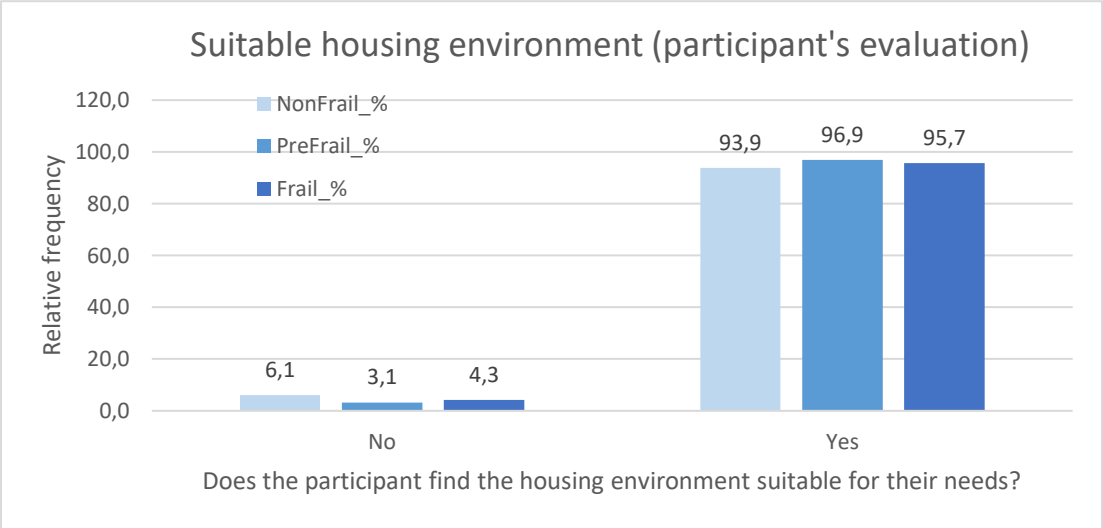
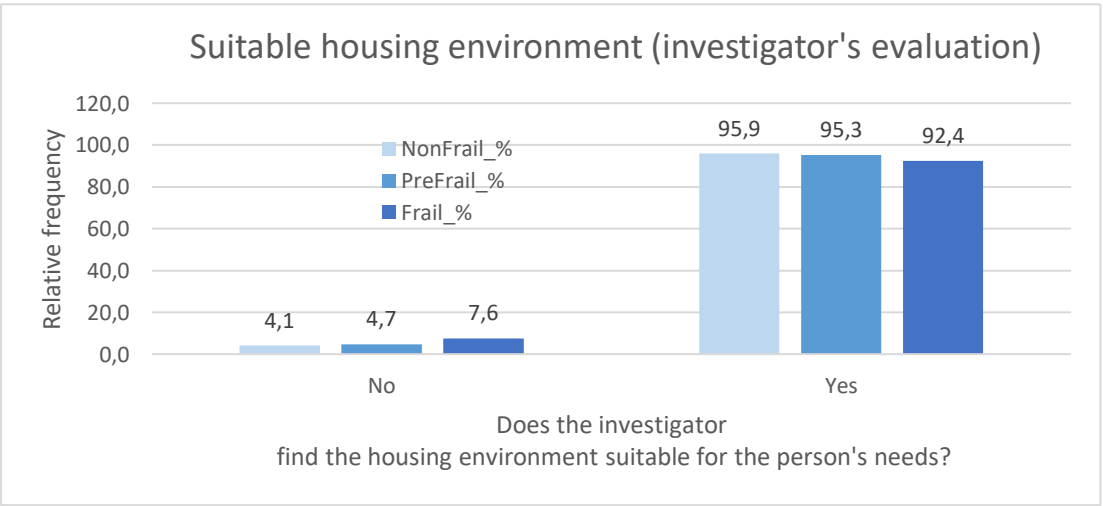


Table 68. Repartition of participants according to the investigator's evaluation of the housings' suitability to the needs of participants, per frailty group.

Housing environment suitable according to investigator's evaluation	NonFrail	PreFrail	Frail	Total N
No	4	6	7	17
Yes	94	122	85	301
	98	128	92	318

Figure 57. Prevalence of housing's suitability to the needs of participants, according to the investigator's evaluation, per frailty group.

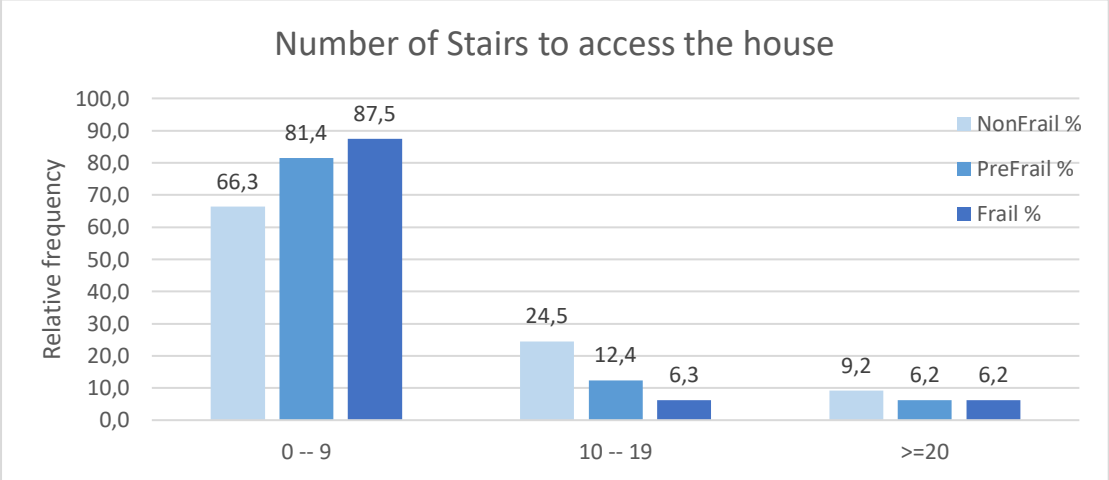


According to both the investigator's and the person's point of view, most of the participants, across all frailty groups, estimate that their housing environment is suitable for their needs.

Table 69. Repartition of participants according to the number of stairs to access the participant's house, per frailty group.

Number of stairs to access the house	NonFrail	PreFrail	Frail	Total N
0 - 9	65	105	84	254
10-19	24	16	6	46
>=20	9	8	6	23
	98	129	96	323

Figure 58. Prevalence of each category of number of stairs to access participant's house, per frailty group.



Frail participants are the dominant group in the category of low number of stairs in order to access one's house. Where the number of stairs exceeds 10, the majority of concerning people belong to the non-frail group.

2.11 Data derived from parameters of the wellness domain

Data presented in this sub-session are derived from questionnaires and visual analogue scales administered during the initial clinical evaluation visit. Table 70 summarizes the min, max and mean values of the results of Visual Analogue Scales (VAS) applied, followed by tables and figures describing the repartition of the study's participants in the various categories of self-evaluated health status and quality of life (QoL).

A score of 0 in the QoL scale represents the worst perception of QoL possible, while a score of 10 implies an excellent QoL. The opposite goes for pain and anxiety VAS, for which a score of 0 means no pain/anxiety at all, while a score of 10 represents the worst pain/anxiety imaginable. Data about anxiety self-rating were presented above (Session 2.8, Table 57, Figure 47).

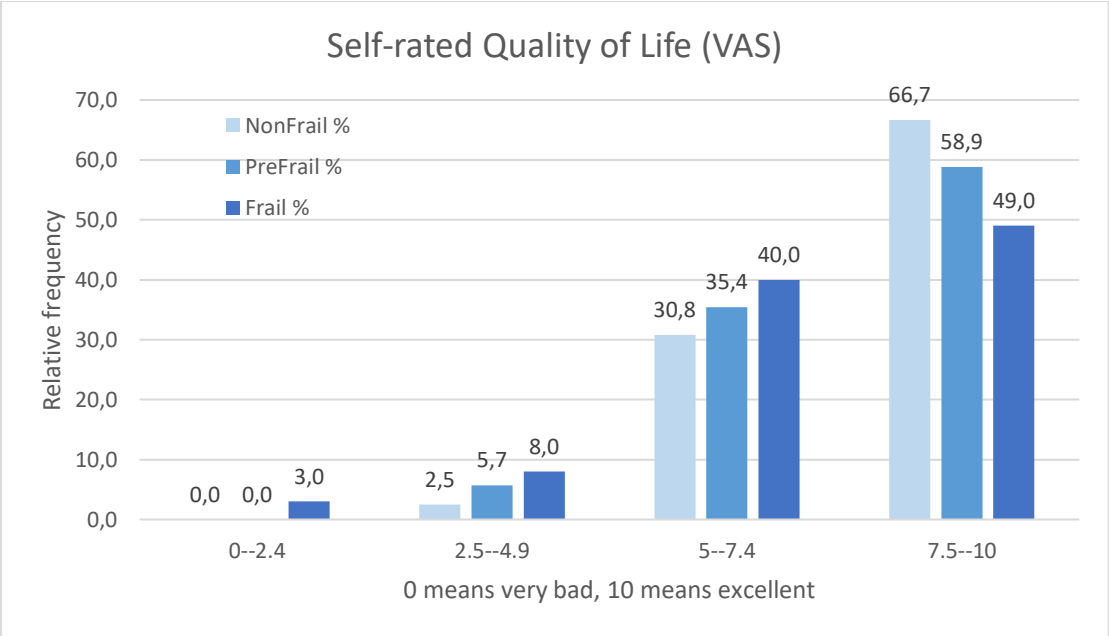
Table 70. Basic descriptive statistics about self-rated QoL, pain and anxiety, as evaluated by visual analogue scales (VAS).

	Minimum	Maximum	Mean
Quality of Life VAS	1,4	10	7,6
Self-rated pain VAS	0	10	3,3
Self-rated anxiety VAS	0	10	4,2

Table 71. Repartition of participants according to categories of the level of Quality of Life, self-evaluated by a Visual Analogue Scale, per frailty group.

Self-rated Quality of Life (VAS)	NonFrail	PreFrail	Frail	Total N
0--2.4	0	0	3	3
2.5--4.9	3	9	8	20
5--7.4	37	56	40	133
7.5--10	80	93	49	222
	120	158	100	378

Figure 59. Prevalence of each category of the level of Quality of Life, self-evaluated by a Visual Analogue Scale, per frailty group.

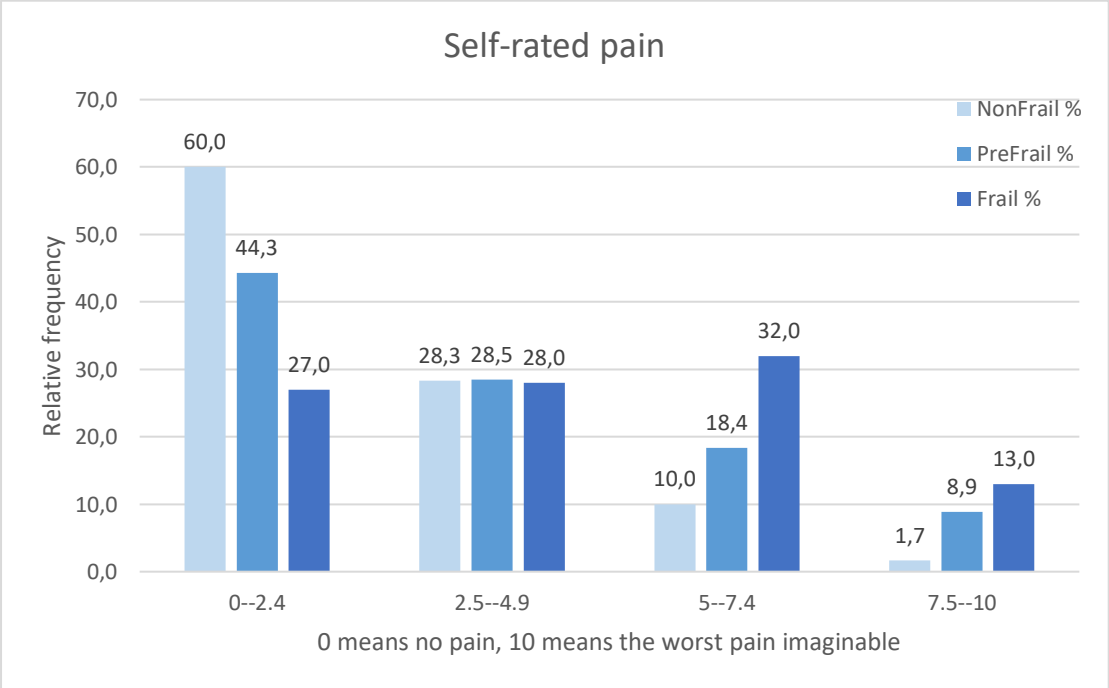


Most of the study's participants report a high level of QoL, according to their personal evaluation (QoL VQS 7.5-10). However, in this high-ranking group, non-frail participants (66.7%) outweigh both pre-frails (58.9%) and frails (49%). The prevalence of non-frails gradually decreases towards lower levels of self-rated QoL, while that of the frails decreases also, but always outweighs the two other frailty groups. Il the lowest QoL category (QoL VAS 0-2.4), there is only a small number of frail people left (3%).

Table 72. Repartition of participants according to categories of the level of pain, self-evaluated by a Visual Analogue Scale, per frailty group.

Self-rated pain (VAS)	NonFrail	PreFrail	Frail	Total N
0--2.4	72	70	27	169
2.5--4.9	34	45	28	107
5--7.4	12	29	32	73
7.5--10	2	14	13	29
	120	158	100	378

Figure 60. Prevalence of each category of the level of pain, self-evaluated by a Visual Analogue Scale, per frailty group.



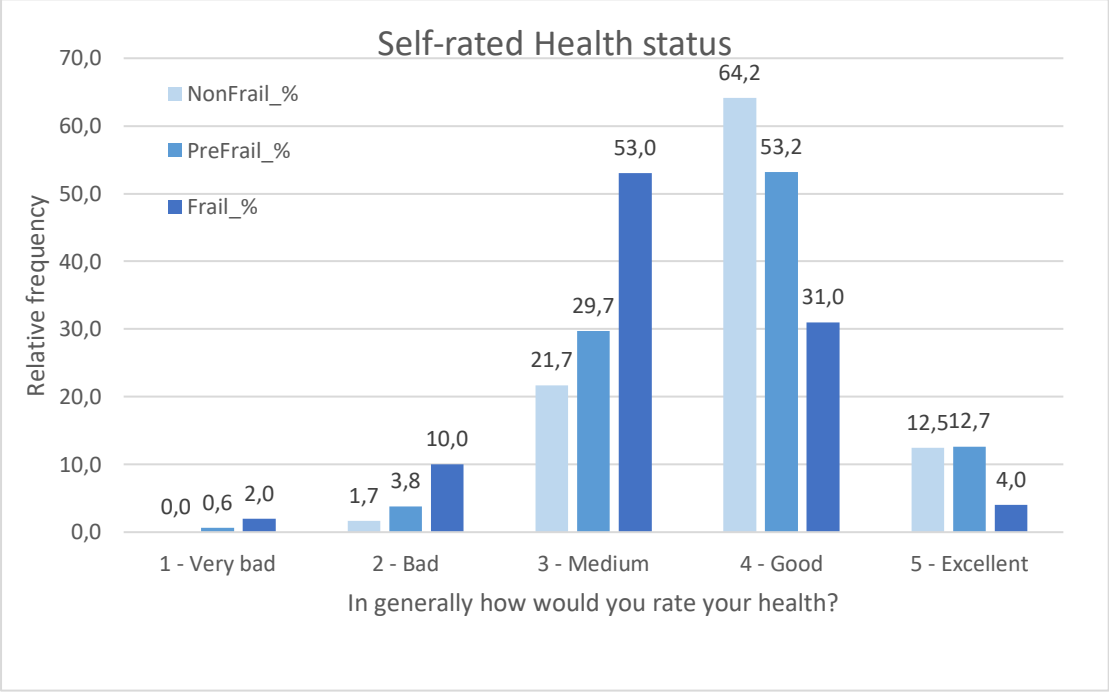
The majority of non-frail participants (60%) report low levels of pain (pain VAS 0-2.4), followed by 44.3% of pre-frails and 27% of frails. Most of frail people (32%) report a

pain level medium-to-high (pain VAS 5-7.4) and 13% of them a very high pain level (pain VAS 7.5-10). The prevalence of pre-frails and non-frails is 8.9 and 1.7% respectively, in this high pain level category.

Table 73. Repartition of participants according to categories of the self-rated health status, per frailty group.

Self-rated health status	NonFrail	PreFrail	Frail	Total N
1 - Very bad	0	1	2	3
2 - Bad	2	6	10	18
3 - Medium	26	47	53	126
4 - Good	77	84	31	192
5 - Excellent	15	20	4	39
	120	158	100	378

Figure 61. Prevalence of each category of self-rated health status, per frailty group.



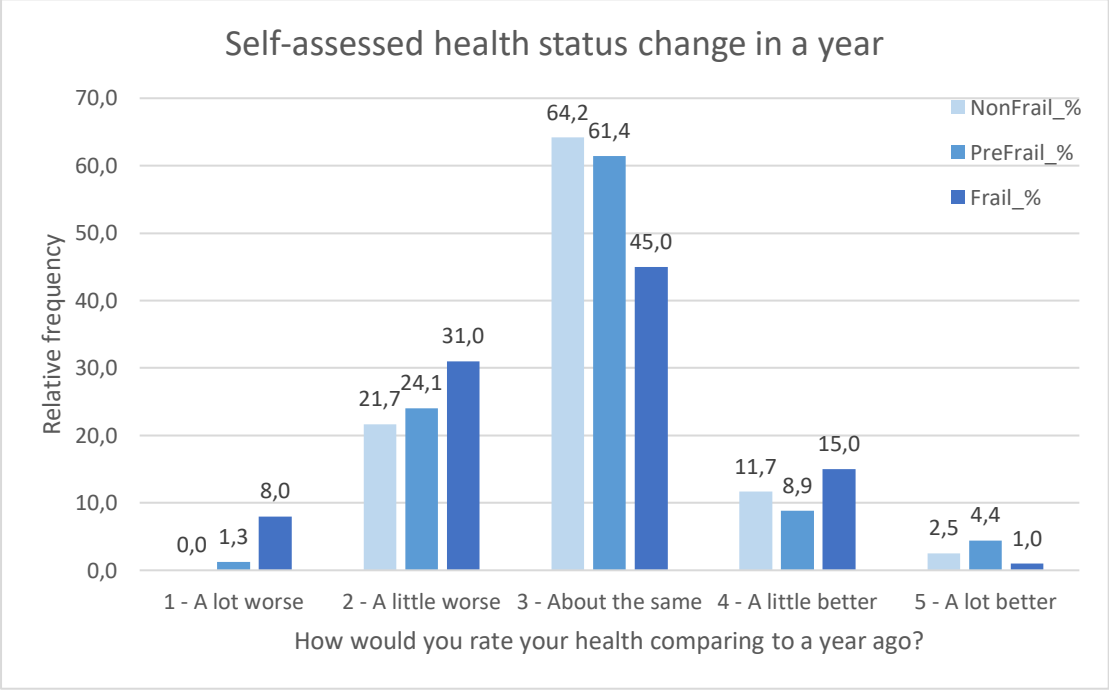
Regarding self-rated health status (Figure 61), frail people most often rate their own health status as negatively-low to medium, outweighing other frailty categories, while non-frails are the dominant group in positively-high ranking health status categories. The prevalence of frail people decreases in the positively evaluated ranks. On the contrary, most non-frail people (64.2%) report a good self-evaluation of their health status, followed by 53.2% pre-frails and 31% of frails. Non-frails and

pre-frails also dominate in the very high rated health status category (excellent health status).

Table 74. Repartition of participants according to categories of self-assessed health status change in a year, per frailty group.

Self- assessed health status change in a year	NonFrail	PreFrail	Frail	Total N
1 - A lot worse	0	2	8	10
2 - A little worse	26	38	31	95
3 - About the same	77	97	45	219
4 - A little better	14	14	15	43
5 - A lot better	3	7	1	11
	120	158	100	378

Figure 62. Prevalence of each category of self-assessed health status change in a year, per frailty group.



Most of all frailty groups' participants report no significant change in their health status in the last year, although the non-frail and pre-frail ones are more numerous in this intermediate category. Thirty-nine percent of frail people negatively evaluate the change in their health status in the last year, while the percentage of non-frails and pre-frails who negatively evaluate their health status change is 21.7 and 25.4% respectively.

2.12 Data derived from the devices used during home visits

In this session, available data derived from the FrailSafe electronic devices, that refer to behavioral parameters, are presented. These data refer to FrailSafe home visit sessions that may be multiple per group B's participant.

Apart from repartitioning the participants according to their behavioural aspects per frailty group, the collection of behavioural parameters for an individual participant are used in order to construct an overall model of the person's behavioural aspects. For each of the parameters considered for behavioural monitoring, e.g. motor skills or nutritional habits, a set of measurements are collected from each individual, over the period of time covered by the home visits. These measurements are collectively used in order to generate or update the Virtual Patient Model for the specific participant, as described in deliverable D4.6. The Virtual Patient Model contains the aggregated information about the current and overall condition of the older person, in terms of all clinical and cognitive aspects relative to frailty, including behavioural aspects.

The overall behavior of a FrailSafe participant with respect to a single measurement type, e.g. gait speed, is estimated as follows. During a number of home visits, tests for assessing gait speed are performed for the participant, and the gait speed is measured and stored. A Virtual Patient Model (VPM) is generated for the participant, using both the already existing measurements, as well as bibliographic evidence regarding the values of gait speed for people in the participant's frailty group. The information stored in the VPM is further utilized by the data analysis methods of WP4, including signal processing algorithms and data mining procedures, in order to discover behavioural patterns. Details are contained in the data analysis-related deliverables of WP4 (e.g. D4.1, D4.2, D4.3, D4.4, D4.14 and D4.15).

Apart from individual deliverables describing the progress in specific aspects of the project, the overall results of the integrated FrailSafe system application and its added value in the early detection of frailty will be presented in the D9.8_Project Final Report, when the progress of the data collection and analysis will be at an adequate level to derive conclusions, based on outcomes' evaluation.

Concerning the use of VERITAS outcomes, the procedures for generating this VPM are based on the user model generators developed within the VERITAS European project [1], and are described in deliverable D4.6. With respect to the semi-automated motor test of VERITAS, they included goniometers, cameras and full body wearable suites. The consortium has decided that these tools would not be easily acceptable for frail persons and therefore we focused on the use of more usable

tools targeting specific aspects of interest in frailty, like IMUs, sensing vest and dynamometers.

2.12.1 Data derived from parameters of the WWS and WWBS monitoring

Wearable Wellness System were available in the form of wearable straps, wrapped around the thorax up until M17. They collected data about electrocardiogram measurements (monitoring heart rate variability in response to the activities), IMU (Inertial Measurement Unit) measurements (for the detection of falls, the fall risk, the positioning, activity classification and activity pattern's recognition), respiration movements' measurements and distances covered. The current Wearable WBAN System version disposes the same properties with the current WWS system, with the addition of two extra IMUs at the level of both arms, in order to monitor upper limbs' mobility. This version is available for use since M17.

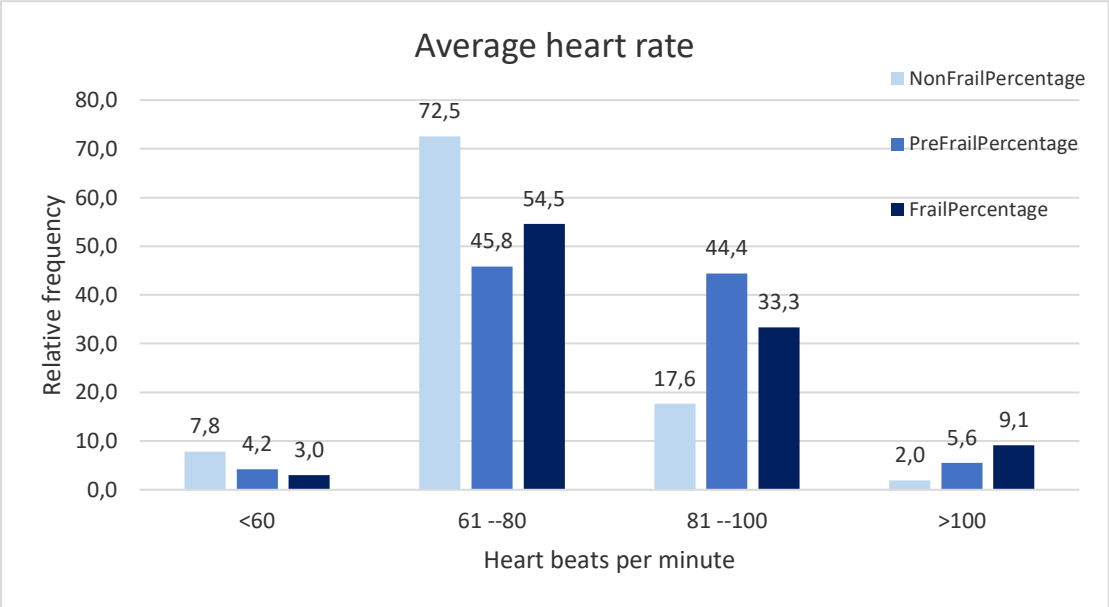
Metrics obtained by the WWS and WWBS systems will be correlated with clinical parameters of the medical, physical, psychological and social domain.

By 20/11/2017, data from a 156 (51 non-frails, 72 pre-frails and 33 frails) participants have been extracted and presented below, mostly regarding heart and breath rate monitoring. Data from IMUs are still being processed.

Table 75. Repartition of participants according to categories of average heart rate, per frailty group.

Average heart rate (beats per minute)	NonFrail	PreFrail	Frail	Total
<60	4	3	1	8
61 --80	37	33	18	88
81 --100	9	32	11	52
>100	1	4	3	8
	51	72	33	156

Figure 63. Repartition of participants according to categories of average heart rate, per frailty group.



Most non-frail people present an average heart rate into the "normal" range between 61 and 80 beats per minute. As we step up to faster heart rate categories, the repartition of pre-frail and frail people becomes more significant. In the "safer" lower range, non-frail individuals are more represented than the other frailty categories, whereas frail people predominate the average heart rate category of more than 100 beats per minute.

Table 76. Repartition of participants according to categories of maximum heart rate, per frailty group.

Maximum heart rate (beats per minute)	NonFrail	PreFrail	Frail	Total
61 --80	1	3	0	4
81 --100	6	4	3	13
101 --160	19	35	11	65
>160	25	30	19	74
	51	72	33	156

Figure 64. Repartition of participants according to categories of maximum heart rate, per frailty group.

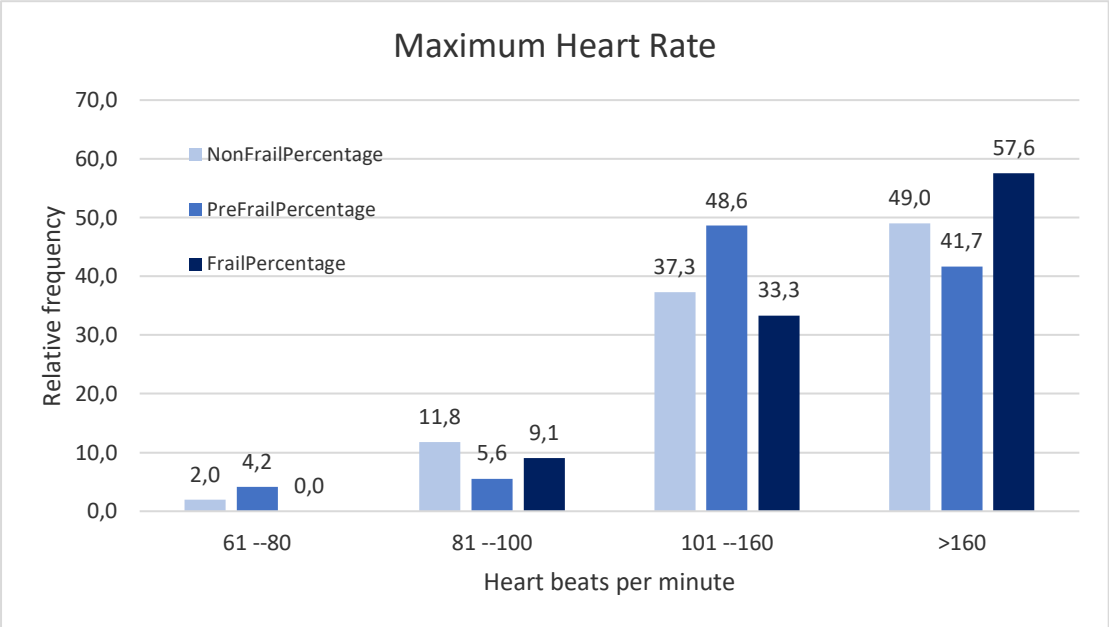
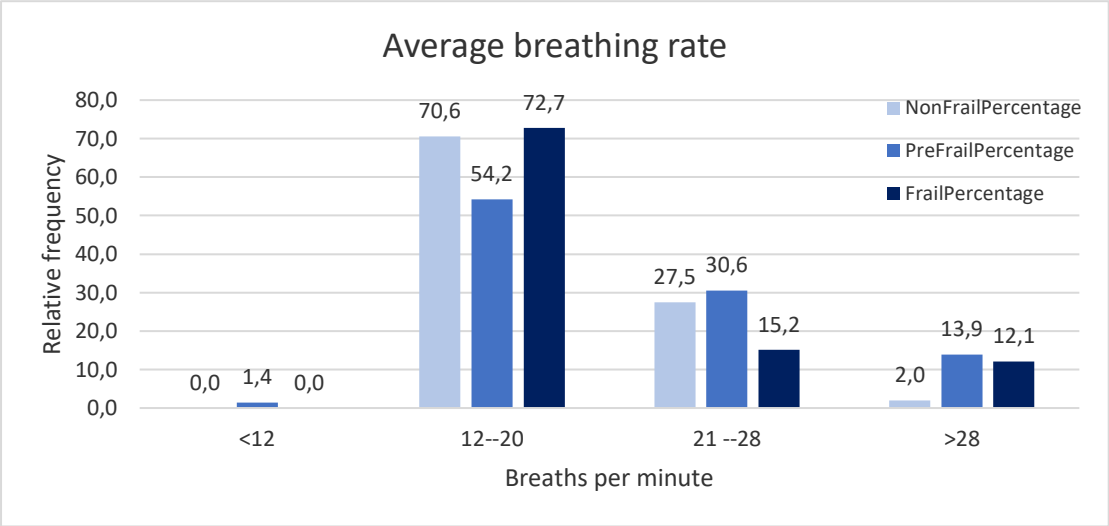


Table 77. Repartition of participants according to categories of average breathing rate, per frailty group.

Average breathing rate (beats per minute)	NonFrail	PreFrail	Frail	Total
<12	0	1	0	1
12--20	36	39	24	99
21 --28	14	22	5	41
>28	1	10	4	15
	51	72	33	156

Figure 65. Repartition of participants according to categories of average breathing rate, per frailty group.



Most participants present an average breathing rate between 12 and 20 breaths per minute. In the extreme range of >28 breaths per minute, there is very little repartition of non-frail individuals.

2.12.2 Data derived from parameters of the GPS monitoring

A smartphone device with a GPS (Global Positioning System) application is administered to all the study's participants during the FrailSafe session duration. Participants are instructed to carry the smartphone with them for as long as possible, both indoors and outdoors.

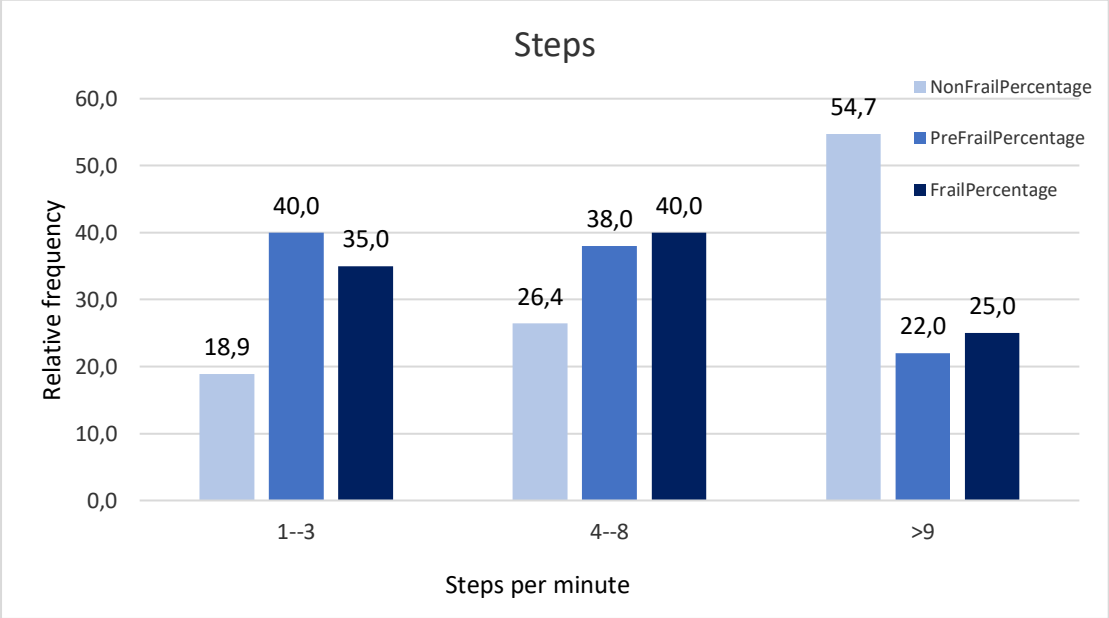
Parameters monitored by the GPS application are the speed of movement, the distance covered while being outdoors, the distance away from starting point, giving indications also about the gait speed, the vehicles' usage and the activity pattern and routine of a person. These metrics will be checked for correlations with clinical parameters of the physical, medical, cognitive and social domain.

Data extracted from the GPS application so far are presented below.

Table 78. Repartition of participants according to categories of average number of steps per minute, per frailty group.

Average breathing rate (beats per minute)	NonFrail	PreFrail	Frail	Total
1--3	10	20	7	37
4--8	14	19	8	41
>9	29	11	5	45
	53	50	20	123

Figure 66. Repartition of participants according to categories of average number of steps per minute, per frailty group

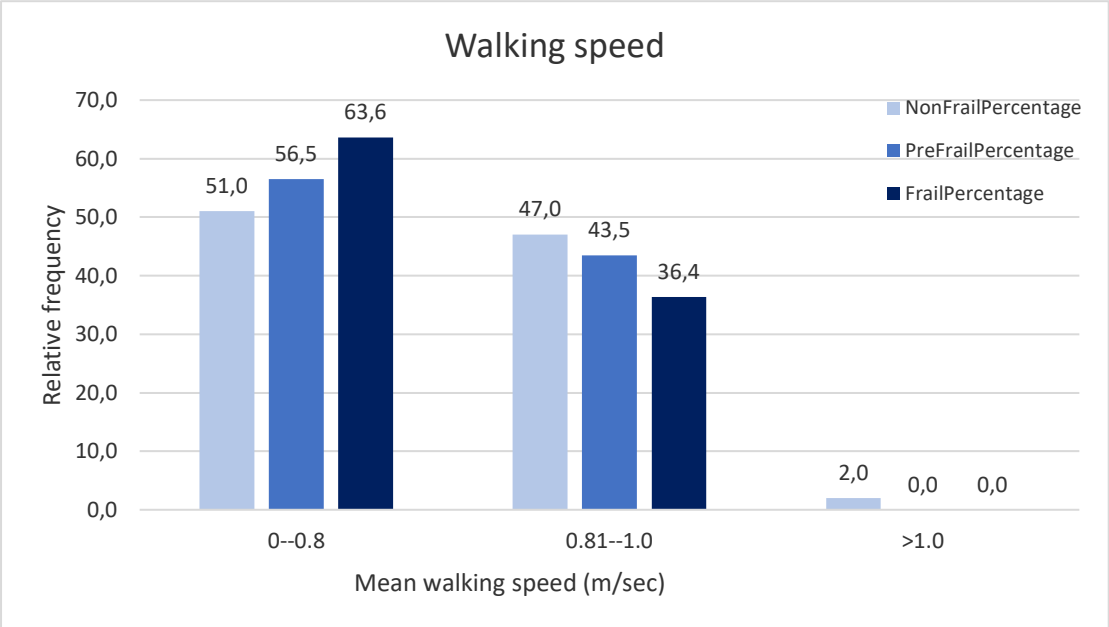


The number of steps per minute of recorded time is an indirect indicator of the activity level of our participants. Frail and pre-frail people indeed present lower activity levels are mostly, whereas, in the higher activity group, the non-frail group predominates, since most non-frail people (54,7%) take an average of more than 9 steps per minute.

Table 79. Repartition of participants according to categories of average walking speed, per frailty group.

Average walking speed (m/sec)	NonFrail	PreFrail	Frail	Total
0--0.8	26	26	14	66
0.81--1.0	24	20	8	52
>1.0	1	0	0	1
	51	46	22	119

Figure 67. Repartition of participants according to categories of average walking speed, per frailty group



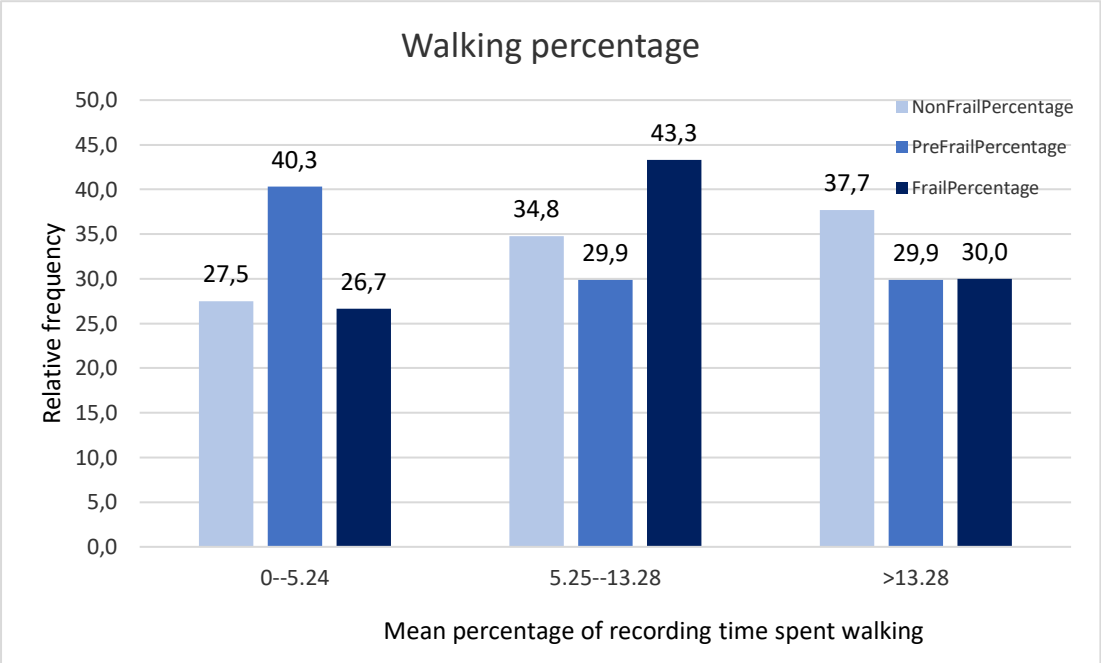
In accordance to the knowledge that the walking speed is an excellent indicator of frailty, our results show that the majority of frail people walk slower (average walking speed <0,8m/s) and no frail person presents a walking speed of more than 1m/s. In this latest category, we observe only a small percentage of non-frail participants. Most of non-frail people are found in the faster gait speed range of >0,8m/sec. Prefrail people follow intermediate gait speed patterns.

Tables 80, 81 and 82 and figures 68, 69 and 70 display the mean percentage of the recorded time spent in several types of activities, such as walking, standing still and vehicle usage respectively, while moving outdoors. Due to lack of standard normal values of these metrics, the 33th and 67th centiles were used as cut off points between classification categories.

Table 80. Repartition of participants according to categories of mean percentage of the recorded time spent outdoors walking, per frailty group.

Mean percentage of the recorded time spent outdoors walking	NonFrail	PreFrail	Frail	Total
0--5.24	19	27	8	54
5.25--13.28	24	20	13	57
>13.28	26	20	9	55
	69	67	30	166

Figure 68. Repartition of participants according to categories of mean percentage of the recorded time spent outdoors walking, per frailty group

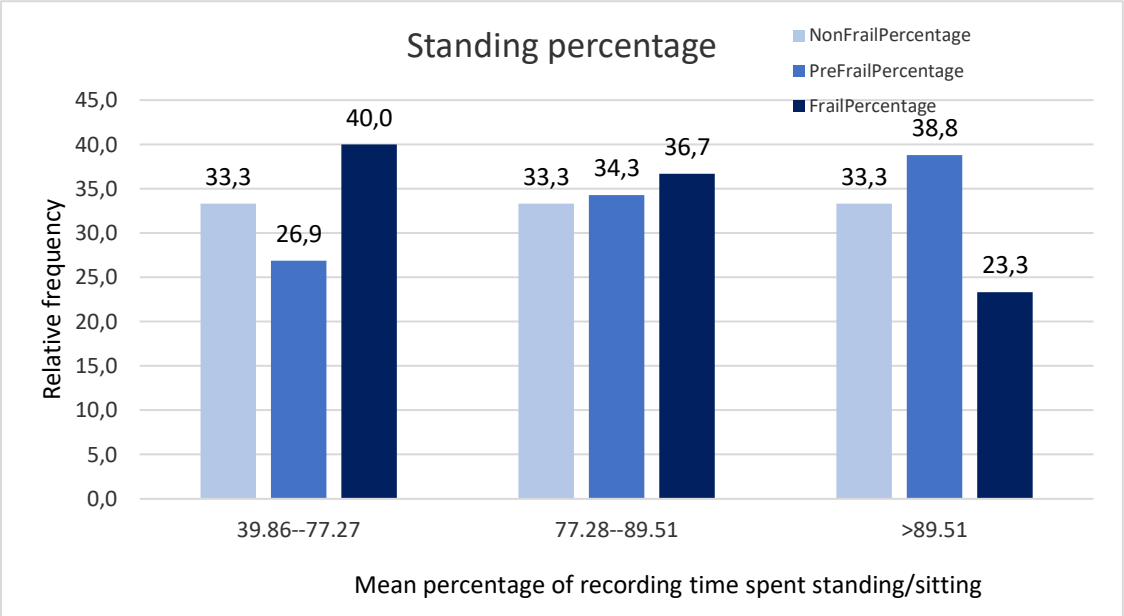


It's non-frail people spend the greater percentage of their outdoor time walking (>13,3%). The majority of frail people spend a mean of 5-13% of their outdoors time walking.

Table 81. Repartition of participants according to categories of mean percentage of the recorded time spent outdoors standing still, per frailty group.

Mean percentage of the recorded time spent outdoors standing still	NonFrail	PreFrail	Frail	Total
39.86--77.27	23	18	12	53
77.28--89.51	23	23	11	57
>89.51	23	26	7	56
	69	67	30	166

Figure 69. Repartition of participants according to categories of mean percentage of the recorded time spent outdoors standing still, per frailty group.

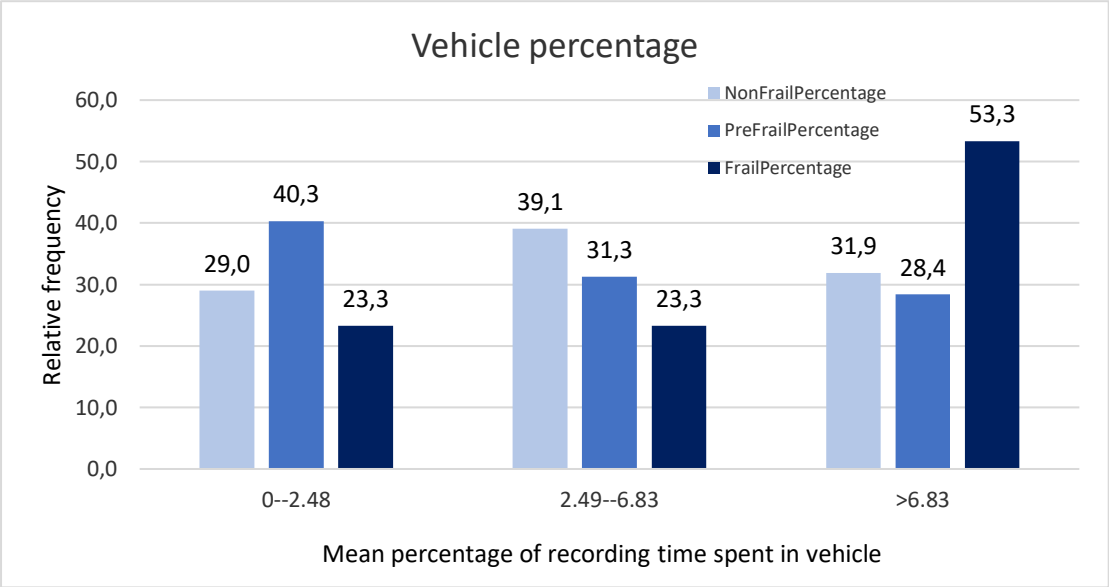


Non-frail people are encountered equally in the three categories of standing time percentage. However, frail people are more prevalent in the lower standing time category. Forty percent of them spend between 40 and 77% of their outdoors time standing still.

Table 82. Repartition of participants according to categories of mean percentage of the recorded time spent outdoors using a vehicle, per frailty group.

Mean percentage of the recorded time spent outdoors using a vehicle	NonFrail	PreFrail	Frail	Total
0--2.48	20	27	7	54
2.49--6.83	27	21	7	55
>6.83	22	19	16	57
	69	67	30	166

Figure 70. Repartition of participants according to categories of mean percentage of the recorded time spent outdoors using a vehicle, per frailty group



Most of frail people spend more time in a vehicle comparing to their peers of other frailty status categories. About 40% of pre-frail people spend a 2,5 to 6,8% of their outdoors time using a vehicle.

2.12.3 Data derived from parameters of the blood pressure home monitoring

Blood pressure home measurements differ from those obtained during the clinical evaluation visit, in the way that they are more ecological, more numerous and reflect better real-life conditions in contrast to a single time measurement during the clinical visit. Twice daily blood pressure measurements have been collected during the FrailSafe home sessions with the help of semi-automated devices lent to participants for some days' time.

However, reporting the data of home blood pressure monitoring is out of the scope of the present deliverable, as these measurements do not reflect participants' behavior.

2.12.4 Data derived from parameters of the Virtual Super Market game (VSM)

Another FrailSafe tool to monitor the cognitive status of older persons is a virtual supermarket game (VSM). It has already been in use in the project and will be further developed until its end thanks to volunteers' feedback.

The VSM simulates the experience of a person shopping in a supermarket in a 3D environment. At the beginning of the game, a list of items is presented and the task of the user is to navigate through the supermarket, select the listed items from the shelves, in the correct quantities, and pay the correct amount at the cashier.

The VSM is designed to mimic daily shopping in a supermarket, one of the most common activities of daily living. After paying, a statistics screen follows. The displayed information includes number and quantities of correct and incorrect items bought and total completion time. The program features four levels of difficulty depending on the number and quantities of different items on the list.

The VSM is aimed at training a multitude of cognitive processes namely visual and verbal memory, executive function, attention, and spatial navigation with the emphasis placed on executive function.

By the time this report is being written, data from the super market game have not yet been fed into the central database platform, and therefore no descriptive results are available.

2.12.5 Data derived from parameters of the Red Wings-dynamometer game

The game is about piloting a plane across a landscape trying to avoid the different obstacles that will come up in the scene moving the plane up and down using the dynamometer.

This game offers the opportunity for testing and exercising both a physical aspect like grip strength, with also a cognitive component (understanding and following the instructions, hand-brain co-ordination). Grip strength, which is mainly tested by this game is a central element of the operational definition of frailty according to Fried. This game offers also the possibility to be played with the finger and not only the dynamometer, for people who find the dynamometer version too challenging or who are facing debilitating physical conditions (whist pain, carpal tunnel syndrome), maintaining all other benefits of the game except for grip strength.

The preliminary data obtained by the redwings game are presented below.

Tables 83-84 and figures 71-72 show the average and maximum game duration per participants in the ensemble of his/her playing sessions. Along with the game duration, another indicator of overall game performance is the game score (Tables 86-86 and figures 73-74). The higher the score is, the better the performance of the participant. These metrics could indicate both manual dexterity and an effective cognitive contribution in game playing.

Table 83. Repartition of participants according to categories of average game duration in seconds, per frailty group.

Average game duration in seconds	NonFrail	PreFrail	Frail	Total
<52.5	35	29	30	94
52.5 -- 81.2	33	34	29	96
>81.2	27	43	25	95
	95	106	84	285

Figure 71. Repartition of participants according to categories of average game duration in seconds, per frailty group

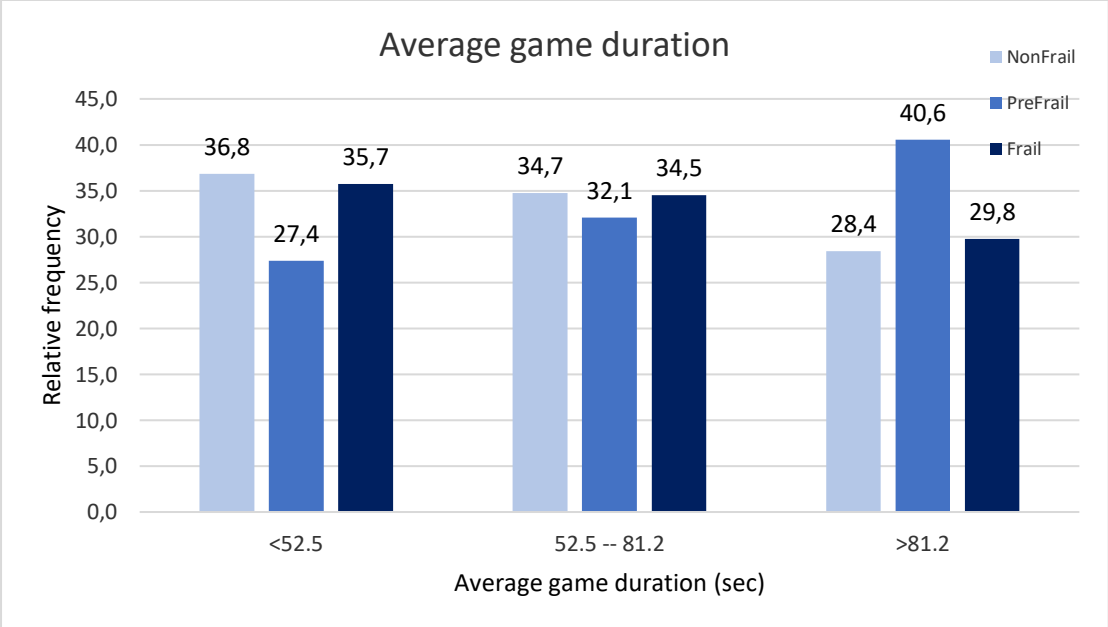
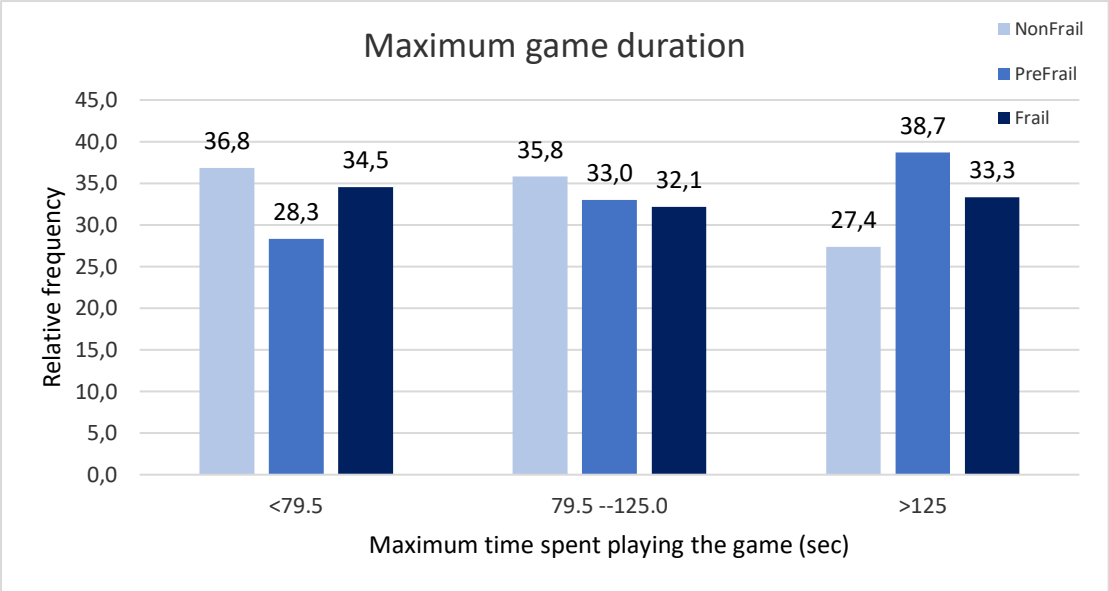


Table 84. Repartition of participants according to categories of maximum game duration in seconds, per frailty group.

Maximum game duration in seconds	NonFrail	PreFrail	Frail	Total
<79.5	35	30	29	94
79.5 --125.0	34	35	27	96
>125	26	41	28	95
Sum	95	106	84	285

Figure 72. Repartition of participants according to categories of maximum game duration in seconds, per frailty group



The variables of average and maximum game duration do not seem to follow a specific pattern according to frailty status. This could be due to the possibility that the time a person devotes to a game activity may depend on other factors as well, like the motivation, the investment, the personal interest and even the requirements of the game in relation to individual competence and skills.

Table 85. Repartition of participants according to categories of average game score (in points accumulated), per frailty group.

Average game score (in points accumulated)	NonFrail	PreFrail	Frail	Total
<219	32	25	37	94
219-356	30	45	22	97
>356	33	36	25	94
	95	106	84	285

Figure 73. Repartition of participants according to categories of average game score (in points accumulated), per frailty group.

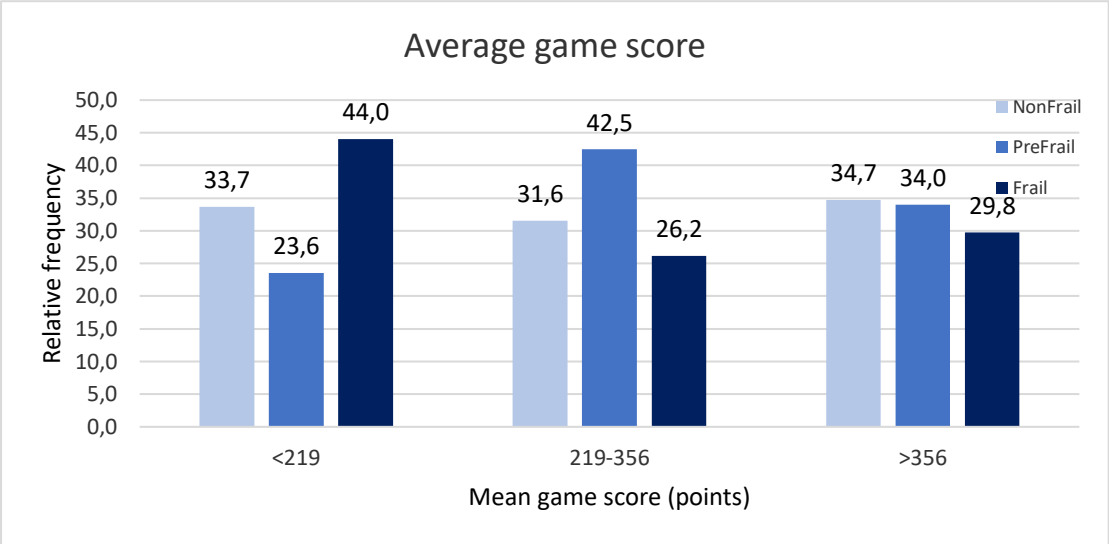
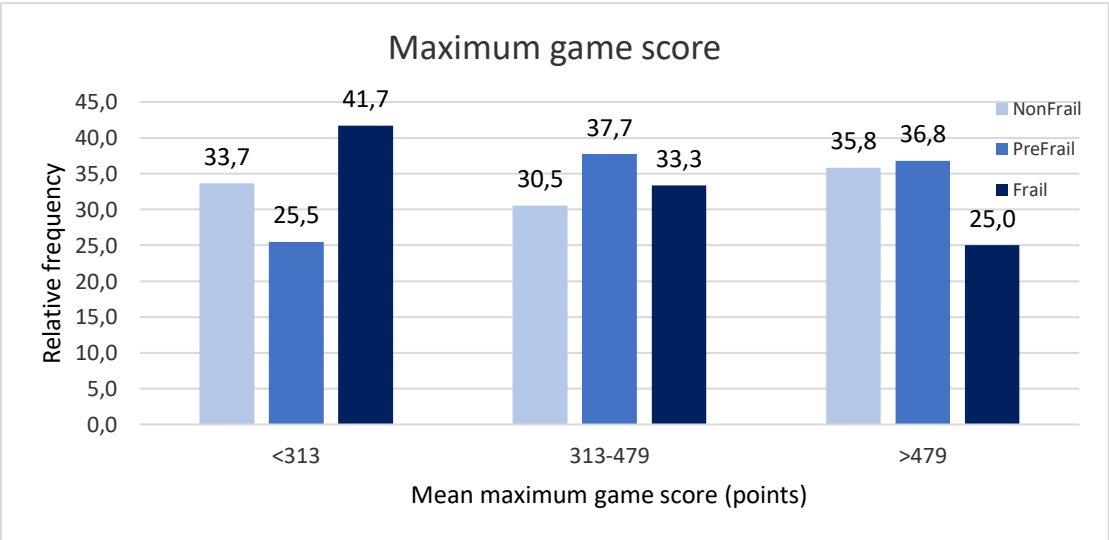


Table 86. Repartition of participants according to categories of maximum game score (in points accumulated), per frailty group.

Maximum game score (in points accumulated)	NonFrail	PreFrail	Frail	Total
<313	32	27	35	94
313-479	29	40	28	97
>479	34	39	21	94
	95	106	84	285

Figure 74. Repartition of participants according to categories of maximum game score (in points accumulated), per frailty group.



Whereas for the non-frail and the pre-frail group maximum game score is less indicative, it seems that frail individuals tend to be less present in the high scoring category, indicating lower overall game performance.

The average of the maximum force applied on the dynamometer has been dichotomized according to the normal values of the maximum grip strength provided by the Fried's frailty operational definition, extrapolated for a mean BMI, per sex. For women the cut off of 17.6 Kg has been retained, whereas for men, the cut-off of 30Kg. Results of the mean maximum force applied during game playing by a participant in several game sessions are presented in tables 87-88 and in figure 75.

Table 87. Repartition of male participants according to categories of mean maximum force applied to the dynamometer (in Kgs), per frailty group.

Mean maximum force applied to the dynamometer (in Kgs) in males	NonFrail	PreFrail	Frail	Total
<30	9	11	14	34
>=30	28	30	23	81
	37	41	37	115

Figure 75. Repartition of male participants according to categories of mean maximum force applied to the dynamometer (in Kgs), per frailty group.

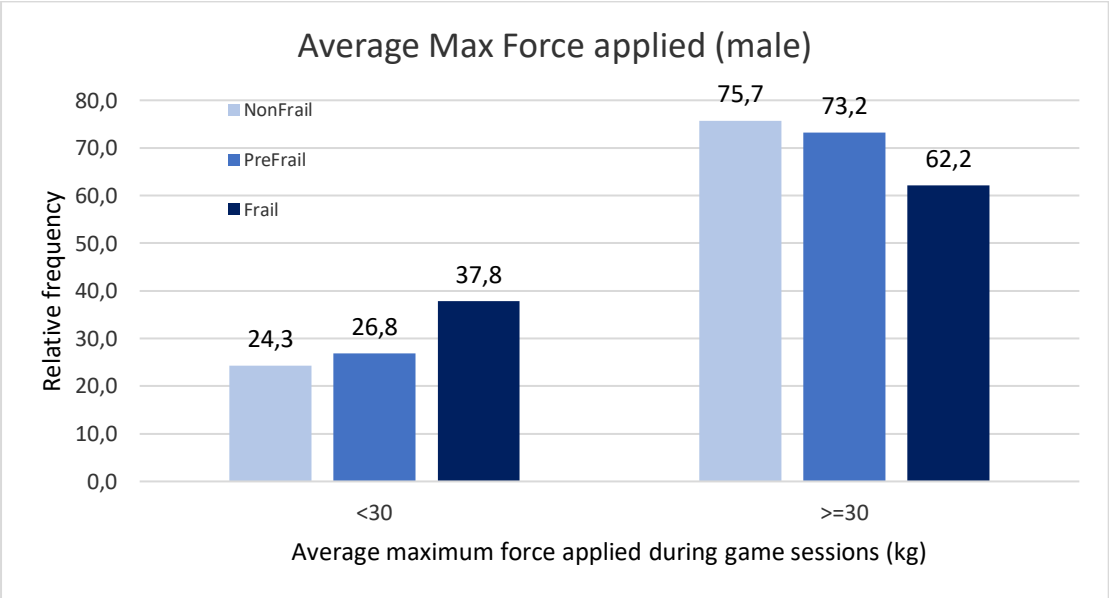


Table 88. Repartition of female participants according to categories of mean maximum force applied to the dynamometer (in Kgs), per frailty group.

Mean maximum force applied to the dynamometer (in Kgs) in females	NonFrail	PreFrail	Frail	Total
<17.6	1	0	0	1
>=17.6	57	64	45	166
	58	64	45	167

For males, the pattern of distribution among frailty groups of the maximum force applied is coherent with their frailty level (non-frail people predominate in the greater force category, while frail ones in the lower force class). On the other hand, in females the results are less clear, since the cut-off point derived from a single effort of force applied in the dynamometer, seems unable to distinguish frail from non-frail participants, having only one person who scored in the lower force level. This finding, however, along with the phenomenon observed in men of most of the total study population scoring in the higher force category, could indicate that older people do better in grip strength when playing games, rather than when they are asked to do so in the context of a frailty medical evaluation. This could also imply a "training" affect who enhances the grip strength performance after repetitive game playing sessions.

Based on the notion of the Grip Work introduced by Bautmans et al [2] (Fig. 76), and a suitable for the redwings game adjustment performed by Brainstorm, a novel metric derived from the game has been developed. This metric expresses the notion of fatigue and endurance, and somehow reflects the effort made by the participant during a game session playing.

Figure 76. Schematic representation of the Grip Work index.

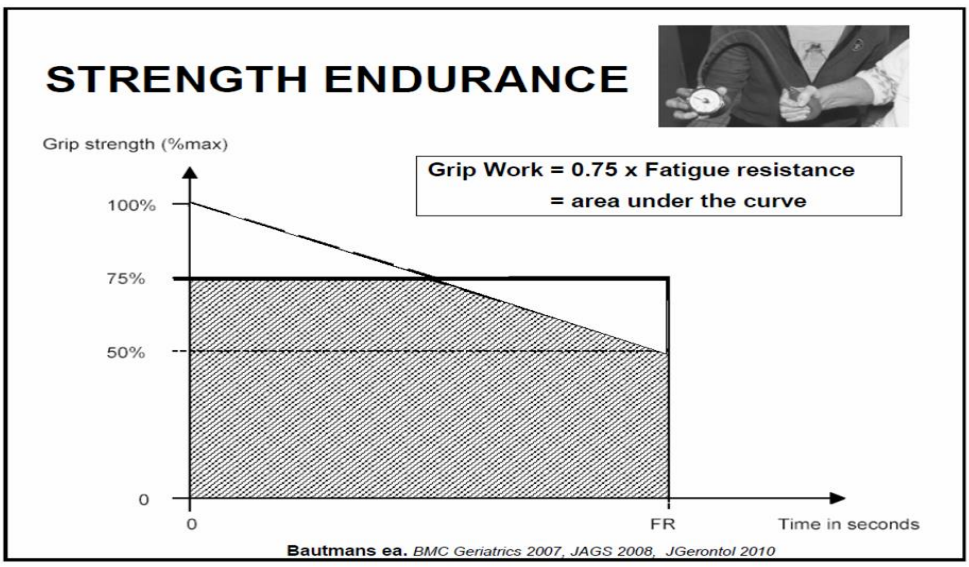


Table 89. Repartition of participants according to categories of mean Endurance index, per frailty group.

Mean Endurance index	NonFrail	PreFrail	Frail	Total
<408	26	31	37	94
408-607	32	39	26	97
>607	37	36	21	94
	95	106	84	285

Figure 77. Repartition of participants according to categories of mean Endurance index, per frailty group.

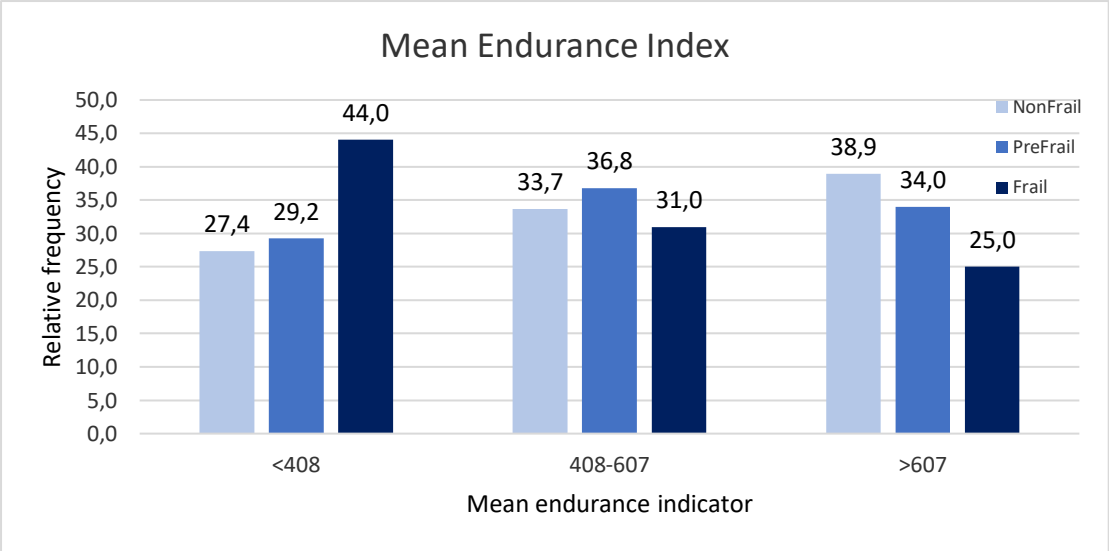
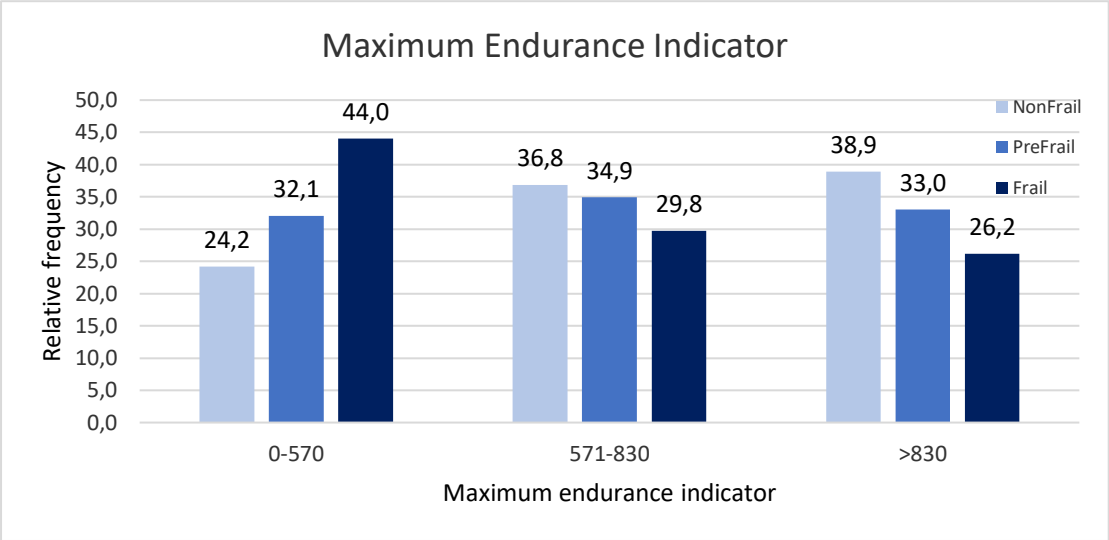


Table 90. Repartition of participants according to categories of maximum Endurance index, per frailty group.

Maximum Endurance index	NonFrail	PreFrail	Frail	Total
0-570	23	34	37	94
571-830	35	37	25	97
>830	37	35	22	94
	95	106	84	285

Figure 78. Repartition of participants according to categories of maximum Endurance index, per frailty group.



Both mean and maximum endurance index seem to correlate well with the frailty status of the participants. Most of the frail participants present low endurance in grip strength monitoring while game playing, whereas, in the higher endurance classes we encounter mainly non-frail individuals. The pre-frail group presents intermediate performances.

3. Feasibility and acceptability issues

One of the challenges and originalities of the FrailSafe project, is the continuous and simultaneous with the running of the study, development and amelioration of its instruments and devices. Core role in this task plays the feedback we receive from the participants and the consideration of feasibility and acceptability issues. Table 91 summarises the various difficulties encountered regarding the use of the available material in their current versions in the initial period of FrailSafe home visits, up until M17, in the three clinical centres. Since then, many of these issues have been resolved after interaction between related WPs and corrective measures.

Table 91. Overlook of FrailSafe sessions of group A and B performed up until 20/5/2017 and the percentage of difficulties encountered in the use of the devices employed.

1rst FS sessions Group A + B *Updated to 20/5/17*		**Patras**	**Nicosia**	**Nancy**	**Total**
Number of sessions performed		75	74	74	**223**
FS devices	Game with dynamometer administered (% of sessions)	37 (49.3%)	33 (44.6%)	35 (47.3%)	**105 (47.1%)**
	Difficulties in games with dynamometer usage (% of devices administered)	14 (37.8%)	32 (97%)	12 (34.3%)	**58 (55.2%)**
	VSM game administered (% of sessions)	60 (80%)	45 (60.8%)	74 (100%)	**179 (80.3%)**
	Difficulties in VSM game usage (% of devices administered)	16 (26.7%)	15 (33.3%)	33 (44.6%)	**64 (35.8%)**
	Smartphone administered (% of sessions)	70 (93.3%)	66 (89.2%)	74 (100%)	**210 (94.2%)**
	Difficulties in smartphone usage (% of devices administered)	1 (1.4%)	19 (28.8%)	18 (24.3%)	**38 (18.1%)**
	Blood pressure monitoring administered (% of sessions)	58 (77.3%)	63 (85.1%)	74 (100%)	**195 (87.4%)**
	Difficulties in blood pressure monitoring usage (% of devices administered)	0 (0%)	1 (1.6%)	5 (6.8%)	**6 (3.1%)**
	WWS administered (% of sessions)	51 (68%)	23 (31.1%)	13 (17.6%)	**87 (39%)**
	Difficulties in WWS usage (% of devices administered)	0 (0%)	23 (100%)	3(23.1%)	**26 (29.9%)**

It seems that the most acceptable device has been the blood pressure monitoring, with only 3.1% of participants reporting a difficulty in its usage.

Difficulties reported with the smartphone device (GPS application), in 18.1% of FrailSafe sessions, mainly concern the forgetfulness of some participants in constantly carrying it with them, especially when leaving the house, in charging and in switching it on again after a battery failure, but also some technical problems that sporadically emerged with the GPS application, that are mostly resolved after appropriate technical intervention.

Difficulties encountered with the strap version of the WWS in about 30% of FrailSafe sessions, mainly concerned some inconveniencies using the strap form of the device (too tightly leading to discomfort or too loosely attached leading to bad signal generation) and some sparse data recording problems. These inconveniencies are expected to be mostly resolved with the new, more adapted, version of WWBS, already available in clinical centres since M18.

More difficulties were present in the application of serious games in our older participants. The playing of the VSM game presented difficulties in 35.8% of FrailSafe sessions, most of which were participant related, but the application's dysfunction has been anecdotal and quickly repairable. On the contrary, most of the acceptability issues consisted of the difficulty of the participants in understanding the instructions of entering and navigating in the game's display, handling and manipulating the tablet as technical device and even strolling through the screen to drag objects. It was not rare the older people, unfamiliar with the mechanistic of touch screen manipulations, found it difficult to engage in game playing. It was mainly these dexterity issues and far less the cognitive requirements of the VSM game playing that put into difficulty our participants. Mainly for individuals of group B, who have many FrailSafe sessions scheduled until the end of the project, we expect that the repetitive use of the tablet as device and the VSM game as virtual environment, will reinforce their learning capacities and limit certain difficulties due to unfamiliarity.

On the other hand, in almost half of FrailSafe sessions (55.2%), there have been problems with the use of the dynamometer in game playing (Red Wings game). Except for those related to individual difficulty due to pathological reasons (wrist arthritis, carpal tunnel syndrome), most of the participants reported blue tooth connectivity difficulties. Some of them were that disappointed that they quitted playing the game. Corrective actions about the connectivity problems have been taken by the game's creator, Brainstorm.

4. Undesirable events

For the purposes of this protocol, an adverse event is defined as any unfavorable and unintended sign, symptom or disease, whatever their nature, intensity, seriousness, and the supposed role (causality) of the experimental procedure. Any adverse event, from the time when a participant entered the study, regardless of when it occurred has been noted by the investigator, as soon as it came to our knowledge. Table 92 presents the characteristics of the 109 undesirable events that occurred since the enrolment of each participants, until M23.

Table 92. Recapitulation of undesirable events.

Updated to 20/11/17		Total
Number of undesirable events		109
Intensity/severity	mild	41
	moderate	40
	severe	28
Relationship to FS device	probably related	1
	possibly related	3
	not related	105
Seriousness	Hospitalisation	37
	Institutionalisation	0
	potential disability	6
	danger to life	2
	death	10
	nothing of the former	54
Anticipated	Yes	15
	No	94
Evolution	cure without afteraffect	58
	cure with afteraffect	22
	subject not recovered yet	12
	unknown	12
	not applicable	5

Most of the undesirable events which occurred during the study have been either of mild or moderate severity and the vast majority of them were not related to the study's devices or procedures. There have been 3 incidences of events possibly related to the FrailSafe material (dizziness, hearing and visual symptoms while playing the tablet serious games), 1 event probably related (wrist pain after

dynamometer-game playing) and 28 serious adverse events, summarized in table 93, among which 10 deaths. None of the latter were associated with the study's procedures.

Table 93. Serious undesirable events.

Participant's ID	Nature of event
1024	Stroke
1080	heart attack, death
1039	coronary artery disease
1037	fall, fracture, death
1025	heart attack, death
1021	Respiratoty arrest, death
1024	Pneumonia, death
1039	upper gastrointestinal hemorrhage
1041	Lung cancer, surgery
1022	Multiple myeloma
1022	Partial prostatectomy
1060	skin cancer on the ear,surgery
1074	Gallbladder removal, surgery
2002	Hip fracture, motor impairement
2003	Stroke, motor/cognitive/visual impairment
2011	Death
2015	Death
2021	Hip fracture, mobility problems
2115	Death
3111	death from lung cancer
3110	coronary heart disease, 3 stents
3101	pancreatic cancer
3117	Fracture
3038	Surgery to remove breast lession
3068	Prostatectomy
3026	Fracture of the humerus
3054	Pulmonary embolism
3078	Death
	Updated to 20/11/17

5. Drop-offs

There have been 57 people who dropped-off from the study, since their inclusion up until M23 (Table 94), most of whom have already been replaced (96.5%). There have been 13 withdrawals from Patras, 22 from Nicosia and 22 from Nancy.

Most of the people who dropped off belonged either to the prefrail (23) or to the frail (19) category, while women were more than two folds more. Group A participants, while twice as numerous as those of group B, present an almost three-fold rate of withdrawal.

The main reason of drop offs was the consent withdrawal (59.6%), followed by death incidence (17.5%) and some emerging condition inhibiting the participation in the study or fulfilling exclusion criteria (15.8%). Finally, 4 (7%) participants were unreachable in contact efforts and lost in follow up.

Table 94. Drop-offs, characteristics and reasoning.

Updated to 20/11/17	**Patras**	**Nicosia**	**Nancy**	**total**
Number of drop-offs	13	22	22	57
Frailty distribution between drop-offs	4 nonfrail 4 prefrail 5 frail	2 nonfrail 11 prefrail 9 frail	8 nonfrail 8 prefrail 5 frail 1 unknown	14 nonfrail 23 prefrail 19 frail 1 unknown
sex distribution between drop-offs	4M + 9F	7M + 15F	5M + 17F	16M+ 41F
group distribution between drop-offs	10 A/ 3 B	19 A/ 3 B	15 A/ 7 B	44A/ 13B
Number of drop-offs replaced	13 (0%)	22 (100%)	20 (90.1%)	55 (96.5%)
Reason for drop-offs				
Death	5	3	2	10 (17.5%)
Consent withdrawal	4	15	15	34 (59.6%)
Emerging condition inhibiting the participation in the study or fulfilling exclusion criteria	1	4	4	9 (15.8%)
Participant unreachable/ Lost in follow up	3	0	1	4 (7.0%)

6. Actions and applications to come

A series of actions and applications aiming at multiplying possible frailty metrics and enhancing and ameliorating behavioural monitoring of our study cohort, either have already started being applied, or are about to be released in the following months.

6.1 Follow up by regular phone calls

The method of following up the participants about major health events (hard outcomes), by phone calls, in the period of intervals between clinical evaluations has been employed in a three month's basis.

Table 95 provides data about the number of phone calls made up until M23. Different number of follow up phone calls between clinical centers are justified by the fact that they started recruiting participants at different times.

Since the phone follow up questionnaire has been only recently added in the eCRF platform, data have been so far kept in a separate database and are being currently fed in the eCRF progressively. For this reason, descriptive results are currently not available yet.

Table 95. Data about phone follow up in a three-month's basis.

Updated to 20/11/17	**Patras**	**Nicosia**	**Nancy**	**Total**
1rst Follow up phonecall	133	124	128	**385**
2nd Follow up phonecall	125	79	89	**293**
3rd Follow up phonecall	116	79	46	**241**
4th Follow up phonecall	93	79	3	**175**
5th Follow up phonecall	25	-	-	**25**
Total	**492**	**361**	**266**	**1119**

6.2 New virtual reality games for the tablet

In the forthcoming period, a series of virtual and augmented reality games will be added to the FrailSafe evaluation tools. These serious games and exergames aim at evaluating, monitoring and, to some extent, even training older people in terms of cognitive or combined cognitive-motor function. Differences in the output metrics in these games' playing over time will reveal useful information about the individual's performance amelioration or deterioration, thus providing evidence for building up a frailty status profile. The games that are being currently prepared are:

- the ***RAIL ROAD*** game

The Game consists of driving a mining truck through a series of rail roads, avoiding obstacles by tilting the body while sitting. It aims at a combined motor and cognitive activity. Mainly requires a motor reaction, but simultaneously tests cognitive abilities, like anticipation and visuospatial orientation.

- the ***SIMON*** game

The game displays a color and sound sequence, increasing in difficulty, so the player must reproduce it. Mainly tests cognitive abilities like working memory.

- The ***MEMORY*** game

This game will help older people training the technique to remember faces, names and objects. The player needs to select two covered images and examine them, trying to find an unusual feature, e.g. eyes, gender or animal type, and then create an association between their characteristic in their minds, so that they can pair the full set of images. Tests cognitive abilities like working memory.

- the ***REFLEX*** game, developed by Brainstorm.

This game will test the elderly´s reflexes. The player has to click the mouse or tap the screen over the lighted items as quick as possible. The player needs to start clicking on the springing elements as fast as possible. This games tests cognitive abilities like anticipation and decision making, requiring at the same time a certain degree of dexterity.

- The ***GRAVITY BALL*** game, developed by CERTH.

A marker-based Augmented Reality game, targeted for mobile devices. The goal is to guide a virtual sphere (highlighted in pink) into the level's hole, the finish point, as

fast and steady as possible by moving the tangible handheld marker (virtual textured terrain) accordingly. This game tests visuospatial perception and brain-hand coordination, requiring at the same time a certain degree of dexterity.

- The ***FLOATING TARGET ARROW*** game, developed by CERTH.

An Augmented Realitygame targeted only for AR glasses. The goal is to track as fast as possible a virtual Target Arrow object, rendered through the optical see-through device, which floats(randomly) around him using a colored tag. This game tests visuospatial perception, brain-hand coordination and reflexes, requiring at the same time a certain degree of dexterity.

6.3 Beacons

Finally, another device that will contribute to behavioural monitoring are the beacons, for the monitoring of indoors' movement and activity. Beacons are installed in each room of the participant's house during the FrailSafe session and will provide an indication of time repartition during the day between activities that are mostly attributed to certain rooms of the house. These indications will be correlated with parameters from the social, physical and psychological domain of the clinical evaluation.

References

[1] EU project VERITAS, "Virtual and Augmented Environments and Realistic User Interactions To achieve Embedded Accessibility DesignS", http://veritas-project.eu/

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7. Annexes

Annex 1

Percentage of the participants of each group presenting each comorbidity (according medical records, self-reporting and corresponding medication).

Reported comorbidities	**Frails**	**PreFrails**	**NonFrails**
Arterial hypertension	64,0	51,3	55,0
Arthralgias	40,0	40,5	41,7
Dyslipidemia	27,0	32,3	42,5
Anxiety	30,0	27,8	26,7
Eye disease	29,0	26,6	26,7
Urinary incontinence	33,0	20,9	26,7
Other comorbidity	18,0	22,8	23,3
Diabetes	23,0	19,6	10,0
Thyroid disease	17,0	15,8	19,2
Osteoporosis	15,0	19,0	14,2
Constipation	23,0	12,7	11,7
Hearing problem	23,0	13,9	8,3
Dyspepsy	16,0	17,1	11,7
Arrythmia	18,0	19,0	5,0
Vertigo	20,0	13,3	4,2
Depression	16,0	10,8	7,5
Prostatic pathology	7,0	12,7	13,3
Cancer	11,0	8,2	12,5
Respiratory disease	15,0	8,9	7,5
Stroke	13,0	11,4	5,8
Anemia	17,0	4,4	5,0
Heart insufficiency	16,0	8,2	0,8
Ischemic heart disease	9,0	9,5	5,0
Lower_limp trauma or operation with residual symptomatology	4,0	7,0	4,2
Cognitive impairment	8,0	0,0	1,7
Parkinson’s disease	8,0	0,6	0,8
Renal insuficiency	3,0	1,9	3,3
Epilepsy	0,0	0,6	0,0

Annex 2

Percentage of the participants of each group for whom each comorbidity is considered significantly affecting their functional status, according to the investigator's clinical judgment.

Significant comorbidities for the person's functional status according to the clinical investigator's evaluation	**Frails**	**PreFrails**	**NonFrails**
Arthralgias	8,0	10,1	4,2
Arterial hypertension	7,0	2,5	3,3
Other	4,0	5,1	2,5
Anxiety	3,0	0,0	5,8
Depression	6,0	0,0	1,7
Osteoporosis	3,0	1,9	0,0
Lower_limp trauma or operation with residual symptomatology	1,0	1,3	2,5
Vertigo	1,0	2,5	0,0
Eye disease	2,0	1,3	0,0
Constipation	1,0	1,3	0,8
Heart insufficiency	3,0	0,0	0,0
Respiratory disease	3,0	0,0	0,0
Dyspepsy	1,0	1,3	0,0
Stroke	2,0	0,0	0,0
Cognitive impairement	2,0	0,0	0,0
Parkinson's disease	2,0	0,0	0,0
Arrythmia	0,0	1,9	0,0
Urinary incontinence	0,0	1,9	0,0
Hearing problem	0,0	1,9	0,0
Cancer	1,0	0,0	0,8
Thyroid disease	0,0	0,0	0,8
Dyslipidemia	0,0	0,0	0,0
Diabetes	0,0	0,0	0,0
Ischemic heart disease	0,0	0,0	0,0
Renal disease	0,0	0,0	0,0
Epilepsy	0,0	0,0	0,0
Prostate pathology	0,0	0,0	0,0
Anemia	0,0	0,0	0,0