SOCIABLE DELIVERABLE D6.1
"Pilot Operations Plan"

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Authors	**Stelios Pantelopoulos (SLG), Anna Papoutsa (SLG), Olga Lymperopoulou (HYGEIA), Eva Rinnen (TRONDHEIM), Reyes Moliner (PREVI), Eva Stamou (SPC), Chiara Zaccarelli (AUSL), Antonela Bandini (COFO), Roberta Annichiarico (FSL), Francesco Barban (FSL)**

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Abstract

The present deliverable provides a detailed plan for the SOCIABLE pilot operations, through describing the main activities entailed in the pilot operations, along with their scheduling and organization. The deliverable illustrates that the pilots will be organized around three main phases, including an informal testing phase, a formal pilot operations phase and a concluding phase which will be devoted to the analysis of the results. The most prominent of these phases is the formal pilot operations phases, which includes all the activities associated with the conduction of a clinical trial, fully in-line with the SOCIABLE clinical protocol. Formal pilot operations are segmented into four (quarterly) time slots, which foresee the involvement of control groups in addition of the experimental groups of elderly users that will enlist and participate in SOCIABLE programmes. The deliverable illustrates the processes associated with the involvement of control groups, which entail multiple cognitive, functional and affective assessment activities for both the control and the experimental groups.

While all pilot operations will evolve around a common pilot operations plan, some aspects (such as the number of pilot operations and the exact timing of the pilot activities) will vary across the different sites. To this end, the deliverable presents the number of users that will be involved in each phase for each of the pilot sites. Especially for the first quarter of the pilot operations, this presentation is more detailed. Also, each site presents the ethical processes that will be applied during the pilot operations, according to the decisions of the SOCIABLE ethical committee and in-line with the national/regional rules and regulations that each site is obliged to follow.

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Executive Summary

The main goal of the SOCIABLE project is to pilot a novel ICT based model for cognitive training and social activation of elderly suffering from mild forms of dementia. The pilot operations of the project will be organized in multiple hospitals and care centers (i.e. AUSL, HYGEIA, FSL, PREVI, COFO, SPC and TRONDHEIM) across four different countries (Greece, Italy, Norway and Spain) for eighteen (18) months. Furthermore, they will involve several hundreds of users and many health professionals (including carers, gerontologists, neuropsychologists and other medical experts). Note that part of the SOCIABLE pilot operations will be devoted to the organization and conduction of a randomized controlled efficacy study with the participation of 350 subjects. As a result, the successful completion of the SOCIABLE pilots asks for the specification of a disciplined and well-organized pilot operations plan. The purpose of this deliverable is to describe the main aspects of this plan, towards ensuring timely and efficient pilot operations.

The pilot operations will be organized around three phases namely an informal pilot operations phase having a three months duration, a formal pilot operation phase having a thirteen months duration, as well as a concluding pilot operations phase spanning the last three months of the project. In the scope of the informal pilot operations phase, the project will have the chance to fine-tune both medical processes and technical developments. Accordingly, the formal pilot operations phase will apply the SOCIABLE clinical protocol in terms of the cognitive, functional and affective assessment of the elderly, as well as their participation in play sessions and leaker tests. Finally, the concluding phase will ensure the proper reporting and analysis of the pilot results from a medical, scientific and techno-economic perspective.

The formal pilot operations phase spans the lion's share of the lifetime of the pilot operations and is very carefully prepared in order to ensure the graceful participation of both elderly users and health professionals in the process. To this end, the project performed a thorough analysis of the number of play sessions and (health professionals) person hours required in order to complete the randomized trial. Different scenarios were investigated comprising different balances between group and individual sessions. This is because group sessions economize on the total number of play sessions that will be required according to the SOCIABLE clinical protocol. The relevant analysis led the pilot sites to plan for involving half of their users in individual sessions and the rest half in group sessions. Also, the formal pilot operations were planned in a way that ensures the involvement of a control group, which will be used to audit the effectiveness of the SOCIABLE approach. The planning emphasized on the optimization of the medical experts person hours required in order to complete the relevant assessment processes i.e. the assessment of the experimental and the control groups. To this end, it was decided that some of the elderly participating in the programme (i.e. those enlisting at later stages of the programme) could be assessed early on in order to serve as a control group in the scope of the programme. The details of this organization are illustrated in the

deliverable. Overall, the deliverable sets a baseline plan for involvement of elderly users and health professionals in terms of the number to be involved and the timeline of the involvement. The various pilot sites might however introduce slight deviations and variations of this baseline plan, in order to accommodate seasonal requirements, as well as site specific organizational requirements.

The formal pilot operations phase is closely related to the ethical management activities of the project. Specifically the pilot operation planning includes also the planning for the ethical management activities, as the later have been endorsed by the SOCIABLE ethics committee. These include the reception of ethical approvals (e.g., from regional committees and council), the management of the informed consent process, as well as the process of the securing access to the pilot operations data. The application and enforcement of these processes is illustrated at both the project level and the individual pilots' level.

In addition to elaborating on the pilot operations plan this deliverable illustrates the main risks associated with the execution of the plan. These risks are mostly associated with organizational factors and delays. Along with the description of the risks contingency plans are illustrated.

Overall the present pilot operations plan is endorsed by all partners and could serve as a basis for gracefully executing and concluding the SOCIABLE pilot operations. At the same time, the creation of this plan served as an opportunity for all project members (especially pilot sites) to understand the challenges associated with a multi-national, multi-site randomized clinical trial and accordingly to devise ways for successfully confronting them.

1. Introduction

The main objective of the SOCIABLE project is to pilot a novel ICT enabled model for cognitive training and social activation of elderly suffering from mild forms of dementia and cognitive decline. Hence, pilot activities are at the heart of SOCIABLE, which is fully in line with the nature of the ICT-PSP programme. SOCIABLE pilot activities aim at large scale validation, and are very demanding due to their following characteristics:

- SOCIABLE pilots involve many elderly users (i.e. over 350 users). SOCIABLE will be nominally and formally used by (at least) 350 users, yet several other elderly may experience the use of the SOCIABLE ICT platform within hospitals and care centers.
- In addition to many elderly end-users, SOCIABLE pilots will involve several health professionals, including medical experts and carers. Moreover, family members may also be involved in the scope of in-home pilots.
- SOCIABLE pilots will take place in seven pilot sites of different types/nature including private hospitals, public hospitals, municipalities and care centers.
- The SOCIABLE pilot process involves a set of disciplined standard procedures, which ensure the project's clinical background along with the credible scientific evaluation of the project's results.
- The SOCIABLE pilots will be supported by a non-trivial ICT infrastructure, including a surface table and the SOCIABLE software/middleware libraries. During the pilot operations, special provisions should be made towards enhancing the SOCIABLE surface computing infrastructure and related applications.

These characteristics involve parameters that are associated with the success of the pilot operations. For example, the availability and active involvement of an adequate number of medical experts is a key prerequisite for the successful conclusion of the key pilot activities such as the cognitive screening of the elderly, as well as their cognitive, functional and affective assessment. Similarly, the careful planning of the enhancements to the SOCIABLE software (such as cognitive training games and the book of life) is a key prerequisite for the graceful evolution of the SOCIABLE technological infrastructure and the associated pilot operations. The above parameters manifest the need for carefully planning the SOCIABLE pilot operations, in terms of their scheduling, timeline, activities and human resources involved.

The present deliverable is devoted to the presentation of the SOCIABLE pilot operations plan. In terms of timing the SOCIABLE pilot operations are organized into three umbrella phases namely: (a) a preparatory phase enabling the use of the platform, testing of the processes and reception of relevant feedback, (b) the phase where the actual pilots will be conducted based on formal SOCIABLE processes and the involvement of appropriate numbers of elderly users and medical experts and (c) a concluding phase emphasizing on assessment, reporting and knowledge

harvesting. The deliverable analyzes the activities of these phases, while also presenting their scheduling.

In terms of human resources, the deliverable elaborates on the planning of the involvement of elderly and medical experts. In the scope of the human resource planning, the project has paid special emphasis in the involvement of control groups. Elderly enlisted for the late phases of the SOCIABLE pilot operations serve initially as a control group population. The rationale behind this process is to economize on the cognitive screening processes, without any essential loss of the clinical credibility of the results. Overall, the control group handling process ensures maximum efficiency of the used resources.

In addition to the planning of the elderly involvement, the deliverable elaborates on the planning of the medical experts' involvement. This is particularly important due to the scarcity of the medical experts that can actively engage in the SOCIABLE sessions. Indeed the large number of elderly users that will be formally involved in the SOCIABLE pilot operations, ask for a high number of cognitive screening/assessment processes, along with a significant number of play sessions. Medical experts are precious resources with extremely busy schedules, which could complicate the process of completing the SOCIABLE pilots. Acknowledging this fact, the SOCIABLE pilot operations plan makes provisions for the availability of medical experts at the various sites. In order to ensure this availability, the SOCIABLE pilot operations plan has identified the optimal distribution of SOCIABLE sessions into individual and group sessions. This is because group sessions can reduce the overall number of play sessions required in the scope of the pilot operations. The final pilot operations plan foresees that almost equal numbers of users participate in individual and group sessions. As explained in the deliverable, this distribution secures the availability of medical experts at the various sites, while at the same time complying with the sites' medical practices and operational plans.

In line with the SOCIABLE Description-of-Work (DoW) document, the present deliverable reviews the ethical processes that will be applied at the various sites. Parts of these processes have already been presented in other deliverables of the project. Instead of repeating information, appropriate pointers to the respective deliverables are provided. It should be noted that the SOCIABLE partners have obtained ethical approvals for the SOCIABLE pilots from relevant ethical committees in accordance to national/regional laws and regulations.

The deliverable presents also a detailed time schedule for the pilot operations, along with major milestones. While a uniform plan has been created for all the sites of the project, the deliverable lists also specific issues that concern the individual sites. Such specific issues are listed in order to reflect the peculiarities of each site, in terms of organization, available resources, deadlines, number of users and more.

The structure of the deliverable is as follows: Section 2 (after this introduction) presents the baseline pilot operation planning, which is applicable for all pilot sites. This includes the presentation of main phases, the scheduling of the pilot operations,

as well as a detailed presentation on the involvement of elderly users and the availability of medical experts. The same section illustrates also the selected distribution between individual and group sessions. Section 3 reviews the ethical procedures to be applied during the pilot operations. Later Sections (Section 4 to Section 9) present site specific issues along the baseline pilot operations plan. Finally, section 10 concludes the deliverable.

2. Baseline Pilot Operations Plan

2.1 Overview and Main Phases of the SOCIABLE Pilots

2.1.1 Overview and Reference Documents

2.1.1.1 Overview

SOCIABLE has devised a baseline pilot operations plan, which is to be followed by all pilot sites. The baseline plan serves the purpose of homogenizing the procedures across the various sites, with a view to easing the pilots' management and organization. Note that minor deviations between the various sites are inevitable given the different processes, resources and national conditions of the various pilot locations. However, the baseline pilot operations plan abides by the SOCIABLE Description of Work (DoW) document (i.e. the annex 1 to the SOCIABLE GA), which specifies that SOCIABLE pilot operation should start by M21 of the project (i.e. 01/02/2011) and have a duration of 18 months (i.e. till the end of the project (M39)).

The baseline pilot plan is built around three main phases, namely:

- An informal pilot testing phase, which emphasizes on resolving pilot issues on the field with a view to ensuring that the formal pilot phase (i.e. the next one) can run gracefully. This informal testing phase will have three months duration.
- A formal pilot operations phase, where pilot operations will take place in accordance to the SOCIABLE clinical protocols. This phase will extend to thirteen months duration, thus occupying more than 2/3 of the overall duration of the pilots.
- A concluding phase with will focus on the collection and analysis of the pilot results.

2.1.1.2 Reference Documents (SOCIABLE Deliverables)

The main activities within each of the above phases are outlined in the following paragraphs. Note however that following paragraphs do not repeat information that is already described in other deliverables, in particular:

- Existing Processes that are already in place in the various pilot sites, which are described in SOCIABLE Deliverable D1.2 titled: «Care Services Providers Requirements».
- The main use cases of the SOCIABLE Platform and services, which are described in Deliverable D1.4 titled: «Use Cases Specification».
- The medical tests comprising the SOCIABLE battery for cognitive, functional and affective assessment of the elderly. These tests are illustrated in the scope of SOCIABLE Deliverable D2.1 titled: «Users Selection and Segmentation».
- The SOCIABLE clinical protocol (including the study design) and associated medical methodology, which specify the pilot details such as the number of sessions comprising a SOCIABLE programme, as well as the duration of each play session. The SOCIABLE clinical protocol is part of the SOCIABLE Deliverable D7.1, titled: «Results Validation Plan».

The above documents illustrate important aspects of the SOCIABLE pilot process and are therefore complementary reference to document to the present deliverable. Note that the processes and details outlined in these deliverables are applicable to all pilot sites. Hence, they should be considered a prerequisite for understanding the baseline pilot plan which is presented in this section.

2.1.2 The Informal Testing Phase

2.1.2.1 Objectives

The informal testing phase is the starting phase of the pilot operation plan, while being a direct extension of the pilot sites preparation phase (which is dealt within WP5 of the project). The main objectives of this phase are:

- To allow end-users (both elderly and health professionals) to acquaint themselves with the operation of the SOCIABLE platform, as well as with the pilot processes specified in the scope of the SOCIABLE clinical protocol.
- To identify and resolve any technical problems that might hinder the (later) graceful execution of the SOCIABLE pilots. These problems will serve as a basis for eliciting lessons learnt and best practices associated with the commencement of (productive) operations with the SOCIABLE platform and services.
- To enable the execution of on-site training processes, as part of WP5 of the project. Training processes will ensure that end-users can use and fully leverage the functionalities of the SOCIABLE platform, as mandated by their role in the pilots.
- To test the graceful operation of the SOCIABLE ICT platform and services in a realistic environment at the various pilot sites. Note that testing activities at this phase will focus on real-life problems/issues that may not be discovered as part of the implementation and testing activities in WP4 of the project. The issues may be concerned with technical matters, but also with the way operational matters affect the platform and games deployment and configuration. As part of resolving organizational issues, the project may attempt the reengineering of medical processes at the various pilot sites.
- To pave the wave for the formal SOCIABLE operations (i.e. as part of the next phase of the pilot operations plan).

2.1.2.2 Main Activities and Characteristics

During this phase the following activities will be performed:

- Medical Experts will use the platform in order to design SOCIABLE session and associated play activities. In the scope of this process they will exercise their knowledge, following the training processes/activities in WP5.
- Elderly users within the pilot sites will have their early experiences with the SOCIABLE platform and services. Similar to medical experts they will have the opportunity to exercise themselves in the use of the ICT platform and services of the project.
- Medical experts and health professionals will engage into the full lifecycle of the SOCIABLE services, using the SOCIABLE platform in a realistic (on-site) context.

The experience of the lifecycle will be based on the running/execution of SOCIABLE cognitive training and social activation sessions. The execution of these sessions will serve a dual objective: (a) to ensure that the SOCIABLE ICT platform and services can fully support the sessions (as envisaged to be planned/organized at the various sites) and (b) to identify any required revisions/reengineering to the site's processes in the light of the use of the SOCIABLE ICT platform and services.

- In this initial phase of the pilot operations, technical partners will provide continuous technical support as requested by the pilot sites. At the end of the phase and prior to the start of the formal pilot operations, an updated version of the platform will be deployed taking into account comments and issues arising from this phase.

Overall, the main characteristics of this pilot phase are:

- The involvement of actual users, including medical experts, caregivers, and elderly users from the various SOCIABLE sites.
- The use of the platform and the services without formal adherence to the SOCIABLE clinical protocol and medical methodologies. While real users will be involved in a realistic context, the play activities will not abide by the mandates of the SOCIABLE protocol. Hence, medical processes (such as cognitive, functional and affective assessment) will not apply. Likewise, no formal programmes will be organized and there will not be any strict application of the envisaged session durations. Moreover, the participating elderly will not be selected based on the processes specified in the SOCIABLE study design.
- No clinical results will be collected as part of this phase and hence no relevant analysis will follow. The emphasis will be on the resolution of problems rather than on collection and analysis of clinical data.
- The end of the phase will be associated with the fine-tuning of the SOCIABLE ICT platform and services, according to feedback received by end-users (including the experience of resolving relevant incidents).

From a timing perspective this informal testing phase will start 01/02/2011 and will have a three month duration (i.e. ending 30/04/2011).

2.1.3 The Formal Pilot Process Phase

2.1.3.1 Objectives

The formal pilot phase will be the main phase of the SOCIABLE pilot operations, where elderly users will enlist in SOCIABLE programmes and will accordingly participate in sessions, fully in-line with the SOCIABLE clinical protocol. The main objectives of this phase will be to:

- Enlist elderly users in the SOCIABLE programmes, as specified by the study design protocol of the project. During this phase each site will involve elderly users from the three target groups of the project (i.e. cognitive intact elderly, MCI patients and Mild AD patients), balanced as specified in the study design protocol.
- Design programmes and sessions according to the SOCIABLE clinical protocols and medical evaluation methodologies.

- Execute the SOCIABLE clinical protocol including all relevant processes such as cognitive, functional and affective assessment of the elderly, leaker tests, as well as engagement of the elderly in personalized play sessions that will be appropriately designed by medical experts.
- To timely and actively involve medical experts, carers and elderly users in order to ensure that the SOCIABLE clinical protocol is applied without deviations.

The following table outlines the main differences between the informal testing phase and the formal pilot phase:

Pilot Process/Characteristic	**Informal Testing Phase**	**Formal Pilot Operations Phase**
Number of Elderly Users	No limits or restrictions; Health Professional will freely employ users based on the everyday activities of the care/day centre or hospital.	A strictly specified number of users will be employed (i.e. 348 users in total) based on a strictly defined distribution of users across the various sites.
Organization of the SOCIABLE session	Ad-Hoc guided by the medical expert or health professional	Strict and formal according to the SOCIABLE clinical protocol; SOCIABLE use cases will be followed faithfully
Cognitive, Functional, Affective Assessment	Ad-Hoc guided by the medical expert	According to the SOCIABLE neuropsychological battery (described in Deliverable D2.1)
Evaluation/Validation	Not Applicable (N/A)	The SOCIABLE Validation/Evaluation methodology will be applied as described in D7.1
Leaker Test	Standard tests applied in line with the SOCIABLE validation methodology	Standard tests applied in line with the SOCIABLE validation methodology

Table 1: Key Differences between SOCIABLE sessions occurring as part of the informal testing phase and the formal pilot operations phase

2.1.3.2 Main Activities

Overall the process to be applied in the scope of the formal pilot process is described in the SOCIABLE clinical protocol and can be summarized as follows:

- The process starts with a cognitive, affective and functional assessment of the elderly, which is based on the SOCIABLE neuropsychological battery for cognitive, functional and affective assessment of the elderly. The battery is administered to the elderly users prior to his/her inclusion in a SOCIABLE programme. The assessment of the elderly serves as a vehicle for classifying the elderly in one of the three SOCIABLE target groups, (normal/healthy elderly, elderly with MCI, elderly with mild AD) and deciding his/her inclusion in the programme. Furthermore, the neuropsychological tests will result in an

assessment of the cognitive skills of the elderly, which will be later used to shape the SOCIABLE programmes administered to the user.

- Following the cognitive, functional and affective assessment of the elderly, and assuming the successful the health professional carries out a number of preparatory activities towards the SOCIABLE sessions. These activities include briefing/training the elderly in the use of the SOCIABLE surface platform, while also preparing his/her sessions on the basis of the cognitive record of the user.
- Execution of a SOCIABLE programme comprising several sessions. Each session involves cognitive training games and the Book-of-Life application for social activation. Furthermore, the elderly is given the opportunity to interact with other elderly via a set of communication applications and services. The duration of a SOCIABLE programme will be 3 months. **In the scope of this programme the elderly will attend two sessions per week, each one featuring sixty minutes (60') duration**.
- A leaker test will follow the completion of a SOCIABLE programme, in order to get users' feedback on the procedure. This leaker test will be an element of the users' evaluation of the SOCIABLE approach.
- A cognitive, functional and affective assessment of the elderly will follow the leaker tests in order to access the positive effects of the programme on the elderly users.
- A follow-up assessment of the elderly can be carried out (approximately three months after the end of the programmes in order to evaluate/assess the longer term impact of the SOCIABLE intervention. Note that this follow-up assessment is performed for evaluation purposes and it not mandatory in order for the elderly to benefit from the SOCIABLE intervention.

Note that the assessment processes include also the leaker and mood induction tests, which will be used to get feedback from the participant and gauge its level of satisfaction and social activation.

All of the above activities are also described as part of deliverables D7.1 and D1.4, which respectively detail the SOCIABLE medical processes and the main use cases of the project. Deliverable D7.1 details also the number of users to be involved at each pilot site. Based on these numbers later paragraphs outline the number of sessions to be held in the scope of this phase.

2.1.3.3 Timing of the Formal Pilot Activities – Quarterly Iterations

The formal pilot operations phase will have a thirteen months duration (1/5/2011 – 31/5/2012). The thirteen months duration accounts for the fact that all pilot sites will not be operational during August 2011, given that this month is a vacations period for almost all partners. **Thus, the thirteen months phase will practically render/lead to a one-year period of formal pilot operations**. Later in this document we conveniently refer to the formal pilot operations as having one year duration, given that no essential activity will be planned for August 2011.

This one year (effective) period will be further subdivided in four (three-month) equivalent quarters, each one dealing with a subset of the users envisaged at each

one of the pilot sites. Each quarter could be seen as an (equivalent) division/iteration of the pilot operations. The division of the formal pilot activities into four quarterly iterations serves the following purposes:

- It allows part of the enlisted users (i.e. those that will be involved in subsequent quarters) to serve as a control group to be compared with users participating in earlier quarters. This tactic minimizes the required cognitive assessment processes, therefore economizing on the needed medical resources. Note however that the SOCIABLE pilots plan make provision for a control group having half size of the total number of users participating in formal pilot operations. This is further explained below.
- It allows process and ICT systems improvements (e.g., business process reengineering, application of patches, software upgrades, new hardware) to be deployed at specific intervals / milestones of the formal pilot activities. In this way it also boosts the WP6 principle/mandate for continuous improvement of the pilot operations.

The benefits of this division are also discussed in subsequent paragraphs.

2.1.4 Concluding Phase

2.1.4.1 Objectives

The concluding phase will be the last stage of the pilot operations. The main objectives of this phase are:

- To consolidate and analyze the results of the formal pilot operations phase in accordance to the project's medical assessment methodology.
- To assess the project's results from a medical, technological and techno-economic viewpoint.
- To assess the wider impact of the project's results, especially in the medical/scientific community.
- To report and document the project results including scientific results, best practices and lessons learnt at both the medical and technological levels.

2.1.4.2 Main Activities and their timing

This phase will rely on experiences and data collected during the formal pilot operations. To this end it is scheduled to start following the end of the pilot operations (i.e. 01/05/2012 (M35 of the project)) and end four months later (i.e. M39 of the project). In this three month period the consortium will undertake the following activities:

- Thorough analysis of the data collected during the pilot operations, in terms of scores in the cognitive tests, leaker tests, as well as feedback and questionnaires received by elderly end-users and health professionals. The analysis will follow the statistically sound methodologies described as part of the study design.
- Identification and consolidation of best practices and lessons learnt.
- Consolidation of guidelines for the wider deployment and exploitation of the SOCIABLE model in a realistic context.

- Authoring and finalization of relevant reports and documentation (including relevant deliverables).

While the phase will be focused on the collection and analysis of the results, play sessions and leaker tests will also continue, in order to allow users within the pilot sites to experiece/use the SOCIABLE surface platform. Note however that these play sessions will not be part of any formalized SOCIABLE programme.

2.2 Involving the Control Group in the SOCIABLE Pilot Operations

The SOCIABLE evaluation methodology foresees the involvement of a control group (not undertaking SOCIABLE based sessions), which will be compared to the experimental group to be employed in SOCIABLE. The involvement of the control group in the pilot operations will occur during the formal operations phase, in a way that minimizes the human resources required for the cognitive, functional and affective assessment. To this end, **the one year effective period of the formal operations phase is subdivided in four quarterly phases**, each one involving a quarter of the total number of users envisaged in the site. Likewise the total number of users (illustrated in Table 2) are divided in four groups each one containing approx. a quarter of the total number of users for each group and pilot site (as listed in Table 3). Note that for the users that will participate in SOCIABLE within the care centers, Table 4 and Table 7 depicts respectively the total number of users and the indicative number of users participating in each quarter of formal pilot operations.

Pilot Site & Country	Group A (Cognitive Intact Elderly)	Group B (Patients with Mild Cognitive Impairment)	Group C (Patients with Mild Alzheimer's Disease)	Total
HYGEIA S.A (Greece)	10	26	24	60
Social Policy Centre of the Municipality of Kifissia (Greece)	60	0	0	60
Commune Forli (Italy)	14	30	0	44
Morgagni Pierantoni Hospital (Italy)	0	50	0	50
Fondazione Santa Lucia (Italy)	0	0	46	46
Trodheim Kommune (Norway)	0	0	48	48
PREVI S.L (Spain)	40	0	0	40
Total	**124**	**106**	**118**	**348**

Table 2: Total Number of Users Participating in the SOCIABLE Pilot Operations

Pilot Site & Country	Group A (Cognitive Intact Elderly)	Group B (Patients with Mild Cognitive Impairment)	Group C (Patients with Mild Alzheimer's Disease)	Total
HYGEIA S.A (Greece)	2-3	6-7	6	15
Social Policy Centre of the Municipality of Kifissia (Greece)	15	0	0	15
Commune Forli (Italy)	14	30	0	11
Morgagni Pierantoni Hospital (Italy)	0	12-13	0	12-13
Fondazione Santa Lucia (Italy)	0	0	11-12	11-12
Trodheim Kommune (Norway)	0	0	12	12
PREVI S.L (Spain)	10	0	0	10
Total	**31**	**26-27**	**29-30**	**87**

Table 3: Indicative/Estimating number of Participating users in the SOCIABLE Pilot Operations in each of the four quarters comprising the one year pilot operations

Pilot Site & Country	Group A (Cognitive Intact Elderly)	Group B (Patients with Mild Cognitive Impairment)	Group C (Patients with Mild Alzheimer's Disease)	Total
HYGEIA S.A (Greece)	6	20	18	**44**
Social Policy Centre of the Municipality of Kifissia (Greece)	56	0	0	**56**
Commune Forli (Italy)	10	20	0	**30**
Morgagni Pierantoni Hospital (Italy)	0	40	0	**40**
Fondazione Santa Lucia (Italy)	0	0	40	**40**

Trodheim Kommune (Norway)	0	0	44	**44**
PREVI S.L (Spain)	20	0	0	**20**
Total	**92**	**80**	**102**	**274**

Table 4: Total Number of Users Participating in the SOCIABLE Pilot Operations with SOCIABLE Care Centers

Pilot Site & Country	Group A (Cognitive Intact Elderly)	Group B (Patients with Mild Cognitive Impairment)	Group C (Patients with Mild Alzheimer's Disease)	Total
HYGEIA S.A (Greece)	6	20	18	**44**
Social Policy Centre of the Municipality of Kifissia (Greece)	56	0	0	**56**
Commune Forli (Italy)	10	20	0	**30**
Morgagni Pierantoni Hospital (Italy)	0	40	0	**40**
Fondazione Santa Lucia (Italy)	0	0	40	**40**
Trodheim Kommune (Norway)	0	0	44	**44**
PREVI S.L (Spain)	20	0	0	**20**
Total	**92**	**80**	**102**	**274**

Table 5: Indicative/Estimating number of Participating users in the SOCIABLE Pilot Operations in each of the four quarters comprising the one year pilot operations

For the purpose of illustrating the involvement and function of the control groups in SOCIABLE we assume that the users will be segmented into fours almost equal groups (based on the dimensioning of Table 5). The segmentation of the SOCIABLE (care center) users in four groups (namely G1, G2, G3, G4) will allow the implementation of the following process (along the thirteen month period of the formal pilot operations (PM1-PM13), which includes a one year effective pilot period (i.e. excluding August 2011)):

- G1 will start their participation in the SOCIABLE programme at PM1. Hence, the participants of the group will undergo the cognitive, functional and affective assessment process at:
    - The beginning of PM1 (May 2011) (i.e. before enlisting in the programme)

  - The end of PM3 (July 2011) (i.e. at the end of the quarter after completing the programme).
  - The end of PM6 (October 2011), where the follow-up assessement will takes place in order to assess the longer term impact of the SOCIABLE programme.
- G2 will start their participation in the SOCIABLE programme at PM4 (September 2011 (since August does not count)). Prior to enlisting in the SOCIABLE programme G2 will serve as a control group for G1. Likewise it will be assessed at:
  - At the end of PM1 (i.e. end of May 2011), in order to serve as a control group of G1. Note that G2 is assessed at the end of May 2011 and not at the beginning of May 2011, in order to ensure a three month duration between the start of their participation in pilot operations (i.e. September 2011) and given that August 2011 does not include SOCIABLE activities.
  - The beginning of PM4 (September 2011) (i.e. before enlisting in the programme, but also as part of serving as a control group to G1).
  - The end of PM7 (November 2011) (i.e. at the end of the quarter after completing the programme)
  - A follow-up assessment for G2 will not be performed in order to economize on the required medical experts resources.
- G3 will start their participation in the SOCIABLE programme at PM7 and hence it will be assessed at PM7, PM10 and PM13. Overall, G3 will be assessed at:
  - The beginning of PM7 (November 2011) (i.e. before enlisting in the programme). This assessment will be used as the starting point for G3 participation in the SOCIABLE programme (play sessions).
  - The end of PM10 (February 2012) (i.e. at the end of the quarter after completing the programme)
  - The end of PM13 (May 2012), where the follow-up assessment will takes place in order to assess the longer term impact of the SOCIABLE programme.
- G4 will start their participation in the SOCIABLE programme at PM9 and hence it will be assessed at PM10 (beginning), PM12 (end) and PM15 (end) (i.e. three months after the end of the formal pilot operations). Prior to enlisting in the SOCIABLE programme G4 will serve as a control group for G3. Hence, it will be assessed in the same intervals as G3 in order to allow the comparison of the two groups. Specifically, it will be assessed at:
  - The beginning of PM7 (November 2011), in order to serve as a control group of G3.
  - The beginning of PM10 (February 2012) (i.e. before enlisting in the programme). This assessment will be used as the starting point for G4 participation in the programme, while also serving as a comparative value against G3 (as part of G4's functioning as a control group).
  - The end of PM13 (May 2012) (i.e. at the end of the quarter after completing the programme).
  - A follow-up assessment for G2 will not be performed in order to economize on the required medical experts' (human) resources.

The following table illustrates the planning of the assessments for the four groups comprising the SOCIABLE elderly users participating in the formal pilot operations phase.

	May 2011 (start)	**May 2011 (end)**	**July 2011 (end)**	**Sep 2011 (start)**	**Oct 2011 (end)**	**Nov 2011 (end)**	**Dec 2011 (start)**	**Feb 2012 (end)**	**Mar 2012 (start)**	**May 2012 (end)**
G1	X		X		X					
G2		X		X		X				
G3							X	X		X
G4							X		X	X

Table 6: Timing of the Cognitive, Functional and Affective Assessments for the four segmented SOCIABLE groups

The above timing and organization of the pilot activities ensures the involvement of a control group for assessing/gauging the SOCIABLE results, while at the same time optimizing the human effort associated with the cognitive assessment processes. However, one should note the following important points:

- Based on the above process (i.e. G2 serving as control group for G1 and G4 serving as control group for G3), a control group will be planned for up to 50% of the SOCIABLE users participating in the formal pilot operations, i.e. 174 users out of the 348 users. This is deemed sufficient for ensuring credible validation and comparable results. Note that the assessment of the rest users will be also useful towards assessing and validating the scientific validity of the SOCIABLE approach (according to the validation protocol of the project).
- As outlined above, up to 50% of the users participating in SOCIABLE will be back-up by a control group. The size of the control group might be smaller in practice (e.g., close to 50% of the total number of users) due to problems associated with early selection of users especially for groups B (MCI) and group C (Mild AD).
- A follow-up assessment will be performed for half of the users participating in pilot operations (i.e. groups G1 and G3). This is again sufficient for assessing/gauging the longer term effect of the SOCIABLE programmes. The rationale behind limiting the number of follow-up assessment is to economize on medical experts (human) resources required to support the formal pilot operations.

2.3 Pilot Users and Session Types (Individual vs. Groups)

2.3.1 Overview

Table 2 illustrates the total number of elderly users that will participate in the formal pilot operations of the project. It does not however clarify, which elderly users will participate in individual and which in group sessions. SOCIABLE has (as part of WP1) specified that both individual and group sessions will be held at the care centres during the pilot operations. However, the exact mix/balance between groups and individual sessions has not been specified. In the scope of the pilot operations planning this balance had to be decided and detailed. Note that the mix between

individual and group sessions has significant implications on the organization of the pilot operations given:

- Time limits associated with the planning of pilot operations i.e. the strict timeframe where all users must complete the SOCIABLE programme as specified in the pilot operations timing outlined in earlier paragraphs.
- Play activities at the care centers require the participation of a supervising health professional. Hence, SOCIABLE pilot operations should be planned in line with the available/planned human resources in the project.

In the sequel we illustrate that half of the SOCIABLE elderly will participate in individual sessions, whereas the rest half in group sessions. We also elaborate on the methodology applied to decide this mix, which proves that it is a realistic and viable solution on the basis of human resources mobilized for the SOCIABLE project.

2.3.2 Parameters Affecting the Planning

The planning of individual and group sessions hinges on sound estimations about a number of parameters that affect the amount of required human resources. These are illustrated in the following table (Table 7):

Process	Estimated Person Hours
Man Hours for the Cognitive Assessment of the Experimental Group	3
Man Hours for the Cognitive Assessment of the Control Group	2
Number of persons in the group	3
Man Hours allocated to play sessions for the duration of the SOCIABLE Programme	24

Table 7: Parameters affecting the amount of human resources supporting/supervising the pilot operations

Note that the parameters in the above tables constitute sound average estimations provided by the medical experts of the consortium. The 24 hours estimation for the play sessions (in total) have been calculated on the basis of that a SOCIABLE programme comprises 24 play sessions (approx. 2 weekly 1h sessions for twelve weeks). While there will be deviations from these numbers, they constitute sound estimations for the analysis that follows in the following paragraphs. It should be however noted that the following numbers are estimations and not exact numbers given also the variations in the numbers of follow-up assessment and the control group assessements outlined above.

The following analysis considers the balance between individual and group sessions in the care centers and therefore it is based on the number of elderly users that will participate in the SOCIABLE pilots in the care centers. These numbers are shown in the following table (Table 8), which depicts numbers that are a subset of those in Table 2 above.

Pilot Site & Country	Group A (Cognitive Intact Elderly)	Group B (Patients with Mild Cognitive Impairment)	Group C (Patients with Mild Alzheimer's Disease)	Total
HYGEIA S.A (Greece)	6	20	18	44
Social Policy Centre of the Municipality of Kifissia (Greece)	56	0	0	56
Commune Forli (Italy)	10	20	0	30
Morgagni Pierantoni Hospital (Italy)	0	40	0	40
Fondazione Santa Lucia (Italy)	0	0	40	40
Trodheim Kommune (Norway)	0	0	44	44
PREVI S.L (Spain)	20	0	0	20
Total	**92**	**80**	**102**	**274**

Table 8: Number of Users Participating in the SOCIABLE Pilot Operations within Care Centers

2.3.3 Scenario Analysis

On the basis of the information provided in the previous paragraphs, three main (boundary) scenarios were considered, namely:

- A scenario where all sessions will be individual (i.e. no group sessions will be held). This scenario is the most (human) resource-intensive.
- A scenario where half of the elderly will participate in group sessions, while the rest half of users will be participating in individual sessions.
- A scenario where all users will be participating in group session, which is the least (human) resource-intensive scenario.

Following paragraphs analyze these scenarios, on the basis of ballpark estimations for the person-hours required to supervise play sessions, as well as on the basis of the effort associated with cognitive assessment processes. Note that the figures provided in the analysis of the scenarios constitute estimates that might slightly deviate from the reality, given that the numbers do not account for cognitive assessment processes associated with the control groups which will used for comparison with the experimental groups (as illustrated in the previous sub-section).

2.3.3.1 Scenario A: All Users Participate in Individual Sessions

The person-hours that medical experts and/or health professionals have to allocate for this scenario is depicted in the table below (Table 9).

Pilot Site & Country	Group A (Cognitive Intact Elderly)	Group B (Patients with Mild Cognitive Impairment)	Group C (Patients with Mild Alzheimer's Disease)	Total
HYGEIA S.A (Greece)	0	580	522	**1102**
Social Policy Centre of the Municipality of Kifissia (Greece)	1624	0	0	**1624**
Commune Forli (Italy)	290	580	0	**870**
Morgagni Pierantoni Hospital (Italy)	0	1160	0	**1160**
Fondazione Santa Lucia (Italy)	0	0	1160	**1160**
Trodheim Kommune (Norway)	0	0	1276	**1276**
PREVI S.L (Spain)	580	0	0	**580**
Total	**2494**	**2320**	**2958**	**7772**

Table 9: Estimation of Health Professionals Involvement (in Person Hours) required in the case where only individual sessions will be organized in the care centers

As evident from the table this scenario requires the allocation of approx. 50 person months from the health professional's side including approx. 10PMs from SPC, 8 PMs from TRONDHEIM and 7-8PMs from each one of FSL, AUSL and HYGEIA.

2.3.3.2 Scenario B: 50% of the Users Participate in Individual Sessions and 50% in Group Sessions

The person-hours that medical experts and/or health professionals have to allocate for this scenario are illustrated in the table below (Table 10).

Pilot Site & Country	Group A (Cognitive Intact Elderly)	Group B (Patients with Mild Cognitive Impairment)	Group C (Patients with Mild Alzheimer's Disease)	Total
HYGEIA S.A (Greece)	0	420	378	**798**
Social Policy Centre of the	1176	0	0	**1176**

Municipality of Kifissia (Greece)				
Commune Forli (Italy)	210	420	0	**630**
Morgagni Pierantoni Hospital (Italy)	0	840	0	**840**
Fondazione Santa Lucia (Italy)	0	0	840	**840**
Trodheim Kommune (Norway)	0	0	924	**924**
PREVI S.L (Spain)	420	0	0	**420**
Total	**1806**	**1680**	**2142**	**5628**

Table 10: Estimation of Health Professionals Involvement (in Person Hours) required in the case where half of the elderly will participate in group sessions (on the basis of groups of three-members) and the rest half in individual sessions

This scenario requires the allocation of approx. 35 person months from the health professional's side including approx. 7-8PMs from SPC, 5-6 PMs from each one of TRONDHEIM, FSL, AUSL and HYGEIA.

2.3.3.3 Scenario C: All Users Participate in Group Sessions

The person-hours that medical experts and/or health professionals have to allocate for this scenario are illustrated in the table below (Table 11).

Pilot Site & Country	Group A (Cognitive Intact Elderly)	Group B (Patients with Mild Cognitive Impairment)	Group C (Patients with Mild Alzheimer's Disease)	Total
HYGEIA S.A (Greece)	0	260	234	**494**
Social Policy Centre of the Municipality of Kifissia (Greece)	728	0	0	**728**
Commune Forli (Italy)	130	260	0	**390**
Morgagni Pierantoni Hospital (Italy)	0	520	0	**520**
Fondazione Santa Lucia (Italy)	0	0	520	**520**
Trodheim Kommune	0	0	572	**572**

(Norway)				
PREVI S.L (Spain)	260	0	0	**260**
Total	**1118**	**1040**	**1326**	**3484**

Table 11: Estimation of Health Professionals Involvement (in Person Hours) required in the case where all the elderly will participate in group sessions (on the basis of groups of three-members)

As evident from the table this scenario requires the allocation of approx. 22 person months from the health professional's side including approx. 5PMs from SPC, and 3-4 PMs from TRONDHEIM, FSL, AUSL and HYGEIA. These numbers lead to a significantly lower number of human resources comparing to the previous scenarios (especially the scenario involving only individual sessions).

2.3.4 Consolidated Decisions

On the basis of the above analysis, the SOCIABLE pilot operations will opt for the second scenario i.e. an almost equal distribution of elderly users into individual and group sessions. This decision ensures that the project can allocate the necessary resources in order to gracefully organize and support the formal pilot sessions. At the same time it is in-line with the project's pilot requirements (established as part of D1.3) and the medical processes at the various sites.

Given this decision, the following tables present a specific distribution of SOCIABLE users to users that will participate in individual sessions and those that will participate in group sessions, along with a more accurate estimation of the required person hours to be contributed by health professionals. Specifically:

- Table 12 and Table 13 depict the individual users and groups that will participate in SOCIABLE play sessions.
- Table 14 illustrates the sum of the number of individuals and groups that will participate in SOCIABLE programmes, which can directly need to the total number of sessions that will be carried out during formal operations.
- Based on the above tables and the parameters outlined in the previous paragraph, Table 15 provides a sound estimation of the person-hours that will have to be allocated by the health professionals to the SOCIABLE formal pilot operations. Note that the estimation in this table takes into account the cognitive, functional and affective assessment processes of the control groups. Hence, the estimated numbers (i.e. person-hours) are higher than those estimated in Table 10.

Pilot Site & Country	Group A (Cognitive Intact Elderly)	Group B (Patients with Mild Cognitive Impairment)	Group C (Patients with Mild Alzheimer's Disease)	Total
HYGEIA S.A (Greece)	4	11	11	**26**
Social Policy Centre of the	28	0	0	**28**

Municipality of Kifissia (Greece)				
Commune Forli (Italy)	6	8	0	**14**
Morgagni Pierantoni Hospital (Italy)	0	19	0	**19**
Fondazione Santa Lucia (Italy)	0	0	19	**19**
Trodheim Kommune (Norway)	0	0	22	**22**
PREVI S.L (Spain)	8	0	0	**8**
Total	**46**	**38**	**52**	**136**

Table 12: Elderly users that will participate in individual sessions within SOCIABLE care centers

Pilot Site & Country	Group A (Cognitive Intact Elderly)	Group B (Patients with Mild Cognitive Impairment)	Group C (Patients with Mild Alzheimer's Disease)	Total
HYGEIA S.A (Greece)	6	9	9	24
Social Policy Centre of the Municipality of Kifissia (Greece)	27	0	0	27
Commune Forli (Italy)	9	12	0	21
Morgagni Pierantoni Hospital (Italy)	0	21	0	21
Fondazione Santa Lucia (Italy)	0	0	21	21
Trodheim Kommune (Norway)	0	0	21	21
PREVI S.L (Spain)	12	0	0	12
Total	**54**	**42**	**51**	**147**

Table 13: Distribution of the Groups (for the group sessions) that will participate in formal SOCIABLE operations

Pilot Site & Country	Group A (Cognitive	Group B (Patients with	Group C (Patients with	Total

	Intact Elderly)	**Mild Cognitive Impairment)**	**Mild Alzheimer's Disease)**	
HYGEIA S.A (Greece)	10	20	20	**50**
Social Policy Centre of the Municipality of Kifissia (Greece)	55	0	0	**55**
Commune Forli (Italy)	15	20	0	**35**
Morgagni Pierantoni Hospital (Italy)	0	40	0	**40**
Fondazione Santa Lucia (Italy)	0	0	40	**40**
Trodheim Kommune (Norway)	0	0	43	**43**
PREVI S.L (Spain)	20	0	0	**20**
Total	**100**	**80**	**103**	**283**

Table 14: Sum of the individual and groups that will participate in distinct play sessions and their distribution across the various pilot sites

Pilot Site & Country	**Group A (Cognitive Intact Elderly)**	**Group B (Patients with Mild Cognitive Impairment)**	**Group C (Patients with Mild Alzheimer's Disease)**	**Total**
HYGEIA S.A (Greece)	194	436	436	**1066**
Social Policy Centre of the Municipality of Kifissia (Greece)	1163	0	0	**1163**
Commune Forli (Italy)	291	388	0	**679**
Morgagni Pierantoni Hospital (Italy)	0	824	0	**824**
Fondazione Santa Lucia (Italy)	0	0	824	**824**
Trodheim Kommune (Norway)	0	0	911	**911**

PREVI S.L (Spain)	388	0	0	**388**
Total	**2036**	**1648**	**2171**	**5855**

Table 15: Person-Hours to be allocated by Health Professionals for the Assessment Processes and for the Play Sessions

2.4 Planning for the Handling of Drop-Outs

According to the SOCIABLE health professionals, there is always a significant possibility that some of the participating users will drop-out of the programme. A drop-out can have several causes such as health problems of the participant, other obligations of his/her, as well as a later decision that they do not feel comfortable with the programme. Handling of drop-outs will occur during the formal pilot operations phase in order to ensure that leaving users are replaced without any essential impact on the SOCIABLE pilot operations. The following strategy will be applied:

- During the user selection/recruitment process, a 10% of the users will be held in a reserve list, with a view to replacing drop-out at the various pilot sites. Such "reserve list" users will be enlisted according to the expressions of interest for participating to the SOCIABLE programme. Note that one reserve list for each pilot site will be created.
- In the case of a drop-out user (in a given pilot site), two additional users will be enlisted in the next phase of the formal pilot operations. This will apply for each one of the quarterly phases comprising formal pilot operations, but for the last one. Note that users drop-out in the last quarter will not be replaced (since the last quarter has not subsequent quarter). We anticipate that the ratio 2:1 for each drop-out users will ensure that the project will end-up with the planned number of users at the end of the pilot operations.

2.5 Timing of the Activities (Gantt Chart)

The activities outlined in the previous paragraph, along with their timing/scheduling are depicted in the pilot operations plan (Gantt Chart) of the SOCIABLE pilot operations.

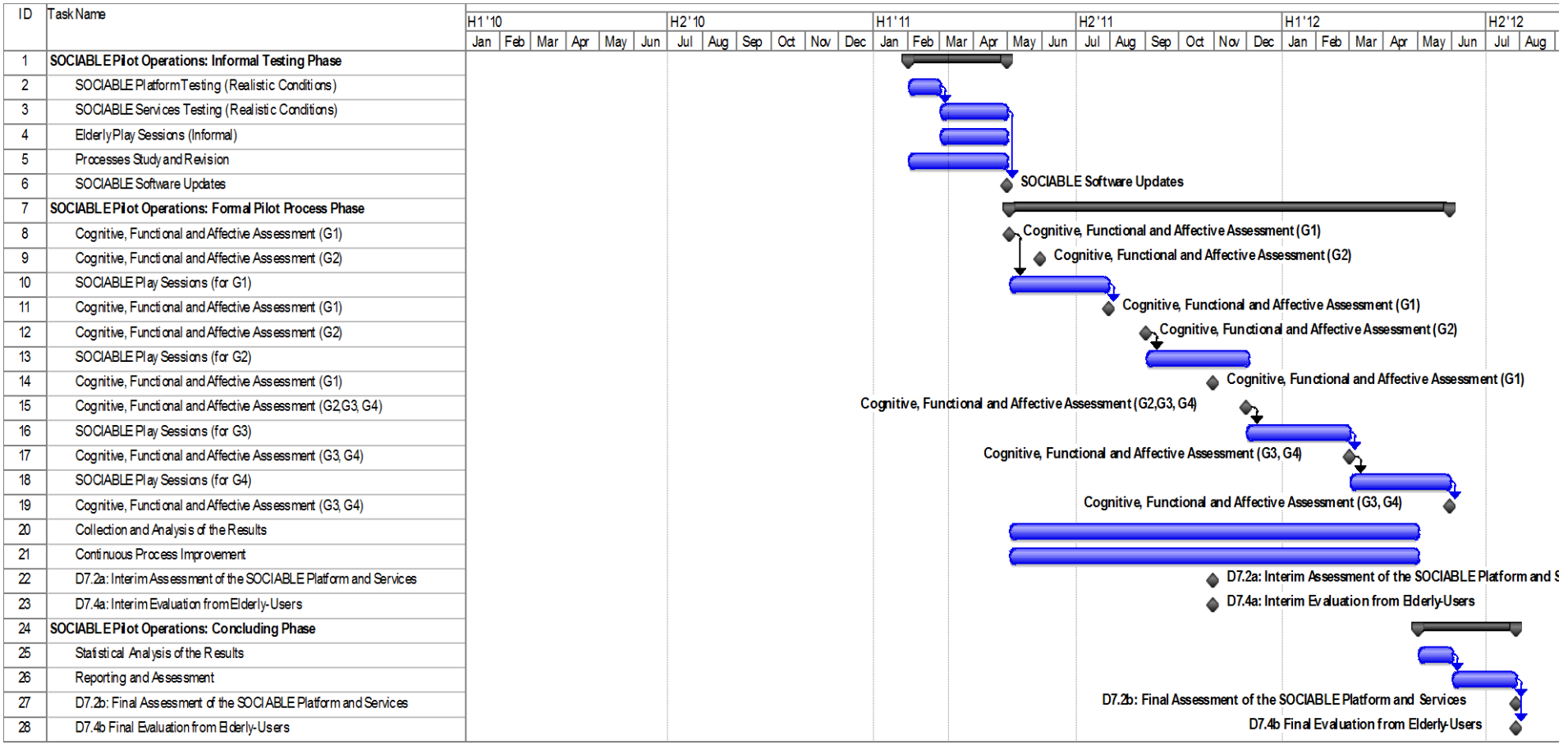

Figure 1: Baseline Timing of the SOCIABLE pilot operations activities (Gantt Chart)

It should be noted that the above baseline timing set the overall framework for conducting the pilot operations. Within pilot phases and across pilot sites, there will be several timing variations in order to accommodate the more specific organizational requirements of the hospitals and care centers (including relevant seasonal/timing constraints). These timing variations and constraints are discussed in later sections which elaborate on site-specific pilot planning considerations.

2.6 Ethical Management Considerations

In the scope of the pilot operations all sites will undertake ethical management activities in accordance to:

- The ethical processes outlined in SOCIABLE Deliverable D9.1 dealing with ethical management.
- Decisions and plans taken by the SOCIABALE Ethics Committee during the meetings of the committee in Rome 14/07/2010 and Athens 02/12/2011.

The ethical management activities to be performed by all sites include:

- Presentation of the SOCIABLE clinical protocol to the regional/local committees or councils entitled to give ethical approvals for the SOCIABLE pilot operations. Such approvals must have been received prior to the commencement of the formal pilot operations phase of the project. All sites have either received the relevant approvals or expecting to receive the approvals after submitting all relevant documentation.
- Informed consent of the participants/subjects participating in the SOCIABLE formal pilot operations. This involves the creation and delivery of appropriate informed consent forms.
- Secure storage, delivery and access of pilot's data (notably personal and private data) in order to safeguard privacy and confidentiality of the data. Mechanisms for secure access include also granting and managing access rights to the SOCIABLE Information. In order to ensure security enforcement for the SOCIABLE data, specific firewalling mechanisms and secure information exchange protocols are implemented over the SOCIABLE platform. The starting point for the implementation of these mechanisms is the TRONDHEIM site, given that such mechanisms are a prerequisite for getting the necessary approvals in Norway.

Following sections illustrate specific actions and activities planned (or already undertaken) by the various SOCIABLE pilot sites.

2.7 Risks and Contingency Plans

The following table (Table 16) illustrates potential risks that may jeopardize the graceful execution of the pilot operations plan. The same table elaborates on possible mitigation and contingency plans that will be activated.

Risk No.	Description	Explanation	Mitigation (or Contingency Plan)
1	Procuremen	Delays in delivering the	• Shift the formal pilot operations slightly

	t Delays	equipment causes delays in the scheduling of the pilots. Currently all sites have received the surface tables with the exception of COFO.	later (to overlap with the concluding phase). • Transfer users/sessions to later quarters of the pilot operations. • Reduce the number of users for COFO (and replace with equal number of users in other sites).
2	Availability of Human Resources associated with Medical Experts at the pilot sites	Some sites (especially municipalities) might have problems securing the required man hours of medical experts required in order to complete the pilots.	• A careful analysis and quantification of the required resources has already taken place in order to credibly estimated/assess the challenge (see also earlier paragraphs). • All municipalities have already contacted medical experts and agreed on the scope of the relevant collaboration and engagement.
3	Sessions Scheduling Problems and Challenges	While the sites have created large pools of interested users, it will be a challenge to enlist them in a three-month programme based on a very tight weekly schedule.	• Sites will discuss with end-users the requirements of the programme in terms of weekly presence. • The scheduling will take into account seasonal, national and site specific requirements (e.g., vacation periods) to facilitate users engagement and participation. • Prior to starting the pilot operations all sites will work out a detailed schedule at day granularity listing names of participants/experts participating in every session.
4	Delays in the some play sessions of specific groups	There might be problems with scheduling and conducting group session, since the later should ensure compatibility between schedules and cultures of different elderly within the same group.	• Experts will capitalize on their prior experience with scheduling group sessions at their sites. • A specific (day-granularity) schedule will be developed and distributed to users (medical experts and elderly users) in advance.
5	Drop-outs	It is likely that several users will drop-out of the programme	• A baseline drop-out strategy has been developed. • The number of drop-outs and the analysis of the causes will be an element of the project's scientific evaluation.

Table 16: Risks and Contingency Planning associated with the planning and execution of the SOCIABLE pilot operations

It should be noted that the above risks concerns the planning of the pilot operations and not technical, technological or other risks, which may also affect the success of the project. The latter are addressed in the general risk management methodology of the project, which is reviewed in the project's periodic reports.

3. Pilot Operations Plan for HYGEIA (HYGEIA)

3.1 Ethical Management Activities

The Ethical management activities for the HYGEIA hospital will all take place during the preparatory phase and include:

- Preparation of an Informed Consent form to be used for getting the consent of the subjects. The form is included as an Appendix in this deliverable.
- Translation of a summary part of the SOCIABLE clinical protocol (established as part of D7.1) in Greek. This translation is also provided as an Appendix in this document.
- Submission of the SOCIABLE Clinical Protocol, the Informed Consent Form and the translated summary for approval to the Scientific Committee of the HYGEIA Hospital.

No other ethical related activities will be undertaken by the HYGEIA hospital, except for those identified in D9.1 of the project.

3.2 Pilot Operations Planning Parameters

The following table lists a number of parameters associated with the specific dimensioning of the pilots at HYGEIA.

Number of Pilot Users	60
Estimated Pilot Users per Quarter of Formal Pilot Operations	16 (4 home users, 6 users participating in individual sessions, 6 users participating in group sessions)
Estimated Number of Users Participating in Individual Sessions	23 (i.e. ~50% of the care center users, as agreed during the meeting in Athens)
Size of the Groups (Group Sessions)	3 Users in each group
Estimated Number of Users Participating in Group Sessions	21 (i.e. ~50% of the care center users) leading to seven groups
Number of Groups with Cognitive Intact Elderly (Group/Type A)	1
Number of Groups with MCI patients (Group/Type B)	3
Number of Groups with Mild AD patients (Group/Type C)	3
Envisaged Number of Medical Experts & Health Professionals Involved	3
Number of Users "Reserved" to replace Drop-Outs	5
Medical Experts Carrying Out Assessments	1

Table 17: Main Parameters and Facts Associated with the Pilots Organization at HYGEIA

3.2.1 Detailed Pilot Operations Planning for Quarter 1 (May2011-July2011)

The following tables provide more details about the planning of the pilot operations during the first quarter of the formal pilot operations.

Activities	Assessment of Users Group G1 (Experimental Group) Assessment of Users Group G3 (Control Group)
Health Professionals Involved (Names)	Olga Lymperopoulou, Neuropsychologist
Date(s) (Estimated)	1st week of May 2011

Table 18: Initial Cognitive Assessment Processes (May 2011)

Activities	Play Sessions (Group Sessions)
Health Professionals Involved (Names)	Olga Lymperopoulou, neuropsychologist Eva Ntanasi, psychologist
Number of Groups	2
Number of Play Sessions Required	24
Date(s)	May2011-July2011

Table 19: Group Play Sessions (May2011-July2011)

Activities	Play Sessions (Individual Sessions)
Health Professionals Involved (Names)	Olga Lymperopoulou, neuropsychologist Eva Ntanasi, psychologist
Number of Individuals	6
Number of Play Sessions Required	24
Date(s)	May2011-July2011

Table 20: Individual Play Sessions (May2011-July2011)

Activities	Assessment of Users Group G1 (Experimental Group end of the SOCIABLE Programme) Assessment of Users Group G3 (Control Group)
Health Professionals Involved (Names)	Olga Lymperopoulou
Date(s)	End of July 2011 (post-intervention) End of October 2011 (follow-up)

Table 21: Final Cognitive Assessment Processes (May 2011-July2011)

4. Pilot Operations Plan for Morgagni-Pierantoni Hospital (AUSL)

4.1 Ethical Management Activities

The Ethical Management activities for the Morgagni-Pierantoni Hospital include the preparation and submission of the required documentation to the Internal Ethical Committee for the approval according to the national/regional rules. The Ethical Committee for clinical trials is an independent body which has the responsibility to safeguard rights, safety and welfare of patients participating in a trial and to provide public assurance of this protection.

The ethical committee normally meets once every three weeks and expresses its opinion about:

- Clinical trials assessing pharmacological interventions
- Clinical trials assessing medical and diagnostic devices
- Observational studies and clinical trials in general medicine

The Ethical Committee examines each trial on the basis of:

1. Scientific ratio and acceptability.
2. Intern or scientific validity of protocols.
3. External validity of results.
4. feasibility within the structure that has requested to make the experimentation
5. economic compatibility, according to art. 6, comma I, Ministerial Decree 12/05/2006
6. Ethical aspects
7. Features of accuracy and completeness of modules employed to provide information to the patients and the General Doctor, and to obtain the Informed consent by the patients

The Ethical Committee expresses, through an open vote, its justified opinion.
In line with the required procedures AUSL has focused on the preparation and collection of the documents required by the Internal Ethical Committee, which include:

- Preparation of an Informed Consent form to be used for getting the consent of the subjects.
- Preparation of an informative document for the patient, with all the information about the study.
- Preparation and translation of a summary of the Clinical Protocol in Italian.

The documents listed above, along with the SOCIABLE Clinical Protocol have been submitted to the Ethical Committee, in order to be processed and evaluated for the approval. Note that the documentation prepared and translated in Italian is included as an Appendix in this document.
In addition to getting ethical approval, the ethical rules mandate that all data that will be collected are stored in a secure way. The relevant secure storage and access processes are prescribed in SOCIABLE D9.1.

4.2 Pilot Operations Planning Parameters

The following table lists the pilot operations planning parameters for the AUSL pilots.

Number of Pilot Users	50
Estimated Pilot Users per Quarter of Formal Pilot Operations	12 (2 home users, 4 users participating in individual session, 6 users participating in group sessions)
Estimated Number of Users Participating in Individual Sessions	16 at Care Center + 10 at home
Size of the Groups (Group Sessions)	3 users each group
Estimated Number of Users Participating in Group Sessions	24
Number of Groups with Cognitive Intact Elderly (Group/Type A)	0
Number of Groups with MCI patients (Group/Type B)	8
Number of Groups with Mild AD patients (Group/Type C)	0
Envisaged Number of Medical Experts & Health Professionals Involved	3
Number of Users "Reserved" to replace Drop-Outs	4 (10%)
Medical Experts Carrying Out Assessments	1

Table 22: Main Parameters and Facts Associated with the Pilots Organization at AUSL

Overall AUSL will follow the main timing guidelines presented in the overview section of the pilots. However, the pilot operations at the second quarter of the pilot operations will be planned in a way that no sessions will be scheduled in August 2011 since this is a vacation period for most of the citizens.

4.2.1 Detailed Pilot Operations Planning for Quarter 1 (May2011-July2011)

The following tables provide more details about the planning of the pilot operations during the first quarter of the formal pilot operations.

Activities	Assessment of Users Group G1 (Experimental Group) Assessment of Users Group G3 (Control Group)
Health Professionals Involved (Names)	Chiara Zaccarelli Neuropsychologist
Date(s)	Last weeks of April 2011 (pre-intervention Experimental Group G1+ assessment Control Group G3)

Table 23: Initial Cognitive Assessment Processes (May 2011)

Activities	Play Sessions (Group Sessions)
Health Professionals Involved (Names)	Chiara Zaccarelli Neuropsychologist

	1external Psychologist in training social health carers in collaboration with COFO, 1 nurse
Number of Groups	2
Number of Play Sessions Required	24 for each group (48 in total)
Date(s)	May 2011- July 2011

Table 24: Group Play Sessions (May2011-July2011)

Activities	Play Sessions (Individual Sessions)
Health Professionals Involved (Names)	Chiara Zaccarelli Neuropsychologist 1external Psychologist in training social health carers in collaboration with COFO, 1 nurse
Number of Individuals	4
Number of Play Sessions Required	24 for each individual (96 in total)
Date(s)	May 2011- July 2011

Table 25: Individual Play Sessions (May2011-July2011)

Activities	Assessment of Users Group G1 (Experimental Group end of the SOCIABLE Programme) Assessment of Users Group G3 (Control Group)
Health Professionals Involved (Names)	Chiara Zaccarelli Neuropsychologist
Date(s)	End of July 2011 (post-intervention+ assessment control group G3) End of October 2011 (follow up)

Table 26: Final Cognitive Assessment Processes (May 2011-July2011)

5. Pilot Operations Plan for FSL

5.1 Ethical Management Activities

The Ethical Management activities for the Santa Lucia Foundation focused on:

- Preparation of the Informed Consent as a part of the document submitted to FSL Ethical Committee. This form will be used to collect consent from the users involved in the project. This form is included in Appendix.
- Translation in Italian of the core of the project especially focused on the clinical protocol submitted. A copy of this summary will be delivered to patients and a copy of the doctor who will care. This form is included in Appendix.
- Submission of the SOCIABLE protocol, informed consent, official request form, Curricula of clinician participant in the protocol have been sent to the FSL Ethical Committee.

As a part of the information sent to the Ethical Committee FSL has guaranteed the secure storage of data collected and private data protection.

5.2 Pilot Operations Planning Parameters

The following table lists planning parameters for the FSL pilot.

Number of Pilot Users	46
Estimated Pilot Users per Quarter of Formal Pilot Operations	11-12 (2 home users, 10 at care centre)
Estimated Number of Users Participating in Individual Sessions	19 at Centre + 6 at ho me
Size of the Groups (Group Sessions)	3 users each group
Estimated Number of Users Participating in Group Sessions	21
Number of Groups with Cognitive Intact Elderly (Group/Type A)	N/A
Number of Groups with MCI patients (Group/Type B)	N/A
Number of Groups with Mild AD patients (Group/Type C)	46
Envisaged Number of Medical Experts & Health Professionals Involved	3
Number of Users "Reserved" to replace Drop-Outs	4
Medical Experts Carrying Out Assessments	1

Table 27: Main Parameters and Facts Associated with the Pilots Organization at FSL

5.2.1 Detailed Pilot Operations Planning for Quarter 1 (May2011-July2011)

Activities	Assessment of Users Group G1 (Experimental Group) Assessment of Users Group G3 (Control Group)
Health Professionals Involved (Names)	Francesco Barban Neuropsychologist
Date(s)	1st week of May 2011

Table 28: Initial Cognitive Assessment Processes (May 2011)

Activities	Play Sessions (Group Sessions)
Health Professionals Involved (Names)	Francesco Barban neuropsychologist and two neuropsychologist in training
Number of Groups	2
Number of Play Sessions Required	48 sessions
Date(s)	May 2011- July 2011

Table 29: Group Play Sessions (May2011-July2011)

Activities	Play Sessions (Individual Sessions)
Health Professionals Involved (Names)	Francesco Barban neuropsychologist and two neuropsychologist in training
Number of Individuals	6
Number of Play Sessions Required	164 sessions
Date(s)	May 2011- july 2011

Table 30: Individual Play Sessions (May2011-July2011)

Activities	Assessment of Users Group G1 (Experimental Group end of the SOCIABLE Programme) Assessment of Users Group G3 (Control Group)
Health Professionals Involved (Names)	Francesco Barban neuropsychologist
Date(s)	End of July 2011

Table 31: Final Cognitive Assessment Processes (May 2011-July2011)

6. Pilot Operations Plan for COFO

6.1 Ethical Management Activities

The municipality of Forlì is committed to the SOCIABLE ethical management processes. These activities are carried out in collaboration with AUSL of Forlì. The ethical management activities included the preparation of an Informed Consent form to be used for getting the consent of the subjects.

6.2 Pilot Operations Planning Parameters

The following table elaborates on the pilot operations parameters that will be taken into account in order to provide the detailed plan for pilot operations at COFO.

Number of Pilot Users	45
Estimated Pilot Users per Quarter of Formal Pilot Operations	10 (2 home users, 3 users participating in individual sessions, 5 users participating in group sessions)
Estimated Number of Users Participating in Individual Sessions	14 (center,) 10 (home)
Size of the Groups (Group Sessions)	3 users in each group
Estimated Number of Users Participating in Group Sessions	21
Number of Groups with Cognitive Intact Elderly (Group/Type A)	3
Number of Groups with MCI patients (Group/Type B)	4
Number of Groups with Mild AD patients (Group/Type C)	0
Envisaged Number of Medical Experts & Health Professionals Involved	4
Number of Users "Reserved" to replace Drop-Outs	4
Medical Experts Carrying Out Assessments	1 (in collaboration AUSL of Forlì)

Table 32: Main Parameters and Facts Associated with the Pilots Organization at COFO

6.2.1 Detailed Pilot Operations Planning for Quarter 1 (May2011-July2011)

The following tables provide more details on the planning of the COFO pilot operations for the 1st quarter. However, the detailed timing cannot be provided given that COFO is currently experiencing delays associated with the delivery of the surface table. In particular, COFO is the only site that has not yet acquired the platform, due to Microsoft EMEA failure to deliver more tables operating based on the first version of the surface software (where all the technical developments of the project occur). Hence, COFO had to rely on an internal reallocation of the available MS Surfaces (i.e. specifically COFO will receive the platform initially intended to SPC

that will operate with the platform used by SLG for the surface software/middleware development). In this way COFO will start the pilot operations as planned, despite the above-mentioned delay.

Activities	Assessment of Users Group G1 (Experimental Group) Assessment of Users Group G3 (Control Group)
Health Professionals Involved (Names)	Neuropsychologist AUSL Forlì

Table 33: Initial Cognitive Assessment Processes (May 2011)

Activities	Play Sessions (Group Sessions)
Health Professionals Involved (Names)	Antonella Bandini social worker; 3 social health carers
Number of Groups	2
Number of Play Sessions Required	24

Table 34: Group Play Sessions (May2011-July2011)

Activities	Play Sessions (Individual Sessions)
Health Professionals Involved (Names)	Antonella Bandini social worker; 3 social health carers
Number of Individuals	3
Number of Play Sessions Required	72

Table 35: Individual Play Sessions (May2011-July2011)

Activities	Assessment of Users Group G1 (Experimental Group end of the SOCIABLE Programme) Assessment of Users Group G3 (Control Group)
Health Professionals Involved (Names)	Neuropsychologist AUSL Forlì

Table 36: Final Cognitive Assessment Processes (May 2011-July2011)

7. Pilot Operations Plan for SPC

7.1 Ethical Management Activities

SPC will make use of the SOCIABLE clinical protocol and its translated summary in the Greek language in order to get ethical approval from the Administrative Council of the SPC. Accordingly SPC will proceed with the reception of Informed Consent by the users prior to the start of the formal operations.

7.2 Pilot Operations Planning Parameters

The following table lists the number of users that will participate in each of the four quarters of the formal pilot operations. It also illustrates the number of user participating in individual sessions, as well as the number of (three-person) groups.

USERS	INDIVIDUALS	GROUPS*	TOTAL	%
G1	9	2	15	25
G2	9	2	15	25
G3	6	3	15	25
G4	6	3	15	25
TOTAL	30	30	**60**	100
%	50	50	100	

Table 37: Individual and Groups sessions distributed within each quarter of the pilot operations

Note that the users are evenly distributed within each phase. Hence, according to the table we are going to have 15 users for each phase of which 50% will be attending individual sessions and the rest 50% group sessions. Since SOCIABLE programmes involve two sessions per week for each user/group, the plan indicates that 22 sessions/week will occur for G1, 22 sessions/week will occur for G2, 18 sessions/week will occur for G3 and 18 sessions/week will be organized for G4.

	PER WEEK		
SESSIONS	**INDIVIDUALS**	**GROUPS**	**TOTAL**
G1	9 x 2 = 18	2 x 2 = 4	22
G2	9 x 2 = 18	2 x 2 = 4	22
G3	6 x 2 = 12	3 x 2 = 6	18
G4	6 x 2 = 12	3 x 2 = 6	18
TOTAL	30	30	60

Table 38: Weekly sessions for each of the four quarters of formal pilot operations

Note that all elderly users at the SPC will be cognitive intact i.e. belonging to SOCIABLE Group A.

7.2.1 Detailed Pilot Operations Planning for Quarter 1 (May2011-July2010)

Activities	Assessment of Users Group G1 (Experimental Group)

	Assessment of Users Group G3 (Control Group)
Health Professionals Involved (Names)	Eva Stamou, Maria Stefa
Date(s)	9/5 – 29/7 1st assessment 1/8 – 8/8 2nd assessment

Table 39: Initial Cognitive Assessment Processes (May 2011)

Activities	Play Sessions (Group Sessions)
Health Professionals Involved (Names)	Eva Stamou, Maria Stefa
Number of Groups	2
Number of Play Sessions Required	48
Date(s)	

Table 40: Group Play Sessions (May2011-July2011)

Activities	Play Sessions (Individual Sessions)
Health Professionals Involved (Names)	Eva Stamou, Maria Stefa
Number of Individuals	9
Number of Play Sessions Required	216
Date(s)	18/4 – 29/4

Table 41: Individual Play Sessions (May2011-July2011)

Activities	Assessment of Users Group G1 (Experimental Group end of the SOCIABLE Programme) Assessment of Users Group G3 (Control Group)
Health Professionals Involved (Names)	Alexandra Vasila
Date(s)	26/4 – 4/5

Table 42: Final Cognitive Assessment Processes (May 2011-July2011)

8. Pilot Operations Plan for PREVI

8.1 Ethical Management Activities

At the time of writing of this document, PREVI has got all the required ethical approvals applicable at the national/regional level, notably the approval of the ethical committee of the centre where SOCIABLE will be applied. To this end, PREVI organized a meeting with the manager of the centre, where the study design and assessment protocols were explained. Furthermore, a document with all the information about the study was provided to the centre in order to facilitate the committee to discuss and approve the study. The ethical committee has already provided their feedback about the SOCIABLE protocol.

8.2 Pilot Operations Planning Parameters

The dimensioning of the pilot operations at PREVI are listed in the following table:

Number of Pilot Users	20 (center) 20 (home)
Estimated Pilot Users per Quarter of Formal Pilot Operations	10 (center) 10 (home)
Estimated Number of Users Participating in Individual Sessions	5 (experimental group)
Size of the Groups (Group Sessions)	2-3
Estimated Number of Users Participating in Group Sessions	5
Number of Groups with Cognitive Intact Elderly (Group/Type A)	5
Number of Groups with MCI patients (Group/Type B)	0
Number of Groups with Mild AD patients (Group/Type C)	0
Envisaged Number of Medical Experts & Health Professionals Involved	3
Number of Users "Reserved" to replace Drop-Outs	3
Medical Experts Carrying Out Assessments	2

Table 43: Main Parameters and Facts Associated with the Pilots Organization at PREVI

8.2.1 Detailed Pilot Operations Planning for Quarter 1 (May2011-July2011)

The following tables illustrate the more detailed organization of the pilot operations at PREVI for the first quarter of the pilot operations.

Activities	Assessment of Users Group G1 (Experimental Group) Assessment of Users Group G3 (Control

	Group)
Health Professionals Involved (Names)	Mila Burguera (psychologist) María Carbonell (psychologist)
Date(s)	4-15 April 2011

Table 44: Initial Cognitive Assessment Processes (May 2011)

Activities	Play Sessions (Group Sessions)
Health Professionals Involved (Names)	Mila Burguera (psychologist) María Carbonell (psychologist)
Number of Groups	2 (1group with 2, 1 group with 3)
Number of Play Sessions Required	12
Date(s)	May 3rd-July 24th 2011

Table 45: Group Play Sessions (May2011-July2011)

Activities	Play Sessions (Individual Sessions)
Health Professionals Involved (Names)	Mila Burguera (psychologist) María Carbonell (psychologist)
Number of Individuals	5
Number of Play Sessions Required	12
Date(s)	May 3rd-July 24th 2011

Table 46: Individual Play Sessions (May2011-July2011)

Activities	Assessment of Users Group G1 (Experimental Group end of the SOCIABLE Programme) Assessment of Users Group G3 (Control Group)
Health Professionals Involved (Names)	Mila Burguera (psychologist) María Carbonell (psychologist)
Date(s)	July 25th to July 31st 2011

Table 47: Final Cognitive Assessment Processes (May 2011-July2011)

9. Pilot Operations Plan for TRONDHEIM

9.1 Ethical Management Activities

In terms of ethical management TRONDHEIM will adhere to the Norwegian rules and regulations, which mandate ethical approvals from the regional committee. To this end, TRONDHEIM has provided to the committee the SOCIABLE clinical protocol, along with its summary in Norwegian. The later is included as an Appendix in this document. Note that the Informed Consent Form in the Norwegian language is also provided in the Appendix.

In addition to getting ethical approvals, the Norwegian ethical rules mandate that elderly data are stored in a secure way. This should apply to data supplied and determined during the assessment processes including personal information, scores in the tests of the SOCIABLE battery, score in LSNS and mood induction tests, scores achieved during play sessions, as well as data managed through the back-end modules of the SOCIABLE platform. The relevant secure storage and access processes are prescribed in SOCIABLE D9.1. As part of the ethical management activities at TRONDHEIM IT personnel is working on securing access to the SOCIABLE platform and services (i.e. through securing the SOCIABLE server that accompanies the surface table).

9.2 Pilot Operations Planning in TRONDHEIM

TRONDHEIM will in general adhere to the baseline pilot operations plan. However, the planning of the pilot sites foresees two main phases (which could be broken thus down into a finer granularity of four quarters). The formal pilot operations will be thus executed twice with 24 elderly in each round. This means that we will finish two groups A and B for the period May2011-October2011 and then start with the last two groups C and D for the period November2011-April2011. For each phase 24 elderly users will be included and divided into two groups. One intervention group (group A) and one control group (group B). All the groups will go through the assessment battery.

Group A will start their period of playing, and it will last 12 weeks. In this period Group B will be control for group A. When group A has finished playing group B will be tested again. Then they will begin their 12 weeks of training/ playing. Group A will be retested 12 weeks after they have ended playing. The same with group B when they have finished the 12- weeks sessions. This is overall in-line with the baseline pilot operations plan.

The organization of the pilots in terms of two six-months (semestrial) periods, instead of four quarterly periods, serves the purpose that TRONDHEIM needs to plan the operations at higher timescales. This is required in order to allow the recruitment of the requirement number of users (at semestrial level), especially for Group C (i.e. patients with mild Alzheimer disease).

In the scope of the TRONDHEIM planning, a break of several weeks during the summer is expected/planned, given the summer holydays in Norway which take place from the end of July to the end of August.

TRONDHEIM perceives drop-outs are a part of the project result, and therefore will not replace them, given also the difficulty of recruiting adequate users from Group C. Following paragraphs provide main parameters associated with the piloting planning at TRONDHEIM. Note that the the first pilot period (May2011-July2011) will provide feedback for adapting planning i.e. the operations will be evaluated and adjusted based on the results of this period.

9.3 Pilot Operations Planning Parameters

The dimensioning of the pilot operations at TRONDHEIM are listed in the following table:

Number of Pilot Users	48
Estimated Pilot Users per Quarter of Formal Pilot Operations	12 intervention 12 control
Estimated Number of Users Participating in Individual Sessions	0 or 24
Size of the Groups (Group Sessions)	3
Estimated Number of Users Participating in Group Sessions	48 or 24
Number of Groups with Cognitive Intact Elderly (Group/Type A)	0
Number of Groups with MCI patients (Group/Type B)	0
Number of Groups with Mild AD patients (Group/Type C)	All of the 48 users
Envisaged Number of Medical Experts & Health Professionals Involved	About 20
Number of Users "Reserved" to replace Drop-Outs	10% , 5 users
Medical Experts Carrying Out Assessments	Memory Clinic, St. Olavs Hospital

Table 48: Main Parameters and Facts Associated with the Pilots Organization at TRONDHEIM

9.3.1 Detailed Pilot Operations Planning for Quarter 1 (May2011-July2010)

Activities	Assessment of Users Group G1 (Experimental Group) Assessment of Users Group G3 (Control Group)
Health Professionals Involved (Names)	No names yet
Date(s)	15 of April

Table 18: Initial Cognitive Assessment Processes (May 2011)

Activities	Play Sessions (Group Sessions)
Health Professionals Involved (Names)	
Number of Groups	2 or 4
Number of Play Sessions Required	48 or 96
Date(s)	May 2011

Table 49: Group Play Sessions (May2011-July2011)

Activities	Play Sessions (Individual Sessions)
Health Professionals Involved (Names)	
Number of Individuals	0 or 6
Number of Play Sessions Required	0 or 144
Date(s)	

Table 50: Individual Play Sessions (May2011-July2011)

Activities	Assessment of Users Group G1 (Experimental Group end of the SOCIABLE Programme) Assessment of Users Group G3 (Control Group)
Health Professionals Involved (Names)	
Date(s)	April and July

Table 51: Final Cognitive Assessment Processes (May 2011-July2011)

10. Conclusions

This deliverable has provided the plan for the graceful organization and completion of the SOCIABLE pilots. The elaboration of the aspects contained in this deliverable have served as a first class opportunities for all the partners to deal with the details of the pilot organization in order to promptly respond to potential problems and contingencies. Furthermore, it has served as a basis for identifying challenges associated with the human resources that will have to be involved in the pilots, especially in terms of the project members that possess the required medical expertise for the SOCIABLE clinical trial.

In general the SOCIABLE pilot operations have been organized around three main phases including:

- An informal pilot phase, aiming at acquainting users (both elderly users and health professional) with the SOCIABLE processes, platform and services. This informal phase will be a key to ensuring that the SOCIABLE clinical trials can proceed without major technical, administrative and organizational issues/problems, given that the later will have been identified and solved in the scope of the preparatory phase. Note that the conclusion of this phase will result in the implementation of business process reengineering procedures at all the SOCIABLE pilot sites, along with upgrades and improvements to the technical implementation of the SOCIABLE platform and services.
- A formal pilot operations phase, which corresponds to the implementation of a clinical trials, in accordance to the SOCIABLE clinical protocol. In the scope of this phase all the formal medical/clinical procedures specified in SOCIABLE will be put into effect, towards deriving and assessing scientifically sound and credible results. The emphasis at this phase is put in the effective allocation of the human resources required (notably medical experts and health professionals), as well as on the effective handling of drop-outs. This phase includes cognitive assessment processes and play sessions (both for individual users and user groups).
- A concluding phase emphasizing the disciplined analysis of the results, as foreseen in the SOCIABLE clinical protocol. This phase will also include some of the last follow-up cognitive assessment processes, while also including all tasks associated with the reporting of results.

Among the above phases, the formal pilot operations phase is the most prominent one, given that it will emphasize the structured execution of all the processes comprising the SOCIABLE clinical trial, hence being a cornerstone in piloting, validating and proving the merits of the SOCIABLE approach. Furthermore, the formal pilot operations phase is the most demanding from an organizational viewpoint, while it entails the allocation of significant human resources (including medical expert resources) from all the SOCIABLE pilot sites. In addition to providing the general organization and timing of the pilot operations activities, this deliverable

has provided a very detailed plan for the operations of the initial phase of the formal SOCIABLE pilot operations, including the health professionals involved, the dates where play sessions and cognitive assessment processes will take place, as well as the number of users to be involved at each phase.

The success of the pilot operations depend on following faithfully the presented plan, while monitoring relevant risks and applying the presented contingency plans whenever required. Note however that in addition to the presented predictive approach, SOCIABLE will apply an adaptive approach that will continuously monitor the evolution of the pilot operations and accordingly adapt the activities timing and organization in order to confront potential problems and deviations.

Appendix I – Baseline SOCIABLE Informed Consent Form (in English)

Patient Information & Informed Consent Form

(including Caregiver Informed Consent)

Project Coordinator:
Site Address:
Site Phone Number:
Subject Identifier: | | | | | | | | |

Project acronym: SOCIABLE
Project full title: Motivating platform for elderly networking, mental reinforcement and social interaction

Version Number # **Date:**

What does giving consent mean?
You are being invited to take part in a research project. Before you, and the person who comes to the clinic with you, decide whether you take part, it is important for you to know why the project is being done and what it will involve. Please take time to read the following information carefully and discuss it if you wish with relatives. Ask us if there is anything that is not clear or if you would like more information.

The person who comes to the clinic with you (your family member or other caregiver) has an important role in this project, and you should decide together whether you want to take part. They are also asked to sign this form to confirm that they understand what they will be asked to do as part of the project.

What are the objectives of this project?
The goal of the SOCIABLE project is to integrate, deploy and operate an innovative Information and Communications Technology (ICT) – assisted service for assessing and accordingly reinforcing the mental state of the elderly through pleasant gaming activities for cognitive training, while at the same time boosting their social networking and activating their day-to-day interpersonal interactions.

What does the project involve?
The project will be piloted with a minimum of 350 users. The consortium includes the following pilots sites that will actively involve users under realistic settings:

- Three municipalities, namely TRONDHEIM Kommune (in Norway), Municipality/City of Forli (in Italy), Social Policy Center of the Municipality of Kifissia (in Greece).
- Two hospitals, namely HYGEIA Hospital in Greece, and Fondazione Santa Lucia (also in Italy)

The SOCIABLE project targets the following groups:

- Cognitively intact elderly
- Elderly with Mild Cognitive Impairment (MCI)
- Elderly with mild Alzheimer's Disease (AD)

Elderly users will make use of the SOCIABLE services in their homes or in care centers. In those places, appropriate surface computing devices comprising surface tables and Tablet PCs offering ergonomic mixed reality user interfaces will be provided. The users will leverage these devices for:

- Individualized/group based computerized cognitive training
- Social interaction with other elderly via the platform

If the doctor decides that you meet all the conditions and can participate in this project, you will be asked to participate in the project for about 3 months. During this time, you will need to visit the site 27 times. These visits will include a baseline assessment visit, 24 intervention visits, a post-intervention assessment visit at the end of the 3 months period and a follow-up assessment visit 6 months after the end of the project. The project staff will make all the appointments for you and will make sure that you and your caregiver know when you need to come to the clinic.

Are there any benefits for taking part in the project?

In terms of functionality, the SOCIABLE platform and services will offer an integrated approach for fighting cognitive decline (either age-related or attributed to neurodegenerative processes) through combining ICT assisted cognitive training with opportunities for social interaction.

Recent advances in neuroscience have produced several discoveries about the health of active brains. All of them, without exception, enhance the principle of "use it or lose it". In the literature, paper-and-pencil cognitive training has been described as possibly useful in maintaining or even improving cognitive function in elderly subjects with or without cognitive decline. However, computerized cognitive training seems to be even more effective due to its obvious advantages including beautiful graphics, exciting entertaining tasks, progressive difficulty levels etc.

In terms of ergonomics, the SOCIABLE platform and services will offer the users the opportunity to exercise their cognitive abilities and socializing skills through novel multi-touch surfaces that enable mixed reality user interfaces. Note that the SOCIABLE use interface has been thoroughly tested ergonomically with hundreds of aged users. Based on these tests, a comfortable play table with appropriate content for software development has been produced and will be used for the SOCIABLE pilots.

Your participation will help us to learn more about the efficacy of computerized cognitive training, which will may result in future benefit for other elderly and patients exhibiting cognitive decline.

Restrictions on use of certain medicines
There are no restrictions on the use of medicines while participating in the project. You are allowed to take all the medicine that your doctors have prescribed.

Do you have to stay in the project?
Participation in this project is completely voluntary, and you and your caregiver can choose to stop participating at any time. If you or your caregiver decides to withdraw from the project, contact your project coordinator or clinic and they will explain the best way for you to stop taking part. Information and data, which has been collected up until the time that you withdraw, will continue to be used by the SOCIABLE Consortium.

In addition, you should know that you may be withdrawn from the project for any of the following reasons:

- If you or your caregiver don't follow the project doctors' instructions
- If you don't attended the scheduled visits
- If the project coordinator decides that it is in the best interest of your health and welfare to withdraw
- If the whole project or the project at this clinic is stopped, for reasons not known now.

A decision not to take part, or to withdraw from the project, will not negatively affect your medical care now or in the future.

Who will have access to medical and personal information about you that is collected in this project?
If you decide to take part in the project, the project coordinator and staff will collect medical and personal information about you as part of the project. The SOCIABLE Consortium members and other like the independent ethics committee or the institutional review board for the project or regulatory authorities will have access to this information at the site in order to check that the project is done properly. The SOCIABLE Consortium members who see this information at the site will keep it confidential.

Your project coordinator will also transfer to the SOCIABLE Consortium members some of the information collected in a coded form. The information transferred will not include your name, initials, address, or other direct identifiers. It will be assigned a code number that only your project coordinator can connect back to your name.
From time-to-time, coded medical information will also be transferred to an independent Data Monitoring Committee made up of medical and statistical experts. Their job will be to monitor the safety of the intervention during the project and to

make recommendations about whether the project should continue and/or whether only certain treatment groups should continue.

Your permission to the project coordinator and staff to use this information or share it with the SOCIABLE Consortium members and others as described below for the project does not automatically end at a particular time.

Medical information about you may be produced as part of the research or project procedures. If at the time of the project, this information is known to be relevant to your medical care, it will be given to the project coordinator who will be encouraged to share it with you or your doctor. While you are in the project, however, the project site will not share certain new medical information about you that is created as part of the project (such as the results of certain tests) unless the project coordinator decides it is medically important to do so. This is done to stop the project results from being distorted. Once the project is over, you will be given access to medical information about you that you are entitled to see. You will be told if any of this medical information requires confirmation using a clinical test. This is important because some research results are for research purposes and may only have limited relevance for clinical diagnosis or treatment. At any time, you may ask your project doctor to let you see your personal information, e.g. name and address and to correct it if necessary.

What will the SOCIABLE Consortium do with the information it gets?
The SOCIABLE Consortium may use the information that the project doctor gives it (i.e. the coded information):

- By storing and analyzing it electronically to find out what this project is telling us
- By sharing it with regulatory authorities or groups that check that research is done properly
- By publishing the results of the project (this will not include any information that directly identifies you)
- By sharing it as part of research with companies or universities for the purpose of further understanding or developing this intervention. If the information is sent to another country, the SOCIABLE Consortium will apply the same level of protection to your information, to the extent permitted by local law.
- By using it to plan new studies or other types of research or other medical purposes related to the development of the intervention.

What payments will be made for the project?
You will not be paid for taking part in the project.

Who should you contact to answer any questions on the project?
You can ask ..... at ..... any questions at any time.

If you have questions about your rights as a subject in a research project, you should contact ..... at .....

Consent and Assent Instructions

Consent: Subjects able to provide consent must sign on the subject line below. Consent is provided by the Legally Authorized Representative for subjects unable to consent.

Assent: Is required for subjects able to express agreement.

Consent Form

Subject's Signature _____ **Date:** _____
DD/MM/YY

Printed name of Subject _____

*** Signature of Legally Acceptable Representative** _____ **Date:** _____
DD/MM/YY

*** Printed name of Legally Acceptable Representative** _____

Signature of Person conducting Consent _____ **Date:** _____
DD/MM/YY

Printed name of Person conduction Consent _____

Caregiver Informed Consent Statement

(This section must be completed to indicate the caregiver's consent on his/her own behalf, even if they have signed above as the patients legally acceptable representative).

I confirm that I have read the statements in the Patient Information and Informed Consent Form version #, date for this project, and that the project staff have explained the project procedures to me. I understand my responsibilities as described in the Patient Information and Informed Consent Form.

I confirm that I have had the chance to ask questions about this project, and I am happy with the answers and explanations that I have been given.

I have been given time to read the information carefully and to discuss it with others.

I agree to accept my responsibilities (as described in the Patient Information and Informed Consent Form) as a caregiver for the patient taking part in this project.

Caregiver Signature _____ **Date:** _____
DD/MM/YY

Printed Name of Caregiver _____ **Date:** _____
DD/MM/YY

Appendix II –SOCIABLE Informed Consent Form (in Spanish)

¿Qué significa dar su consentimiento?

Usted ha sido invitado a participar en un proyecto de investigación. Antes de que usted y la persona que viene al centro con usted, decidan si participa, es importante que sepa los motivos por los que se realiza este proyecto y lo que implica. Por favor, tómese su tiempo para leer detenidamente la siguiente información y discutirlo si lo desea con sus familiares. Pregúntenos si hay algo que no está claro o desea obtener más información.

La persona que viene al centro con usted (el miembro de su familia u otro cuidador) tiene un papel importante en este proyecto, y deben decidir juntos si quieren tomar parte. A ellos también se les pedirá que firmen este formulario para confirmar que entienden lo que se les pedirá que hagan como parte del proyecto.

¿Cuáles son los objetivos de este proyecto?

El objetivo del proyecto SOCIABLE es integrar, implementar y poner en marcha un servicio innovador basado en Tecnologías de la Información y las Comunicaciones (TIC) para la evaluación y posterior refuerzo del estado mental de las personas mayores a través de actividades de juego agradables para la formación cognitiva, y al mismo tiempo, impulsar sus redes sociales y activar sus interacciones personales del día a día.

¿En qué consiste el proyecto?

El proyecto será puesto a prueba con un mínimo de 350 usuarios. El consorcio incluye a los siguientes sitios piloto que involucrarán activamente a los usuarios en entornos realistas:

- Tres municipios, a saber, TRONDHEIM Kommune (en Noruega), Municipio / Ciudad de Forli (Italia), Centro de Política Social de la Municipalidad de Kifissia (en Grecia).
- Dos hospitales, a saber, HYGEIA Hospital de Grecia, y la Fondazione Santa Lucia (también en Italia).
- Centro de Día para Mayores: 'Tres Forques' del Ayuntamiento de Valencia (en España).

Los destinatarios del proyecto SOCIABLE son los siguientes grupos:

- Ancianos cognitivamente intactos
- Ancianos con deterioro cognitivo leve
- Ancianos con enfermedad de Alzheimer leve

Los usuarios harán uso de los servicios SOCIABLE en sus hogares o en los centros. A los centros se les proporcionarán los dispositivos informáticos necesarios, lo que comprende mesas de superficie (Surface) y a los usuarios en sus casas ordenadores (Tablet Pcs), que proporcionan interfaces de usuario ergonómicos de realidad mixta. Los usuarios aprovecharán estos dispositivos para:

- Entrenamiento cognitivo individualizado/grupo en ordenador.
- Interacción social con otras personas mayores a través de la plataforma

Si el médico decide que usted cumple todos los requisitos y puede participar en este proyecto, se le pedirá que participe en el proyecto durante 3 meses aproximadamente. Durante este tiempo, tendrá que visitar el sitio 27 veces. Estas visitas incluirán una visita de evaluación inicial, 24 visitas de intervención, una visita de evaluación post-intervención al final de los 3 meses y una visita de evaluación de seguimiento 6 meses después del final del proyecto. El personal del proyecto le preparará todas las citas y se asegurará de que usted y su cuidador sepan cuando tienen que acudir al centro.

¿Hay algún beneficio por participar en el proyecto?

En términos de funcionalidad, la plataforma y los servicios SOCIABLE ofrecen un enfoque integrado para luchar contra el deterioro cognitivo (bien relacionado con la edad o atribuido a los procesos neurodegenerativos) a través de la combinación del entrenamiento cognitivo asistido por las TIC con oportunidades para la interacción social.

Los últimos avances en neurociencia han producido varios descubrimientos sobre el bienestar del cerebro activo. Todos ellos, sin excepción, mejoran el principio de "úsalo o piérdelo". El entrenamiento cognitivo con lápiz y papel tradicionalmente se considera útil para mantener o incluso mejorar la función cognitiva en ancianos con o sin deterioro cognitivo. Sin embargo, la formación cognitiva informatizada parece ser aún más efectiva debido a sus evidentes ventajas ya que incluyen gráficos atractivos, funciones de entretenimiento, niveles de dificultad progresiva, etc.

En términos de ergonomía, la plataforma y servicios SOCIABLE ofrecerán a los usuarios la oportunidad de ejercitar sus capacidades cognitivas y habilidades sociales a través de novedosas 'surfaces multi-touch' que permiten interfaces de usuario de realidad mixta. Tenga en cuenta que la interfaz de uso de SOCIABLE ha sido probada a fondo de forma ergonómica con cientos de usuarios de edad avanzada. Basándonos en estas pruebas, se ha fabricado una mesa de juego cómoda, con un desarrollo de software apropiado y esta mesa se utilizará para los pilotos SOCIABLE.

Su participación nos ayudará a aprender más acerca de la eficacia del entrenamiento cognitivo computerizado, lo que puede llevar a un futuro beneficio para otros pacientes de edad avanzada que presentan un deterioro cognitivo.

Restricciones sobre el uso de ciertos medicamentos.

No hay restricciones sobre el uso de medicamentos durante su participación en el proyecto. Está autorizado a tomar todos los medicamentos que sus médicos le hayan prescrito.

¿Tiene que permanecer en el proyecto?

La participación en este proyecto es completamente voluntaria, y usted y su cuidador pueden optar por dejar de participar en cualquier momento. Si usted o su cuidador deciden retirarse del proyecto, comuníqueselo a su coordinador del proyecto o responsable del centro y se le explicará la mejor manera de dejar el proyecto. La información y los datos, que se hayan recogido hasta el momento en el que usted se retire, seguirán siendo utilizados por el Consorcio SOCIABLE. Además, usted debe saber que puede ser retirado del proyecto por cualquiera de las siguientes razones:

- Si usted o su cuidador no siguen las instrucciones de los expertos del proyecto.
- Si usted no asiste a las visitas programadas.
- Si el coordinador del proyecto decide que es mejor retirarse por el interés de su salud y su bienestar.
- Si todo el proyecto o el proyecto en este centro se para, por razones que actuadamente desconocemos.

La decisión de no participar o retirarse del proyecto, no afectará de forma negativa a su atención médica, ahora o en el futuro.

¿Quién tendrá acceso a la información personal y médica que se recoge en este proyecto?

Si decide participar en el proyecto, el coordinador del proyecto y el personal recopilarán la información personal y médica sobre usted como parte del proyecto. Los miembros del Consorcio SOCIABLE y otros como el comité de ética independiente o la junta de revisión institucional para el proyecto o las autoridades reguladoras tendrán acceso a esta información en el sitio a fin de comprobar que el proyecto se lleva a cabo correctamente. Los miembros del Consorcio SOCIABLE que vean esta información se ajustarán a la confidencialidad de los mismos.

Su coordinador de proyecto también transferirá a miembros del Consorcio SOCIABLE alguna de la información recopilada de forma codificada. La información transferida no incluirá su nombre, iniciales, dirección ni otros identificadores directos. A dicha información se le asignará un número de código que sólo el coordinador del proyecto puede asociar de nuevo con su nombre.

De vez en cuando, la información médica codificada también se transferirá a un Comité de Supervisión de Datos independiente formado por expertos médicos y estadísticos. Su tarea será vigilar la seguridad de la intervención durante el proyecto y formular recomendaciones acerca de si el proyecto y/o solo ciertos grupos de tratamiento deberían continuar.

El permiso que usted otorga al coordinador del proyecto y al personal para utilizar esta información o compartirla con los miembros del Consorcio SOCIABLE y otros, tal como se describe a continuación, para el proyecto no finalizará automáticamente en un momento determinado.

Se puede generar información médica sobre usted como parte del proyecto o los procedimientos de investigación. Si en el transcurso del proyecto, esta información se sabe que es relevante para su atención médica, se le proporcionará al coordinador del proyecto, quien la compartirá con usted o su médico. Sin embargo, mientras usted esté en el proyecto, el sitio del proyecto no compartirá la información médica que se genere sobre usted como parte del proyecto (tales como los resultados de determinadas pruebas) a menos que el coordinador del proyecto decida que es médicamente importante hacerlo. Esto se hace para evitar que los resultados del proyecto se distorsionen. Cuando el proyecto finalice, se le dará acceso a su información médica, dado que tiene derecho a verla. Se le comunicará si cualquiera de esta información médica requiere confirmación mediante una prueba clínica. Esto es importante debido a que algunos resultados de la investigación se generan con fines de investigación y pueden solamente tener una relevancia limitada para el diagnóstico clínico o tratamiento. En cualquier momento, le puede pedir a su médico del proyecto que le permita ver su información personal, por ejemplo nombre y dirección y corregirlo si es necesario.

¿Qué hará el Consorcio SOCIABLE con la información que consigue?

El Consorcio SOCIABLE puede utilizar la información que el médico del proyecto le dé (es decir, la información codificada):

- Almacenándola y analizándola electrónicamente para averiguar qué nos dice este proyecto.
- Compartiéndola con las autoridades o grupos reguladores que comprueban que la investigación se hace correctamente.
- Mediante la publicación de los resultados del proyecto (esto no incluirá ninguna información que le identifique a usted directamente).
- Compartiéndola como parte de la investigación con empresas o universidades con el fin de profundizar en la interpretación o el desarrollo de esta intervención. Si la información se envía a otro país, el Consorcio SOCIABLE aplicará el mismo nivel de protección a su información, de acuerdo a las leyes locales.
- Usándola para planificar nuevos estudios, otros tipos de investigación u otros fines médicos relacionados con el desarrollo de la intervención.

¿Qué pagos realizará el proyecto?

No se le pagará por participar en el proyecto.

¿Con quién debería usted contactar para responder cualquier pregunta sobre el proyecto?

Usted puede preguntar a Carolina Pérez Holguin en el 'Centro de Día para Personas Mayores Tres Forques', c/ Tres Forques, 87, tel. 962 061 992 en cualquier momento.

Si usted tiene preguntas acerca de sus derechos como sujeto de un proyecto de investigación, debe ponerse en contacto con .Milagros burguesa Lledó. en el teléfono 96 3536100.

Consentimiento e instrucciones del dictamen de conformidad

Consentimiento: Los sujetos capaces de dar su consentimiento deben firmar en la línea que aparece a continuación. Para sujetos incapaces de consentir, dicho consentimiento lo proporciona el representante autorizado legalmente.

Dictamen de conformidad: Se requiere para los sujetos capaces de expresar que están de acuerdo.

Formulario de Consentimiento

Firma del sujeto **Fecha**

DD / MM / AA

Nombre del sujeto:

Firma del punto de vista jurídico: **Fecha**

DD / MM / AA

Representante

*** Imprima el nombre del punto de vista jurídico del Consentimiento:**

DD/ MM / AA

Declaración de Consentimiento Informado médico

(Esta sección debe completarse para indicar el consentimiento del médico en su propio nombre, incluso si se han firmado los de arriba como representante legalmente aceptable de los pacientes).

Confirmo que he leído el documento de Información para el paciente y el Formulario de Consentimiento Informado versión , la fecha para este proyecto, y que el personal del proyecto me ha explicado los procedimientos del proyecto.

Entiendo mis responsabilidades tal y como se describen en la Información del Paciente y Formulario de Consentimiento Informado.

Confirmo que he tenido la oportunidad de hacer preguntas acerca de este proyecto, y que estoy satisfecho con las respuestas y explicaciones que se me han dado.

Se me ha dado tiempo para leer cuidadosamente la información y discutirla con las demás personas.

Estoy de acuerdo en aceptar mis responsabilidades (tal y como se describe en la Información del Paciente y Formulario de Consentimiento Informado) como médico del paciente que participa en este proyecto.

Firma del médico: **Fecha** DD/MM/AA

Nombre del Cuidador: **Fecha** DD/MM/AA

Appendix III –SOCIABLE Informed Consent Form (in Italian) (FSL Sample)

FOGLIO INFORMATIVO PER LA RICHIESTA DI CONSENSO INFORMATO ALLA PARTECIPAZIONE AD ATTIVITA' DI RICERCA SCIENTIFICA ED AL CONSEGUENTE TRATTAMENTO DEI DATI PERSONALI

Gentile Signore/a ……..

la Fondazione Santa Lucia è un Istituto di Ricovero e Cura riconosciuto a Carattere Scientifico, che svolge, insieme all'attività di assistenza, quella di ricerca sanitaria e di formazione nel settore della riabilitazione neuromotoria e delle neuroscienze.

Nell'ambito di tale esercizio, è in corso una ricerca il cui scopo è quello di valutare la performance cognitiva e la interazione sociale in soggetti sottoposti ad un training cognitivo-sociale basato sull'uso di nuove tecnologie. Il training verrà effettuato attraverso l'utilizzo di una piattaforma Microsoft sviluppata nell'ambito di un progetto Europeo ICT (Information Communication Technology), realizzato in cooperazione tra 11 centri in Europa dal titolo "Sociable".

Obiettivo del progetto è quello di migliorare la performance cognitiva e/o ridurre il decremento cognitivo in soggetti affetti da M. di Alzheimer. Attraverso questo sistema innovativo, inoltre, si vuole valutare la possibilità di migliorare l'interazione sociale in questa fascia di popolazione.

Il sistema in esame è costituito da una piattaforma Microsoft posizionata su un supporto tipo "tavolo" che permetterà a più utenti di interagire contemporaneamente con la stessa e di interagire fra di loro. Attraverso questa piattaforma saranno proposti agli utenti alcuni esercizi di riabilitazione cognitiva che verranno svolti grazie al sistema di touchpad previsto dalla piattaforma. La popolazione oggetto dello studio presso la Fondazione S. Lucia è rappresentata da soggetti affetti da Malattia di Alzheimer in fase lieve, sottoposti ad una valutazione neuropsicologica, mediante test standardizzati, e funzionale.

Non sono prevedibili effetti collaterali in quanto i soggetti non saranno sottoposti a trattamenti attivi fisici o farmacologici.

Con il presente modulo Le viene proposto di prendere parte al programma di studio, il cui responsabile scientifico è la Dott.ssa Roberta Annicchiarico.

Se Lei deciderà di partecipare allo studio, sarà inserito, dopo la raccolta dei suoi dati da parte del personale addetto, nel gruppo di studio.

Durante lo studio verrà effettuata una valutazione multidimensionale funzionale consistente nella somministrazione di questionari ed una valutazione neuropsicologica per la valutazione delle capacità cognitive.

L'impegno a Lei richiesto per partecipare allo studio consiste nella disponibilità ad utilizzare la piattaforma per svolgere esercizi di riabilitazione

cognitiva presso Laboratorio di Tecnologia per l'Assistenza della Fondazione IRCCS Fondazione Santa Lucia.

La durata del Suo impegno è prevista in due giorni a settimana (una ora per ogni seduta) per un periodo complessivo di tre mesi.

Il medico referente, nella persona della Dott.ssa Roberta Annicchiarico, sarà sempre a Sua disposizione per qualsiasi chiarimento, La informerà prontamente di qualunque notizia si renda disponibile durante lo studio e provvederà a sospendere la Sua partecipazione allo studio qualora ciò risulti nel suo interesse, comunicandoLe i motivi di tale sospensione.

Nel corso dello studio al quale prenderà parte, Lei sarà assicurato a copertura di eventuali danni da esso derivante.

La partecipazione allo studio non comporta per Lei alcun aggravio di spesa.

Lo studio è stato approvato dal Comitato Etico Indipendente della Fondazione Santa Lucia ed il suo svolgimento ed i suoi risultati sono monitorati dallo stesso Comitato.

Lei ha il diritto di non partecipare allo studio che Le viene proposto. Questo non comporterà assolutamente una minore assistenza nei Suoi confronti e Lei sarà in ogni caso sottoposto al miglior trattamento possibile per il suo stato di malattia.

Anche nel caso di accettazione a partecipare allo studio, Lei ha il diritto di ritirarsi dallo stesso in qualsiasi momento, senza essere obbligato a fornire alcuna giustificazione.

Si precisa che i risultati dello studio verranno portati a conoscenza della comunità scientifica ed i dati raccolti durante la sperimentazione non potranno rimanere di proprietà di singoli o gruppi che li possano utilizzare secondo il loro esclusivo interesse.

La procedura dello studio garantisce, peraltro, la riservatezza dei Suoi dati personali con riferimento al relativo Codice (D.lgs. del 30 giugno 2003, n. 196), ai sensi del cui art. 13 si sottopone la seguente informativa.

> *in conformità alle disposizioni del Codice in materia di protezione dei dati personali (di seguito "Codice"), la Fondazione Santa Lucia La informa che intende svolgere attività di trattamento di dati personali (di seguito "Dati"), anche sensibili[1], che La riguardano.*

[1] L'art. 4 del Codice definisce "*sensibili*" i dati personali idonei a rivelare l'origine razziale ed etnica, le convinzioni religiose, filosofiche o di altro genere, le opinioni politiche, l'adesione a partiti, sindacati, associazioni od organizzazioni a carattere religioso, filosofico, politico o sindacale, nonché i dati personali idonei a rivelare lo stato di salute o la vita sessuale.

FINALITA' E MODALITA' DEL TRATTAMENTO DEI DATI

I Dati forniti vengono acquisiti e trattati nel rispetto della normativa sopra richiamata, con il supporto di mezzi cartacei, informatici o telematici atti a memorizzare, gestire e trasmettere i dati stessi e comunque mediante strumenti idonei a garantire la loro sicurezza e riservatezza, nel rispetto delle regole fissate dal Codice, per le finalità della ricerca in precedenza descritta riguardo agli obiettivi, alle procedure, ai benefici ed rischi della partecipazione, all'impegno operativo e temporale richiesto

NATURA DEL CONFERIMENTO E CONSEGUENZE DI UN EVENTUALE RIFIUTO

L'eventuale rifiuto di fornire i Dati funzionali all'esecuzione della ricerca su menzionata, non comporta alcuna conseguenza relativamente ad eventuali trattamenti terapeutici in corso, salva l'eventuale impossibilità di dare seguito alle operazioni connesse alla ricerca.
Lei è libero/a di non partecipare alla ricerca o di ritirarsi dallo stessa anche senza preavviso o motivazione. Qualora, durante la ricerca, divengano disponibili dati che possano influenzare la Sua volontà di continuare Lei sarà tempestivamente ed opportunamente informato e, se necessario, Le sarà richiesto nuovamente il Consenso Informato a proseguire il trattamento in corso

COMUNICAZIONE DEI DATI

I Dati potranno inoltre venire a conoscenza dei responsabili della cui opera la Fondazione Santa Lucia si avvale nell'ambito di rapporti di esternalizzazione per la fornitura di servizi, nonché dei responsabili e degli incaricati del trattamento dei dati per le finalità di cui alla presente informativa, l'elenco aggiornato dei quali è a disposizione presso la sede della Fondazione Santa Lucia.

I Dati relativi ai risultati della ricerca sono strettamente confidenziali e soggetti ad anonimato. I risultati potranno essere portati a conoscenza di terzi o pubblicati, ma escludendo ogni possibile riferimento personale al paziente

DURATA DEL TRATTAMENTO

I Dati verranno trattati dalla Fondazione Santa Lucia

solamente per la durata della ricerca prevista in 3 anni.

DIRITTI DELL'INTERESSATO

L'art. 7 del Codice riconosce all'interessato numerosi diritti che La invitiamo a considerare attentamente. Tra questi, Le ricordiamo sinteticamente i diritti di:

- *ottenere la conferma dell'esistenza o meno dei Dati che lo riguardano, anche se non ancora registrati, e la loro comunicazione in forma intelligibile;*
- *ottenere l'indicazione dell'origine dei Dati, delle finalità e modalità del trattamento, degli estremi identificativi del titolare, dei responsabili, dei soggetti o delle categorie di soggetti ai quali i Dati possono essere comunicati o che possono venirne a conoscenza in qualità di responsabili o incaricati;*
- *ottenere l'aggiornamento, la rettificazione o l'integrazione dei Dati (qualora vi sia un interesse in tal senso) ovvero la cancellazione, la trasformazione in forma anonima o il blocco dei dati trattati in violazione di legge, nonché l'attestazione che tali operazioni sono state portate a conoscenza di coloro ai quali i Dati sono stati comunicati o diffusi;*
- *opporsi, in tutto o in parte, al trattamento dei Dati che lo riguardano per motivi legittimi ovvero per fini di invio di materiale pubblicitario o di vendita diretta o per il compimento di ricerche di mercato o di comunicazione commerciale.*

Lei, per l'intera durata del trattamento, potrà chiedere informazioni o porre domande al medico circa i dati acquisiti nel corso della sperimentazione e circa l'andamento della stessa relativamente al suo caso; allo stesso modo, al termine della ricerca, se richiesto, i risultati che La riguardano saranno comunicati a Lei ed al suo medico di base.

TITOLARE DEL TRATTAMENTO

Titolare del trattamento è la Fondazione Santa Lucia, Via Ardeatina, n. 306, Roma.

Per qualsiasi ulteriore informazione, chiarimento e comunicazioni a disposizione Il responsabile dei dati è: Dott.ssa Roberta Annicchiarico

Dott. Responsabile della sperimentazione: Dott.ssa Roberta Annicchiarico

Reparto: UOC

Roma, lì

MODULO CONSENSO INFORMATO

Io sottoscritto ……., familiare del paziente…… dichiaro di aver preso visione del protocollo concernente lo studio **"Sociable : una piattaforma tecnologica per la riabilitazione cognitiva:"**

In particolare dichiaro

- di aver ricevuto, all'interno di tale foglio illustrativo, l'informativa prevista dall'articolo 13 del D.lgs. 196/2003 riguardo al trattamento dei dati personali.
- di avere avuto a disposizione tempo sufficiente per poter leggere attentamente e comprendere quanto contenuto nel suddetto foglio illustrativo.
- di aver ricevuto dalla Dott.ssa Roberta Annicchiarico che opera presso la UOC esaurienti spiegazioni in merito alla richiesta di partecipazione allo studio.
- di essere stato informato del diritto di ritirarmi dalla ricerca in qualsiasi momento, senza dover dare spiegazioni e senza compromettere l'assistenza medica futura.
- Di aver ricevuto il nominativo del Dott.ssa Roberta Annicchiarico come medico referente per qualsiasi ulteriore chiarimento o informazione relativa alla sperimentazione
- Di aver avuto modo di esporre le mie considerazioni e di domandare ulteriori precisazioni, nonché di avere avuto il tempo necessario per prendere una decisione ponderata e non sollecitata.

Pertanto, sono consapevole delle attività previste e delle modalità di una mia adesione.

Ciò premesso dichiaro

di acconsentire □

di non acconsentire □

a partecipare allo studio ed al conseguente trattamento dei miei dati personali sensibili.

cognome e nome della persona firma della persona

_____ _____

oppure

cognome e nome del rappresentante legalmente valido firma del rappresentante legalmente valido

_____ _____

cognome e nome del medico che raccoglie il consenso firma del medico che raccoglie il consenso

_____ _____

NB: il presente modulo è valido solo se accompagnato dal corrispondente foglio illustrativo

Appendix IV – Clinical Protocol Summary Translation in Norwegian (and Informed Consent Form)

Forespørsel om deltakelse i forskningsprosjektet

"SOCIABLE"

Bakgrunn og hensikt

Dette er et spørsmål til deg om å delta i et prosjekt der det skal prøves ut mental stimulering og trening ved hjelp av dataspill. Målgruppen er personer over 65 år. Prosjektet skal foregå i Trondheim kommune, og er en del av et større EU-prosjekt der Italia, Hellas, Spania og Norge deltar. Bakgrunnen for prosjektet er at nyere forskning viser at det å trene hodet (hukommelse, oppmerksomhet, orienteringsevne, planleggingsevne) ved hjelp av dataspill kan være med å vedlikeholde og bedre våre mentale ferdigheter.

Hva innebærer prosjektet for deg?

Gruppe A

Din deltagelse i prosjektet vil gå over en periode på 6 måneder (24 uker). Etter at du er inkludert i prosjektet skal du gjennom en kartleggingsundersøkelse utført av lege. Her vil du få spørsmål og oppgaver som tester din hukommelse, oppmerksomhet, orienteringsevne, planleggingsevne. En av dine nære pårørende vil bli intervjuet om dine daglige aktiviteter, og hvordan vedkommende opplever at du klarer deg i hverdagen. Undersøkelsen vil ta ca 1,5 time. Når dette er gjort, skal du begynne å spille dataspill. Spillingen skal foregå ved Valentinlyst Helse- og velferdssenter. Spilleperioden varer i 3 måneder (12 uker). Du skal spille to ganger i uka med en varighet på 1 time hver gang. Prosjektet er lagt opp slik at du skal spille sammen med to eller tre andre deltagere. Det vil alltid være en medhjelper til stede. 3 måneder etter at du er ferdig med å spille, vil du og din pårørende bli innkalt til en avsluttende kartleggingsundersøkelse.

(Det er også lagt opp til at det skal gjøres noen observasjoner og registreringer underveis i spilleperioden. ***Er dette fortsatt aktuelt?***)

Gruppe B

Din deltagelse i prosjektet vil gå over en periode på 9 måneder (36 uker). Etter at du er inkludert i prosjektet skal du gjennom en kartleggingsundersøkelse utført av lege. Her vil du få spørsmål og oppgaver som tester din hukommelse, oppmerksomhet, orienteringsevne, planleggingsevne. En av dine nære pårørende vil bli intervjuet om dine daglige aktiviteter, og hvordan vedkommende opplever at du klarer deg i

hverdagen. Undersøkelsen vil ta ca 1,5 time. Så vil det følge en periode på 3 måneder der du skal gjøre dine vanlige, daglige aktiviteter. Etter disse 3 månedene vil du og din pårørende bli innkalt til en ny kartleggingsundersøkelse. Når dette er gjort, skal du begynne å spille dataspill. Spillingen skal foregå ved Valentinlyst Helse- og velferdssenter. Spilleperioden varer i 3 måneder (12 uker). Du skal spille to ganger i uka med en varighet på 1 time hver gang. Prosjektet er lagt opp slik at du skal spille sammen med to eller tre andre deltagere. Det vil alltid være en medhjelper til stede. 3 måneder etter at du er ferdig med å spille, vil du og din pårørende bli innkalt til en avsluttende kartleggingsundersøkelse.

Mulige fordeler og ulemper *(Ta bort dette avsnittet?)*
Du vil få anledning til å delta på utprøving av flere dataspill, og gi dine tilbakemeldinger om hva du syns om denne type aktivitet. Spillingen vil nødvendigvis oppta noe av tiden din, og du binder deg til å gjennomføre spillingen og møte til testing som anført i punktet over.

Hva skjer med testresultatene og informasjonen om deg?
Testresultater og informasjon som registreres om deg skal kun brukes slik det beskrives her. Alle data behandles konfidensielt og lagres i avidentifisert form i en database slik at deltagerne kun er registrert med et løpenummer. Resultater og navneliste vil bli oppbevart forskriftsmessig. Det er kun autorisert personell knyttet til prosjektet som har adgang til navnelisten og som kan finne tilbake til deg. Prosjektmedarbeiderne har taushetsplikt i henhold til Forvaltningslovens § 13 og Helsepersonellovens § 21. Opplysninger vil ikke bli overført til andre. Resultatene fra prosjektet vil publiseres i form av en lokal rapport og i vitenskapelige artikler i internasjonale medisinske tidsskrifter. Det vil ikke være mulig å identifisere deg i resultatene fra prosjektet når disse publiseres. Data vil bli anonymisert senest ved prosjektslutt ……..

Frivillig deltakelse
Det er frivillig å delta i prosjektet. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke til å delta i prosjektet. Dette vil ikke få noen konsekvenser for deg eller din videre kontakt med helsetjenestene i Trondheim kommune. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Om du nå sier ja til å delta, kan du senere trekke tilbake ditt samtykke uten at det påvirker dine øvrige helsetilbud fra kommunen. Dersom du senere ønsker å trekke deg eller har spørsmål til prosjektet, kan du kontakte Eva Rinnan (mob: 95263290) eller Ann-Elin Johansen (jobb: 72576280/ mob: 92450113).

Rett til innsyn og sletting av opplysninger om deg og sletting av prøver
Hvis du sier ja til å delta i prosjektet, har du rett til å få innsyn i hvilke opplysninger som er registrert om deg. Du har videre rett til å få korrigert eventuelle feil i de

opplysningene vi har registrert. Dersom du trekker deg fra prosjektet, kan du kreve å få slettet innsamlede testresultater og opplysninger, med mindre opplysningene allerede er inngått i analyser eller brukt i vitenskapelige publikasjoner.

Som deltager har du rett til å få informasjon om resultatet av prosjektet.

Samtykke til deltakelse i prosjektet

Jeg er villig til å delta i prosjektet

(Signert av prosjektdeltaker, dato)

Stedfortredende samtykke når berettiget, enten i tillegg til personen selv eller istedenfor

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(Signert av nærstående, dato)

Jeg bekrefter å ha gitt informasjon om prosjektet

(Signert, rolle i prosjektet, dato)

Appendix V – Clinical Protocol Summary Translation in Greek

Σύνοψη Πρωτοκόλλου

Σύντομη Εισαγωγή στο Έργο SOCIABLE

Το SOCIABLE αποτελεί ένα συνεργατικό έργο που συγχρηματοδοτείται από την Ευρωπαϊκή Επιτροπή στο πλαίσιο του προγράμματος CIP-PSP (Competitive Innovation Programme – Pilot Support Programme), το οποίο και εστιάζει στην πιλοτική εφαρμογή νέων καινοτομικών τεχνολογιών. Το SOCIABLE εκπονείται από κοινοπραξία έντεκα (11) εταίρων από τέσσερις διαφορετικές χώρες (Ελλάδα, Ιταλία, Ισπανία, Νορβηγία), μεταξύ των οποίων το νοσοκομείο «ΥΓΕΙΑ», ο Δήμος Κηφισιάς, αλλά και η εταιρία πληροφορικής SingularLogic.

Αντικείμενο του έργου αποτελεί η ευρεία πιλοτική εφαρμογή νέων μεθόδων για την άσκηση των γνωστικών λειτουργιών των ηλικιωμένων, που βασίζονται στη χρήση υπολογιστών επιφάνειας ("surface computing"). Ειδικότερα, η πιλοτική αυτή εφαρμογή αφορά στην οργάνωση και εκπόνηση προγραμμάτων γνωστικής άσκησης για ηλικιωμένους στο πλαίσιο των οποίων οι συμμετέχοντες θα αξιοποιούν υπολογιστές επιφάνειας -κυρίως στη μορφή τραπεζιού (surface tables)- για την ολοκλήρωση κατάλληλων εξατομικευμένων ασκήσεων που έχουν σχεδιαστεί από ειδικούς νευροψυχολόγους. Σημειώνεται ότι οι τεχνολογίες υπολογιστικών επιφανειών, έχουν αποδειχθεί ιδιαίτερα εργονομικές ακόμα και για ηλικιωμένους, και αναμένεται να επιτρέψουν τη δημιουργία ενός ευχάριστου εργονομικού και αποτελεσματικού περιβάλλοντος για τη διενέργεια των σχετικών προγραμμάτων.

Η ευρεία πιλοτική εφαρμογή των νέων αυτών τεχνικών στοχεύει στο να εξετάσει το κατά πόσο αυτές μπορούν να συνεισφέρουν ουσιαστικά στη σταθεροποίηση ή ακόμα και τη βελτίωση των γνωστικών λειτουργιών των συμμετεχόντων. Για το λόγο αυτό, οι συνεδρίες γνωστικής άσκησης θα βασιστούν σε ένα καλά σχεδιασμένο πρωτόκολλο που συνοψίζουμε στη συνέχεια.

Το Κλινικό Πρωτόκολλο του Έργου

Τα προγράμματα γνωστικής άσκησης του Έργου SOCIABLE απευθύνονται σε τρεις ομάδες-στόχους:

- Ομάδα Α: Χρήστες 65 ετών και άνω χωρίς γνωστικές διαταραχές.
- Ομάδα Β: Ασθενείς 65 ετών και άνω που πάσχουν από Ήπια Νοητική Διαταραχή (Mild Cognitive Impairment) σύμφωνα με τα κριτήρια του Petersen (2001) και βαθμολογία MMSE μεταξύ 25-30.
- Ομάδα Γ: Ασθενείς 65 ετών και άνω που πάσχουν από ήπιας μορφής νόσο Alzheimer σύμφωνα με τα κριτήρια NINCDS-ARDRA και βαθμολογία MMSE μεταξύ 20-24.

Η διαδικασία που θα ακολουθηθεί περιλαμβάνει την αξιολόγηση της κατάστασης των χρηστών (γνωστικής, συναισθηματικής και λειτουργικής) σε τρεις χρονικές

στιγμές και συγκεκριμένα πριν την ένταξή τους στο πρόγραμμα, αμέσως μετά την ολοκλήρωση του προγράμματος (που περιλαμβάνει 24 ωριαίες συνεδρίες), αλλά και τρεις μήνες αργότερα για τη αξιολόγηση της μακρόχρονης επίδρασης του προγράμματος στη γνωστική, συναισθηματική και λειτουργική κατάσταση των συμμετεχόντων. Για κάθε ηλικιωμένο που συμμετέχει στο πρόγραμμα, προβλέπονται τα παρακάτω βήματα:

- Ενημέρωση σχετικά με το πρόγραμμα και συμπλήρωση της φόρμας συγκατάθεσης (informed consent form), για την εξασφάλιση της συγκατάθεσης του ηλικιωμένου και του φροντιστή του πριν την ένταξή του στο πρόγραμμα.
- Εκτίμηση της γνωστικής, συναισθηματικής και λειτουργικής του κατάστασης. Οι κλίμακες και οι δοκιμασίες που θα χρησιμοποιηθούν είναι κοινά για όλους τους πάροχους υπηρεσιών υγείας που συμμετέχουν στο έργο και θα χορηγούνται από κατάλληλα εκπαιδευμένους επαγγελματίες υγείας.
- Εκπαίδευση στη χρήση της πλατφόρμας. Η διαδικασία της εκπαίδευσης θα πραγματοποιείται από κάποιο επαγγελματία υγείας ο οποίος θα εποπτεύει στη συνέχεια την εξέλιξη του προγράμματος.
- Ένταξη σε πρόγραμμα γνωστικής άσκησης. Οι συνεδρίες που θα οργανωθούν θα είναι δύο ειδών: ομαδικές και ατομικές. Κάθε ασθενής θα ενταχθεί είτε σε πρόγραμμα ατομικών συνεδριών, είτε σε πρόγραμμα ομαδικών συνεδριών (ομάδες 3 ατόμων). Κάθε συνεδρία θα περιλαμβάνει την εκτέλεση γνωστικών ασκήσεων που θα έχουν επιλεγεί από τον ειδικό. Οι ασκήσεις θα έχουν τη μορφή παιχνιδιών και θα συνδυάζονται σε πολλές περιπτώσεις με στοιχεία της καθημερινότητας (π.χ. δραστηριότητες που εκτελούν συχνά οι ηλικιωμένοι στην καθημερινότητά τους). Ένα από τα παιχνίδια ονομάζεται Βιβλίο της Ζωής (Book-of-Life) και θα επιτρέπει στους ηλικιωμένους να δημιουργούν ένα βιβλίο με βάση τα βιώματα και τα ενδιαφέροντάς τους. Η διάρκεια του προγράμματος για κάθε συμμετέχοντα θα είναι τρεις μήνες, στο πλαίσιο των οποίων ο ηλικιωμένος θα συμμετέχει σε 24 συνεδρίες με ρυθμό 2 συνεδριών ανά εβδομάδα. Κάθε συνεδρία θα έχει διάρκεια μιας ώρας. Μετά την ολοκλήρωση κάθε συνεδρίας, ο επαγγελματίας υγείας θα καταγράφει την αξιολόγηση της συνεδρίας από τον ηλικιωμένο με στόχο τη συνεχή βελτίωση της διαδικασίας.
- Στο τέλος του προγράμματος (δηλ. μετά το πέρας των τριών μηνών), θα γίνει επανεκτίμηση των γνωστικών λειτουργιών, της συναισθηματικής και της λειτουργικής κατάστασης του χρήστη εφαρμόζοντας τις ίδιες κλίμακες και δοκιμασίες που χρησιμοποιήθηκαν για την αρχική εκτίμηση. Μια ακόμα εκτίμηση των γνωστικών λειτουργιών θα πραγματοποιηθεί τρεις μήνες αργότερα για την εκτίμηση των μακροχρόνιων αποτελεσμάτων της διαδικασίας του προγράμματος των γνωστικών ασκήσεων.

Αριθμός Χρηστών

Ο παρακάτω πίνακας απεικονίζει τον αριθμό των χρηστών από κάθε ομάδα που θα συμμετέχουν στο πρόγραμμα, για κάθε έναν από τους πάροχους χους υγείας που συμμετέχουν στο πρόγραμμα.

Πάροχος Υγείας & Χώρα	**Ομάδα Α**	**Ομάδα Β**	**Ομάδα Γ**	**Σύνολο**
Νοσοκομείο	10	26	24	60

Υγεία - Ιατρείο Μνήμης (Ελλάδα)				
Δήμος Κηφισιάς (Ελλάδα)	60	0	0	60
Commune Forli (Ιταλία)	14	30	0	44
Morgagni Pierantoni Hospital (Ιταλία)	0	50	0	50
Fondazione Santa Lucia (Ιταλία)	0	0	46	46
Trodheim Kommune (Νορβηγία)	0	0	48	48
PREVI S.L (Ισπανία)	40	0	0	40
Σύνολο	**124**	**106**	**118**	**348**

Από το σύνολο των παραπάνω χρηστών οι περισσότεροι θα συμμετέχουν στο πρόγραμμα προσερχόμενοι σε κέντρα υγείας/ημέρας, ενώ κάποιοι θα συμμετέχουν και από το σπίτι τους χρησιμοποιώντας κατάλληλους φορητούς υπολογιστές επιφάνειας.

Περισσότερες Λεπτομέρειες - Σχετικά Έγγραφα – Έγγραφα Αναφοράς

Πέρα από το ιατρικό πρωτόκολλο του έργου (που συνοδεύει αυτή την περίληψη), για την παραπάνω διαδικασία διατίθεται αναλυτική τεκμηρίωση (στην Αγγλική γλώσσα) σε σειρά εγγράφων του έργου SOCIABLE (διαθέσιμα στον ιστότοπο www.sociable-project.eu). Ειδικότερα:

- Ο τρόπος εκτέλεσης των συνεδριών και οι ρόλοι των διαφόρων εμπλεκομένων περιγράφονται με λεπτομέρεια στο έγγραφο-παραδοτέο Deliverable D1.4 με τίτλο «Use Cases Specification».
- Οι κλίμακες και οι δοκιμασίες που συνιστούν το SOCIABLE battery for cognitive, functional and affective assessment περιγράφονται με λεπτομέρεια στο έγγραφο-παραδοτέο SOCIABLE Deliverable D2.1 με τίτλο «Users Selection and Segmentation».
- Η οργάνωση και το χρονοδιάγραμμα της διαδικασίας πιλοτικής εφαρμογής, περιγράφεται στο έγγραφο-παραδοτέο Deliverable D6.1 με τίτλο «Pilot Operations Plan».

Τα παραπάνω έγγραφα μπορούν να θεωρηθούν ως συμπληρωματικά του πρωτοκόλλου και της παρούσας περίληψης.

Appendix VI – Clinical Protocol Summary Translation in Italian

Sociable: una Piattaforma tecnologica per la riabilitazione cognitiva

Introduzione

Uno dei principali trend socio-demografici che attualmente interessa molti Paesi occidentali è rappresentato dal progressivo invecchiamento della popolazione. Spesso, però, all'aumento della longevità non corrisponde un effettivo miglioramento della sua qualità, ma un incremento di patologie quali la demenza, la comorbilità e la disabilità, intesa come incapacità che un individuo incontra nello svolgimento delle attività basilari della vita quotidiana.

La demenza è una sindrome che può essere causata da varie malattie progressive che colpiscono la memoria, il pensiero, il comportamento e la capacità di svolgere le normali attività quotidiane della vita. La malattia di Alzheimer è la più comune causa di demenza. Tra le altre cause ci sono la demenza vascolare, la demenza a corpi di Lewy e la demenza frontotemporale.

Sebbene la demenza colpisca prevalentemente le persone anziane, vi è una crescente consapevolezza di casi che iniziano prima dei 65 anni. Dopo i 65 anni, la probabilità di essere colpiti da demenza raddoppia circa ogni 5 anni.

Nel Rapporto Mondiale Alzheimer del 2009, Alzheimer's Disease International ha calcolato che ci sono attualmente 35,6 milioni di persone affette da demenza nel mondo, che aumenteranno a 65.7 milioni nel 2030 ed a 115.4 milioni entro il 2050. Circa due terzi vivono in nazioni a basso e medio reddito pro capite, dove è previsto il maggior aumento numerico.Il costo stimato mondiale per il 2010 della demenza ammonta a US$604 Miliardi.

I costi sono attribuiti all'assistenza "informale" (assistenza non rimborsata sostenuta da famiglie ed altri), costi diretti di assistenza sociale (fornita da operatori della comunità, e in strutture residenziali) e costi diretti dell'assistenza sanitaria (costi per il trattamento della demenza e patologie simili in strutture sanitarie primarie o secondarie).

Da questi dati emerge che vi è urgente necessità di sviluppare servizi integrati di assistenza sanitaria e sociale, economicamente efficienti, che vadano incontro ai bisogni delle persone affette da demenza e di coloro che se ne prendono cura durante il decorso della malattia.

Nel tentativo di cercare le soluzioni più appropriate per soddisfare i bisogni di questa fascia di popolazione, vogliamo proporre un progetto il cui scopo è quello di valutare performance cognitiva e la interazione sociale in soggetti sottoposti ad un training cognitivo-sociale attraverso l'utilizzo di una piattaforma Microsoft sviluppata nell'ambito di un progetto Europeo ICT (Information Communication Technology), realizzato in cooperazione tra 11 centri in Europa dal titolo "Sociable" che vede la Fondazione Santa Lucia come Unità Operativa.

Il sistema in esame è costituito da una piattaforma Microsoft posizionata su un supporto tipo "tavolo" che permetterà a più utenti di interagire contemporaneamente con la stessa e di interagire fra di loro. Attraverso questa piattaforma saranno proposti agli utenti alcuni esercizi di riabilitazione cognitiva che verranno svolti grazie al sistema di touchpad previsto dalla piattaforma.

La popolazione oggetto dello studio presso la Fondazione S. Lucia è rappresentata da soggetti affetti da Malattia di Alzheimer in fase lieve, sottoposti ad una valutazione multidimensionale che comprende una valutazione neuropsicologica e funzionale mediante test standardizzati,.

Obiettivo dello studio

Obiettivo del progetto è quello di valutare le modificazioni della performance cognitiva in soggetti affetti da M. di Alzheimer. Attraverso questo sistema innovativo, inoltre, si vuole valutare la possibilità di migliorare l'interazione sociale in questa fascia di popolazione.

Materiali e Metodi

La Fondazione Santa Lucia selezionerà un totale di 46 soggetti con Malattia di Alzheimer lieve secondo i criteri del DSM IV (MMSE compreso tra 20 e 24).

I soggetti in esame saranno reclutati in ospedale tra i pazienti ricoverati presso il Day Hospital C e i pazienti seguiti presso l'ambulatorio UVA.

I criteri di inclusione prevedono:

- diagnosi di probabile AD secondo la NINCDS-ADRDA
- età maggiore 65 anni,
- scolarità minima di 6 anni;
- la presenza di un caregiver formale;
- punteggio al MMSE compreso tra 20 e 24;
- punteggio pari ad 1 alla CDR (Clinical Dementia Rating) equivalente ad una demenza di tipo lieve;
- assenza di deficit di tipo sensoriale;

I criteri di esclusione comprendono:

- presenza di malattie neurologiche (stroke,TIA) e psichiatriche (depressione non controllata da terapia farmacologica) di severa entità;
- trauma cranico;
- abuso di sostanze;
-compromissione di grado severo a livello motorio, sensoriale o a livello della comunicazione.

Valutazione dei pazienti

I pazienti verranno selezionati attraverso una valutazione multidimensionale che terrà conto del profilo neuropsicologico ma anche delle capacità funzionali e dell'aspetto sociale attraverso l'utilizzo di scale standardizzate (Tab.1)

In particolare per quanto riguarda le funzioni cognitive verranno indagate le seguenti aree: orientamento spazio-temporale, capacità di ragionamento, memoria verbale (a lungo termine), prassia costruttiva, memoria visuo-spaziale (a breve termine), funzioni esecutive, attenzione, linguaggio.

Il tono dell'umore verrà valutato utilizzando la Geriatric Depression Scale (GDS) nella versione breve.

Lo stato funzionale sarà individuato attraverso le seguenti scale:

- ADL
- IADL

Infine, il grado di severità della demenza sarà classificato secondo la CDR.

Tabella 1. Valutazione Multidimensionale

COGNITION	
Orientation	Mini Mental State Examination
Abstract reasoning	Clock Drawing Test
Verbal memory (long term)	Rey's Auditory Verbal Learning Test
Constructional praxis	Rey's Complex Figure (copy)
Visuo-spatial memory	Rey's Complex Figure (delayed recall)
Verbal memory (short term)	Digit Span
Executive functions	Phonological Verbal Fluency
Attention	Trail Making Test (parts A and B)
Language	Naming Test (specific for each country)
AFFECTION	Geriatric Depression Scale (short form)
FUNCTIONAL ABILITIES	ADL, IADL
SEVERITY OF DEMENTIA	Clinical Dementia Rating

La valutazione del livello di interazione sociale si baserà sull'uso delle seguenti scale:

- LSNS – 18

Studio sperimentale

L'efficacia riabilitativa della piattaforma Sociable verrà valutata attraverso uno studio controllato randomizzato.

I soggetti saranno randomizzati in due gruppi: il primo gruppo inizierà immediatamente il trattamento riabilitativo con la piattaforma, il secondo gruppo inizierà tre mesi più tardi. In questo modo il secondo gruppo costituirà il gruppo di controllo del primo gruppo. E' stato deciso di procedere in questo modo per garantire a tutti gli utenti il trattamento riabilitativo con la piattaforma.

La randomizzazione sarà stratificata per centro e secondo le caratteristiche dei soggetti (soggetti normali, soggetti MCI e soggetti AD) in blocchi di 4 pazienti

In particolare, la Fondazione Santa Lucia selezionerà un totale di 46 pazienti con Malattia di Alzheimer lieve secondo i criteri del DSM IV (MMSE compreso tra 20 e 24).

Le sessioni riabilitative con la piattaforma Sociable si svolgeranno in gruppi di 2 o 3 soggetti oppure individualmente presso la Fondazione Santa Lucia, sotto la supervisione del personale clinico addestrato.

I soggetti si recheranno presso la Fondazione 2 volte la settimana per tre mesi consecutivi e parteciperanno ad una sessione della durata di circa 60 minuti divisa in 30 minuti di riabilitazione cognitiva e 30 minuti di attività di socializzazione .

Il primary outcome dello studio è quello di documentare un'eventuale riduzione della progressione nel tempo dei deficit cognitivi rilevati nella valutazione neuropsicologica iniziale.
Il secondary outcome è quello di valutare il livello di interazione sociale dei partecipanti prima e dopo le sedute riabilitative.

I pazienti saranno valutati all'inizio e alla fine del trattamento riabilitativo e a distanza di 3 e 6 mesi dal trattamento.

Analisi statistica dei dati

L'analisi statistica avrà lo scopo di mettere a confronto il gruppo trattato con la piattaforma Sociable ed il gruppo di controllo e di evidenziare la presenza di un differente decremento delle funzioni cognitive.
Saranno confrontati i risultati ottenuti nei i due gruppi di pazienti, cioè tra il gruppo in studio e il gruppo di controllo.
Verranno messi a confronto anche i dati riguardanti le modalità di socializzazione dei due gruppi e le eventuali differenze.
Infine verrà analizzata l'eventualità di una correlazione tra grado di decadimento cognitivo e livello di interazione sociale.

Riassumendo:

- durata prevista del protocollo: 3 mesi

- numero totale delle sessioni: 24

- frequenza richiesta: 2 sessioni a settimana

- durata delle sessioni: 60 minuti ciascuna, 30 minuti per la riabilitazione cognitiva e 30 minuti per attività di socializzazione

- le sessioni seguiranno le stesse modalità sia nella modalità individuale che in gruppo

- il follow up è previsto dopo 3 mesi e dopo 6 mesi

La piattaforma Sociable

Microsoft Surface e' un sistema costituito da un touchscreen e da un PC, con il quale l'utente interagisce toccando la superficie. Lo schermo è composto da un sistema a retroproiezione inserito in un contenitore (un tavolino), mentre gli input tattili vengono riconosciuti tramite una videocamera a infrarossi . Lo scopo di questo prodotto e' di creare una NUI: Natural User Interface con cui chiunque può interagire in modo naturale usando le proprie dita.

Dentro Microsoft Surface gira un processore da 3GHz con 2GB di ram, controllato da videocamere e sistemi infrarossi per far usare il prodotto da più persone contemporaneamente. Le immagini vengono visualizzate tramite un proiettore inserito sotto la superficie che proietta immagini a 1024x768 pixel.

Figure 2: Microsoft Surface

In alcune sessioni individuali sarà utilizzato in alternativa alla piattaforma un tablet pc con sistema touchpad.

Figure 3: Tablet pc

La riabilitazione cognitiva consisterà nello svolgimento di esercizi di riabilitazione cognitiva basati sulle terapie tradizionali che sono stati specificamente adattati per l'utilizzo attraverso il supporto tecnologico.

Grazie a questa soluzione sarà possibile per l'utente:

- interagire direttamente con lo schermo spostando gli oggetti con il semplice movimento delle dita sullo schermo
- utilizzare informazioni audiovisive
- svolgere esercizi in gruppo
- utilizzare sistemi di mixed reality (ad es. riconoscimento del sistema di oggetti di uso quotidiano (bicchieri, chiavi, occhiali). Uno degli esercizi pone la domanda: "posiziona gli oggetti sui corrispondenti disegni che vedi sullo schermo".

Il programma di riabilitazione sarà personalizzato e si baserà sulle funzioni cognitive che sono risultate deficitarie nella valutazione neuropsicologica iniziale dell'utente.

Per ciascuna funzione cognitiva sono stati sviluppati una batteria di esercizi specifici che la piattaforma proporrà all'utente in base al suo profilo cognitivo. Nel caso in cui i soggetti lavorino in gruppo i componenti del gruppo saranno selezionati in base al profilo cognitivo.

Cognitive Skill	**Total Number**
Memory	8
Executive Functions	5
Executive functions/Logical Reasoning	1

Attention	4
Language	3
Logical Reasoning	2
Reasoning	1
Visuospatial abilities	1
Orientation	2
Total	**27**

Table 52: Numero di esercizi realizzati per area cognitiva

Per quanto riguarda le attività di socializzazione queste hanno lo scopo di migliorare le capacità di comunicazione del paziente e ridurre l'isolamento sociale attraverso la condivisione di ricordi e interessi comuni con gli altri utenti.

Per fare questo verrà utilizzato il "Book of Life" una sorta di diario digitale dove il paziente potrà annotare i suoi pensieri, i ricordi, le emozioni ed inserire materiale come foto , video , suoni ed altro materiale multimediale.