SOCIABLE DELIVERABLE D7.2b
"Final Assessment of the SOCIABLE Platform and Services"

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This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

Revision History

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0.1	Stelios Pantelopoulos, Chiara Zaccarelli	SLG, AUSL	05/10/2012	Structure and Table of Contents, Introduction
0.2	Annicchiarico Roberta, Francesco Barban	FSL	01/11/2012	Analysis of the results
0.3	Stelios Pantelopoulos	SLG	05/11/2012	Executive Summary and Main Conclusions
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Abstract

This deliverable presents the results of the final evaluation of SOCIABLE and services 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 full duration of the SOCIABLE formal pilot operations, which took place from May2011 to July2012. This information has been analyzed statistically as explained within the deliverable.

Note that the document corresponds to the second version of D7.2 deliverable (D7.2b), which extends the results presented during a first version of the deliverable (D7.2a) that focused on the interim evaluation of the SOCIABLE pilot operations. In the scope of the deliverable a comparative assessment has been performed between the interim and the final evaluation results. Overall, the results of the final evaluation demonstrated benefits of the SOCIABLE approach to all target groups, thereby confirming that SOCIABLE could be a good tool for both patients in the prodromal phases of dementia and cognitively intact elderly. For the latter group, it could also be used as a preventive intervention. Note that different cognitive skills were positively affected for the different groups, as stated in detail in the analysis of the results.

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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 is the final version of D7.2, which enhances/enriches results and conclusions outlined in the scope of the earlier (interim) version of the deliverable. Hence, it takes into account the assessment scores of all the elderly that participated in the SOCIABLE clinical trial. In particular the deliverable analyzes the assessment scores of elderly users that participated in the SOCIABLE pilot phase (May2012-July2012). 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 Cognitively Intact elderly, elderly with Mild Cognitive impairment (MCI) and patients suffering from Mild Alzheimer's Disease (AD)). The final evaluation analysis was performed over a total of 318 subjects, a number lower that the total of 350 subjects that were actually involved in the study. This was due to the fact that several patients dropped out of the study. Note that the deliverable includes a comparative assessment of the results of the interim evaluation with the results of the final evaluation. This is performed intentionally in order to present the evolution of the pilot operations and the relevant findings.

In terms of main conclusions drawn, the analysis of the results revealed a sustainable positive effect of the SOCIABLE intervention on the cognition of healthy elderly. This effect actually confirmed a similar trend, which had been observed since the interim evaluation cycle. At the same time, the analysis of the assessment scores of the

elderly/patients that participated in SOCIABLE sessions, along with the comparison with a control group, revealed that SOCIABLE can improve the cognitive skills of elderly belonging to all three target groups participating in the study. For example, cognitively intact elderly experienced improvement in almost all cognitive functions, while MCI patients and mild AD patients experienced a positive effort on global cognition measures, memory and executive functions. Overall, the analysis of the results is positive and will be used as an asset in supporting the SOCIABLE partners' exploitation and sustainability plans, since it will act as initial evidence of the validity of the SOCIABLE approach. Nevertheless, there is room for significantly enhancing and reinforcing this evidence by organizing and performing wider clinical studies. This is a direction that same of the SOCIABLE partners intend to pursue in the coming months/years.

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 foresees the involvement of more than 350 users across seven pilot sites in four countries. Following intense efforts to integrate the SOCIABLE ICT platform, prepare the seven pilot sites and commerce the pilot operations, the project has focused on the 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. Note that the pilot operations were organized in four quarterly cycles as explained in deliverable D6.1 The present version of the deliverable focuses on the analysis of the full set of data (assessment scores) derived during the whole duration of pilot operations spanning in terms of calendar dates the period 01/05/2011-31/07/2012. Hence, this deliverable constitutes the final version of D7.2, which complements an earlier version comprising the interim clinical assessment of the SOCIABLE pilot operations based on data derived during the first seven months of the pilot operations. Hence, the evaluation is characterized as "final", since it comprises data from almost all the participants to the SOCIABLE clinical trial, as the latter was designed/specified in the scope of the SOCABLE study design and pilot operations plans.

The structure of this final version of the D7.2 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 is devoted to a brief outline of the results of the interim evaluation, in an attempt to provide a link between the interim and the final version of deliverable. Section 4 is devoted to the presentation of the results from the cumulative analysis of all the assessment scores of the elderly that participated in SOCIABLE pilot operations. Specifically, Section 4 illustrates the selected/analyzed population, the outcomes of the analysis, as well as the main conclusions. Section 6 concludes this version of the deliverable. As part of the conclusion a comparative assessment between the findings of the interim version and those of the final version is attempted. Overall, the conclusions of the present deliverable provide some initial clinical evidence about the validity of the SOCIABLE approach. This evidence will be used as part of the project's exploitation and marketing efforts, given that the clinical validity of the SOCIABLE approach is among the assets of the project's exploitation strategy.

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. The methodology described in the following paragraphs was followed in the scope of both the interim and the final evaluation cycle of the project.

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 assessments are conducted simultaneously in both groups (experimental and control) at enrollment and after three and six months thereafter.

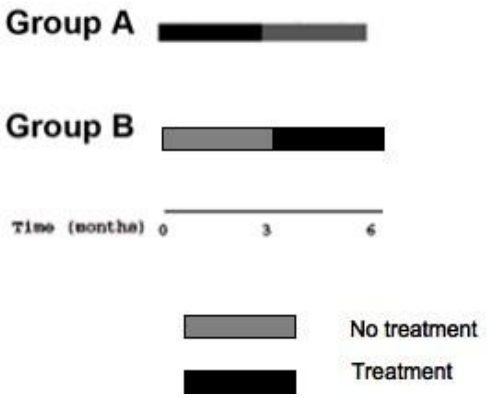


Figure 1: Description of the different treatment and NO treatment sessions of the experimental group (A) and control group (B). A different assessment will be conducted at the 0, 3 and 6 months.

The principal outcome for the study is the progression over time of the neuropsychological deficit in different cognitive 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 trough the defined scales.

2.1.2 Randomization of Participants

In the scope of the study, subjects were randomly allocated in the experimental or control group, separately for each pilot site and for each group (elderly, MCI and AD) as illustrated in Table 1. Note that the numbers listed in the table present some deviations from the numbers planned originally in the SOCIABLE study as part of deliverables D5.1 and D6.1. This deviation was a result for the need to revising/reallocating some numbers in order to keep the study on track and given the difficulty of some pilot sites to recruit the appropriate number patients from the needed/appropriate target groups. The reasons of these revisions have been detailed in deliverable D6.2 of the project, as well as in the scope of the project's periodic report (which include a description of the risk management methodology associated with the SOCIABLE study).

	Group A	Group B	Group C	Drop out	Total
TRONDHEIM	0	0	5	3	**8**
HYGEIA	5	29	17	15	**66**
COFO	24	19	0	7	**50**
AUSL	0	48	7	2	**57**
FSL	0	12	54	2	**68**
PREVI	35	0	0	5	**40**
SPC	60	0	0	0	**60**
TOTAL	**124**	**108**	**83**	34	**348**

Table 1: Distribution of subjects between the different pilot sites

Note that 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.

2.1.3 Methodology for the analysis of the results

The data collected from the different neuropsychological tests and socialization scales were 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 the control group.
- These results will be analyzed separately in each group (Normal, MCI, AD).
- Different socialization level in the experimental and the control group.
- Possible correlation between cognitive performance and social level will be

evaluated.

The deliverable analyzes the results of the all the cycles of the SOCIABLE formal pilot operations and reports the main conclusions. Note that the timing of the pilot operations does not coincide with the calendar start and finish of the specified quarterly periods, given that several sites started or finished the period in different calendar intervals (for reasons explained in deliverables D6.2 and D6.3). However, in the scope of the deliverable we conveniently refer to four quarterly periods in terms of the actual conduction of the pilot operations, not to calendar periods.

In-line with the SOCIABLE methodology for clinical/medical evaluation, we executed an interim analysis separately for each measure assessing cognitive, behavioral, functional and social abilities. A detailed list of the tests that were administered as part of the final evaluation cycle is provided in a following paragraph (as part of Table 3).

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 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 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 were provided to partner FSL, which is in charge of the statistical processing/analysis according to the presented study design procedures.

Note that during the period between the interim and the final evaluation the back-office module (of the SOCIABLE platform) has been enhanced (as part of WP4) in terms of its ability to support the assessment procedures (that are associated with the clinical evaluation/assessment), as well as the procedures of collecting/exporting the assessment scores. Thus, the collection and processing of the results during the final evaluation cycle was greatly facilitated by these enhancements to the back-office module. The process of collecting the results was overall easier that the respective process of the interim evaluation cycle.

3. Summary of the main findings of the interim assessment (May2011-December2011)

The interim clinical evaluation of the SOCIABLE pilot operations had focused on the assessment of the SOCIABLE cognitive training and social activation paradigm from a clinical perspective. To this end, the assessment scores of all elderly that participated in the SOCIABLE pilot operations in the period May2011-December2011 have been collected and processed. The assessment relied on the SOCIABLE evaluation framework presented in D7.1, which makes use of the tests and questionnaires specified as part of SOCIABLE battery for cognitive, functional and affective assessment of the elderly. Note that the evaluation involves the comparison of the assessment scores of an experimental (composed of elderly participating in the SOCIABLE pilot operations) and a control group (composed of elderly that do not participate in the pilot operations with the SOCIABLE platform). The assessment results have been presented in a progressive manner, first for the first quarterly cycle of the pilot operations and them cumulative i.e. for the first two quarterly cycles of pilot operations. The presentation of the cumulative results is associated with the interim assessment of the SOCIABLE paradigm, given that they are based on the assessment scores of almost half of the patients expected to participate according to the study design. Note that the interim assessment took into account a set of 117 subjects (in total) that participated in the first two quarterly cycles of SOCIABLE pilot operations.

The interim analysis revealed a significant positive effect of the treatment. After the treatment period we observed an improvement on test performance on almost all the measures that we recorded. This emerged in the form of significant (or trends to significance) interactions between time and group. Although no formal analysis was conducted on follow-up effects (which will be performed at the end of the study), a visual inspection of data revealed a positive trend towards maintaining the effect of the treatment after its end, at least for healthy elderly and MCI patients. This suggests that there might be a possibility for executing continuously the treatment for AD patients, though this needs to be validated in following phases of the experimentation as well. The treatment also improved social abilities since most of the subjects performed the treatment in small groups. This finding is especially important since it seems that participation in the SOCIABLE program reduces social retirement that is typical during the early stages of AD and negatively affects cognitive abilities and mood.

These preliminary results were definitely encouraging. As the pilot operations evolved, more data were gathered and analyzed. The relevant analysis of the final evaluation cycle is illustrated in following sections.

4. Final Clinical Assessment associated with the SOCIABLE Pilot Operations (final evaluation cycle)

4.1 Demographics of the SOCIABLE population (all quarterly cycles)

Figure 2 below and Table 2 show average age, years of formal education and Mini Mental State Examination (MMSE) at T0 for the experimental group (the group that received first the treatment and then the rest period) and the control group (the group that received first the rest period and then the treatment period). The graph depicts the fact that the experimental and control group exhibited similar characteristics (in terms of age, education and MMSE T0 scores) at the beginning of the study.

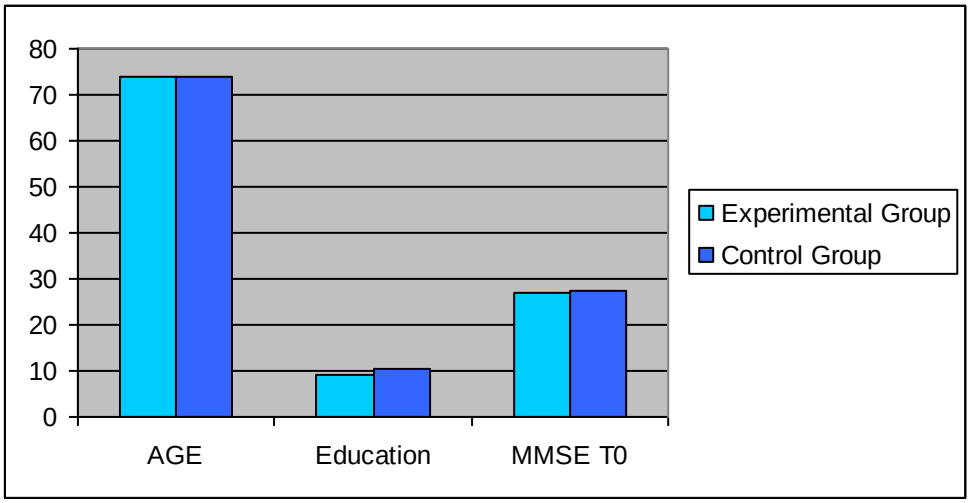


Figure 2: The equivalence experiment and control groups in the scope of the final evaluation cycle of the project (spanning the full duration of the SOCIABLE pilot operations)

Also, Figure 3 and Table 2 illustrate the distribution of the sample of the study across the different target groups participating in the SOCIABLE pilot operations (i.e. cognitively intact elderly, MCI and AD patients).

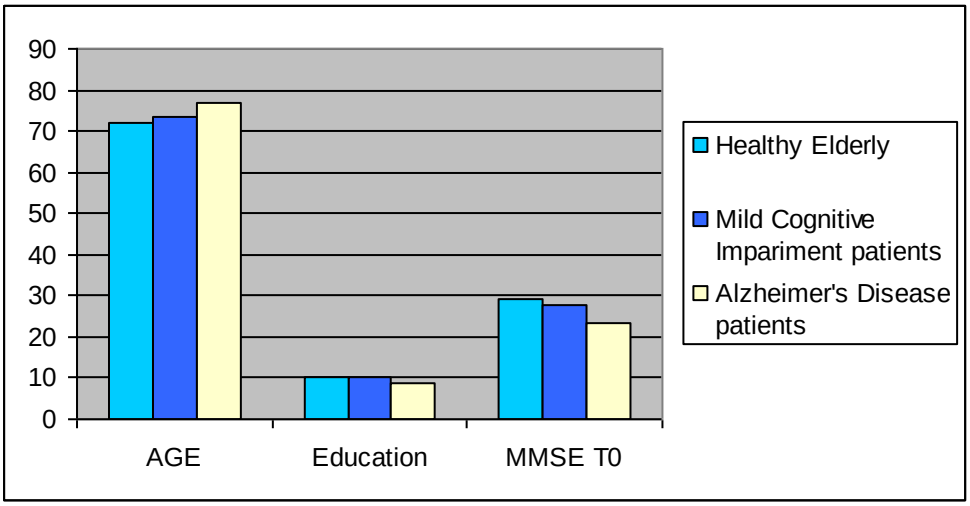


Figure 3: Demographic characteristics across the three target groups of the SOCIABLE study (Group A: Cognitively intact Elderly, Group B: MCI Patients and Group C: AD Patients)

		AGE				Education				MMSE T0			
	Group	M	SD	t	p	M	SD	t	p	M	SD	t	p
HE (A)	CNT	73	7			10	4			29	1		
	EXP	71	6			10	4			29	1		
	Total	72	7	-1.5	ns	10	4	-0.6	ns	29	1	0.27	ns
MCI (B)	CNT	73	6			11	5			28	1		
	EXP	75	6			9	4			27	2		
	Total	74	6	1.64	ns	10	5	-2.3	0.022	28	2	-1.96	0.05
AD (C)	CNT	77	6			9	4			23	2		
	EXP	77	6			9	4			23	2		
	Total	77	6	-0.2	ns	9	4	-0.7	ns	23	2	0.11	ns
Total	CNT	74	6			10	4			27	3		
	EXP	74	6			9	4			27	3		
	Total	74	6	0.02	ns	10	4	-2.33	0.021	27	3	-1.13	ns

Table 2: Distribution of the experimental (EXP) and control (CNT) samples across the different SOCIABLE patient groups: Healthy elderly (HE), Mild Cognitive Impairment (MCI) and Alzheimer's Disease (AD). For each row mean (M), standard deviation (SD), t-test (t) and probability of the t-test (p) are reported. In red the statistical significant differences among the two groups.

4.2 Analysis of the Results

4.2.1 Description of measures, variables and samples

As part of the analysis of the elderly's assessment scores during the final evaluation cycle, we executed a separate analysis for each cognitive, behavioral, functional and social measure (Table 3).

The neuropsychological assessment was performed on three occasions: at T0, at T1 (after 3 months from T0) and at T2 (after 6 months from T0). Data were collected for the experimental group (G1 and G3; i.e. the groups that received SOCIABLE treatment first and then rested for three months) and for the control group (G2 and G4; i.e. the groups that rested for three months and then received SOCIABLE treatment during the following three months).

Subjects were randomly allocated in one of the two parallel groups (experimental and control) in each pilot site and for each kind of group: A (cognitively intact elderly), B (MCI patients) and C (mild AD patients). The analysis was performed on a total of 348 subjects, half in experimental group (G1+G3) and half in control group (G2+G4). About one third of the total subjects were cognitively intact subjects (n= 139), one third were MCI (n=109) and one third AD patients (n=100). Drop-outs were 10%. We collected data from all pilot sites, but only data from subjects that completed all the three evaluations (t0-t1 and t2) were entered in the analysis.

ABILITIES	AREA	TEST
COGNITIVE	GLOBAL FUNCTIONING	Mini Mental State Examination (MMSE)
	REASONING	Clock Drawing Test
	MEMORY- VERBAL-SHORT	Digit span forward
	MEMORY-VERBAL	Rey's auditory Verbal Learning Test-immediate
	MEMORY-VERBAL-LONG	Rey's auditory Verbal Learning Test-delayed
	MEMORY-VISUOSP-LONG	Rey's Complex Figure-delayed recall
	PRAXIS	Rey's Complex Figure-copy
	EXECUTIVE FUNCTIONS	Phonological Verbal Fluency
		Trial Making Test B
		Digit span backward
	ATTENTION	Trial Making Test A
	LANGUAGE	Naming test (country-specific)
BEHAVIOURAL	DEPRESSION	Geriatric Depression Scale (GDS)
FUNCTIONAL		Activities of daily living (ADL)
		Instrumental Activities of daily living (IADL)
		Clinical Dementia Rating Scale (CDR)
SOCIAL		Lubben social network scale (LSNS) Social preferences questionnaire SOCIABLE

Table 3: Measures/Tests included (and taken into account) in the scope of the analysis of the results (final evaluation cycle)

The random allocation of participants within the two groups (experimental and control) meant to prevent a possible selection bias. To be sure that MMSE at T0, age and years of formal education were homogeneously distributed between the experimental and the control groups, we performed an independent sample T-test for MMSE at T0, age (n of years) and education (n of years) as preliminary analysis. A significant ($p<.05$) difference emerged for education between the experimental and control group and, within MCI group, also for MMSE at T0. These variables were entered as covariate of no interest during the analysis of variance (ANOVA) to exclude that the difference between the two groups was due to demographic differences.

4.2.2 Description of the analysis

We performed some repeated measure ANOVA 3x2 with as within factor the time (t0-t1-t2) and as between factor the group (experimental-control). We were interested in the interaction between these two factors that indicates the presence of a treatment effect. In fact, in presence of a treatment effect, the experimental group should have an increase of test scores between T0 and T1, whereas the control group between T1 and T2.

For those tests that showed a significant effect of the training, we also tested the follow-up maintenance of the training effects. With this aim, we tested, with a mixed

2x2 ANOVA, the interaction between time, only with t0 and t2, and group, experimental and control group. We assumed that, in the case of follow-up effects, the experimental group should show a greater difference between t0 and t2 because of the effect of the training and its carry-over effect during the follow-up period compared to the control group that had only the training effect.

For functional scales, since the variability of the scores was very low, we performed the chi-squared analysis. We coded as 0 all the cases in which the users worsened between T0 and T1 and between T1 and T2, and 1 all the cases in which the users improved or remained stable. Then we compared the proportion of users that worsened/improved during the rest period and the training period.

4.2.3 Presentation of Results

Table 4 reports all the tests of the battery with the significance of the interaction between group and time period for all three groups together and for each one separately: Healthy elderly (HE), Mild Cognitive Impairment (MCI) and mild Alzheimer's Disease (AD).

			P values of the ANOVA			
ABILITIES	**AREA**	**TEST**	**ALL**	**HE(A)**	**MCI (B)**	**A(C)**
COGNITIVE	GLOBAL COGNITION	MMSE	<.001	0.113	0.002	0.004
	REASONING	Clock Drawing Test	0.095	ns	ns	0.084
	MEMORY- VERBAL-SHORT	Digit span forward	0.041	0.062	0.024	ns
	MEMORY-VERBAL	RAVL test -immediate	0.003	0.138	0.060	0.002
	MEMORY-VERBAL-LONG	RAVL test -delayed	<.001	0.001	0.012	0.001
	MEMORY-VISUOSP-LONG	Rey's Complex Figure-delayed recall	0.154	ns	ns	ns
	PRAXIS	Rey's Complex Figure-copy	0.025	0.003	ns	ns
	EXECUTIVE FUNCTIONS	Phonological Verbal Fluency	0.004	0.008	0.012	ns
		Trial Making Test B	0.111	0.092	ns	ns
		Digit span backward	0.002	0.061	ns	0.014
	ATTENTION	Trial Making Test A	0.118	0.158	ns	0.057
	LANGUAGE	Naming test (country-specific)	0.012	0.03	ns	ns
SOCIAL		Lubben - family	0.128	ns	ns	0.02
		Lubben - neighbours	ns	ns	ns	0.007
		Lubben - friends	0.006	ns	0.162	0.008
		Social Preferences	ns	ns	ns	0.082

Table 4: Significance of the interaction between time (t0-t1-t2) and group (experimental/control) for all the three groups together and separately for healthy subjects, MCI and AD (in red significant results, in yellow the approaching significance results, ns= non significant results).

Furthermore, Table 5 reports all the behavioral and functional scales of the battery and the significance of chi-squared tests period for all three groups together and for

each one separately: Healthy elderly (HE), Mild Cognitive Impairment (MCI) and mild Alzheimer's Disease (AD).

			P values of the Chi-squared			
BEHAVIORAL	DEPRESSION	Geriatric Depression Scale	0.004	0.148	0.104	0.107
FUNCTIONAL		ADL			ns	ns
		IADL			ns	0.123
		CDR			ns	ns

Table 5: Significance of the chi-squared test between treatment an rest period (comparing users that decreased vs. users that remained stable or increased the performance) for all the three groups together and separately for healthy subjects, MCI and AD (in red significant results, in yellow the approaching significance results, ns= non significant results).

When we conducted the analysis with ALL the three groups taken together (column ALL in Table 4), a significant or approaching significance effect of the treatment emerged for the almost all the measures of the assessment (as you can see in Table 5. red p values). In particular, the treatment exerted a significant positive effect on a global cognitive measure as the MMSE, on memory and executive functions, which were the two cognitive functions most actively treated during the training. A positive effect was also present in praxis and language. Also social abilities showed a positive effect of the treatment. On the contrary, mood scale showed an increase of negative mood after training. This might be a side effect of the increase of the level of consciousness that it is usually associated with the improvement in cognitive abilities.

The analysis conducted separately for each group of subjects revealed:

- For healthy elderly an effect of the treatment was present for almost all the cognitive functions. The effect was not evident for reasoning and global cognition tests (MMSE and Clock Drawing Test) probably because of a ceiling effect.
- For MCI patients a positive effect was present for global cognition, memory and executive functions.
- For AD patients a positive effect was present for global cognition, memory, executive functions and social abilities. A trend was also present for IADL functional scale.

A follow up effect emerged only for Healthy Elderly at the memory test 'RAVLT delayed' ($p<.05$) and a trend toward significance emerged at the language test 'Naming Names' ($p=.1$).

The following diagrams (Figure 4 through Figure 16) compare the experimental and control groups in terms of the their assessment scores in the various tests of the SOCIABLE battery, e.g., Mini Mental State Examination (MMSE), Ray's words verbal learning test (RAVLT).

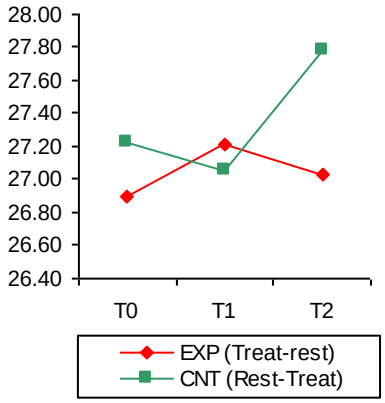


Figure 4: GLOBAL COGNITION / MMSE (mean total score on the y axis) comparison between the experimental and control group (all subjects)

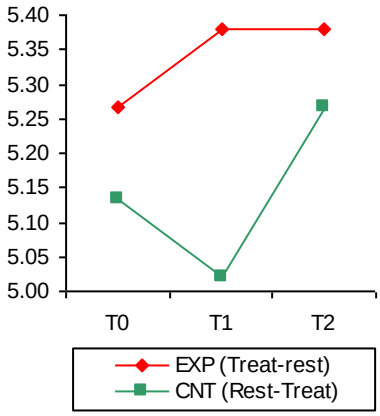


Figure 5: SHORT TERM MEMORY / DIGIT SPAN forward (mean n of digits on the y axis) comparison between the experimental and control group (all subjects)

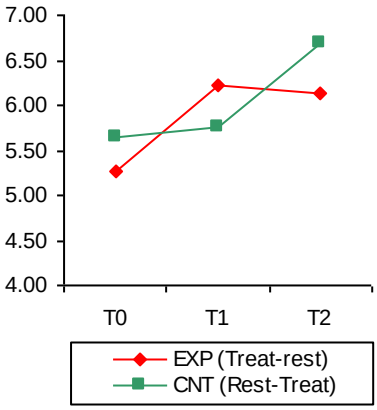


Figure 6: LONG TERM MEMORY / RAVL test delayed (mean n of words recalled on the y axis) comparison between the experimental and control group (all subjects)

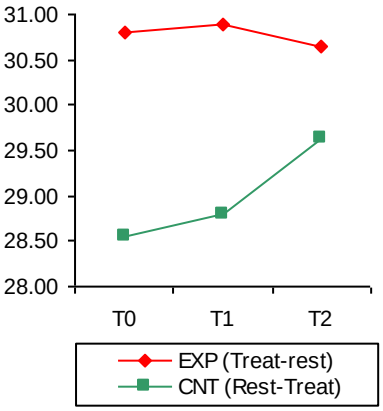
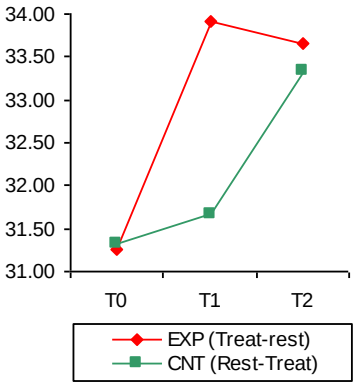
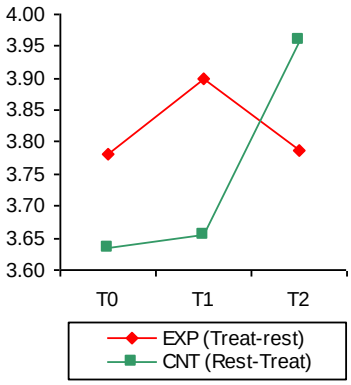


Figure 7: CONSTRUCTIONAL PRAXIS / Rey's Complex Figure-copy (mean score on the y axis) comparison for the different target groups



A



B

Figure 8: EXECUTIVE FUNCTIONS / (A) Verbal fluency (mean n of words on the y axis) and (B) Digit span backward (mean n of digits on the y axis) comparison between the experimental and control group (all subjects)

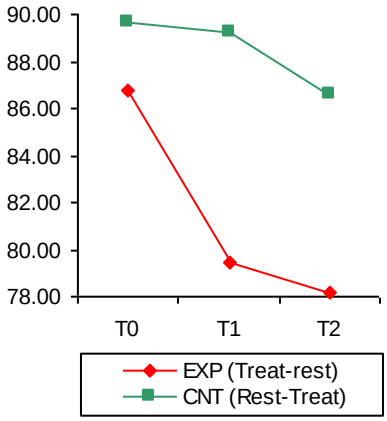


Figure 9: ATTENTION / Trail making test A (mean n of seconds on the y axis) comparison between the experimental and control group (all subjects)

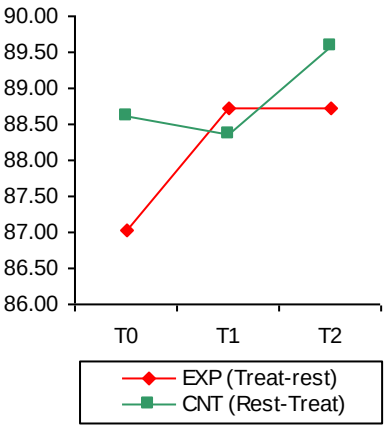
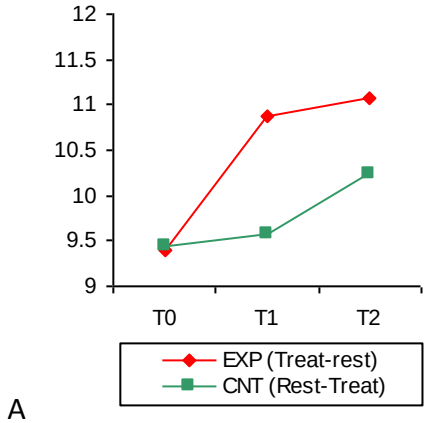
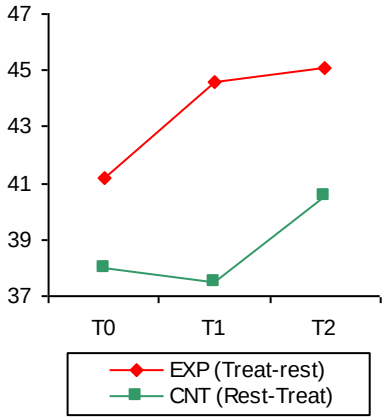


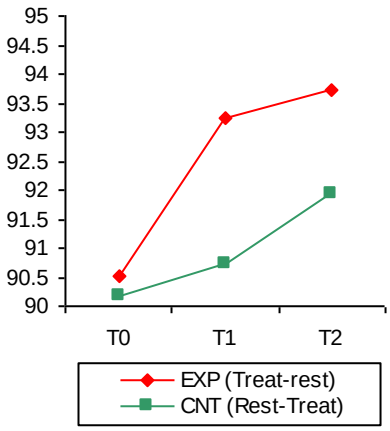
Figure 10: LANGUAGE / Naming test (% of names on the y axis) comparison for the different target groups



A

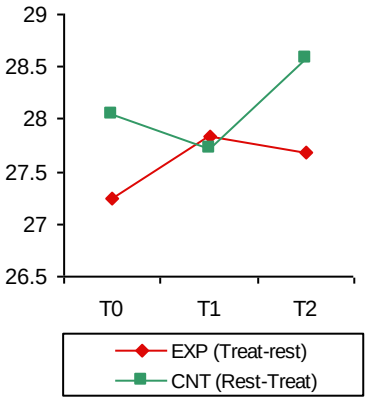


B

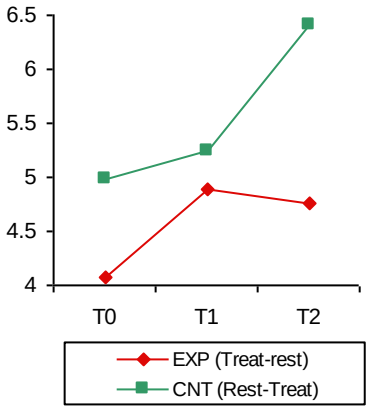


C

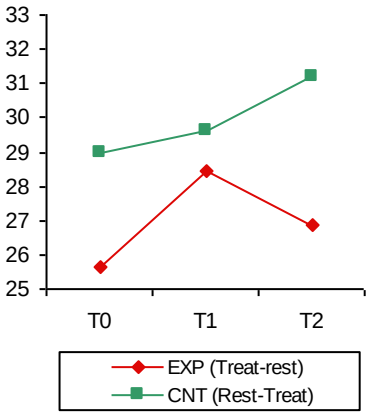
Figure 11: HEALTHY ELDERLY (GROUP A) RAVLT delayed, (B) verbal fluency and (C) naming test comparison for the healthy elderly group


29
28.5
28
27.5
27
26.5
T0
T1
T2
EXP (Treat-rest)
CNT (Rest-Treat)

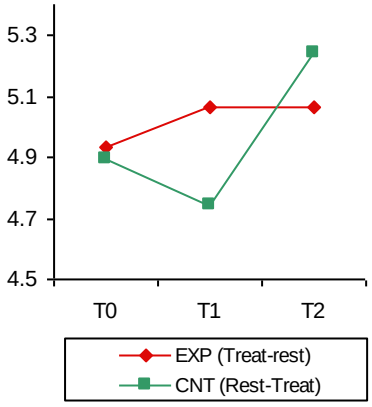
A


6.5
6
5.5
5
4.5
4
T0
T1
T2
EXP (Treat-rest)
CNT (Rest-Treat)

B

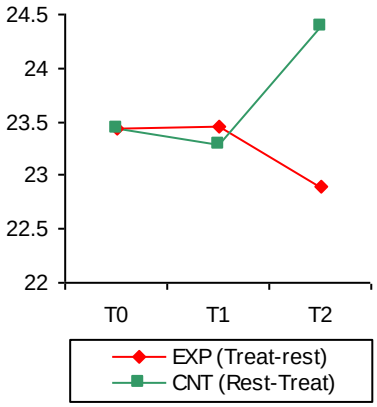

33
32
31
30
29
28
27
26
25
T0
T1
T2
EXP (Treat-rest)
CNT (Rest-Treat)

C

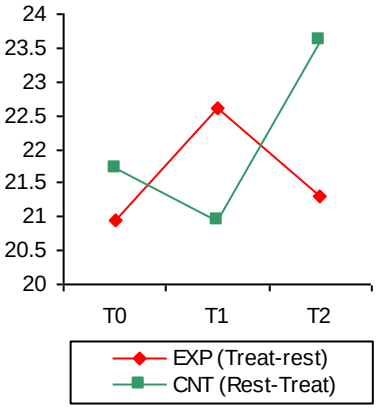


D

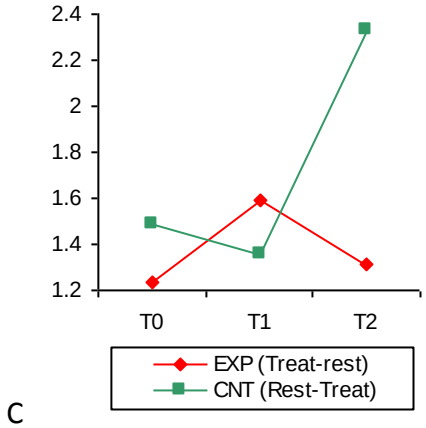
Figure 12: MILD COGNITIVE IMPAIRMENT (MCI) PATIENTS (GROUP B) MMSE, (B) RAVLT delayed, (C) verbal fluency and (D) digit span forward test comparison for the MCI group



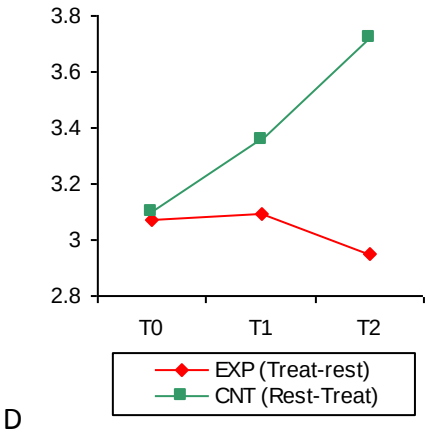
A



B



C



D

Figure 13: ALZHEIMER'S DISEASE (AD) PATIENTS (GROUP C)
(A) MMSE, (B) RAVLT immediated, (C) RAVLT delayed and (D) digit span backward test comparison for the AD group

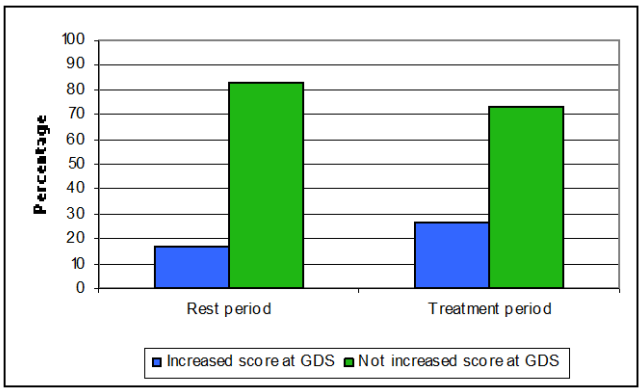


Figure 14: MOOD Geriatric Depression Scale(GDS)(all subjects) Comparison between the rest period and the treatment period in the number of subjects that increased and decreased the score at the GDS scale.

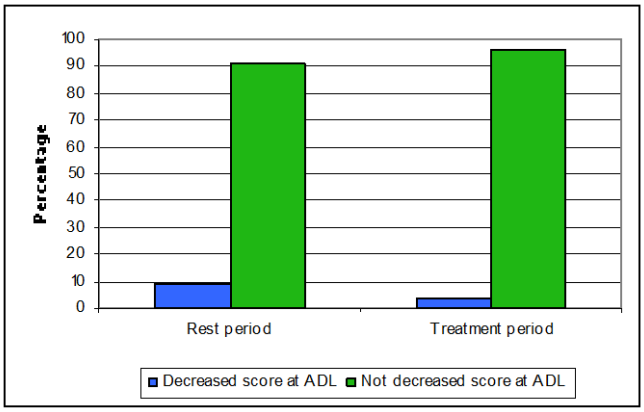


Figure 15: FUNCTIONAL Activity of Daily Living Scale (ADL)(Alzheimer's Disease patients) Comparison between the rest period and the treatment period in the number of subjects that increased and decreased the score at the ADL scale.

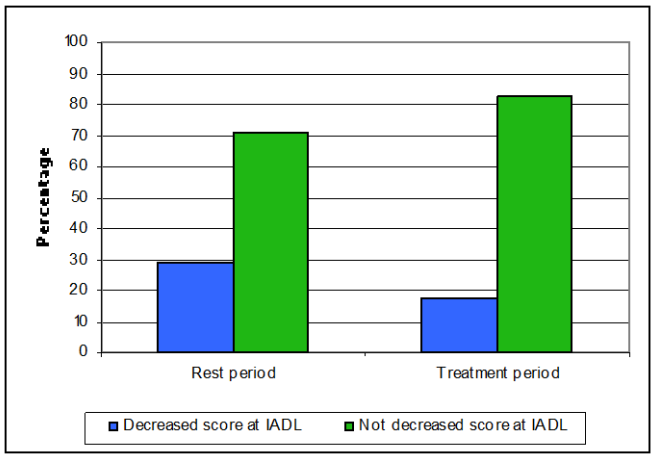


Figure 16: FUNCTIONAL Increased Activity of Daily Living Scale (IADL)(Alzheimer's Disease patients) Comparison between the rest period and the treatment period in the number of subjects that increased and decreased the score at the IADL scale.

4.3 Main Conclusions Associated with the Analysis of the final evaluation cycle

Overall, in mild Alzheimer's Disease and during its prodromal phases, i.e. the Mild Cognitive Impairment, the SOCIABLE intervention had a positive effect on global functioning, as expressed by the MMSE score. Additionally, we observed a positive effect on memory and executive functions, which were the two cognitive functions that were the ones most actively treated during the training. Patients showed an improvement in social as well as in functional abilities. The latter are an indirect evidence of efficacy of the training that corroborate its effects. Mood showed an opposite trend getting worse after training, probably due to the increase of self-consciousness related to the improvement of cognitive functioning.

All the cognitive functions of healthy elderly were improved after training, and in particular memory, language, praxis and executive functions. Moreover, they showed a follow-up effect during the rest period after training in memory and a positive trend in language. This was not the case of Alzheimer's Disease patients.

In conclusion, these results indicate that SOCIABLE is an effective intervention suitable for patients suffering from MCI and mild AD. Additionally, SOCIABLE has also been proven to be useful for cognitively intact elderly as a means of cognitive decline prevention. In this latter case, the treatment, could be administered not necessarily continuously, but also spaced out with periods of rest since we demonstrated that the effect of the training in healthy subjects remains 3 months after the end of the intervention.

5. Conclusions

This deliverable has reported the main results of the final evaluation of the SOCIABLE services from a clinical perspective. This final evaluation has taken into account the assessment scores of all the elderly that successfully concluded their participation in the SOCIABLE sessions, as part of the project's pilot phase. The evaluation process has been based on the SOCIABLE study design (and more specifically on its latest revision), as well as on the clinical assessment methodology specified as part of deliverable D7.1 of the project (dealing with the overall evaluation framework for the SOCIABLE results).

Overall, the results of the clinical evaluation are positive and show that SOCIABLE had a positive treatment effect on all target groups. In particular, cognitively intact elderly experienced a positive effect on almost all (studied) cognitive functions (with reasoning and global cognition being the sole exceptions). MCI patients on the other hand, experienced a positive effort on global cognition, memory and executive functions. The same functions were also improved in the case of mild AD patients, who additionally showed a positive effect on their social abilities as well, along with an improvement in their IADL functional scale.

The analysis of the results in the scope of the final evaluation cycle indicates that SOCIABLE can serve as an effective non pharmacological intervention for the treatment of patients with MCI and mild AD. . At the same time, SOCIABLE has also proven to be a useful tool for cognitively intact elderly, as a means of cognitive decline prevention. In this latter case, the treatment could be administered not continuously but also spaced out with periods of rest, since we demonstrated that the effect of the training in healthy subjects remains 3 months after the end of the intervention.

The positive results of the final evaluation cycle are very important for the partners' business, exploitation and sustainability strategies. The SOCIABLE pilot sites will capitalize on these results in order to justify the effort of continuing to offer SOCIABLE sessions in their sites/centers, while at the same time using them for advertising SOCIABLE to elderly/patient communities. As far as the SOCIABLE exploitation and commercialization planning is concerned, the SOCIABLE partners will use the results of this clinical assessment as initial evidence for the effectiveness and merit of the SOCIABLE platform and tools. Such evidence is needed as an integral element of the marketing plans of the partners, in their efforts to promote and sell SOCIABLE platforms to interested parties.

The proclaimed importance of the SOCIABLE clinical evaluation for the partners' business and sustainability plans is a very good reason for conducting additional clinical studies associated with the effectiveness of SOCIABLE. There are different possibilities regarding the aims and scope of these studies, for example:

- Conducting new studies focusing on the involvement of additional elderly populations in SOCIABLE sessions (e.g., in terms of additional elderly/patients,

but also in terms of new groups/segments of the patient population). The aim of these studies would be to certify the results of the clinical assessment on the basis of wider elderly groups, as well as to evaluate the impact of SOCIABLE on other groups of demented individuals.

- Expanding the scope of the SOCIABLE applicability to target groups beyond demented patients, such as patients suffering from both dementia and additional diseases (such as depression). Such studies may lead the consortium towards new market segments and additional revenue streams.

The consortium is motivated by the importance of such studies, which fall within the imminent or longer terms plans of some of the partners (including both clinical and technical partners). In this context, the assessment results described in the present deliverable could be also seen as a starting point towards these (additional) studies beyond the scope of the SOCIABLE project.