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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

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. Along with the presentation of each variable's measurements, some elements about feasibility and acceptability issues will also be mentioned.

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.

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Abstract (for dissemination)	This deliverable 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 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 Positioning 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
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, M12) have not yet occurred in a sufficient incidence to draw conclusions, the several metrics are still being seen from a descriptive point of view. Analytical statistical and the effort to relate these measurements to frailty evolution and significant outcomes, will soon follow, as data from the second clinical evaluation of the main group (group B) and the phone follow up of all participants so far recruited have started to be fed in the electronic databases recently (M17).

This report aims to give a first view of the data that has been collected through the eCRF platform, on 19/06/2017. 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, most of them have already 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 entered into the eCRF database up until 19/06/2017.

Total_records	Total_Frail	Total_PreFrail	Total_NonFrail
378	100	158	120

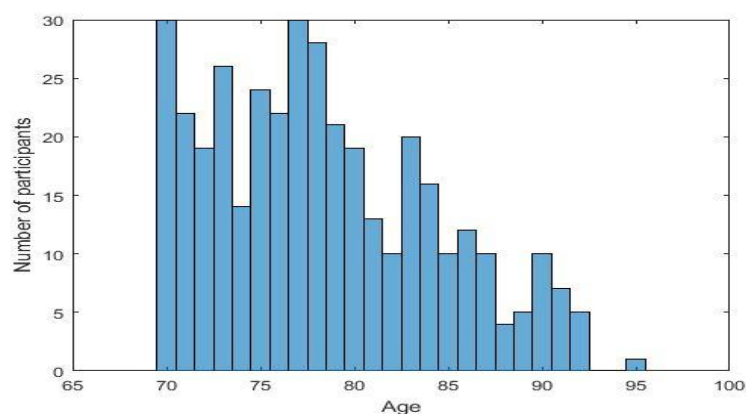
Table 2. Sex repartition of the participants entered into the eCRF database up until 19/06/2017.

Total_records	Total_Male	Total_Female
378	142	236

Table 3. Age range repartition of the participants entered into the eCRF database up until 19/06/2017, 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 only descriptive data. Comparative analysis between sub groups has not been performed yet.

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. eCFR data description

The present report will follow 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

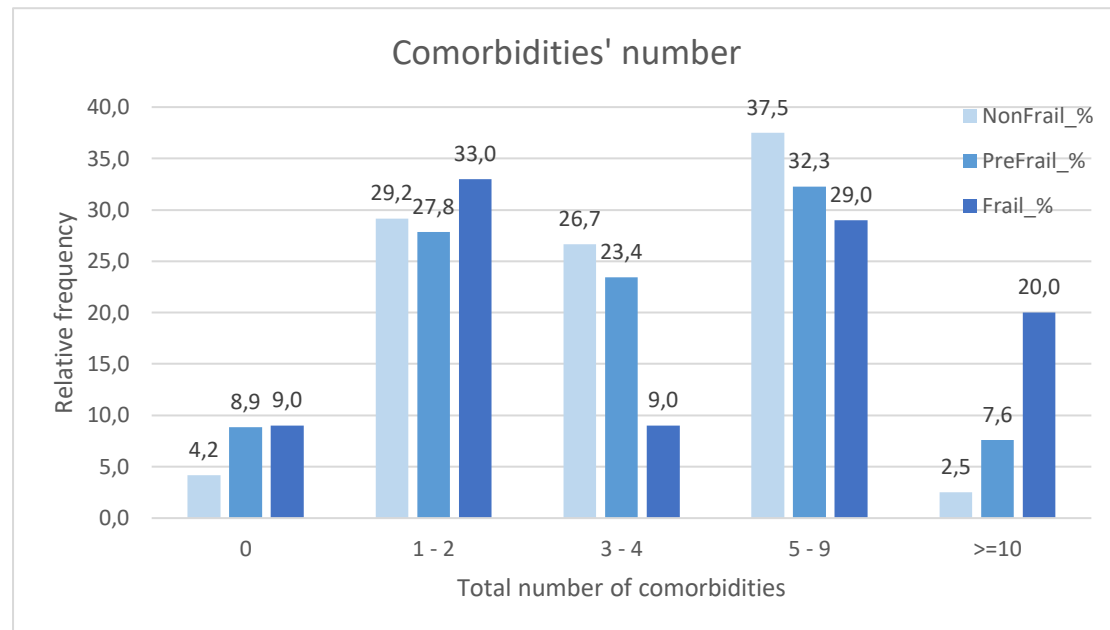
	Minimum	Maximum	Mean
Number of comorbidities	0	17	4,5
Number of significant comorbidities	0	5	0,3
Number of medication taken	0	17	3,9
Hospitalisation in the last year	0	15	0,4
Hospitalisation in the last three years	0	30	0,7

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.

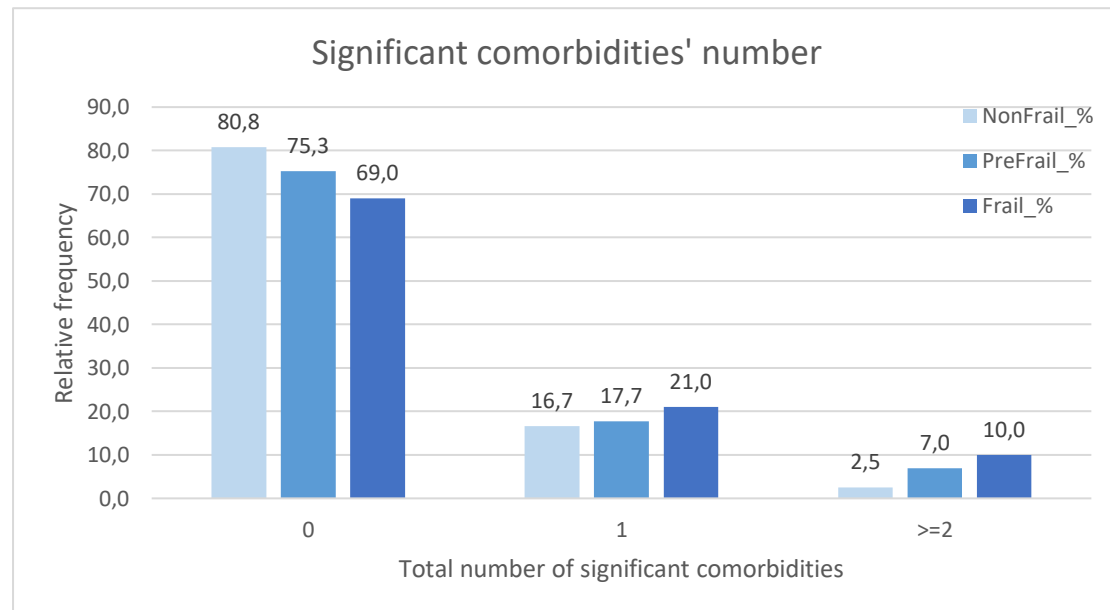


We observe that the repartition of multimorbidity in all categories below 10 comorbidities is quite random regarding the frailty level of the participants. However, frail individuals predominate in the group of 10 or more comorbidities (20%), in which the percentage of non-frail subjects is very limited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

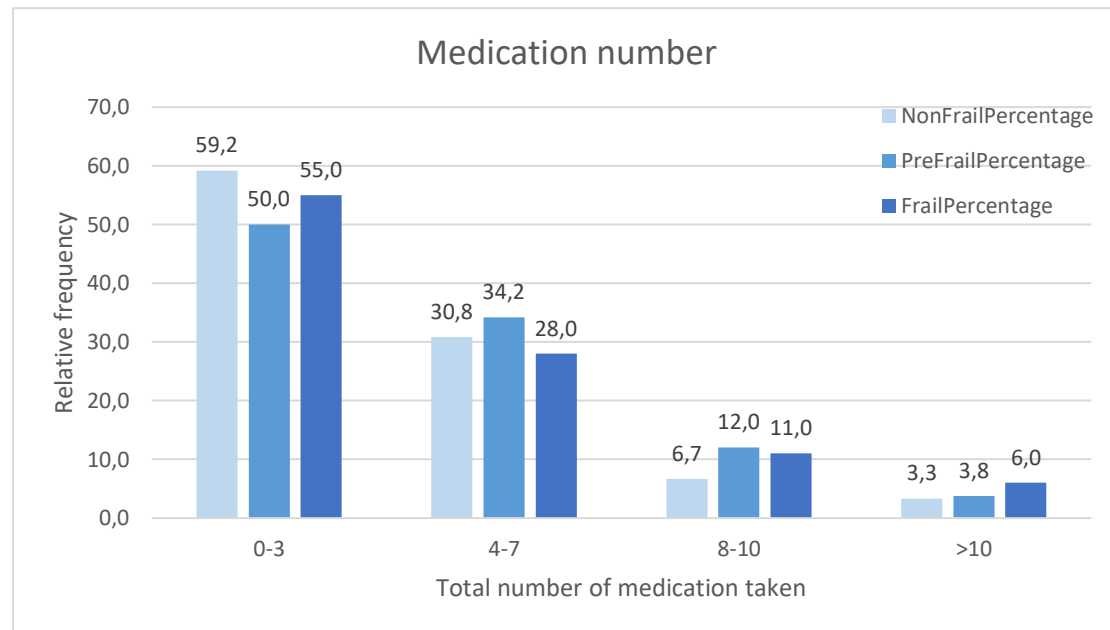


The majority of participants do not present a comorbidity that significantly effects their functional level, according to the clinician's evaluation, even though in the category of no significant comorbidity, those that outnumber are the non-frail (80.8% vs 69% for frails). As significant comorbidities 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 7. Repartition of participants in each category of number of medication taken per day, according to frailty group.

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 4. Repartition of percentages in each category of number of medication taken per day, according to frailty group.



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.

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 limb 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.

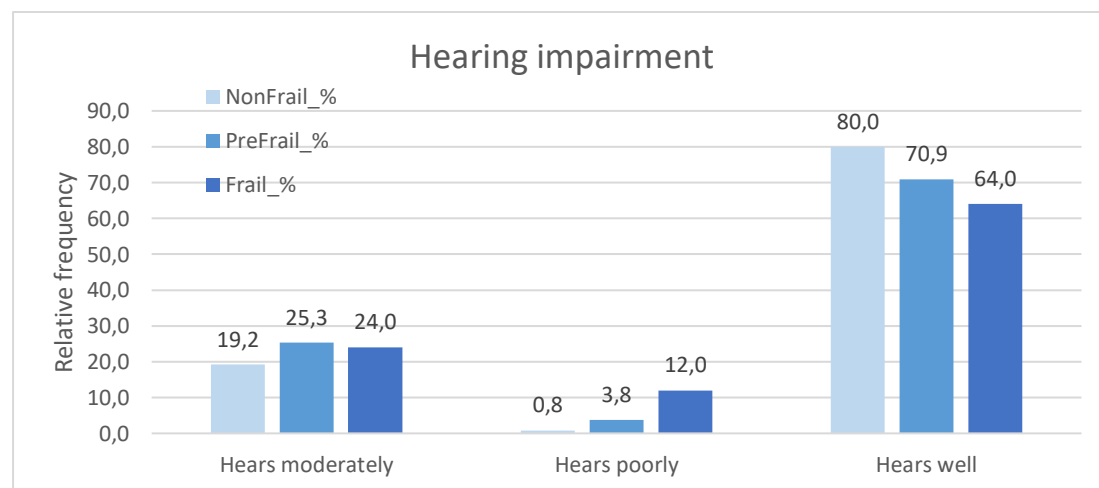
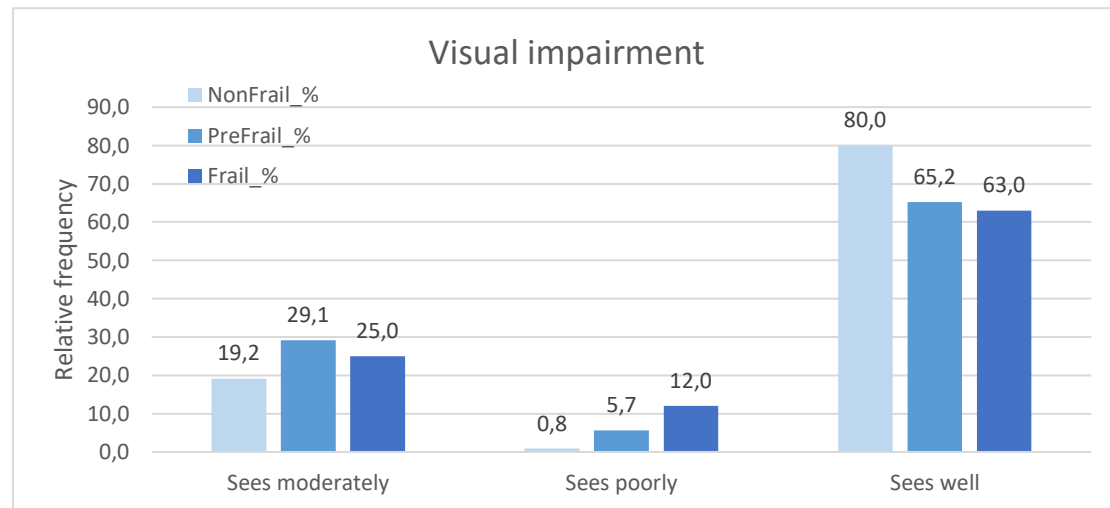


Table 9. Repartition of participants in each category of visual impairment, according to frailty group.

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 10. Repartition of participants in each category of number of hospitalizations in last year, according to frailty group.

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 7. Repartition of percentages in each category of number of hospitalizations in last year, according to frailty group.

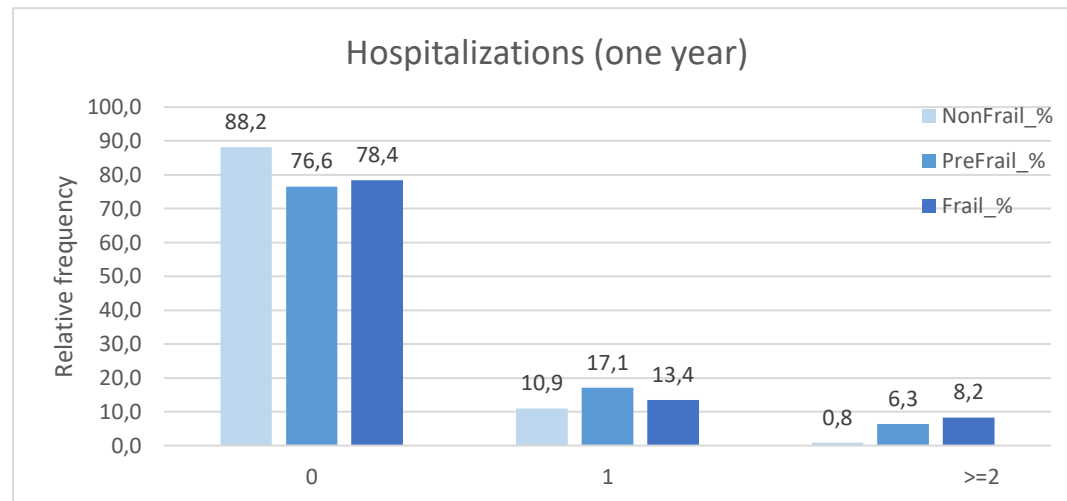
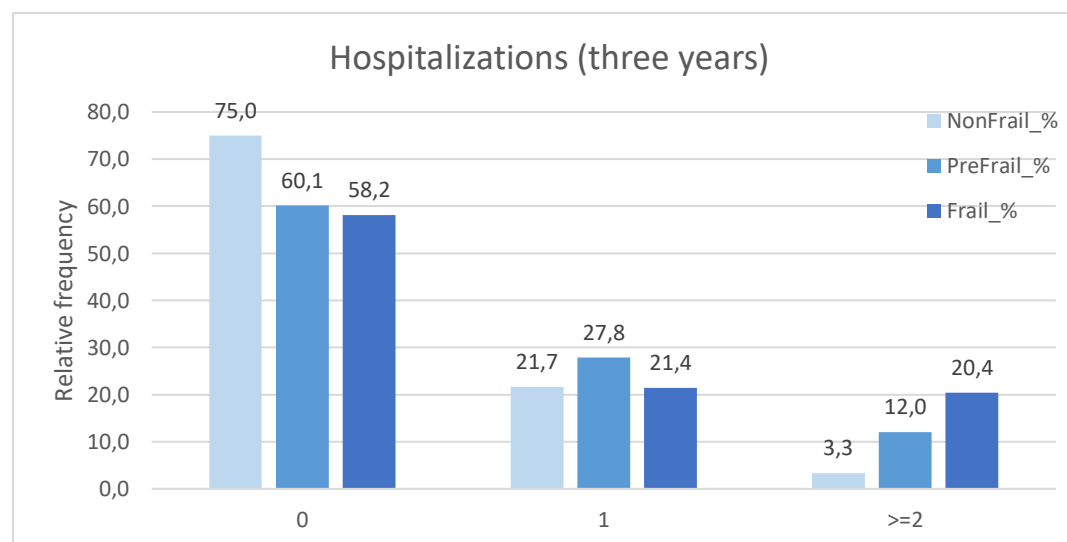


Table 11. Repartition of participants in each category of number of hospitalizations in last 3 years, according to frailty group.

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 8. Repartition of percentages in each category of number of hospitalizations in last 3 years, according to frailty group.



Regarding hospitalizations both in one and three years' time, the group of non-frails is more prevalent in the no hospitalization category, while that of frails, predominate in the category of 2 or more hospitalizations in one but mostly in three years' time.

2.1.2 Instrumental measurements'-derived data

Data presented in this sub-session are derived from instrumental measurements during the 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

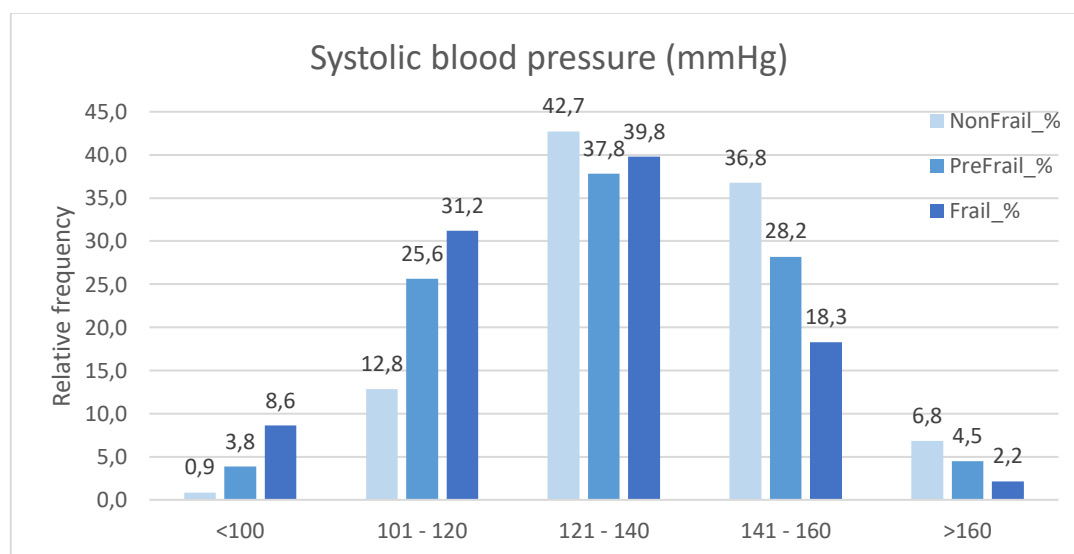
Instrumental measurements	Minimum	Maximum	Mean
Systolic blood pressure	80	180	133,1
Diastolic blood pressure	52	150	79,8
Heart frequency	46	102	71,9
Pulse Wave Velocity	9,5	15,8	12,0

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.

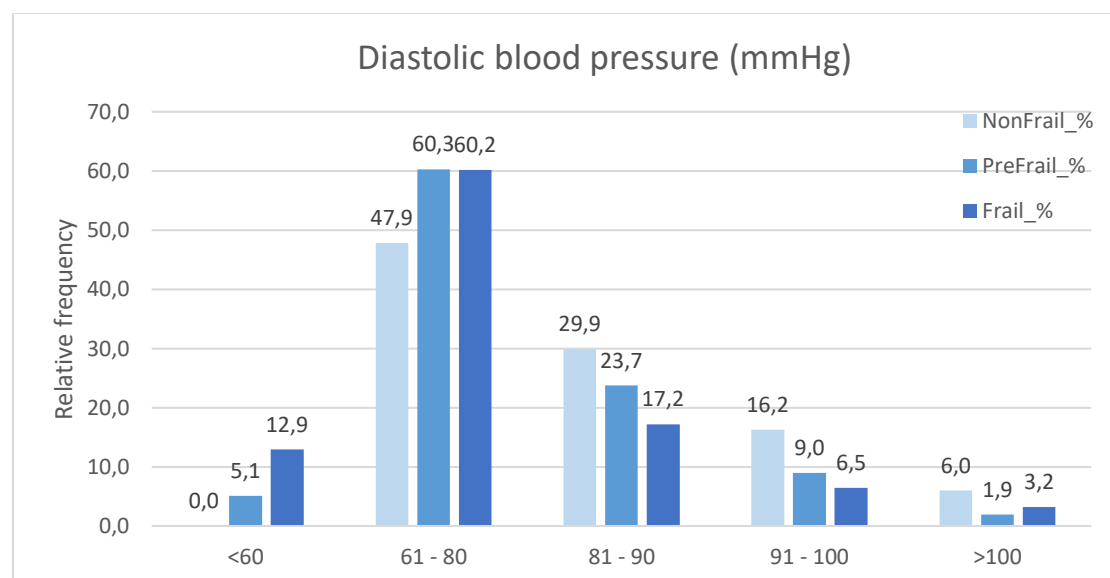


An interesting observation is that the ranks of low systolic blood pressure are mainly dominated by frail participants, while higher systolic blood pressure ranges are mostly observed in non-frail individuals. This could imply either an arterial hypertension overtreatment effect, less well compensated 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.

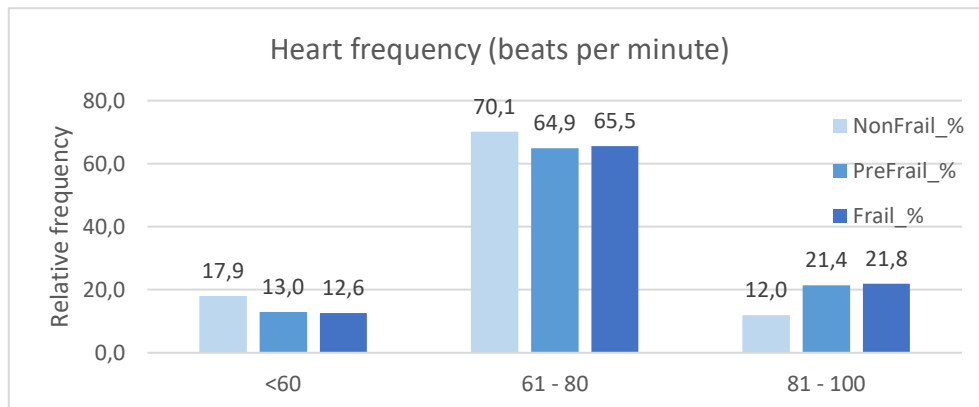


Similarly to systolic, low diastolic blood pressure levels are most prevalent among frail individuals.

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.

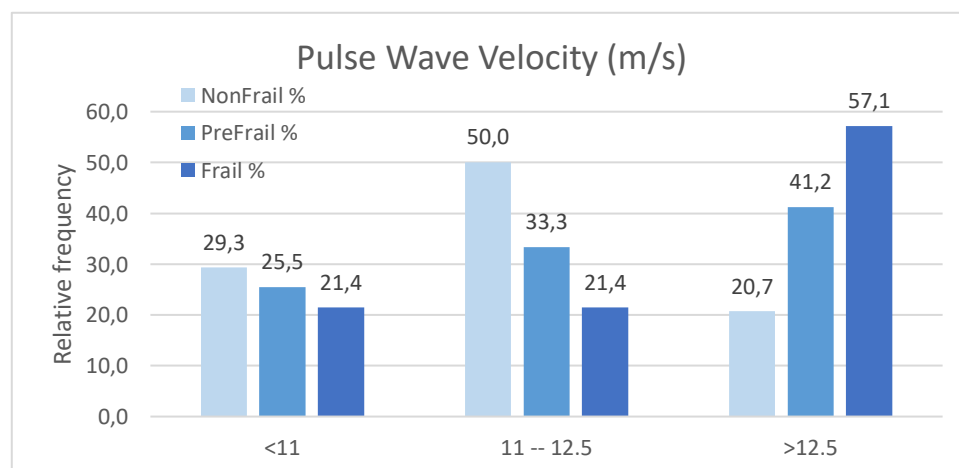


In the case of heart frequency ranges, frail and pre-frail individuals seem to present similar values, with the majority of them in the mean category of 61-80 beats per minute (bpm). Non-frails slightly outweigh others in the lower ranges of <80 bpm and also in the <60 bpm category.

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.

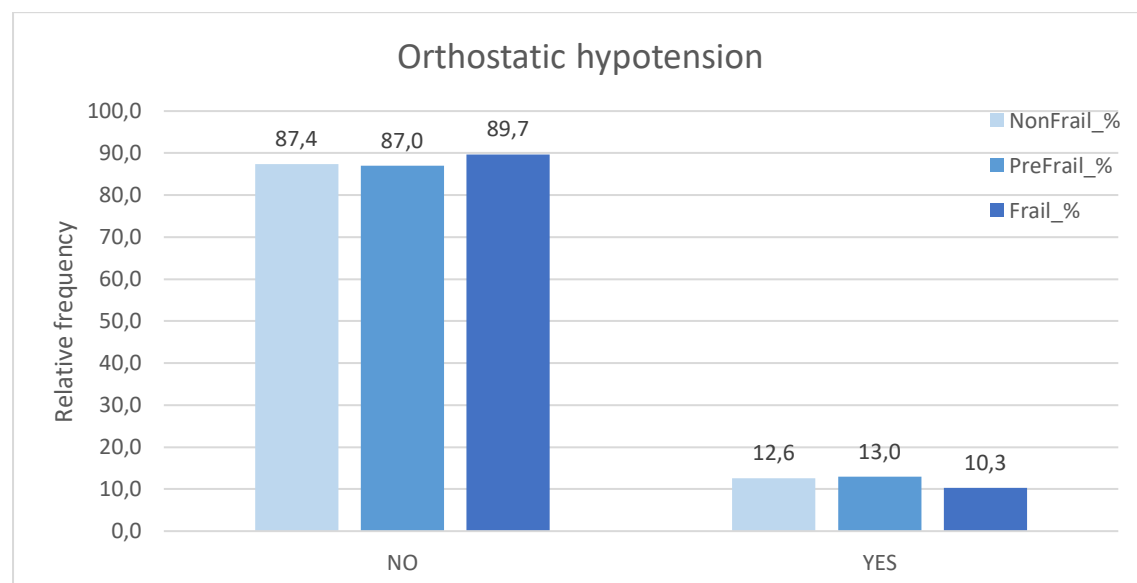


Pulse Wave Velocity (PWV) expresses arterial stiffness, a classical index of vascular aging. In the lower categories of PWV, expressing less arterial stiffness and therefore arterial condition resembling more to younger individuals, the dominant group are the non-frails (29.3% for PWV<11m/s and 50% for 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.

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.

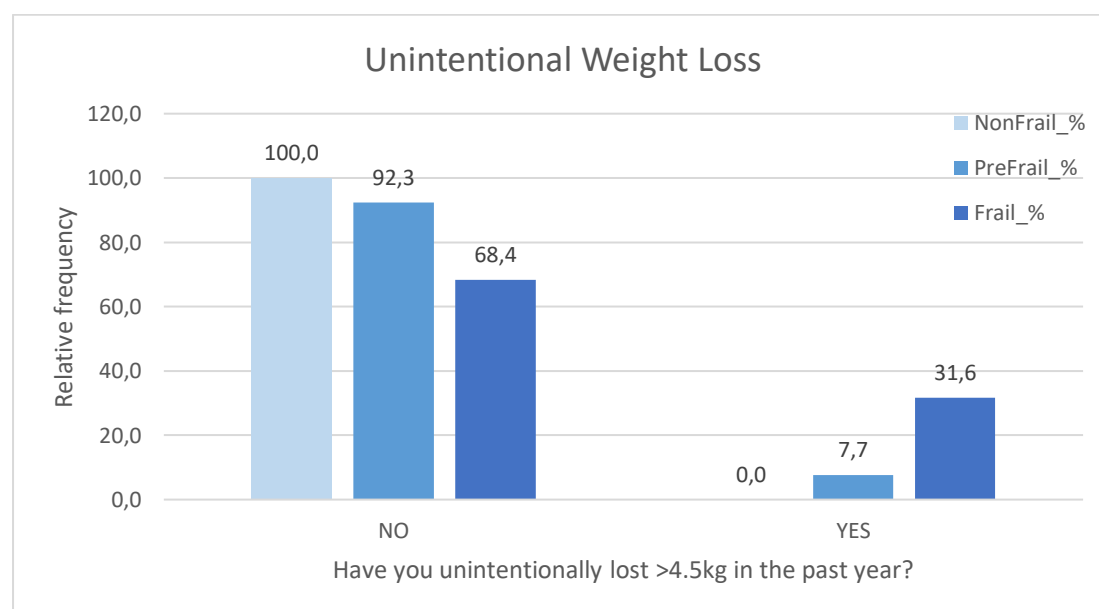
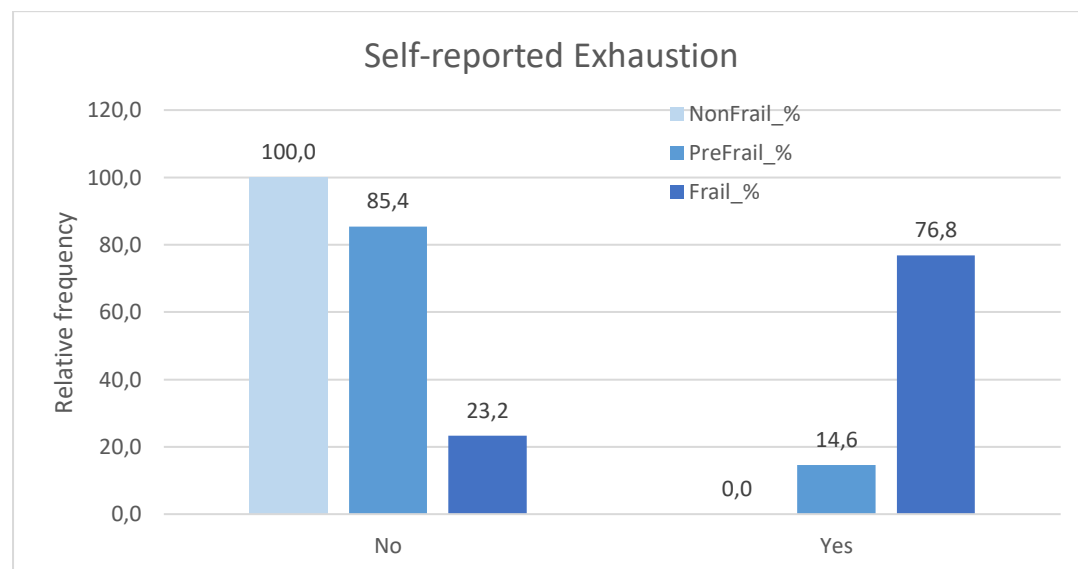


Table 19. Repartition of participants according to the self-reported exhaustion, per frailty group.

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 20. Basic descriptive statistics about alcohol consumption

	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 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.

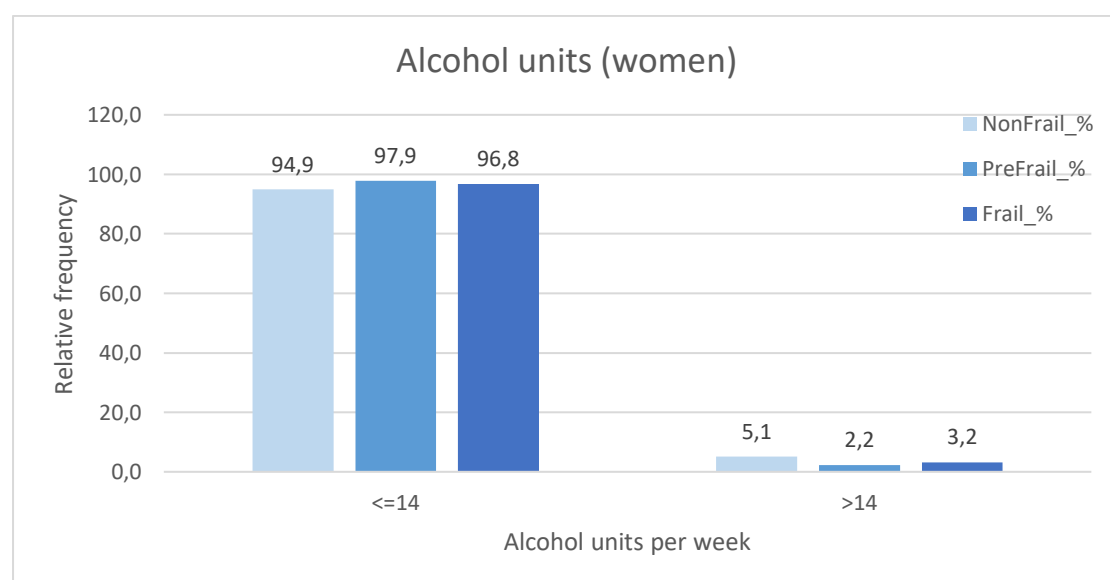
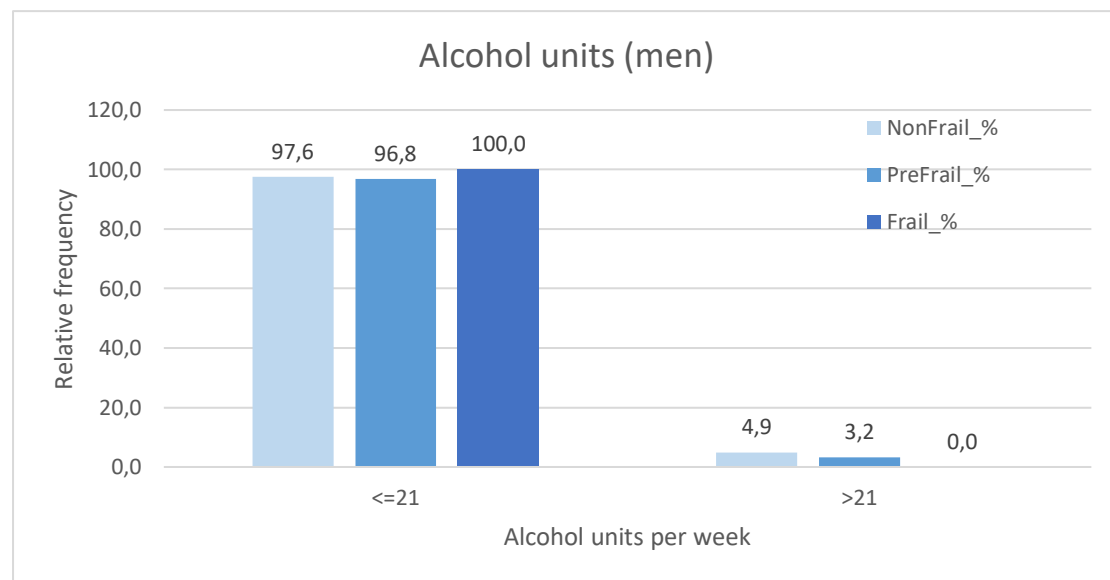


Table 22. Repartition of participants according to the alcohol consumption by men, per frailty group.

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 23. Repartition of participants according to the smoking status, per frailty group.

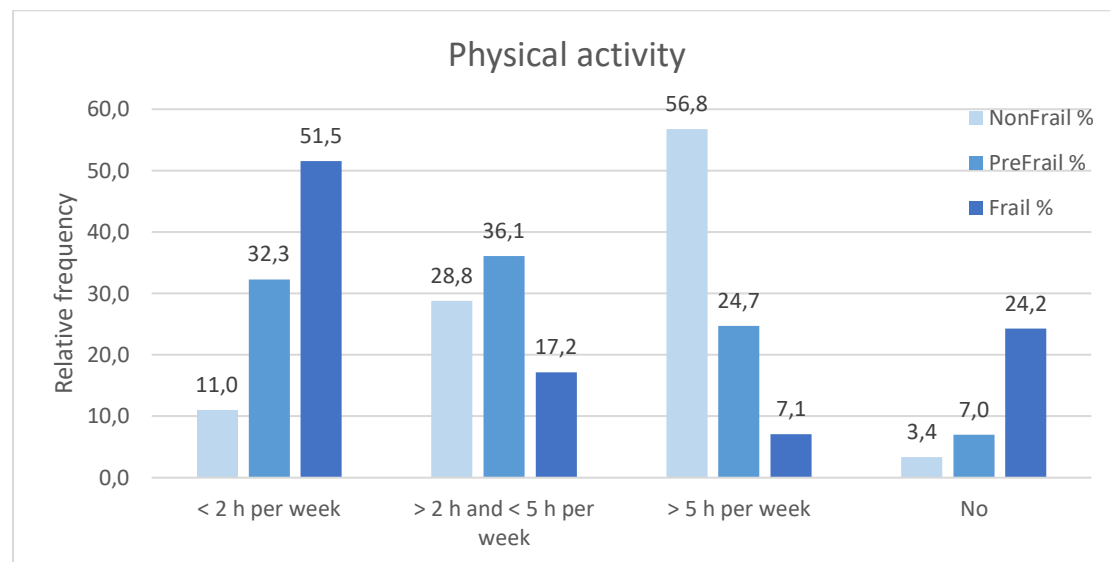
Smoking status	NonFrail	PreFrail	Frail	Total N
Current smoker	7	11	8	26
Never smoked	71	98	59	228
Past smoker (stopped at least 6 months)	40	49	33	122
	118	158	100	376

Figure 18. Prevalence of each category of smoking status, per frailty group.

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.

Table 24. Repartition of participants according to categories of physical activity, per frailty group.

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 19. Prevalence of each category of physical activity, per frailty group.

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%) report a physical activity for more than 5 hours per week, even of mild intensity, 28.8% an activity between 2 and 5 hours, 11% an activity of less than 2 hours per week and only 3.4% no physical activity at all. For frail individuals, on the contrary, no physical activity is reported by 24.2% of them. 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

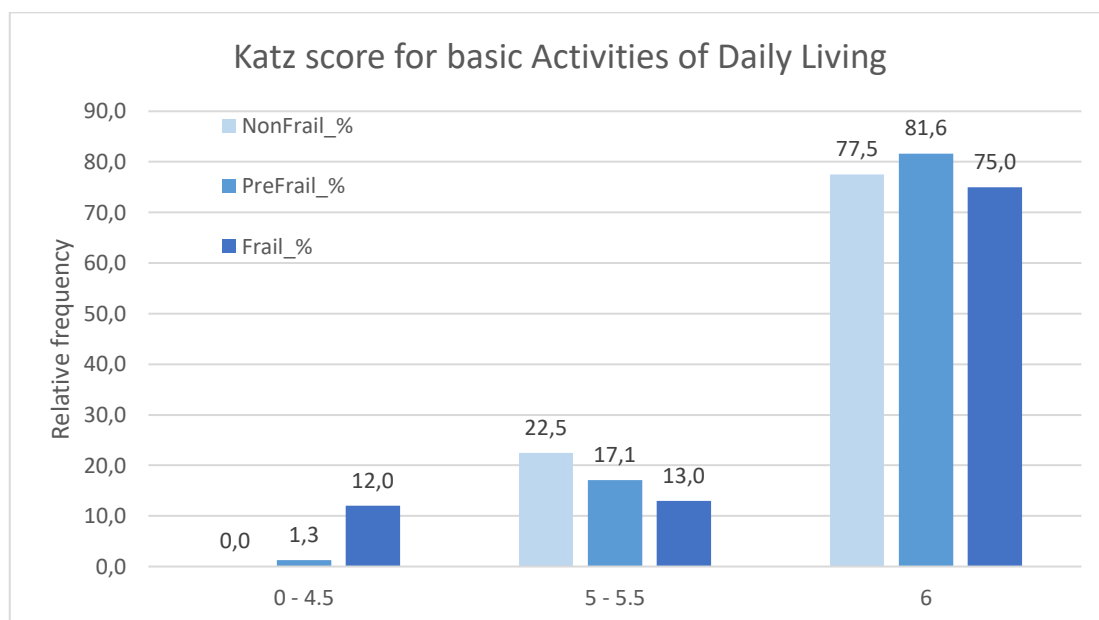
Data presented in this sub-session are derived from questionnaires performed during the clinical evaluation visit.

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, we avoided an additive total score and we 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%).

The tables that follow show similar results for all 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 26. 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.

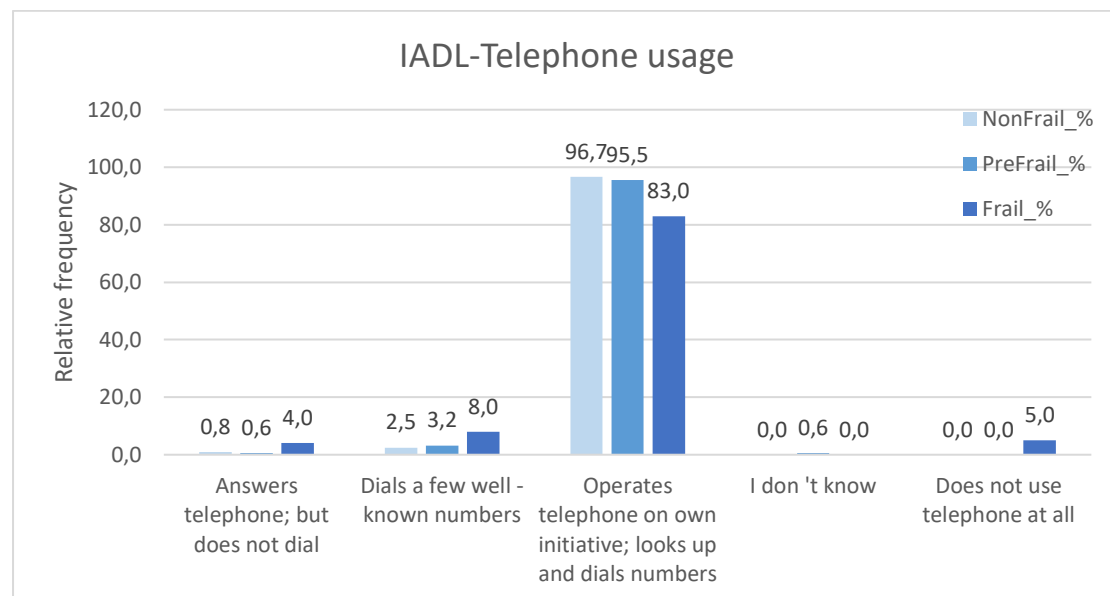


Table 27. Repartition of participants according to performance in the shopping item of IADL, per frailty group.

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

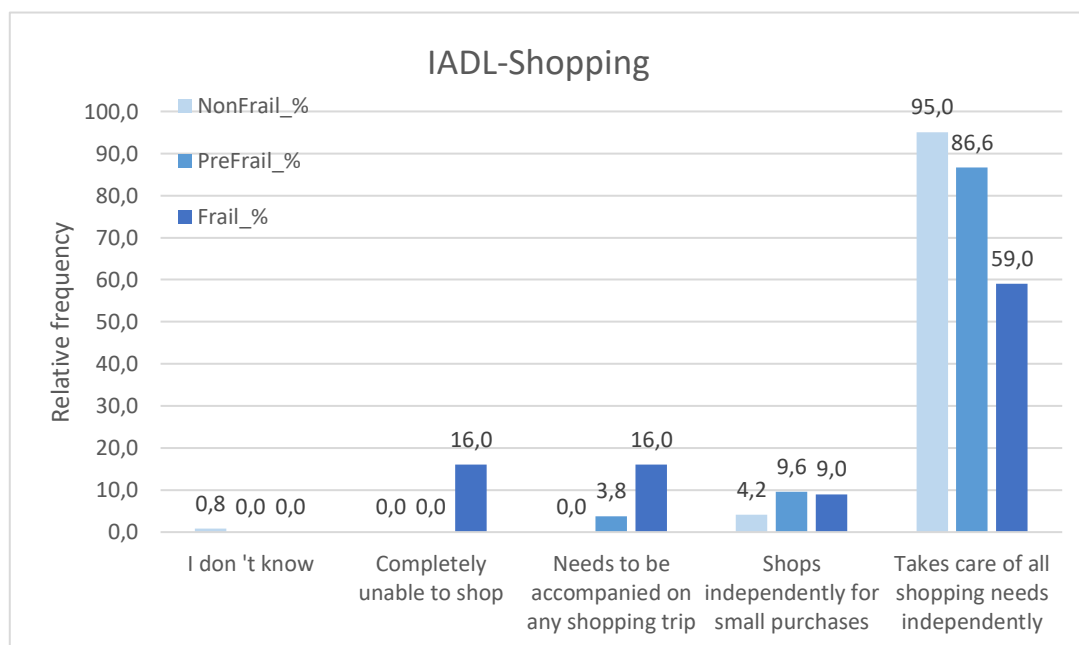
Figure 22. Prevalence of each category of performance in the shopping item of IADL, per frailty group.

Table 28. 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.

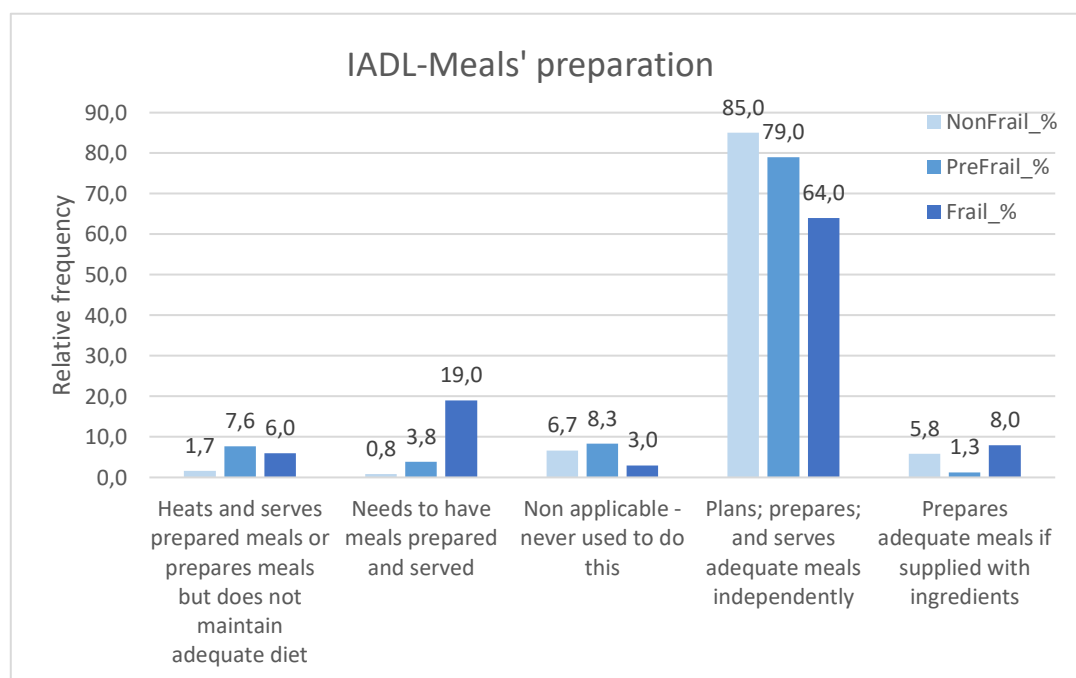


Table 29. Repartition of participants according to performance in the housekeeping item of IADL, per frailty group.

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

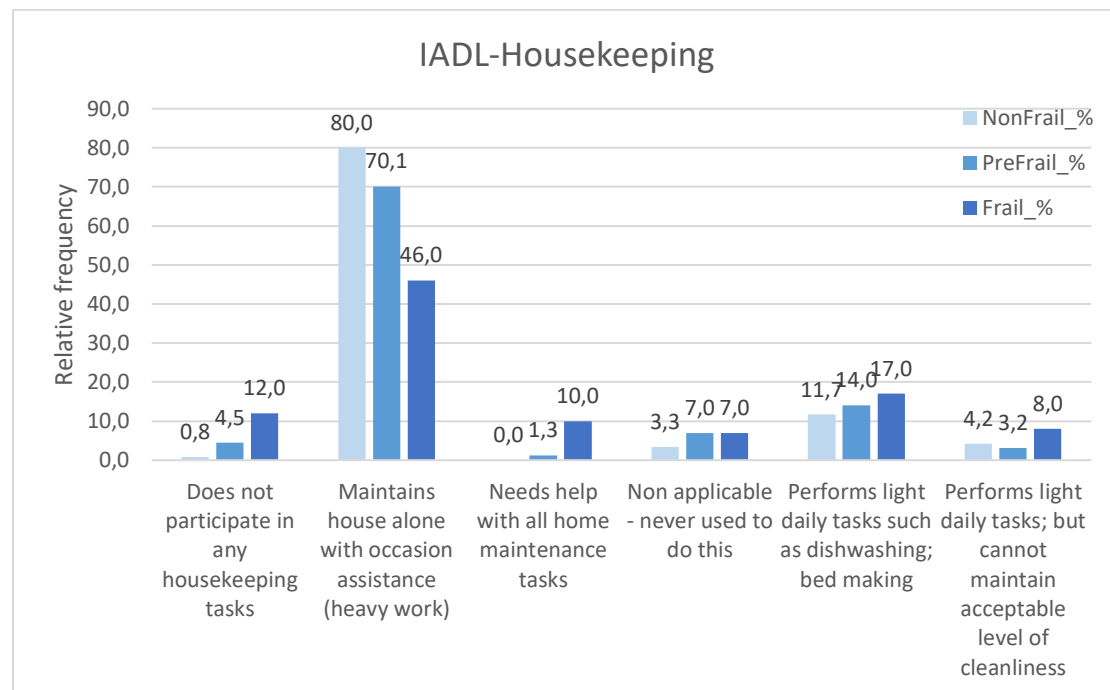
Figure 24. Prevalence of each category of performance in the housekeeping item of IADL, per frailty group.

Table 30. 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.

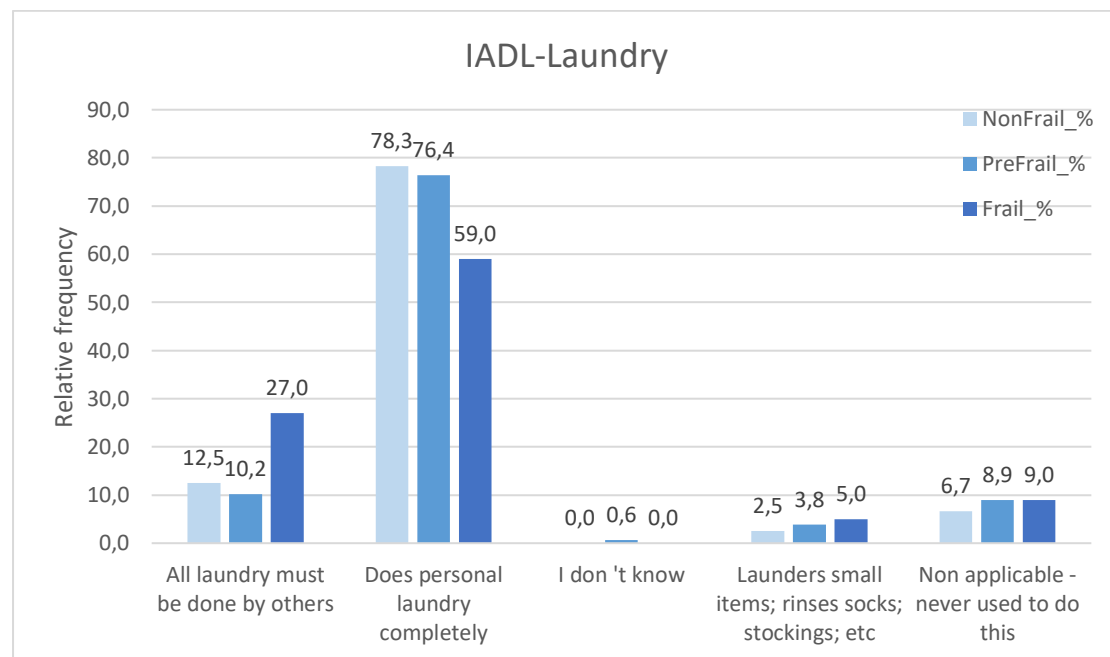


Table 31. Repartition of participants according to performance in the mode of transportation item of IADL, per frailty group.

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

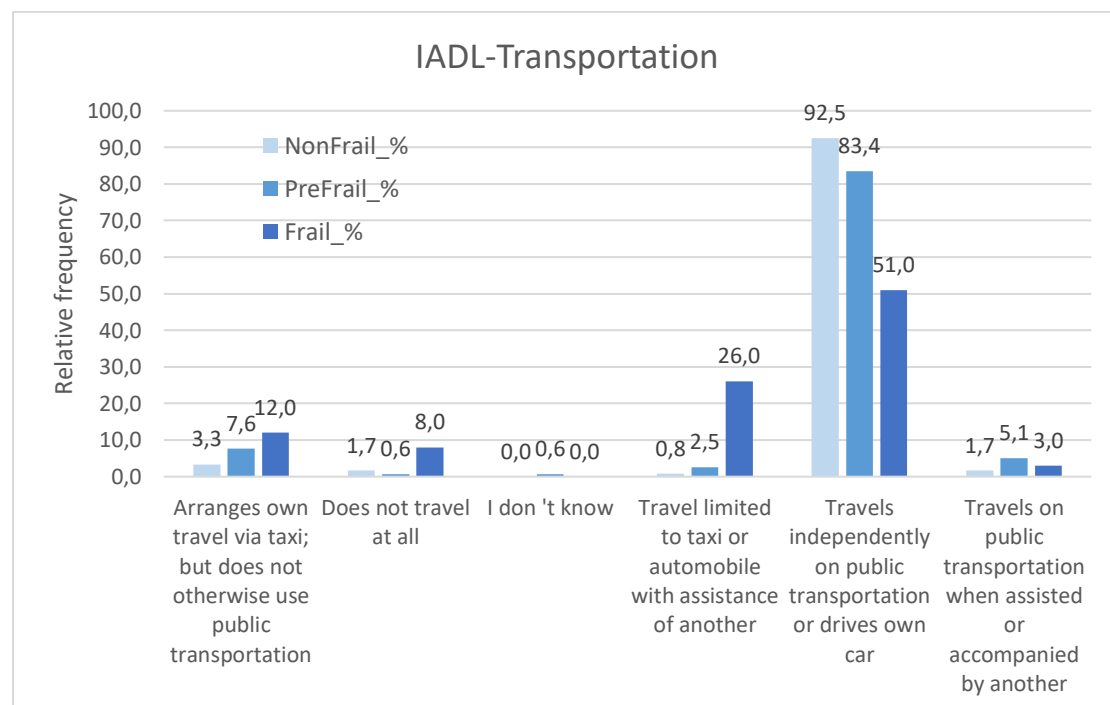
Figure 26. Prevalence of each category of performance in the mode of transportation item of IADL, per frailty group.

Table 32. 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.

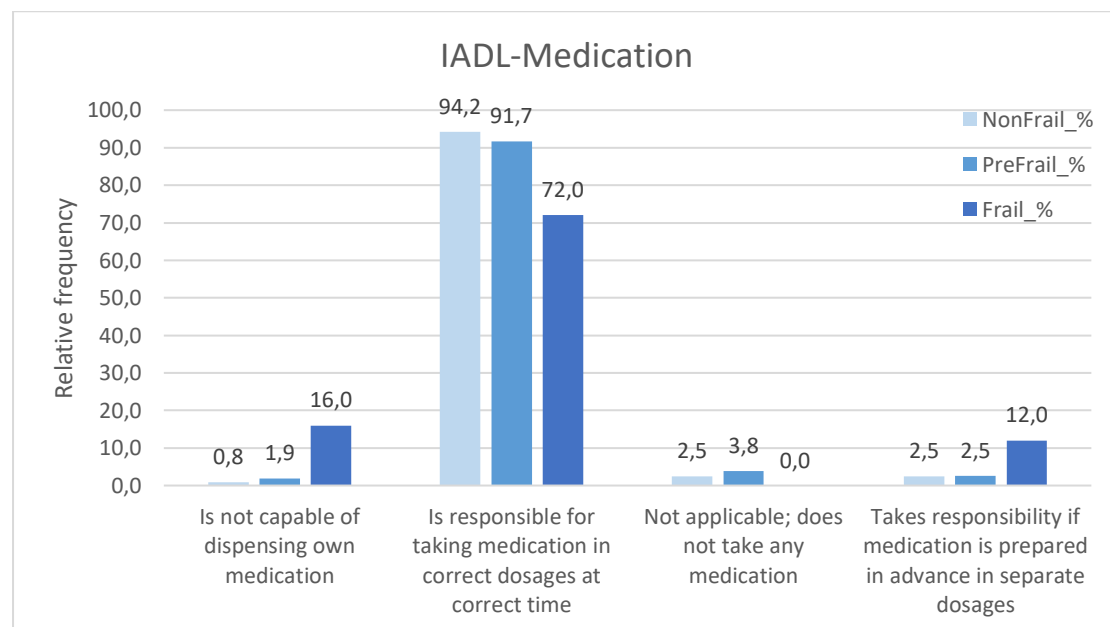
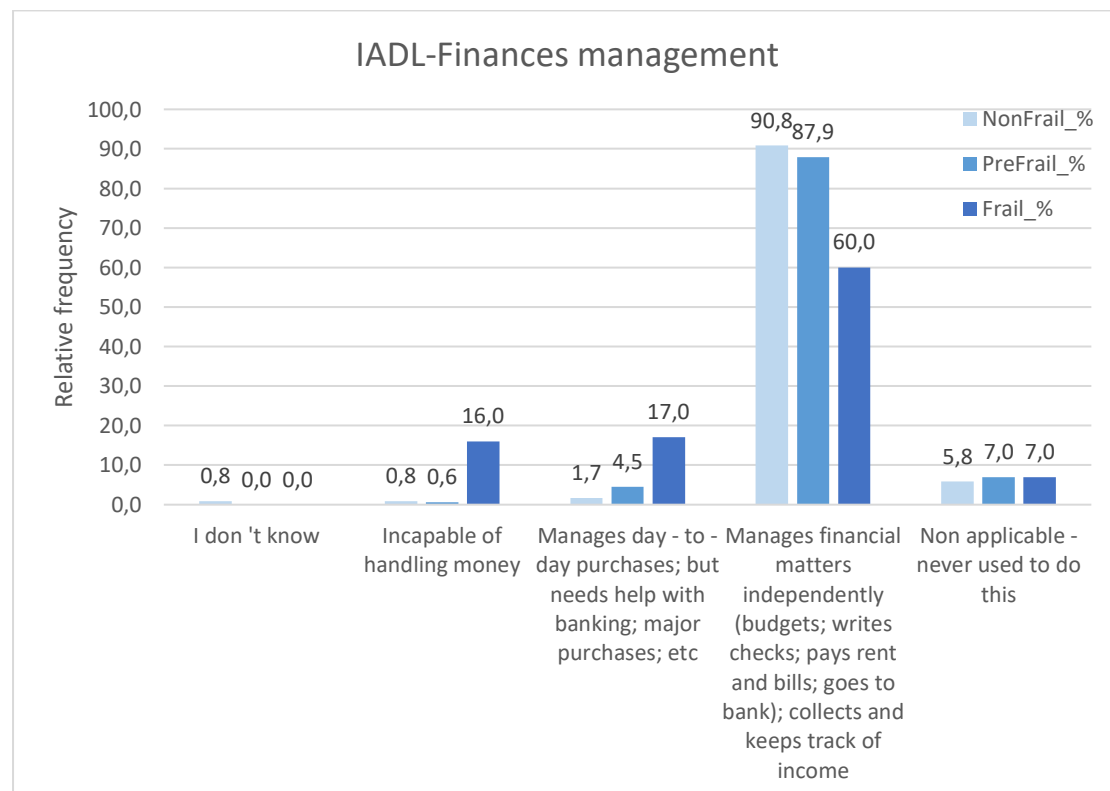


Table 33. Repartition of participants according to performance in the finances' management item of IADL, per frailty group.

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 34 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.

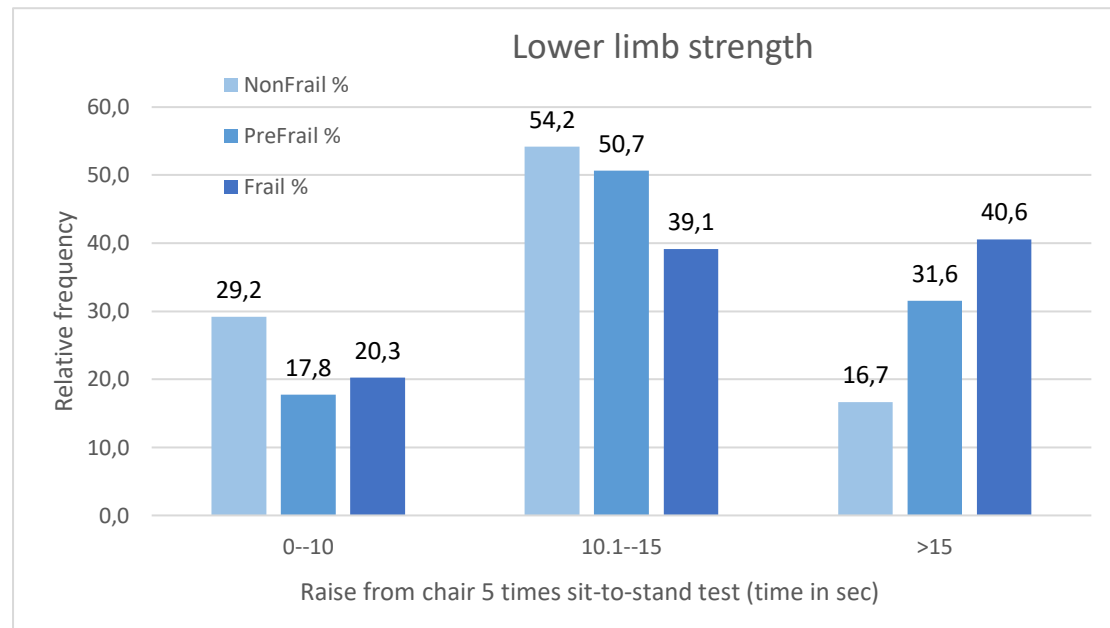
Table 34. Basic descriptive statistics about physical tests' performance.

	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 35. 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.

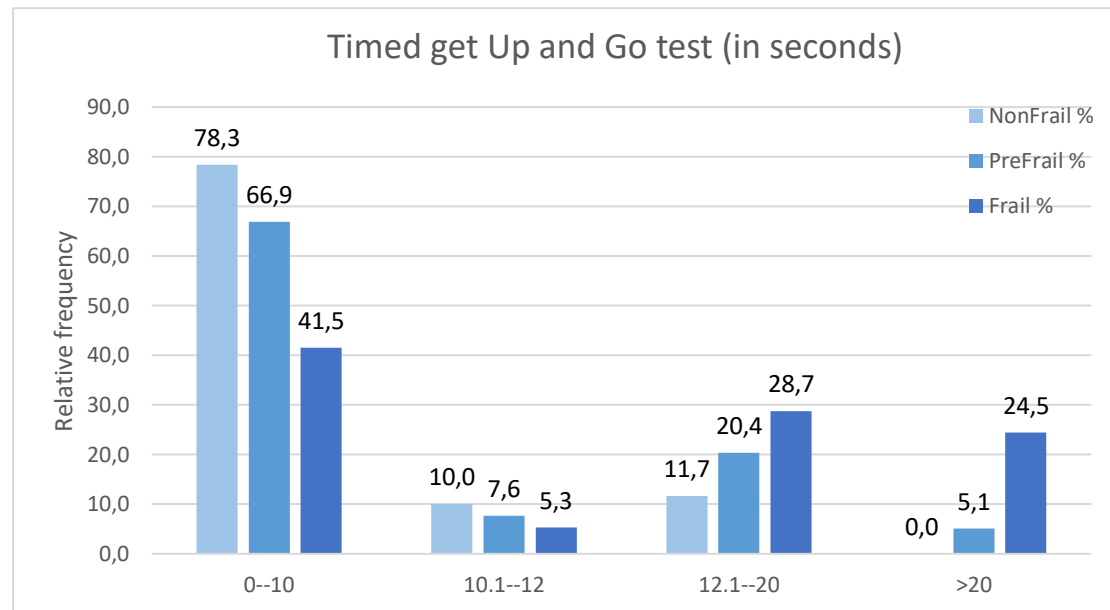


The predominant group in the category with the worst performance in the 5-times sit-and-stand test (time >15seconds) is the frail one. An almost equal percentage of them (39.1%) find themselves in the intermediate category of 10-15 seconds, while only 20.3% of them can perform the test in less than 10 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 36. 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.

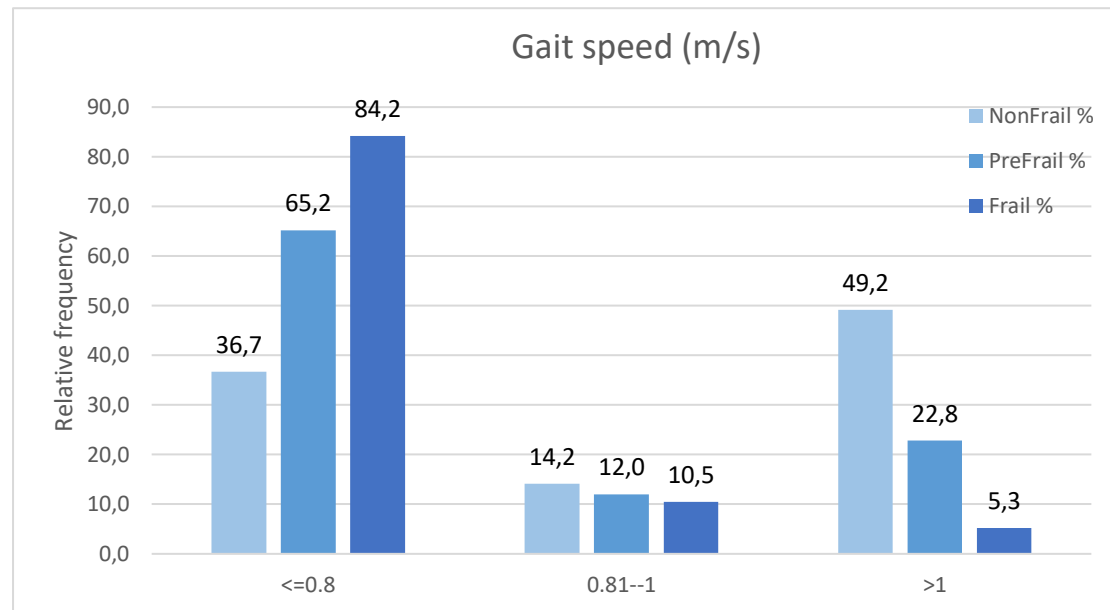


Most of the study's participants perform the Timed get Up and Go test (TUG) in less than 10 seconds. Still, in this category the predominant groups are the non-frail and the pre-frail ones, and less than half frail people (41.5%) belong in this category. While few non-frails and pre-frails perform the 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 37. Repartition of participants according to gait speed (4 meters' straight walk), per frailty group.

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

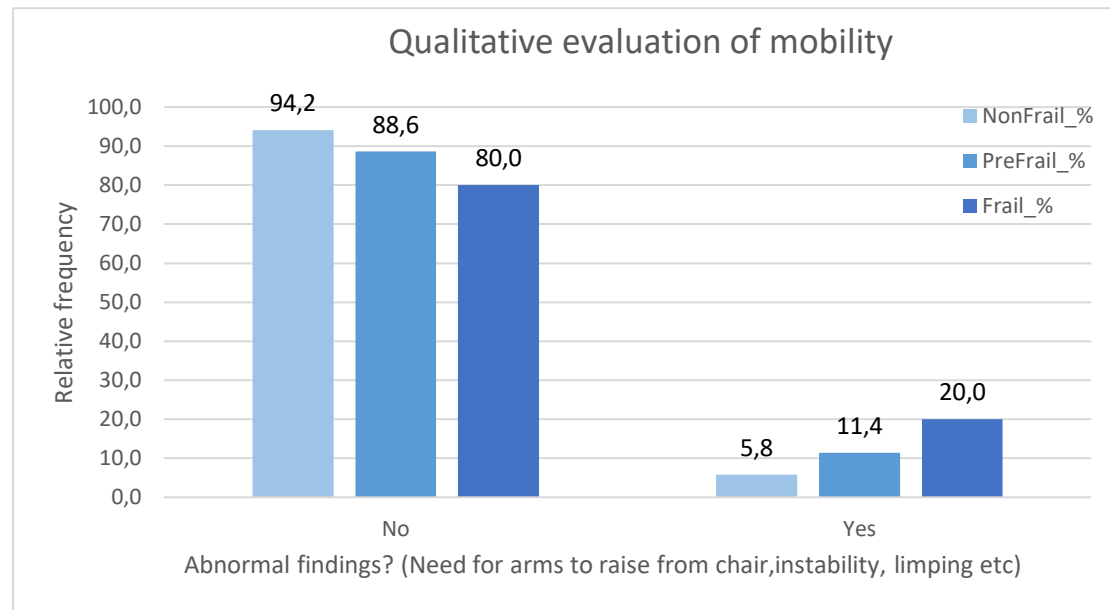


Although in the intermediate category of medium gait speed the results are not very indicative, the extreme categories reveal a clear relation between the slow gait speed and frailty. Eighty-four percent of frail people have a gait speed of less than 0.8m/s, while their percentage in the high speed category (>1 m/s) is only 5.3%. The non-frails perform mostly >1 m/s (49.2%), a 14% of them perform between 0.81 and 1m/s and 36.7% in the low speed category of ≤ 0.8 m/s. The pre-frail group shows intermediate performances between the frails and the non-frails.

Table 38. 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.

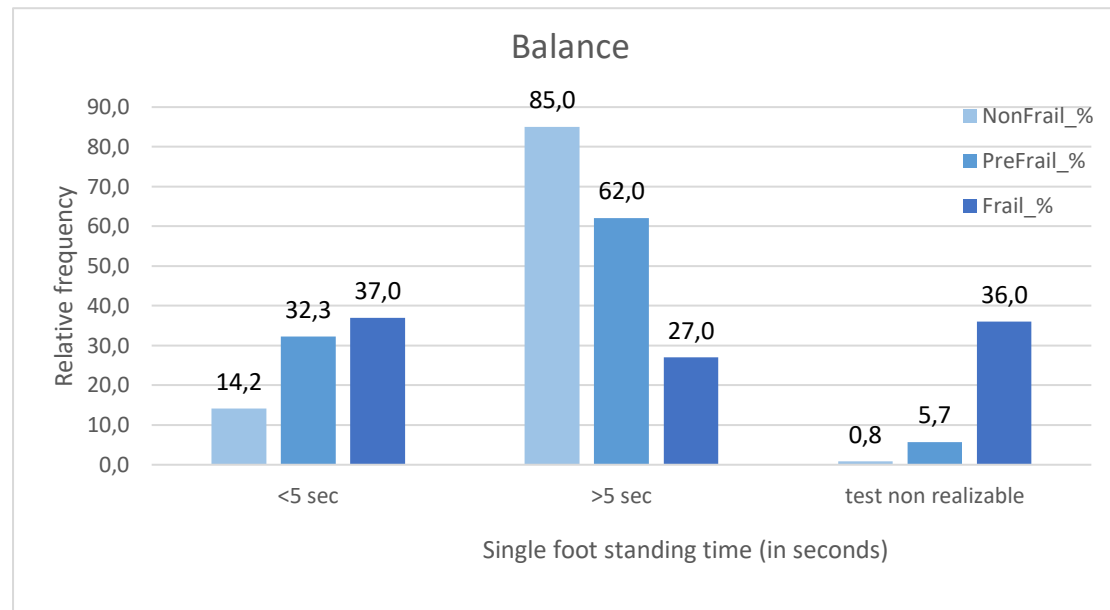


In terms of the qualitative evaluation of gait, most people with normal finding belong to the non-frail group (94.2%), followed by pre-frails and frails (88.6 and 80% respectively), whilst the opposite is observed in the group with abnormal qualitative gait findings: the majority are frail (20%), followed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

Table 39. 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.

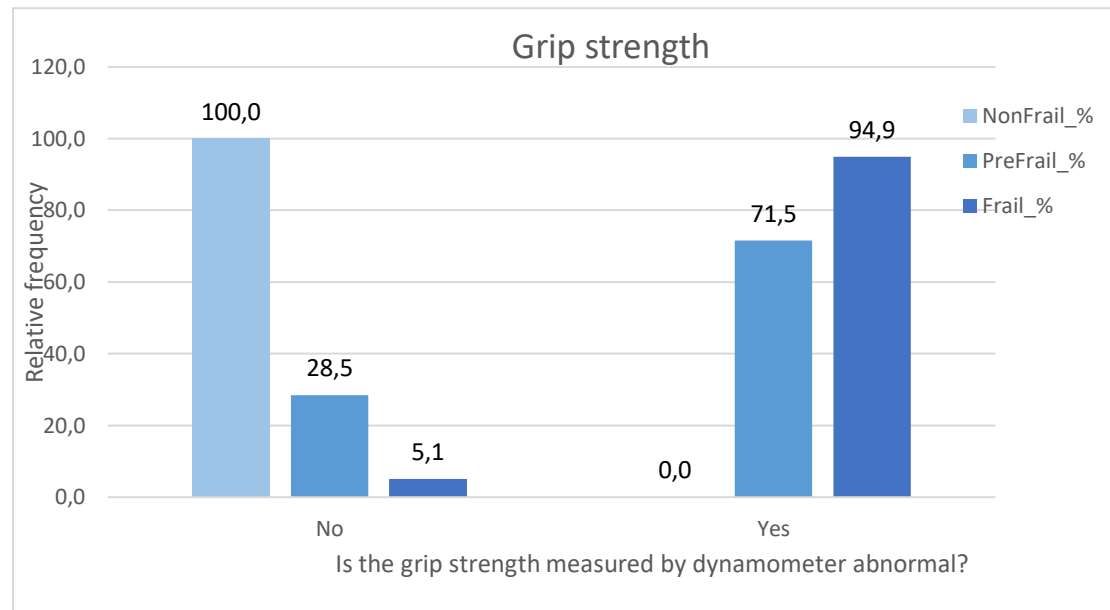


Not surprisingly, most of the people performing well in the balance test belong to the non-frail group, while most people with poor balance are frail. Also, frail ones stand out in the category of the inability to perform the test, usually due to important mobility restriction reasons.

Table 40. Repartition of participants according to performance in the grip strength measurement, per frailty group.

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 34. Prevalence of abnormal performance in the grip strength measurement, per frailty group.

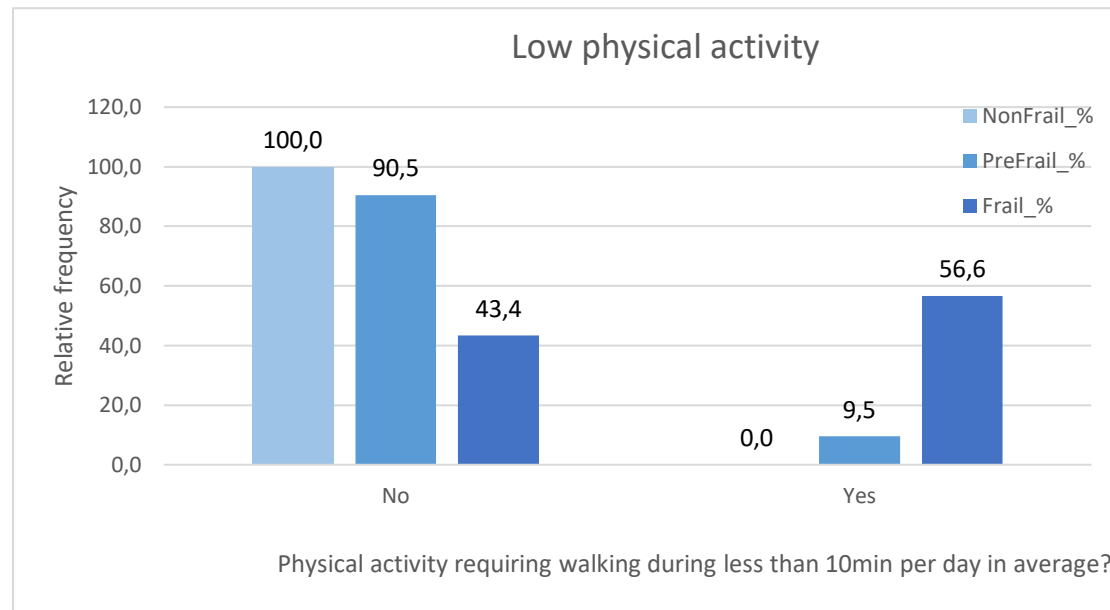


As abnormal grip strength is a frailty criterion, according to the presently employed Fried's frailty categorization, it is normal that all non-frail people belong to the normal grip strength category. Very few frail people show normal grip strength performance, while the majority of them (95%), have this criterion positive. The prevalence of abnormal grip strength is rather prevalent also in the pre-frail group, where 1-2 frailty criteria need to be fulfilled. It seems that this specific criterion positivity is the case in 71.5% of pre-frail cases.

Table 41. Repartition of participants according to the presence of low physical activity, as defined by Fried's criterion, per frailty group.

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 35. Prevalence of low physical activity, as defined by Fried's criterion, per frailty group.

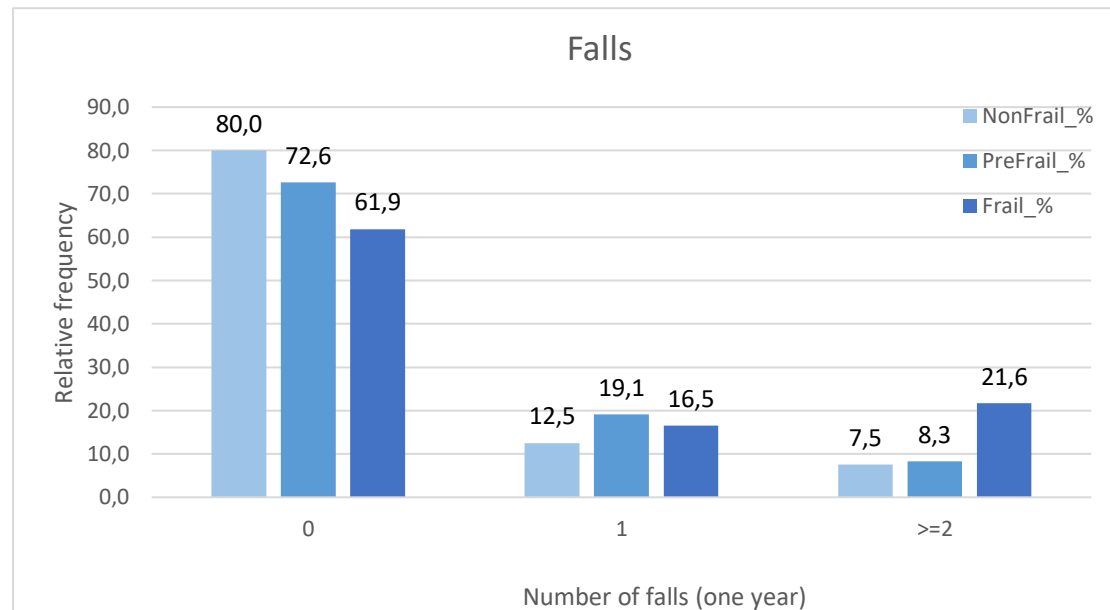


Similarly to grip strength, low physical activity, defined as mobile activity for less than 10 minutes per day, is another Fried's frailty criterion, employed in the present categorization into frailty groups. Thus, there are no non-frails in the low physical category group, while those who dominate this category are the frails (56.6%), 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).

Table 42. Repartition of participants according to category of number of falls in the last 12 months, per frailty group.

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 36. Prevalence of each category of number of falls in the last 12 months, per frailty group.

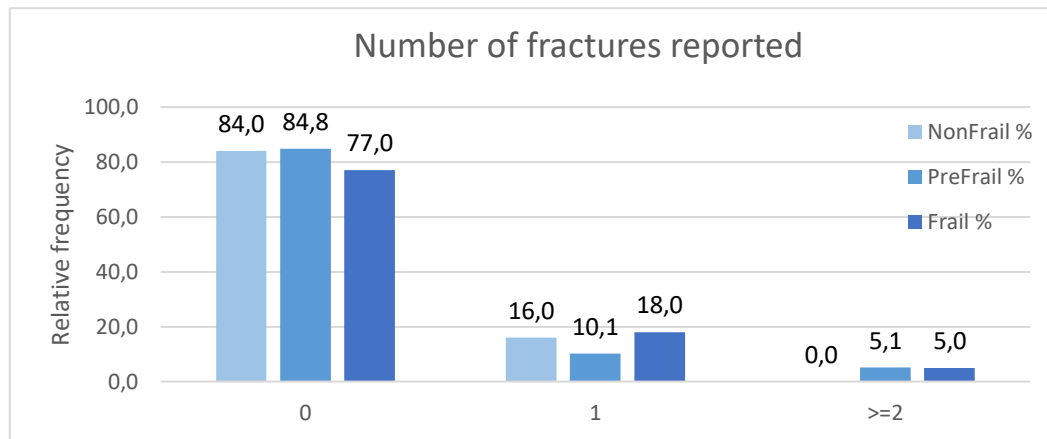


The dominant frail group in the no falls category is the non-frails, while the frails predominate in the category of 2 or more falls in the last year.

Table 43. 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 fractures, 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.

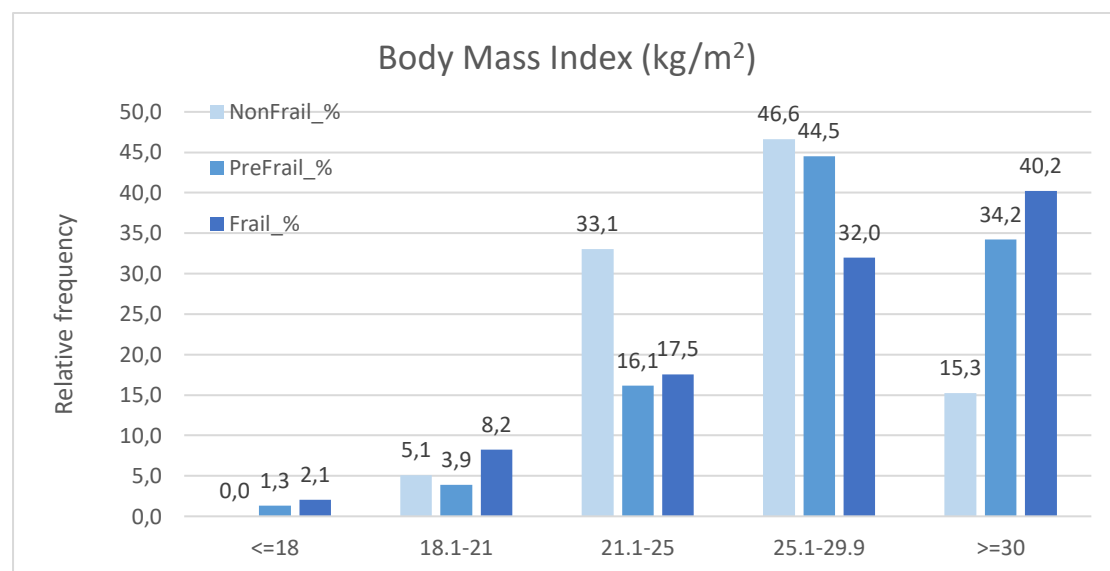
Table 44 presents basic descriptive statistics about minimum, maximum and mean values of continues variables evaluated in this domain, followed by tables describing the distribution of the study's participants to each category of these variables, according to their frailty status, as well as by histograms depicting the same data in the form of percentages.

Table 44. 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
<i>BMI: Body Mass Index, MNA: Mini Nutritional Assessment</i>			

Table 45. 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/m². 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 46. 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.

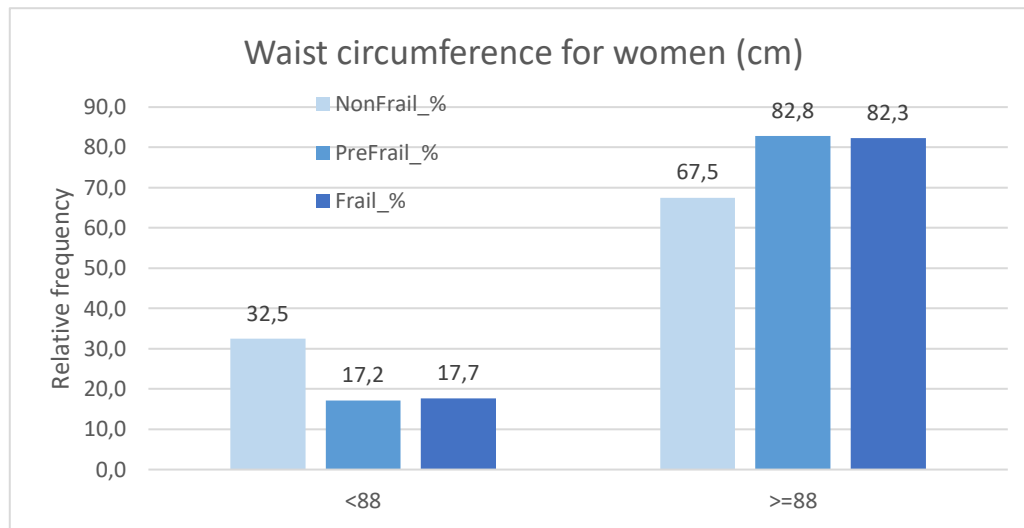
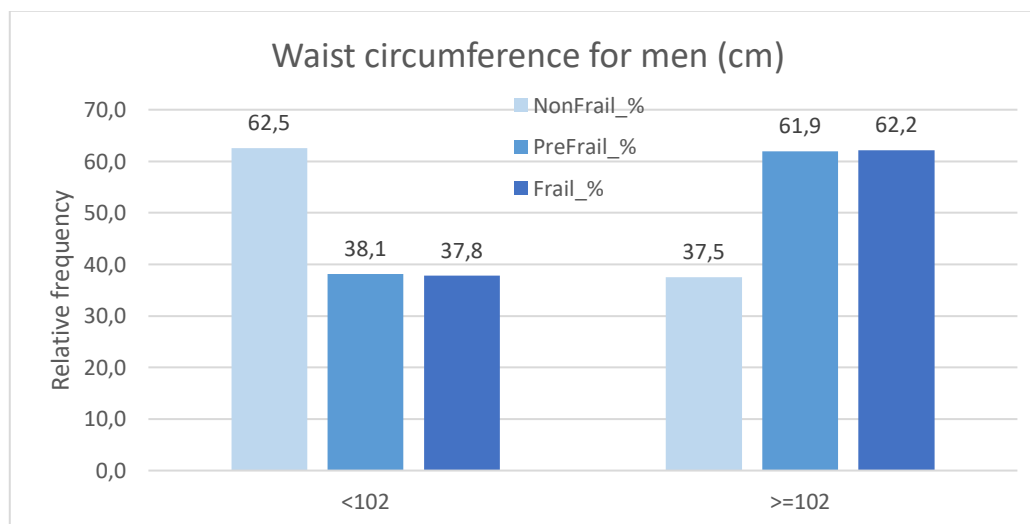


Table 47. Repartition of participants according to waist circumference category for men, per frailty group.

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.

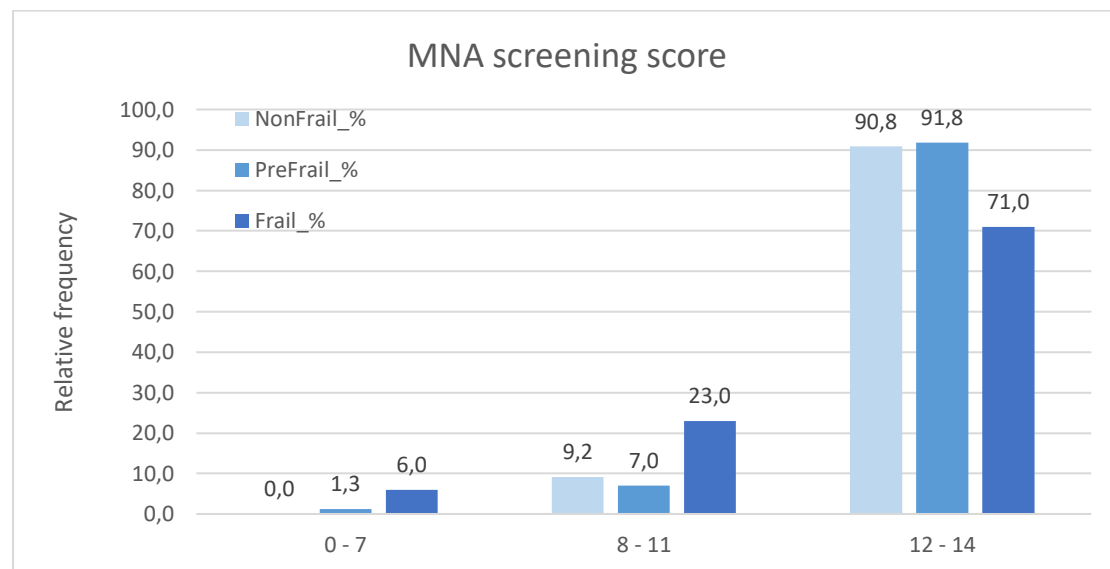


The majority of women of all frailty groups have a waist circumference superior than 88 centimeters, but the percentage of non-frails in this category is lower in comparison to the percentages of frails and pre-frails. The same pattern goes also for men, in whom, however, the non-frail group mostly belong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

Table 48. Repartition of participants according to categories in the Mini Nutritional Assessment (MNA) screening test score, per frailty group.

MNA screening score	NonFrail	PreFrail	Frail	Total N
0 - 7	0	2	6	8
8 - 11	11	11	23	45
12 - 14	109	145	71	325
	120	158	100	378

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



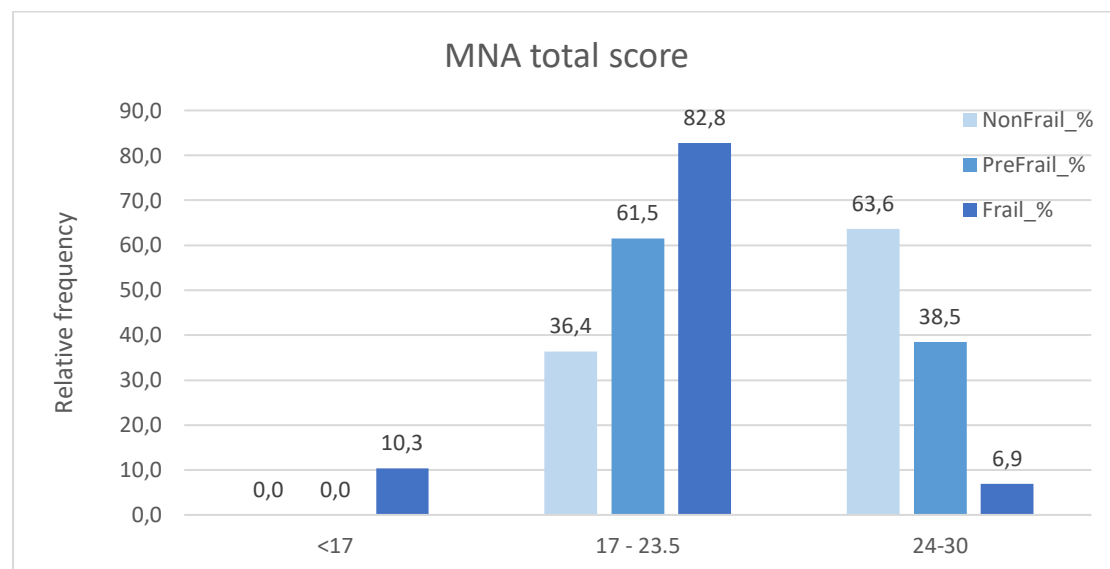
The Mini Nutritional Assessment (MNA) screening score, works as a discriminator for those who need to undergo the MNA total score, who are those who have a score <12 in the screening test. The vast majority of non-frail and pre-frail participants (90.8 and 91.8% respectively), have MNA screening scores 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 49. Repartition of participants according to categories in the Mini Nutritional Assessment (MNA) total test score, per frailty group.

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.



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.

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.

Table 50 presents 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 50. Basic descriptive statistics of cognitive tests performed.

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

Table 51. Repartition of participants according to categories in the Mini Mental State Examination (MMSE) score, per frailty group.

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.

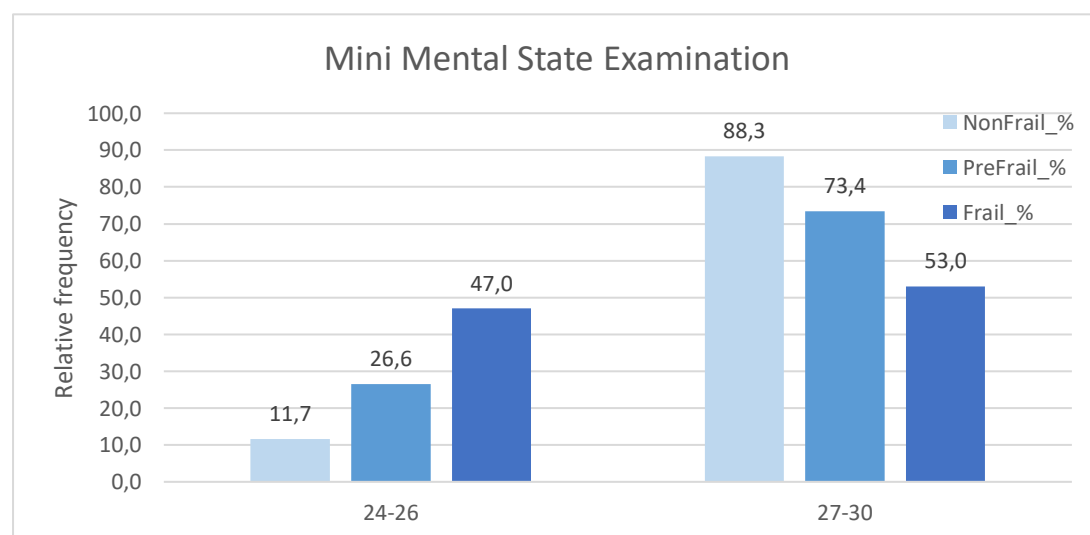
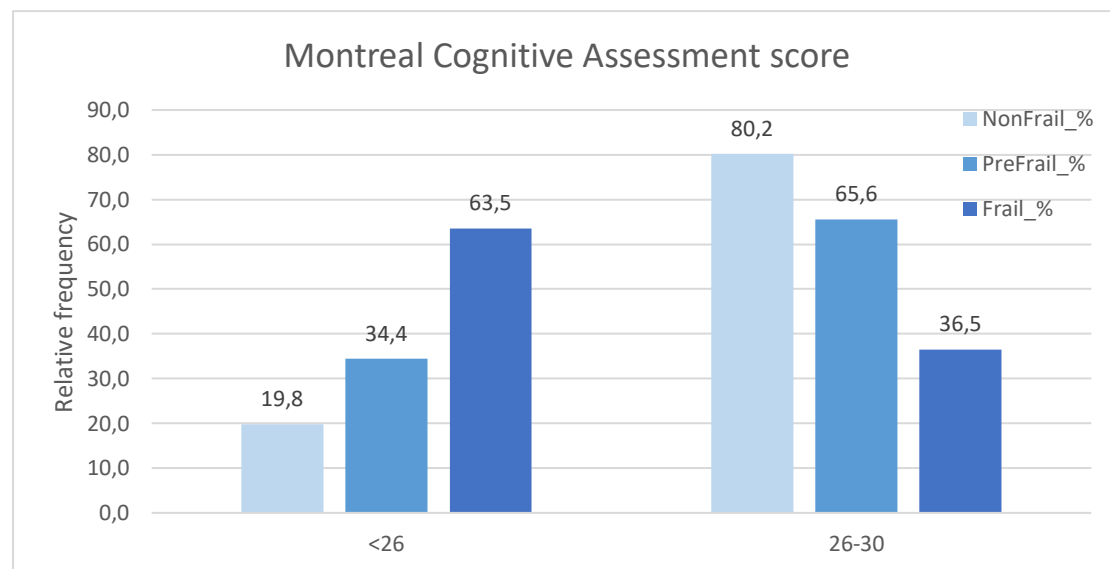


Table 52. Repartition of participants according to categories in the Montreal Cognitive Assessment (MoCA) score, per frailty group.

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.

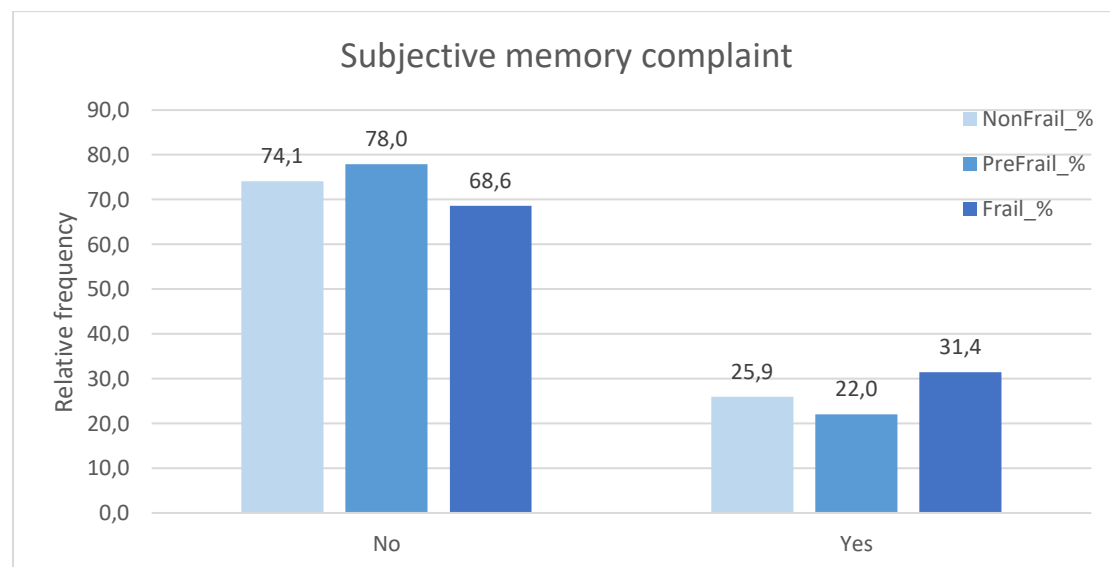


Performance in both MMSE and MoCA scores follow the same pattern of values' distribution. The dominant group in the lower cognitive performance category is the frail group, both for MMSE (47%) and for MoCA (63.5%). Only 11.7% of non-frail people have a MMSE <27, while 88.3% of them have a MMSE between 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 53. 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 clinical evaluation visit. Their minimum, maximum and mean values are presented in table 54.

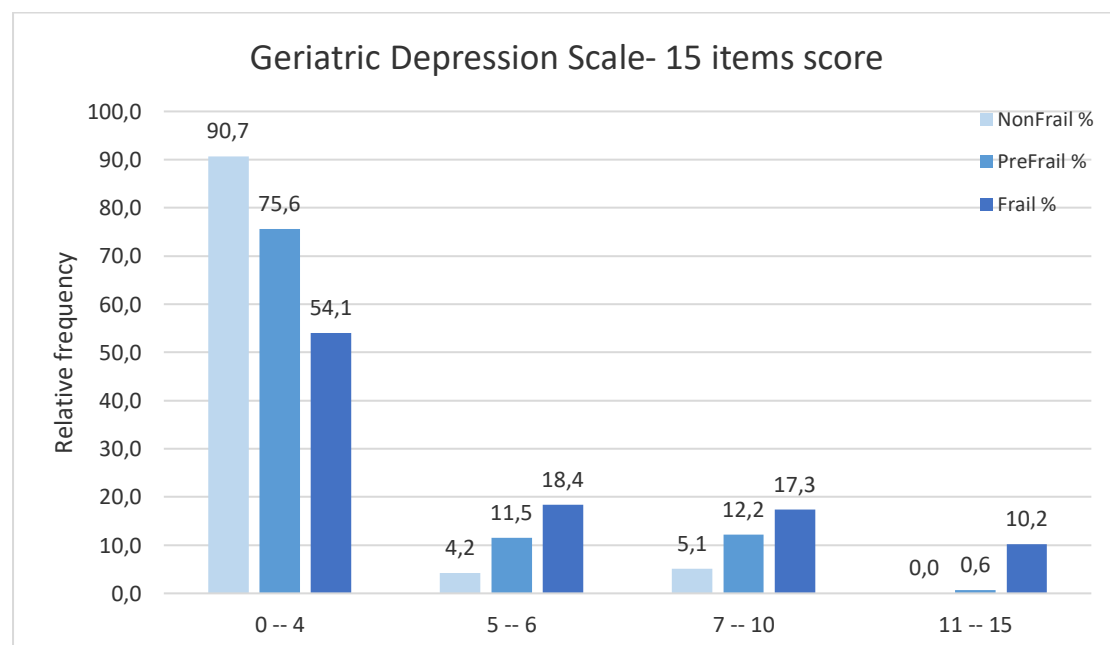
Table 54. Basic descriptive statistics about GDS (Geriatric Depression Scale) -15 items score and the VAS (Visual Analogue Scale) for the anxiety self-rating.

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

Table 55. 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.



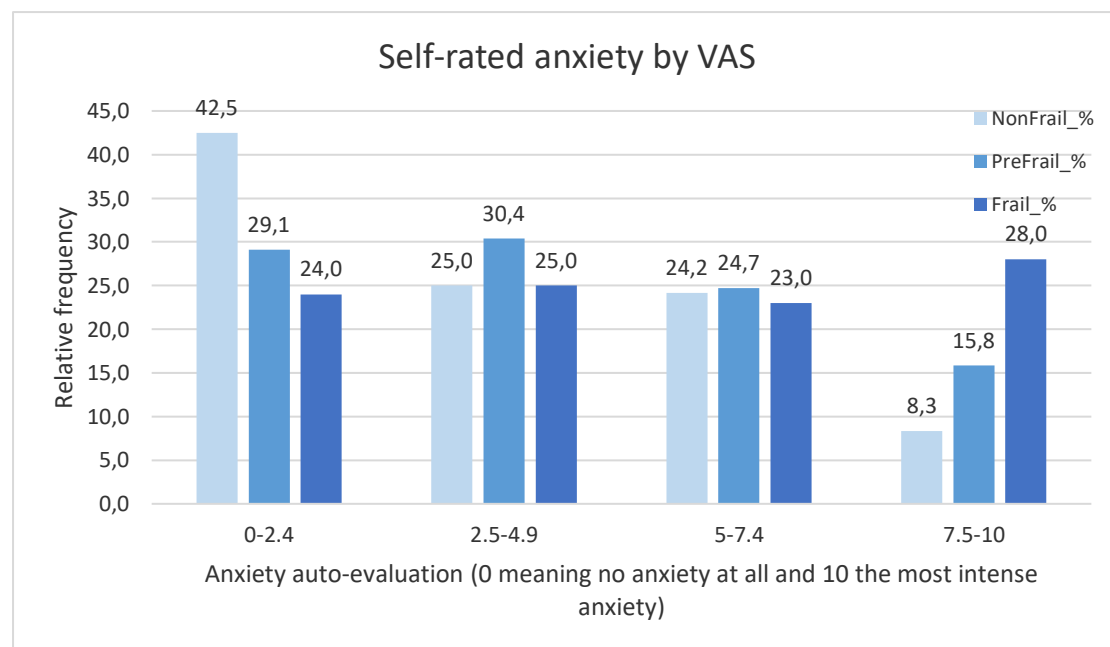
It is clear, observing this diagram, that most of non-frail participants (90.7%) belong to the lowest scores of depression (GDS<5). In this category also enter the majority of pre-frail (75.6%) and frail individuals (54.1%), with descending prevalences. On the other hand, the dominant group in all GDS 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 56. 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 clinical evaluation visit.

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.

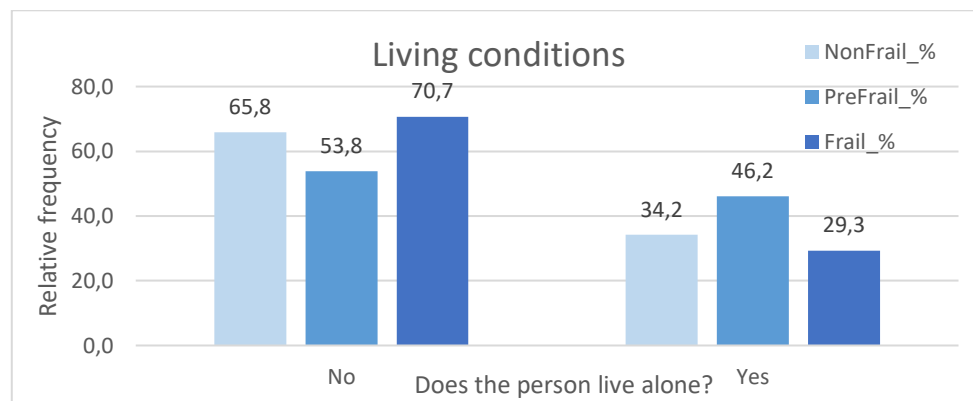
Table 57 provides the minimum, maximum and mean values of the quantitative variables, followed by tables and figures displaying both qualitative and quantitative variables, relevant to the social domain description.

Table 57. Basic descriptive statistics describing the quantitative variables that compose the social domain.

<i>All measurements refer to a week's time</i>	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 58. Repartition of participants according to their living conditions, per frailty group.

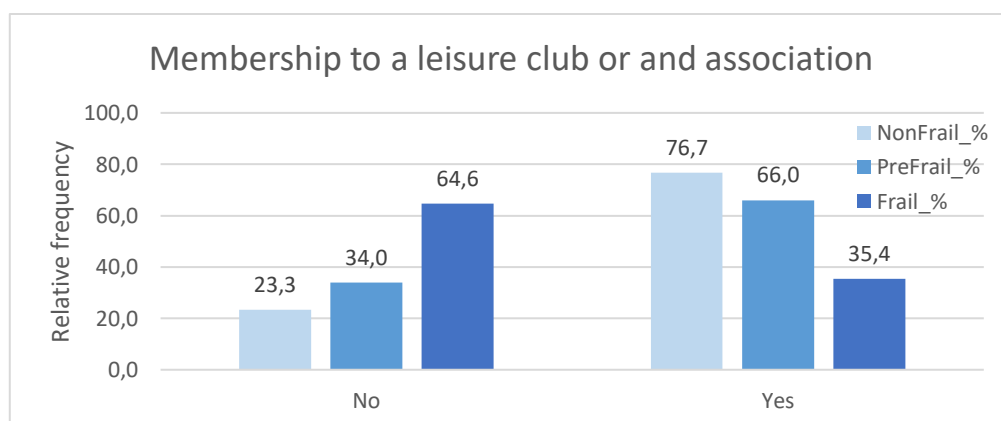
Living conditions (does he/she live alone?)	NonFrail	PreFrail	Frail	Total N
No	79	84	70	233
Yes	41	72	29	142
	120	156	99	375

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 59. 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

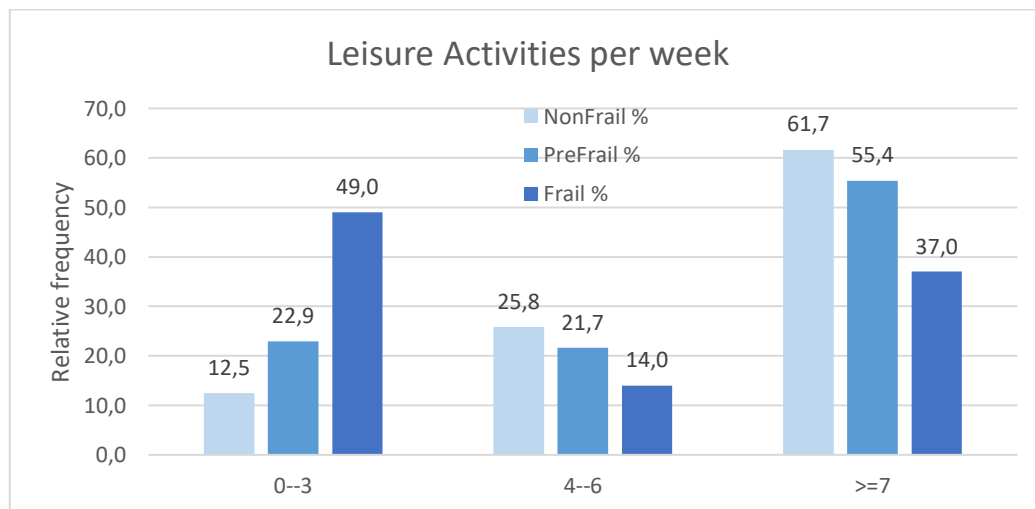
Figure 49. Prevalence of membership to a leisure club or association, per frailty group.

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 60. 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 61. 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.

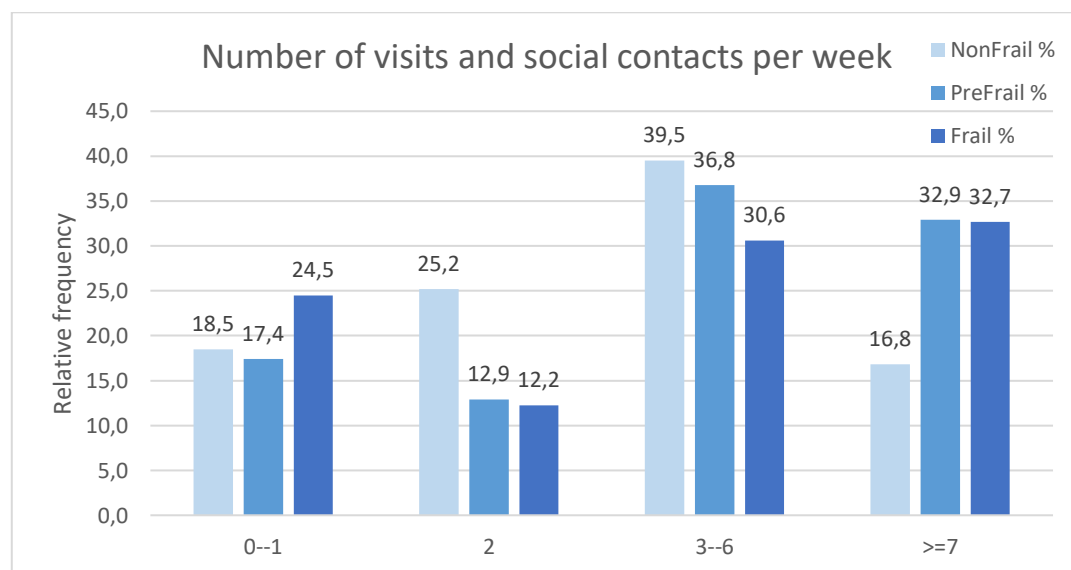
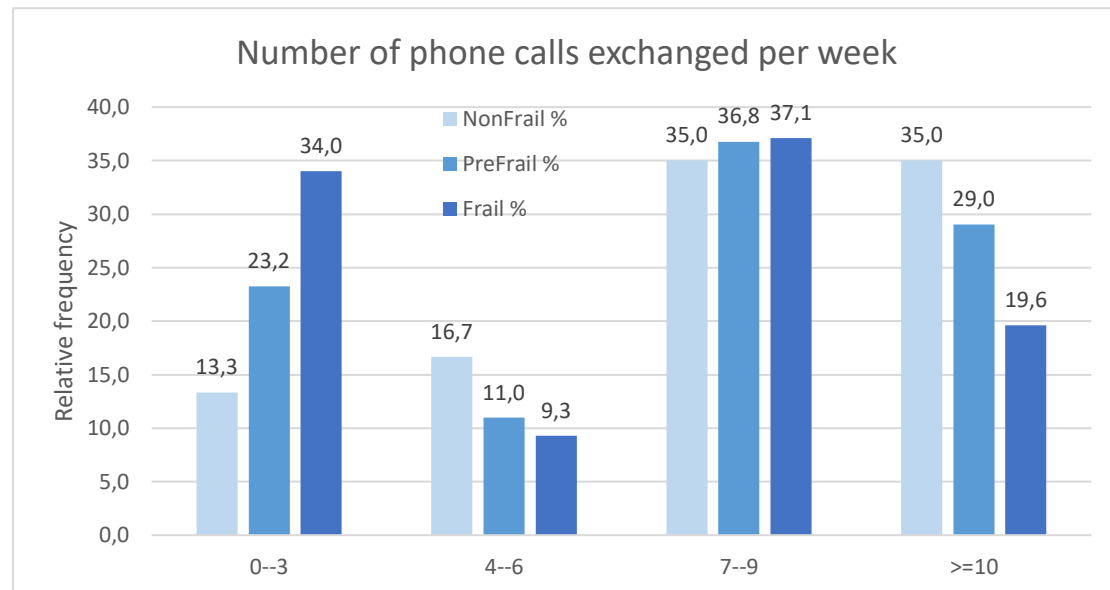


Table 62. Repartition of participants according to categories of number of phone calls exchanged per week, per frailty group.

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.

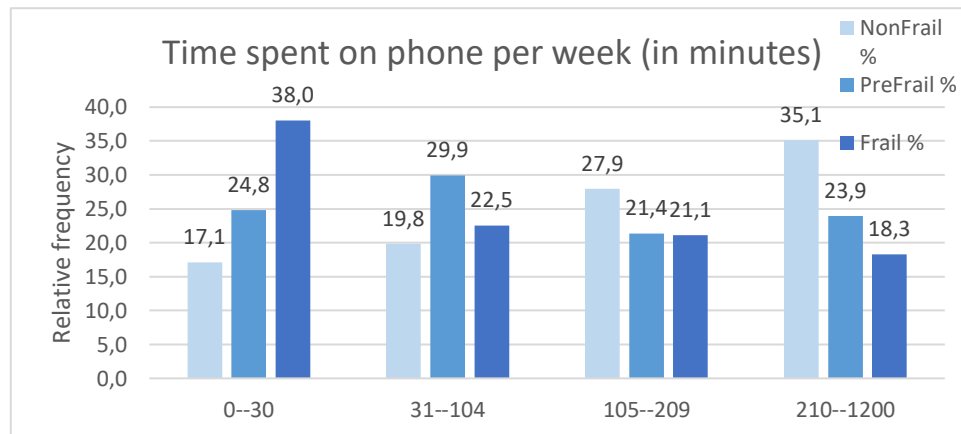


Both for the number of social interactions and phone calls exchanged per week, it's hard to identify a pattern between according to frailty status, although the frail group outweighs the rest in the less frequent phone call communication.

Table 63. 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.

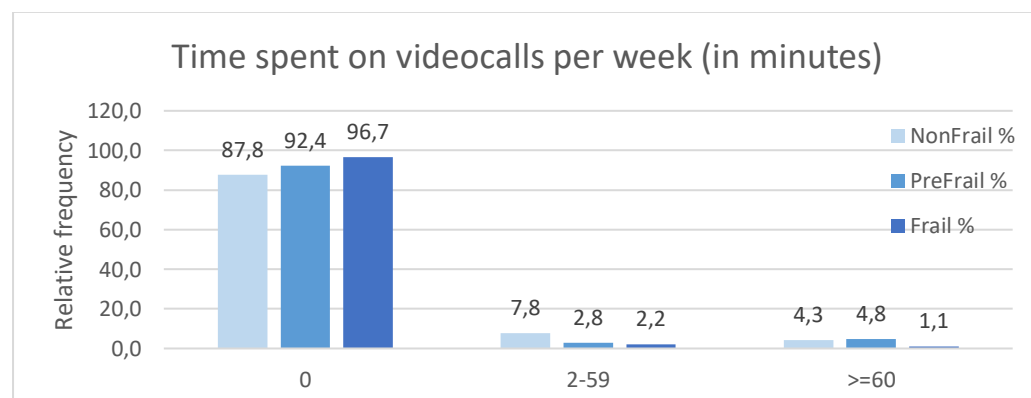


Regarding the time spent on the phone per week, it seems that frail participants are more prevalent in the less-time-spent-on phone categories, while non-frails ones, tend to spend more time on telephone.

Table 64. 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.

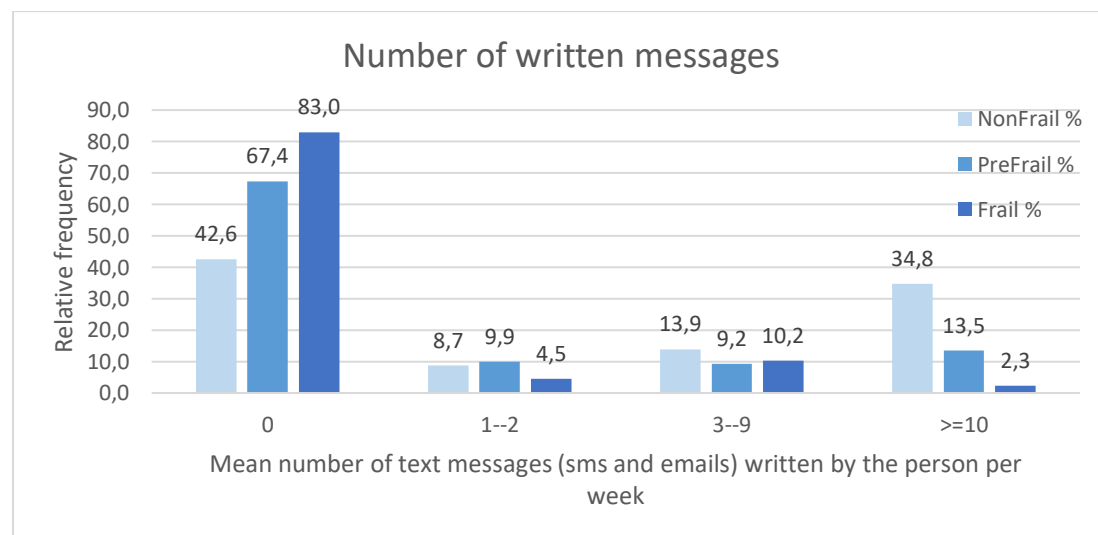


Very few of our study participants use distance video-communication means (like skype®), revealing also their limited familiarity with computers' and internet usage.

Table 65. 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 home visit for the FrailSafe session. In this way, the investigator can form an opinion of the participant's environment.

Table 66. 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.

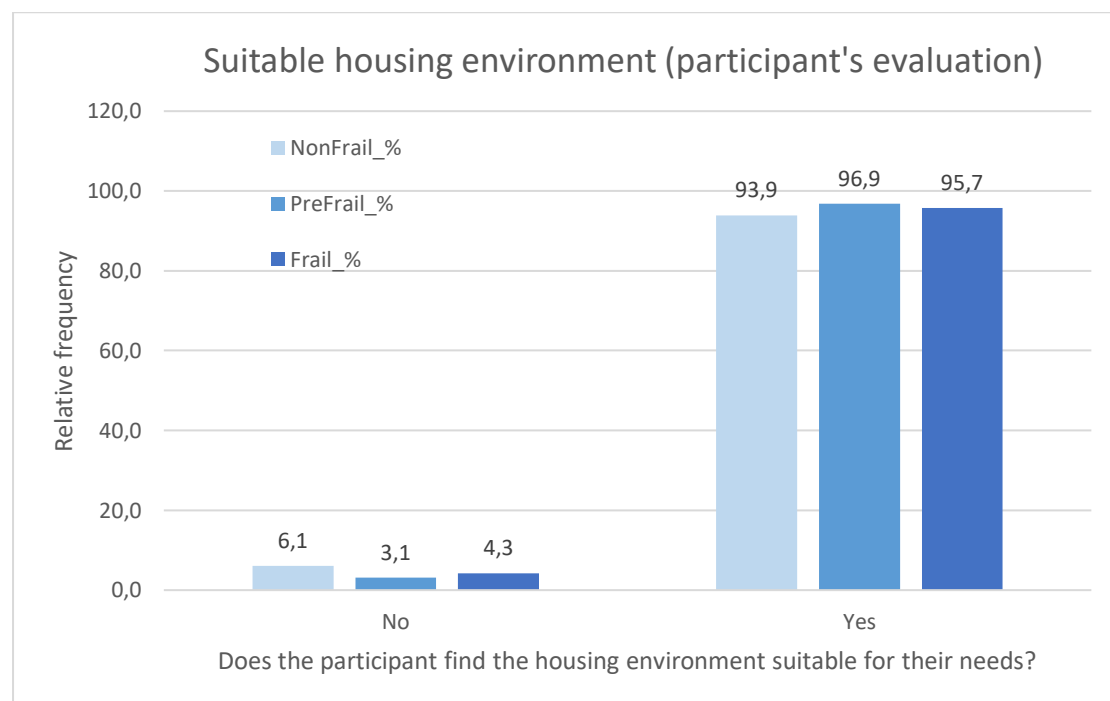
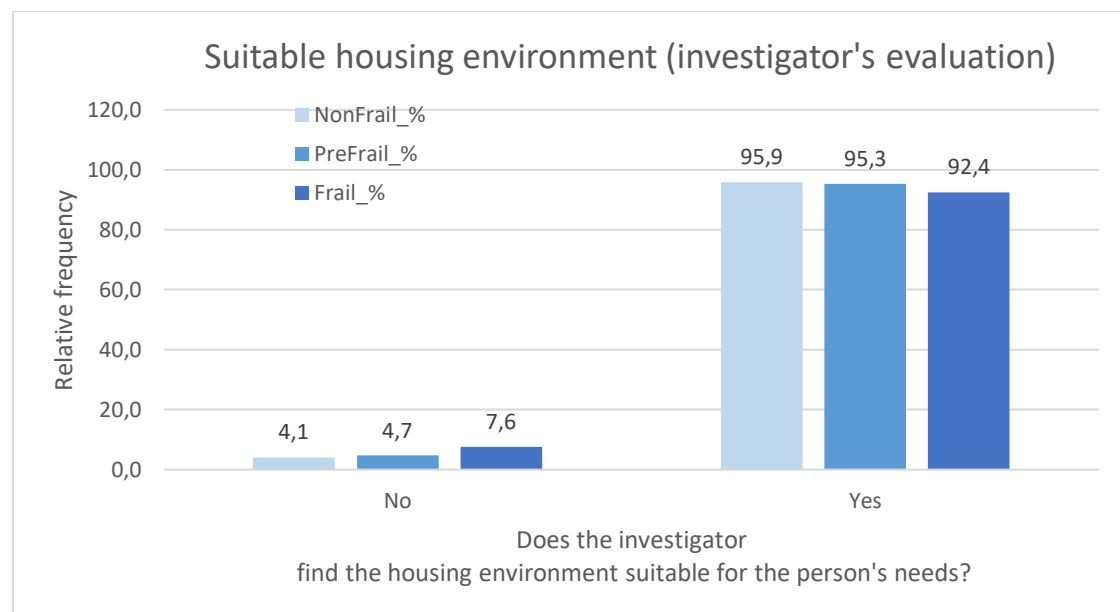


Table 67. Repartition of participants according to the investigator's evaluation of the housings' suitability to the needs of participants, per frailty group.

Housing 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.

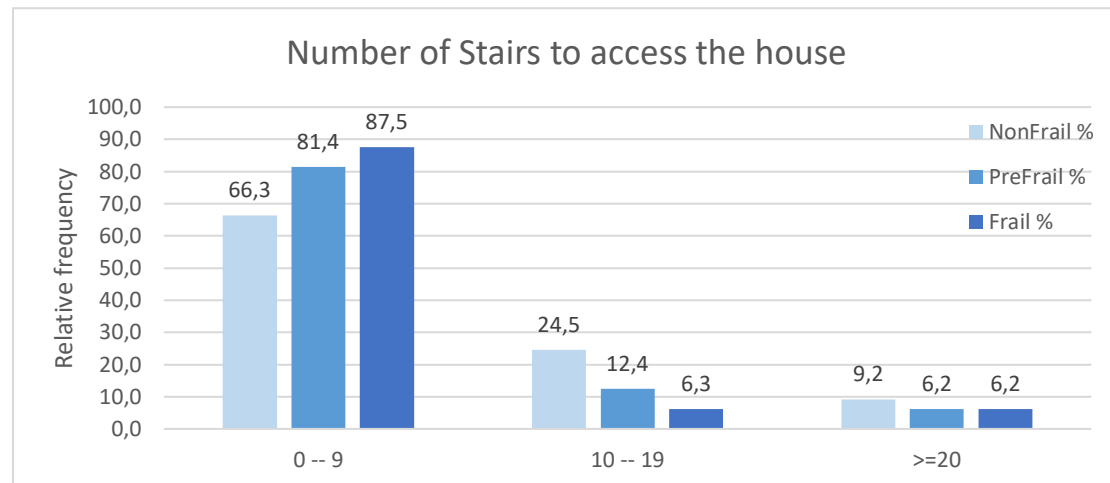


According to both the investigator's and the person's point of view, most of the participants, across all frailty groups, estimate that their housing environment is suitable for their needs.

Table 68. 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 clinical evaluation visit. Table 69 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 56, Figure 47).

Table 69. Basic descriptive statistics about self-rated QoL, pain and anxiety, as evaluated by visual analogue scales (VAS).

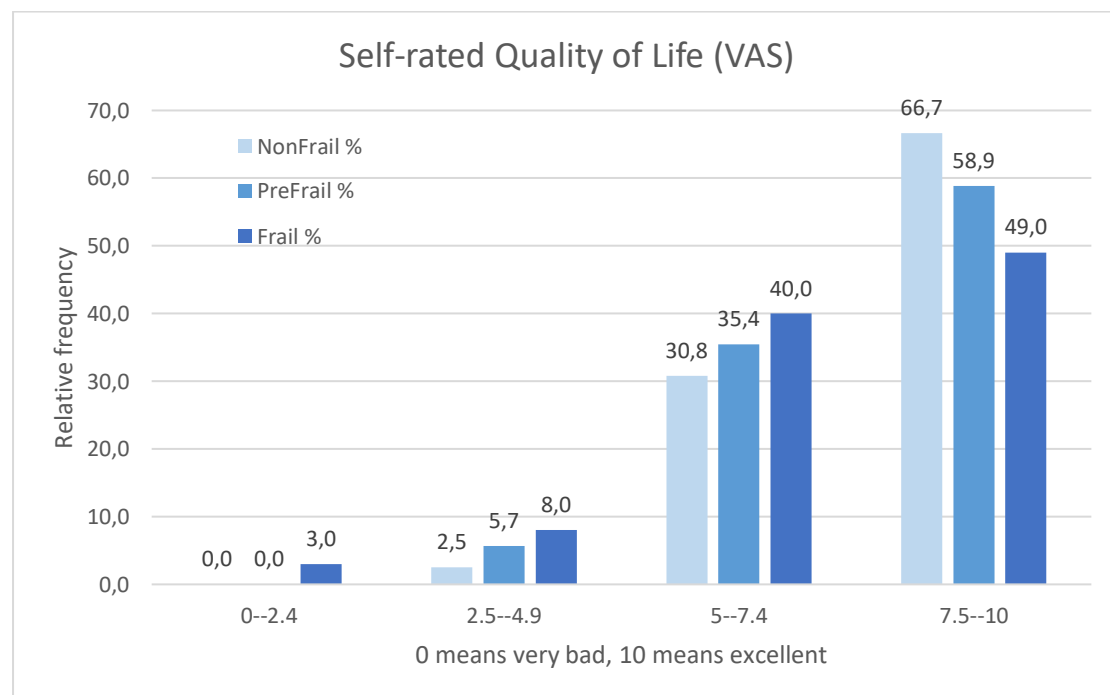
	Minimum	Maximum	Mean
Quality of Life VAS	1,4	10	7,6
Self-rated pain VAS	0	10	3,3

Self-rated anxiety VAS	0	10	4,2
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Table 70. 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.

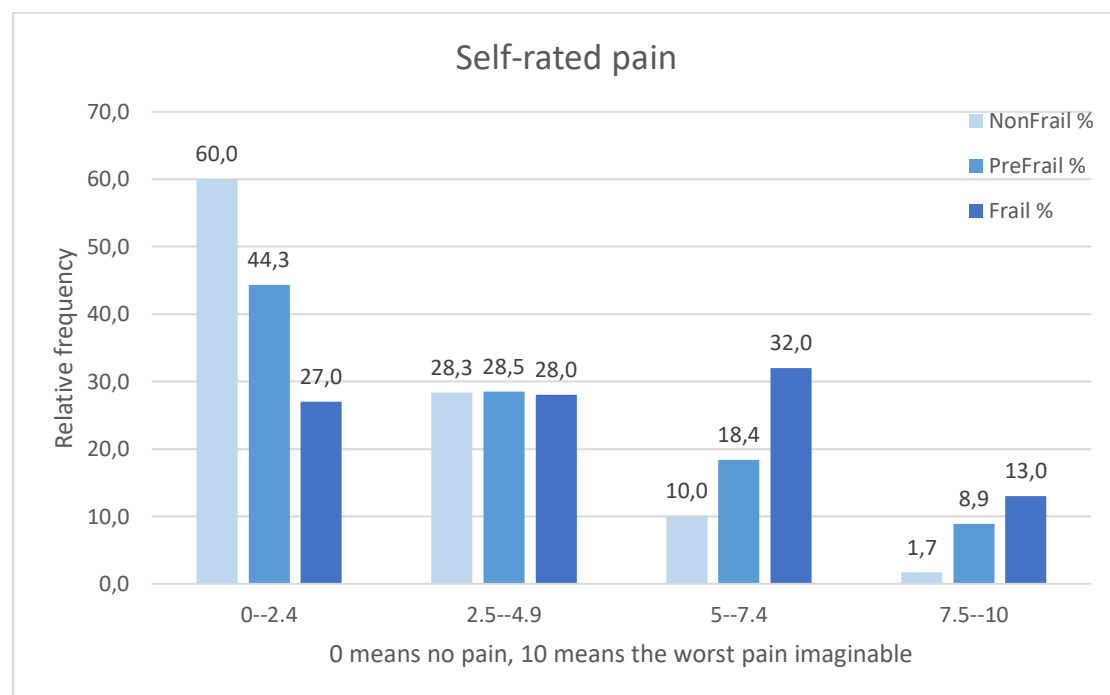


Most of the study's participants report a high level of QoL, according to their personal evaluation (QoL VQS 7.5-10). However, in this high-ranking group, non-frail participants (66.7%) outweigh both pre-frails (58.9%) and frails (49%). The prevalence of non-frails gradually decreases towards lower levels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

Table 71. 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.

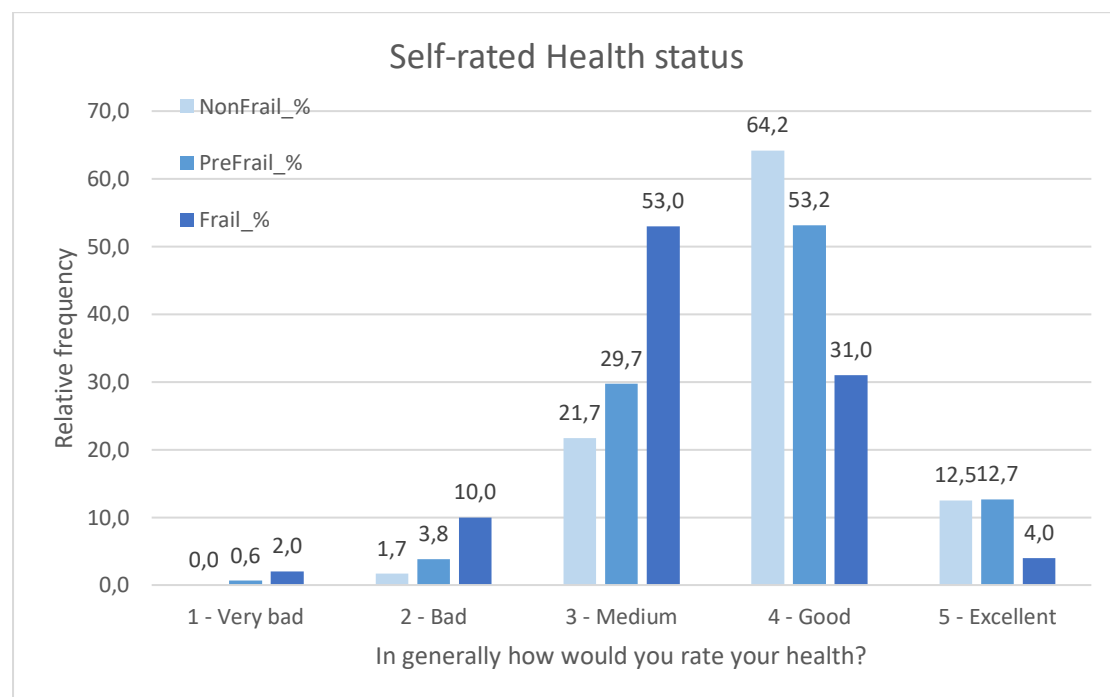


The majority of non-frail participants (60%) report low levels of pain (pain VAS 0-2.4), followed by 44.3% of pre-frails and 27% of frails. Most of frail people (32%) report a pain level medium-to-high (pain VAS 5-7.4) and 13% of them a very high pain level (pain VAS 7.5-10). The prevalence of pre-frails and non-frails is 8.9 and 1.7% respectively, in this high pain level category.

Table 72. 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.

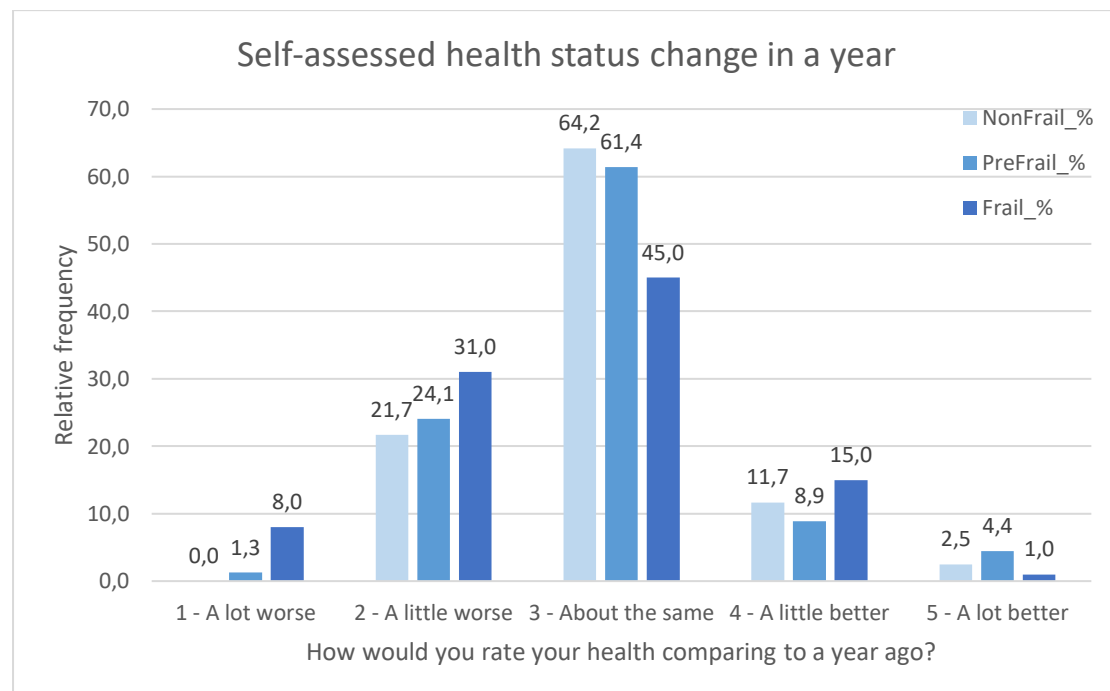


Regarding self-rated health status (Figure 61), frail people most often rate their own health status as negatively-low to medium, outweighing other frailty categories, while non-frails are the dominant group in positively-high ranking health status categories. The prevalence of frail people decreases 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 73. 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 parameters of the WWS 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.

By 20/5/2017, the WWS strap version had been administered to 87 participants. By the time this report is being written, data from a 56 (26 non-frails, 24 pre-frails and 6 frails) participants have been extracted and presented below.

Figures 63, 64 and 65 present the repartition of participants according to categories of heart rate while sitting or standing, lying and walking. Figures 66, 67 and 68 present similar data about breathing rate.

Figure 63. Repartition of participants according to categories of heart rate while sitting or standing, per frailty group.

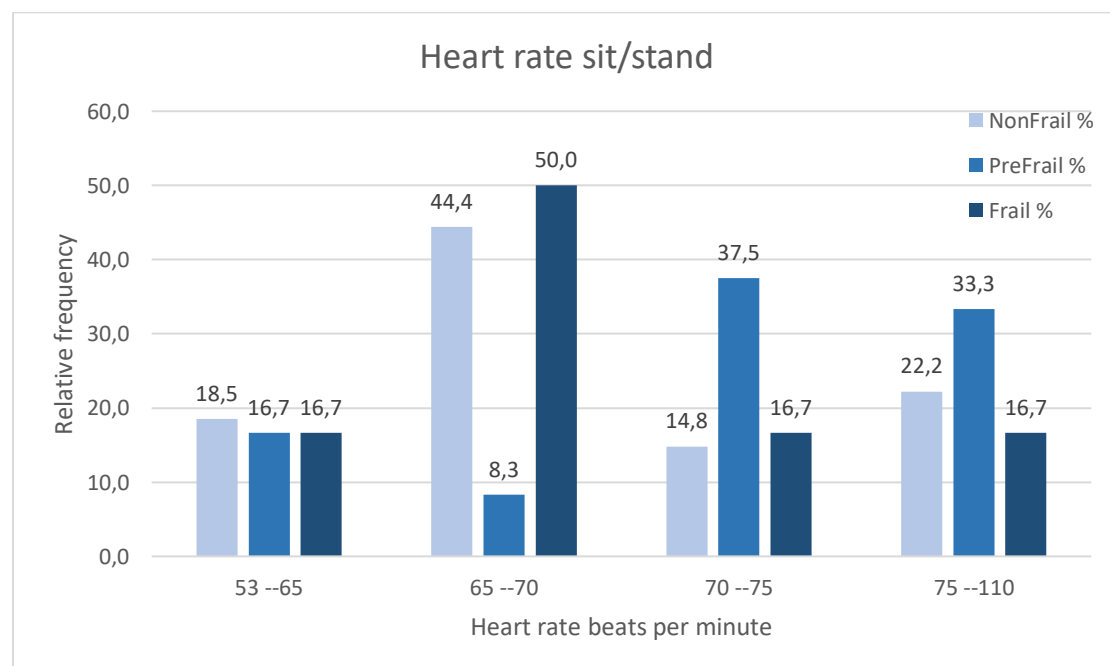


Figure 64. Repartition of participants according to categories of heart rate while lying, per frailty group.

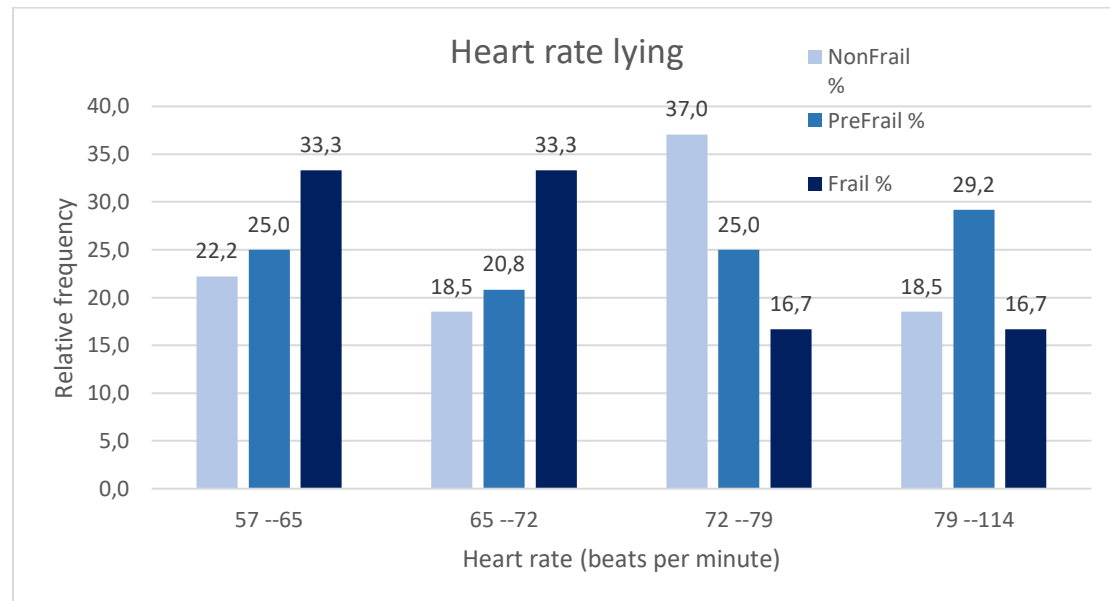


Figure 65. Repartition of participants according to categories of heart rate while walking, per frailty group.

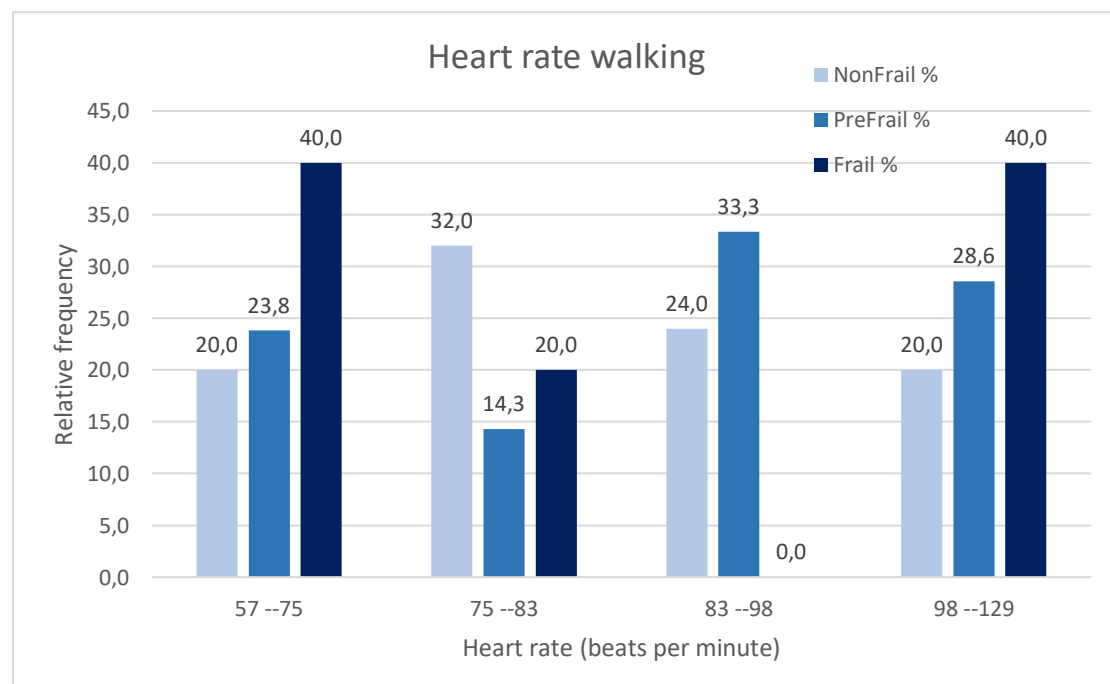


Figure 66. Repartition of participants according to categories of breathing rate while sitting or standing, per frailty group.

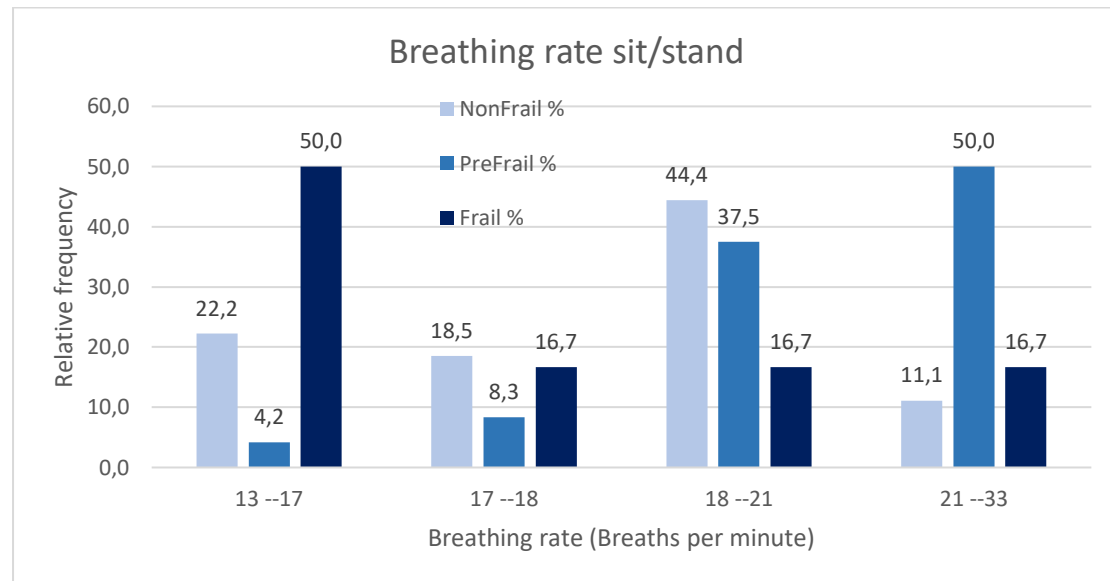


Figure 67. Repartition of participants according to categories of breathing rate while lying, per frailty group.

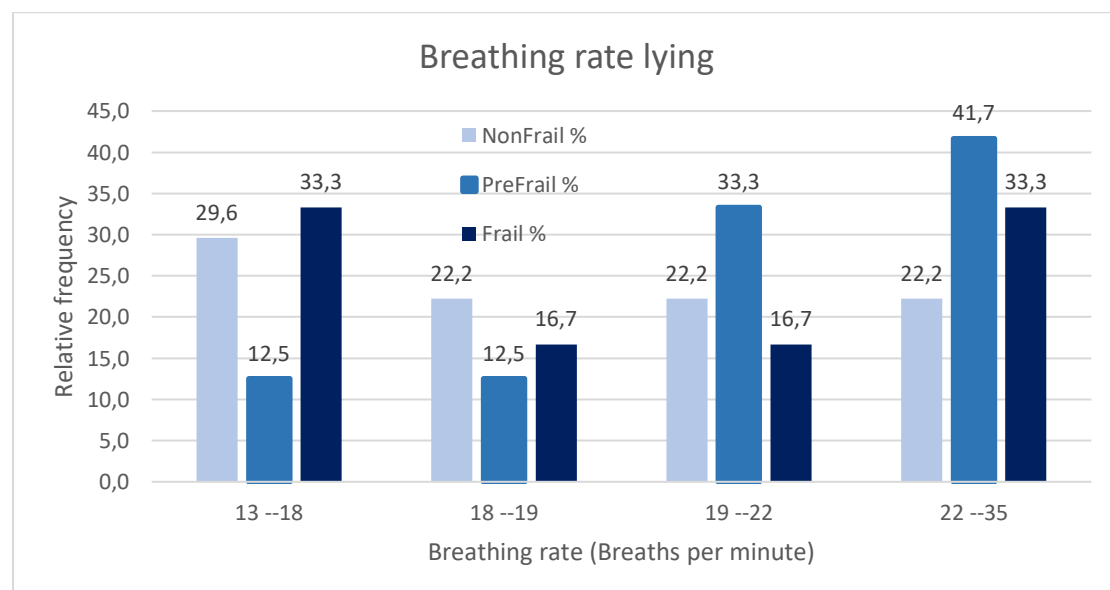
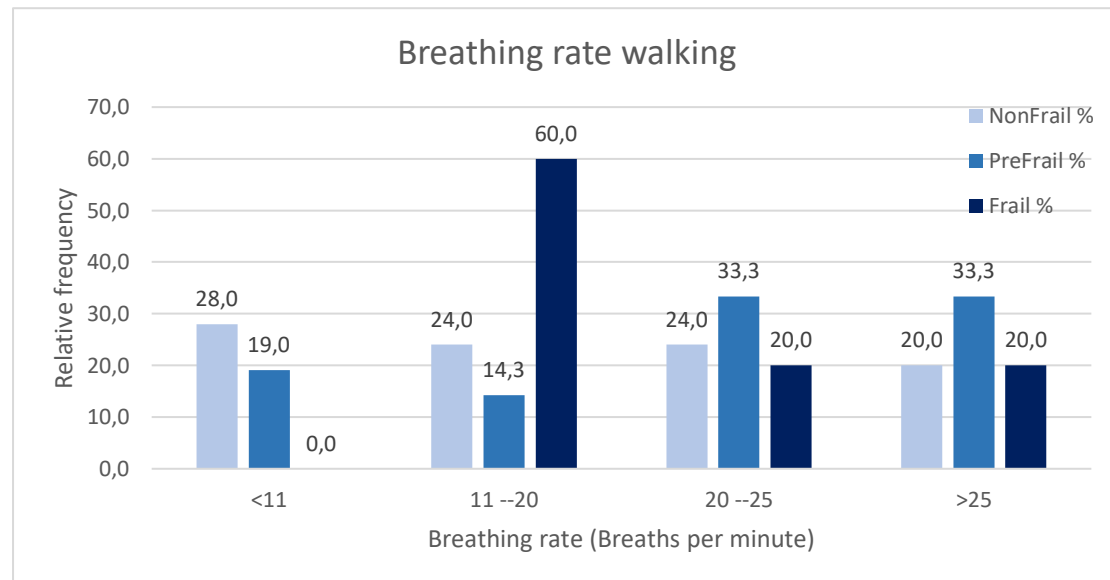


Figure 68. Repartition of participants according to categories of breathing rate while walking, per frailty group.



The group of frail people is very small to give conclusive results. Evaluating the two other groups, we observe that re-frail people show the tendency to present higher heart and breathing rates in almost all positions.

2.13 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.

By 20/5/2017, the smartphone with the GPS application had been administered to 210 participants. However, by the time this report is being written, the initial analysis of these data has not yet been completed and therefore no descriptive results are available.

2.14 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.

By 20/5/2017, the blood pressure home monitoring device had been administered to 195 participants. However, by the time this report is being written, these data have not yet been fed into the central database platform, and therefore no descriptive results are available.

2.15 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 20/5/2017, the VSM game had been administered to 179 participants. However, by the time this report is being written, these data have not yet been fed into the central database platform, and therefore no descriptive results are available.

2.16 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.

By 20/5/2017, the Red Wings dynamometer game had been administered to 105 participants. However, by the time this report is being written, these data have not yet been fed into the central database platform, and therefore no descriptive results are available.

2.17 Data from written text collection and self-administered questionnaires

Another way to monitor behaviour is the social media and self-administered questionnaires, collected with the purpose to investigate the relation of older people with social media and the big five traits of personality in order to perform natural language analysis. Table 74 depicts the number of data collected for the purposes of WP 6 up until M17.

Table 74. Progress of data collection concerning WP6 (natural language analysis and social media relation).

updated to 20/5/17	Patras	Nicosia	Nancy	Total
Sample of written text	116	89	111	316
Self-administered questionnaires	120	115	71	306

Analysing this data exceeds the scope and expertise of WP2. Other tasks (4.4, 4.5 and relevant deliverables will handle this issue.

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 75 summarises the progress of the FrailSafe sessions up until M17 in the three clinical centers, as well as the various difficulties encountered regarding the use of the available material in their current versions.

Table 75. Overview 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.

1st FS sessions Group A + B <i>Updated to 20/5/17</i>		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 recently taken (M17) 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 76 presents the characteristics of the 39 undesirable events that occurred since the enrolment of each participants, until M17.

Table 76. Recapitulation of undesirable events.

<i>Updated to 20/5/17</i>		Total
Number of undesirable events		39
Intensity/severity	mild	13
	moderate	16
	severe	9
Relationship to FS device	probable related	0
	possibly related	3
	not related	36
Seriousness	Hospitalisation	8
	Institutionalisation	0
	potential disability	1
	danger to life	0
	death	5
	nothing of the former	25
Anticipated	Yes	7
	No	32
Evolution	cure without afteraffect	21
	cure with afteraffect	4
	subject not recovered yet	4
	unknown	5
	not applicable	5

Most of the undesirable events which occurred during the study have been either of mild or moderate severity and the 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) and 9 serious adverse events, summarized in table 77, among which 5 deaths.

Table 77. Serious undesirable events.

Participant's ID	Nature of event
1025	stroke
1080	heart attack, death
1039	coronary artery disease
1037	fall, fracture, death
1025	heart attack
2011	death
3111	death from lung cancer
3110	coronary heart disease, 3 stents
3101	pancreatic cancer

5. Drop-offs

There have been 40 people who dropped-off from the study, since their inclusion up until M17 (Table 78), half of whom have already been replaced (52.5%). Withdrawals are almost equally distributed between clinical centres (12 from Patras, 12 from Nicosia and 16 from Nancy).

Most of the people who dropped off belonged either to the prefrail (17) or to the frail (13) 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 (35%), followed by death incidence (12.5%) and some emerging condition inhibiting the participation in the study or fulfilling exclusion criteria (12.5%). Finally, 4 (10%) participants were unreachable in contact efforts and lost in follow up.

Table 78. Drop-offs, characteristics and reasoning

<i>Updated to 20/5/17</i>	Patras	Nicosia	Nancy	total
Number of drop-offs	12	12	16	40
Frailty distribution between drop-offs	3 nonfrail	1 nonfrail	5 nonfrail	9 nonfrail
	4 prefrail	6 prefrail	7 prefrail	17 prefrail
	5 frail	5 frail	3 frail	13 frail
			1 unknown	1 unknown
sex distribution between drop-offs	6M + 6F	3M + 9F	3M + 13F	12M+ 28F
group distribution between drop-offs	11 A/ 1 B	8 A/ 4 B	10 A/ 6 B	29 A/ 11 B
Number of drop-offs replaced	0 (0%)	5 (41.7%)	16 (100%)	21 (52.5%)
Reason for drop-offs				
Death	3	1	1	5(12.5%)
Consent withdrawal	5	11	10	26 (65%)
Emerging condition inhibiting the participation in the study or fulfilling exclusion criteria	1	0	4	5 (12.5%)
Participant unreachable/ Lost in follow up	3	0	1	4 (10%)

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 79 provides data about the number of phone calls made up until M17. 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 79. Data about phone follow up in a three-month's basis.

<i>Updated to 20/5/17</i>	Patras	Nicosia	Nancy	Total
1st Follow up phonecall	120	80	77	277
2nd Follow up phonecall	108	78	3	189
Total	228	158	80	466

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 game tests cognitive abilities like anticipation and decision making, requiring at the same time a certain degree of dexterity.

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

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 CETH.

An Augmented Reality game 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 WWBS current version

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.

6.4 Beacons

Finally, another device that will contribute to behavioural monitoring are the beacons, for the monitoring of indoors' movement and activity. Beacons will be 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.

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
Arrhythmia	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_limb 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 impairment	2,0	0,0	0,0
Parkinson's disease	2,0	0,0	0,0
Arrhythmia	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