



# **SOCIABLE DELIVERABLE D2.1** "User Selection and Segmentation"



Project Acronym	SOCIABLE	
Grant Agreement No.	238891	
Project Title	Motivating platform for elderly networking,	
	Mental reinforcement and social interaction	
Deliverable Reference Number	SOCIABLE_WP2_D2.1	
Deliverable Title	"User Selection and Segmentation"	
Revision Number	V1.1	
Deliverable Editor(s)	CEDAF, HYGEIA	
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Project co-funded by the European Commission within the ICT Policy Support Programme		
Dissemination Level		
С	Confidential, only for members of the consortium and the	С
	Commission Services	

#### Statement of originality:

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### **Revision History**

Revi sion	Author(s)	Organiza tion(s)	Date	Changes
0.1	Paolo Mattareli	CEDAF	24/11/20 09	Provision of Structure and Table of Contents
0.2	Stelios Pantelopoulos, Paolo Mattareli	SLG	23/12/20 09	Revisions to Table of Contents
0.3	Olga Lymperopoulou	HYGEIA	30/12/20 09	Description of Elderly User Groups in SOCIABLE
0.4	Chiara Zaccarelli, Roberta Annicchiarico	AUSL, FSL	14/01/20 010	Contribution from AUSL and FSL on user selection processes
0.5	Paolo Mattareli	CEDAF	27/01/20 10	Milestone Draft Version for Discussion in the SOCIABLE Consortium Meeting at Valencia
0.6	Olga Lymperopoulou	HYGEIA	12/02/20 10	Revision of the document and documentation of the neuropsychological battery based on agreements during the SOCIABLE Consortium Meeting at Valencia
0.7	Reyes Moliner	PREVI	15/02/20 10	Rationale behind social activation services
0.8	Roberta Annicchiarico, Alessia Federici	FSL	2/03/201 0	Revision of the document, incorporation of final/agreed neuropsychological tests and user's assessment
0.9	Stelios Pantelopoulos	SLG	03/03/20 10	Fine Tuning of the document and incorporation of review comments from HYGEIA
1.0	Stelios Pantelopoulos	SLG	03/03/20 10	Executive Summary, Abstract, Conclusions
1.1	Stelios Pantelopoulos	SLG	09/03/20 10	Addressing Internal Review Comments from AUSL and TRONDHEIM



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#### Abstract

The present deliverable focuses on two important processes of the SOCIABLE pilot programme, namely user selection/segmentation and cognitive/functional/affective assessment. In terms of user selection, the deliverable presents and justifies the project's decision to deal with three distinct elderly groups, including intact elderly, older adults with Mild Cognitive Impairment, as well as patients suffering from mild Alzheimer's disease. For each of the above groups, the deliverable illustrated the rationale behind its selection/specification, along with a set of inclusion and exclusion criteria that will respectively drive the enlistment or the exclusion of elderly users from the SOCIABLE programme. As far as cognitive, functional and affective assessment is concerned, the deliverable presents the agreed battery of neuropsychological tests, which will be administered to all the users of the SOCIABLE The presentation of the battery is accompanied references/citations to the scientific references that define the various tests in more detail. It should be noted that the presented battery is the result of consultation among the medical experts of the consortium. The consultation made provision for fully covering the needs of the project, while also taking into account criteria associated with the availability of the tests at the consortium countries.

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#### **Executive Summary**

The main objective of the SOCIABLE project is to introduce and pilot a novel ICT based approach to the cognitive training and social activation of elderly individuals. The approach will be pilot in seven different sites, across four European countries. Each site will undertake the process of enlisting users for the pilots, while at the same time assessing their cognitive, functional and affective status. The assessment will take place during the elderly registration/enlistment in the SOCIABLE pilot programme, as well as at later time instants as part of the SOCIABLE medical-related evaluation. In order to support the above-mentioned processes, the project has established scientifically sound criteria and methodologies for selecting users and assessing their cognitive, functional and affective status. Criteria and methodologies have been defined by the medical experts of the consortium, following a consensus process that took into account the project needs, as well as the peculiarities (e.g., availability of neuropsychological tests) of the various participating counties. The adoption of a common agreed uniform approach to user selection and assessment is expected to boost the SOCIABLE pilots, given that all partners will have to apply a common process that will serve as a reference point for all the pilots.

The present deliverable focuses on two important processes of the SOCIABLE pilot programme, namely user selection/segmentation and cognitive/functional/affective assessment. In terms of user selection, the deliverable presents and justifies the project's decision to deal with three distinct elderly groups, including intact elderly, older adults with Mild Cognitive Impairment (MCI), as well as patients suffering from mild Alzheimer's Disease (AD). For each of the above groups, the deliverable illustrated the rationale behind its selection/specification, along with a set of inclusion and exclusion criteria that will respectively drive the enlistment or the exclusion of elderly users from the SOCIABLE programme. As far as cognitive, functional and affective assessment is concerned, the deliverable presents the agreed battery of neuropsychological tests, which will be administered to all the users of the SOCIABLE project. The presentation of the battery is accompanied by proper references/citations to the scientific references that define the various tests in more detail. It should be noted that the presented battery is the result of consultation among the medical experts of the consortium. The consultation made provision for fully covering the needs of the project, while also taking into account criteria associated with the availability of the tests at the consortium countries.

Overall, this deliverable paves the ground for the application of a common scientifically sound user selection and assessment methodology during the SOCIABLE pilots. This application will reinforce the medical validity of the SOCIABLE pilots, while also facilitating the validation of the process. The medical validity of the process will serve as an asset for the commercial exploitation of the SOCIABLE platform and services, given that they will lead to medically proven benefits for the elderly users. These benefits will add up to the already acknowledged benefits in

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background projects (such as ElderGames (<a href="http://www.eldergames.org">http://www.eldergames.org</a>) and Happy Neuron (<a href="http://www.happy-neuron.com">http://www.happy-neuron.com</a>).

#### 1. Introduction

The goal of the SOCIABLE project is to successfully pilot (under realistic conditions) a unique approach to cognitive training and social activation of older adults. The main characteristic of this approach is that it combines the ever important human care factor with the benefits of a novel surface computing ICT platform. In the scope of the SOCIABLE pilots, health professionals are expected to leverage computers (such as TabletPCs) in order to manage the health records of the elderly, while older adults will be able to engage in cognitive training games and social interaction activities in the scope of a motivating and ergonomic surface computing environment. Overall, both health professional and the elderly will be able to pilot a SOCIABLE programme, comprising several cognitive training and social activation activities, as well as the systematic assessment of the elderly cognitive, affective and functional assessment. The steps comprising the typical workflow of a SOCIABLE programme, include (Figure 1):

- The cognitive, affective and functional assessment of the elderly prior to his/her inclusion in the programme. This assessment is also used for the categorization of the elderly in one of the three SOCIABLE target groups, comprising normal/healthy elderly, elderly with MCI, as well as elderly with mild AD.
- 2. A number of play sessions comprising the cognitive training and/or social activation programme. The typical duration of a programme is 3 months. In the scope of this programme the elderly attend to two sessions per week. The typical duration of a session is 45 min.
- 3. The assessment of the elderly cognitive, functional and affective status and social interaction characteristics following the successful conclusion of the programme.
- 4. A follow-up assessment of the elderly, outside the scope of the programme, in order to evaluate/assess the longer term impact of the SOCIABLE intervention.

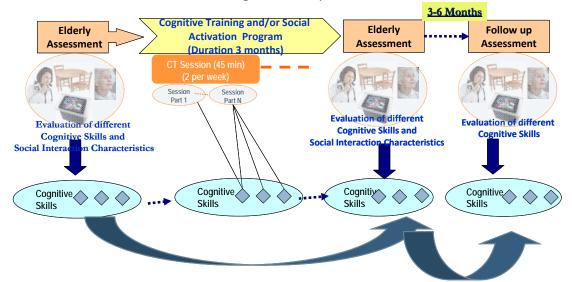


Figure 1: Typical Workflow in the scope of a SOCIABLE Intervention

The present deliverable emphasizes on the first step of the above workflow, dealing with the cognitive, affective and functional assessment of the elderly, their categorization to one of the groups, and their ultimate inclusion in the SOCIABLE programme. The deliverable presents the three SOCIABLE target groups and the rationale for their selection towards the SOCIABLE pilots. The selection of each one of the groups takes into account scientific evidence about the benefits of cognitive training and social interaction activities on the specific group.

In addition to presenting the groups, the deliverable elaborates on the cognitive, affective and functional assessment processes for the elderly, including the specific neuropsychological tests that will be applied by all SOCIABLE sites during the pilots. The neuropsychological assessment includes a set of tests evaluating the functional efficiency of the patient in different cognitive domains according to theoretical models of cognitive functioning. Tests to be used for clinical purpose must be standardized and provide of normative data, representing the contribution of demographic variables (i.e. sex, age, schooling), for the discrimination between normal and pathological performances. This kind of assessment is particularly important in the differential diagnosis between normal and pathological cognitive deterioration and for a quantitative and qualitative characterization of the cognitive profile. Note that the inclusion and management of the scores of neuropsychological tests (selected as part of the shared battery to be administered to the subjects involved in the experimentation), within the SOCIABLE platform is of extreme importance for the pilots. Indeed, this will provide invaluable aid in collecting and recording data and in making faster and easier the performance monitoring and the comparison of results relating to the impact of the SOCIABLE approach. It would also remarkably simplify data collection and analysis, in order to draw up scientifically sound conclusions.

The above mentioned neuropsychological tests are directly related to the elderly users' selection process. The selection of the individuals for the pilot phase of the project will be performed by administering a comprehensive neuropsychological battery, already agreed among the medical experts, in order to classify of the elderly in the three different target groups. Following the elderly classification, a number of inclusion and exclusion criteria will be used for determining whether the elderly is eligible to participate in the SOCIABLE programme or not.

The deliverable is structured as follows: Section 2 following this introductory section provides an overview of the three groups of elderly considered in SOCIABLE, along with the rationale behind their selection. Accordingly, Section 3 provides an overview of the user assessment and selection process in SOCIABLE. Section 4 elaborates on the Cognitive, Affective and Functional Assessment Process in SOCIABLE, while section 5 documents the user selection process based on appropriate inclusion and exclusion criteria. Finally, section 6 concludes the deliverable.

#### 2. SOCIABLE Target Groups (HYGEIA)

#### 2.10verview

The main goal of the SOCIABLE project is to integrate and pilot in several European countries (Greece, Italy, Norway, Spain) an integrated ICT service empowering the elderly to improve their mental ability, while at the same time boosting their social interaction. The service will be offered to end-users (aged individuals) at specialized care centres, but also within their home environment.

SOCIABLE is motivated by recent research results manifesting that mental activity, as well as social interaction, are key prerequisites for alleviating dementia and cognitive problems. In offering its services, SOCIABLE will combine the - ever important - human care and support factor with innovative ICT enabled services and independent living technologies. Specifically, SOCIABLE will integrate human support and care services offered by care centres and specialized/expert operators with state-of-the-art ICT infrastructure and independent living technologies.

Old age is an age of losses (physical changes, social displacement, loss and loneliness of people, etc.). All these losses can produce depressive symptoms, in some cases may arise diagnoses of depressive disorders. Older people often mistakenly believe that mental health problems such as depression, are "natural" on age, according to the survey by the National Mental Health Association, about 58% of people over 65 years believed it was "normal" to be depressed as part of aging. However, depression is not a normal part of aging, although its incidence increases when other medical conditions are present. Unfortunately, symptoms of depression are often under-recognized and under-treated, especially when they coincide with other diseases of old age.

The importance of social ties in the lives of older people is becoming increasingly recognized as strong associations have consistently been found between social support networks with physical and mental health outcomes.

Social support is important in daily activities for the elderly living in community settings, and several studies have provided evidence of an association between social support and cognitive function. A socially engaging lifestyle is correlated with higher cognition scores in both community and nursing home settings. Because social activities provide the challenge of effective communication and participation in complex interpersonal exchanges, social support has been thought to inhibit cognitive decline in the elderly.

A longitudinal study from Bassuk & colleagues (1999) found that elderly persons who had no social ties were at increased risk for cognitive decline, compared with those who had five or six social ties. Using frequency of contact with friends and colleagues as an indicator for social support, Boult & colleagues (1994) found that social support was associated with a reduced risk of developing disability up to 4 years later. In a prospective cohort study that followed 1,203 non-demented aged 75 and over for 3

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years, Fratiglioni and colleagues (2000) found that a social network reduced the incidence of dementia.

Except for Fratiglioni et al.'s study (2000), research regarding the cognitive status of the elderly and social support generally has been limited by sample size and by the absence of adjustment for potential confounders, such as education or health status. Because respondents were usually self-referred, selection bias in data collection has also been present.

The concept of social support has been difficult to measure. Several studies have used proxy indicators such as occupational status to make inferences about the effect of social activities on cognition. Some have treated prior favorable socioeconomic status as synonymous with social activity in old age, while others have used composite activity scales as proxies for social engagement.

Social contacts and perceived social support from family members, friends and acquaintances are important for fulfilment of different social needs.

Therefore people with active social lives later in life are less likely to develop dementia, researchers suggest several possible explanations: Social networks may help to prevent brain pathology by facilitating access to health care and encouraging healthy behaviours. Another possibility is that social engagement may reduce stress and depression.

According to the SOCIABLE contract, the project's target group comprises individuals as follows: "The primary target group for the SOCIABLE services will be comprised of individuals with mild cognitive impairments in the form of subtle but measurable memory disorders. These people experience memory problems greater than normally expected, yet dementia is still mild i.e. it has not affected their severely their ability to comprehend and act on messages, understand or use words and identify objects".

From the collection and analysis of the User Requirements, the following target groups have been selected to participate in the SOCIABLE project:

- Group A: normal (healthy) elderly aged 65+ (patients' caregivers and/or people attending Municipal Recreation Centres).
- Group B: elderly aged 65+ with MCI according to the Petersen, 2001 criteria (MMSE score 25-30).
- Group C: elderly aged 65+ with mild AD according to the NINCDS-ARDRA criteria (MMSE score 20-24).

Different sites will focus on different user groups. This is unavoidable, given that different user types are found in each of the project's sites (e.g., municipal recreation centres are likely to have more healthy elderly, whereas memory clinics work mainly MCI and mild AD patients). However, this diversity provides a golden opportunity for evaluating the effect of SOCIABLE services over a wide range of user types/groups. Below follows a brief description of the characteristics of the target user groups selected to participate in the SOCIABLE project, together with the rational supporting their inclusion.

#### 2.2Group A: Normal (healthy) elderly aged 65+

Aging, the process of growing old, is defined as the gradual biological impairment of normal function, probably as a result of changes made to cells and structural components. These changes consequently have a direct impact on the functional ability of organs, biological systems and ultimately, the organism as a whole. The aging process is of course a biological reality which has its own dynamic, largely beyond human control. However, it is also subject to the constructions by which each society makes sense of old age. In the developed world, chronological time plays a paramount role. The age of 65, roughly equivalent to retirement ages in most developed countries is said to be the beginning of old age (Gorman, 2000).

Most elderly face late life with changes in cognitive function that affect quality of life and increase mortality. Cognitive vitality in old age is impaired by what is called "normal cognitive aging" (Fillit et al, 2002). Normal aging is defined as "typical" aging rather than "ideal" aging. Elderly people tend to decline in the following areas: attention, language (naming, fluency), some visuospatial skills and, most notably, memory. Within memory, the acquisition of new information (learning) seems to be most affected by the normal aging process (Petersen, 1995). Although the cognitive impairments associated with normal aging have been defined and may impair quality of life, cognitive decline with aging is not inevitable (Fillit et al, 2002). Epidemiological and preclinical studies suggest that mental activity levels may alter dementia risk.

Cognitive training is defined as an intervention providing structured practice on tasks relevant to aspects of cognitive functioning, such as memory, attention, language or executive function (Clare, 2003). It may be offered in various forms, including individual or group sessions, and tasks may be presented in various modalities, including paper-and-pencil or computerized versions. Systematic review of cognitive training in healthy older individuals confirmed effectiveness and durability of cognitive training interventions in improving targeted cognitive abilities and found persistent protective effects on longitudinal neuropsychological performance (Ball et al, 2002). Computerized games in particular may offer elderly users new ways of social interaction. This aspect underlying computerized cognitive training could be a central motivator to engage elderly people in daily cognitive stimulation routines, as well as an important key to get older adults without experience closer to digital technologies (IJsselsteijn, Nap & de Kort, 2007).

Brain aging is characterized by a loss of brain substance and a reduction in synapses and neurotransmitters. The neuroscientific model supporting the potential effectiveness of cognitive training is that activities and chemical agents promote neuronal repair and are protective and might also promote neuronal growth and plasticity. Cognitive training could also strengthen synapses that would otherwise be lost to lack of stimulation (Settersen, 1999).

However, it should be useful to highlight the fact that more RCTs are needed before being allowed to claim without doubt that structured cognitive intervention

programs delay or slow progression to Alzheimer's disease in healthy elderly (Papp, Walsh & Snyder, 2009).

#### 2.3 Group B: Elderly aged 65+ with Mild Cognitive Impairment (MCI)

MCI is an evolving condition referring to a transitional state between the cognition of normal aging and mild dementia. It is used in clinical research to describe a group of elderly subjects who have cognitive impairments, often involving memory, not of sufficient severity to warrant the diagnosis of dementia. MCI patients usually complain of memory difficulties. Typically, the complaints include trouble remembering the names of people they recently met, following the conversation flow and increased tendency to misplace personal belongings. In many cases, the individuals with MCI are aware of these difficulties and compensate with increased reliance on notes and other external memory aids.

Implicit in the MCI concept is the idea that these subjects are at increased risk of developing dementia. Depending on the cohort source and definition, between 19 and 50% of MCI patients progress to dementia (usually AD) over 3 years (Chertkow, 2002).

Presumably, individuals who are evolving to dementia will go through a transitional phase of mild cognitive impairment. Although the prototypical scenario for the onset of MCI likely involves the initial development of a memory deficit followed by other cognitive difficulties, other profiles are also possible (Petersen, 1995). The concept of MCI may be quite heterogeneous. Most subjects with MCI will progress to AD, while others may progress in other forms of dementia. Therefore, it is possible to recognize different MCI subtypes. For the purposes of the SOCIABLE project, we will focus on the *amnestic MCI* subgroup of patients to ensure maximum homogeneity among end-users. The amnestic MCI subtype is characterized by memory disturbances (recent episodic memory impairment, in particular), either solely or in conjunction with other subtle cognitive deficits.

The MCI stage may be the optimum point at which to intervene with preventive therapies (Chertkow, 2002), such as cognitive training. It has been suggested that if we could delay the onset of Alzheimer's disease by five years, we could actually reduce the number of cases by 50%. Additionally, patients with MCI are considered to be ideal participants for cognitive training interventions since they have more cognitive reserves, increased awareness of their deficits (which subsequently leads to increased motivation to stay mentally active) and less neuropsychiatric disturbances than demented patients.

Most of the research on the effect of cognitive training in MCI has reported improved performance following traditional or computerized training on the cognitive domains targeted by the interventions (interestingly, the effect sizes were moderate to large), whereas a minority reported no significant effect. (Belleville, 2008). Yet, the evidence base is currently very small and thus, it is hard to draw firm conclusions. Before this therapy can be recommended for widespread use, more research is required in the form of properly designed randomized controlled trials with larger samples.

#### 2.4Group C: Elderly aged 65+ with mild AD

AD is a progressive, fatal neurodegenerative condition characterized by deterioration in cognition and memory, progressive impairment in the ability to carry our activities of daily living, and a number of neuropsychiatric and behavioral symptoms. AD is the most common form of dementia among elderly persons and accounts for approximately two thirds of cases of dementia and between 60 and 70% of cases with progressive cognitive impairment in older adults. The prevalence of AD is expected to increase as the population ages (Jalbert, Daiello & Lapane, 2008).

AD typically begins insidiously and progresses gradually. Presentations of AD can vary, and a range of neuropsychological profiles can be observed. However, memory is usually the first function to be affected, although the impairments are evident only in certain memory systems, particularly episodic memory. Attention, executive function and word finding may also be affected. As the disorder progresses, psychomotor functions become impaired and deficits in memory, attention, language and executive function become more extensive. A decline in global cognitive functioning becomes evident, together with obvious decline in everyday functioning. Behavioral changes, including agitation, aggression and apathy, are also frequently reported in AD.

In early stages, when impairments are predominantly in the cognitive domain, cognitive training is particularly useful, especially with regard to memory functioning. Up to now, it has been offered in various formats, including individual or group sessions, conventional paper-and-pencil exercises or computerized mentally challenging games etc (Clare, 2008). Cognitive training is proved to offer benefits for people with early-stage AD in terms of maintaining cognitive function and improving functional abilities. Interestingly, greater effect sizes are observed for studies using individual treatment modalities over group modalities. It would be useful to highlight the fact that in progressive diseases such as AD, it may not be possible to maintain gained benefits in cognitive or functional abilities, but the follow-up findings in the literature suggest that the rate of decline may be slower in patients receiving cognitive training (Sitzer, Twamley & Jeste, 2006).

#### 3. Overview of User Assessment and Selection in SOCIABLE

A grand total of 350 individuals (healthy elderly, MCI patients and mild AD patients) will be selected to participate in the project. The user selection process will be performed on-site by the medical experts comprising the clinical staff (e.g. neurologists, geriatricians, psychologists, social workers, nurses). It is important to highlight the fact that the process described below will be followed by all the pilot sites. Municipalities will collaborate with a specialized staff (e.g. neuropsychologists) in order to perform the neuropsychological assessment.

The initial visit will require approximately 1-1 ½ hour to complete. At this visit, thorough history-taking will be performed -including medical, psychiatric and social background information- along with a routine physical examination. The potential user will then participate in a comprehensive neuropsychological assessment performed by a trained medical expert to define the level of his/her cognitive functioning. The tests used will be standardized and provide normative data representing the contribution of demographic variables for the discrimination between normal and pathological performances. The neuropsychological battery will be comprised by tests assessing the following cognitive domains: attention, perception, memory (verbal and visual material), orientation, executive functions, constructional praxis and language.

Next, the user's affective status will be assessed, followed by assessment of his/her functional abilities. Functional assessment will be performed in the form of semi-structured interview with the user's primary caregiver to detect difficulties in carrying out instrumental activities of daily living (IADL). IADLs are complex activities that enable a person to live independently (e.g. preparing meals, performing housework, taking drugs, managing finances), thought to be mildly impaired in the case of MCI and -especially- mild AD.

Subsequently, appropriate blood tests and brain imaging will be requested by the clinician in order to establish the diagnosis of MCI or mild AD (this last step will be omitted in the case of users who prove to be cognitively intact on the basis on the neuropsychological assessment results) and the next appointment will be scheduled. At the second visit, the medical experts will have an overall look of the available information (medical and social history, results of the neuropsychological, affective and functional assessment, blood tests, brain imaging)<sup>1</sup>, on the basis of which they will decide if the user fulfils the inclusion criteria and determine which target group she/he belongs to.

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<sup>&</sup>lt;sup>1</sup> Given that SOCIABLE is not focused on medicine testing, but on experimentation about the efficacy of ICT based cognitive training and social activation, blood tests and brain imaging are not necessary. In practice, these data/tests represent additional medical information that the clinician must take into account in order to establish the correct diagnosis. However, they may not be part of the study protocol.

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In case the user fulfils the above criteria, details about the SOCIABLE project will be described to the user and his/her caregiver (rational behind the project, procedures, anticipated results and benefits, confidentiality, rights and obligations). The user and the caregiver will be given ample time to completely read the Inform Consent Form and ask project related questions. Before signing the forms, the clinician will establish that they fully understand the study and agree with the study related procedures. A copy of the singed Informed Consent Form will be given to the user and his/her caregiver and another will be retained on-site.

# 4. Cognitive, Affective and Functional Assessment Process in SOCIABLE

A battery of neuropsychological tests will be administered to all the users of the SOCIABLE.

The battery will enclose several standardized neuro-psychological tests assessing the following cognitive domains:

- o Orientation
- Abstract reasoning
- Verbal and visuo-spatial memory
- Constructional praxis
- Executive functions
- o Attention
- o Language
- Affective status
- Functional assessment

The patients' functional and affective status will also be assessed by rating scales with the users. The table summarizes the standardized tests for SOCIABLE users, as these tests have been agreed among the medical experts of the project.

these tests have been agreed anno	ing the medical experts of the project.
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

Table 1: Standardized Tests to be used in SOCIABLE

#### **4.1 Cognitive Assessment**

The SOCIABLE project pays special attention to the neuro-psychological evaluation of the users, due to the special characteristics of the population target of the project itself. The neuro-psychological assessment consists of a set of tests evaluating the functional efficiency of a patient in different cognitive domains according to theoretical models of cognitive functioning. Tests used for clinical purposes are standardized and they provide of normative data, representing the contribution of demographic variables (i.e. sex, age, schooling), for the discrimination between

normal and pathological performances. This kind of assessment is particularly important in the differential diagnosis between normal and pathological cognitive deterioration and for a quantitative and qualitative characterization of the cognitive profile. Moreover, the neuropsychological evaluation is applied in forensic and, particularly relevant for this project, in rehabilitative settings. In this latter case, the evaluation of the cognitive profile of a patient after damage in the central nervous system is fundamental for the planning of a rehabilitative project. For this purpose, very important is to know which cognitive functions are impaired, their level of impairment and if the ability to generalize strategies is preserved.

A team of neurologists and neuro-psychologists, expert in such procedures, have joined the existing staff of the project, providing the know-how needed to select the proper tests in order to provide the necessary information about cognition and affectivity and to directly examine the users participating in the final test of the platform.

#### 4.1.1 The Instruments

#### 4.1.1.1 Mini Mental State Examination (MMSE)

The mini-mental state examination (MMSE) is a brief 30-point questionnaire test that is used to assess cognition. It is commonly used in medicine to screen for dementia. In the time span of about 10 minutes, it samples various functions, including arithmetic, memory and orientation. It was introduced by Folstein et al in 1975<sup>2</sup>, and is widely used with small modifications<sup>3</sup>. Any score over 24 (out of 30) is effectively normal. The normal value is also corrected for degree of schooling and age. Low to very low scores correlate closely with the presence of dementia, although other mental disorders can also lead to abnormal findings on MMSE testing. The presence of purely physical problems can also interfere with interpretation if not properly noted; for example, a patient may be physically unable to hear or read instructions properly, or may have a motor deficit that affects writing and drawing skills.

<sup>&</sup>lt;sup>2</sup> Folstein MF, Folstein, SE and McHugh PR (1975) Mini-Mental State: A practical method for grading the state of patients for the clinician, Journal of Psychiatric Research, 12: 189-198

<sup>&</sup>lt;sup>3</sup> Anthony JC, LeResche L, Niaz U, VonKorff MR and Folstein MF (1982) Limits of the mini-mental state as a screening test for dementia and delirium among hospital patients. Psychological Medicine, 12: 397-408.

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#### 4.1.1.2 Clock Drawing Test (CDT)

This is a simple test that can be used as a part of a neurological test or as a screening tool for Alzheimer's and other types of dementia. There are a number of scoring systems for this test<sup>4</sup>. For this test, all SOCIABLE partners will use the same scoring system, in particular the 10-point scoring system introduced by Sunderland et al (1989).

#### 4.1.1.3 Rey Auditory Verbal Learning Test (15-words)

This is a learning and recall test of unstructured material and it is particularly important to evaluate the presence of verbal amnesia<sup>5</sup>. The test evaluates both short and long term components of verbal memory. The immediate recall assesses both the episodic short and long term memory whereas the delayed assesses only the episodic long term memory. The difference between the two tests can give a measure of the forgetting of the subject.

- o **Immediate**. The examiner reads 15 words aloud at the rate of 1 sec for five times and immediately after each presentation the patient is asked to recall as many words as possible in any order (score range 0-75).
- Delayed. After 15-min interval, with interposed visuospatial tasks, the patient is asked to recall, without list repetition, as many words as possible in any order (score range 0-15).

#### 4.1.1.4 Rey's Figure (copy)

This test assesses the ability to reproduce a visually presented model. This test is important to assess visuo-spatial analysis of a model and the strategies of the patient to reconstruct it with the same spatial relations between its elements. This test evidences even small deficits of visuo-spatial analysis and constructional praxis because the stimulus is a geometrical complex figure. It is also used in detecting visual neglect.

A freehand copy of a complex geometrical line figure is asked to the patients on a separate sheet of paper (score range 0-36).

<sup>&</sup>lt;sup>4</sup> Lam, LCW. et al. 1998. Clock-face drawing, reading and setting test in the screening of dementia in Chinese elderly adults. Journal of Gerontology. 53B:353-357.

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<sup>&</sup>lt;sup>5</sup> Carlesimo GA, Caltagirone C, Gainotti G. The Mental Deterioration Battery: normative data, diagnostic reliability and qualitative analyses of cognitive impairment. The group for the standardization of the Mental Deterioration Battery. European Neurology 1996b;36:378-384.

#### 4.1.1.5 Rey's Figure (recall)

This is a test used to assess visuo-spatial amnesia. The immediate recall assesses both the episodic visuo-spatial short and long term memory whereas the delayed assesses only the episodic visuo-spatial long term memory<sup>6</sup>. The difference between the two tests can give a measure of the forgetting of the subject.

- o **Immediate**. A freehand copy of a complex geometrical line figure is required to the patient on a separate sheet of paper. Thirty seconds following the completion of the copy, the patient is requested of a memory reproduction without representation.
- o **Delayed**. After 20-min, with interposed verbal tasks, the patient is asked to reproduce the Rey's Figure without representation.

Separate scores are given for immediate and delayed tests according to accuracy in figure reproduction (score range 0-36).

#### 4.1.1.6 Digit span

Two items in the Wechsler and Stanford-Binet IQ tests are known as "forward digit span" and "backward digit span." Digit span is a common measure of short-term memory. As is usual in short-term memory tasks, here the person has to remember a small amount of information for a relatively short time, and the order of recall is important. In the forward version, the subject repeats a random sequence of one-digit numbers given by the examiner, starting with two digits and adding another with each iteration. The subject's score is the number of digits that he can repeat without error on two consecutive trials.

Digits-backward works exactly the same way except that the digits must be repeated in the opposite order (Kaplan (1991)).

#### 4.1.1.7 Phonological Verbal Fluency

This test is important to assess the extent of the lexical-semantic storage but also the ability to generate strategies to access it, i.e. the patient's mental flexibility. Moreover, this test assesses the degree of self-driven intentions because the patient, after an initial instruction, is asked to generate responses without any further input from the examiner<sup>7</sup>.

The patient has to generate words beginning with the letters "A," "F," and "S." Each of the three trials lasts 60 seconds. The score is the number of legal words produced (proper names excluded).

<sup>6</sup> Carlesimo GA, Buccione I, Fadda L, Graceffa A, Mauri M, Lorusso S, Bevilacqua G and Caltagirone C. Standardizzazione di due test di memoria per uso clinico: Breve Racconto e Figura di Rey. Nuova Rivista di neurologia 2002;12:1-1.

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#### 4.1.1.8 Trail Making Test A

This test involves several abilities such as visual scanning, number recognition, numeric sequencing and motor speed. It is important to assess selective attention, visual scanning and spatial neglect.

The patient is required to connect a series of consecutively numbered circles as quickly as possible. A run task as training is provided. Number of errors and total time required to complete the test are collected<sup>8</sup>.

#### 4.1.1.9 Trail Making Test B

This test assesses mental flexibility in maintaining more than one stimulus at time and shifting between two categories of stimuli on the course of an ongoing activity. Errors in alternation of the two categories or abnormal delay between form A and B of the test reveal a set-shifting deficit.

The patient is required to connect a series of numbered and lettered circles, alternating between the two sequences as quickly as possible. A run task as training is provided. Number of errors and total time required to complete the test are collected<sup>9</sup>.

#### 4.1.1.10 Naming Test (specific for each country)

These tests are designed to assess naming and expressive language skills. the Naming Test is the only test that will necessarily be different across sites since there isn't a single standardized naming test appropriate for participants from all countries involved in the SOCIABLE project.

#### 4.2Affective Assessment

The affective assessment of the users will be based on the Geriatric Depression Scale-short form. The GDS is a self-report inventory, constructed to assess depression and general well-being in the elderly (Yesavage et al., 1983). The GDS has been widely accepted by clinicians because of its ease of use (Dunn & Sacco, 1989; Olin et al., 1992), and the absence of items assessing somatic and vegetative symptoms makes it more appropriate for administration to the frail elderly than other symptom-based scales (Hyer & Blount, 1984), such as the Beck Depression Inventory (BDI). To facilitate the use of the GDS as a rapid screen for a clinically significant levels of depression in the elderly, shorter versions of the scale have been

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<sup>&</sup>lt;sup>8</sup> Giovagnoli AR, Del Pesce M, Mascheroni S, Simoncelli M, Laiacona M and Capitani E. Trail Making Test: normative values from 287 normal adults controls. Italian Journal of Neurological Sciences, 1996;17:305-309.

<sup>&</sup>lt;sup>9</sup> Giovagnoli AR, Del Pesce M, Mascheroni S, Simoncelli M, Laiacona M and Capitani E. Trail Making Test: normative values from 287 normal adults controls. Italian Journal of Neurological Sciences, 1996;17:305-309.

published (Almeida & Almeida, 1999), the most widely used being a 15-item version (GDS-15) constructed by Sheikh and Yesavage (1986). The items selected for this scale have content that is primarily focused on symptoms consistent with a clinical diagnosis of depression, whereas the full scale includes a broader range of items and is more sensitive to mild to moderate changes in mood.

#### 4.3 Functional Assessment

The functional abilities of the users will be assessed by Activities of Daily Living (ADL) and the Instrumental Activities of Daily Living (IADL).

The Katz Index of Independence in Activities of Daily Living, commonly referred to as the Katz ADL, is the most appropriate instrument to assess functional status as a measurement of the client's ability to perform activities of daily living independently. Clinicians typically use the tool to detect problems in performing activities of daily living and to plan care accordingly. The index ranks adequacy of performance in the six functions of bathing, dressing, toileting, transferring, continence, and feeding. Clients are scored yes/no for independence in each of the six functions. A score of 6 indicates full function, four (4) indicates moderate impairment, and two (2) or less indicates severe functional impairment<sup>10</sup>.

The Instrumental Activities of Daily Living (IADL, also called Lawton's scale) was developed by Lawton and Brody in 1969 and is based on a very useful questionnaire to evaluate the capacity of the subject to perform daily tasks governed by cognitive functions (judgement, language, orientation, calculation, memory, planning). Thus, IADL measures the degree of autonomy of an elderly individual. This test, which assesses the health status of an elderly person in a global manner, appears complementary to the Mini Mental State Examination (or MMSE) that rather evaluates an individual's cognitive functions. For example, a subject with memory disorders or difficulty of calculating (assessed by MMSE test) shows a reduced score. It is thus used in the clinical diagnosis of dementia in parallel with the MMSE.

Although the complete questionnaire appears interesting, 4 tests are particularly important since they are well correlated with cognitive functions evaluated by the MMSE test. They include the ability to: 1Use telephone 2 Use transportation 3 Take medication 4 Handle finances. For example, using a telephone under his own

<sup>&</sup>lt;sup>10</sup> Abrams, W.B., Beers, M.H., Berkow, R. (1995). The Merck Manual of Geriatrics. Whitehouse Station, N.J.: Merck Research Laboratories.

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initiative is related to the intention and planning of a task (to look up the name of somebody in a phone book) and to the comprehension of language (to have a conversation). On the other hand, to be limited to a small number of well known phone numbers, to answer the telephone without calling the correspondent or taking his already prepared drugs imply automatic mechanisms. An evaluation of these 4 activities makes possible early detection of cognitive deterioration, several years (approximately 3 to 5) before a dementia is diagnosed. Detection of an alteration of at least one of these 4 activities calls for a more precise neurological assessment<sup>11</sup>.

#### 4.4Severity of dementia

The **severity of dementia** will be evaluated using the Clinical Dementia Rating (Hughs et al, 1982; Morris, 1993). The Clinical Dementia Rating scale (CDR) is administered in the form of a semi-structured interview with the patient and an appropriate informant and rates impairment in six categories (memory, orientation, judgment and problem solving, community affairs, home and hobbies, and personal care) on a five-point scale.

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<sup>&</sup>lt;sup>11</sup> Lawton M.P. and Brody E.M. Assessment of older people: self-maintaining and instrumental activities of daily living. Gerontologist. 9, 179-186, 1969

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#### 5. User Selection Process in SOCIABLE

#### 5.10verview

The selection of the individuals for the experimentation phase of the project will be performed by administering a comprehensive neuropsychological battery, agreed among the medical experts, in order to classify the elderly in the different target groups identified (A,B,C).

The neuropsychological assessment, as described in the previous paragraph, must include a set of tests evaluating the functional efficiency of the patient in different cognitive domains according to theoretical models of cognitive functioning.

Tests to be used for clinical purpose must be standardized and provide of normative data, representing the contribution of demographic variables (i.e. sex, age, schooling), for the discrimination between normal and pathological performances.

This kind of assessment is particularly important in the differential diagnosis between normal and pathological cognitive deterioration and for a quantitative and qualitative characterization of the cognitive profile.

The neuropsychological battery to be used for the selection of the end-users and the follow-up of the experimentation has been agreed by the medical experts of the project, identifying the most suitable tests for a comprehensive evaluation of the end-users.

Accordingly, the battery must be the same for all sites involved, in order to facilitate the comparison of the data and the data collection itself.

It should be noted that the implementation within the SOCIABLE platform of at least part of the neuropsychological testing (i.e. the shared battery to be administered to the subjects involved in the experimentation) will facilitate the conduction of the SOCIABLE programme. Note that such an implementation would represent a useful aid in collecting and recording data, and in making faster and easier the performance monitoring and the comparison of results. It would remarkably simplify the data collection and its analysis, in order to ensure the drawing up of scientific conclusions. To this end it is considered appropriate to investigate the conditions and requirements (legal issues and copyrights) necessary in order to do that, and to identify the most appropriate tests.

A comprehensive neuropsychological Battery, composed by a set of tests evaluating the efficiency of the patient in different cognitive domains, will be administered to the elderly, in order to assess their cognitive status and classify them in the different target groups. The affective and functional status of the elderly will be also assessed by rating scales with the subject and a structured interview with the caregiver. It's important to underline that the neuropsychological battery to be used for the selection of the end-users and the follow-up of the experimentation will be the same for all sites involved, in order to facilitate the comparison of the data and the

**data collection itself**. In the sequel, we report in detail the user selection process for each target group.

#### 5.2 Group A

This group includes elderly people aged 65+, without degenerative diseases. Normal elderly people could be identified among patients and/or people attending Municipal Recreation Centres in different sites and must be selected according to MMSE score and according to the absence of cognitive impairments assessed through the administration of a comprehensive neuropsychological battery.

#### 5.2.1 Inclusion criteria

Elderly belonging to this group will be included as soon as they are/have:

- o Aged 65 years +
- o Fluent in native language
- o A minimum of 6-year formal education
- Cognitively intact
- o Mini Mental State Examination score: 26-30
- o A score of 0 on the Clinical Dementia Rating (no dementia)
- o Absence of sensory deficits
- Willing to commit

#### 5.2.2 Exclusion criteria

Elderly belonging to this group will be excluded in case they are/have:

- Major neurological (e.g. stroke, transient ischemic attack) or psychiatric illness (e.g. depression not controlled by medication).
- o Traumatic brain injury.
- Current substance abuse.
- Significant communicative / motor / sensorial impairments.

#### 5.3 Group B

This group includes elderly people aged 65+, with diagnosis of MCI, in particular of amnestic-MCI (aMCI).

The Diagnostic Criteria (Peterson, 1999) for amnestic MCI(aMCI) are:

- Memory concerns, usually by the patient, preferably corroborated by an informant (relative);
- Objective memory impairment for age (evidenced by tests);
- Preservation of general cognitive functioning;
- Preservation of functional abilities of daily living;
- Absence of diagnosed dementia.

#### 5.3.1 Inclusion criteria

Elderly belonging to this group will be included as soon as they are/have:

- Aged 65 years +.
- o Fluent in native language.
- o A minimum of 6-year formal education.
- o Presence of a formal caregiver.
- Mini Mental State Examination score: 25-30.
- A score of 0.5 on the Clinical Dementia Rating (questionable dementia) with a memory score of at least 0.5.
- Absence of sensory deficits.
- o Willing to commit.

#### 5.3.2 Exclusion criteria

Elderly belonging to this group will be excluded in case they are/have:

- Major neurological (e.g. stroke, transient ischemic attack) or psychiatric illness (e.g. depression not controlled by medication).
- Traumatic brain injury.
- Current substance abuse.
- o Significant communicative / motor/ sensorial impairments.

#### 5.4Group C

This Target Group includes elderly people aged 65+ with diagnosis of mild AD. For the diagnosis of Mild Alzheimer Disease, the reference is to the Diagnostic Criteria of DSM-IV (Diagnostic and Statistical Manual for Mental Disorders, American Psychiatric Association) and National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) — Alzheimer's Disease and Related Disorders Association (ADRDA) criteria, and the MMSE score (20-25).

Dementia is a clinical state characterized by loss of function in multiple cognitive domains. The most commonly used criteria for diagnoses of dementia is the DSM-IV (Diagnostic and Statistical Manual for Mental Disorders, American Psychiatric Association). Diagnostic features include: memory impairment and at least one of the following: aphasia, apraxia, agnosia, disturbances in executive functioning. In addition, the cognitive impairments must be severe enough to cause impairment in social and occupational functioning. Importantly, the decline must represent a decline from a previously higher level of functioning. Finally, the diagnosis of dementia should NOT be made if the cognitive deficits occur exclusively during the course of a delirium.

#### DSM-IV criteria for the diagnosis of Dementia of the Alzheimer's Type 12

A. The development of multiple cognitive deficits manifested by both:

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<sup>&</sup>lt;sup>12</sup> The criteria applied will be the NINCDS-ADRDA

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- A1. Memory impairment (impaired ability to learn new information or to recall previously learned information)
- A2. One or more of the following cognitive disturbances:
  - (a) aphasia (language disturbance)
  - (b) apraxia (impaired ability to carry out motor activities despite intact motor function)
  - (c) agnosia (failure to recognize or identify objects despite intact sensory function)
  - (d) disturbance in executive functioning (i.e., planning, organizing, sequencing, abstracting)
- B. The cognitive deficits in criteria A1 and A2 each cause significant impairment in social or occupational functioning and represent a significant decline from a previous level of functioning.
- C. The course is characterized by gradual onset and continuing cognitive decline.
- D. The cognitive deficits in Criteria A1 and A2 are not due to any of the following:
  - (1) other central nervous system conditions that cause progressive deficits in memory and cognition (e.g., cerebrovascular disease, Parkinson's disease, Huntington's disease, subdural hematoma, normal-pressure hydrocephalus, brain tumor)
  - (2) systemic conditions that are known to cause dementia (e.g., hypothyroidism, vitamin B or folic acid deficiency, niacin deficiency, hypercalcemia, neurosyphilis, HIV infection)
  - (3) substance-induced conditions

E. The deficits do not occur exclusively during the course of a delirium.

#### 5.4.1 Inclusion criteria

Elderly belonging to this group will be included as soon as they are/have:

- Aged 65 years +.
- o Fluent in native language.
- o A minimum of 6-year formal education.
- o Presence of a formal caregiver.
- o Mini Mental State Examination score: 20-24.
- A score of 1 on the Clinical Dementia Rating (mild dementia) with a memory score of at least 1.
- Absence of sensory deficits.
- Willingness to commit.
- o Fulfillment of the NINCDS-ADRDA criteria for probable AD.

#### 5.4.2 Exclusion criteria

Elderly belonging to this group will be excluded in case they are/have:

- Major neurological (e.g. stroke, transient ischemic attack) or psychiatric illness (e.g. depression not controlled by medication).
- o Traumatic brain injury.
- Current substance abuse.
- Significant communicative / motor/ sensorial impairments.

#### 6. Conclusions

This deliverable has presented the SOCIABLE approach towards:

- Selecting the target elderly groups that could benefit from the SOCIABLE approach. The main characteristics of these groups are illustrated in an earlier section, which also discussed their suitability for SOCIABLE.
- Assessing the elderly participants from a cognitive, functional and affective perspective. The deliverable includes a detailed specification of the neuropsychological tests to be used for the assessment at the various SOCIABLE sites. The specification of these tests was a result of consultation among SOCIABLE medical providers.
- Including and excluding users from the SOCIABLE programme. To this end, a number of inclusion and exclusion criteria have been specified and will be followed during the users' enlistment processes.

The specification of a common approach to elderly users' selection, inclusion and assessment is an important milestone for the project, which will have a number of positive impacts:

- o It will allow all pilot sites (hospitals and municipal care centers) to work in a common uniform way towards selecting and assessing users. This will optimize the project resources, in terms of training pilot sites and users, as well as in terms of support of the pilot sites in medical issues (from the consortium experts).
- It will serve as a common scientifically sound framework, which will support the uniform validation and evaluation of the SOCIABLE pilot services. The abovementioned framework will provide a basis for reporting, validating and evaluating the SOCIABLE pilots from a medical perspective.
- It will boost the commercial exploitation of the SOCIABLE platform and services, given that the overall SOCIABLE approach will be based on a scientifically sound framework.

Overall, this deliverable will serve as a handbook for the pilot sites. Specifically, pilot sites will consult the deliverable and related references in order to prepare for the conduction of the user selection and assessment processes. It is envisaged that these processes will be carried out by medical experts, even in municipal sites which do not employ such experts in house. We expect that medical experts (especially those that have not contributed to the development of this document) will find the present deliverable informative and useful.

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