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Medical and Scientific Evaluation Final Version

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0.3	06.11.2015	Final version	R. Annicchiarico (FSL)	Document refinement for internal review

EXECUTIVE SUMMARY

The aim of this deliverable is to illustrate the final results of the scientific evaluation of the project based on medical outcomes extracted from the clinical evaluation described in the D7.1 Based on this methodology the IDF pilot sites have provided detailed information (including numbers of participating elderly, scores of their mobility, cognitive and functional assessments and demographic information) about the entire period of pilot operations spanning the period from Dec 2013 to Aug 2015. This information has been statistically analysed as explained within the deliverable.

Document Information

CIP Project Number	297225	**Acronym**	I-DONT-FALL
Full title	Integrated prevention and Detection sOlutioNs Tailored to the population and risk factors associated with FALLs		
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GLOSSARY

ADL	Activity of Daily Living
CPM	Coloured Progressive Matrices
DoW	Description of Work
FES	Fall Efficacy Scale
GDS	Geriatric Depression Scale
IDF	I-DONT-FALL
GCP	Good Clinical Practice
IADL	Instrumental Activity of Daily Living
MMSE	Mini Mental State Evaluation
PIADS	Psycho Social Impact of Assistive Devices Scale
QUEST	Quebec User Evaluation of Satisfaction
RCT	Randomised controlled clinical trial
TMT	Trail Making Test
WHOQOL	World Health Organisation Quality of Life
6MWT	Six Minute Walk Test

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1 INTRODUCTION

The I-DONT-FALL project is strongly based on obtaining results from the deployment and testing a range of personalized solutions for fall detection and prevention management. These solutions are important, as they are the fundamental components to be verified and validated at the pilot sites throughout the project. The clinical trial involves 500 users across seven pilot sites in four countries. Two earlier deliverables (D2.1, D7.1) have specified the evaluation methodology of the project, which covers clinical evaluation aspects including mobility, cognitive and functional evaluation. The main objective of this deliverable is to present the clinical evaluation of the IDF platform and services, based on the methodology of D7.1. The present version of the deliverable focuses on the analysis of data derived from the entire period of the IDF formal pilot operations (pilot operations that took place in the period 01/12/2013-30/08/2015). The present deliverable reports on the evaluation of the IDF platform and services from a medical/clinical perspective, which is based on the IDF study design that compares mobility, cognitive, functional performance (including the evaluation of a fear of falling) before and after a treatment period, as described in D2.1. The comparison is performed on the basis of the cognitive, functional and affective status of the elderly, which is assessed on the basis of the IDF assessment battery (D7.1). In this respect the evaluation is characterized as «final» which comprises results and conclusions derived based on the total number of pilot participants.

2 FALL PREVENTION: FINAL ANALYSES

Mobility and cognition, in particular attention and executive functions, seem to be both implicated in the risk of falls [1,2]. In the I-DONT-FALL study we assessed the differential effect of ICT solutions based on motor exercises vs. cognitive exercises vs. their combination on the risk of falls, fear of falls, mobility, cognitive abilities, functional abilities and behavior of elderly at risk of falls.

2.1 Summary of methodology

The whole sample of the final analyses comprises 500 participants from 7 pilot sites that participated to the I-DONT-FALL project (Figure 1).

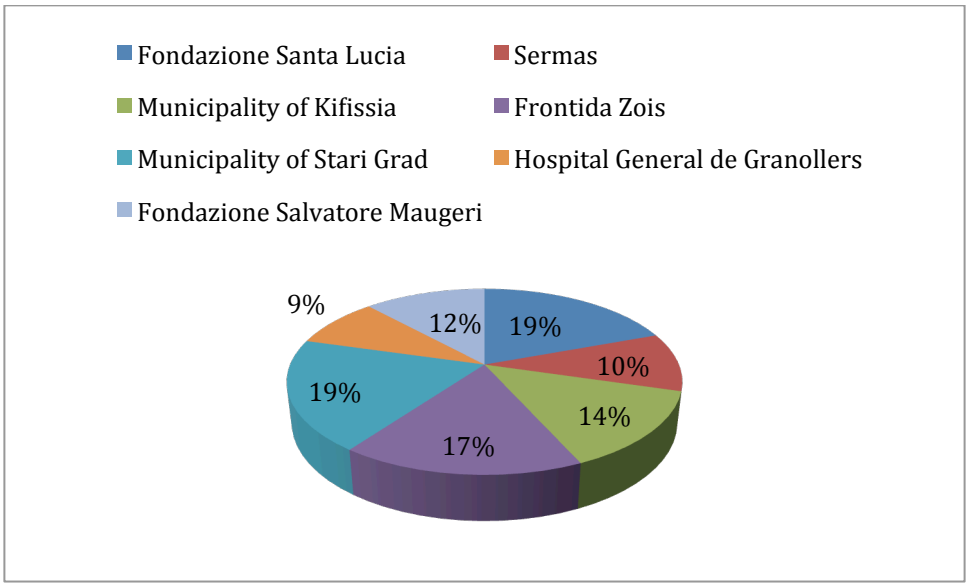


Figure 1 - Distribution of the final sample subjects for pilot sites.

The analyses of results were executed on 423 participants, 73 participants were excluded as drop-outs (14,7%). Each participant of the whole sample was randomized into the 4 arms (kind of treatments) of the study (i.e., mixed, pure motor, pure cognitive, placebo) (Figure 2) following a two steps randomization for: i) motor (motor, mixed) and non-motor (cognitive, placebo) and ii) for cognitive (cognitive, mixed) and non-cognitive (motor, placebo).

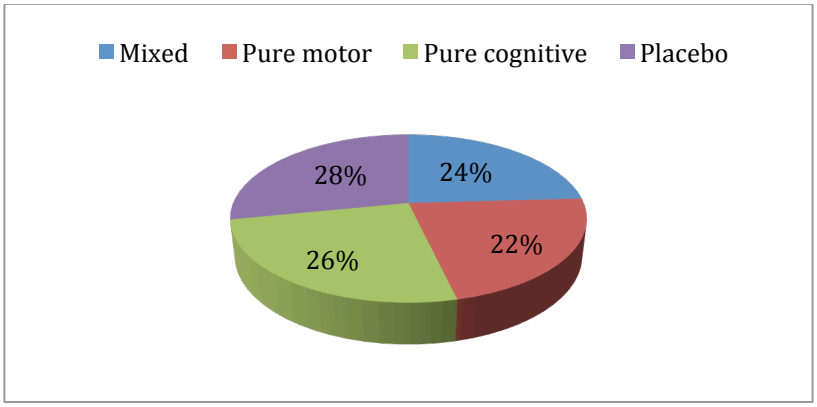


Figure 2 - Randomization of the final sample subjects into the 4 different arms.

For this reason, the results will come from the comparison between:

- **motor/non-motor** conditions;
- **cognitive/non-cognitive** conditions;
- and finally also comparing (as post-hoc analysis) **the 4 different kinds of treatment** (motor, cognitive, mixed and placebo).

We acquired all **mobility**, **cognitive**, **behavioural** and **functional** outcomes:

- before the start of the period of treatment (PRE-T0);
- after the 3-month period of treatment (POST-T1);
- after a 3-month period of follow-up (FU-T2).

For this reason we analysed each outcome separately with six different mixed analyses of variance (ANOVA):

- with as between subject variable the **kind of condition or treatment** (motor/non-motor; cognitive/non-cognitive; 4 different treatments)
- with as within subject variable **time** with 2 time-points (PRE-T0/POST-T1) and three time-points to evaluate the effect of the follow-up (PRE-T0/POST-T1/FU-T2).

2.2 Descriptive statistics at baseline

Table 1 resumes all baseline (PRE-T0) means and standard deviations for demographic variables and each single outcome variable. We also compared with a one-way ANOVA any differences for each variable between the different kinds of treatment. We found no significant differences comparing motor/non-motor, cognitive/non-cognitive and comparing the 4 different arms.

According to the inclusion criteria, we included in the sample:

- **elderly** (age 65-97 years) (64.3% females), with 10 years of formal education on average;
- **at risk of falls** (Tinetti scale ≤ 20 and/or at least 1 fall in the previous year)[3];
- **without dementia** (MMSE score ≥ 20).

Table 1 - Sample description at baseline.

Motor/non-motor		Motor		Non motor	
Cognitive/non-cognitive		Non cognitive	Cognitive		Non cognitive
Kind of treatment		Motor	Mixed	Cognitive	Placebo
Domain	Variable	f(m)	f(m)	f(m)	f(m)
Demoghraphic	Sex	61(33)	72(30)	60(48)	79(40)
		m(sd)	m(sd)	m(sd)	m(sd)
	Age	74,2(7,3)	74,8(8)	73,7(7,1)	75,7(8,7)
	Education	10,2(4,1)	9,6(4,4)	9,8(4,1)	10(4)
Mobility	N of falls	1,2(1,2)	1,4(1,2)	1,6(1,3)	1,2(1)
	Tinetti_Balance	12(3,3)	11(3,5)	11(3,3)	11(3,2)
	Tinetti_Gait	8,6(2,6)	8,2(2,8)	8,1(2,5)	8,3(2,9)
	FES-I_Total	30,4(10,6)	31,4(9,7)	30(9,9)	31,5(11,4)
	6MWT_meters	306,1(156,2)	296,7(157)	307,1(167)	307,7(177,4)
	10MWT_seconds	13(8,8)	14,2(9)	17,4(26,7)	13,8(8)
Cognitive	MMSE_Total	25,6(4,9)	25,7(4,5)	26(4,1)	25,7(4,7)
	Clock	6,7(3,3)	6,9(3,1)	7,2(3,1)	6,8(3,1)
	RAVLT_Immediate recall	33,4(13,1)	31,9(12,7)	34,2(13,3)	32,3(11,2)
	RAVLT _Delayed recall	6,1(3,7)	5,8(3,5)	6(3,6)	5,8(3,6)
	ROCF_Copy	25,6(9,7)	23,7(9,9)	25,8(9,7)	24,3(9,6)
	ROCF _Immediate recall	11,6(8,1)	10,5(7,3)	11,3(7,8)	9,6(7,2)
	ROCF _Delayed recall	10,4(7,9)	8,2(6,8)	10,2(7,3)	7,6(6,4)
	Digit Span_foreward	5,7(1,5)	5,2(1,4)	5,5(1,3)	5,5(1,9)
	Digit Span_backward	3,6(1,5)	3,5(1,2)	3,7(1,2)	3,6(1,5)
	Corsi Span_foreward	4,9(1,4)	4,6(1,2)	4,8(1,2)	4,6(1,6)
	Corsi Span_backward	3,8(1,4)	3,5(1,2)	3,8(1,3)	3,5(1,3)
	Coloured Progressive Matrices	24,8(7,5)	23,8(6,8)	25,2(7,4)	23,2(7,6)
	Trail Making Test_A	87,9(52,8)	80,5(51,7)	73(31)	88,3(45,5)
	Trail Making test_B-A	100,7(68,2)	126,3(77,9)	107,7(68,2)	98,6(61,1)
	Verbal Fluency	25,6(12,7)	24,8(12,7)	24,6(12,4)	25,3(10,9)
	Boston Naming	43,7(9,7)	42,1(10,5)	44,8(9,5)	42,8(11)
Behavioral	STAI Y_State	38,4(9,6)	38,6(10,8)	36,8(9,5)	37,1(10,3)
	STAI Y_Trait	41,5(8,5)	41(9,9)	40,3(9,1)	40,1(9,2)
	GDS	5(3,1)	5,2(3,3)	4,8(2,9)	5,7(3,2)
Functional	WHOQoL_Physical area	21,2(3,5)	21,1(3,4)	21,3(3,4)	21,8(3)
	WHOQoL_Psychological area	19,7(3,1)	19,4(3)	19,6(2,8)	19,7(2,9)
	WHOQoL_Social area	10,4(2)	10,2(2,2)	10,2(2,1)	10,1(2,1)
	WHOQoL_Environment area	27,4(5)	28,3(4,8)	27,6(4,6)	27,4(5,2)
	Barthel Index	86,7(18,7)	86,4(19,6)	86,1(20,5)	86,2(18,1)
	IADL	6,2(2,3)	6,3(2,3)	6,1(2,2)	5,9(2,5)

3 PRE-POST TREATMENT EFFECTS AND FOLLOW-UP EFFECTS OF THE I-DONT-FALL SOLUTION.

A summary of results of our analysis is presented in Table 2 for each outcome and for each of the six ANOVAs that we performed.

Table 2 - Results for the whole sample for the three different ANOVAs (motor/non-motor; cognitive/non-cognitive; all treatments) with 2 time-points (pre/post) and 3 time-points (pre/post/follow-up) reporting F and p. Significant results (p<.05) are highlighted, whereas others results are approaching significance (0.05>p<.2).

		Motor/nonMotor				Cognitive/nonCognitive				Post-hoc (all treatments)			
		Pre/post treatment		Follow-up		Pre/post treatment		Follow-up		Pre/post treatment		Follow-up	
		F	p	F	p	F	p	F	p	F	p	F	p
Mobility	Tinetti_Balance	2,534	0,112	3,434	**0,045**	-	-	-	-	-	-	-	-
	Tinettit_Gait	-	-	-	-	-	-	-	-	-	-	-	-
	FES-I_Total	5,981	**0,015**	2,374	0,097	-	-	-	-	2,367	0,071	1,976	0,071
	6MWT_meters	2,356	0,126	2,344	0,111	-	-	-	-	-	-	-	-
	10MWT_seconds	-	-	-	-	-	-	-	-	-	-	-	-
Cognitive	MMSE_Total	-	-	-	-	-	-	-	-	-	-	-	-
	Clock	-	-	-	-	-	-	-	-	-	-	-	-
	RAVLT_Immediate recall	-	-	-	-	2,771	0,097	-	-	-	-	-	-
	RAVLT _Delayed recall	-	-	-	-	3,329	0,069	6,508	**0,002**	1,782	0,15	2,504	**0,024**
	ROCF_Copy	-	-	-	-	-	-	-	-	-	-	-	-
	ROCF_Immediate recall	-	-	-	-	2,698	0,101	-	-	-	-	-	-
	ROCF_Delayed recall	-	-	-	-	6,471	**0,011**	2,388	0,097	2,391	0,068	-	-
	Digit Span_foreward	-	-	-	-	-	-	-	-	-	-	-	-
	Digit Span_backward	2,093	0,149	-	-	-	-	-	-	-	-	-	-
	Corsi Span_foreward	-	-	-	-	-	-	-	-	-	-	-	-
	Corsi Span_backward	-	-	2,456	0,09	-	-	-	-	-	-	-	-
	Coloured Progressive Matrices	-	-	-	-	-	-	-	-	1,737	0,159	-	-
	Trail Making Test_A	-	-	-	-	-	-	-	-			-	-
	Trail Making Test_B-A	-	-	-	-	-	-	-	-	1,715	0,164	-	-
	Verbal Fluency	-	-	-	-	-	-	-	-	-	-	-	-
	BostonNaming	-	-	-	-	-	-	-	-	-	-	-	-
Behavioral	STAI Y_State	3,447	0,064	-	-	-	-	2,88	0,059			1,475	0,187
	STAI Y_Trait	4,941	**0,027**	-	-	-	-	2,345	0,099	1,808	0,145	1,468	0,189
	GDS	-	-	-	-	-	-	-	-	-	-		
Functional	WHOQoL_Physical area	-	-	-	-	-	-	-	-	-	-	-	-
	WHOQoL_Psychological area	-	-	-	-	2,444	0,119	-	-	-	-	-	-
	WHOQoL_Social area	-	-	-	-	-	-	-	-	-	-	-	-
	WHOQoL_Environment area	-	-	-	-	-	-	-	-	-	-	-	-
	Barthel Index	-	-	-	-	-	-	-	-	-	-	-	-
	IADL	-	-	-	-	-	-	-	-	-	-	-	-

4 RESULTS ON PRIMARY OUTCOMES: FEAR OF FALLING, RISK OF FALLS AND MOBILITY.

4.1 Fear of falling

The main result that we obtained was a significant **reduction of fear of falling** measured with the FES-I scale [4] after the **motor condition** compared to the non-motor condition (Figure 3) as evidenced by the significant interaction ($p<0.05$). However, during the follow-up period the effect of the motor condition was lost (Figure 3).

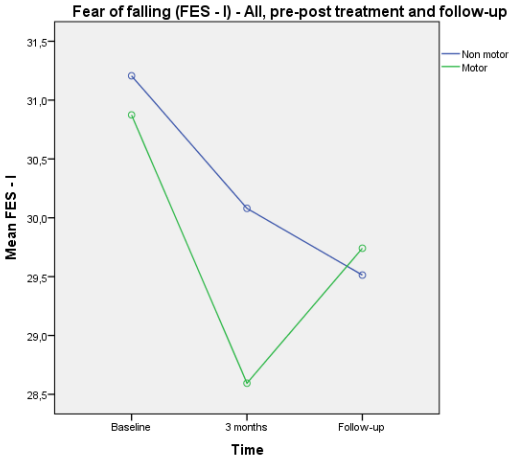


Figure 3 - Effect of the motor treatment on fear of falling (FES – I).

Looking at the effect of different arms of the study (approaching significance $p=0.071$), the driving treatments were the **mixed** and the **pure motor treatment,** whereas the effect was absent for the cognitive and the placebo conditions (Figure 4).

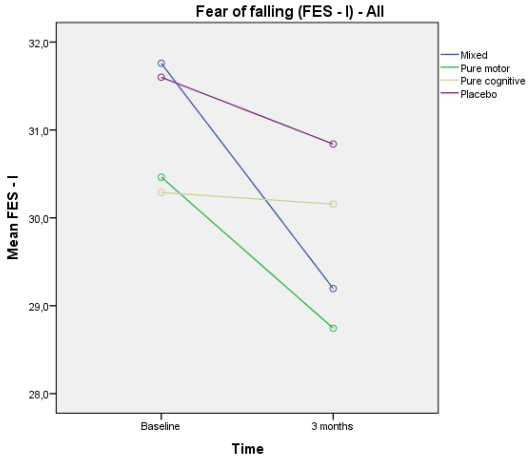


Figure 4 - Effect of the mixed and pure motor treatment on fear of falling (FES – I).

4.2 Risk of falling

We also obtained a trend towards a **reduction of risk of falls** since we obtained after the **motor condition** compared to the non-motor condition an approaching significance (p=0.1) **increased of balance** measured with Tinetti POMA scale of balance and it seems that the effect on balance was primarily driven by the **mixed** treatment (Figure 5).

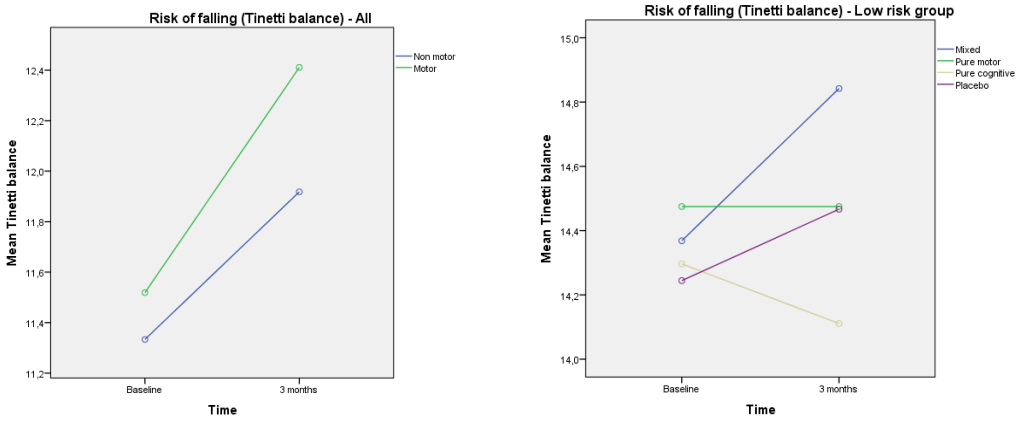


Figure 5 - Effect of the motor treatment on risk of falling (Tinetti balance).

4.3 Mobility.

Moreover, an approaching significance (p=0.1) **increase of the mobility** of participants is present after the **motor condition** measured with 6-Minute Walking Test (6MWT) [5] that tends to be maintained after the treatment (Figure 6).

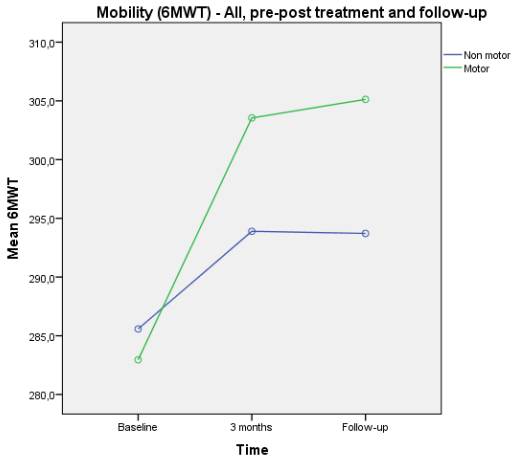


Figure 6 - Effect of the motor treatment on mobility (6MWT).

Finally, we obtained **a general reduction of about 43% of number of falls** comparing the year before to be enrolled into the study and the nine months after the enrolment comprising the training period of 3 months and a follow-up period of 6 months (Figure 7).

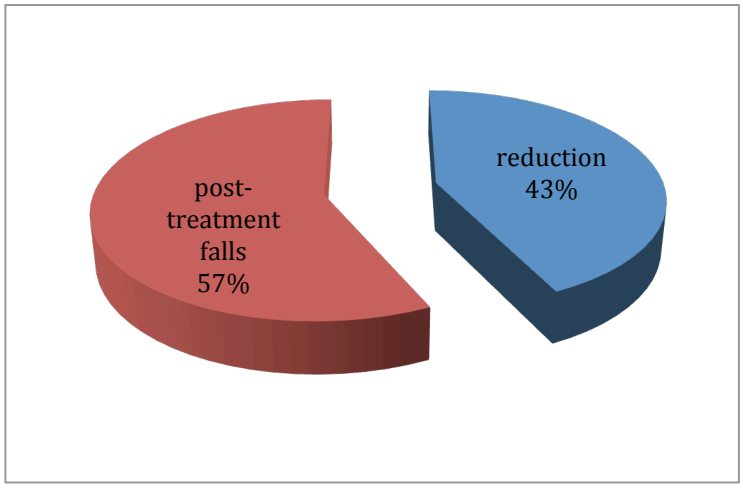


Figure 7 - Reduction of falls

4.4 Analyses High vs Low risk of falls

We were interested in the effect of the **level of risk of falls** of participants on primary outcomes and to see whether the **mixed treatment** compared to single treatments might be more effective as prevention tool in the low risk participants.

Thus, we split our sample into 2 sub-samples (high and low risk of falls) according to two criteria, i.e. number of falls in the previous year and total score at Tinetti (see Table 1). Subjects with 1 fall and with Tinetti higher than 20 were considered at low risk, all the others were at high risk of falls.

Table 3 - Criteria used for high/low risk group classification

n of falls (previous year) / Score at Tinetti	≤ 1	≥ 2
≥ 21	Low risk	High risk
≤ 20	High risk	High risk

We obtained two groups: 167 subjects were at low risk and 256 at high risk. The two samples differed for age and education and for all motor variables ($p<0.01$). Then, we performed two different 3-ways mixed ANOVAs, one for **FES-I** and **Tinetti Balance** as dependent variable, with as between subject factors the level of fall risk (high/low) and the kind of treatment (mixed, single and placebo), and within subject factor the time (pre/post training).

We obtained for both outcomes significant 2-way interactions (time x fall risk level; $p<.01$) suggesting (see Figure 8) that the **high risk group showed only a general improvement**, whereas the **low risk group improved more after the mixed treatment** respect to the single training conditions and the placebo condition.

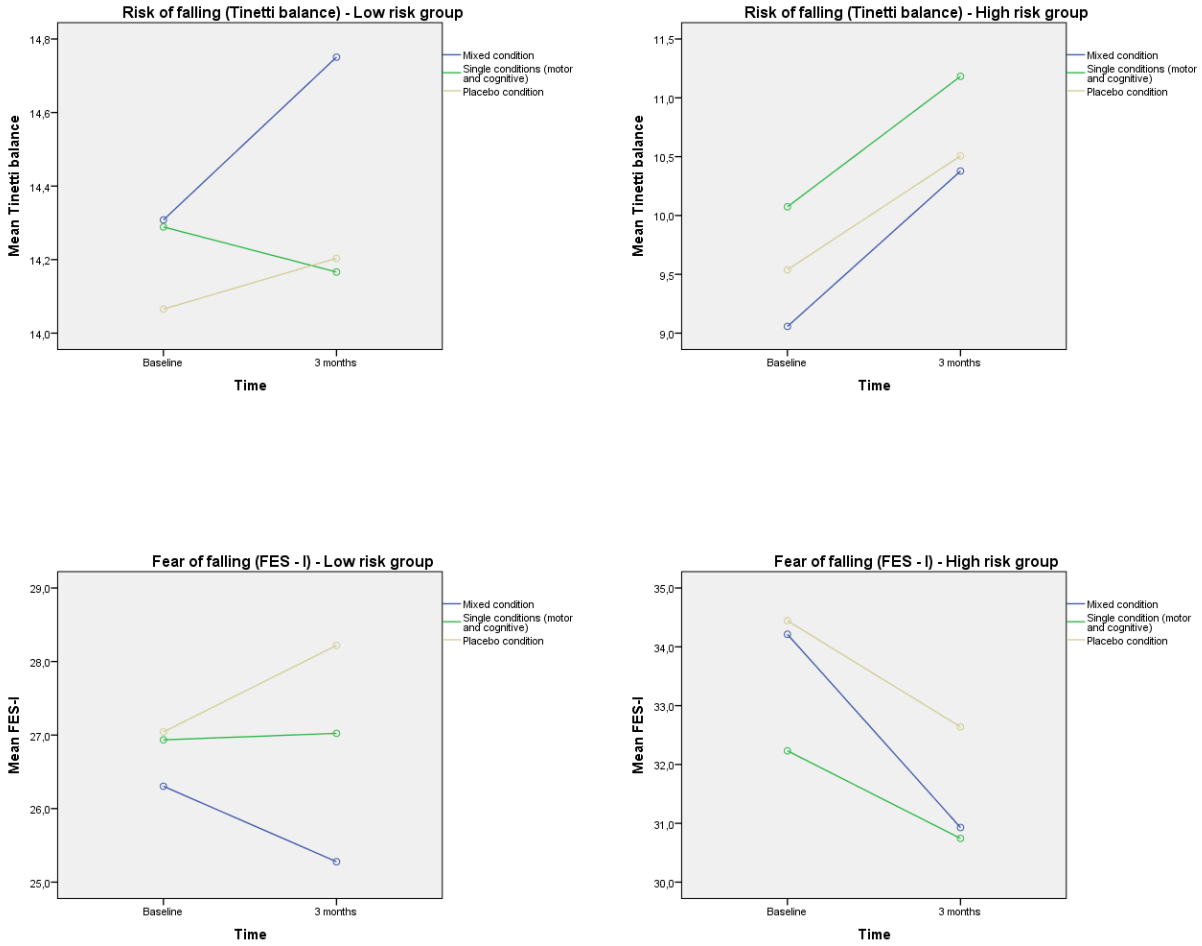


Figure 8 - Effects on primary outcomes of risk of falls and different treatments.

In conclusion, the results on **primary outcomes** support the I-DONT-FALL project hypothesis that a 3-month period of **motor treatment alone or mixed treatment** with a cognitive treatment on executive functions, contributes to **reduce the fear of falling** and **the risk of falling** that are the main mobility outcome measures of this study. Although improvements in mobility seem to be maintained during the follow-up period it is not the same for fear of falling that seems to increase back after the end of the treatment. Moreover, the **mixed treatment** seems to be particularly indicated for **prevention** since it seems to be the best treatment to improve balance (thus reducing the risk of falls) and reduce the fear of falling in participants with a low risk of falls. Elderly with a high risk of fall seems to benefit from all kinds of treatment since they are more severely damaged.

5 RESULTS ON SECONDARY OUTCOMES: COGNITION, BEHAVIOUR, FUNCTIONAL ABILITIES AND IMPACT OF TECHNOLOGY.

5.1 Cognition

About cognitive outcomes we obtained some significant improvements in **episodic memory** after the **cognitive condition**, in particular verbal memory measured with Rey Auditory Verbal Learning Test – delayed recall (RAVLT)[6] that is a memory test with a strong **executive** component, and visuo-spatial memory, measured with Rey Osterrieth Complex Figure - delayed recall (ROCF)[7]. For verbal memory, we obtained also some significant effects ($p<.01$) also for the follow-up period (Figure 9).

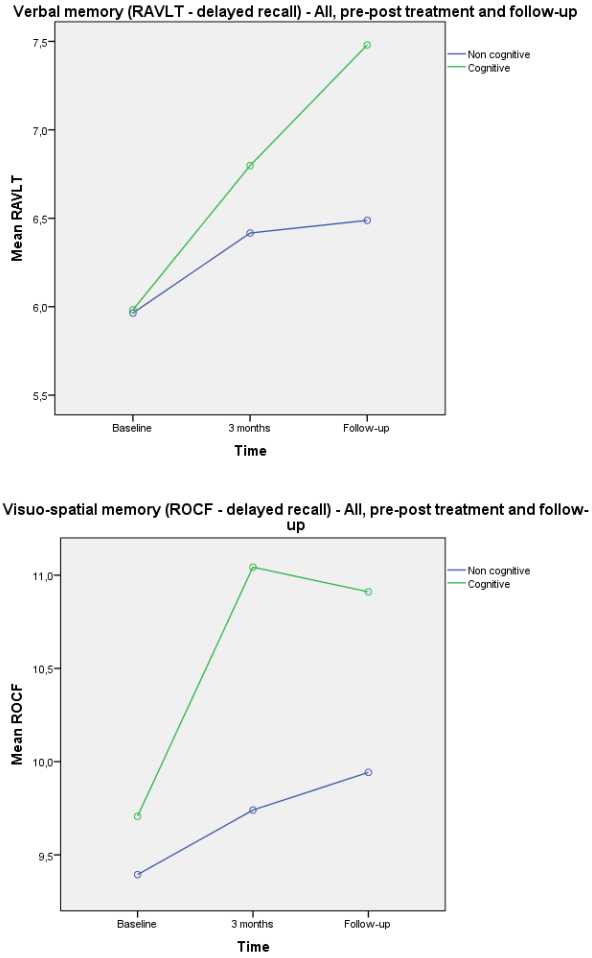


Figure 9 - Effect of the cognitive treatment on verbal memory (RAVLT) and visuo-spatial memory (ROCF test)

It is interesting to note that the improvement after the cognitive treatment at the RAVLT test was similar to the one after the motor treatment (Figure 10). This might be probably due to the executive function component of motor exercises and the common neural substrate to motion and executive functions (i.e., the fronto-parietal network).

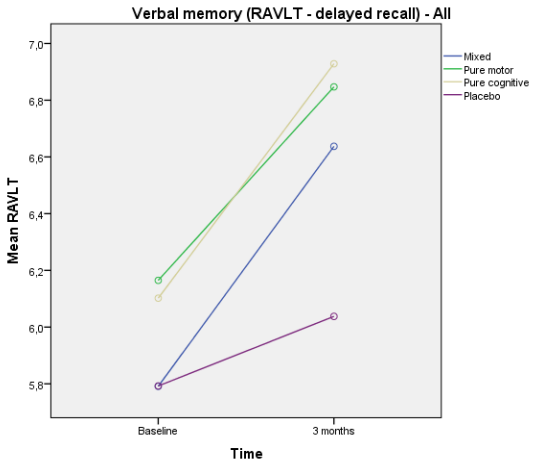


Figure 10 - Effect of the different treatments on verbal memory (RAVLT)

Finally, on two tests of **executive functions**, the Coloured Progressive Matrices (CPM)[8] and Trail Making Test – version B-A (TMT)[9] we found a trend toward significant results (p=0.16) comparing all **4 treatments**. However, also in this case the effect of the motor treatment was similar to the one of the cognitive treatment and in the case of the reasoning test (Coloured Progressive Matrices) it seems that the combination between the two treatments, i.e. the **mixed condition**, produces even larger effects (Figure 11).

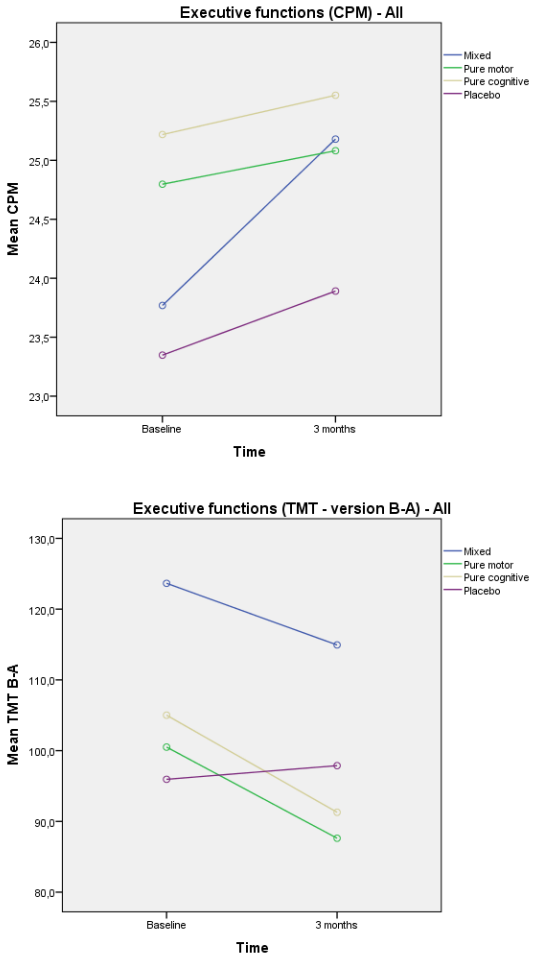


Figure 11 - Effect of the different treatments on executive functions tests (CPM and TMT)

5.2 Behaviour

We obtained also a significant (p<.0.05) reduction of **anxiety** of participants after the motor condition measured with the State Trait Anxiety Inventory Y – Trait scale (STAI Y)[10] (Figure 12). In this case it is interesting to note that the effect was primarily driven by the **mixed treatment**.

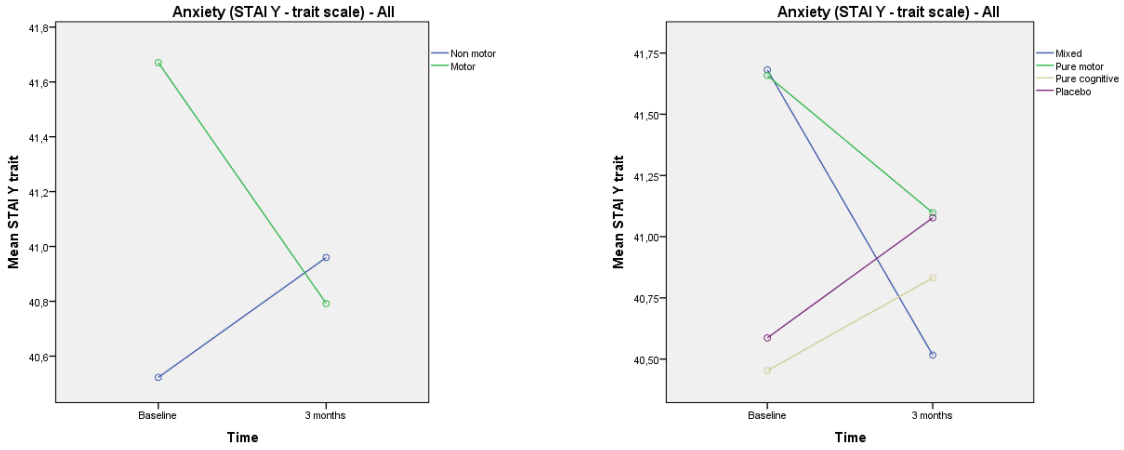


Figure 12 - Effect of the motor condition and of the different treatments on anxiety (STAI Y, trait scale).

5.3 Functional

Although we observed only a general improvement of functional abilities, from an inspection to the Barthel Index [11] effects across the different kinds of treatment we can observe a trend towards a greater effect for the **mixed treatment** respect to the others (Figure 13).

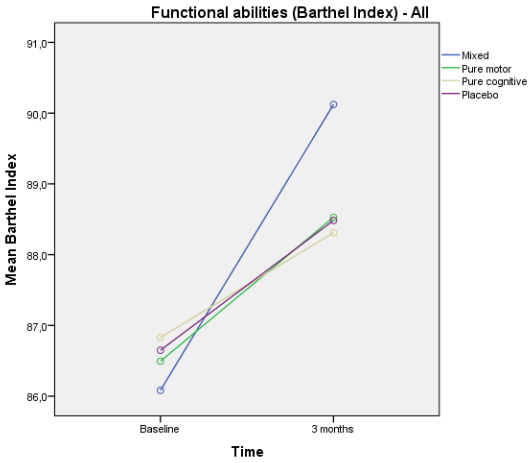


Figure 13 - Effect of the different kinds of treatment on functional abilities (Barthel Index).

About **quality of life**, we found a trend toward a significant positive effect (p=0.1) of **cognitive condition** on the **psychological area** of the WHOQoL questionnaire [12](Figure 14).

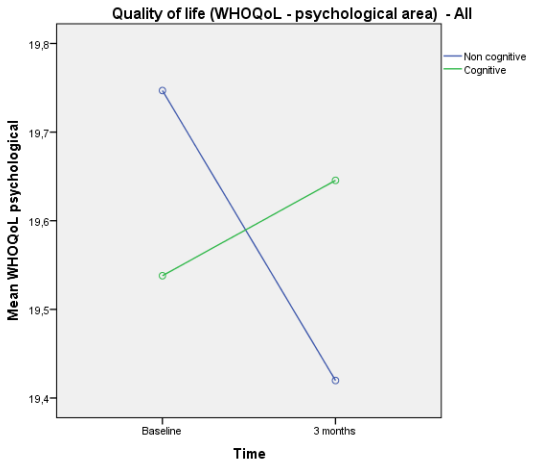


Figure 14 - Effect of the cognitive condition on the psychological area of quality of life.

Finally, about the **impact of technology**, we obtained positive effects on user's satisfaction measured with Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST)[13] and with the Psychological Impact of Assistive Device Scale (PIADS)[14] (Table 3) that did not differ across different kinds of treatment.

Table 4 - Impact of technology.

	Kind of treatment					
	Mixed	Motor	Cognitive	Placebo		
	m(sd)	m(sd)	m(sd)	m(sd)	F	Sig.
PIADS_Ability	1(0,9)	1,1(1)	0,9(1)	1,1(0,1)	0,482	0,695
PIADS_Adaptability	1(0,9)	1,2(1)	0,7(0,9)	0,9(0,8)	1,531	0,209
PIADS_SelfEsteem	0,6(0,6)	0,8(0,9)	0,7(0,8)	0,6(0,8)	0,745	0,527
QUEST_Devicesatisfaction	4,2(0,8)	4,1(0,7)	4(0,7)	4,2(0,6)	1,293	0,277
QUEST_Servicersatisfaction	4,5(0,6)	4,5(0,5)	4,5(0,5)	4,6(0,5)	0,627	0,598

In conclusion, we obtained some positive effects of **cognitive treatment** on **memory** and **executive functions**. Particularly interesting is the **similar effect that emerged between cognitive and motor treatment** with a trend toward an **additive effect of the two in the mixed treatment** in an executive function test. This stronger effect of the **mixed** condition seems to be suggested also by results on **functional abilities and behaviour** since the mixed and motor treatments significantly reduced anxiety of participants.

5.4 Conclusions

The main outcome of this study was to evaluate the impact of different kinds of treatments on the **risk of falls** and the main indicators of risk of falls are previous falls, mobility and fear of falling. Our expectations were not to avoid any further falls during the study, although we found a reduction of 43% of falls in general respect to the year prior to the inclusion in the study. Instead, we were interested in some appreciable indexes of fall risk to detect differences

among different kinds of treatment: a motor, a cognitive and the combination of the two. The results of the validation study of the I-DONT-FALL project confirm the existing literature that a **motor treatment** reduces the risk of falls in elderly that are at risk of subsequent falls. Moreover, motor treatment seems to benefit also executive functions abilities that are fundamental for mobility and might increase, if damaged, the risk of falls in the elderly. Moreover, our study suggest that combination of the motor treatment with a cognitive one focused on executive functions, i.e. a **mixed treatment**, might increase balance of elderly, especially the one with only a low risk of falls and thus it might be a more effective solution for fall risk **prevention**. The mixed condition seems to be also the one that is more effective to reduce anxiety and to improve functional abilities. Finally, all devices used in the I-DONT-FALL solution exerted positive impact.

The present results contribute to improve knowledge about the complementarity of mobility and cognition in order to develop a more effective ICT solution to prevent and reduce falls in the elderly.

6 FALL DETECTION

During a detection period of three months, users at home were monitored by the WIMU/i-Walker the system identifies a possible fall of the user and produces an alarm event. The configured call centre receives the alarm notification and an operator tries to contact the patient on the mobile phone, to check if the user actually fallen. A sample of 19 users (4 drop outs, 21%) participated to the fall detection part of the IDF study and Table 4 presents demographic and baseline characteristics of this sample. We also compared pre/post outcomes with a non parametric Wilcoxon test and we found a significant improvement in gait abilities ($z=-2.831$; $p<0.01$) and global cognition ($z=-2$; $p<0.05$) and an approaching significance effect on functional abilities measured with the Barthel index ($z=-1.3$; $p<0.194$).

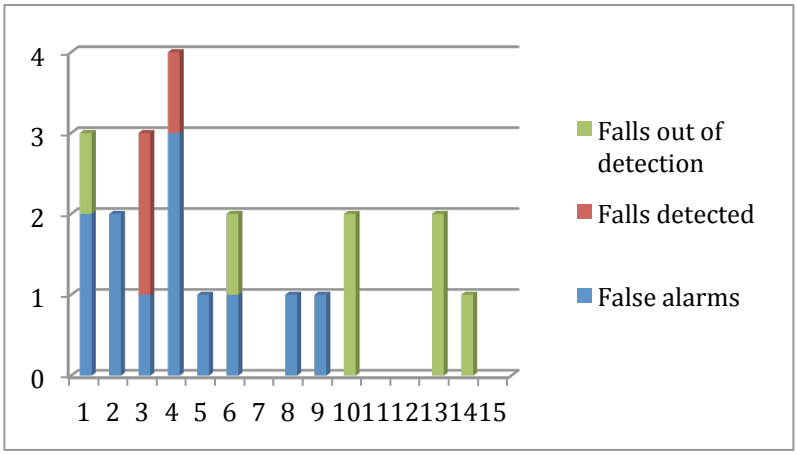
Table 5 - Demographic data of the participants and Pre-post detection period outcomes. In yellow the significant improvements.

	T0		T1	
	f/m			
Sex	5/10			
	Mean	**Dev.st.**	**Mean**	**Dev.st.**
Age	73,7	7,9		
Education	13,1	3,7		
Tinetti Balance	11,4	3,0	11,9	2,8
Tinetti Gait	8,3	2,3	9,8	2,5
FES I	26,3	4,8	27,5	4,3
MMSE	27,7	2,7	27,8	2,8
WHOQoL TotalPhisical	22,9	2,0	22,4	1,7
WHOQoL Totalpsycological	18,9	2,9	18,5	2,6
WHOQoL Totalsocial	11,5	1,8	11,1	1,7
WHOQoL Totalenvironmental	27,9	4,4	28,2	4,0
Barthel	80,7	13,5	84,6	9,6
IADL	5,1	1,8	5,3	2,0

6.1 Analyses of falls

This section will analyse the validity of the fall detector according to alarms received by TESAN call centre. First, Table 5 shows the distribution of the falls and false alarms in different users.

Figure 15 - Distribution of falls and false alarms among different users



From the information gathered, the parameters needed for the validation of the fall detector are:

- **True positives - TP (a fall occurred and it was detected):** 3
- **False positives - FP (there was not a fall, but the sensor said it was):** 12
- **False negatives - FN (there was a fall, but the sensor didn't recognise it):** 0
- **True negatives - TN (there was not a fall, and the sensor didn't provide any kind of alarm):** 1335 – This number has been obtained as the total number of days for the users in the detection sample during which no alarm was generated and there was not falls.

We calculated sensitivity that measures the proportion of falls correctly identified as such and specifiticy that measures the proportion of non falls that are correctly identified as such.

The performance parameters of the fall detector that can be derived from this numbers are:

- **Sensitivity [true positive/(true positive + false negative)]:** 100 %
- **Specificity [true negative/(true negative + false positive)]:** 99 %

6.2 Conclusions

These results indicated a high detection performance of IDF detection system with the very good result of no missed condition in which there were a fall but the system did not detect it and with a low number of false positive. All falls that occurred when the system was operating were detected. Most of the falls that happened when the system was not operating occurred in the bathroom and during the night which are the conditions in which falls most occur. Moreover, the detection system seems to improve mobility and functional abilities of participants.

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ANNEX I IDF WIMU

Six Minutes Walking Test: WIMU-based assessment

Background

Trunk movement during walking plays a critical role in successful locomotion and contributes to gait stability among older people [1]. This has been the primary motivation for investigating several gait variables derived from trunk accelerometry, with the aim to predict the risk of falls [2]. In a broader perspective, a wearable inertial sensor system that can efficiently capture and analyze quantitative mobility data could improve fall risk assessment [3]. To date, inertial sensor use in fall risk assessment has varied by study methodology and assessment variables. The approach pursued in the IDF project was inspired by recent works, which include [4][5][6].

The purpose of the assessment study during IDF was thus to determine whether properly selected gait variables derived from lower trunk accelerometry were associated with the fall risk; another purpose of the IDF assessment study was to discover the relation of these gait variables with the physical and cognitive performance of the subjects involved in the study.

Experimental scenario

In the IDF experiments, lower trunk accelerations were measured using the WIMU, configured as a wireless data-logger of magneto-inertial sensor data integrated with an android smartphone, during a six minutes walking test (6MWT). The WIMU was mounted at the L3 spinous process (lower trunk) using a Velcro belt carefully placed not to restrict the subjects' movement. Subjects were asked to stand still in their upright posture for few seconds before starting the test. No specific instructions were given to the operators to calibrate the WIMU sensors; care was required in fixing the WIMU to the body so as to align the device local frame to the anatomical axes. Trunk linear accelerations were measured along the vertical (VT), anteroposterior (AP) and mediolateral (ML) axes, sampled at 100 Hz. Collected data were uploaded to the android smartphone via Bluetooth. The stored data were transferred to the Careportal, following a standardized protocol.

Rationale

The gait variables chosen for the WIMU-based 6MWT assessment were (see below for an explanation of their meaning and method of computation):

- Stride time
- Cadence
- Stride time variability
- Root Mean Square (RMS) of the VT acceleration
- Harmonic Ratio (HR) of the AP, VT and ML accelerations

Recently, these gait variables, or a subset of them, have been considered in several research reports [7], sometimes with a specific focus in the study of falls

[5]. Moreover, another parameter was the walked distance, D. The walked distance was not computed using the WIMU sensor data, but it was measured manually. Walked distance can be considered a proxy to walking speed, which can be estimated indeed as the ratio between D and the time elapsed during the test. Recently, a number of papers have been published concerning the application of smartphone technology to the development of a practical and easy-to-use tool for the rehabilitation professionals to manage the 6MWT [8]. Strike timing and walked distance estimation were performed in a semi-automatic way using the inertial sensors embedded in the smartphone. While a similar approach would have been considered here, we preferred to opt for the use of an external sensor unit, namely the WIMU. This was pursued with the aim to extend the number and type of gait variables that could be involved in the assessment (in particular, the HRs) and to be compliant with the experimental setups that are described in the literature [4][5][6].

Gait variables

Basic prerequisites for gait analysis are the assessment of spatio-temporal gait variables and the analysis of movements within subsequent stride cycles. This parameterization of gait requires the detection of subsequent foot contacts (onset and end of stride cycles). As a matter of convention, the stride cycle is defined as the interval between two subsequent right foot contacts. Hence, the stride starts with a left step, which is followed by a right step.

The stride time T, expressed in seconds, is the time elapsed from the first contact of the (right) leg with the ground to the next. A gait variable related to stride time is the cadence Cad, expressed in beat per minute (bpm), namely the number of steps per minute:

$$Cad = 120/T \quad (1)$$

The stride time variability T_d is the coefficient of variation of T (standard deviation divided by mean value x 100). T and T_d were considered in [5]. The issue of gait variability is challenging since variability in motor function can be regarded either as a marker of impaired motor control or as a positive sign of system adaptation [9]. Gait involves cycles that are characterized by regularity, but also balance components characterized by variability. Identifying such components, while taking into account noise random error, is challenging. In case of large random error, the reliability will be low, and all the variables will show a large variability. Thus the variability caused by random error may be even misinterpreted as an indicator of either adaptability or impairment.

The RMS value of acceleration components, and in particular the one along the VT direction, RMS_{VT} is a popular kinematic measure. RMS_{VT} is applied to the estimation of (a) the energy expenditure in activity counters [10], (b) the walking speed, using machine learning techniques [11] or simple biomechanical models (i.e., biped rolling foot and the inverted pendulum model) [12].

HRs are dimensionless quantities that, derived from trunk accelerations, offer insight into the underlying mechanism of balance control during gait [13]. HRs provide information on the ability of subjects to control their trunk smoothly during walking, giving an indication of whole body balance and coordination

(gait stability). HRs were measured in the three anatomical directions, namely HRML (medio-lateral HR), HRVT (vertical HR), and HRAP (antero-posterior HR). Significantly lower HRs were found in unstable older adults (self-reported falls or unsteadiness) when compared to normal groups. Higher HRs indicate smoother and more stable trunk movement during gait [14].

Typical AP and VT acceleration patterns of the lower trunk during walking exhibit two major acceleration peaks per stride, one for each step; thus, frequency decomposition through Fourier analysis yields a dominance of the second harmonic and subsequent even harmonics. The even harmonics for the AP and VT indicate the in-phase components of the signal, whereas the odd harmonics comprise the out-of-phase components (minimized in healthy gait). HR_{VT} and HR_{AP} were calculated by dividing the even harmonics (summed amplitudes of the first 20 even harmonics) by the odd harmonics (summed amplitudes of the first 20 odd harmonics). Conversely, the ML accelerations exhibit one acceleration peak per stride, resulting in dominance of the first harmonic and subsequent odd harmonics. Here, the odd harmonics are in-phase and even harmonics are out-of-phase. Therefore, HR_{ML} was calculated from a ratio of the odd harmonics divided by the even harmonics.

Method

The methods that are usually considered as gold standards for detecting foot contacts are impractical or even impossible to use when gait is studied under real-life conditions (e.g. optoelectronics, sensing mats), hence the suggested use of body-fixed sensors and well-proven methodologies for their application. Several studies have addressed the relationship between measured accelerations (on trunk, thigh, shank and foot) and spatio-temporal gait parameters. The gait variables of interest were extracted using the assessment code, developed at SSSA and written in MATLAB (The Mathworks, Natick MA). We adapted the method proposed by Zijlstra and Hof [15] for stride time determination, see block Step detector in Fig. 16.

This method was originally validated in normal-walking conditions (healthy adults), although it has been used without substantial modifications for experiments carried on older people and pathologic subjects [16][17]. The consensus in the literature is that the waist location can be critical to have an accurate and robust detection of the contacts of the foot with the ground. In this regard, the shank can be a better anatomical placement site [18][19]. Our decision was to slightly modify the original Zijlstra method. Peak detection was applied to the low-pass filtered VT acceleration (coarse-search) – the low-pass filter was a 4th order dual-pass Butterworth filter with cut-off frequency at 2 Hz. In a refinement of the coarse-search method for stride timing, the AP acceleration was analyzed for the first peak preceding the peak of the low-pass filtered VT acceleration, whose time location was taken as the instant of foot contact at the start of each gait step. For the fine-search procedure, the AP acceleration was filtered using a 4th order dual-pass Butterworth filter with cut-off frequency at 10 Hz. The ML acceleration was low-pass filtered using a 4th order dual-pass Butterworth filter with cut-off frequency at 2 Hz before being used to disambiguate steps that were initiated with the right and left foot, yielding the stride time.

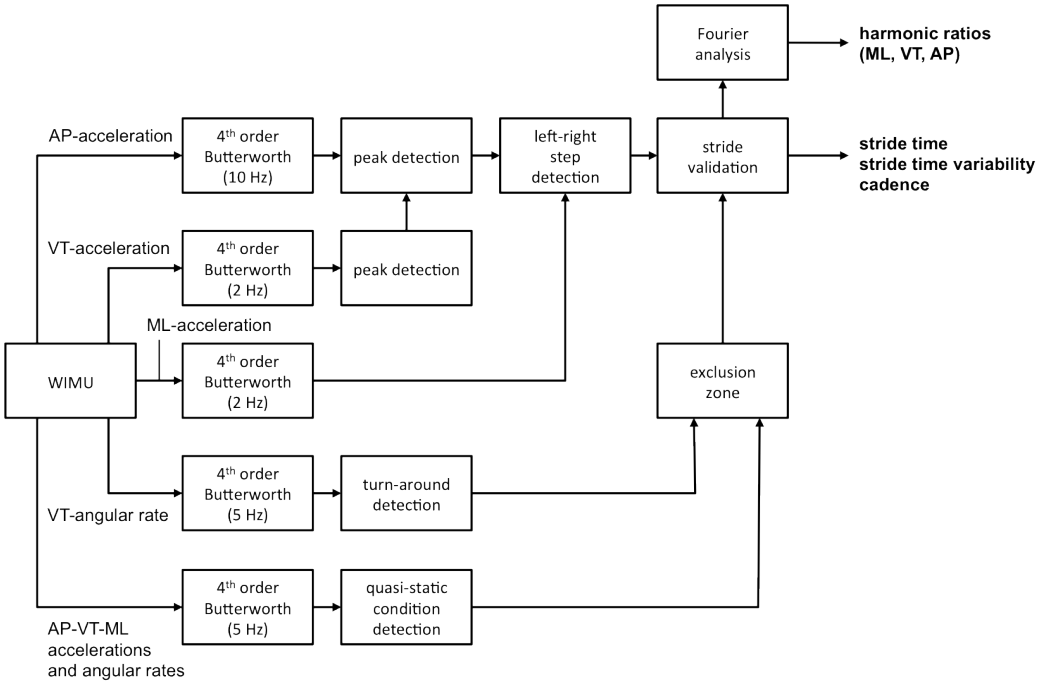
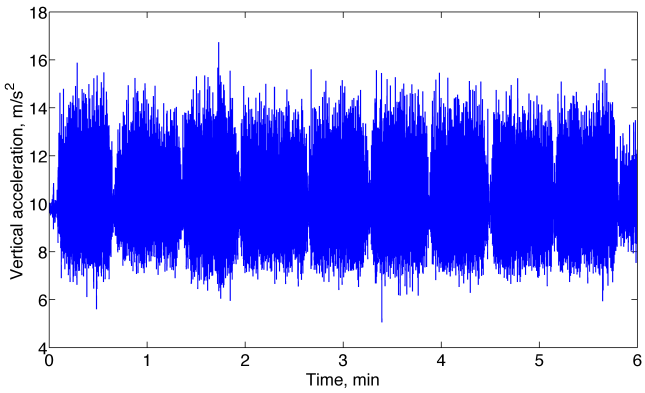


Figure 16 - Flow-chart of the assessment code.

The 6MWT was implemented by asking patients to walk along a corridor with two small landmarks on the floor to mark the start and end points of each trip. Accordingly, when subjects were involved in the turn-around motion, the stride detection method failed to work properly. We propose to use the VT angular velocity, low-pass filtered using a 4th order dual-pass Butterworth filter with cut-off frequency at 5 Hz, to compute what we call exclusion zones. The filtered angular velocity was evaluated respect to a fixed threshold value to identify approximately where the turn-around motions took place. Actually, another problem of stride validation occurred since subjects, sometimes, stopped walking, maybe for having some rest or due to sudden balance problems. We implemented a method to detect quasi-static conditions based on inertial sensor data (accelerometer and gyroscope) [20]. Finally, the exclusion zone was taken from two seconds before to two seconds after each region of turn-around or quasi-static conditions. Stride times occurring within the exclusion zones were then discarded, Fig. 17.



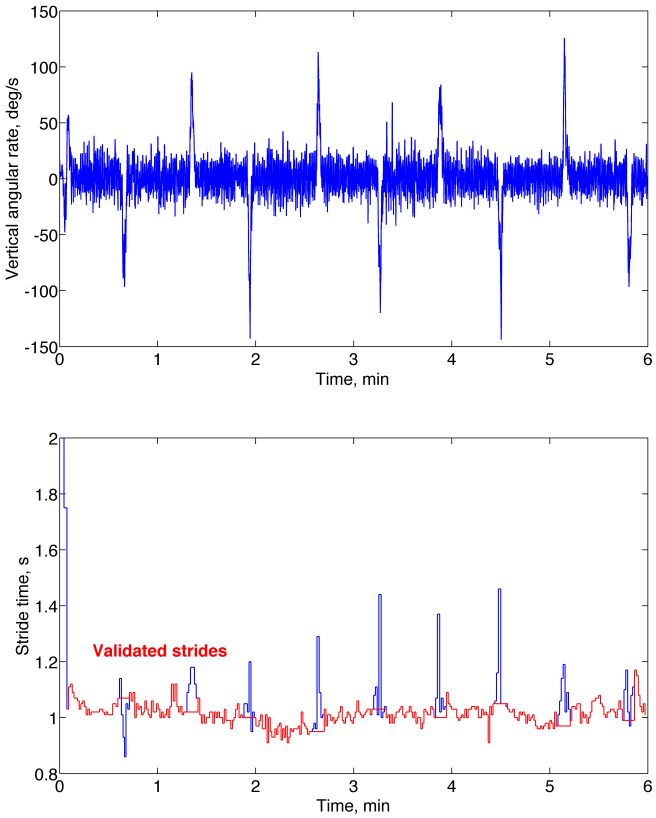
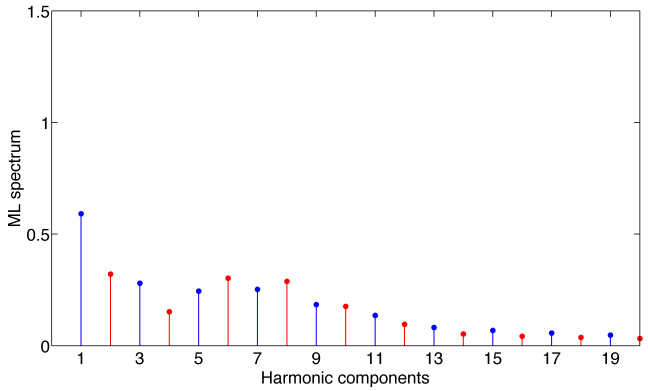


Figure 17 - Representative plots from the IDF-dataset: (a) vertical acceleration along the vertical direction; (b) angular velocity around the vertical direction; (c) outcome of the stride validation procedure. The outlying measurements shown in blue in panel (c) help demonstrate the stride validation procedure. The combined action of the turn-around and quasi-static detectors (see text) allow identifying the exclusion zones, where the computed stride times are not correct. The validated strides are shown in red. The values of the gait variables are computed only for the gait strides highlighted in red in panel (c).

HRs were determined separately in all three anatomical directions using digital Fourier transformation in each direction individually applied to gait strides. Data for each acceleration component and validated stride were submitted to Fourier analysis using methods of functional analysis to compute the harmonic coefficients. Partial sum series retained up to N = 20 terms in the Fourier expansion, Fig. 18.



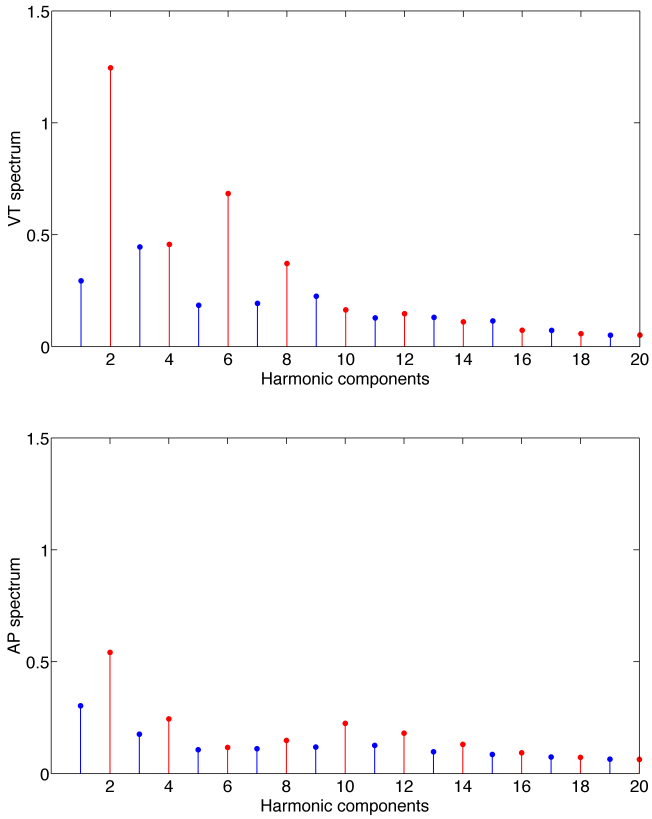


Figure 18 - Amplitudes of the first twenty harmonics. Odd harmonics are shown in blue; even harmonics are shown in red. Note that the AP spectrum and the VT spectrum exhibit a predominance of even harmonics, in contrast with the ML spectrum, where the dominant harmonic component is odd. This reflects the biphasic and monophasic natures of the signals involved in each gait cycle [13].

Results

The IDF dataset analyzed so far consists of N = 219 subjects, assessed at the time T_0 (baseline assessment) and at the time T_1, three months later. The main characteristics of the subjects are summarized in Table 6.

Table 6 - Participants' characteristics (baseline assessment).

Parameter	
Male/female	72/147
Age	75.1 ± 8.4
Mini Mental State Examination, MMSE (scores 0-30)	26.3 ± 3.0
Geriatric Depression Score, GDS (scores 0-30)	6.1 ± 3.7
Tinetti-balance (scores 0-16)	12.0 ± 3.1
Tinetti-gait (scores 0-12)	8.2 ± 2.6
Tinetti-total (scores 0-28)	20.2 ± 4.8
Falls in the reference period	0.8 ± 1.0

Since the WIMU data were available only upon specific request to the pilots, the dataset was built upon the WIMU-data files that the pilots returned. Only a very limited number of WIMU-data files were discarded for technical issues (i.e., faults in the data collection process). The estimated gait variables for each subject and time of assessment were imported into SPSS 19 for Windows

analysis software (SPSS Inc., Chicago, IL, USA). According to the treatment they received in the time from T_0 to T_1, four groups of subjects were considered, namely placebo ($N_{placebo}$ = 50), cognitive ($N_{cognitive}$ = 60), motor (N_{motor} = 50), and mixed (N_{mixed} = 59). A second criterion of grouping was also defined. First, the fall risk score was computed based on the information reported in Table 7, using an approach similar to [21]. Subjects were then divided into two groups: subjects at high risk of falls (high fall-risk) and subjects at low risk of falls (low fall-risk), based on the fall risk score being greater than the cut-off value of 5.

Table 7 - Calculation of the fall risk-score from MMSE (corrected for age and education), GDS and Tinetti-total.

Cognition	MMSE ≤ 17	17 < MMSE ≤ 23	24 < MMSE ≤ 30
Score	2	1	0
Description	Severe	Moderate	No/insignificant
Depression	19 < GDS ≤ 30	9 < GDS ≤ 19	GDS ≤ 9
Score	2	1	0
Description	Severe	Moderate	No/insignificant
Balance/gait	Tinetti < 19	19 ≤ Tinetti ≤ 24	24 < Tinetti
Score	4	2	0
Description	Severe	Moderate	No/insignificant
History of falls	$2 \leq N_{fall}$	$1 \leq N_{fall} < 0$	$N_{fall} = 0$
Score	4	2	0
Description	Multiple faller	Single faller	No faller
Fall risk-score	Summation of the above score [0-12]		

Table 8 reports the values of the gait variables, including the walked distance at T_0 and T_1 for the low-risk and high-risk subjects.

Table 8 - Gait variables in terms of mean ± standard deviation (SD), for different subjects' groups and times of assessment.

	Time of assessment	
	T_0	T_1
Low-risk		
Walked distance, m	326 ± 128	351 ± 139
Cadence, bpm	102 ± 13	102 ± 14
Stride time, s	1.19 ± 0.2	1.20 ± 0.2
Stride time variability, %	6.7 ± 3.5	5.7 ± 3.7
RMS (vertical acceleration), m/s^2	1.96 ± 0.81	1.91 ± 0.74
HR (ML component)	1.76 ± 0.47	1.90 ± 0.51
HR (VT component)	2.03 ± 0.70	2.19 ± 0.80
HR (AP component)	1.82 ± 0.66	2.00 ± 0.68
High-risk		
Walked distance, m	244 ± 131	253 ± 134
Cadence, bpm	96 ± 13	95 ± 13
Stride time, s	1.28 ± 0.2	1.29 ± 0.2
Stride time variability, %	8.4 ± 3.9	8.1 ± 4.0

RMS (vertical acceleration), m/s^2	1.61 ± 0.80	1.36 ± 0.52
HR (ML component)	1.67 ± 0.36	1.85 ± 0.38
HR (VT component)	1.67 ± 0.49	1.85 ± 0.74
HR (AP component)	1.59 ± 0.44	1.75 ± 0.62

In the following, Cad was retained for analysis in place of T. The reciprocal function applied to T to obtain Cad, see (1), allowed normalizing the distribution of Cad, as demonstrated by applying the Kolmogorov-Smirnov (KS) test (p > 0.2). The log-transformed values of the other gait variables were generally normally distributed within each risk and treatment group according to the KS test (p > 0.2); in all cases when the test failed, the violation was mild. Outliers, when present, were not extreme, as assessed by inspecting boxplots and q-q plots.

Gait variables D, Cad, T_d, RMS_{VT}, HR_{VT} and HR_{AP} were submitted to factor analysis (principal component method). The suitability of the factor analysis was assessed prior to analysis. Inspection of the correlation matrix showed that all variables had at least one correlation coefficient greater than 0.3. The overall Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy was 0.793 (from middling to meritorious). Bartlett's test of sphericity was statistically significant [$\chi^2(15) = 650.82$, $p < 0.001$], indicating that the data were likely factorizable. PCA revealed two components that had eigenvalues greater than one and which explained 57.6% and 18.5% of the data variance. Visual inspection of the scree plot also indicated that two components should be retained. A varimax orthogonal rotation was employed to aid interpretability. The interpretation of the data was consistent with the gait attributes described in [22]. The first factor loaded heavily on walked distance, RMS_{VT} and Cad, and was termed the pace factor. The second factor loaded heavily on Td, HR_{VT} and HR_{AP}, and was termed the variability factor. Component loadings and communalities are presented in Table 9.

Table 9 - Rotated structure matrix for PCA with varimax rotation. Component loadings less than 0.4 (absolute value) were omitted from the table.

	Pace factor	Variability factor	Communalities
Distance	0.837		0.799
RMS (vertical acceleration)	0.911		0.842
Cadence	0.789		0.700
HR (VT direction)		0.813	0.806
HR (AP direction)		0.861	0.778
Stride time variability		-0.786	0.639

The factor scores were summed and normalized to unit standard deviation, yielding the global gait score (z-score). A possible interpretation of the global gait score is that a higher z-score on global gait corresponds with better gait. To analyze the relationships of these data with the clinical scores, we combined the information from MMSE, GDS, Tinetti-total to produce a global clinical z-score. The plot in Fig. 19 shows that the correlation existing between the global gait score and the global clinical score (z-score) was fair.

It may be tempting to use gait variables, or a subset of them, in place of the clinical scores as for their potential to predict fall risk. Two gait variables were considered: D, to represent the pace factor, and HR_{VT}, to represent the variability factor. A decision tree was built in SPSS, using the CART growing method. Other specifications of the design were the maximum tree depth, specified to two, the minimum cases in parent and child nodes were both set to five. The *N*-fold cross-validation was used (*N* = 10). Results are shown in Fig. 20. Table 10 summarizes the performance statistics of the proposed classification tree.

We performed a total of eight analyses of variance ANOVA, for two outcome measures (D, HR_{VT}) and two patients' groups (low-risk, high-risk) by each treatment (motor, cognitive). We used mixed ANOVA with time (T_0 vs. T_1) as within-subjects factor, and treatment, i.e., motor vs. non-motor and cognitive vs. non-cognitive, as between-subjects factor. More specifically, cognitive treatment was obtained by collapsing data from cognitive and mixed treatments and non-cognitive treatment was obtained by collapsing data from motor and placebo treatments.

Conversely, motor treatment was obtained by collapsing data from motor and mixed treatments, whereas non-motor treatment was obtained by collapsing data from cognitive and placebo treatments. Table 6 reports the main results of the ANOVA tests.

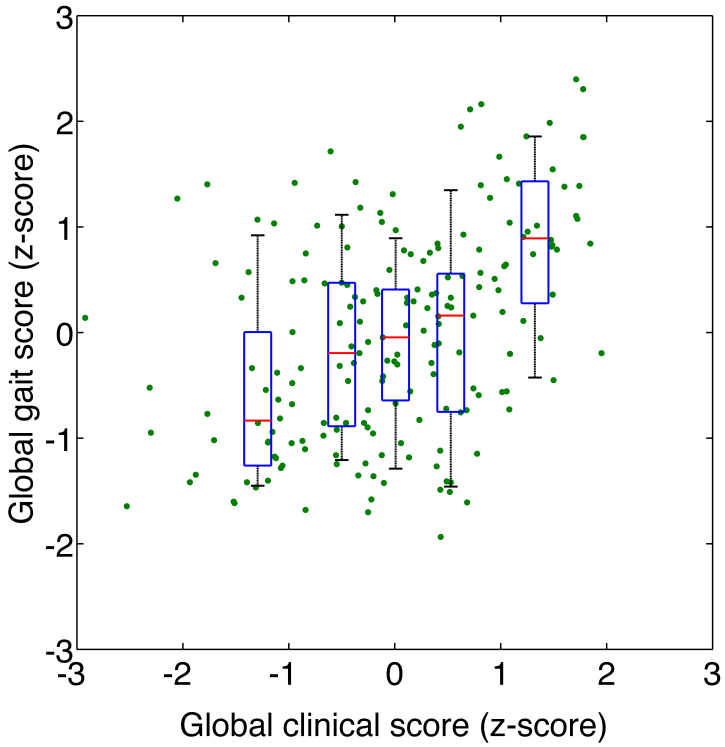


Figure 19 - The association between global clinical score and global gait score. Scatterplot of global gait score against global clinical score, including a boxplot representing the 90th, 75th, median, 25th, and 10th percentile of global gait score within quintiles of global clinical score.

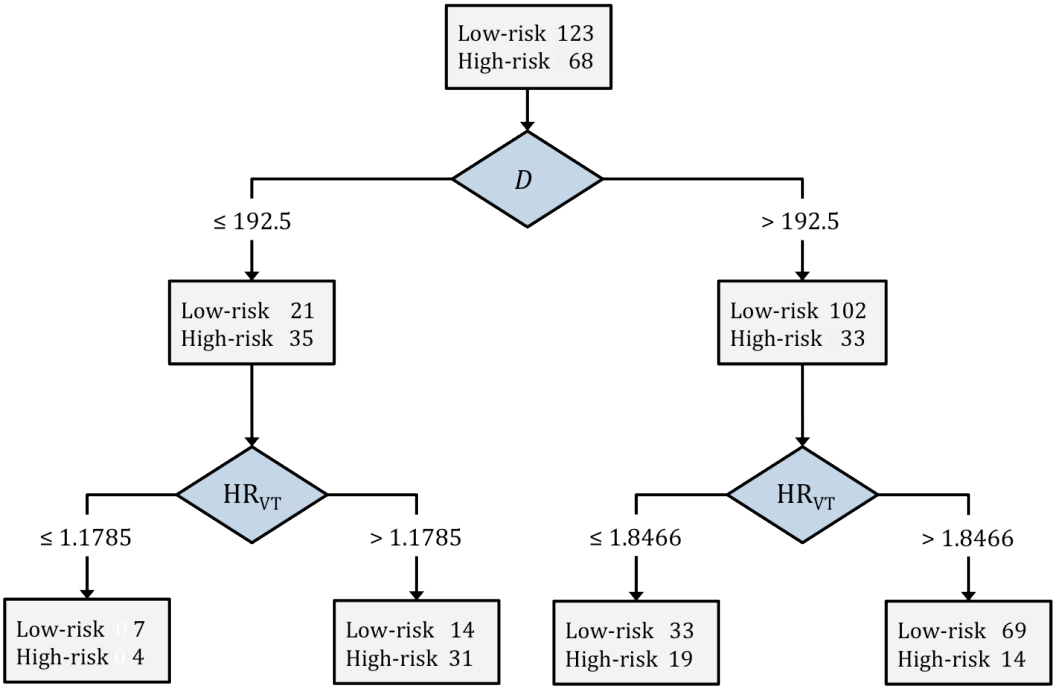


Figure 20 - Classification tree for individual fall risk (baseline assessment). The gait variables considered in building the classification tree are the walked distance D and the harmonic ratio of the vertical acceleration HRVT.

Table 10 - Confusion matrix and classification results evaluation for the classification tree model.

		Predicted	
Observed	Low risk	High risk	Total
Low risk	109	14	123
High risk	37	31	68
Total	146	45	191
Accuracy	73.3%		
Sensitivity	74.7%		
Specificity	68.9%		
Negative predictive value	45.6%		
Positive predictive value	88.6%		

Walked distance

There was no statistically significant two-way interaction between treatment and time. We found a general non-specific effect of treatment on the walked distance for the low-risk subjects only. This was showed by a main effect of time for both motor [$F(1, 121) = 11.060$, $p < 0.001$, partial $\eta^2 = 0.084$] and cognitive [$F(1, 121) = 10.211$, $p < 0.002$, partial $\eta^2 = 0.078$] treatment on the walked distance. No group effects emerged for both treatments.

Vertical harmonic ratio

There was a statistically significant two-way interaction between treatment and time for the low-risk subjects only: $F(1, 121) = 4.714$, $p < 0.032$, partial $\eta^2 = 0.037$ (motor training); $F(1, 121) = 4.727$, $p < 0.032$, partial $\eta^2 = 0.038$ (cognitive training). Post-hoc comparisons with paired t-tests showed a significant effect

between T_0 and T_1 for the motor treatment ($t(61) = -3.708$, $p < 0.0001$) and not for the non-motor treatment ($t(60) = -0.510$, $p < 0.612$); for the non-cognitive treatment ($t(53) = -3.048$, $p < 0.004$) and not for the cognitive treatment ($t(68) = -0.897$, $p < 0.373$). We found a general non-specific effect of treatment on the vertical harmonic ratio for the high-risk subjects. This was showed by a main effect of time for both motor [$F(1, 66) = 5.329$, $p < 0.024$, partial $\eta^2 = 0.075$] and cognitive [$F(1, 121) = 5.434$, $p < 0.023$, partial $\eta^2 = 0.076$] treatment on the vertical harmonic ratio. No group effects emerged for both treatments. Figure 21 reports the estimated marginal means of HR_{VT} (low-risk subjects' group) at T_0 and T_1.

Table 11 - Main results of the two-way ANOVA.

Low-risk	Motor/non-motor		Cognitive/non-cognitive	
Outcome	Time	Time × treatment	Time	Time × treatment
D	$p < 0.001$	ns	$p < 0.002$	ns
HR_{VT}		$p < 0.032$		$p < 0.032$
High-risk	Motor/non-motor		Cognitive/non-cognitive	
Outcome	Time	Time × treatment	Time	Time × treatment
D	ns	ns	ns	ns
HR_{VT}	$p < 0.024$	ns	$p < 0.023$	ns

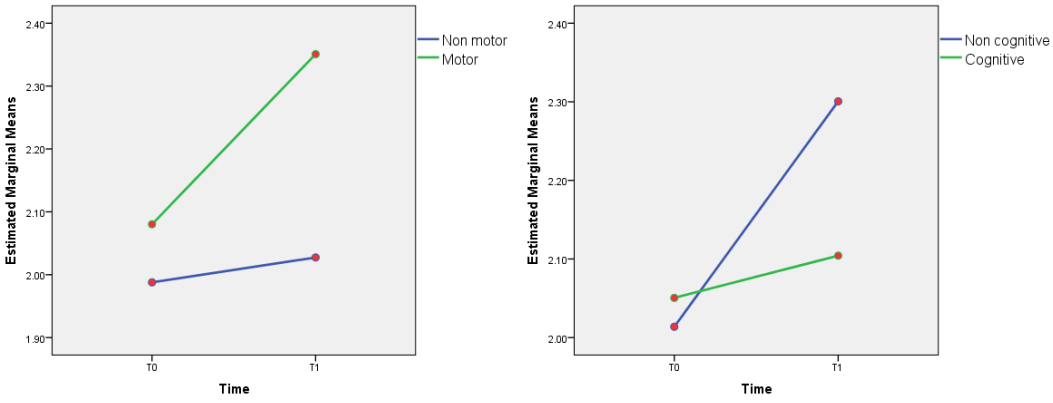


Figure 21 - Estimated marginal means of HRVT at T0 and T1 (low-risk group).

7.1 Discussion and conclusions

The main results achieved so far can be summarized in the following points.

The pilots were capable of managing the instrumented 6MWT and no particular difficulties emerged during the documented testing period.

The WIMU-data files available from the follow-up at T_2 (follow-up) helped confirm this claim, although they were not included in the study described in this document; this was done to avoid the limitations in the sample size otherwise occurring. Technically, only very few faults in the acquisition process occurred, which shows the good maturity of the adopted technical solution to pair a Bluetooth-based inertial measurement unit to an android smartphone.

Minimal technical expertise is required to the operators in charge of the instrumented 6MWT.

The computational procedures developed to estimate the gait variables do not require that the WIMU sensors (tri-axial accelerometer and tri-axial gyroscope) be calibrated before being uses. In any case, the calibration procedure is straightforward and does not require more than few minutes to be performed. On the other hand, it is required that the WIMU is carefully positioned on the anatomical landmark, so as to properly align the local frame to the anatomical directions, since HRs, for instance, are direction-dependent.

The WIMU-based gait variables were generally correlated with one another and with the clinical scores (namely, MMSE, GDS, and Tinetti-total).

The PCA results we obtained were in good agreement with recent findings concerning the identification of independent gait domains derived from quantitative assessments [22]. The association between the global gait *z*-score and the global clinical *z*-score revealed in Fig. 19, for instance, showed trends similar to those reported in research papers that used inertial sensor-based gait assessment [4][6]. This observation casts evidence about the feasibility of using our device to estimate gait variables, whose informative content has clinical relevance for assessing the fall risk.

Two gait variables were of great interest for the WIMU-based assessment: the walked distance, a proxy to the walking speed, and the vertical HR.

Both variables have been often considered in past works for their clinical relevance. In clinical practice a person's freely selected walking speed is one of the better indicators of how well a person walks. It decreases in times of injury and pain and increases with recovery. Gait speed can also be used to assess the effectiveness of different exercise programs for improving ambulation in the elderly. HRs derived from trunk acceleration signals and based on amplitudes in frequency spectra are offering insight into the underlying mechanisms of balance control during gait. By measuring the rhythm of the accelerations, HRs provide information on the ability of subjects to control their trunk smoothly during walking, providing an indication of whole body balance and coordination.

To examine the ability of these gait variables to predict falling, we investigated their predictive abilities as for the discrimination between subjects at high risk of falls and subjects at low risk of falls. The term "low" and "high" have to be considered in connection with the definition of a fall risk score as outlined above. In this regard, we are investigating different means for constructing fall risk scores, and different machine learning methods to learn the correct decision boundaries in the parameter space [23]. **The exemplary approach described in this Annex led to classification performance metrics well aligned with those reported in the current literature.**

Finally, we examined gait variables in their behaviour across time (namely, their variations induced by effects of training). Pathologic gait is slower, more variable (as assessed by, e.g., stride time variability) and less stable and smooth (particularly in the vertical direction) than normal gait. The results of the

factor analysis showed a remarkably strong relation existing between walked distance, cadence and vertical RMS (pace factor), and stride time variability and vertical and frontal HRs (variability factor). It is expected that walked distance and vertical HR, in particular, increased as a beneficial effect of training.

The results of the ANOVA study we performed showed the beneficial effects of the motor treatment on the ability of the low-risk subjects to control their trunk smoothly during walking; otherwise, we only observed a general non-specific effect of treatment for the high-risk subjects. The same findings did not extend to the analysis of walked distance results, for which we only observed a general non-specific effect of treatment for the low-risk subjects. It is worth noting that the results of mixed ANOVAs based on the outcome of the Tinetti Performance Oriented Mobility Assessment (not reported here) lead to similar conclusions concerning the existence of specific effects of the motor treatment on the performance of low-risk subjects against general non-specific effects of treatment for the high-risk subjects.

We conclude that the gait variable usually taken as the outcome measure of a 6MWT, namely the walked distance, is not capable of revealing subtle changes in the gait performance as the vertical HR offers promise doing.

In this regard, we also conclude that the WIMU technology offers promise as a valuable asset to support the clinical decision process in the IDF platform.

7.2 References

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ANNEX II IDF *i*-WALKER

i-Walker analyses

Parameters of average speed and force were recorded by the *i*-Walker in a subsample of 77 IDF participants (Table 12) of three pilot sites (FSL, SERMAS and Granollers) divided high (n=66) and low (n=11) risk of fallers. Low risk of falls were considered participants with 1 previous fall during the previous year and a Tinetti Total >20.

Table 12 - Demographic and baseline mobility assessment of the whole sample

	f/m	
Sex	53/24	
	Average	**St. Dev.**
Age	82,5	8,3
Education	8,1	4,2
Tinetti Tot.	17,5	4,3
Tinetti Gait	10,0	2,7
Tinetti Balance	7,5	2,2
FES-I	33,1	11,8
6MWT	194,6	94,3
10MWT	23,7	25,5
MMSE	25,5	3,2

Average speed

At Baseline, we compared between the high and *low risk* of fallers, the average speed during the 10 minute walking test taking in consideration the central 6 minute of the task (from the 3rd until the 7th) with a one way analysis of variance (ANOVA) and we found a significant difference in average speed between the two subsamples [F(1,76)=12,073, p=.001].

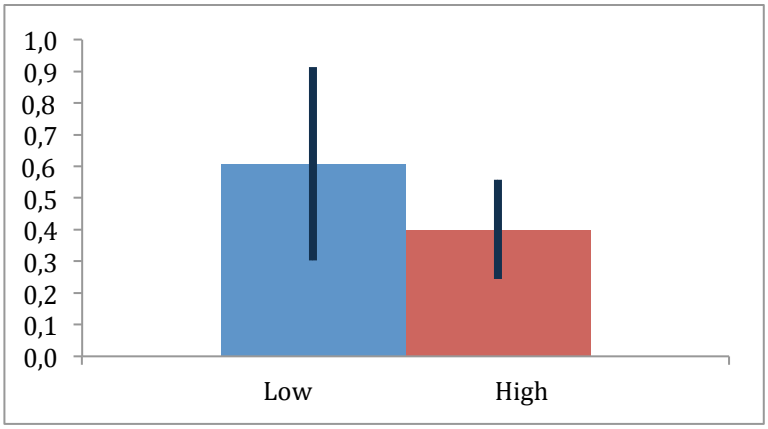
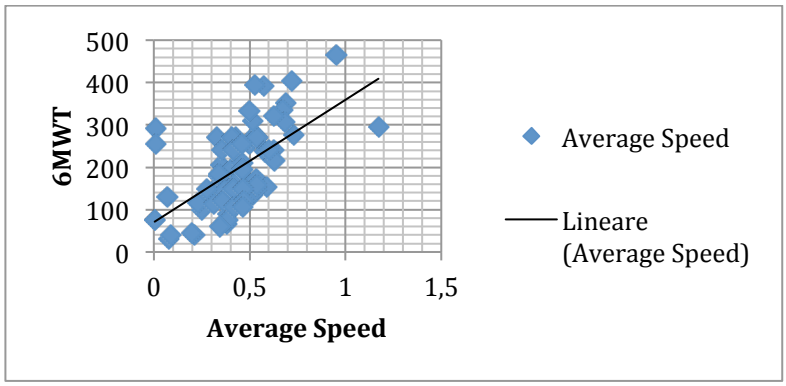
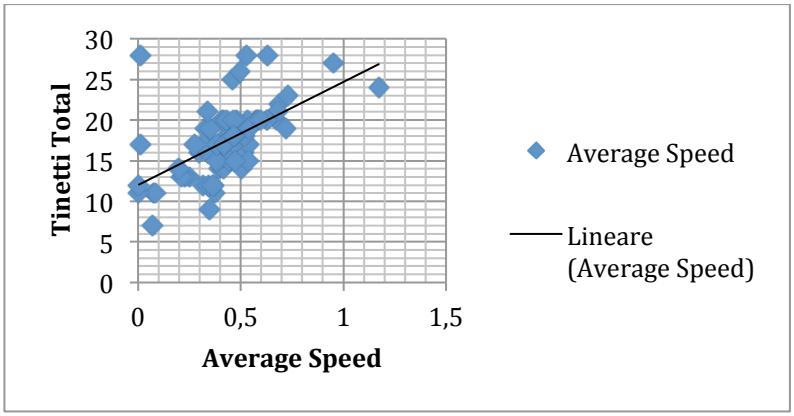


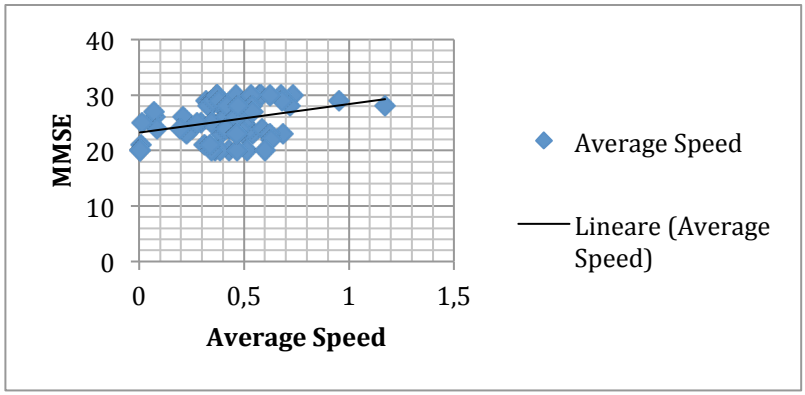
Figure 1. Mean average speed for participants at high and low risk of falls.

Moreover, at baseline, the average speed in the whole sample was positively correlated with the meters performed at the 6MWT (r=.601; p<.001), with the Tinetti (r=.575; p<.001) and with the MMSE (r=.318; p<.01). Moreover, it was negatively correlated with the FES-I that measures (r=-.490; p<.001).

Figure.



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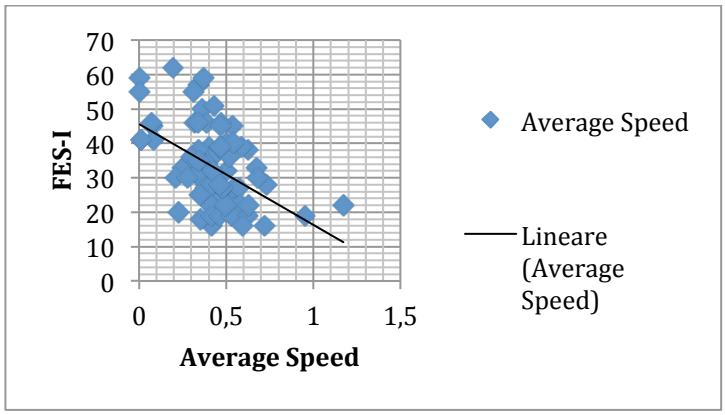
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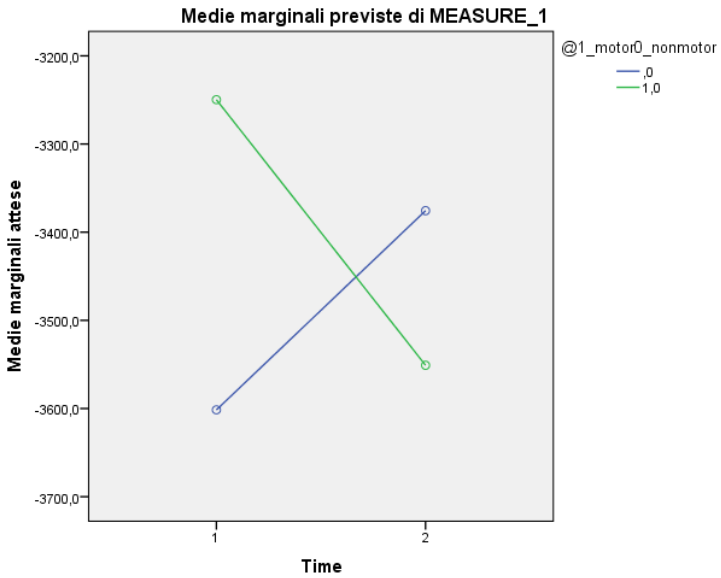
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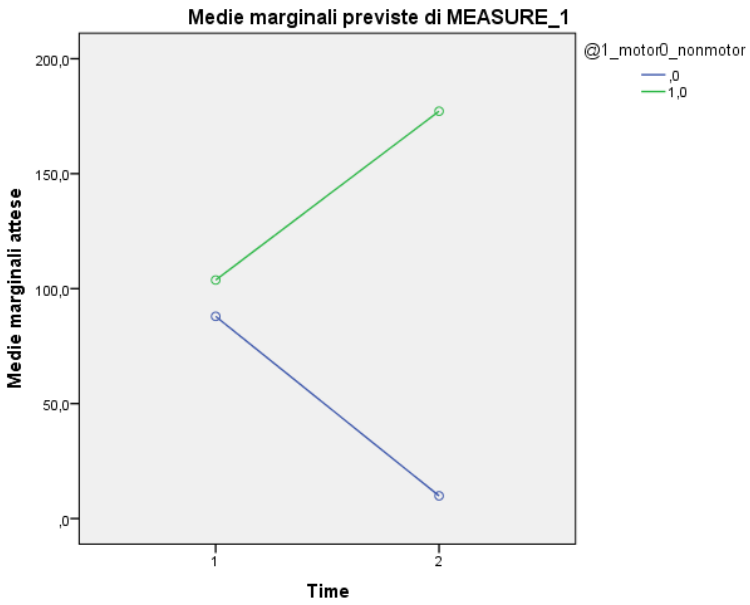

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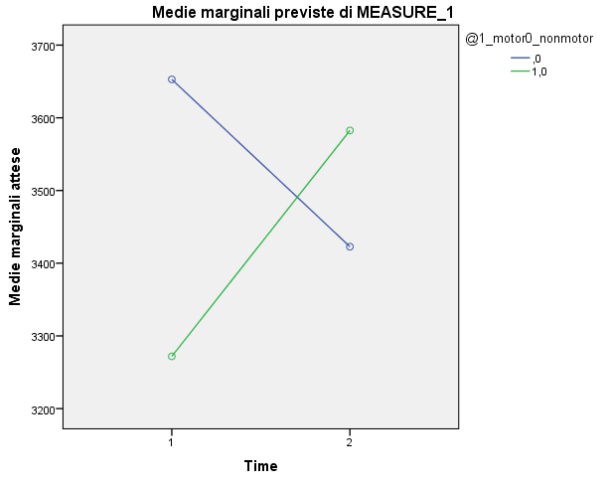
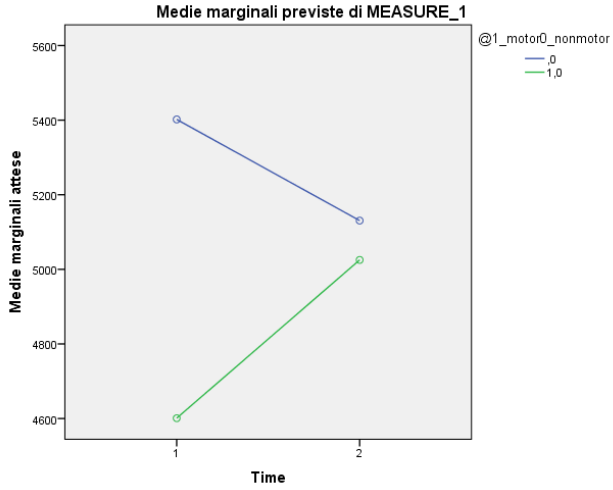


Total



Predicting Fall risk using 10MWT and 6MWT data

Method: Logistic Regression (with L1 regularization) trained with the T0 data.

Because the dataset is very unbalanced (14% *low risk*, 86% *high risk*) the baseline prediction has 86% accuracy predicting always *high risk.*
10fold cross validation mean accuracy: 0.88710317460317467 (stdev= 0.11818287119157285)

Coefficients of the regression model:
('10meters_FxR_avg_T_0', 0.0131756149181001)
('10meters_Ftotal_T_0', -0.001925402008483732)
('10meters_Av. Speed_T_0', -0.019405525884632766)
('6meters_FzR_avg_T_0', -0.035002323532411027)
('6meters_FLmean_T_0', 0.0021116725914520963)
('6meters_FRmean_T_0', -0.032856095225198577)
Interceptor = [9.22205754]

A graphical representation of each of these variables is shown at the end of this Annex. Each page contains the information collected for each variable when each volunteer was interacting with *i*-Walker at T_0. We include the result for each variable in the three pilots for their comparison.

Accuracy Train/Confusion Matrix with the T_0 data accuracy = 0.961038961039

	NF	F
NF	10	1
F	2	64

	Precision	recall	f1-score	support
NF	0.83	0.91	0.87	11
F	0.98	0.97	0.98	66
avg/total	0.96	0.96	0.96	77

The model behaves relatively good, both classes are predicted with high precision/recall.

Accuracy Test/Confusion Matrix using the T0 model for the T1 data

Accuracy = 0.883116883117

	NF	F
NF	7	4

F	5	61

	Precision	recall	f1-score	support
NF	0.58	0.64	0.61	11
F	0.94	0.92	0.93	66
avg/total	0.89	0.88	0.89	77

Precision is lower, it could be argued that *something* has changed from T_0 to T_1, but there is not enough data in the sample to state a clear conclusion.

Separating the T_1 data using treatment/placebo variable.

Accuracy Test/Confusion Matrix for placebo accuracy = 1.0

	NF	F
NF	2	0
F	0	22

	Precision	recall	f1-score	support
NF	1.00	1.00	1.00	2
F	1.00	1.00	1.00	22
avg/total	1.00	1.00	1.00	24

The model fits perfectly T_1 data, this is what expected because there has not been any action that changed individual performance.

Accuracy Test/Confusion Matrix for treatment accuracy = 0.830188679245

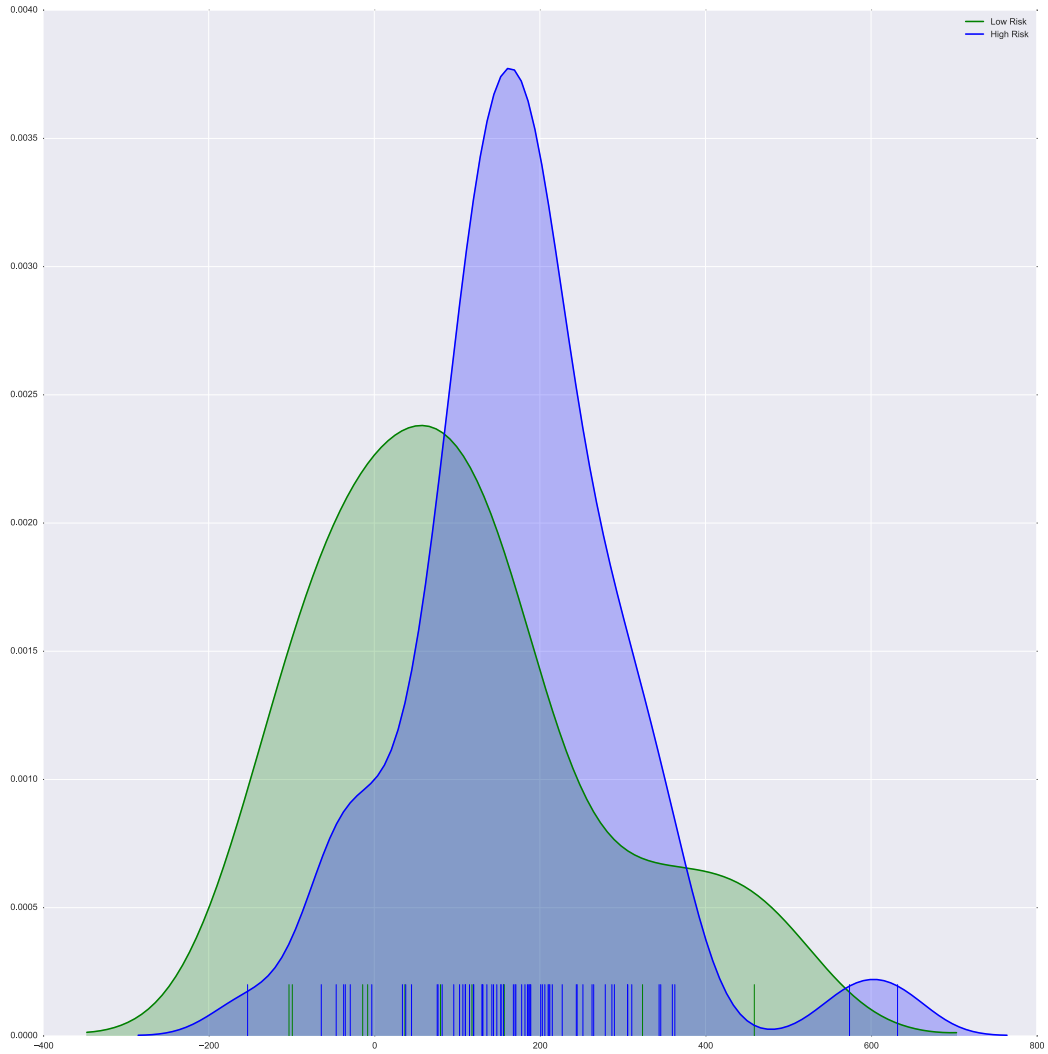
	NF	F
NF	5	4

F	5	39

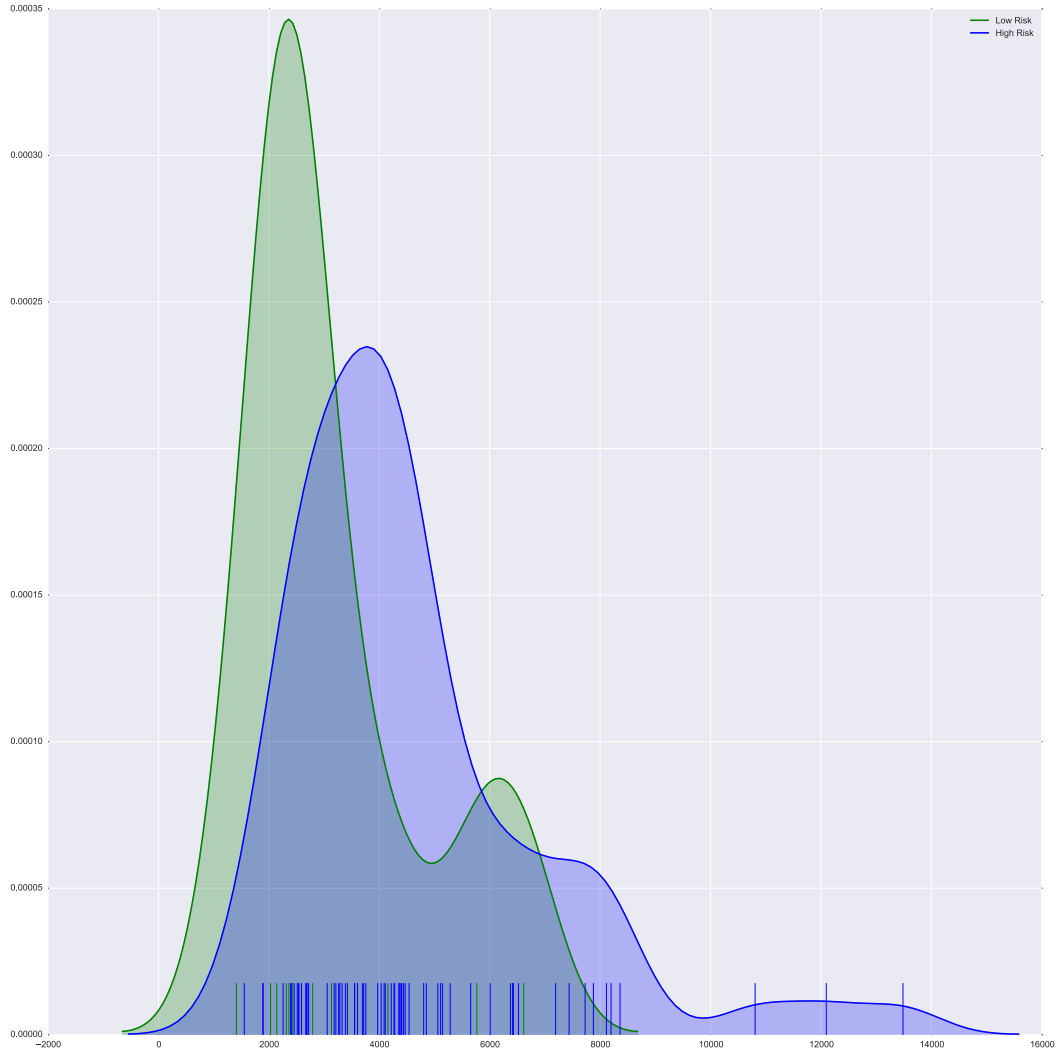
	Precision	recall	f1-score	support
NF	0.50	0.56	0.53	9
F	0.91	0.89	0.90	44
avg/total	0.84	0.83	0.83	53

The model works badly for NF individuals, and about a 10% worse for F individuals. It is difficult to argue much, some of the NF may have change because of treatment, but a large per cent of F individuals also have changed, probably because of reasons different than the treatment.

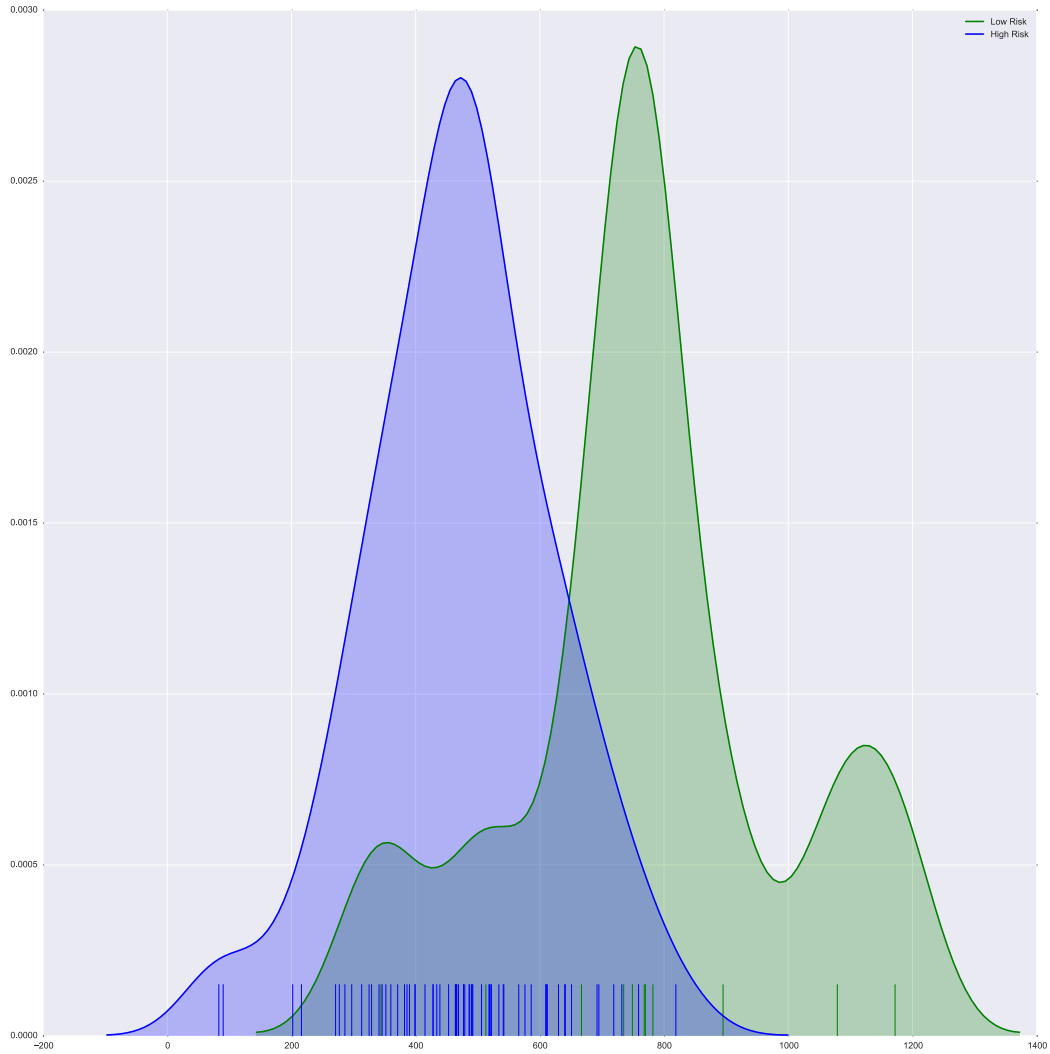
10meters_FxR_avg (T0)



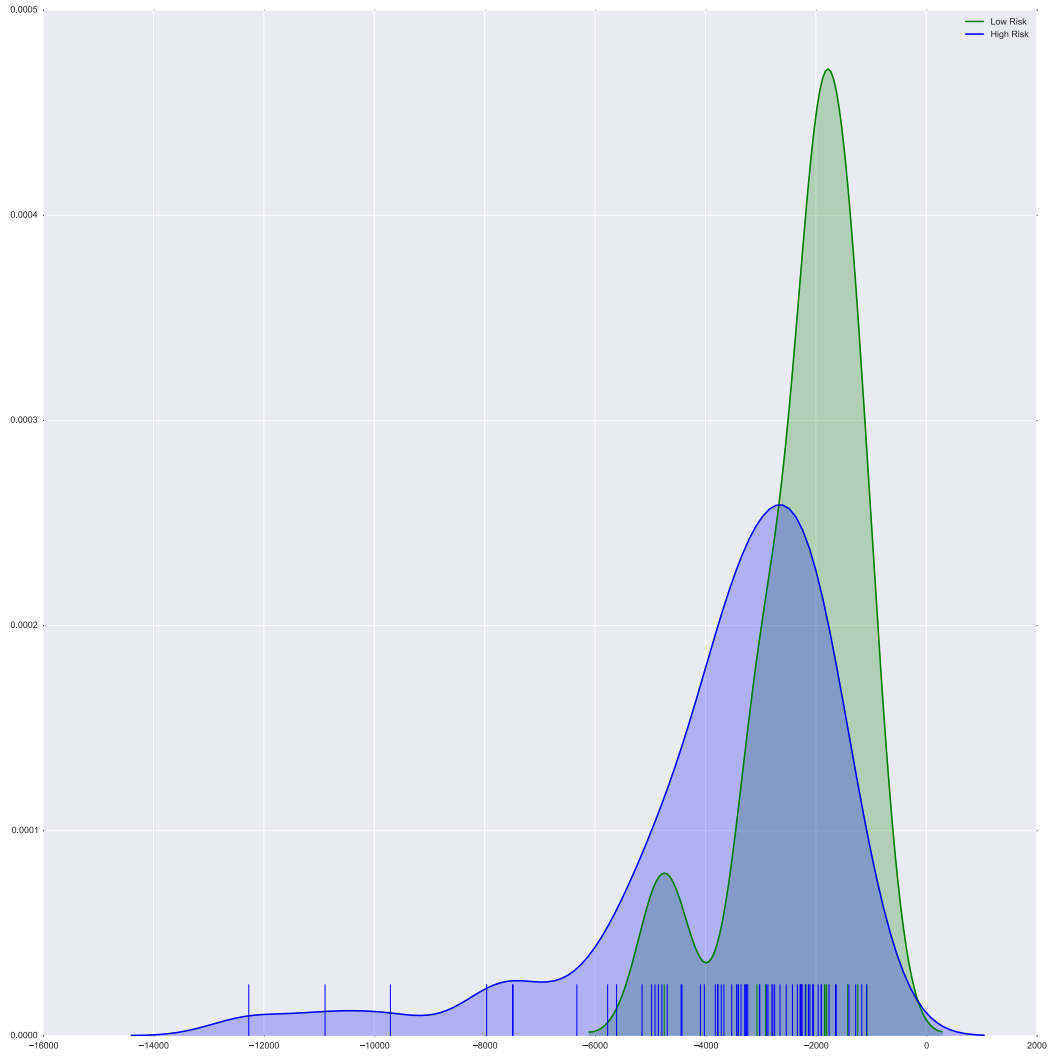
10meters_Ftotal (T0)



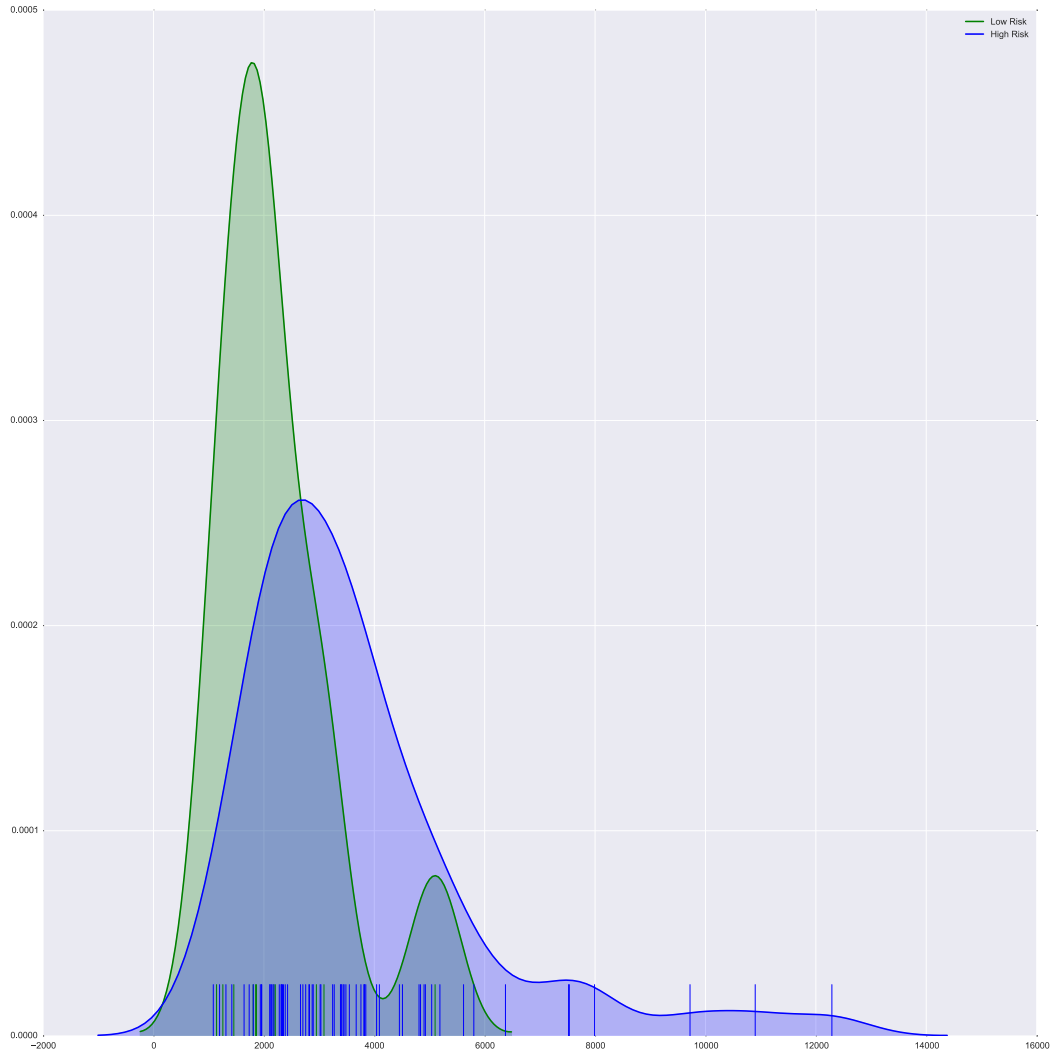
10meters_Av. Speed (T0)



6meters_FzR_avg (T0)



6meters_FRmean (T0)



6meters_FLmean (T0)