SOCIABLE DELIVERABLE D6.2
"Final Report on the SOCIABLE Pilots"

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0.7	Eva Stamou	SPC	31/08/2012	Inputs from SPC
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1.1	Stelios Pantelopoulos	SLG	18/09/2012	Final Version

Abstract

This deliverable provides a comprehensive report on the organization and conduction of the SOCIABLE pilot operations. It focuses on the presentation of key issues associated with the conduction of pilot operations including recruitment processes, drop-out users, as well as the most common issues associated with the scheduling of the pilot operations. The deliverable reports and explains the number of elderly/patients that were included in the SOCIABLE study, along with their evolution throughout pilot period. The reporting is performed per site, but also for the project as a whole (total numbers). Based on the experiences of the various sites, a number of conclusions are drawn, along with best practices and lessons learnt that could be useful to organizations / consortia undertaking similar studies.

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Executive Summary

The pilot operations of the SOCIABLE (ICT based) approach to the cognitive training and social activation of elderly individuals are at the heart of the project, actually being one of the most prominent tasks. The SOCIABLE pilot operations included a randomized multi-site clinical trial, which was regulated by a relevant clinical protocol. Apart from pilot operations according to this protocol, several users engaged in cognitive training session in an informal fashion, thereby extending the duration and scope of the pilot processes.

The present deliverable reports on the SOCIABLE pilot operations. Initially the document provides an overview of the SOCIABLE pilot operations as a whole, including information about the planned number of users and the number of users ultimately involved in pilot operations. As part of this overview, the deliverable illustrates also the evolution of the pilot operations including the main control points (milestones) and key decisions (including decisions for revising the SOCIABLE study). During the course of the evolution of the pilot operations, the consortium had to revise the SOCIABLE protocol, in order to accommodate changes to the number and type of elderly users that each one of the pilot sites involved in the study. Such changes became necessary as a result of the fact that few SOCIABLE pilot sites could not recruit patients suffering from mild cognitive impairments or mild forms of the Alzheimer's disease. Overall, the SOCIABLE pilot study was concluded on the basis of the involvement of over 350 users in the SOCIABLE study. The assessment scores of these users are currently analyzed as part of the project's evaluation processes. Relevant results will be reported as part of the respective evaluation deliverables of the project in WP7.

In addition to an overview presentation of the pilot operations and their evolution, the deliverable includes reports from the individual pilot sites of the SOCIABLE project. In these reports, all pilot sites reported factual information (e.g., number and type of users, number of session), along main incidents/problems encountered during the pilot operations (such as recruitment issues and drop-out users). Furthermore, each of the pilot sites attempted an overall assessment of the portion of the pilot operations where it participated. All the pilot sites encountered issuers/problems associated with users' recruitment and participation, as well as technical/technological problems. Nevertheless, all pilot sites reported that the SOCIABLE experience was positive and beneficial for all stakeholders (including elderly end-users and health professionals).

Based on the individual reports of the pilot sites, the project has compiled a number of best practices associated with recruitment issues, the organization of individual and group sessions, provisions for dealing with technical problems, the planning of sessions and programme, as well as number and diversity of the needed/required cognitive games. These best practices are addressed to care services providers wishing to adopt the SOCIABLE model for offering ICT-based cognitive training services. Moreover, they could be also of interest to solution providers and

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integrators in terms of the number of games that they should integrate within the SOCIABLE platform. These best practices provide a sound basis for successfully offering the SOCIABLE services on the basis of the corresponding surface computing platforms (i.e. surface tables and Surface/TabletPCs).

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1. Introduction

SOCIABLE is in the phase of concluding its pilot operations regarding a novel ICT based paradigm to the cognitive training of elderly individuals. These pilot operations have been conducted for more than fifteen months (15) in seven pilot sites (operating by the consortium partners) across four different countries. The consortium has early on allocated significant effort towards preparing the sites for the pilot operations, as well as towards planning/scheduling the pilot operations. Furthermore, a medically and statistically sound clinical protocol has been prescribed in order to ensure the scientific value of the pilot operations and the validity of the results to be derived.

Despite the prescription of the SOCIABLE protocol and the creation of a detailed plan (i.e. course of actions) for conducting the pilot operations, all pilot sites had to deal with incidents/events that led to changes and adaptation of the original plan to the new conditions. Such events included difficulties in the scope of recruitment processes, users that abandoned the study, technical problems/issues (already described in deliverable D6.2), as well as wider organizational issues of the pilot study (e.g., changes in the mix of users to be recruited in the study). The adaptation of the original plan (i.e. the plan described in D6.1) was a result of the risk management procedures of the project, which had accounted for most of the issues that are outlined above. The relevant contingency plans were put into effect at two complementary levels: first problems/issues (such as recruitment and participation issues) were addressed at the level of each individual site. Second, and in cases where problems/issues could not be addressed from a single site, the consortium has performed a higher level adaptive reorganization of the pilot operations, which typically required the mobilization of resources and contributions from more than one sites.

Given the issues outlined above (and the respective adaptive planning), the present deliverable reports on the evolution of the pilot operations across all the pilot sites of the project. As a first step the deliverable reports the overall recruitment of patients/elderly in the SOCIABLE study, including how it has evolved across the different quarters of pilot operations (from 01/05/2011 till 31/07/2012). The presentation of the relevant numbers is accompanied by detailed explanations on the recruitment pace, including key events that led to the accelerating or slowing down this pace. Special emphasis is put on the explanation of the conditions that led to revisions to the study design, which impacted the recruitment processes across multiple sites of the consortium. This revision was a contingency measure applied in order to abide by the total target number of patients/elderly that had to be included in the study according to the SOCIABLE clinical protocol and in-line with relevant commitments to the EC (as part of the project's Description of Work).

In addition to the illustration of the total numbers of patients involved across the various sites, the present deliverable includes also pilot operations reports from the individual pilot sites. Individual reports elaborates on issues associated with the

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recruitment of patients, experiences about drop-outs, as well as other organizational issues that had an impact on the execution of the pilot operations plan. Furthermore, a critical assessment of the pilot process is presented (from the perspective of each one of the pilot sites). Note that the technical issues associated with the pilot operations (i.e. issues associated with the operation of the SOCIABLE ICT platform) have been reported in deliverable D6.3. For this reason, this deliverable does not delve into details about technical issues.

The structure of the deliverable is as follows:
- Section 2 following this introductory section provides an overview of the pilot operations at all SOCIABLE pilot sites. It provides insights on the number of users involved in the pilot operations per quarter and per pilot site.
- Sections 3 through 9 illustrate the reports on pilot operations from the seven pilot sites of the project (HYGEIA, FSL, COFO, AUSL, TRONDHEIM, SPC, PREVI).
- Section 10 consolidates a critical overall assessment of the organization and the conduction of the SOCIABLE pilot operations, while illustrating the main lessons learnt.
- Section 11 is the final concluding section of the deliverable.

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2. Overview of the SOCIABLE pilot operations

Following paragraphs provide a factual overview of the SOCIABLE pilot operations. They illustrate the original planning of the pilots, which was based on the SOCIABLE trial protocol and is illustrated in SOCIABLE deliverable D6.1. At the same time, they report on one major revision to the SOCIABLE study design, which was carried out in response to recruitment issues/problems in a couple of pilot sites.

2.1 Pilot Operations Planning and the SOCIABLE Trial Protocol

The SOCIABLE pilot operations were originally planned on the basis of the design of the SOCIABLE study. The SOCIABLE study design specified the protocol of the SOCIABLE clinical trial, on the basis of specific inclusion/exclusion criteria, number of elderly/patients to be involved, as well as specific techniques for the statistical analysis of the results. A detailed presentation of the SOCIABLE study design has been performed in the scope of earlier deliverables D5.1 and D6.1 and is therefore out of the scope of the present deliverable. The following table (Table 1) presents the planned distribution of elderly/patients across the various pilot sites, as included/specified in the original study design. Note that 348 patients/elderly was the target number of patients as part of the original planning of the study. The figures also depicted the distribution of the users across the three groups of elderly/patients, namely cognitive intact elderly aged 65+ (Group A), elderly with mid cognitive impairment (Group B) and elderly with mild Alzheimer's disease (Group C). The detailed definition of these three groups is provided in deliverable D2.1, along with relevant inclusion/exclusion criteria.

		CARE CENTER			HOME				
		A: NH	B: MCI	C: AD		A: NH	B: MCI	C: AD		
Country	Pilot Site				Total per site				Total per site	TOTAL
Greece	HYGEIA S.A	6	20	18	44	4	6	6	16	60
Greece	SPC - Khfissia	56			56	4			4	60
Italy	Commune Forli	10	20		30	4	10		14	44
Italy	Morgagni Pierantoni		40		40		10		10	50
Italy	FSL			40	40			6	6	46
Norway	Trodheim			44	44			4	4	48
Spain	PREVI S.L	20			20	20			20	40
	TOTAL	92	80	102	274	32	26	16	74	348

Table 1: Distribution of elderly/patients across the SOCIABLE pilot sites according to the initial study design

The SOCIABLE pilot operations protocol specified also the detailed process of involving a patient/elderly in SOCIABLE sessions, including relevant inclusion and exclusion criteria. The latter criteria were specified on the basis of the SOCIABLE neuropsychological battery for cognitive, functional and affective assessment, which is presented in detail as part of deliverable D2.1.

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2.2 Pilot Operations Scheduling

The SOCIABLE clinical trial/study protocol specified the number of patients per SOCIABLE site, as outlined above. Accordingly, each pilot sites planned for the inclusion of those patients as detailed in SOCIABLE D6.1. The planning was performed in the scope of four cycles of SOCIABLE sessions, which mapped to quarterly periods (i.e. three-month period). The objective was to include an almost equal number of patients/elderly per pilot site per quarterly period. In practice several sites experience deviations from this objective i.e. they end-up involving many more patients in one quarter comparing to other quarters. The main reason for this deviation was the fact that some sites experienced difficulties in involving the planned number of users. Furthermore, seasonal issues (e.g., inability to carry out pilot operations in August), weather issues and technical issues (e.g., problems with the operation of the surface table) contributed also to several deviations. Moreover, the organization task has been very challenging given the need to involve a control group (i.e. for comparison with the participants to the pilot sessions), which was assessed in analogous intervals yet they did not participate in the SOCIABLE study.

In general the (almost) quarterly planning of the SOCIABLE pilot operations proven to be a very good practice, since it provided/imposed specific control milestones where the pilot operations (at each one of the sites) were reassessed and adapted to emerging conditions. Indeed, most of the pilot sites exploited the quarterly assessment as a means to adapt their planning with a view to meeting the target number of users. In cases where such adaptations were not possible, the consortium had to escalate the issue at the project management level, which dealt with the issue on the basis of revisions to the study design, as well as on the basis of reallocating users from one partner to another. Note that these practices were part of the project's risk management and contingency planning strategies.

2.3 Main Issues and Deviations

Given the quarterly (re)planning and adaptation of the pilot operations scheduling, in the sequel we present/report the evolution of the pilot operations at the various sites for the various (almost quarterly) cycles.

2.3.1 Overview of Pilot Operations Evolution during the first three cycles

Following tables illustrate the number of elderly users that have (successfully) participated in the SOCIABLE pilot operations during the first three quarters of formal pilot operations (Q1, Q2, Q3). Specifically:

- Table 2 illustrates the number of elderly users involved in pilot operations during the first quarter of the SOCIABLE pilots (Q1).
- Table 3 illustrates the number of elderly users involved in pilot operations during the second quarter of the SOCIABLE pilots (Q2).
- Table 4 illustrates the number of elderly users involved in pilot operations during the third quarter of the SOCIABLE pilots (Q3).

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	Group A	Group B	Group C	Care Center	In-Home	Individual	In-Groups	Drop-Outs	Total
TRONDHEIM	0	0	0	0	0	0	0	0	**0**
HYGEIA	0	1	2	3	0	3	0	0	**3**
COFO	7	2	0	9	0	3	6	2	**9**
AUSL	0	12	0	12	0	3	9	1	**12**
FSL	0	0	12	12	0	3	9	0	**12**
PREVI	10	0	0	5	5	7	3	1	**10**
SPC	15	0	0	15	0	6	9	0	**15**
TOTAL	**32**	**15**	**14**	**56**	**5**	**25**	**36**	**4**	**61**

Table 2: Number of Elderly Users that were involved in pilot operations during the first quarter (Q1) of formal pilot operations (during the calendar period May11-July11)

	Group A	Group B	Group C	Care Center	In-Home	Individual	In-Groups	Drop-Outs	Total
TRONDHEIM	0	0	3	3	0	0	3	0	**3**
HYGEIA	2	6	4	9	3	9	3	8	**12**
COFO	11	1	0	12	0	2	10	1	**12**
AUSL	0	15	0	14	1	6	8	0	**15**
FSL	0	0	12	8	3	5	6	1	**11**
PREVI	10	0	0	5	5	7	3	1	**10**
SPC	15	0	0	15	0	9	6	0	**15**
TOTAL	**38**	**22**	**19**	**66**	**12**	**38**	**39**	**11**	**78**

Table 3: Number of Elderly Users that were involved in pilot operations during the second cycle/quarter (Q2) of formal pilot operations (during the calendar period Sep11-Dec11)

	Group A	Group B	Group C	Care Center	In-Home	Individual	In-Groups	Drop-Outs	Total
TRONDHEI	0	1	4	5	0	5	0	1	**5**
HYGEIA	3	11	7	19	3	17	5	4	**22**
COFO	8	6	0	5	9	9	5	1	**14**
AUSL	0	12	3	12	3	4	8	0	**15**
FSL	0	0	10	7	3	4	6	0	**10**
PREVI	10	0	0	5	5	7	3	3	**10**
SPC	15	0	0	14	1	6	9	0	**15**
TOTAL	**36**	**30**	**24**	**67**	**24**	**52**	**36**	**9**	**91**

Table 4: Number of Elderly Users that were involved in pilot operations during the third cycle/quarter (Q3) of formal pilot operations (during the calendar period Dec11-Mar12)

	Group A	Group B	Group C	Care Center	In-Home	Individual	In-Groups	Drop-Outs	Total
TRONDHEIM	0	1	7	8	0	5	3	1	**8**
HYGEIA	5	18	13	31	6	29	8	12	**37**
COFO	26	9	0	26	9	14	21	4	**35**
AUSL	0	39	3	38	4	13	25	1	**42**
FSL	0	0	34	27	6	12	21	1	**33**
PREVI	30	0	0	15	15	21	9	5	**30**
SPC	45	0	0	44	1	21	24	0	**45**
TOTAL	**106**	**67**	**57**	**189**	**41**	**115**	**111**	**24**	**230**

Table 5: Total Number of Elderly Users that were successfully involved in pilot operations cycle/since the beginning of formal pilot operations (calendar period May11-Feb12)

In terms of the planning and the evolution of the pilot operations during the first three quarters, the following remarks are important:

- Pilot sites COFO, PREVI, SPC, AUSL and FSL have abided by their pilot operations plans, in terms of the number of users involved.
- COFO has had some issues with the inclusion of users from Group B (MCI), but in agreement with the partners' in-charge of the study design, it has compensated for this based on the inclusion of Group A elderly instead.
- HYGEIA did start with a lag, but managed to fully execute its plan for the second quarter (Q2). In Q3 it has intensified efforts towards achieving its planned (total) numbers. The assessment of HYGEIA's situation during the reporting period,

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showed that the sites is on track for recruiting the required/planned number of patients. Note however that HYGEIA has the most significant number of drop-out patients, comparing to the rest sites where very few drop-outs took place.

- TRONDHEIM was clearly lagging behind of the targeted numbers. Therefore, TRONHDEIM created an action plan for remedying the significant lags. The plan included activities towards recruiting users from neighboring centers. However, the assessment of the situation at the pilot site during the end of the reporting period (i.e. end of Jan12) reveals that the site has problems including the specified number of Group C users for the following main reasons:
  - The fact that Group C is the most difficult group to recruit, among the three SOCIABLE groups. This was observed at all pilot sites. However, in the case of municipalities (such as TRONDHEIM) the problem is more evident, since they do not deal with Alzheimer patients (as a primary activity).
  - The initial delay created an important gap, which could not be easily remedied in the remaining period, despite the efforts of TRONDHEIM and the improvement in the rate of recruitment.

These remarks are also illustrated in Figure 1, which depicts the status of the pilot operations at the end of the third cycle and how this compares to the original planning of the pilot operations. Note the total numbers of users involved (including drop-outs) was overall very close to the planned numbers.
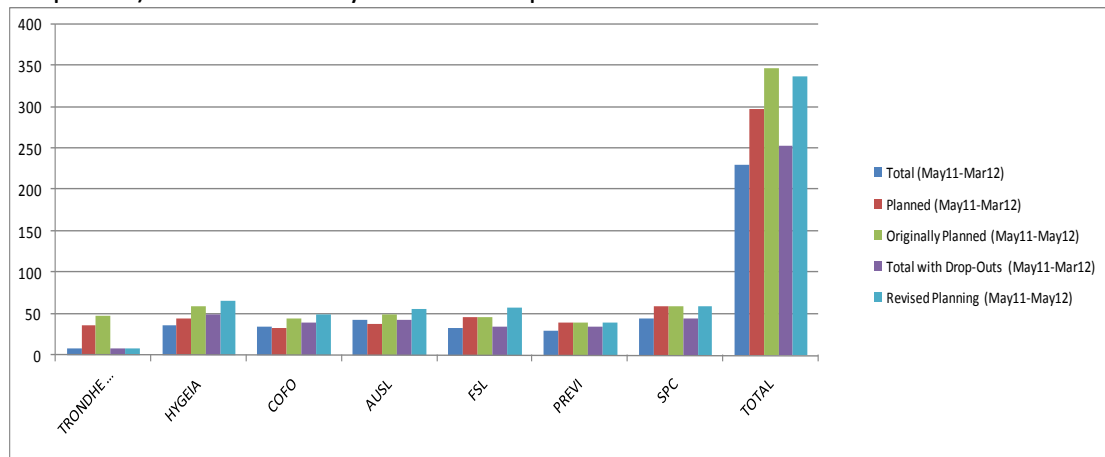
Figure 1: Comparison between the planned number of elderly users to be involved in the pilot operation and those actually involved

On the basis of the above remarks and the relevant assessment of the situation by the SOCIABLE partners, the consortium has activated a set of remedial actions which are outlined in the following paragraph.

2.3.2 Revisions to the SOCIABLE Protocol

The assessment of the situation regarding the progress of the study had led the consortium to consider the activation of remedial actions according to project's risk management planning (which is illustrated at later sections of the report). In particular, the consortium decided to increase the number of patients (GroupB,

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GroupC) to be involved in the study at the hospitals of the consortium (FSL, HYGEIA, AUSL) in order to compensate for the fact that TRONDHEIM could not recruit Group C users. Furthermore, it was agreed that COFO will also carry out an increased number of sessions (more Group B patients) in collaboration with AUSL, which will help in the recruitment. The relevant changes will be carried out in a way that ensures the validity of the study design. The following tables depict the changes in particular:

- Table 6 lists the number of patients included in the study as part of the original design of the SOCIABLE study, where TRONDEIM was expected to recruit/involve in the study 48 Group C users.

- Table 7 lists the number of patients included in the study as part of the revised design of the SOCIABLE study, where HYGEIA and AUSL have undertaken to include six Group C users each, while a greater number of Group B users are assigned to COFO and FSL. Note that the study has been revised from the statistical of SOCIABLE in order to be able to render/result in meaningful analysis. As part of the revision, the total number of Group C users has been reduced, while the total number of Group B patients has been increased. Furthermore, the total number of the patients to be included in the study has been slightly reduced.

	Group A	Group B	Group C	Care Center	In-Home	Total
TRONDHEIM	0	0	48	44	4	**48**
HYGEIA	10	26	24	44	16	**60**
COFO	14	30	0	30	14	**44**
AUSL	0	50	0	40	10	**50**
FSL	0	0	46	40	6	**46**
PREVI	40	0	0	20	20	**40**
SPC	60	0	0	56	4	**60**
TOTAL	**124**	**106**	**118**	**274**	**74**	**348**

Table 6: Total Number of Users to be involved in pilot operations according to the original SOCIABLE Study Design (INITIAL PLANNING)

	Group A	Group B	Group C	Care Center	In-Home	Total
TRONDHEIM	0	0	8	8	0	**8**
HYGEIA	10	26	30	50	16	**66**
COFO	29	21	0	36	14	**50**
AUSL	0	50	6	46	10	**56**
FSL	0	12	46	52	6	**58**
PREVI	40	0	0	20	20	**40**
SPC	60	0	0	56	4	**60**
TOTAL	**139**	**109**	**90**	**268**	**70**	**338**

Table 7: Total Number of Users to be involved in pilot operations according to the revised SOCIABLE Study Design (REVISED PLANNING)

Moreover, the following table shows the differences between the original and revised planning for each one of the sites involved:

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PLANNED (MAY 11)	Group A	Group B	Group C	Total	
TRONDHEIM	0	0	48	48	
HYGEIA	10	26	24	60	
COFO	14	30	0	44	
AUSL	0	50	0	50	
FSL	0	0	46	46	
PREVI	40	0	0	40	
SPC	60	0	0	60	
TOTAL	124	106	118	348	
PLANNED (FEB 12)	**Group A**	**Group B**	**Group C**	**Total**	**Difference**
TRONDHEIM	0	0	8	8	-40
HYGEIA	10	26	30	66	6
COFO	29	21	0	50	6
AUSL	0	50	6	56	6
FSL	0	12	46	58	12
PREVI	40	0	0	40	0
SPC	60	0	0	60	0
TOTAL	139	109	90	338	-10

Table 8: Comparison of the patient involvement per site between the revised and the original study design (HYGEIA, COFO and AUSL will involve 6 more patients, FSL 12 more patients, while TRONDHEIM will involve 40 less group C patients)

Note that the above tables refer to the elderly/patients that were decided to be involved in SOCIABLE as part of the revised study design and the need to analyze the results on the basis of a clinically sound methodology. The revision of the methodology has also taken into account the results of the interim analysis of the assessment scores, which manifested that the SOCIABLE treatment had less significant effects on Group B (MCI) users. Based on this fact, the revised version of the study includes more Group B users than planned. The purpose is to have a higher probability in obtaining significant results on the effect of the SOCIABLE study on Group B, given that such significant results have up to date been obtained for Group A and Group C.

In addition to these patients the pilot sites decided to include butterfly users, while TRONDHEIM carried out additional sessions (according to the SOCIABLE procedures) with group A patients. Overall, the total number of elderly involved in SOCIABLE far exceeded the number of 350 users that is quoted in the project's Annex1 to the contract (Description of Work document). **As a last note, and following reviewers' suggestion, the consortium (through partner FSL) included 10 more Group C (elderly/patient) users, in order to ensure the involvement of 100 Group C patients in the SOCIABLE study**.

2.3.3 Overview of Pilot Operations Evolution during the last cycle

Based on the decisions outlined in the previous paragraph, as well as the relevant revisions to the study design, the following tables illustrate the numbers of elderly involved in the fourth/last cycle of pilot operations (April12-July12) (Table 9), as well as the total number of elderly involved throughout the duration of the pilot study

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(Table 10). Furthermore, Figure 2 compares the different figures per pilot site i.e. planned figures (according to both the original and the revised planning) to actual/achieved figures (including elderly that completed the study and drop-outs).

	Group A	Group B	Group C	Care Center	In-Home	Individual	In-Groups	Drop-Outs	Total
TRONDHEIM	10	2	2	14	0	14	0	2	14
HYGEIA	0	11	4	14	1	10	5	3	15
COFO	3	12	0	4	11	7	8	3	15
AUSL	0	12	3	12	3	4	8	1	15
FSL	0	12	21	33	0	6	27	1	33
PREVI	10	0	0	5	5	7	3	0	10
SPC	15	0	0	14	1	9	6	0	15
TOTAL	38	49	30	96	21	57	57	10	117

Table 9: Number of Elderly Users that were involved in pilot operations during the fourth cycle/quarter (Q4) of formal pilot operations (during the calendar period Apr12-July12)

	Group A	Group B	Group C	Care Center	In-Home	Individual	In-Groups	Drop-Outs	Total
TRONDHEIM	10	3	9	22	0	19	3	3	22
HYGEIA	5	29	17	45	7	39	13	15	52
COFO	29	21	0	30	20	21	29	7	50
AUSL	0	51	6	50	7	17	33	2	57
FSL	0	12	55	60	6	18	48	2	66
PREVI	40	0	0	15	20	28	12	5	40
SPC	60	0	0	58	2	30	30	0	60
TOTAL	144	116	87	280	62	172	168	34	347

Table 10: Number of Elderly Users that were involved in pilot operations during all cycles of formal pilot operations (during the calendar period May11-July12)
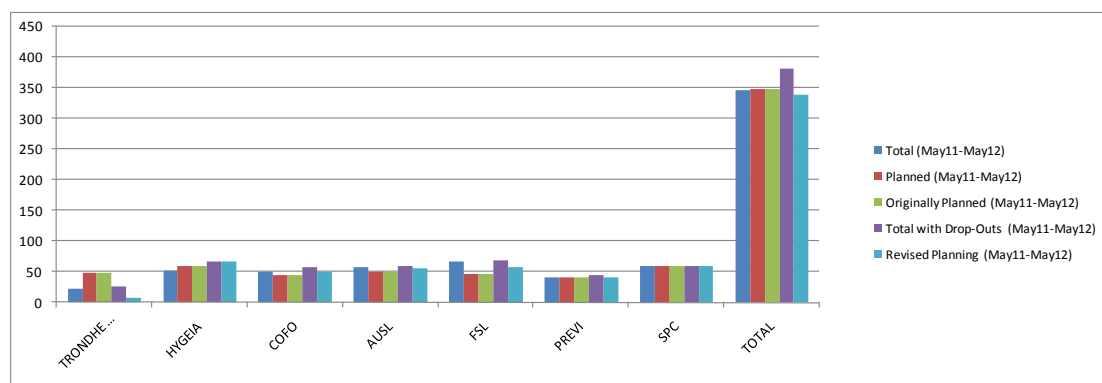
Figure 2: Total Number of Elderly/Patients involved in the SOCIABLE Pilot Operations (all four cycles)

Note that the above figures concern the number of patients involved according to the (revised) SOCIABLE protocol. The total number of involved users (including the drop-out) is the target number set by the revised protocol. As already outlined, the consortium partners involved numerous additional users that participated as butterfly users (i.e. without following the processes of the SOCIABLE protocol). Only TRONDHEIM included 22 butterfly users, in addition to several Group A users that were not taken into account in the scope of the statistical analysis. Note that the tables above include the 10 additional Group C users that were involved through FSL in order to ensure the involvement of a minimum of 100 Group C users in the scope of the SOCIABLE pilot operations.

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3. Report on Pilot Operations at HYGEIA (HYGEIA)

3.1 Overview

The following table provides overview information about the SOCIABLE pilot operations at the HYGEIA hospital.

Start Date of the Pilots	May 26th, 2011
End Date of the Pilots	June 29th, 2012
Location(s) of the pilot operations	Memory Clinic, Hygeia Hospital
(Names of) Medical Experts and Health Professionals Involved	Dr Paraskevi Sakka, neuropsychiatrist Olga Lymperopoulou, neuropsychologist Eva Ntanasi, psychologist
Total Number of Group A Users Involved	5
Total Number of Group B Users Involved	29
Total Number of Group C Users Involved	17
Number of Individual Sessions	35 users
Number of Group Sessions	16 users
Total Number of Individual Sessions	707
Total Number of Group Sessions	108
Total Number of Drop-outs	15

Table 11: Overview Information for SOCIABLE Pilot Operations at the HYGEIA Pilot Site

3.2 Organization Issues

No major organization issues arose during the pilot phase of the project.

3.3 Recruitment Processes and Related Issues

In the case of HYGEIA, the SOCIABLE users were either patients / family caregivers using the services of the Memory Clinic or elderly who showed interest in participating to the project after attending the SOCIABLE Open Days organized by the Hospital. During the recruitment process, various problems arose, which however were successfully dealt with.

i. **Difficulty in recruiting users due to the financial crisis affecting Greece**:
   The financial crisis has strongly affected the recruitment process in various ways. There has been a great number of elderly who showed strong interest in SOCIABLE, but finally decided not to participate due to the transport expenses

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they would have to cover in order to reach the hospital (note that HYGEIA is located in the north suburbs of the city and up to an hour drive from the city center) and the heavy traffic they would have to face due to the anti-austerity strikes and protests organized in every day basis. As it will be later described, the same issue had also affected the number of drop-outs.

ii. **Difficulty in recruiting users during summer**:
The grand majority of elderly in Greece are out of town for summer vacations from early June to late August. Thus, only a very limited number of elderly were willing to attend SOCIABLE sessions during summertime. This caused serious recruitment problems during the first period of the project (Q1) since only 3 instead of 15 users were recruited. However, we managed to effectively overcome the problem by organizing large-scale SOCIABLE Open Days and finally, were able to recruit more users during the following periods.

iii. **Difficulty in recruiting mild AD patients**:
Despite the large number of AD patients visiting the Memory Clinic, only few of them were willing to participate to the project. As already mentioned, HYGEIA is located rather far from the city center. In order for a mild AD patient to attend the scheduled sessions, he/she should be either able to use transportation services alone (which is usually not the case) or have a caregiver available to accompany him/her on regular basis (which is equally challenging). Hence, finding mild AD patients willing to commit to the responsibilities related to the project, proved to be quite problematic. As a result, when we were asked to recruit 6 more mild AD users during period Q4 in order to compensate for the recruitment problems of Trondheim, we were unsuccessful in our efforts and after discussing with FSL, it was agreed to recruit MCI users instead.

3.4 Drop-Out Users

The major problem related to the pilot operations at HYGEIA was the large number of drop outs (15 in total). As described in the table below, the main reason why users left the study were issues related either directly or indirectly to the financial crisis and the riots in Athens. Obviously, this is a factor that could not be either predicted or controlled.

Number of Drop-outs	Main Reasons
2	Health problems
10	Issues related to the riots in Athens (transportation problems, financial issues)
2	Personal problems
1	Lost contact with the Memory Clinic

Table 12: Drop-out users at the HYGEIA pilot site

3.5 Assessment of the Pilot Process

HYGEIA's experience during the pilot phase of the SOCIABLE project has been very positive and rewarding. The vast majority of the elderly users referred a perceived improvement of their cognitive skills and mood having a direct impact on their

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quality of life. Additionally, they described their participation in the sessions as fun and stimulating. The above mentioned notions were confirmed by their family members, who expressed an equally high degree of satisfaction. It would be useful to highlight that many of the elderly users explicitly requested to repeat the training, while a large number of caregivers asked to be notified when SOCIABLE becomes available as a service of our Memory Clinic. As far as the medical experts involved in the pilot operation are concerned, they described their experience with SOCIABLE as rewarding, fruitful and motivating, since they had the opportunity to experience the advantages of using cutting edge technologies in the field of cognitive training.

Given the positive overall experience described above, HYGEIA is proud to announce that has recently decided to offer SOCIABLE as a service of the Memory Clinic of the Hospital. The service is addressed to cognitively intact elderly, elderly with MCI and patients suffering from mild AD, and is offered both as an in-hospital and in-home service. SOCIABLE is expected to replace 80% of the cognitive training sessions performed currently at the hospital.

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4. Report on Pilot Operations at AUSL

4.1 Overview

The following table provides general information about the pilot operations at the AUSL pilot site.

Start Date of the Pilots	9/05/2011
End Date of the Pilots	28/07/2012
Location(s) of the pilot operations	Dedicated rooms at the Specialized Memory Centre-Morgagni Pierantoni Hospital-AUSL Forlì
(Names of) Medical Experts and Health Professionals Involved	Dr. Chiara Zaccarelli (Neuropsychologist) Neuropsychologist volunteer involved in the training programs
Total Number of Group A Users Involved	0
Total Number of Group B Users Involved	50
Total Number of Group C Users Involved	6
Number of Individual Sessions	25 users
Number of Group Sessions	31 users
Total Number of Individual Sessions	16 users for individual sessions +9 users for sessions with tablet(total sessions:500)
Total Number of Group Sessions	31 users (total sessions:620)
Total Number of Drop-outs	2

Table 13: Overview Information for SOCIABLE Pilot Operations at the AUSL Pilot Site

4.2 Organization Issues

In AUSL Pilot Site there have been some initial problems in finding appropriated spaces, with the adequate characteristics and infrastructures, where to allocate the MS Surface and the Tablet PCs for the SOCIABLE Training. Finally an appropriate room within the Specialized Memory Centre rooms has been selected as the best option where to install the MS Surface, while, lately in the Pilot Operations, the Tablet PCs have been used in different rooms of the Geriatric Department.

Other organization issues concerned the availability of specialized personnel to be involved in the whole process of the SOCIABLE Pilot Operations, including the neuropsychological assessments of the users and especially the carrying out of the Training sessions, that required a huge amount of effort in terms of hours of work and involvement of human resources.

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This has been a quite complex issue, that we tried to overcome through the exploitation of psychologists volunteer and other internal resources of the hospital, that helped especially in carrying out the Sociable sessions with the users, under the steady supervision of the medical experts accountable for the project, and after being trained about the functioning of the MS Surface and Tablet PCs (in cooperation with CEDAF) and about the clinical protocol.

4.3 Recruitment Processes and Related Issues

The following table reports the main incidents associated with recruitment issues in the AUSL pilot site.

Date	Recruitment Issue	Solution/Remedy
2011, April – 2012, May	Some initial difficulties in finding patients with the adequate inclusion criteria to participate to the Pilot Operations	We involve the medical doctors operating in the Specialized Memory Centre, in order to help us in selecting the possible candidates among the patients they daily visit, illustrating them the Clinical Protocol and the inclusion/exclusion criteria about the end users.
2011, April – 2012, May	Difficulties in finding the appropriate candidates for the in-home training with the Tablet PCs both in terms of acceptability by the patients and their families, and for the presence of adequate environment features	In the AUSL Pilot Site we opted to carry on the individual training with the Tablet PCs in the hospital instead of at users' homes.
2011, April – 2012, May	Some difficulties in sessions planning and scheduling	We tried to schedule the training programs according to the availability of the spaced and personnel and also to the users' requirements. Some changes and shifts in the calendar have been made during the training programs, and also some changes in composition of groups.

Table 14: Main Recruitment Issues associated with the AUSL pilot site

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4.4 Drop-Out Users

The following table illustrates the main reasons for the two drop-out elderly in the AUSL pilot site:

Number of Drop-outs	Main Reasons
1	The user decided not to continue the training since she got worsen in the disease very quickly and the Sociable training started getting too complicated for her, besides increasing the already high level of anxiety
1	The user decided not to continue the training since the family was not compliant and collaborative with the medical experts, due to the lack of awareness about the disease.

Table 15: Drop out users at the AUSL pilot site

4.5 Other Issues

In AUSL some problems emerged in SOCIABLE sessions' attendance by the elderly in specific periods of the year. We realized that Sociable sessions should be programmed so as not to be held during the most hot or cold months during the year, connected to the practical difficulties to move for the elderly due to the too hot weather or, at the opposite to the risks in case of snow and connected presence of ice.

4.6 Assessment of the Pilot Process

AUSL experience with SOCIABLE project, was totally positive both for the users satisfaction and the outcome achieved.

First of all, as we can infer by the very little amount of drop-out cases during the whole Pilot Operations, almost all users recruited carried out the whole SOCIBLE training programs without any problems nor need of pressure by the medical experts or the families, and, furthermore, many of them explicitly requested to continue the training longer or to have the possibility to do it again.

As for what concerns the level of subjective satisfaction by the elderly users about the SOCIABLE experience, from the administration of the Satisfaction Questionnaires after the end of the training, it emerged a general positive impact on the elderly involved, as they perceived the experience of the SOCIABLE training as positive and stimulating, both in terms of the specific activities proposed and the subjective perception about the effects on their functionalities and abilities. Most of the users referred a perceived improvement of their cognitive skills (memory, concentration, reasoning) and a positive effect on the enhancement of the mood, besides an increase of their social life, with a consequent decrease of their sense of social isolation.

The subjective outcomes, expressed by the elderly users, had a confirmation from the data collected from the neuropsychological assessment, administered before and after the training and after a follow up period of 3 months, that showed a general improvement in the elderly performances on most of the cognitive tests

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administered, and, besides that, a general persistence of this positive effect on the cognitive skills also after a 3 months period without training, detectable especially in the MCI patients.

In conclusion, the SOCIABLE experience in AUSL has been proved as a positive experience both for the elderly users involved, that expressed a clearly positive opinion about it, and the willingness to repeat the training in the future and to suggest it to friends and other elderly with the same problems, and for the medical experts involved, in terms of positive impact on their daily work and enhancement of the knowledge in the field of non-pharmacological instruments existing in the treatment of dementia, opening a new interesting field for future research studies.

Given the general positive experience with SOCIABLE, AUSL decided to include it as a new service of the Specialized Memory Centre of the hospital to be added to the other existing services of the Centre, in particular replacing the traditional cognitive training/rehabilitation programs, currently used for the elderly people with cognitive impairment. The service is going to be addressed to elderly people that have access to the Memory Centre, in particular to cognitively intact elderly with initial perception of cognitive problems, elderly with MCI and patients suffering from mild AD, and is going to be offered as an in-hospital service, and, eventually, as in-home service too.

In the scope of this, and connected to the big request by many elderly and their relatives informed about the project, AUSL has already organized a new SOCIABLE training session, currently carried out on a group of 11 elderly users.

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5. Report on Pilot Operations at FSL

5.1 Overview

The following table provides general information about the pilot operations at FSL.

Start Date of the Pilots	May 9th, 2011
End Date of the Pilots	August 9Th 2012
Location(s) of the pilot operations	Santa Lucia Foundation
(Names of) Medical Experts and Health Professionals Involved	Dr. Roberta Annicchiarico, geriatrician Dr. Francesco Barban, psychologist Dr. Alessia Federici, geriatrician
Total Number of Group A Users Involved	0
Total Number of Group B Users Involved	12
Total Number of Group C Users Involved	54
Number of Individual Sessions	18 users
Number of Group Sessions	48 users (16 groups)
Total Number of Individual Sessions	415
Total Number of Group Sessions	365
Total Number of Drop-outs	2

Table 16: Overview Information for SOCIABLE Pilot Operations at the FSL Pilot Site

5.2 Organization Issues

No major organization issues occurred during the pilot period.

5.3 Recruitment Processes and Related Issues

Patients (group B and C) were recruited through the outpatient dementia service of Santa Lucia Foundation. No issue occurred during the recruitment phase of the project.

5.4 Drop-Out Users

During the training we had 2 drop-out during the rest period due to health problems of the subjects. All patients that started the training completed it successfully.

Number of Drop-outs	Main Reasons
2	Health problem

Table 17: Drop-out users at FSL

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5.5 Assessment of the Pilot Process

Santa Lucia Foundation experience was very positive. Patients and care-givers found the training interesting, the platform easy to be used, the ones that performed the training in group found this experience very stimulating and established pleasant relationships among participants. The training duration was adequate to be not too long and caregivers were very collaborative to bring patients to the training sessions. Medical experts were satisfied about the results obtained and the compliance of patients. Moreover, external medical experts were interested to be informed about the project. Based on positive results we decided to investigate brain plasticity processes related to the training with state-of-the-art neuroimaging techniques in a further study that will be conducted at the foundation.

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6. Report on Pilot Operations at COFO

6.1 Overview

The following table provides general information associated with the pilot operations at the COFO site.

Start Date of the Pilots	09/05/2011
End Date of the Pilots	27/07/2012
Location(s) of the pilot operations	Associazione Anziani Due Tigli – via Orceoli 15, Forlì (social-aggregation center for elderly people) Associazione Onlus La Rete Magica – via Curiel 15, Forlì (non-profit association for people suffering from different diseases and their families)
(Names of) Medical Experts and Health Professionals Involved	Mariangela Bertoni, Loredana Casamenti, Arianna Manfredi, Oretta Mariotti, Alessandra Sanna (Social health workers)
Total Number of Group A Users Involved	29
Total Number of Group B Users Involved	21
Total Number of Group C Users Involved	0
Number of Individual Sessions	20 users
Number of Group Sessions	30 users
Total Number of Individual Sessions	340
Total Number of Group Sessions	544
Total Number of Drop-outs	7

Table 18: Overview Information for SOCIABLE Pilot Operations at the COFO Pilot Site

6.2 Organization Issues

In terms of the availability of medical experts, the Municipality of Forlì has no medical experts within its staff, since it is not an health organization, but it cooperates with different associations, so as to have social-health workers who provide the social-assistance services to the citizens, therefore, at the beginning of the project, COFO selected one of these associations (namely the CAD cooperative) to subcontract, in order to have some health professionals available to follow the training with Sociable users. Once the subcontracting had been approved, a selection of the personnel took place, so as to choose the most suitable people to follow the training. Finally, the selected personnel has been trained on the functioning of MS Surface and tablet PCs and on the clinical protocol to be followed thanks to the cooperation of CEDAF and AUSL.

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As far as the availability of space and other infrastructures, COFo had to select the appropriate place where to install the MS Surface and so a long and careful investigation about the possible sites has been carried out, taking into consideration both social-aggregation centres and associations. The Due Tigli aggregation center (and lately the Rete Magica association) ended up being the best option (even though COFO had the need to set up the internet connection at the Due Tigli association) regarding accessibility, location, availability of parking lots or bus lines in the immediate surroundings and the availability of a room that was quiet and that could be closed (so as not to damage the equipment) and the availability of the volunteers that run the centre.

Finally and especially at the beginning of the project a lot of meetings with the other partners of the Forlì area (CEDAF and AUSL) had to be organized to plan, schedule and coordinate the project-related activities.

6.3 Recruitment Processes and Related Issues

The following table reports the main recruitment issues associated with the pilot operations at COFO.

Date	Recruitment Issue	Solution/Remedy
2011, April – 2012, May	Difficulties in finding MCI patients to enroll in the project	Social-health workers helped in the recruitment of users thanks to dissemination and promotional activities on the Forlì territory. Contacts with the local sanitary partner (AUSL) to have some names of possible participants from them. Moreover open meetings with the citizenship were held.
2011, July – 2011, August	Difficulties in having more than 2 people playing on the Microsoft Surface platform at the same time	Social-health workers deal with relational issues, taking turns and sometimes the different level of cognitive abilities among players during the sessions. Tried to have groups with just 2 people.
2011, April – 2012, May	It is very difficult to find the appropriate conditions to start the pilot operations at home.	Social-health workers helped in the recruitment of users thanks to dissemination and promotional activities on the Forlì territory.
2011, April – 2012, May	Session planning	The calendar has been changed several times, some sessions have been put off or anticipated when necessary, some groups changed composition.
2012, March – 2012, May	Need to enroll 6 more patients	Social-health workers helped in the recruitment of users thanks to dissemination and promotional activities on the Forlì territory. Contacts with the local sanitary

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		partner (AUSL) to have some names of possible participants from them.
Summer and winter	Low motivation of users to follow the training with bad / hot weather	A snow storm in winter and the heat wave of summer lowered the motivation of Sociable users. Social-health workers had the need to convince people to continue the training till the end despite the weather or the holidays.

Table 19: Overview of main recruitment issues encountered at the COFO pilot site

6.4 Drop-Out Users

In the scope of the pilot operations at COFO, seven people dropped out of the SOCIABLE study.

Number of Drop-outs	Main Reasons
1	The user decided not to continue the training since she had too many commitments (G3)
1	Lost contact after evaluation with AUSL (G4)
3	Training left due to personal reasons (G1-G4)
2	Training left due to health problems (G1-G4)

Table 20: Drop-out elderly users at the COFO pilot site

6.5 Other Issues

COFO has seen that SOCIABLE sessions should be programmed so as not to be held during the most hot or cold months during the year, since when there is snow outside it is not safe for elderly people to go out to reach the social aggregation center since they could slip on the ice and fall. On the contrary, when it is really hot, elderly people had better stay at home without going out during the hottest hours of the day. If these meteorological conditions make the training stop for a long period it is really hard to convince people to continue it afterwards.

Similar remarks about the association of SOCIABLE sessions with weather conditions have also been reported by AUSL (see earlier section), which is also located in the Forli area.

6.6 Assessment of the Pilot Process

Many users involved in SOCIABLE reported that they were satisfied with it and they had a lot of fun in solving the games. They also declared that memory and attention improved with the passing of time, but just as far as games are concerned. Talking about day to day life, instead, they do not see any significant change in their memory and attention performances.

COFO thinks that the users' perception could be somehow wrong, since a significant improvement of their skills has taken place and this can be easily verified by the assessment results, but there if the chance to think that people had benefits also in

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their day to day life. For example, people that forgot about the training, at last, managed to go to the sessions without the need to call them beforehand.

As far as social life is concerned, there seem to be no major changes for people who had individual sessions, since these users came into contact just with the social health worker that followed the session. As for group sessions, elderly people tried to have a friend playing with them or, if they did not know any of the people taking part in SOCIABLE, they just got in contact with them during the programme, but not much outside of it. In any case, it was a satisfaction for them to know that they had something to do on that day, a commitment to follow, etc. so, somehow, they developed a better relationship with the outer world and they developed the possibility to socialize with other people in the future, since many people were not familiar with the social aggregation centre, so they discovered a new place where they can go and play cards, meet other elderly people, etc.

For example this can be proved by the fact that most users participated in the final party that COFO held in the Due Tigli aggregation centre (those who could not attend the party were very sorry) and they reported that SOCIABLE was fun and stimulating, that it made them feel better and that they would be willing to repeat the training.

COFO agrees with these statements and thinks that SOCIABLE can be a good instrument to prevent cognitive skills' decrease.

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7. Report on Pilot Operations at TRONDHEIM

7.1 Overview

The following table provides general overview information about the pilot operations at TRONDHEIM. On the basis of the table it is evident that the pilot sites did not deliver the initially planned number of users (in terms of group C users). However, TRONDHEIM has carried out a significant number of sessions with Group A and Group B users, while also involving a remarkable number of butterfly users (i.e. users that engaged in the use of SOCIABLE without undergoing all the assessment processes described as part of the SOCIABLE study design).

Start Date of the Pilots	August 2011
End Date of the Pilots	October 2012
Location(s) of the pilot operations	Valentinlyst Health and welfare centre
(Names of) Medical Experts and Health Professionals Involved	Helge Garåsen Ann Elin Johansen Julie Krutå Mona Johansen Mimmi Næss Julie Lunde Eva Rinnan
Total Number of Group A Users Involved	10
Total Number of Group B Users Involved	3
Total Number of Group C Users Involved	9
Number of Individual Sessions	19 users
Number of Group Sessions	3 users
Total Number of Individual Sessions	360 sessions
Total Number of Group Sessions	24 sessions
Total Number of Drop-outs	3
Butterfly- users	22 (MMSE bellow 20)

Table 21: Overview Information for SOCIABLE Pilot Operations at the TRONDHEIM Pilot Site

7.2 Organization Issues

The training sessions took place at Valentinlyst health and welfare centre. A group of health professionals and one technical expert planned and organized the

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assessments and training- sessions. The platform was localized in special room at the centre. For the training session d both the surface platform and a tablet was used.

The project group had meetings every week to coordinate and organize the pilot operations.

7.3 Recruitment Processes and Related Issues

TRONDHEIM had to deal with a number of recruitment issues, which led the pilot sites to continually change/adapt its pilot operations plan. In the sequel we report the evolution of these issues for pilot operations duration. The report takes into account major incidents at specific time instants, which had a significant impact of the site's pilot operations plan.

7.3.1 Recruitment and Related Issues during the period May 2011-Octover 2011

TRONDHEIM pilot site was delayed in the pilot operation with one period, because of unfortunate surface platform damage in the first quarter of the first intervention period. The consequence was that the original plan for training - sessions with 12 intervention users had to be postponed for about 3 months.

In the second quarter the pilot site managed to include 4 users in the intervention group and 1 in the control group. The plan for the control group was to start the intervention period in the second period – the 6 last months. This meant that about 40 new users had to be recruited for the second period of intervention.

7.3.2 Recruitment and Related Issues during the period November 2011-January 2012

TRONDHEIM t site examined the possibility for users from nearby municipalities to join the SOCIABLE training sessions. There are 4 nearby municipalities in the area of 30 – 40 km from TRONDHEIM. By doing this the actual population would increase from 170 000 inhabitants to about 250 000 inhabitants. The actual municipalities are Klæbu, Malvik, Melhus and Skaun. The memory clinic at St. Olav`s University Hospital included the users from Trondheim. They also have the responsibility to assess inhabitants from these nearby municipalities. The staff at the clinic was informed about the possibility to also include users from these municipalities in October 2011 and started to look for the possible target group from the nearby municipalities. According to the staff at the memory clinic, they saw the possibility to be able to include one user pr. week that fits the inclusion criteria.

TRONDHEIM pilot site arranged meetings with The Local Dementia Society in November 2011. In the meeting the information about the Sociable project was be repeated. and they were also invited to discuss how they could be helpful recruiting users and inform about the project to their members.

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In an attempt to fulfill its planned obligations, TRONDHEIM made a plan to double capacity of the training sessions in the last period. The pilot site was going to use both the surface platform and the tablet. A decision was made to extend the inclusion group to also include group B in November/ December after an evaluation of the situation. A new application was send to the Ethical committee and was approved in January 2012.

7.3.3 Recruitment and Related Issues during the period February 2012- September 2012

Despite the extension of target groups, the pilot site didn`t succeed in recruiting as many users as we were supposed to do. Our experience was that the inclusion criteria were too narrow and could not be fulfilled by the target users/population of the pilot site (despite the efforts to enlarge the pool of potential elderly/users). In particular, while the pilot site and the memory clinic approached potential participants that could join the SOCIABLE study, in practice the individuals turned to have either a wrong diagnose and/or MMSE bellow the inclusion scale. Some of these patients were offered training sessions as butterfly – users. The total number of butterfly user was 22.

In March 2012 after the partner meeting in Forli, it was decided that TRONDHEIM could include users from group A. A third application was send to the Ethical committee which was approved in the end of March 2012. Then Group A users were included in the study leading to the total numbers reported in earlier tables.

7.4 Drop-Out Users

TRONDHEIM experience four (4) drop-out users for reasons detailed in the following table:

Number of Drop-outs	Main Reasons
3	**They didn`t turn up to the adequate number of sessions - less than 17**

Table 22: Drop-out users at TRONDHEIM

7.5 Other Issues

Other issues that required attention and affected the progress of the pilots, include technical problems associated with the surface platform, the cognitive games and the operation of the back-office application. These issues have been also raised as part of deliverable D6.3 and they have been communicated to the technical partners of the consortium in order to implement appropriate remedies. A brief discussion of these issues follows in the paragraphs below.

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7.5.1. Issues with the Surface platform

Both Surface version 1 and version 2 have been problematic, causing delays. This has resulted in the Tablet PCs become the main platform in the gaming sessions. The first period was postponed for about 3 months due to this, as it took some time to receive the Tablet PCs..

Surface 1 had severe hardware problems. We first experienced the hard-drive failing, and we had to replace this unit. This could not be done by the local technician as this unit is specially designed. Getting this done by Microsoft took a long time. The Surface 1 broke down again at a later time (this time the screen). This was a problem that could not be fixed, and it was decided to wait for Surface 2 as this was soon available.

Surface 2 is not currently in use, but hopefully will be soon. The new version of Surface was extremely sensitive to light, and is reacting to palms as well as fingers, making it difficult to use. We have installed LED-lights, which made the experience better, but not good enough for the users. We are currently awaiting the new version of the Cognitive Games, which are being coded especially for this sensitivity, which is supposed to resolve this problem.

7.5.2. Issues with the cognitive games

The design of some cognitive games did not function as they were supposed to, and could not be used. Solving this issue has taken long time. A consequence of this is several of the users getting bored. The technical partners have undertaken related remedial actions for most of the games. However, even at late stages of the project, there have been signs of poor performance for some games, especially the games «My Home» and «Travelling in Europe».

7.5.3. Issues with the Back office module

The Back Office has been rarely used towards the users of the platform. The software had several bugs, which in early stages preventing the registration of patients. The menu system needs a better design, as the registering of patients from the start is not logically designed.

7.6 Assessment of the Pilot Process

Overall, SOCIABLE has been a valuable experience for TRONDHEIM, especially in terms of how to perform cognitive training by using ICT technologies. The experience provided insights on the planning/organization, monitoring and evaluation of ICT cognitive training. The included users -both formal intervention users and butterfly users- were satisfied and enjoyed playing the SOCIABLE training games and using the Book of life.

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From the health professionals' perspective, TRONDHEIM sees potential for further use of cognitive training in a systematic way that SOCIABLE provides. TRONDHEIM will therefore continue to use SOCIABLE both in a therapeutic way and as a social activity for people suffering from cognitive decline.

In terms of main issues and challenges, the main challenge experienced by TRONDHEIM concerned the recruitment of the promised number of users. Towards remedying this problem, TRONDHEIM broadened the scope of the targeted groups, with a view to include not only Group C users but also Group A and Group B users as well. Hence, the total number of users / patients in TRONDHEIM pilot site operation is 22 inclusion users and 22 butterfly- users.

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8.   Report on Pilot Operations at SPC

8.1 Overview

The following table provides overview information about the pilot operations at SPC.

Start Date of the Pilots	16/5/2011
End Date of the Pilots	11/7/2012
Location(s) of the pilot operations	SOCIAL WELFARE CENTER (S.P.C.) ONE ROOM FOR SOCIABLE
(Names of) Medical Experts and Health Professionals Involved	Eva Stamou, Social Worker Maria Stefa, Social Worker Yiannis Roxanis , Psychologist , specialized in neurophysiologist tests , Irida Koraki ,Psychologist (volunteer) Elvira Ellinodeli, Psychologist (volunteer) Ntaniela Kiriazi, Psychologist (volunteer) Vasia Velmaxou, Social Worker (volunteer)
Total Number of Group A Users Involved	60
Total Number of Group B Users Involved	0
Total Number of Group C Users Involved	0
Number of Individual Sessions	30 users
Number of Group Sessions	30 users
Total Number of Individual Sessions	624 individual sessions(43 of them at home, 2 users, first user 19 sessions & second 24 sessions at home)
Total Number of Group Sessions	227 group sessions
Total Number of Drop-outs	0

Table 23: Overview Information for SOCIABLE Pilot Operations at the SPC Pilot Site

8.2 Organization Issues

S.P.C. confronted some initial problems regarding the allocation of the MS Surface – we decided to place the platform in the Municipality's Medical center but due to some changes (the Medical Center had to close up and move to another area) - we finally placed the platform in S.P.C.
We also confronted some issues regarding the personnel that would get involved in the program because of the bureaucracy that the municipalities follow in terms of hiring personnel, but we overcame the difficulties maintaining steadiness in the staff involved in the program.

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8.3 Other Issues

Some problems came up during the sessions (especially in the 1st period) regarding the attendance. Many users had some obvious obstacles (e.g., distance, cold/hot weather) but some lost their interest from the very beginning and were coming up with excuses. When a user didn't want to continue with participating in the program and withdrew from the first sessions, it wasn't a problem because we were able to replace the user. In the users' selection for the next periods we paid great attention in the willingness of the applicants to fully attend all the sessions.

8.4 Assessment of the Pilot Process

SPC completed all the sessions in each period on time according to the planned without unresolved problems. Almost all users, carried out the whole SOCIABLE training program without obstacles and we had very few drop out cases. The user's experience of the participation in the program was very positive, they found it very interesting and auxiliary and requested to continue the training longer and repeat the sessions.

Regarding the subjective satisfaction by the users according to the Satisfaction Questionnaires after the end of the training, a positive impact on the elderly appeared – many users referred to a feeling of improvement in their cognitive skills and in their psychological status (mood, feeling of loneliness etc.)

To end up the SOCIABLE project for SPC was a very functional and assistive project both for the elderly and for the experts who received positive impacts from a non medicine treatment.

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9. Report on Pilot Operations at PREVI

9.1 Overview

The following table provides general information about the pilot operations at the PREVI pilot site.

Start Date of the Pilots	May 2011
End Date of the Pilots	September 2012
Location(s) of the pilot operations	Valencia (Spain)
(Names of) Medical Experts and Health Professionals Involved	María Francesca Rubio Mercedes Requejo Verónica Guillén
Total Number of Group A Users Involved	40
Total Number of Group B Users Involved	0
Total Number of Group C Users Involved	0
Number of Individual Sessions	32 users
Number of Group Sessions	12 users
Total Number of Individual Sessions	768
Total Number of Group Sessions	288
Total Number of Drop-outs	5

Table 24: Overview Information for SOCIABLE Pilot Operations at the PREVI Pilot Site

9.2 Organization Issues

During the pilot operations at PREVI, there have not been major organizational issues. Nevertheless, PREVI's personnel have realized that it is easier and more motivating for users to use SOCIABLE when they feel supported by medical expertise. Specifically, PREVI's personnel have concluded that they are more willing to use the surface and PCs when they attend one of the centers. Because of this, we have offered a constant telephone contact to keep in touch with the user and we have also approached this problem by going to the users home to help him/her out with the sessions.

Also, a main problem associated with the infrastructure has been the fact that Tres Forques Centre was closed during the summer (July/August), and therefore users where unable to attend and finish the corresponding sessions.

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9.3 Recruitment Processes and Related Issues

The recruitment process has been difficult when trying to find home users, given that they are reluctant to work independently at home. One must take into account that home users are elderly aged more than 65 and most of them have never been in contact with new technologies. For this reason, when they are initially offered the opportunity of joining the project they are generally not willing to. Things are different regarding end-users willingness to participate in care center programmes. This is because in the care centre most centre users are used to enroll/enlist in different guided activities and workshops, and therefore they were offered to join SOCIABLE they were much more willing and motivated to do so.

In order to overcome the home-users problem, PREVI has tried to present the project to members of the team´s family or people who were in some way related to PREVI (neighbors, friends etc.), bearing in mind that they would be eligible candidates for the project according to age and health status. PREVI has also trained close relatives of these home users so that the elderly would feel supported by someone at home who can guide them through the activities. At the same time, PREVI offered its own help (i.e. support by PREVI personnel), through both direct contents in the elderly homes, as well as through telephone contacts.

9.4 Drop-Out Users

During the pilot operations at PREVI, five drop-outs were observed. The main reasons are outlined in the following table:

Number of Drop-outs	Main Reasons
1	The user passed away
2	Stopped attending the day care centre because of personal health issues so they could not finish all the sessions required to be recorded in the data
2	Their PC was installed in their homes but they moved to a different city during the summer.

Table 25: Drop-out users at PREVI

Drop-outs users have affected the pilots because within PREVI's pilot operations plan there was a specific number of candidates expected to follow the program. Hence, drop-outs caused deviations from the original pilot plan. Throughout the project there have been a few other dropouts apart from the ones listed on the above table, but these happened before the users started with the (formal) sessions. Thus, PREVI had the time to look for more users. Nevertheless, an initial delay was introduced in terms of the start day of the pilots, given that all new users had to previously be recruited and evaluated before starting the sessions. This initially delay proopagated inevitably within PREVI's pilot plan.

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9.5 Other Issues

No other essential issues were encountered, apart from those discussed in the previous sections.

9.6 Assessment of the Pilot Process

Bearing in mind that PREVI uses new technologies (such as virtual reality) for the treatment of different psychological and/or emotional pathologies, the fact that SOCIABLE project follows similar working patterns has been a both rewarding and fruitful professional experience.

Regarding our pilot process itself, it is important to note, though, at the beginning of the project we expected recruitment to be something reasonably easy to achieve as we thought personal contacts would be sufficient to fulfill the required number of users for the project. It turned out to be quite difficult to find willing users as their age, personal situations and their fear for new technologies stopped them in some cases to enroll on the project.

From this experience we have learnt that for future projects we should focus deeper on our dissemination programs and activities but not only at a business level (marketing experience) but as an initial step for recruitment with the objective of enlarging our sample range.

In conclusion, from our experience we can say that users have shown to benefit from SOCIABLE project as a enriching and motivating experience, for it has enabled them to realize that they are capable of using new technologies as well as finding a new way to train their cognitive capacities. We are still waiting for concluding results that will certify whether there has been a cognitive skill improvement.

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10. Overall Assessment and Lessons Learnt

The SOCIABLE pilot operations have been the core activity of the project, which was associated with several medical/clinical, ICT and management aspects. Clinical aspects are related to the SOCIABLE clinical study, which was the main part of the pilot operations. ICT aspects are related to the deployment and use of the SOCIABLE surface computing platforms across the various pilot sites of the project. Finally, management aspects are related to the need for planning and monitoring the evolution of the pilot operations, while at the same time managing quality and key risks. As a result, the conduct of the SOCIABLE pilot operations has been a quite complicated task with a host of medical, technical and management implications.

In order to deal with this complexity, the SOCIABLE partners (notably the pilot sites) have prepared in advance for the pilots (as part of WP5 of the project), while they have also created elaborate plans of the pilots (including plans for the participation of specific numbers of elderly and health professionals). Despite this early and elaborate planning, the project had to deal with significant deviations from the original plans. This deviation were caused by a variety of factors/incidents, including technical failures, problems with recruitment processes, whether conditions, drop outs, as well as revisions to the protocol of the SOCIABLE clinical study. Some deviations were minor and could be remedied on the basis of slight rescheduling/reprogramming of some sessions. However, there were also more serious deviations which demanded revisions to the SOCIABLE study. These more serious deviations were directly associated with the recruitment issues, and more specifically with the fact that municipalities (i.e. municipal care centers) experienced problems in recruiting patients with mild cognitive impairment and mild Alzheimer's disease (i.e. Group B and Group C). This problem was not observed in hospitals (such as FSL, AUSL and HYGEIA), which have in general access to many more demented elderly comparing to municipal care centers and/or day centers.

Despite recruitment and other issues, SOCIABLE managed to gracefully complete the pilot operations, with the involvement of the planned number of elderly/patients. This success was largely due to the continuous monitoring and adaptive planning processes that were adopted and applied throughout the lifecycle of pilot operations. As part of these processes the status of the pilot operations was regularly assessed and related remedial plans were activated.

Note that the SOCIABLE study involved control groups as a means of assessing comparatively the effects of the SOCIABLE based cognitive training. The inclusion of control groups incurred additional effort for assessing patients within the control group, as well as for comparing their performances with elderly/patients participating in SOCIABLE cognitive training. This additional effort and complexity however should not be considered an integral element of the SOCIABLE ICT-based cognitive training model. We expect that the elimination of this effort will facilitate

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the wider deployment and adoption of the SOCIABLE cognitive training model during the commercialization and sustainability phase of the project.

The pilot operations were positively assessed by the various stakeholders, including the care services providers, the participating health professionals, as well as the elderly/patients. This positive assessment will be quantified in the scope of the evaluation deliverables of the project in WP7. However, all pilot sites reported the reception of positive feedback from the participants, which pave the ground for the wide penetration and the successful adoption of the SOCIABLE model as part of the project's exploitation plan.

In addition to the overall assessment of the pilot operations outlined above, the various reports and experiences of the pilot sites have lead to the following lessons learnt:

- **1st Lesson Learnt – Back-up technical solution required**: Technical issues are inevitable where ICT programmes and devices are used. They can range from hardware failures to software problems, and they can have an adverse impact on the graceful completion of the pilot operations. Therefore, care services providers need to have a back-up technical solution enabling the reliable completion of the sessions. The SOCIABLE experience has shown that Tablet/Surface PCs can provide an appealing and low-cost solution for the case of failures/problems associated with the surface table.

- **2nd Lesson Learnt – Drop outs:** There are several reasons that could lead a patient/elderly to abandon a SOCIABLE programme. These reasons could be other conventional causes associated with the schedule and/or the attitude of the elderly, yet they could also be associated with the SOCIABLE platform (e.g., the lack of acceptance of the electronic service). Care services providers and health professionals need therefore to establish policies and course of action for dealing with drop outs.

- **3rd Lesson Learnt – Patients Recruitment (Group B, Group C):** The inclusion of patients from SOCUABLE groups B and C (i.e. patients with mild cognitive impairment and mild Alzheimer's disease) is not trivial. The percentages of such patients in conventional day/care center seem to be rather low. Therefore, inclusion criteria associated with these groups are very restrictive and could make the process of designing/executing relative studies rather difficult.

- **4th Lesson Learnt – Balancing Group and Individual Sessions:** Care services providers should balance the amount of individual sessions to the amount of group sessions on the basis of the medical (human) resources that they have available.

- **5th Lesson Learnt – Number and diversity of games:** A rich collection of games (featuring different topics and difficulty levels, while targeting different cognitive skills) is required for the offering of a SOCIABLE programme. Experience showed that when the elderly play only a small set (e.g., less than 12 games), they can easily get bored. The final number of SOCIABLE games (i.e. more than 25 games) is a good starting point to alleviate this problem.

- **6th Lesson Learnt – Planning Sessions in Advance:** Care services providers should plan SOCIABLE programmes and session in advance i.e. prior to the

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commencement of the first session of a SOCIABLE programme. This advance planning facilitates the organization of the programmes, while allowing for remedial actions in the case of problems/incidents.

- **7th Lesson Learnt – Full electronic management of cognitive training sessions:** Thanks to the back-office module, health professionals can use the SOCIABLE platform in order to realize the full electronic management of the cognitive training sessions. Such a management increases efficiency and productivity.

The above best practices should be taken into account by care services providers (e.g., hospitals, day centers, care centers) wishing to offer SOCIABLE compliant cognitive training services. Some of these are also useful towards producing later versions of the SOCIABLE platform, which will boost the commercialization/exploitation of the project's results.

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11. Conclusions

This deliverable has presented a brief yet comprehensive report of the SOCIABLE pilot operations, including an overview report of the pilot operations, as well as more specific reports for each one of the pilot sites involved. In general, pilot operations have been completed successfully, given that all quantitative targets have been met, both in terms of the number of elderly/patients involved, but also in terms of their distribution across the three target groups. Despite the successful conclusion of the pilot operations, their evolution did not follow the original planning. Several deviations occurred for various reasons, the most prominent one being that some of the sites could not recruit the target number of users. This was mainly due to the fact that day/care centers do not have access to many patients with mild cognitive impairment (MCI) or mild Alzheimer's disease. Even though the consortium has successfully activated contingency strategies which alleviated these problems, the process of staying aligned to the SOCIABLE study design (and its revisions) was laborious and involved continuous monitoring of the evolution of the pilot operations.

In terms of the total number of elderly/patients involved in the study, the project achieved the involvement of approx. 350 elderly/patients, which however include several elderly that dropped-out of their programme. As part of the evaluation deliverables of the project (in WP7) the assessment scores of the users will be analyzed towards eliciting the main clinical conclusions associated with the study. As part of this deliverable all pilot sites have observed that the vast majority of the participants had a positive attitude against the SOCIABLE cognitive training model (based on the relevant surface platforms). In addition to the involvement of approx. 350 in the study (based on the SOCIABLE clinical protocol), the consortium has involved several butterfly users, who used SOCIABLE without formally applying all relevant assessment processes. While these butterfly users are not part of the SOCIABLE clinical study, their feedback will be also analyzed in order to understand the users' reaction against the wider use of the platform.

Based on the pilot operations reports of the individual sites and based on the overall assessment of the pilots, the project has documented seven best practices concerning the deployment and offering of the SOCIABLE services. These best practices concern clinical, technical (ICT) and organizational aspects of the study and should be taken into account by care services providers organizing and offering cognitive training and social activation services on the basis of the SOCIABLE model. These best practices will be complemented with conclusions and guidelines that will be produced on the basis of the quantitative clinical and end-users' evaluation of the project's results (including an evaluation of the pilot operations process). We believe that care services provider and other stakeholders will find these best practices useful.