

SOCIABLE DELIVERABLE D7.2a

“Interim Assessment of the SOCIABLE Platform and Services”



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Revision History

Revision	Author(s)	Organization(s)	Date	Changes
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0.2	Stelios Pantelopoulos	SLG	19/10/20 11	Introduction
0.3, 0.4	Roberta Annicchiarico	FSL	27/10/20 11	Analysis of the Results, Main Conclusions of the Study
0.4, 0.5	Stelios Pantelopoulos	SLG	15/11/20 11	Description of the methodology and the statistical sample
1.0	Roberta Annicchiarico , Stelios Pantelopoulos	SLG, FSL	21/11/20 11	Completion of Interim Version based on data of the first quarter of pilot operations

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Abstract

This deliverable presents results associated with the interim evaluation of the SOCIABLE and services, mainly from a clinical perspective. The evaluation process is based on the clinical evaluation methodology described in earlier deliverable D7.1. Based on this methodology the SOCIABLE pilot sites have provided detailed information (including numbers of participating elderly, scores of their cognitive assessments and demographic information) about the first quarter of the formal pilot operations spanning the period May2011-July2011. This information has been analyzed statistically as explained within the deliverable. In the scope of the document, results corresponding to this first quarter are presented in the form of an interim clinical evaluation of the SOCIABLE platform and services. Later versions of this deliverable (leading to the final release D7.2b) will gradually analyze and incorporate more results, as the SOCIABLE pilot operations evolve.

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Executive Summary

SOCIABLE has introduced a new surface computing based model to cognitive training and social activation of elderly individuals, which is piloted in seven sites across four different countries. Following the successful deployment of the SOCIABLE model (including all the associated ICT services), the project's effort have been shifted towards the evaluation of the introduced approach from a clinical, technical, technological and usability perspective. The evaluation activities of the project include also the collection and analysis of feedback from all stakeholders including elderly users, medical experts, technical experts, health professionals, caregivers, as well as family members of the participating elderly. The evaluation activities are planned on the basis of the evaluation framework of the project (which is detailed in deliverable WP7) and their results are reported in three distinct deliverables of the WP7 of the project.

The present deliverable reports on the evaluation of the SOCIABLE platform and services from a medical/clinical perspective, which is based on the SOCIABLE study design that compares elderly participating in SOCIABLE sessions to an appropriately selected control group, as described in D7.1. 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 SOCIABLE neuropsychological battery. Based on the comparison a number of conclusions are drawn.

Note that the present version of the deliverable constitutes an interim rather than a final version. This is because it takes into account a subset of the elderly that participate in the SOCIABLE clinical trial, rather than the full set of elderly participants in the same trial. Specifically, the deliverable relies on data collected through the neuropsychological assessment in two occasions: (a) at the beginning of the SOCIABLE formal pilot operations i.e. 01/05/2011 and after three months of formal pilot operations i.e. 31/07/2011). Data were collected for the experimental group (i.e. the one that received SOCIABLE treatment), as well as for a control group (i.e. a group that did not receive SOCIABLE treatment). Subjects were randomly allocated between the two parallel groups (experimental and control) in each pilot site and for each kind of group studied by SOCIABLE (groups A, B and C corresponding respectively to Healthy elderly, elderly with Mild Cognitive Impairment (MCI) and Mild Alzheimer's Disease (AD)). The analysis was performed on a total of 114 subjects, half belonging to the experimental group (n=57) and half to the control group (n=57). About half of the total subjects (n= 59) were healthy subjects and the remaining were one half MCI (n=27) and AD (n=28). The deliverable provides more detailed on the analysis and characteristics of the analyzed sample of elderly/patients.

Based on the analysis of these results, the deliverable reports some important and positive, yet early results. In particular, it is deduced that the treatment has an overall significant positive effect. According to the analysis the experimental group which underwent the treatment showed a greater difference between the

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evaluation at the two time instants (T0 and T1) compared with the control group that did not underwent any treatment. In particular, when the analysis was conducted on all the three groups together, the treatment positively influenced the global cognitive and functional abilities of the participants as demonstrated with the MMSE and CDR tests. The cognitive functions that most benefited from the treatment were attention, verbal memory and language. Taking the three groups separately, the healthy subjects sample was the one that most benefited from the treatment showing a positive effect on several measures of cognitive functions (memory, attention, executive functions), on mood and social relationships. We expect that the collection and analysis of assessment results from more elderly users of the SOCIABLE clinical trials will provide opportunities for deepening and probably strengthening these early results.

It should be noted that the present evaluation report is part of the interim version of the deliverable. As more elderly conclude their involvement in SOCIABLE programmers/sessions, more results will be analyzed and included in this deliverable. The final version of this deliverable (due at the end of the project) is expected to contain the collective analysis of results derived from all the elderly participants to the study (i.e. nearly 348 participants as planned in the scope of the study design). Furthermore, the opinion of medical experts, health professionals and care givers will be provided in order to strengthen the results. During the evolution towards the final version of deliverable, the present interim version could be gradually enriched with results from more patients. In this way, the present interim version could be transformed to a living document that will gradually incorporate more and more assessment results, which will be derived as elderly/patients conclude their participation in the SOCIABLE clinical trial.

1. Introduction

The SOCIABLE project is organizing a clinical trial towards evaluating a novel ICT based approach to cognitive training and social activation of the elderly. The clinical trial involves 350 users across seven pilot sites in four countries. Following intense efforts to integrate the SOCIABLE ICT platform, prepare the seven pilot sites and commence the pilot operations, the project is dedicating effort to the evaluation and assessment of the pilots. This is the main subject and objective of WP7 of the project. An earlier deliverable (D7.1) of this workpackage has specified the evaluation methodology of the project, which covers a variety of evaluation aspects including business evaluation, technological evaluation, usability evaluation, as well as the clinical evaluation of the SOCIABLE platform. The later clinical evaluation will be based on the SOCIABLE study design, which details the statistical selection and processing of the sample of participating elderly.

The purpose of the present deliverable is to present the clinical evaluation of the SOCIABLE 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 first quarter of the SOCIABLE formal pilot operations (i.e. the pilot operations that took place in the period 01/05/2011-31/07/2011). In this respect the evaluation is characterized as «interim». As the pilot operations evolve, more data will be gathered and analyzed, thereby leading to more credible conclusions. In this sense, the present deliverable can be also seen as a living document that will be gradually updated as more and more pilot sessions are completed and respective data are gathered. As outlined in the SOCIABLE contract, the evolution of this deliverable will lead to its final version, which will comprise results and conclusions derived based on the total number of pilot participants.

The structure of this interim version of the deliverable is as follows: Section 2 after the introductory section illustrates the SOCIABLE methodology. The aim of the section is not to repeat the steps already outlined in D7.1. Rather, Section 2 attempts to provide more details on the operative analysis of the results. Section 3 presents the selected/analyzed population in the scope of this interim version. Accordingly, Section 4 presents the outcome of the analysis. Section 5 concludes this version of the deliverable. Given that this is an interim version of the deliverable, the conclusions cannot be considered final and consolidated. We expect additional findings and conclusions to emerge as more pilot sessions are conducted and more data are analyzed.

2. Summary of the Evaluation Methodology

2.1 Methodology – Study Design

The clinical evaluation methodology has been described as part of D7.1 of the SOCIABLE project. In the sequel we briefly present the SOCIABLE study design, including how the results are analyzed and processed.

2.1.1 Introduction to the Study Design

The efficacy of SOCIABLE treatment is evaluated with a **randomized controlled study**. Based on this study, subjects are randomized to initiate immediately the SOCIABLE treatment or to delay for three months its initiation. The group with delayed treatment acts as “control” for the group of immediate treatment. This solution has been adopted to guarantee the SOCIABLE treatment to all the included subjects. Randomization is stratified for center and for characteristics of the subjects (Normal, MCI, AD) with blocks of four patients. The treatment consists in cognitive training sessions with SOCIABLE platform. During the control condition subjects will not receive any treatment. Neuropsychological assessment are conducted simultaneously in both groups (experimental and control) at enrollment and after three and six months thereafter.

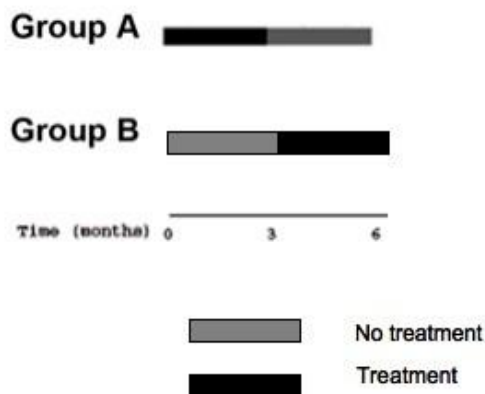


Figure 1: Description of the different treatment and NO treatment sessions of the experimental group (A) and control group (B). A different assessment will be conducted at the 0, 3 and 6 month.

The principal outcome for the study is the progression over time of the neuropsychological deficit in different domains assessed with the defined battery of tests (see deliverables D2.1 and D7.1 for the detailed presentation of the battery). The difference in the test scores at enrollment and after three months is compared in the two groups of subjects randomly assigned to immediate or delayed treatment. The second outcome of the study will be a change in a social approach of participants. This will be evaluated through the defined scales.

2.1.2 Randomization of Participants

In the scope of the study, subjects are randomly allocated in the experimental or control group, separately for each pilot site and for each group (elderly, MCI and AD)

		CARE CENTER				HOME			
		A: NH	B: MCI	C: AD		A: NH	B: MCI	C: AD	
Country	Pilot Site				Total per site				Total per site
Greece	HYGEIA S.A	6	20	18	44	4	6	6	16
Greece	SPC – Khfissia	56			56	4			4
Italy	Commune Forli	10	20		30	4	10		14
Italy	Morgagni Pierantoni		40		40		10		10
Italy	FSL			40	40			6	6
Norway	Trodheim			44	44			4	4
Spain	PREVI S.L	20			20	20			20
	Total per group	92	80	102	274	32	26	16	74

Table 1: Distribution of subjects between the different pilot sites

SOCIABLE sessions are conducted in groups of three subjects or individually. Part of the individual sessions takes place in care centers and part at home. Please note that the total number of group sessions must be at least the 50% of the total subjects of each centre. This is in-line with the planning of the SOCIABLE pilot operations which has been described in D6.1.

2.1.3 Analysis of the results

The data collected on different neuropsychological tests and socialization scales will be analyzed through a repeated measure analysis of variance 3 x 2 ANOVA with as within factor the assessment (0, 3, 6 months) and between factor the group (experimental vs. control).

The statistical analysis evaluates:

- A different decrement in the cognitive performance in the experimental and in the control group.
- These results will be analyzed separately in each group (Normal, MCI, AD).
- Different socialization level in the experimental and in the control group.
- Possible correlation between the cognitive performance and the social level will be evaluated.

The deliverable analyzes the results of the first three months of the SOCIABLE formal pilot operations and reports the main conclusions.

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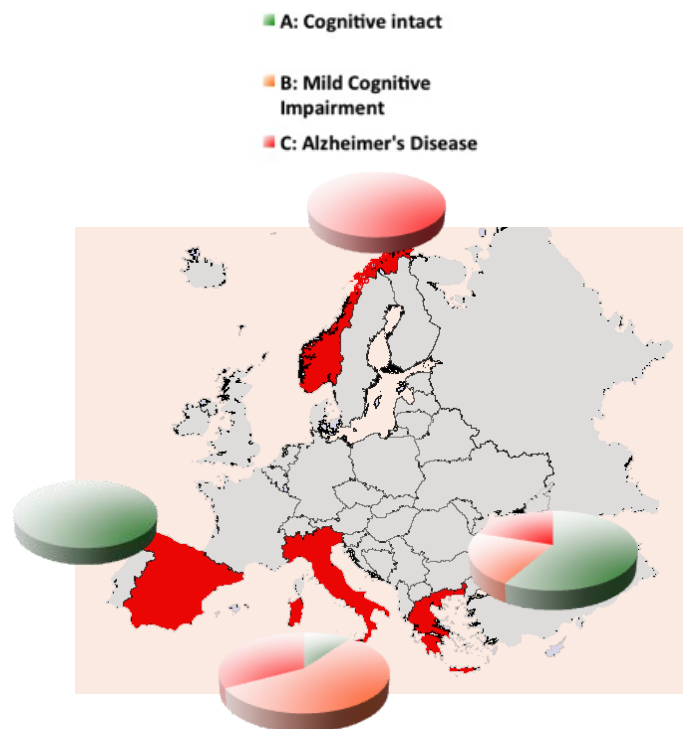
2.2 Collection of Results – (using the Back-Office Module)

According to the presented clinical evaluation methodology, the analysis of the results presupposes the structured collection of the battery scores for each one of the participating elderly, along with demographic information from the elderly participants. The collection of the results is facilitated by the back-office module of the SOCIABLE platform, which holds/stores the values of the tests while also enabling their export from the platform to spreadsheets for further processing. The export process is controlled by the health professionals and/or the IT administrators at the pilot sites. The results of the export procedures are provided to partner FSL, which is in charge of the statistical processing/analysis according to the presented study design procedures.

3. Analysis of the Population - Demographics

The following figures illustrate the demographics of the population that participated in the first quarter of the SOCIABLE formal pilot operations and whose results are analyzed in the scope of this version of the deliverable. In particular:

- Figure 2 illustrates the distributed of the elderly users across the various countries and target SOCIABLE group.
- Figure 3 illustrates the distribution of the Sample across the experimental and control groups.
- Figure 4 illustrates the distribution of the sample across the different SOCIABLE patient groups.

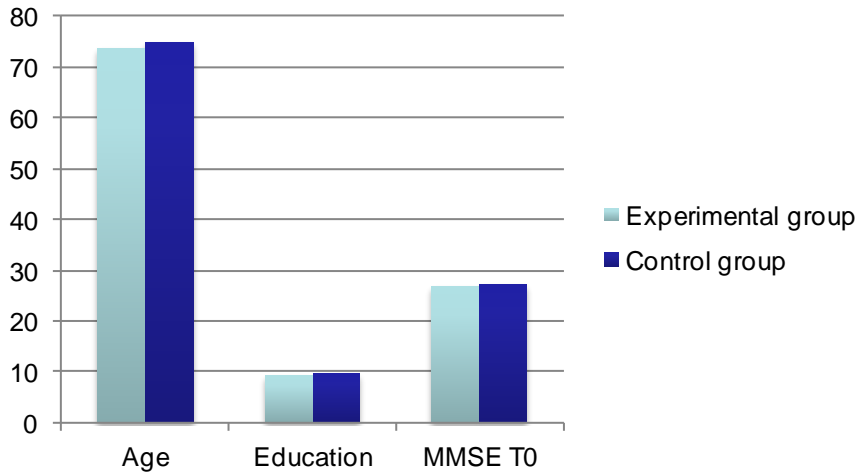


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Figure 2: Distribution of users per country and SOCIABLE group

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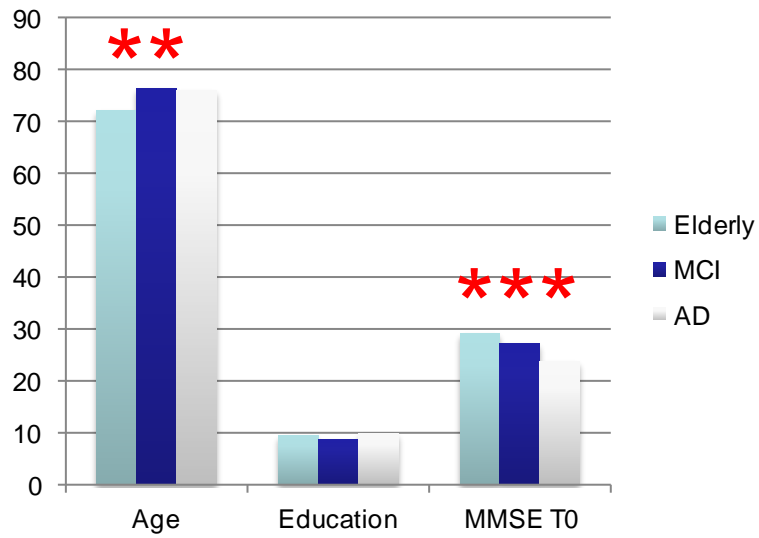


Variable	t	df	Sig. (2-tailed)
Age	-1,045	112	0,298
Education	-0,853	112	0,396
MMSE T0	-0,473	112	0,637

Variable	Group	N	Mean	Std. Deviation	Std. Error Mean
Age	Experimental group	57	73,49	6,451	0,854
	Control group	57	74,75	6,454	0,855
Education	Experimental group	57	9,04	3,664	0,485
	Control group	57	9,67	4,223	0,559
MMSE T0	Experimental group	57	27,04	2,958	0,392
	Control group	57	27,28	2,569	0,34

Figure 3: Distribution of the Sample across the experimental and control groups

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Age	Mean	Std. Deviation	N
Elderly	72,29	6,808	59
MCI	76,3	5,441	27
AD	75,89	5,567	28
Total	74,12	6,455	114
Education	Mean	Std. Deviation	N
Elderly	9,46	3,697	59
MCI	8,63	4,55	27
AD	9,82	3,897	28
Total	9,35	3,949	114
MMSE T0	Mean	Std. Deviation	N
Elderly	28,93	1,258	59
MCI	27	2,386	27
AD	23,57	1,665	28
Total	27,16	2,761	114

Figure 4: Distribution of the Sample across the different SOCIABLE patient groups

4. Analysis of the Results

4.1 Description of measures, variables and samples

In-line with the SOCIABLE methodology for clinical/medical evaluation, we executed an interim analysis separately for one measure of each cognitive, behavioral, functional and social abilities (Table 2).

ABILITIES	AREA	TEST
COGNITIVE	GLOBAL FUNCTIONING	Mini Mental State Examination
	REASONING	Clock Drawing Test
	VERBAL MEMORY-LONG TERM	Rey's auditory Verbal Learning Test- immediate
	PRAXIS	Rey's Complex Figure-copy
	VISUO-SPATIAL MEMORY	Rey's Complex Figure-delayed recall
	VERBAL MEMORY-SHORT TERM	Digit span
	EXECUTIVE FUNCTIONS	Phonological Verbal Fluency
	ATTENTION	Trial Making Test A
	LANGUAGE	Naming-names
BEHAVIORAL	DEPRESSION	Geriatric Depression Scale
FUNCTIONAL		CDR
SOCIAL		Lubben

Table 2: Measures included in the interim analysis of the results (covered in the present deliverable)

All these data were collected through the neuropsychological assessment in two occasions: at T0 (of the pilot operations i.e. 01/05/2011) and after 3 months at T1 (of the pilot operations i.e. 31/07/2011). Data were collected for the experimental group (G1; i.e. the one that received SOCIABLE treatment) and for the control group (G2; i.e. the group that did NOT receive SOCIABLE treatment). Subjects were randomly allocated between the two parallel groups (experimental and control) in each pilot site and for each kind of group (A, B and C; i.e. Healthy elderly, MCI and mild AD). The analysis was performed on a total of 114 subjects, half of G1 (n=57) and half of G2 (n=57). About half of the total subjects (n= 59) were healthy subjects and the remaining were one half MCI (n=27) and AD (n=28).

The random allocation of participants within the two groups (experimental and control) meant to prevent a possible selection bias determining differences in known factors such as MMSE score, age and educational level. To be sure that these factors were homogeneously distributed between the experimental and the control groups we performed as preliminary analysis an independent sample T-test for MMSE at T0, age and education. All the three tests were not significant: MMSE $t(112) = -0,473$, $p = ,637$, age $t(112) = -1,045$, $p = ,298$ and education $t(112) = -0,853$, $p = ,396$.

The difference between the experimental and control group was not significant also taking separately each group of subjects (Healthy elderly, MCI and mild AD) - Healthy

elderly: MMSE $t(57)= 0,418$, $p=0,677$, age $t(57)= -1,534$, $p= 0,131$, education $t(57)= -0,471$, $p= 0,640$; MCI: MMSE $t(25)= -1,136$, $p=0,267$, age $t(25)= 1,266$, $p= 0,232$, education $t(25)= -1,122$, $p= 0,273$; mild AD: MMSE $t(26)= -674$ $p=0,506$, age $t(26)= -0,775$, $p= 0,445$, education $t(26)= 0,143$, $p= 0,888$.

4.2 Description of the analysis

We performed some repeated measure ANOVA 2x2 with as within factor the time (t0-t1) and as between factor the group (experimental-control). We were interested in the interaction between these two factors, i.e. whether the presence of the treatment (experimental group) between t0 and t1 exerted a stronger effect respect to the absence (control group). For this reason we looked for the interaction between time (t0-t1) and group (experimental-control). A positive effect of the treatment could generate two different effects: an improvement of the performance on the experimental group and a stability or decrease on the control group; a stability of the performance on the experimental group and a decrease on the control group. The first situation might be more likely for healthy subjects, instead the second for patients (MCI and AD).

4.3 Results Presentation

In Table 3 we report all the test of the battery with the significance of the interaction between group and time period for all three groups together and separately for each one (Healthy elderly, MCI and mild AD).

ABILITIES	AREA	TEST	ALL	HE(A)	MCI (B)	A(C)
COGNITIVE	GLOBAL FUNCTIONING	Mini Mental State Examination	<.05	<.05	ns	=.188
	REASONING	Clock Drawing Test	ns	ns	<.05	ns
	VERBAL MEMORY-LONG TERM	Rey's auditory Verbal Learning Test-immediate	=.001	<.001	ns	ns
	PRAXIS	Rey's Complex Figure-copy	ns	ns	ns	=.079
	VISUO-SPATIAL MEMORY	Rey's Complex Figure-delayed recall	ns	=.173	ns	ns
	VERBAL MEMORY-SHORT TERM	Digit span	ns	<.05	ns	ns
	EXECUTIVE FUNCTIONS	Phonological Verbal Fluency	ns	<.05	ns	ns
	ATTENTION	Trial Making Test A	=.091	<.05	ns	ns
	LANGUAGE	Naming-names	<.01	ns	ns	<.05
	BEHAVIOURAL FUNCTIONAL	DEPRESSION	Geriatric Depression Scale	ns	<.05	ns
		CDR	=0,059		ns	=.191
SOCIAL		Lubben	ns	=.053	ns	ns

Table 3: Significance of the interaction between time (t0/t1) and group (experimental/control) for all the three groups together and separately for healthy subjects, MCI and AD (in red significant results, in blue the approaching significance results).

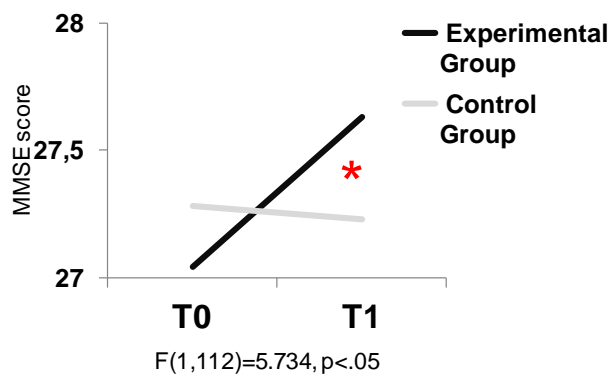
When we conducted the analysis with all the three groups together a significant or almost significant effect of the treatment emerged for the cognitive and functional measures. In particular the treatment exerted a positive effect on a global cognitive measure as MMSE, on verbal memory, attention and language. Moreover, we observed a positive effect also on functional abilities as emerged in the Clinical Dementia Rating scale. The analysis conducted separately for each group of subjects revealed an effect of the treatment on healthy subjects on almost all the cognitive functions and also on behavioural and social abilities. The effect of the treatment on MCI and AD was confined to one single measure (i.e. reasoning for MCI and language for AD) but it should be noted that the analysis on healthy subjects were conducted on a sample that was double (n= 59) respect to the one of MCI (n= 27) and AD (n= 28). Moreover, a trend to a significant interaction was present for AD also for global cognitive functioning, praxis and functional abilities.

4.4 Diagrammatic Representations

Following diagrams depict major outcomes of the analysis that lead to the conclusions of the next sessions. In particular:

- Figure 5 illustrates the comparison between the experimental and the control groups on the basis of the evolution of their MMSE scores at the beginning and the end of the three month SOCIABLE programme. The figure illustrates that the experimental group (i.e. the group experiencing SOCIABLE) has improved their cognitive status in comparison to the control group, which is an early yet clear indication of the benefits associated with the participation in the SOCIABLE programme.
- Figure 6 illustrates the comparison of the MMSE score of the experimental and control groups, for each one of the three target groups involved in SOCIABLE (cognitive intact elderly, MCI, mild AD).
- Figure 7 illustrates the positive effect of SOCIABLE in the Ray word scores of the experimental group (compared to the control group), which demonstrates that SOCIABLE had a positive effect on the seniors' ability to recall words.
- Figure 8 analyzes further the results of the Ray's word test comparisons, through providing the details for the three different groups.
- Likewise the rest figures (Figure 9, Figure 10, Figure 11, Figure 12, Figure 13, Figure 14, Figure 15, Figure 16) compare the experimental and control groups on the basis of the rest test of the SOCIABLE battery. As in the cases of the previous tests, the comparison is performed on the total number of subjects (of the experimental and control groups) and later analyzed per each one of the involved groups. The positive effects of SOCIABLE programme is further reinforced. However, the main conclusion (based on the stronger evidence available are summarized in the following section).

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Assessment	Group	Mean	Std. Deviation	N
T0	Experimental	27,04	2,958	57
	Control	27,28	2,569	57
	Total	27,16	2,761	114
T1	Experimental	27,63	2,736	57
	Control	27,23	2,739	57
	Total	27,43	2,733	114

Figure 5: MMSE comparison between the experimental and control group

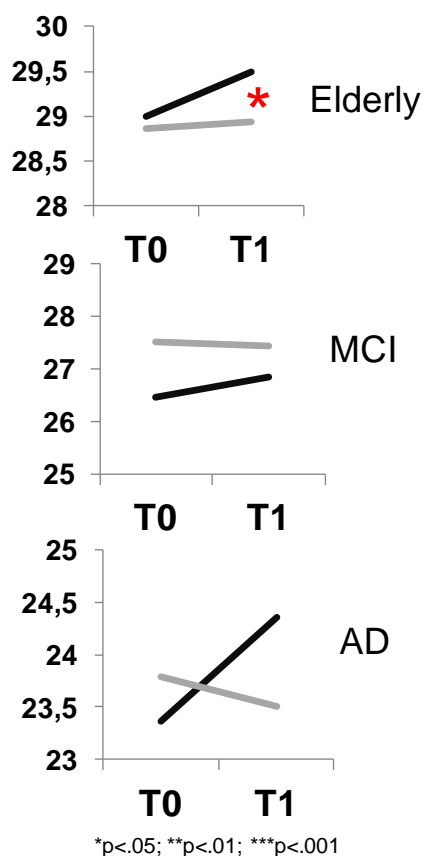
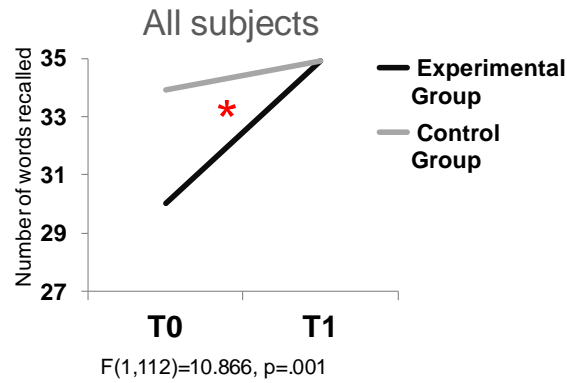


Figure 6: MMSE Comparison for the different target groups



Assessment	Group	Mean	Std. Deviation	N
T0	Experimental	30,02	16,044	57
	Control	33,93	15,967	57
	Total	31,97	16,055	114
T1	Experimental	34,91	19,102	57
	Control	34,91	15,977	57
	Total	34,91	17,531	114

Figure 7: Rey’s word comparison between the experimental and control group

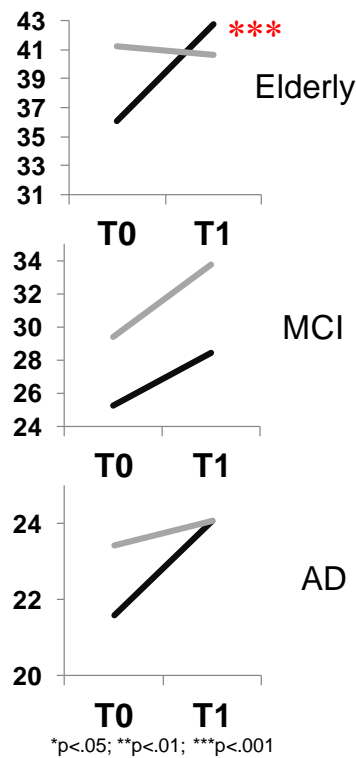
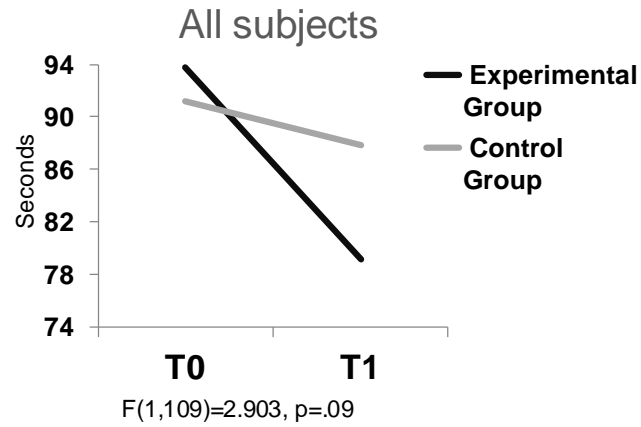


Figure 8: Rey’s word comparison for the different SOCIABLE target groups (cognitive intact elderly, MCI, mild AD)



Assessment	Group	Mean	Std. Deviation	N
T0	Experimental	93,73	48,562	55
	Control	91,2	38,422	56
	Total	92,45	43,56	111
T1	Experimental	79,13	42,435	55
	Control	87,84	36,467	56
	Total	83,52	39,599	111

Figure 9: Trail Making Test comparison between the experimental and control group

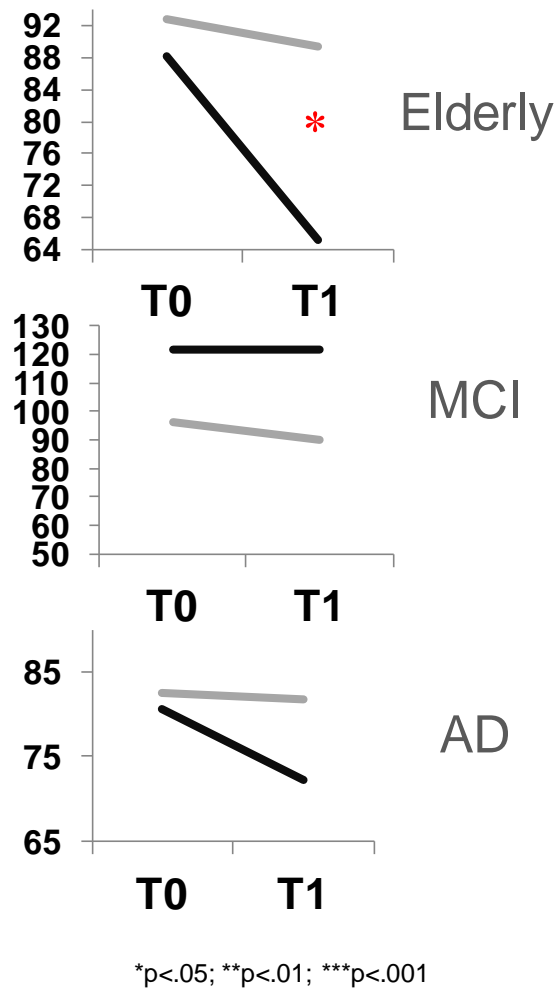
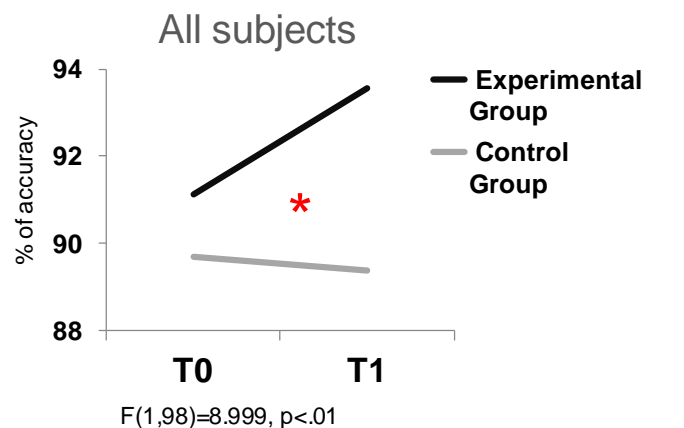


Figure 10: Trail Making Test comparison for the different SOCIABLE target groups (cognitive intact elderly, MCI, mild AD)



Assessment	Group	Mean	Std. Deviation	N
T0	Experimental	91,11	9,131	48
	Control	89,7	13,694	52
	Total	90,38	11,691	100
T1	Experimental	93,56	7,681	48
	Control	89,38	14,076	52
	Total	91,39	11,597	100

Figure 11: Language (Naming games) comparison between the experimental and control group

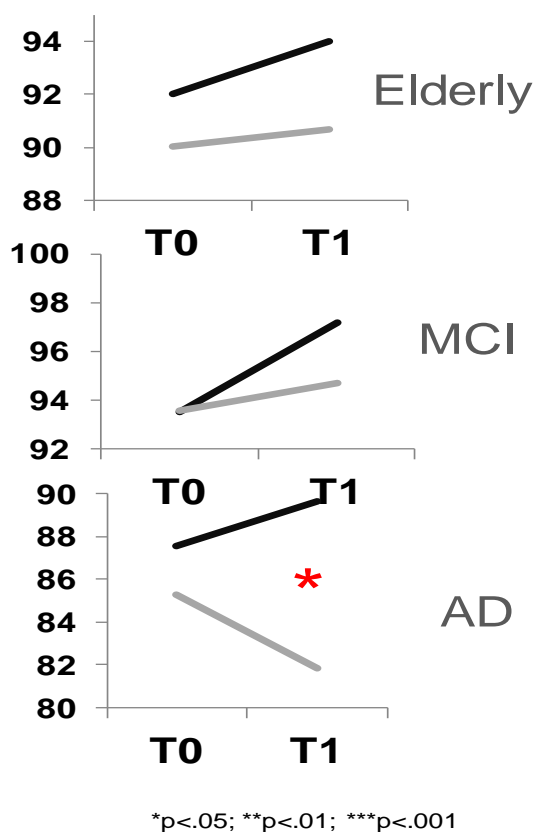


Figure 12: Language (Naming games) comparison for the different SOCIABLE target groups (cognitive intact elderly, MCI, mild AD)

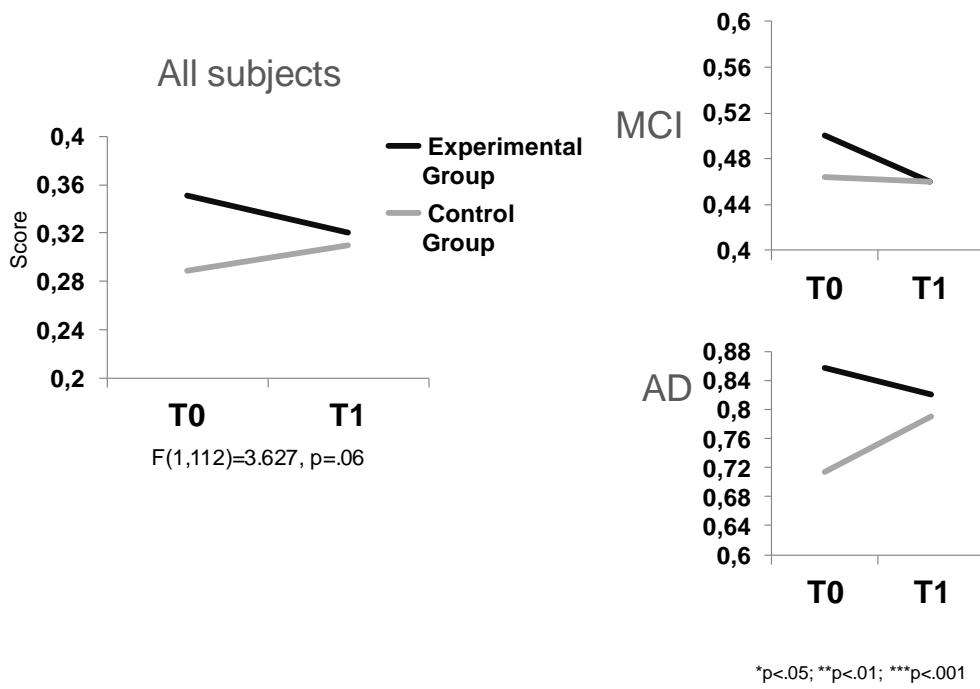


Figure 13: Comparisons Associated with the Clinical Dementia Rating Scale Test

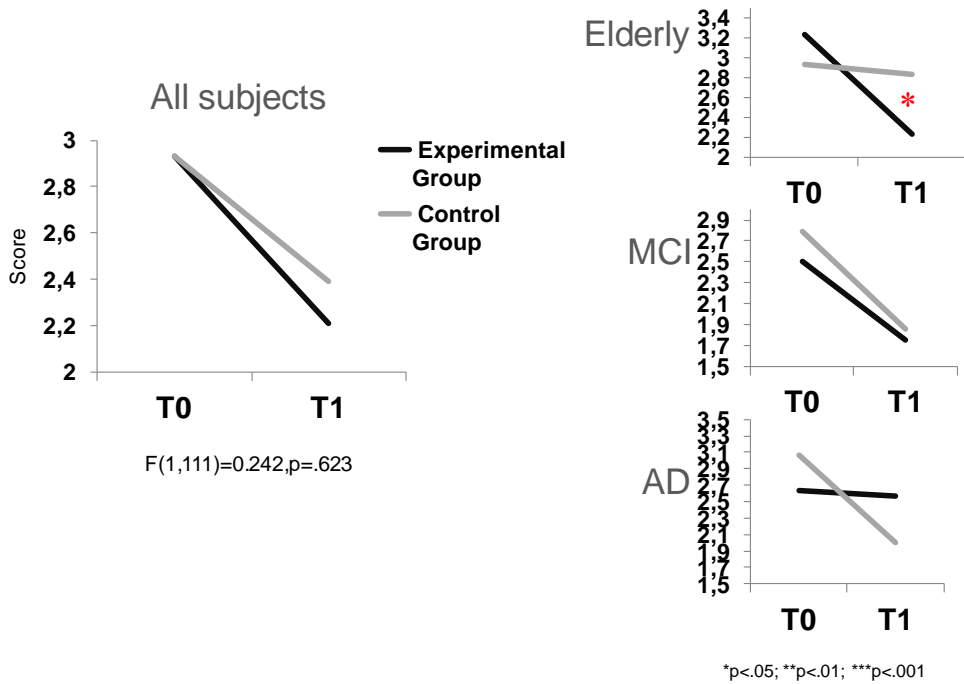


Figure 14: Comparisons Associated with the Geriatric Depression Scale Test

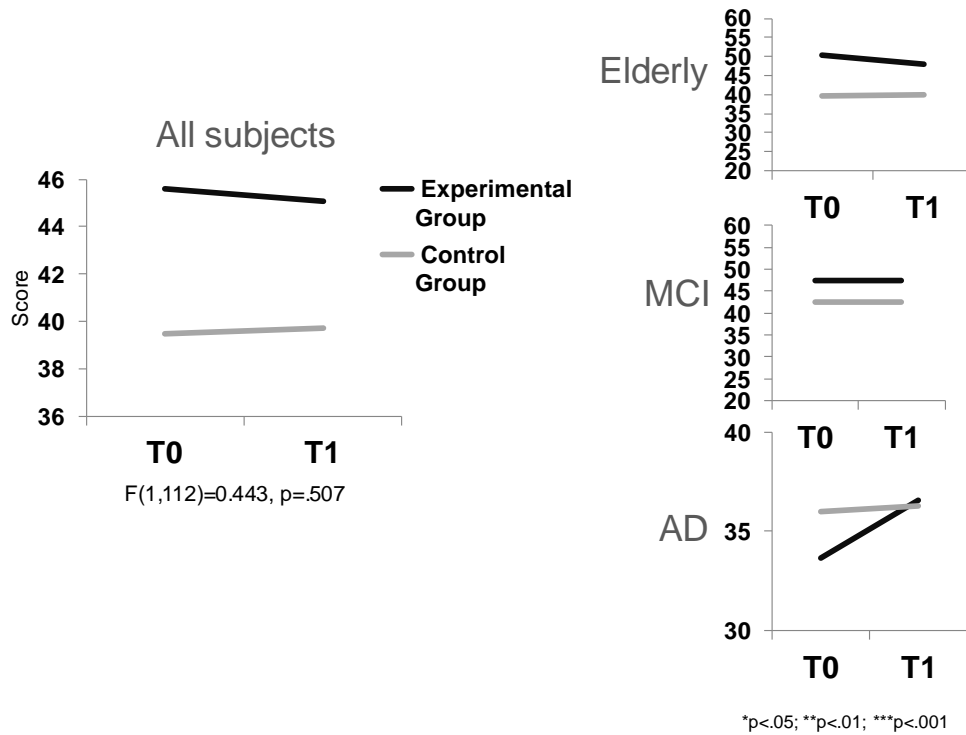


Figure 15: Comparisons Associated with the Lubben Scale Test

Satisfaction

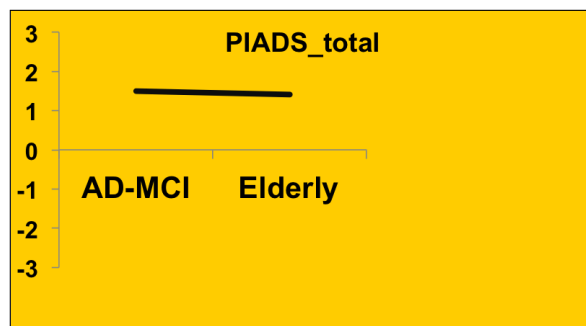


Figure 16: Comparisons Associated the Psychosocial Impact of Assistive Devices Scale (PIADS) (i.e. satisfaction and impact of ICT)

5. Conclusions

In the scope of this deliverable we have processed results from the first quarter of formal pilot operations at the SOCIABLE sites. This interim analysis revealed a significant positive effect of the treatment. In fact, a significant interaction between the time of evaluation (T0 and T1) and group (experimental and control) emerged for all three groups of subjects (healthy subjects, MCI and mild AD) on several neuropsychological tests that measure cognitive, behavioral, functional and social abilities. This means that the experimental group that underwent the treatment showed a greater difference between the evaluation at T0 and T1 compared with the control group that did not undergo any treatment. In particular, when the analysis was conducted on all the three groups together, the treatment positively influenced the global cognitive and functional abilities of the participants as demonstrated with the MMSE and CDR. In particular, the cognitive functions that most benefited from the treatment were attention, verbal memory and language. Taking the three groups separately, the healthy subjects sample was the one that most benefited from the treatment showing a positive effect on several measures of cognitive functions (memory, attention, executive functions), on mood and social relationships. MCI showed a positive effect on abstract reasoning whereas mild AD on global cognitive and functional abilities, on praxis and language. These preliminary results are definitely encouraging continuing to collect data as to enlarge the sample of participants. This might let us obtain some stronger significant effect of the treatment on all the three groups and in the most of the abilities treated and evaluated.

The above set of conclusions stems from an initial analysis that takes into account a set of 57 subjects that participated in the first three months of the SOCIABLE pilot operations. The SOCIABLE pilot operations plan (which is currently executed) foresees the involvement of a total of 348 users, which will allow more detailed and accurate conclusions to be derived. The analysis of the whole sample (along with the related conclusions) will lead to the final version of the present deliverable. In the meantime, additional intermediate versions of the present deliverable could be delivered as more users participate in the project.