	SEVENTH FRAMEWORK PROGRAMME Information and Communication Technologies
Grant agreement number	FP7-611650
Project acronym	DOREMI
Project Title:	Decrease of cOgnitive decline, malnutrRtion and sedEntariness by elderly empowerment in lifestyle Management and social Inclusion

Deliverable Number:	D2.2
Title of Deliverable:	Active Ageing Lifestyle Protocol
WP related to the Deliverable:	WP2
Dissemination Level: (PU/PP/RE/CO)*:	PU
Nature of the Deliverable: (R/P/D/O):**	R
Contractual Date of Delivery to the CEC:	30/06/2014
Actual Date of Delivery to the CEC:	07/07/2014

WP responsible for the Deliverable:	CNR IFC
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Abstract

The deliverable D2.2 "Active Ageing Lifestyle Protocol" is focused on the description of selection, profiling, treatment and results evaluation process for DOREMI participants. Cognitive, physical and nutritional parameters/tests as also exclusion criteria are described in DOREMI user selection process. For DOREMI participants a complete profiling, composed by data collection of personal information, lifestyle habits, cognitive/physiological parameters and cardiovascular examination is foreseen. This phase is preparatory for the "Active Ageing Lifestyle Protocol" treatment: all the protocols for physical activity, nutrition, cognitive decline and social environment are described in each section. Finally, the D2.2 describes the evaluation process based on indicators of effectiveness and on primary key performance indicators for clinical and social environment.

Keywords

Ageing, Malnutrition, Sedentariness, Cognitive Decline, Protocol, User Profile, Cardiovascular disease, Functional Scales, Social interaction, Gamification.

ICT / Specific Targeted Research Projects (STReP)

FP7-611650

DELIVERABLE D2.2

Title

D2.2 – Active Ageing Lifestyle Protocol

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Organization: **CNR IFC, SI4Life, Extracare, Accord, UOC**

Version: V1.3

Date: 07/07/2014

Distribution: **WP2**

Code: **D2.2**

LIST OF BENEFICIARIES

Ben. No.	Beneficiary Name	Short name	Country	Enter Date	Exit Date
1	CONSIGLIO NAZIONALE DELLE RICERCHE – IFC (Coordinator)	CNR-IFC	IT	1	36
10	SI4LIFE – SCIENZA E IMPRESA INSIEME PER MIGLIORARE LA QUALITA' DELLA VITA SRL	SI4LIFE	IT	1	36
6	THE EXTRACARE CHARITABLE TRUST	Extra	UK	1	36
11	ACCORD HOUSING ASSOCIATION LIMITEDIPS	Accord	UK	1	36
5	FUNDACIO PER A LA UNIVERSITAT OBERTA DE CATALUNYA	UOC	SP	1	36

VERSION HISTORY

Version	Primary Author	Version Description	Date Completed
0.1	SI4LIFE, CNR-IFC	ToC Release	27/03/2014
0.2	CNR-IFC	Contribution on PA and dietary protocols, Chapter 6	07/05/2014
0.3	CNR-IFC	Contribution to Chapter 4	15/05/2014
0.4	CNR-IFC	Contribution to Chapters 7 and 8	20/05/2014
0.5	SI4LIFE	Contribution to Chapter 6	21/05/2014
0.6	UOC	Contribution to Chapters 4, 5, 6 and 8	23/05/2014
0.7	CNR-IFC	Further details in Chapters 6 and 7	26/05/2014
0.8	Si4LIFE	Contribution to Chapters 4, 5 and 6	11/06/2014
0.9	DMU	Comments and suggestions for Chapters 4-5-6	13/06/2014
1.0	Accord, Extracare	Contributions in Chapters 4,5,6,7	20/06/2014
1.1	SI4LIFE	Final contribution on Chapters 4-5-6	25/06/2014
1.2	UOC, Accord	Additional information on Social and QoL tests and document revision	05/07/2014
1.3	CNR-IFC	Final check, submission	07/07/2014

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1. ABBREVIATIONS

6MWT: six-Minutes Walk Test

ADL: Activities of Daily Living

BBS: Berg Balance Scale

BMI: Body Mass Index

BMR: Basal Metabolic Rate

CF: Cardiac Function

CSST: Chair sit to stand test

CVD: Cardio-Vascular Disease

CRT-D: Cardiac Resynchronization Therapy Defibrillator

ECG: Electrocardiogram

FFM: Fat-Free Mass

FLSA: Functional Living Skills Assessment

HDL: High-Density Lipoprotein

HGT: Haemoglobin Glucose Test

ICD: Implantable Cardioverter-Defibrillator

ICF: International Classification of Functioning

KPI: Key Performance Indicator

LDL: Low-Density Lipoprotein

MCI: Mild Cognitive Impairment

MMSE: Mini Mental State Examination

MNA: Mini Nutritional Assessment

MOS-SS: Medical Outcomes Study Social Support Survey

mMOS-SS: modified Medical Outcomes Study Social Support Survey

NYHA: New York Heart Association

PA: Physical Activity

PASE: Physical Activity Scale for the Elderly

RDA: Recommended Daily Allowance

RPP: Rate Pressure Product

TBW: Total Body Water

UDH: Unhealthy Dietary Habits

WSN: Wireless Sensor Network

2. EXECUTIVE SUMMARY

Deliverable D2.2 is focused on definition of the Active Aging Lifestyle Protocol (DOREMI protocol). This activity foresees a first phase based on the selection of DOREMI user population (§4) by:

- Inclusion criteria; a set of parameters indicating age, sex, living alone, basic computer skills, capability to actively choose diet

- Exclusion criteria (§4.1); a set of criteria/pathologies able to negatively influence the DOREMI experience

- Cognitive parameters (§4.2); MMSE and Montreal test are the reference tests for the evaluation of user cognitive level

- Unhealthy Dietary Habits (UDH) (§4.3.1): MNA and BMI are chosen to evaluate the under- and over-nutritional user condition

- Sedentariness (§4.3.2 and 4.3.3): PASE and BERG tests are administered to potential DOREMI user to define physical activity and stability level

If a user is included in parameters/criteria's' list described above, this will be selected to participate to DOREMI experimentation. The second phase foresees user profiling (§5) in terms of data collection related to personal data, cognitive profiling, lifestyle habits, physiological parameters and instrumental cardiovascular examination.

The document describes the DOREMI protocols (§6), composed by a series of activities necessary to contrast sedentariness (§6.1), UDH (§6.2), cognitive decline (§6.3) as well as protocols to monitor and improve social interaction (§6.4).

The deliverable ends with the description of the Active healthy aging effectiveness indicators (§7), a set of parameters and relative improvement level, the definition of primary key performance indicators (§8), a series of indicators useful to evaluate the clinical and social performance of the DOREMI end-users, and the description of WHO International Classification of Functioning, Disability and Health (§9) and its use in DOREMI project.

The detailed description of the lifestyle protocols is aimed at: 1. Providing feedbacks to the technical partners for the construction of the human activity recognition, reasoning (Tasks of WP4), and gamification of social and cognitive activities (Tasks of WP5); 2. Furnishing all medical information mandatory for the project application to the local Ethics Committees in Italy and UK, according to T2.3 description; 3. describing the end-points and the key performance indicators to be applied at the clinical trial (Task 6.4).

3. INTRODUCTION

According to the project's objectives, the DOREMI Active Ageing Lifestyle Protocol is intended to represent a systemic solution for the elderly, able to prolong and stimulate their functional and cognitive capacities, as well as their dietary habits. In this way it is meant to improve quality of life of the elderly, at least preventing and delaying progression of age-related diseases.

Indeed sedentariness, malnutrition and cognitive decline have been chosen as target areas to be studied and improved: in this context, within the DOREMI Protocol the 3 different clinical protocols related to these domains **are integrated**, in order to translate them in a set of parameters to be monitored during the project.

This overall protocol also defines the tools, the evaluation procedures and the time-schedule of the project, so that each partner is able to share the whole process.

The DOREMI Protocol is essential for the implementation of the further technical activities concerning monitoring, contextualization and gamification of the protocol itself. In this context, cooperation among different professional roles, both clinicians and technicians is thus an asset for the project's achievements.

Indeed, as healthcare representatives dealing with cognitive aspects are coming from different European countries, sharing the protocol is really important so that the evaluation process is homogeneous and based on the same tools, also because values to be measured are not clinical data, but functionalities. On the other side, technological partners should have a clear idea of the DOREMI Protocol values and tools, in order to effectively and properly drive the ICT development needed to release a set of prototypes to be validated in the pilot study. Collaboration is also necessary to take into account the full set of complementary impact factors (such as the combination of cognitive decline with physical activity monitoring nutritional behaviour, social interaction.

Considering that the project is intended to do a research involving both a study group and a control group, needing indications for carrying out activities, the protocol should also include the control population, at least providing them with guidelines regarding a healthy diet, adequate physical exercise and a proper cognitive stimulation. Therefore every protocol (sedentariness, malnutrition and cognitive decline) should include a booklet of instructions suggesting good daily life habits, as a suggestion for the control group.

4. DOREMI USER POPULATION SELECTION METHODOLOGY

DOREMI project foresees a well-defined workflow process, divided in user selection (paragraph 4) and user profiling (paragraph 5), as also described by Figure 1.
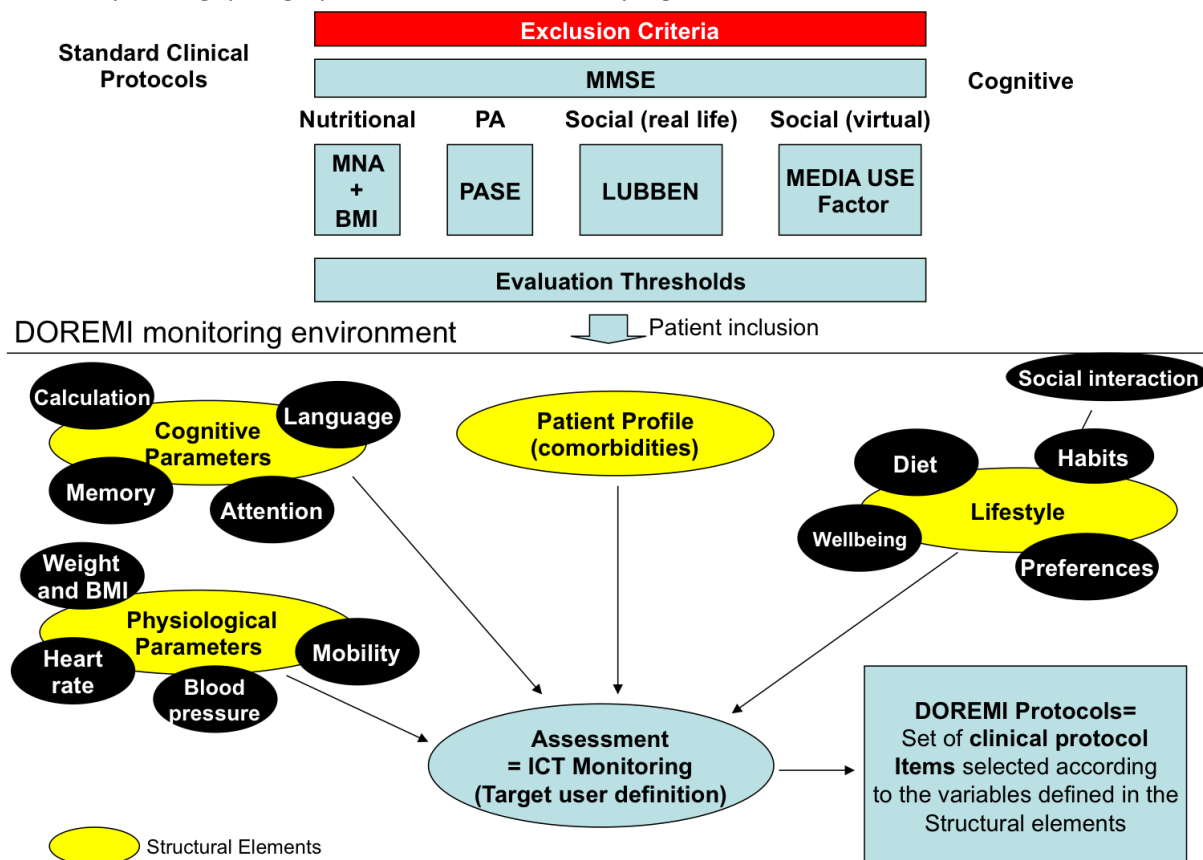
Figure 1. DOREMI workflow.

DOREMI user selection presents first selection level where users are evaluated according to the following inclusion criteria:

- Age. People between 65 and 80 years will be enrolled.
- Sex. A balanced male/female ratio will take in account in the composition of DOREMI population.
- Living alone on their own at home or in nursing homes
- Having basic computer skills (they should know what is internet, what are games)
- Having chance of actively choosing diet

At this first screening, users are evaluated in terms of exclusion criteria, a series of pathologies able to negatively influence the DOREMI user experience. The second level of selection is the MMSE: this test is necessary to include older people with a mild cognitive impairment, able to follow the DOREMI active ageing lifestyle protocol (§6.3, D2.1). Finally, the third level will help to characterize people in terms of nutritional and physical activity habits with the help of MNA/BMI and PASE/BERG tests, respectively (§6.1 and §6.2, D2.1).

4.1 Exclusion criteria

During ambulatory medical evaluation performed by local GP involved in the selection of the potential DOREMI participants, and based on case history, medical records and physical examination, the following criteria/pathologies will be considered as exclusion criteria:

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- Advanced cancer
- Speech, hearing and vision problems which may interfere with physical activity
- Severe neurological disorders (epilepsy, multiple sclerosis, Parkinson disease, Alzheimer disease)
- History of head injury and substance abuse
- Moderate to severe aortic stenosis
- Hypertrophic cardiomyopathy
- NYHA III/IV heart failure
- Patients with an implanted ICD or CRT-D
- Severe chronic renal failure (glomerular filtration rate GFR<30 ml/min, or blood creatinine >2.4 mg/dl for males, >1.9 mg/dl for females)
- Severe hepatic failure
- Chronic obstructive pulmonary disease
- Uncompensated diabetes mellitus
- Chronic hematologic disorders
- Peripheral arteriopathy (Leriche-Fontaine Class III)
- Severe disabilities due to osteoarticular pathologies.
- Severe mobility impairment
- Oxygen saturation below 95%
- Resting heart rate over 100 bpm
- Chronic atrial fibrillation

The non-clinical exclusion parameter is the lack of basic ICT skills related to using social networks; ability of surfing on internet; capability of smart phone use.

4.2 MMSE and Montreal test

The **Mini Mental State Examination (MMSE)** introduced by Folstein Marshall (1975) [1] is a screening tool to assess mental status. The MMSE is one of the most valid assessment tools to identify older people who have a cognitive impairment. It's one of the tools most commonly used in clinical and research. Apart from this, it's easy to apply and allows to follow the course of a disease and the response of a subject to a treatment in time.
It consists of 11 items that measure 5 different areas of cognitive function:

- ✓ Orientation
- ✓ Registration
- ✓ Attention and calculation
- ✓ Recall
- ✓ Language and Praxis

The maximum score is 30 and it takes about 5-10 minutes to administer.
The cut-off score is 24. The score between 24 and 30 indicates a normal cognitive function, between 19-23 it indicates a mild to moderate impairment situation. The score under 19 highlights a severe impairment.
For the test administration, some objects are needed, like a wrist watch, a pencil, an eraser, blank sheets of paper and a paper saying "Close your eyes." In Appendix (§11.1), the MMSE test and its instructions, already described in D2.1, are reported.

> **Selection criteria for MMSE will consider a range score of:**
>
> # 22 – 26*
>
> *** = with correction for scholarization and age**

4.3 MNA, BMI, PASE, BERG

4.3.1 MNA, BMI

The MNA® is a validated nutrition screening and assessment tool that can identify geriatric patients age 65 and above who are malnourished or at risk of malnutrition (defect). The **MNA**® (18 questions, Table 27, §11.2), is composed of an anthropometric assessment, a questionnaire about diet characteristics, food intake, fluids intake, weight loss, mobility, psychological stress or acute disease, drugs, presence of dementia or depression, global health and environment, and a self-evaluation of health and nutritional state (**assessment**). In Appendix (§11.2), the MNA test, already described in D2.1, form is reported.

As a result of the screening score and the assessment, the final **MNA**® **MALNUTRITION INDICATOR SCORE** classifies nutritional state as:

Normal nutritional status   (score 24-30)

at risk for malnutrition   (23.5-17)

and malnourished   (<17)

> **Selection criteria for MNA will consider a range score of:**
>
> # 17 – 23.5

Associated with important changes in body composition and metabolism, the prevalence of malnutrition from excess until obesity, is rising progressively among over 65 [2].

According to WHO definition, as the international tool in the classification of overweight and obesity, the **B**ody **M**ass **I**ndex (**BMI**) is commonly used as a simple and validated index of weight-for-height, to categorize both situations. In Appendix (§11.3), the BMI calculation and graphic, already described in D2.1, are reported.

The standard weight status categories associated with BMI ranges for adults are shown in the following table:

BMI	WEIGHT STATUS	DOREMI DEFINITION
BMI ≤ 18.5	underweight	unhealthy dietary habits for deficiency
BMI 18.5-24.9	normal range	
BMI 25-29.5	mild overweight	unhealthy dietary habits for excess
BMI≥ 30	obesity	unhealthy dietary habits for excess

> ***Selection criteria for BMI will consider a range score of:***
>
> # 17– 32

4.3.2 PASE

As a screening tool to help the identification of the physical status of the Elderly, the **PASE** test (Physical Activity Scale for the Elderly) is a brief, easily scored, reliable and valid instrument for the assessment of physical activity in studies of older people. In Appendix (§11.4) the PASE test, already described in D2.1, is reported.

The PASE questionnaire (Table 28, §11.4) consists of questions regarding the frequency and duration of leisure activity (e.g., sports, jogging, swimming, strengthening and endurance exercise), household activity, and work-related activity during the previous 7-day period and can be administered by telephone, mail or in-person.

The questions are scored differently. Participation in leisure-time and strengthening activities are scored as never, seldom (1-2 days per week), sometimes (3-4 days per week), and often (5-7 days per week). The duration of these activities is scored as less than 1 hour, 1-2 hours, 2-4 hours and more than 4 hours. Household and work related activities are scored as yes or no. In work related activities, paid or unpaid work is scored in hours/week. The total PASE score is computed by multiplying either the time spent in each activity (hours per week) or participation (i.e., yes/no) in an activity, by empirically derived item weights and then summing overall activities [3].

It is possible to divide the elderly into four categories of physical activity: inactive, low physical activity, activity moderate physical activity and vigorous physical activity [4] (Table 1).

PHYSICAL ACTIVITY - QUARTILES	*PASE SCORE*
INACTIVITY - SEDENTARINESS	<42
LOW PA – BOTTOM QUARTILE	43-105
MODERATE PA– MIDDLE QUARTILE	106-145
HIGHT PA– TOP QUARTILE	>146

Table 1. Categories of physical activity according to the PASE scales.

> ***Selection criteria for PASE will consider a range score of:***
>
> # <42 – 105

4.3.3 BERG Scale

The Berg Balance Scale (BBS) measures the degree of balance among older people by assessing the performance of functional tasks.

As the gold standard assessment of balance used for the evaluation of the effectiveness of interventions and for quantitative descriptions of function, it may be used as a quality grade in the way of suggesting a personalized PA plan.

As a matter of fact, the quality of each PA exercise must be part from the BBS level, grading different patients' balance abilities to be evaluated over time in response to DOREMI treatment [5-9]. In Appendix (§11.5), the BERG scale, already described in D2.1, is reported.

A study of the BBS level completed in Finland, indicates that a change of eight (8) points is required to reveal a genuine change on function between two separate assessments among older people [10].

Description:
- The Berg is a test of 14 items (Table 29, §11.5); it is performance based and has a scale of 0-4 for each item (higher score for independent performance) with a maximum score of 56.

Completion:
- Time: 15-20 minutes

Scoring:
- Total Score = 56

Interpretation:
- 41-56 = low fall risk
- 21-40 = medium fall risk
- 0-20 = high fall risk

Selection criteria for BBS will consider a range score of:

30 – 56

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5. DOREMI USER PROFILE

5.1 Integration of parameters for impairment evaluation of user profile

Users profile definition requires the integration of various information: personal data and clinical data (physiological and cognitive data). Furthermore, as the project's goal is also to motivate change of attitude and improve the users' lifestyle, it is necessary to collect, besides these data which might be included in any case history, complementary information concerning daily activities and the way of living of the ageing persons, before and after participation to DOREMI trials, thus assessing the impact of the gamified environment.

5.2 User profile

For DOREMI patient profiling, a set of complete data, composed by personal, clinical, physiological, instrumental, cognitive parameters, lifestyle habits, will be collected. These data will be processed by reasoning system and integrated in order to personalize the DOREMI protocol for each user.

5.2.1 Personal data

The **patient characteristics** that are the covariates variables of the DOREMI Reference Model (see Figure 10) are as follows:

- Age (65-80)
- Gender (M, F)
- Education (less than secondary graduation; secondary graduation; postsecondary graduation)
- Marital status (single, married/cohabitant, widow; separated/divorced)
- Retirement status (retired; non-completely retired)
- Health Status (see §5.2.4)
- Behavioural risk factors (were smokers, heavy drinking, were physically inactive, that could be consider in one single variable with the following risk factor scale: none, one, two, three)
- ICT Attitude-Readiness (we propose the media use scale of Rosen at al. [11]) that combine a list of media with an attitude subscale..

5.2.2 Cognitive parameters

Broadly, a person's cognition refers to the underlying brain processes that make it possible for them to think, remember and learn. Cognition can be divided in to sub divisions which fall in to the categories below:

- Perception
- Attention
- Language
- Memory
- Problem solving
- Reasoning
- Executive functioning

The DOREMI intervention aims to target individuals with mild impairments in these cognitive processes. Mild cognitive impairment is characterised by impairments in any cognitive domain which are greater than expected for the individual's age and education level, but that are not severe enough to warrant a diagnosis of a dementia [12] (see section 6.1.3 for further discussion of cognitive decline). Although cognition declines with age, the brain retains the ability to learn and can restore depleted cognitive functions (this is known as brain plasticity [13-15]. The fact that the brain retains this plasticity and flexibility in later life provides support for cognitive training interventions as proposed in DOREMI in order to delay or reverse cognitive impairments. In order to evaluate the success of a cognitive intervention, it is necessary to take a number of cognitive assessments or parameters before and after the intervention.

In their report of a computerised brain plasticity training program, Mahnke et al. [13] suggest that in addition to evaluating general cognitive functioning (with the MMSE for example), it is important to evaluate directly trained functions targeted by the intervention. DOREMI participants will be subjected to a cognitive test battery at baseline, during the pre-intervention screening phase, and again at post intervention follow-up. Selected cognitive tests cover a range of cognitive domains which will be trained during the intervention.

In order to give a further insight of some specific cognitive functions, the following set of tools (shown in Table 2) has been suggested and adopted in the DOREMI protocol:

TEST	FUNCTION
MMSE	- Orientation (in time and place)
	- Memory (Registration and recall)
	- Attention
	- Calculation
	- Language
	- Visual construction (praxis)
Semantic Fluency	- Semantic verbal fluency
Phonemic Fluency	- Phonemic verbal fluency
Attentional Matrices	- Selective visual attention
Token Test	- Listening comprehension
MoCA	- Visuospatial skills
	- Executive function
	- Conceptual thinking
	- Memory
	- Language
	- Calculation
	- Abstraction
	- Attention
Digit Span	- Memory span
Reaction time	- Processing speed, vigilance, attention

Table 2. Cognitive tests and relative investigated function.

Information concerning cognitive abilities result first from the MMSE, which provides an overall evaluation of the subject. The score achieved within this test also represents the preliminary threshold value to proceed with the person inclusion in the project.

5.2.2.1 Semantic Fluency

The Semantic Verbal Fluency Task assesses semantic memory and language (see Appendix §11.6). Participants will be asked to name as many items as they can that belong to a particular category in a timed 1 minute period. At baseline and follow-up in both the UK and Italy, the categories will be fruits (baseline) and animals (follow up). Improvement will be assessed in terms of a statistically significant increase in number of words in the category recalled at follow up.

5.2.2.2 Phonemic Fluency

The phonemic fluency test (see Appendix §11.7) follows the same principle as the semantic fluency test but participants will be asked to name as many words in the given time beginning with a set letter in the on minute interval. The letters advised for this test differ for Italian and UK cohorts due to language differences (see Novelli et.al [14] and Strauss, Sherman & Spreen [15] for Italian and English versions respectively). At baseline, both the UK and Italian cohorts will be asked to state as many words as possible beginning with the letter F. At follow up, UK participants will list words beginning with the letter A, and the Italian cohort with letter L.

See the following Table 3:

Ù

Italian version	English version
F	F
L	A
P	S

Table 3. Letters for Phonemic Fluency test.

5.2.2.3 Attentional Matrices

Selective visual attention will be measured using attentional matrices (see Appendix §11.8) at baseline and follow up. In both cohorts the test will be the same. Three matrices of numbers will be administered; each constituting 13 rows of 10 numbers from 0-9 arranged randomly. The participant will be asked to cross out target numbers and the administrator will record the time of completion. Improvement will be assessed by statistically significant improvement in completion time.

5.2.2.4 Token Test

Listening comprehension and aphasia will be assessed by the Token test at baseline and follow up (see Appendix §11.9). The Token test is comprised of 36 verbal instructions divided into 6 sections of increasing difficulty. The tokens are various shapes in different sizes and colours, a typical instruction will be '"please touch the red circle". Participants are scored in terms of response accuracy. Improvement in listening comprehension will be assessed by a statistically significant increase in accuracy score between baseline and follow up. Age, reaction time increases [16,17] as our ability to quickly processes stimuli decreases. The complex reaction time test can be utilized to assess both speed of processing and accuracy. The complex reaction time task (requiring a decision about a stimuli and a timed response) captures deficits in selective attention and reaction time to complex stimuli. The test will be administered at baseline and follow up using a laptop. Speed of response, accuracy of response and false responses will be recorded. As there is a tendency for older people to monitor their activities more closely, preferring slower but more accurate performance on tasks [18], both speed of response and accuracy of response will be evaluated at baseline and follow up.

5.2.2.5 Montreal Cognitive Assessment (MoCA)

Administration and Scoring Instructions

The Montreal Cognitive Assessment (MoCA) (Figure 2) was designed as a rapid screening instrument for mild cognitive dysfunction. It assesses different cognitive domains: attention and concentration, executive functions, memory, language, visuoconstructional skills, conceptual thinking, calculations, and orientation. Time to administer the MoCA is approximately 10 minutes. The total possible score is 30 points; a score of 26 or above is considered normal.

MONTREAL COGNITIVE ASSESSMENT (MOCA)
Version 7.1 Original Version

NAME :
Education :   Date of birth :
Sex :   DATE :

VISUOSPATIAL / EXECUTIVE		POINTS

Copy cube

Draw CLOCK (Ten past eleven) (3 points)

[ ]   [ ]   [ ]   [ ]   [ ]   __/5
                         Contour Numbers   Hands

NAMING

[ ]   [ ]   [ ]   __/3

MEMORY	Read list of words, subject must repeat them. Do 2 trials, even if 1st trial is successful. Do a recall after 5 minutes.		FACE	VELVET	CHURCH	DAISY	RED	No points
		1st trial						
		2nd trial						

ATTENTION Read list of digits (1 digit/ sec.).

Subject has to repeat them in the forward order [ ] 2 1 8 5 4

Subject has to repeat them in the backward order [ ] 7 4 2   __/2

Read list of letters. The subject must tap with his hand at each letter A. No points if ≥ 2 errors

[ ]   F B A C M N A A J K L B A F A K D E A A A J A M O F A A B   __/1

Serial 7 subtraction starting at 100   [ ] 93   [ ] 86   [ ] 79   [ ] 72   [ ] 65   __/3

4 or 5 correct subtractions: **3 pts**, 2 or 3 correct: **2 pts**, 1 correct: **1 pt**, 0 correct: **0 pt**

LANGUAGE Repeat : I only know that John is the one to help today. [ ]

The cat always hid under the couch when dogs were in the room. [ ]   __/2

Fluency / Name maximum number of words in one minute that begin with the letter F   [ ] _____ (N ≥ 11 words)   __/1

ABSTRACTION Similarity between e.g. banana - orange = fruit   [ ] train – bicycle   [ ] watch - ruler   __/2

DELAYED RECALL	Has to recall words **WITH NO CUE**	FACE [ ]	VELVET [ ]	CHURCH [ ]	DAISY [ ]	RED [ ]	Points for UNCUED recall only	__/5
Optional	Category cue							
	Multiple choice cue							

ORIENTATION [ ] Date   [ ] Month   [ ] Year   [ ] Day   [ ] Place   [ ] City   __/6

© Z.Nasreddine MD   **www.mocatest.org**   Normal ≥ 26 / 30   TOTAL   __/30

Administered by: _____   Add 1 point if ≤ 12 yr edu

Figure 2. MOCA test

1. Alternating Trail Making

Administration: The examiner instructs the subject: "*Please draw a line, going from a number to a letter in ascending order. Begin here [point to (1)] and draw a line from 1 then to A then to 2 and so on. End here [point to (E)].*"

Scoring: Allocate one point if the subject successfully draws the following pattern:
1 –A- 2- B- 3- C- 4- D- 5- E, without drawing any lines that cross. Any error that is not immediately self-corrected earns a score of 0.

2. Visuoconstructional Skills (Cube)

Administration: The examiner gives the following instructions, pointing to the cube: "*Copy this drawing as accurately as you can, in the space below*".

Scoring: One point is allocated for a correctly executed drawing.
- Drawing must be three-dimensional
- All lines are drawn
- No line is added
- Lines are relatively parallel and their length is similar (rectangular prisms are accepted)

A point is not assigned if any of the above-criteria are not met.

3. Visuoconstructional Skills (Clock)

Administration: Indicate the right third of the space and give the following instructions: "*Draw a clock. Put in all the numbers and set the time to 10 past 11*".

Scoring: One point is allocated for each of the following three criteria:
- Contour (1 pt.): the clock face must be a circle with only minor distortion acceptable (e.g., slight imperfection on closing the circle);
- Numbers (1 pt.): all clock numbers must be present with no additional numbers; numbers must be in the correct order and placed in the approximate quadrants on the clock face; Roman numerals are acceptable; numbers can be placed outside the circle contour;
- Hands (1 pt.): there must be two hands jointly indicating the correct time; the hour hand must be clearly shorter than the minute hand; hands must be centred within the clock face with their junction close to the clock centre.

A point is not assigned for a given element if any of the above-criteria are not met.

4. Naming

Administration: Beginning on the left, point to each figure and say: "*Tell me the name of this animal*".

Scoring: One point each is given for the following responses: (1) lion (2) rhinoceros or rhino (3) camel or dromedary.

5. Memory

Administration: The examiner reads a list of 5 words at a rate of one per second, giving the following instructions: "*This is a memory test. I am going to read a list of words that you will have to remember*

now and later on. Listen carefully. When I am through, tell me as many words as you can remember. It doesn't matter in what order you say them". Mark a check in the allocated space for each word the subject produces on this first trial. When the subject indicates that (s)he has finished (has recalled all words), or can recall no more words, read the list a second time with the following instructions: "*I am going to read the same list for a second time. Try to remember and tell me as many words as you can, including words you said the first time*." Put a check in the allocated space for each word the subject recalls after the second trial.

At the end of the second trial, inform the subject that (s)he will be asked to recall these words again by saying, "I will ask you to recall those words again at the end of the test."

Scoring: No points are given for Trials One and Two.

6. Attention

Forward Digit Span

Administration: Give the following instruction: "*I am going to say some numbers and when I am through, repeat them to me exactly as I said them*". Read the five number sequence at a rate of one digit per second.

Backward Digit Span:

Administration: Give the following instruction: "*Now I am going to say some more numbers, but when I am through you must repeat them to me in the backwards order*." Read the three number sequence at a rate of one digit per second.

Scoring: Allocate one point for each sequence correctly repeated, (N.B.: the correct response for the backwards trial is 2-4-7).

Vigilance:

Administration: The examiner reads the list of letters at a rate of one per second, after giving the following instruction: "*I am going to read a sequence of letters. Every time I say the letter A, tap your hand once. If I say a different letter, do not tap your hand*".

Scoring: Give one point if there is zero to one errors (an error is a tap on a wrong letter or a failure to tap on letter A).

Serial 7s:

Administration: The examiner gives the following instruction: "*Now, I will ask you to count by subtracting seven from 100, and then, keep subtracting seven from your answer until I tell you to stop.*" Give this instruction twice if necessary.

Scoring: This item is scored out of 3 points. Give no (0) points for no correct subtractions, 1 point for one correction subtraction, 2 points for two-to-three correct subtractions, and 3 points if the participant successfully makes four or five correct subtractions. Count each correct subtraction of 7 beginning at 100. Each subtraction is evaluated independently; that is, if the participant responds with an incorrect number but continues to correctly subtract 7 from it, give a point for each correct subtraction. For example, a participant may respond "92 − 85 − 78 − 71− 64" where the "92" is

incorrect, but all subsequent numbers are subtracted correctly. This is one error and the item would be given a score of 3.

7. Sentence repetition

Administration: The examiner gives the following instructions: "*I am going to read you a sentence. Repeat it after me, exactly as I say it* [pause]: *I only know that John is the one to help today*." Following the response, say: "*Now I am going to read you another sentence. Repeat it after me, exactly as I say it* [pause]: *The cat always hid under the couch when dogs were in the room*."

Scoring: Allocate 1 point for each sentence correctly repeated. Repetition must be exact. Be alert for errors that are omissions (e.g., omitting "only", "always") and substitutions/additions (e.g., "John is the one who helped today;" substituting "hides" for "hid", altering plurals, etc.).

8. Verbal fluency

Administration: The examiner gives the following instruction: "*Tell me as many words as you can think of that begin with a certain letter of the alphabet that I will tell you in a moment. You can say any kind of word you want, except for proper nouns (like Bob or Boston), numbers, or words that begin with the same sound but have a different suffix, for example, love, lover, loving. I will tell you to stop after one minute. Are you ready?* [Pause] *Now, tell me as many words as you can think of that begin with the letter F*. [time for 60 sec]. *Stop*."

Scoring: Allocate one point if the subject generates 11 words or more in 60 sec. Record the subject's response in the bottom or side margins.

9. Abstraction

Administration: The examiner asks the subject to explain what each pair of words has in common, starting with the example: "*Tell me how an orange and a banana are alike*". If the subject answers in a concrete manner, then say only one additional time: "*Tell me another way in which those items are alike*". If the subject does not give the appropriate response (fruit), say, "*Yes, and they are also both fruit*." Do not give any additional instructions or clarification. After the practice trial, say: "*Now, tell me how a train and a bicycle are alike*". Following the response, administer the second trial, saying: "*Now tell me how a ruler and a watch are alike*". Do not give any additional instructions or prompts.

Scoring: Only the last two item pairs are scored. Give 1 point to each item pair correctly answered. The following responses are acceptable:

- Train-bicycle = means of transportation, means of travelling, you take trips in both; Ruler-watch = measuring instruments, used to measure.

- The following responses are not acceptable: Train-bicycle = they have wheels; Ruler-watch = they have numbers.

10. Delayed recall

Administration: The examiner gives the following instruction: "*I read some words to you earlier, which I asked you to remember. Tell me as many of those words as you can remember*." Make a check mark (√) for each of the words correctly recalled spontaneously without any cues, in the allocated space.

Scoring: Allocate 1 point for each word recalled freely <u>without any cues</u>.

Optional:

Following the delayed free recall trial, prompt the subject with the semantic category cue provided below for any word not recalled. Make a check mark (√) in the allocated space if the subject remembered the word with the help of a category or multiple-choice cue. Prompt all non-recalled words in this manner. If the subject does not recall the word after the category cue, give him/her a multiple choice trial, using the following example instruction, "Which of the following words do you think it was, NOSE, FACE, or HAND?"

Use the following category and/or multiple-choice cues for each word, when appropriate:

FACE: category cue: part of the body

VELVET: category cue: type of fabric

CHURCH: category cue: type of building

DAISY: category cue: type of flower

RED: category cue: a colour

multiple choice: nose, face, hand multiple choice: denim, cotton, velvet multiple choice: church, school, hospital multiple choice: rose, daisy, tulip multiple choice: red, blue, green

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Scoring: No points are allocated for words recalled with a cue. A cue is used for clinical information purposes only and can give the test interpreter additional information about the type of memory disorder. For memory deficits due to retrieval failures, performance can be improved with a cue. For memory deficits due to encoding failures, performance does not improve with a cue.

<u>11. Orientation</u>

Administration: The examiner gives the following instructions: "*Tell me the date today*". If the subject does not give a complete answer, then prompt accordingly by saying: "*Tell me the [year, month, exact date, and day of the week]*." Then say: "*Now, tell me the name of this place, and which city it is in.*"

Scoring: Give one point for each item correctly answered. The subject must tell the exact date and the exact place (name of hospital, clinic, office). No points are allocated if subject makes an error of one day for the day and date.

TOTAL SCORE: Sum all subscores listed on the right-hand side. Add one point for an individual who has 12 years or fewer of formal education, for a possible maximum of 30 points. A final total score of 26 and above is considered normal.

The MoCA has a score range between 0 and 30 and the following ranges may be used to grade severity of cognitive symptoms:

18-25= mild cognitive impairment,
10-17= moderate cognitive impairment

< 10= severe cognitive impairment.

In DOREMI, participants have will have already been screened with the MMSE for mild cognitive impairment and it is anticipated that most participants will fall in the range of 18-26 on the MoCA at baseline. The MoCA has been shown to be more a more sensitive measure than the MMSE for the lower levels of cognitive impairment typical of DOREMI participants and may be able to detect subtle changes in cognitive functioning following the DOREMI intervention.

Suggested functional classification:

Class A	>24
Class B	20 - 24
Class C	<20

5.2.2.6 Digit span test

Working memory and attention will be assessed using a computerised version of the digit span test from the Wechsler Adult Intelligence Scale-Fourth edition (WAIS) [19], programmed on SuperLab software by DMU. The takes around 7 minutes to complete and will be administered at baseline and follow up using a laptop.

The digit span test is one of the most commonly used assessments of short term memory, working memory and attention. Higher scores indicate cognitive flexibility, use of rehearsal and mnemonic strategies and concentration abilities. The test comprises 3 sections, digit span forwards, digit span backwards and digit span sequencing tests. For the forward digit recall test, participants will be presented with a set of digits and asked to recall them in the same order immediately following the presentation. A higher number of digits will be presented after successful recall of two trails with a set of digits. For example, set one would have two trials of two digits (e.g. 6, 2,).If successful in one of these two digit trials, they will be presented with a series with an additional digit, (e.g. 8, 7, 2,). If they fail both trails of a given series, the test is discontinued. If they respond correctly, the test continues until 9 digit series are being presented. Participants will complete a practice of 3 sets of digits before the test begins. The score is the highest number of digits repeated without error in either of the two trails (if a participant recalls 6 digits, they receive a score of 6). The backwards digit test follows the same principle, but participants are required to respond to recall the presented digits backwards. E.g if 2, 1, 9 are presented, the participant must recall 9,1,2 to receive a correct score. As in the forward test, participants will complete a practice of 3 sets of digits before the test begins. For digit span sequencing, the participant will be presented with a sequence of numbers (8, 4, 2, 9) and be asked to recall the numbers in ascending order (2, 4, 8, 9). As with digits forward, digits backwards and digit sequencing tests will be discontinued if participants fail both trials of a given number series. If the participants fail on any of the digit span tests, the other digit span tests should still be administered as the subject may be more impaired in short term memory than working memory).

Scoring:

• 0 points per trial if an incorrect response given, participant says they don't know the answer or there is no response after 30 seconds.

• 1 point per trial if an individual gives a correct response.

• 2 point per trial if both number sets are recalled correctly

Total item score = sum of scores from the individual trials 0 (failed both trials), 1 (passed one trial) or 2 (passed both trials).

The total score on the digit span test is the sum of the number of digits recalled in the forwards and backwards tests (range 0-48).

- • Digit forward total raw score is the sum of scores for all digit span forward items administered (score range 0-16)

- • Digit backwards total raw score is the sum of scores for all digit span backwards items administered.(score range 0-16)

- • Digit sequencing total raw score is the sum of scores for all digit sequencing items administered.(score range 0-16)

Improvement in short term and working memory will be assessed by a statistically significant increase in digits recalled between baseline and follow up.

Digit spans scores under half of the total score of 48 approximate an overall recall of <5 digits per trial (considered to be indicative of sub-normal functioning). Individuals scoring within the lowest 50% of the possible score range will be classified into Class C. The remaining score range has been split into Class B and Class A.

Class A	37 - 48
Class B	24 - 35
Class C	<24

5.2.2.7 Reaction time test

Participants will be assessed on measures of simple and complex reaction time using a computerised test (programmed on SuperLab software by DMU). For the simple reaction time test, participants will be presented with a stimuli on a laptop screen (an asterix) and will be asked to press the space bar on the keyboard as quickly as the stimuli is presented. Data will be converted into elapsed time in milliseconds. For the complex reaction time test, testing higher order cognitive functions, participants will be asked to only respond when the letter 'p' is presented on the screen, not when the letter 'd', a distractor stimuli is presented.

The tests take around 13 minutes to administer and will be based on those described by Altena et al. [20] a full description of the tasks is quoted from the original paper in full below:

"For the first 'simple' vigilance task, 110 asterisks would sequentially appear on the screen on the same location but with variable and random time intervals of between 1 and 10 s. Prior to the task, there was a brief training session of five targets, allowing the subjects to get acquainted with the task and the screen layout. Subjects were instructed to press the left of the two mouse buttons with their dominant hand as quickly as possible whenever they saw the target. They were told that the task had a duration of approximately 13 min and were asked to maintain their concentration as well as they could throughout the task.

In the second task, the 'complex' vigilance task, either the target letter 'p' or the distracter letter 'd' would appear in the middle of the screen. The stimuli were drawn randomly from a list of 10 targets and 10 distracters without replacement, such that the maximum (though very unlikely) number of targets or non-targets appearing consecutively would be 10.

The time intervals between successive stimuli changed randomly between 0.5 and 5 s. This ensured that the average interval between targets, the number of targets and the duration of the task would be the same as for the 'simple' vigilance task. The target and distracter letters 'p' and 'd' were chosen because the shape and size of the letters were the same, whereas they differed only in their orientation. There was a brief training session of 10 stimuli (five targets) preceding the task. Subjects were instructed to respond as accurately and as quickly as possible to the targets while ignoring the

distracters. A total of 220 stimuli were presented on the screen, of which 110 were target stimuli" [20].

For the attention tasks, for all analyses, the first three target stimuli were discarded, in order to eliminate start-up problems [20]. Thus, there were 107 target stimuli, for each test, included in the analyses.

To evaluate simple and complex reaction times before and after the intervention, the following data will be recorded: reaction times (in milliseconds [ms]), lapses and false-positive responses, defined as follows:

- Lapses – a lapse will be defined as a non-response, or a response slower than 500ms on the 'simple' task [20]; and slower than 637ms for the 'complex' reaction time task (the complex task requires on average 137ms more than the simple vigilance task).
- False-positive responses – on the complex vigilance task, the number of false-positive responses to the distractor stimuli will be scored.
- Reaction times (RTs) – consisting of a single trial RT (in milliseconds) to the target stimuli. For purposes of calculating mean RT and all other statistical analyses, the responses scored as lapses will be ignored.

Although research suggests that simple and complex reaction time is increased in mild cognitive impairment compared to healthy controls [21], it is difficult to provide population norms for our specific test for functional classification. One possibility will be to take the RT of our sample and categorise using a tertile split. If this seams unfeasible following baseline data collection, simple and complex RT will be analysed as a secondary outcome measure following the intervention but not used in the functional classification.

5.2.2.8 DOREMI cognitive games

The cognitive games developed will train the areas assessed by the cognitive test battery at baseline and follow up. It is important that the key performance indicators which are assessed at baseline and follow up are trained during DOREMI but presented in a different way, in order to minimise practice effects of the tests between baseline and follow up. For example, short term recall (assessed by the digit span test at baseline and follow up) could be trained during DOREMI by a game which presents a set of cards face down and asking players to match the images of the cards in pairs. To incorporate the other important areas of exercise and nutrition in the DOREMI project, the cards could have pairs of healthy foods (two apples) or activity related pictures (two tennis rackets). If this game is successful in training short term recall, we would expect to see an improvement on the digit span test at follow up.

5.2.3 Lifestyle

This paragraph aims at proposing metrics for the evaluation of the motivation and social interactions of the DOREMI target groups during the intervention.

According to the scope of the project, the literature review conducted in D2.1 and the DOREMI evaluation reference model described in Figure 10, we propose three types of metrics for measuring intermediate and final outcomes of DOREMI projects.

As explained in §6.4, the DOREMI reference model aims at describing the key causality relationships that we expect to find- through evidences collected during the intervention - amongst stimuli produced on elderly by the "DOREMI gamified environment" and the behavioural lifestyle changes (intermediate outcomes of the project) in health care and social interactions of the elderly persons involved in the trial. Moreover, as described in the model, we also expect that these lifestyle changes

will produce benefits on health status of the participants and on their perception of loneliness and wellbeing (final outcomes of the project).

A synthesis of the metrics and the relevant selected literature review explaining their use and key characteristics are presented in **the following table 4.**

In particular the **intermediate outcomes** will be measures with the following metrics:

- metrics measuring motivational changes in self-care management (set of variables "C "in the Table)
- metrics measuring social interaction (set of variables "D1" in the Table)
- metrics measuring media use and on-line social interaction (set of variables "D2" in the Table)
- metric measuring (perceived) social support (set of variables "E" in the Table)

While the **final outcomes** will be measured with the following metrics:

- metrics for self perceived health (set of variables "F1" in the Table)
- metrics measuring the loneliness status (set of variables "F3" in the Table)
- metrics measuring the wellbeing status (set of variables "F4" in the Table)
- metrics health status (see the metrics proposed by CNR-IFC and the other clinical partners)

All the metrics are based on a literature review (see §6.4) of recent publications that show their use in trials with aged persons which partially integrates and expand the findings already included in D2.1 (see §6.4.3).

In §6.4 the selected metrics listed above will be adapted to the scope of DOREMI project ad duly customized to the characteristics of the target group of the project participating to the Pilots' Trials.

All the above metrics are useful to assess from which the motivation degree and characteristics of social interaction (baseline) start the target group of individuals participating to the trials activities, as well as to assess the intermediate and final progress of the target groups in the trial to achieve the expected intermediate and final outcomes of the project.

Moreover they can be used to assess the initial and final motivational and social status of the control group as explained in the §6.4.

Set of Variables	Description	Scales	References
(A) - Covariants	Patients characteristics	Age; Gender; Income; Marital Status; Education; Retirement Status; Health Status; Behavioural risk factors, ICT Attitude-Readiness	
(C) – Intermediary outcomes	Self care management	21-items Hibbard scale	Hibbard, JH, Stockard, J, Mahoney ,ER, & Tusler, M., (2004).
(D1) – Intermediary outcomes	Social Inclusion (Physical)	18-items Lubben scale	Lubben J, Gironda M. (2004)
(D2) – Intermediary outcomes	Social Inclusion (Virtual)	12-items Use Media Factor scale	L.D. Rosen ⇑, K. Whaling, L.M. Carrier, N.A. Cheever, J. Rokkum, (2013)
(E) – Outcomes/KPI	(perceived) Social support	19-items MOS-SS scale	Hays RD, Sherbourne CD, Mazel RM. (1996)
(F1) – Outcomes/KPI	Perceived Health status	SF36 scale	http://www.rand.org/health/surveys_tools/mos/mos_core_36item_survey.html
(F2) – Outcomes/KPI	Monitored Health status	Health data	D2.2 Chapter 5 and Chapter 6
(F3) – Outcomes/KPI	Perceived Loneliness	20-items UCLA Loneliness scale	Russell 1996; Russell, Peplau, & Cutrona (1980)
(F4) – Outcomes/KPI	Perceived wellbeing	SF36 scale	http://www.rand.org/health/surveys_tools/mos/mos_core_36item_survey.html

Table 4. Variables, metrics and scales proposed for assessing the impact of the gamified environment on ageing persons' Outcomes (KPI).

5.2.4 Physiological parameters

- Weight and BMI
- Heart rate will be assessed by cardiac auscultation for 3'
- Blood pressure measurements will be performed either by manual or by automatic sphygmomanometers available in the medical office according to current guidelines [22]. A systolic blood pressure of 120-130 and a diastolic blood pressure of 80-85 mmHg will be considered as normal.
- Respiratory rate will be conventionally assessed by visual inspection. A respiratory rate between 12 and 20 breaths per minute will be considered as normal.
- Temperature: will be assessed by electronic thermometer.
- Oxygen saturation will be measured by Pulse oximetry. Fingertip pulse oximeters available in the medical offices will be used for this purpose. An oxygen saturation ≥ 96% will be considered normal.
- Haemoglobin Glucose Test (HGT) or A1C test t is based on the attachment of glucose to haemoglobin, the protein in red blood cells that carries oxygen. The A1C test is useful to diagnose type 2 diabetes and pre-diabetes [23]. Its results are reported as a percentage. The higher the percentage, the higher a person's blood glucose levels have been. A normal A1C level is below 5.7% (Table 5).

Diagnosis	A1C Level (%)
Normal	< 5,7
Pre-diabetes	5.7 – 6.4
Diabetes	> 6.4

Table 5. A1C blood levels and relative diagnosis.

A1C can be measured by different techniques as: High-Performance Liquid Chromatography (HPLC); immunoassay; enzymatic system; capillary electrophoresis.

- Lipid profile is a screening test for identification of abnormalities in lipid levels, recommended by Adult Treatment Panel (ATP) III guidelines [24]. The lipid profile is performed by enzymatic technique and includes Low-density lipoprotein (LDL), High-density lipoprotein (HDL), Triglycerides and Total cholesterol quantification.

LDL Cholesterol levels:
Optimal: Less than 100 mg/dL (2.59 mmol/L)
Near/above optimal: 100-129 mg/dL (2.59-3.34 mmol/L)
Borderline high: 130-159 mg/dL (3.37-4.12 mmol/L)
High: 160-189 mg/dL (4.15-4.90 mmol/L)
Very high: Greater than 190 mg/dL (4.90 mmol/L)

Total Cholesterol levels:
Desirable: Less than 200 mg/dL (5.18 mmol/L)
Borderline high: 200-239 mg/dL (5.18 to 6.18 mmol/L)
High: 240 mg/dL (6.22 mmol/L) or higher

HDL Cholesterol levels:
Low level, increased risk: Less than 40 mg/dL (1.0 mmol/L) for men and less than 50 mg/dL (1.3 mmol/L) for women
Average level, average risk: 40-50 mg/dL (1.0-1.3 mmol/L) for men and between 50-59 mg/dl (1.3-1.5 mmol/L) for women
High level, less than average risk: 60 mg/dL (1.55 mmol/L) or higher for both men and women

Triglycerides levels:
Desirable: Less than 150 mg/dL (1.70 mmol/L)
Borderline high: 150-199 mg/dL(1.7-2.2 mmol/L)
High: 200-499 mg/dL (2.3-5.6 mmol/L)
Very high: Greater than 500 mg/dL (5.6 mmol/L)

- Stability level as assessed by BERG balance scale with a scale range of 30-56

5.2.5 Instrumental cardiovascular examination

The following instrumental cardiovascular (CV) examinations will be performed in each subject at the beginning of the study and at the end of treatment, in order to obtain important and easily-derived information on the CV conditions of the enrolled subject:

12 lead ECG will be recorded in each patient by standard equipment according to current guidelines [25]. A basal 12 lead ECG provides important and readily available information in terms of heart rate, underlying cardiac rhythm, QRS morphology and recognition of the presence of a bundle branch block, P morphology and ST-T morphology. Particular attention is requested to the proper placement of the precordial leads, which must be placed as indicated in Figure 3.
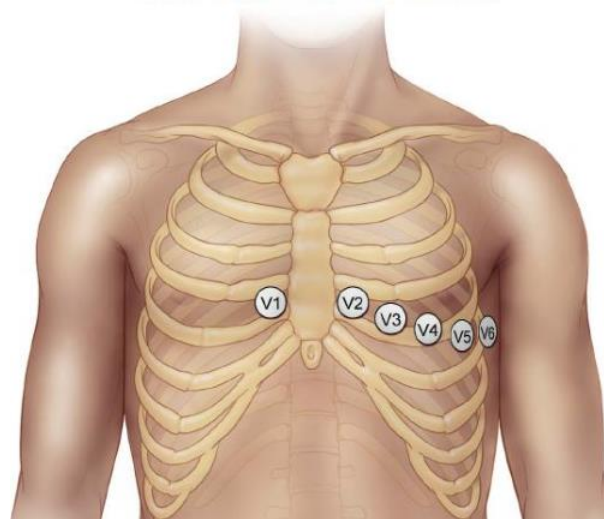
Figure 3. Proper placement of 6 chest leads.

24 hour Holter monitoring should be available, although not mandatory for cardiovascular characterization in DOREMI study. It will be performed according to standard procedures and guidelines with commercially available instruments [26]. This technique is particularly useful for the evaluation of cardiac rhythm, for both supraventricular and ventricular and for the assessment of changes of the ST-T segments which could unmask potential episodes of myocardial ischemia.

6' Walking Test measures the distance an individual is able to walk over six minutes on a hard, flat surface. The goal is to walk as far as possible in 6', thus providing information about the ability of the subject to perform activities of daily living. This test will be performed according to published guidelines [27]. In the literature, the participant distance across studies varies which is likely due to the need to use what is readily available. The ATS recommends an indoor, 30 meter corridor or walkway with cones placed at the beginning and end of the 30 meter boundary to indicate turns. Encouragement is often given and is typically standardized, although it varies in frequency across studies from providing encouragement every 30 seconds to every 2 minutes. Encouragement increases the distance walked and if used, the exact protocol should be reported, to reduce differences in test response related to different operators.

6. ACTIVE AGING LIFESTYLE (DOREMI) PROTOCOLS

DOREMI protocol foresees the involvement of UK and Italy sites where platform experimentation will be carried out. Two groups will perform the trial in different times, according to a new trial timescale (Figure 4A) which foresees 10 days of baseline evaluation, 15 days of training, 60 days of treatment and 5 final days for treatment evaluation (total 90 days) for each group. The study will start in UK (Figure 4B) (EXTRACARE and ACCORD, 10 participants for each one), then in 2 months DOREMI platform will be transferred in Italy and assembled in Seregno and Genoa sites where will be performed the second part of the pilot study (10 participants for each site). Both cases (30) and controls (10) will be monitored by the WSN and bracelet during the 90 day trial.

TRIAL STRUCTURE & TIMESCALE A

| 10 days | 15 days | 60 days | 5 days |
| Baseline | Training | Training | Final evaluation |

= 90 days

PILOT STUDY TIMESCALE B
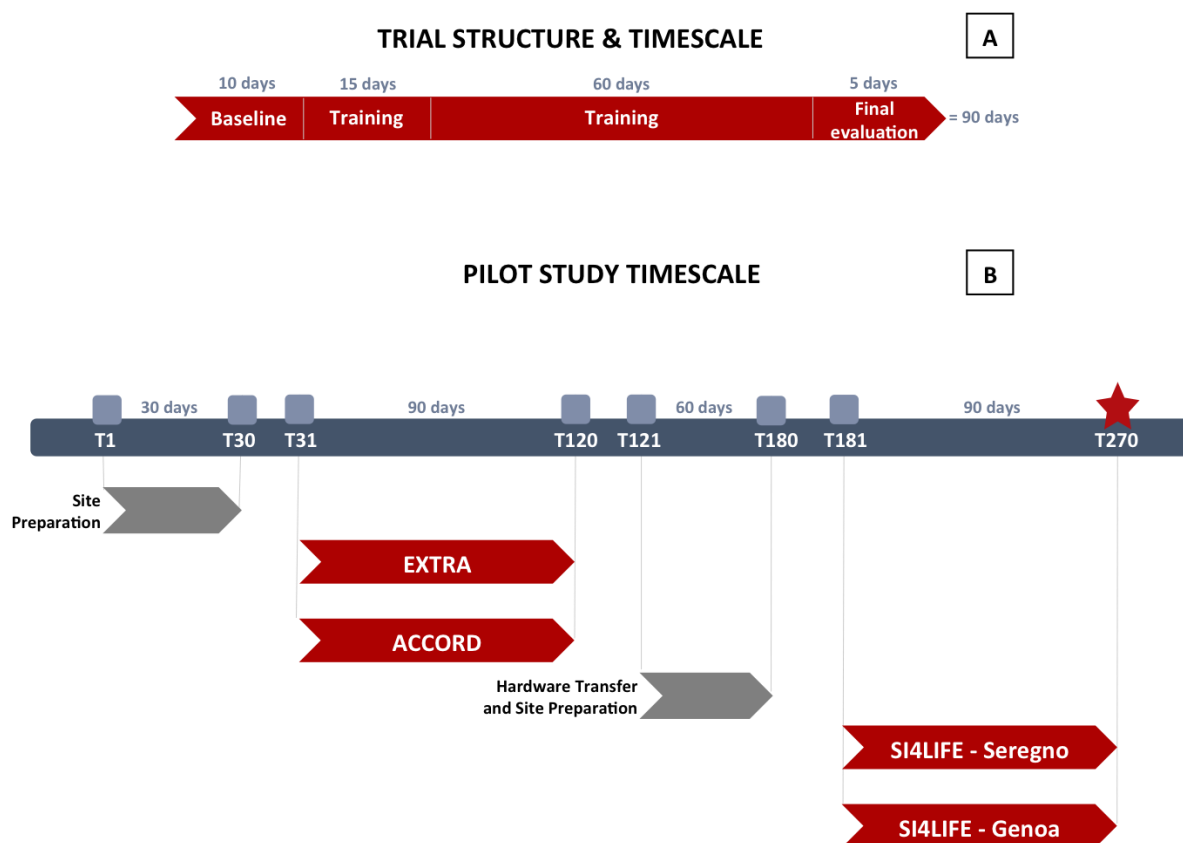
Figure 4. DOREMI protocol timeline and trial distribution between UK and Italy sites.

6.1 Sedentariness

6.1.1 Introduction

Physical activity (PA), health and quality of life are closely interconnected: the human body is designed to move and therefore needs regular PA in order to function optimally and avoid illness. Regular PA increases the general wellbeing state, improves the psychological and physical health, helps to maintains self-sufficiency, prevents specific metabolic disorders, such as type 2 diabetes, metabolic syndrome, hypercholesterolemia. On the contrary, it has been observed in literature that a sedentary lifestyle is a risk factor for the development of many chronic illnesses, including cardiovascular diseases, osteoporosis, breast and colon cancer, depression and cognitive decline. The psychological discomfort linked to growing old can be modified or minimized by a pleasant and shared PA. Sedentary people who become more physically active report feeling better from both a physical and a mental point of view, and enjoy a better quality of life.

A recent meta-analysis has shown that to obtain significant effects of physical activity interventions in the elderly, the typical dose of the physical activity prescription **is 20–60 min of aerobic activity three times weekly**.

Since adherence to mobility enhancement **recommendations** by older subjects is generally low, it is important that participants undergoing training **should be followed-up by in-person interviews or use of mobility monitoring tools**. Therefore, DOREMI trial will foresee a regular check of PA by PASE questionnaire and a monitoring of user mobility by the wrist bracelet.

Another important issue addressed by DOREMI PA protocol will be the indoor activity, since the proportion of sedentary time is strongly related to metabolic risk, independent of physical activity. *Literature results suggest that older people may benefit from reducing total sedentary time and avoiding prolonged periods of sedentary time by increasing the number of breaks during sedentary time.* Therefore, an indoor PA program tailored to increase the number of breaks during sedentary

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time, as assessed by the accelerometer and WSN, will be designed and personalized according to the individual habit of PA and sedentariness times.

As general recommendations, the WHO 2010 Guidelines [28] will be followed in DOREMI PA protocol (see D2.1 - §4.2).

For older people the goal recommended by the WHO 2010 Guidelines is to achieve up to 30 minutes of mild- moderate intensity PA 5 days a week. The necessary dose of PA can be accumulated in bouts of at least 10 minutes and can also consist of a combination of mild-moderate intensity periods. Activities to increase muscular strength and endurance should be added 2 to 3 days per week.

The final protocol for PA for the older population will present 6 recommendations, which have been already agreed to be applicable to the development of specific Guidelines on PA for elderly people; each of them is considered to be an accurate and evidence-based item:

1. Older adults who participate in any amount of PA gain some health benefits, including maintenance of good physical and cognitive function. Some PA is better than none, and more physical activity provides greater health benefits.

2. Older adults should aim to be active daily. Over a week, activity should add up to at least 150 minutes (2½ hours) of mild-moderate intensity activity in bouts of 10 minutes or more – one way to approach this is to do 30 minutes on at least 5 days a week.

3. For those who are already regularly active at moderate intensity (those without sedentariness impairment enrolled in the trial), comparable benefits can be achieved through 75 minutes of more vigorous intensity activity spread across the week or a combination of moderate and vigorous activity.

4. Older adults should also undertake PA to improve muscle strength on at least *two days a week*.

5. Older adults at risk of falls should incorporate PA to improve balance and co-ordination on at least two days a week. Therefore, the BERG balance scale should select and prescribe extent and quality of PA in subjects at risk of falls.

6. All older adults should minimize the amount of time spent being sedentary (sitting) for extended periods.

Moderate-intensity aerobic activity is any activity that causes a slight but noticeable increase in breathing and heart rate. One way to gauge moderate activity is with the "talk test"—exercising hard enough to break a sweat but not so hard you can't comfortably carry on a conversation. This simple rule will be taught to the participant, in order to graduate the imposed PA according to the ability to maintain a slight conversation with another participant.

Furthermore, the DOREMI PA protocol will pursue the following physiological objectives:

- Respiratory system: reduction of oxygen demand and respiratory engagement during a certain movement
- Cardiovascular system: increase of maximum cardiac output, increase coronary blood flow, better utilization of peripheral oxygen by the working muscles
- Maintenance of the most physiologic maximum oxygen consumption (VO_2max) in advancing ageing
- Strength and flexibility: strength and gait increase, improvement of balance.

Finally, it will be necessary to define **engagement tricks** (e.g. gaming, recommendations, interactions with the trainer, members of the family, friends and others) to stimulate and encourage a change in participant attitudes, recognized as wrong or harmful to his health.

As far as the PA Protocol is concerned, the DOREMI PA Protocol will be divided as reported below (Figure 5).

BASELINE	TRAINING	TREATMENT	FINAL EVALUATION

| 1 DAY | 10 DAY | 25 DAY | 85 DAY | 90 DAY |

General PA recommendations — *Daily PA training by Coach or videos* — *Limited Coaching supply on demand*

CASES AND CONTROLS:
BLOOD AND URINE TESTS

CLINICAL & INSTRUMENTAL EVALUATION

MONITORING PHYSICAL ACTIVITY (PA) HABITS FOR QUANTITATIVE EVALUATION OF SEDENTARINESS (WSN & BRACELET)

SIX-MINUTE WALKING TEST (6MWT)

PASE & BERG SCALES

GENERAL PA RECOMMENDATIONS

CASES
STUDY OF PA PERSONALIZED PLAN FOR DOREMI TREATMENT

CASES
PERSONALIZED WEEKLY PA PLAN (7+7 DAYS)

PA COACHING

PA PROTOCOL VIDEOS

MOTIVATIONAL TRAINING

EXERGAMES

CONTROLS:
GENERAL PA RECOMMENDATIONS

PA AS USUAL

CASES AND CONTROLS:
MONITORING PA BY WSN & BRACELET

CASES
PERSONALIZED PA PLAN (15 DAYS + 15 DAYS + 30 DAYS)

PA COACHING ON DEMAND

PA PROTOCOL VIDEOS

EXERGAMES

CONTROLS
GENERAL PA RECOMMENDATIONS
PA AS USUAL

CASES AND CONTROLS:
MONITORING PA BY WSN & BRACELET

CASES AND CONTROLS FINAL EVALUATION

BLOOD AND URINE TESTS

PASE & BERG SCALES

MONITORING PA BY WSN & BRACELET

SIX-MINUTE WALKING TEST

QUESTIONNAIRES

Figure 5. PA Protocol: the three DOREMI interventional phases.

6.1.2 Baseline phase

Starting from the first day of **BASELINE phase – 10 days -** all Users will be involved in interviews, questionnaires, monitoring of Activities of Daily Living (ADL) indoor and outdoor. Their ADL will be checked in order to have a quantitative evaluation of the level of sedentariness (WSN & Bracelet).

A specific evaluation will be proposed by the Coaching in order to evaluate functional limits to perform single movements and specific diseases which require others.

PASE test will join the **Six Minute Walking Test** in the completion of the main table recruitment.

As far as the concept of PA in the Elderly is concerned, the impairment of functional capacity as balance, transferring and turning may sometimes cause deterioration in ADL. The functional impairments may be strictly linked to the sedentary lifestyle: for this reason functional capacity must be evaluated by testing certain tasks in the ADL in order to reduce related risks and to receive precious tools in the identification of individual risks. The above quoted functional impairments will be used as indicators in the prevention of falls related to everyday activities helping the identification of high-risks subjects.

The **Berg Balance Scale** (BBS) is considered the gold standard assessment of balance with small intra-inter rate feasibility and good internal validity. The Berg's utility includes grading different patients' balance abilities, monitoring functional balance over time and to evaluating patients' responses to different protocols of treatment.

In this first step, common sessions will act in the way of explain the use of the simple smart application, calibrated for our targeted Users, finalized for the DOREMI treatment. Basic elements of anatomical mobility will be thought in order to empower our Users on the importance of the daily Physical Activity (D2.1 – §6.2.1).

According to the 2008 Physical Activity Guidelines, general lines of active behaviour will be showed to Participants and Controls. During the training period a personalized PA, based on the baseline survey, will be provided to all Participants directly by the Coaching.

6.1.3 Training phase

In the **TRAINING** phase – 15 DAYS - a personalized plan will be given to our **Participants**. The daily easy exercises will be performed with the help of Coach and will have a planned increase in length and quality. The daily protocol will be supported by video available on the smart tablet; session on motivational training are previewed joined with exergames. As far as the motivational lever is concerned, it could be considered the nomination of a switchable "Leader" inside the group in order to act like Coach during the treatment time.

Controls will play ADL as usual but will be monitored with WSN & Bracelet as **Participants**.

6.1.4 Treatment phase

In the **TREATMENT** phase – 60 DAYS - the heart of DOREMI, **Participants** will maintain a personalized plan, the support of videos and exergames but the role of the Coaching will be limited and on demand.

Controls will have ADL as usual; **Control** and **Participants** will be monitored by WSN and Bracelet.

The final aim of **DOREMI PA TREATMENT** protocol will be:
- the empowerment of ADL (increase of physical activity level as described in §6.1.6) with the acquisition of simple elements related to the specific physical activity **according to personalized pathologies, physical limits and status**;
- the verification of the effect of the physical activity in the treatment time;
- the engagement of the Users through appropriate stimulation and **game-based motivations** which will support his **behavioural changes in the adherence of better lifestyle management protocols**;
- the evaluation of educational intervention for improving movement and lifestyle behaviour in the Elderly on metabolic and physiological functions plus cognitive/psychological functions;
- **the compliance to methodologies and results obtained to set improved ICT/technologies/ instrument calibrated for our Users.**

6.1.5 Final Evaluation phase

At the end of the treatment phase in the **FINAL EVALUATION,** PARTICIPANTS AND CONTROLS will be involved in the final evaluation - 5 days - and submitted to clinical, physical tests and specific questionnaires.

6.1.6 PA Protocol

DOREMI PA Protocol is organized in three phases with three different levels of engagement, as described in Table 6: the first is necessary to furnish to users the guidelines for an active lifestyle, levels 2 and 3 are focused to improve a satisfying level of physical activity and ensure its maintenance. PA protocol foresees outdoor and indoor activities. In outdoor activities a working leader will be selected between DOREMI participants and trained by local personal trainer in order to ensure users' participation and favour the social environment development.

BASELINE	TRAINING	TREATMENT
Record of user physical activity level	DOREMI PA Protocol Starting level: as resulted from baseline recording	DOREMI PA Protocol Possibility to increase level at corresponding increase of PA

Table 6. PA Protocol and level of engagement.

Level 1 is based on 7 points, necessary for users to learn the DOREMI active lifestyle rules. These are:
1. Know advantages of a regular physical activity

2. Learn walking techniques
3. Regulate aerobic activities
4. Learn new activities or start again old ones
5. Learn exercises to improve articular mobility and stretching
6. Learn to lift and move weights
7. Favour social activities involving other older peoples to favour situations where it is possible to have diversified motor stimuli

Level 2 and 3
These advisees are necessary to maintain an active lifestyle
1. 20-60 minutes of aerobic exercise for 3 days each week
2. Exercises to improve force in lower limbs, upper limbs and abdominal muscles 2 times each week
3. Daily exercises for balance and articular mobility
4. Frequent exercises and activities to stimulate motor control and learning

Level 1
3 outdoor sessions + 2 indoor each week sessions for a total of 195 minutes (WHO 2010 recommended guidelines)
Start with autotest

Outdoor session crono-program (46' 30'', e.g. Monday-Wednesday-Friday)
11' 30' articular mobility and stretching (needs a stable support, like a chair; can be performed indoor)
10' walking
5' exercises to improve walking activity
15' walking
5' articular mobility and wearying stretching, cooling down (needs a stable support, like a chair; can be performed indoor)

Indoor session crono-program (31' 30'', e.g. Tuesday-Thursday)
11' 30'' articular mobility and stretching
15' muscular strengthening
5' sit-ups and backbone unloading
In conclusion, autotest

Level 2
3 outdoor sessions + 2 indoor sessions each week for a total of 235 minutes (WHO 2010 recommended guidelines)

Outdoor session crono-program (56' 30'', e.g. Monday-Wednesday-Friday)
11' 30'' articular mobility and stretching (needs a stable support, like a chair; can be performed indoor)
15' walking
5' exercises to improve walking activity
20' walking
5' articular mobility and wearying stretching, cooling down (needs a stable support, like a chair; can be performed indoor)

Indoor session crono-program (36' 30'', e.g. Tuesday-Thursday)
11' 30'' articular mobility and stretching

20' muscular strengthening
5' sit-ups and backbone unloading

In conclusion, autotest

Level 3

3 outdoor sessions + 2 indoor sessions each week for a total of 260 minutes (WHO 2010 recommended guidelines)

Outdoor session crono-program (61' 30'', e.g. Monday-Wednesday-Friday)
11' 30'' articular mobility and stretching (needs a stable support, like a chair; can be performed indoor)
20' walking
5' exercises to improve walking activity
20' walking
5' articular mobility and wearying stretching, cooling down (needs a stable support, like a chair; can be performed indoor)

Indoor session crono-program (41' 30'', e.g. Tuesday-Thursday)
11' 30'' articular mobility and stretching
25' muscular strengthening
5' sit-ups and backbone unloading
In conclusion, autotest

6.1.6.1 Walking exercises
Dynamic equilibrium exercises
Walking is the leading activity in DOREMI PA protocol. To ensure a reliable result during DOREMI treatment, it is fundamental to follow some rules, described below, for an effective walk:

- Feet: Foot has an important role for legs, pelvis, buts, arms and shoulders' movements. Feet rest parallel on the ground. Initially, foot comes into contact with ground with heel, then the support is transferred to the arch of the foot, able to absorb weight loading. Finally , force arrives to toes and movement finishes when big toe lose contact with ground. Stronger is push exerted on foot, greater will be ground response, knee will be pushed up, stride will be longer and walk will result energetically less demanding.
- Legs: Movement must be energetic to stimulate muscles. Legs has two roles: support, for body weight, and thrust, modulated by feet with help of thigh posterior muscles.
- Hips and Bust: Hip movement let to develop right walking velocity and maintain a flowing and harmonious action
- Arms: these move forward and backward describing s large arc. Elbow falls back at shoulder level, while hand arrives to an imaginary point between navel and breastbone. Hands are half-open.
- Shoulders: Shoulders follow arms' movement. Bust must be held erect but not stiff.
- Neck and Head: Head must be held erect.

Perform initially in an area, then long a 5 meters long line (Total time 5')
1. Walk on a 5 meters long line, 1'
2. Walk on a 5 meters long line, perform a complete turn and continue to walk, 1'
3. Walk on a 5 meters long line, bending knee at each step against the chest, 1'
4. Walk on a 5 meters long line with closed eyes, guided by someone, 1'
5. Walk on a 5 meters long line with closed eyes without support, 1'

6.1.6.2 Articular mobility

The articular mobility is the capability of articulations to freely move covering totally their range of movements, without limits and pain.

It is related to subject orthopaedic characteristics. Thanks to the exercise, it is possible to preserve the functional autonomy as also prevent and control articular painful syndromes.

The training must be carried out through exercises repetition covering the maximal articular range.

In older person this type of exercises develops coordination, strengthens cartilages, improves perception of personal capabilities.

Stretching

The contraction muscle capability is directly proportional to its capability to stretch: the more is able to extend itself, the more is able to contract and finally to develop force. Stimulating muscular and connective tissue flexibility, elasticity and movement capabilities are improved. Articulations are more resistant to degenerative diseases with a reduced incidence of calcifications.

Muscular stretching positions must be held for 10 seconds without generate an extreme tension. Flexing must be avoided to let to musculature to reduce the contract tone. Stretching is improved by a relaxed breathing.

Exercises for articular mobility and stretching

Exercises for cervical portion of spinal column (Total exercises time 11' 30''):

1. Right , left, front and back flexion of cervical portion of spinal column, 20'' + 10'' of recovery (Total time 1')
2. Shoulders circling, clockwise and counter clockwise for 20''+ 10'' of recovery (Total time 1')
3. Leg circling, clockwise and counter clockwise, right and left for 20''+ 10'' of recovery (Total time 2')
4. Bust torsion, clockwise and counter clockwise for 20''+ 10'' of recovery (Total time 30'')
5. Ankle circling, clockwise and counter clockwise, right and left for 20''+ 10'' of recovery (Total time 2')
6. Bend and forward stretch back for 20''+ 10'' of recovery (Total time 30'')
7. Slightly bended forward, turn the arm on left and right sides, in order to display different times of the watch (3, 6, 9, 12 o'clock) 20''+ 10'' of recovery (Total time 2')
8. Push on the knee and stretch calf, 20''+ 10'' of recovery (Total time 1')
9. Bend leg on a chair and stretch quadriceps, 20''+ 10'' of recovery (Total time 1')
10. Bend pelvis forward as much as possible and stretch posterior leg muscles, 20''+ 10'' of recovery (Total time 30'')

Exercises nr. 2, 4 , 6, 7 and 8 are the chosen ones during the "5' exercises to improve walking activity" and "5' sit-ups and backbone unloading" exercises.

6.1.6.3 Muscular strengthening

From a physiological point of view, the force can be described as to ability to outdo a resistance or oppose it through muscular contraction. These activities heavily involve muscular mass for a limited working time. Muscular force and resistance are fundamental for functional autonomy and to prevent falls.

To improve older people healthy condition the lower limbs must be stimulated with regularity and right intensity as well as an important role is represented by postural exercise of abdominal musculature and upper limbs dynamic function.

For these exercises, for their availability and cheap cost variable resistance elastics are used. These let to perform exercises for different muscular groups and to adapt to each person a specific work loading.

Force exercises
Lower limbs, free style (Table 7).

Nr.	Exercise	Level 1	Level 2	Level 3
1	On feet, leaned against back chair, keeping legs closed stand up on the feet points with then come back slowly to the starting position.	20'' + 10'' of recovery Repeat 2 times (Total time 1')	20'' + 10'' of recovery Repeat 2 times (Total time 1')	20'' + 10'' of recovery Repeat 3 times (Total time 1' 30'')
2	On feet, leaned against back chair, keeping legs closed bend hip to hold this position for 1 second then come back slowly to the starting position.	20'' + 10'' of recovery for each leg Repeat 2 times (Total time 2')	20'' + 10'' of recovery for each leg Repeat 2 times (Total time 2')	20'' + 10'' of recovery for each leg Repeat 3 times (Total time 3')
3	On feet, leaned against back chair, keeping legs closed bend knee then come back slowly to the starting position.	20'' + 10'' of recovery for each leg Repeat 2 times (Total time 2')	20'' + 10'' of recovery for each leg Repeat 2 times (Total time 2')	20'' + 10'' of recovery for each leg Repeat 3 times (Total time 3')
4	On feet, leaned against back chair, keeping legs closed abduct leg then come back slowly to the starting position.	20'' + 10'' of recovery for each leg Repeat 2 times (Total time 2')	20'' + 10'' of recovery for each leg Repeat 2 times (Total time 2')	20'' + 10'' of recovery for each leg Repeat 3 times (Total time 3')
5	Seated on a chair, leaned back, place a rolled towel under knees and stretch it to where is possible then come back slowly to the starting position.	20'' + 10'' of recovery for each leg Repeat 2 times (Total time 2')	20'' + 10'' of recovery for each leg Repeat 2 times (Total time 2')	20'' + 10'' of recovery for each leg Repeat 3 times (Total time 3')
	Exercises with half-litre water bottle			
6	*(Brachial muscle)* On feet, rested arm on the back chair, legs at the same distance of shoulders. Grasp the bottle, palm of the free hand up. Bend and stretch slowly forearm.	20'' + 10'' of recovery for each arm (Total time 1')	20'' + 10'' of recovery for each arm Repeat 2 times (Total time 2')	20'' + 10'' of recovery for each arm Repeat 2 times (Total time 2')
7	*(Arms and shoulders)* On feet, rested arm on the back chair, legs at the same distance of shoulders. Grasp the bottle, palm of the free hand up. Stretch the arm laterally until the same high of shoulders and return, slowly.	20'' + 10'' of recovery for each arm (Total time 1')	20'' + 10'' of recovery for each arm Repeat 2 times (Total time 2')	20'' + 10'' of recovery for each arm Repeat 2 times (Total time 2')
8	*(Bust)* On feet, rested arm on the back	20'' + 10'' of recovery for	20'' + 10'' of recovery for	20'' + 10'' of recovery for

	chair, legs at the same distance of shoulders. Grasp the bottle, palm of the free hand up. Stretch the arm forward until the same high of shoulders and return, slowly.	each arm (Total time 1')	each arm Repeat 2 times (Total time 2')	each arm Repeat 2 times (Total time 2')
9	*(Pectoral muscle)* On feet, rested arm on the back chair, legs at the same distance of shoulders. Grasp the bottle, palm of the free hand up. Bend and stretch elbow in front the bust.	20'' + 10'' of recovery for each arm (Total time 1')	20'' + 10'' of recovery for each arm Repeat 2 times (Total time 2')	20'' + 10'' of recovery for each arm Repeat 2 times (Total time 2')
10	*(Upper portion bust muscles)* On feet, rested arm on the back chair, legs at the same distance of shoulders. Grasp the bottle, palm of the free hand straight. Half-bended arm at the same high of back chair, stretch back as much as possible.	20'' + 10'' of recovery for each arm (Total time 1')	20'' + 10'' of recovery for each arm Repeat 2 times (Total time 2')	20'' + 10'' of recovery for each arm Repeat 2 times (Total time 2')
11	*(Abdominal muscles)* Seated on a chair, arms up, bend the bust stretching arms forward.	20'' + 10'' of recovery Repeat 2 times (Total time 1')	20'' + 10'' of recovery Repeat 2 times (Total time 1')	20'' + 10'' of recovery Repeat 3 times (Total time 1' 30'')
		TOTAL TIME 15'	***TOTAL TIME 20'***	***TOTAL TIME 25'***

Table 7. Force exercises.

For each exercise, regular breathing during effort is fundamental to take under control arterial pressure variations caused by strong muscular contraction. Position with rested arm on the back chair ensures stability.

Back must not be overloaded, people must present a relaxed posture and the central part of body (CORE) will furnish the required stability.

The calculated time for strengthening exercises is calculated for the effective working time but, during each session, longer breaks can be foreseen increasing total time.

6.1.6.4 Autotest

Chair sit to stand test (CSST)

CCST test furnishes a quantification of lower limbs muscular force as well as give information about subject capabilities to perform a series of daily actions like go up the stairs, get in or out a car, get in or out of bath.

The 30 second chair stand involves recording the number of stands a person can complete in 30 seconds rather then the amount of time it takes to complete a pre-determined number of repetitions. In Table 8 and 9 are summarized the scores for men and women, respectively.

Age	below average	average	above average
60-64	< 14	14 to 19	> 19
65-69	< 12	12 to 18	> 18
70-74	< 12	12 to 17	> 17
75-79	< 11	11 to 17	> 17
80-84	< 10	10 to 15	> 15
85-89	< 8	8 to 14	> 14
90-94	< 7	7 to 12	> 12

Table 8. CSST men's results.

Age	below average	average	above average
60-64	< 12	12 to 17	> 17
65-69	< 11	11 to 16	> 16
70-74	< 10	10 to 15	> 15
75-79	< 10	10 to 15	> 15
80-84	< 9	9 to 14	> 14
85-89	< 8	8 to 13	> 13
90-94	< 4	4 to 11	> 11

Table 9. CSST women's results.

The six-Minutes Walk Test (6MWT)

The 6MWT is useful to evaluate the aerobic functionality and measures the distance an individual is able to walk over a total of six minutes on a hard, flat surface. The goal is for the individual to walk as far as possible in six minutes. Covered distance will be quantified in meters and heart rate is recorded by bracelet.

6.2 UDH – Eating Behaviour assessment and protocol

6.2.1 Introduction

The importance of adequate nutritional status in the elderly is critical for the prevention of age-related diseases such atherosclerosis, type 2 diabetes, neuro-degenerative disorders causing cognitive decline, and ends with the reduction of medical and social costs crossing through the main concept of the quality of life [29] (D2.1 - §4.1) .

Based on the statement that a correct diet is an important factor in preventing age-related diseases in those over 65 years old, at the moment the NU-AGE project - www.nu-age.eu - develops dietary concepts addressing specific needs of this target of population for an healthy ageing in Europe, including the study of a new food pyramid to meet the nutritional specific needs of the elderly.

The NU-AGE project [30], funded by the European Commission, conducts studies with the aim of creating functional foods for healthier diets in Europe's ageing population. The results of the one-year trial, which include targeted nutritional recommendations, will feed into scientific evidence on the effect of a whole diet on preventing age-related decline. The NU-AGE project results will provide guidance to over 65s in order to optimize the diet and help to prevent age-related diseases. Reaching the major European dietary guidelines for senior citizens, the new pyramid will reach all the nutritional needs of our targeted category as water, fibres, vitamins (D-B12) etc, aimed at proposing a well balance diet taking extremely care to nutrient density [31].

The trial results will provide strong insights for the optimization of the dietary management in DOREMI's pilot study, in which knowledge of food's influence on preventing age diseases will permit to personalize and suggest dietary habits related to existent comorbidities. These DOREMI's actions and effects will be improved by the exploitation of ICT technologies (diet games) in combination to an educational intervention for improving eating and lifestyle behaviour in the Elderly.

Concerning the relationship between Unhealthy Dietary Habits and CVD, the leading cause of death worldwide, an important role can be assigned to dietary fat intake and in particular high saturated fatty acids and cholesterol intake. The involvement of dietary fat intake in **atherosclerosis,** the inflammatory-degenerative process that affects medium and large calibre arteries, need to be considered. For example the reduction of saturated fats and hydrogenated oils, and their substitution with monounsaturated and polyunsaturated fats may contribute to reduce the risk to develop atherosclerosis. In the whole, a control of dietary fat intake , consumption of fruits, fresh vegetables, pulses, high biological level proteins through fish, lean meats and milk products (taking into account the moderate intake), will be some of recommendations for our Users [32,33].

According to major studies, the reduction of sodium chloride (one component of table salt) in our diet can lower **blood pressure**, helping to prevent arterial hypertension, one of the major risk factor in CVD. Vegetables and fruits are low in sodium, in calories and saturated fats, and must take an important place in healthy dietary habits. Instead of using salt or added fat to flavour foods, it will be important to suggest the use of spices and herbs (D2.1 - §4.1.1).

Nowadays research demonstrates that higher adherence to the Mediterranean diet, characterized by unsaturated fatty acids - mostly in the form of olive oil, high intake of fish, vegetables, legumes, fruits, cereals, and low intake of dairy products, meat and saturated fatty acids, a regular but moderate intake of alcohol (red wine), is associated with a trend for reduced risk of developing **Mild Cognitive Impairment** (MCI) and with reduced risk of MCI conversion to Alzheimer disease [34-36] (D2.1 - §4.1.2) .

As far as **metabolic alterations** (type 2 diabetes, metabolic syndrome) are concerned, diet should be low in saturated fats, cholesterol, sodium and simple sugar; the correct intake of vegetables, whole grains, fish and fruits, as well as a correct hydration, should be encouraged in the vision that maintenance of physiologic lean mass and fluid balance control (D2.1 - §4.1.3).

According to the " Clinician's guide to prevention and treatment of **osteoporosis**", the advise on a diet rich in fruits and vegetables which includes adequate amounts of total calcium intake (1,000 mg per day for men 50-70; 1,200 mg per day for women 51 and older and men 71 and older) and the advise on vitamin D intake (800-1,000 IU per day), including supplements if necessary for individuals age 50 and older, are the priority council in the modification of UDH (D2.1 - §4.1.4).

Concerning the results of the screening tools, classifying the malnutrition impairment for excess or for defect, DOREMI study will start with the evaluation of the nutritional status and habits of our subjects potentially suitable for study enrolment (D2.1 – §6.1; §7.1). This assessment will be strictly necessary to set up an educational strategy to improve eating behaviour.

Starting from the first day of baseline phase, all Users (Cases and Controls) will be involved in interviews, questionnaires and diary for dietary screening, monitoring of eating behavior.

In addition it will be performed a short training period and trial on the use of the simple METADIETA technology, an easy-to-use smart diary, specifically calibrated for the targeted population.

Streamlined communications of the European general guidelines for a healthy diet according to the **NU-AGE** project, (www.nu-age.eu) will be communicated to all groups by our Nutritionists.

In order to involve and empower Users, the connection with **FLABEL** www.flabel.com the European Community's Seventh Framework Programme (2008-2012) coordinated by the European Food Information Council (EUFIC), will be exploited to enable a correct approach of nutritional labels reading, in order to improve familiarity and knowledge of logos or nutrients they can pay attention to make healthy food choices and safeguard health [37] .

Trough METADIETA software (see Appendix §11.10), a personalized diet will be formulated close to the end of BASELINE on the basis of results of an initial survey directed by the Nutritionist and organised as follows:

1. **Personal Details of the Patient**: user profiling and personal data insertion in METADIETA software;
2. **Reporting of measurements resulting from laboratory tests**: insertion of physical and biological parameters (weight, height, BMI, blood and urine tests included in DOREMI protocols);
3. **Clinical evaluation**: collection of the clinical history, the anamnestic features, physiological and pathological conditions concerning specific diseases in the way of personalize dietary suggestions;
4. **The filter unit**: exclusion of foods that are not allowed on the basis of specific disorders (including multiple or cross pathologies); food allergies or intolerances; seasonality, foods unwelcome to the patient;
5. **The total body evaluation**: formulation of total body evaluation with multiple assessments, according to BIVA measurements and derived values;
6. **Survey and development of a diet**: development of a healthy personalized diet carried out by the Nutritionist collecting all previous data and feedback from the User. The report of the dietary protocol will include the type of foods and food preparations prescribed, their amount and the intake in macro and micronutrients, expressed as weight and as percentage of daily values (percentage of the Recommended Daily Allowance (RDA);
7. **Management of the daily nutritional requirements**: assessment of all prescribed nutrients intake and relation with Recommended Daily Allowance (RDA).

During this initial approach, the Nutritionist will play an active role in order to develop a personalized dietary protocol for each User.

The final aim of DOREMI dietary protocol will be:

- the empowerment of **healthy dietary habits** through the acquisition of simple elements related to the new food pyramid for seniors, and the indications of dietary needs (the amount of Recommended Daily Allowance- RDA) expressed in terms of portion of healthy foods **depending on pathologies and status** (personalized recommendations).
- the evaluation of the impact of educational intervention on the dietary behaviour followed the subsequent 2 months of treatment ;
- the engagement of User through appropriate stimulation and **game-based motivations** which will support his **behavioural changes in the adherence to better lifestyle management protocols**;
- the evaluation of educational intervention (for improving eating and lifestyle behaviour in the Elderly) on marker related to nutritional status, metabolic and physiological functions plus cognitive/psychological functions;

- **the compliance to methodologies and results obtained to set improved ICT/technologies/ instrument calibrated for our Users.**

As far as the experimental protocol is concerned, the DOREMI dietary intervention plan will be divided into three phases plus a final evaluation phase (Figure 6).
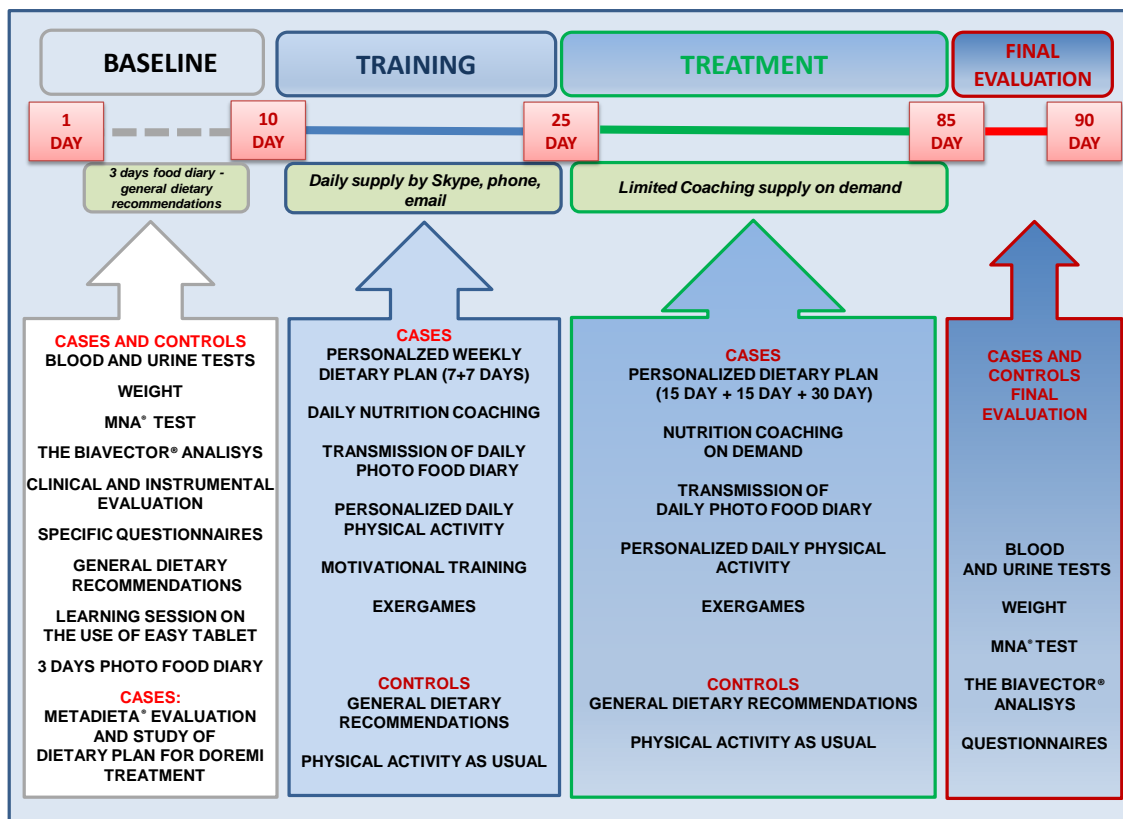

Figure 6. UDH: the DOREMI's interventional phases.

6.2.2 Baseline phase

Starting from the first day of baseline period, all Users (30 Participants and 10 Controls), will be:

- submitted to blood and urine tests (white and red blood cells count, glycaemia, total cholesterol, HDL, LDL, triglyceride levels, target vitamins and minerals);
- submitted to clinician and instrumental evaluation in order to define comorbidities;
- submitted to weight and height measurements;
- submitted to **MNA®** (18 questions www.mna-elderly.com),composed of an anthropometric assessment, a questionnaire about diet characteristics, food intake, fluids intake, weight loss, mobility, psychological stress or acute disease, drugs, presence of dementia or depression, global health and environment, and a self-evaluation of health and nutritional state (assessment) (D2.1 – §6.1). The result of the screening score and the assessment will help in identify malnutrition problems in the Users;
- submitted to Bioelectrical Impedance Vector Analysis BIVA®-, the complementary method for body-composition assessment–whole body, which is able to evaluate the hydration and body mass composition in any clinical condition, regardless of weight for providing a semi-quantitative assessment of body composition based on direct measurements (D2.1 – §6.1);

The nomogram **Biavector®** graphically will show the physiological state of a subject, allowing a quick check of the results. The nomogram is composed of three areas, defined ellipses of confidence (50%),

tolerance (75%) abnormalities (95%) and is able to highlight with excellent sensitivity and specificity of the real state of hydration in any clinical condition (D2.1 – §6.1);

- monitored in their eating behaviour and involved in the compilation of questionnaires developed to have a feedback on dietary habits including the distribution of meals during the day, the motivation to eat and its related sensations(e.g. appetite, satiety, fullness, discomfort, etc.) ;
- involved in the use of a food diary in order to evaluate actual food intake including a selection of food categories and cooking procedures and presenting notes on good practise for the selection of meals and the knowledge of sources to be introduced (calcium, iron, protein, characteristic of a good breakfast);
- involved in the compilation of questionnaires in order to evaluate the degree of comprehension of the nutritional training employed at the baseline time;
- involved in active trials to approach to the easy METADIETA technology, - in particular the Photo Diary –a simple smart technology calibrated for the targeted population and enabling the Nutritionist to receive a daily feedback on the effect of the DOREMI treatment (D2.1 – §7.3);

This application will be run for a 3 day period, in order to give the User simple instructions and train them to the use of the smart touch photo diary (Figure 7).

Figure 7. Representation of the METADIETA application with the remote connection with the Nutritionist.

As far as this step is concerned, in these 3 days all our Users from the database will:
- choose the reference meals;
- visualize foods' category;
- choose the foods' group;
- visualize foods in three different portions each;
- choose photo with the selected amount.

With the option "small" – "medium" – "large", they will be able to select the amount of food intake.

Due to the extreme flexibility of this database, it allows easily the entry of new foods, recipes and sources.

The selection of foods comes from official and certified sources, in particular by: Database of Food Composition for Epidemiological Studies in Italy (IEO), Atlas Reasoned Power Institute *Scotti Bassani* and in addition from the most important commercial nutritional labels.

The current database, fully printable, boasts over 4,000 foods/recipes and 114 bromatological components, including index and glycaemic load, ORAC (Oxygen Radical Absorbance Capacity) and PRAL (Potential Renal Acid Load).

As far as the visual quantity of portions is concerned, the system will display the approximate amount of the weight of each food, expressed in the suitable unit measurement joined to the nutritional and energy intake (Figures 8A, B, C).

The chemical analysis concerning nutrients and molecules of nutritional interest is specified at every step in order to help Nutritionist to set up the right balance of intake.

A

B

C
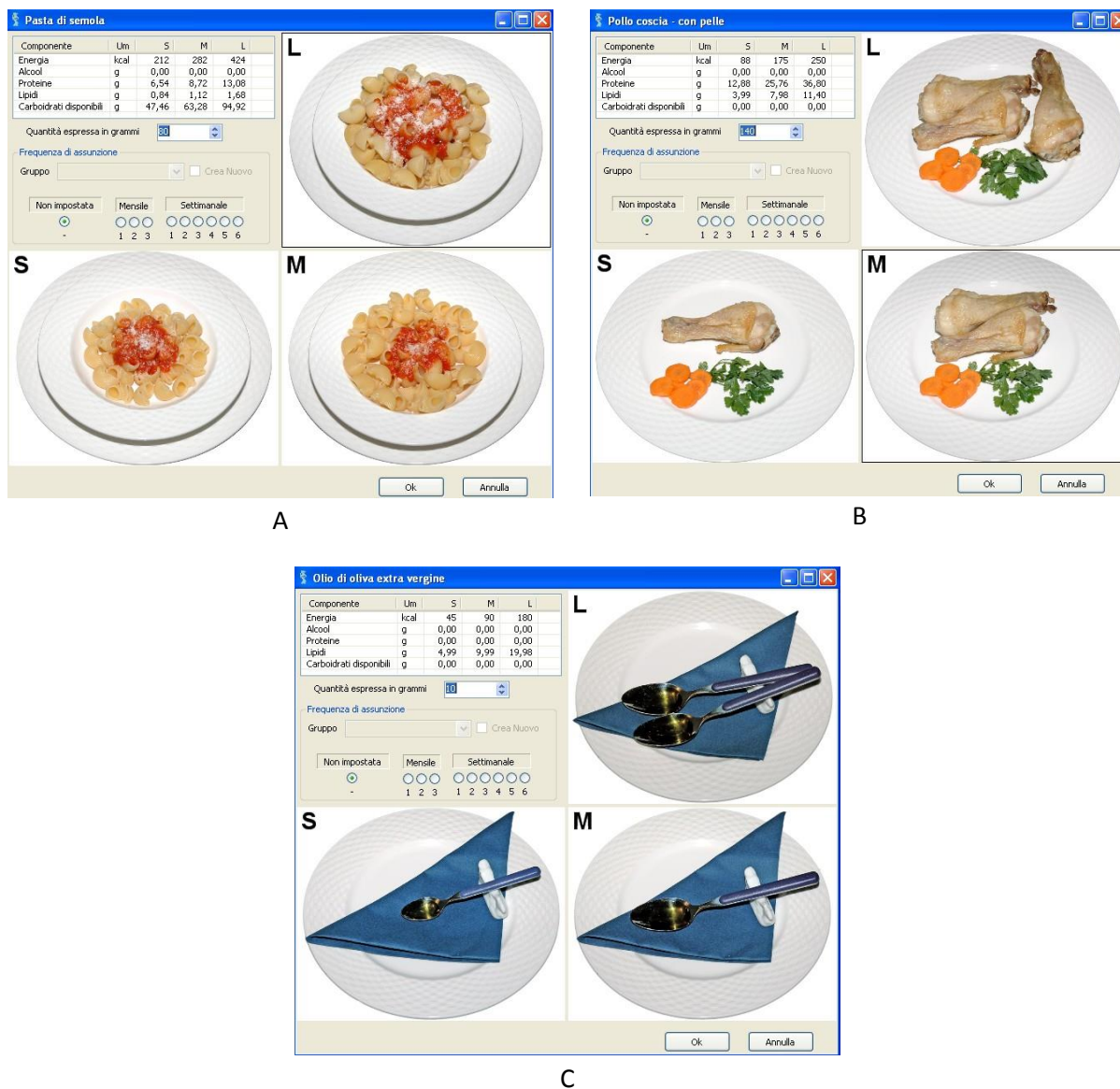
Figure 8. METADIETA photo diary: (A) "pasta" food in the three size "small" – "medium" – "large"; (B) "chicken" food in the three size "small" – "medium" – "large"; (C) oil portions.

As far as the development of the dietary strategy is concerned, the whole group of **Participants** and **Controls** will be:
- involved in learning sessions regarding basic elements of General Dietary Recommendations. Streamlined communications of the European general guidelines for a healthy diet according to the **NU-AGE** project, will be communicated to all groups by our Nutritionists.
- involved in the understanding of nutrition labels, logos or nutrient content in order to improve their familiarity to these tools that could help healthy food choices (in connection with **FLABEL** www.flabel.eu)

BASELINE activities of PARTICIPANTS
Starting from the day 5, the group of **Participants**, will be:
- involved in the METADIETA Interactive Education Programme.

The User will be interviewed directly by the Nutritionist for the initial sitting of detection that METADIETA software organizes through the outlined passages *(§The METADIETA Interactive Education Programme: steps and details).* Using the specific software, the Nutritionist will formulate a personalized diet to be used in the DOREMI treatment.

BASELINE activities of CONTROLS
Starting from the day 5, the Control Group will continue to follow the general dietary habits and to have physical activity as usual.

6.2.4 Training phase

Training activities of PARTICIPANTS
Participants will:
- receive **a personalized 2 week dietary plan**;
- *the dietary plan covering of 15 days divided into two weekly plan each (7+7), will report several choices for meals planning according to the personalized diet through METADIETA. The Cases will be able to choose freely the kind of meals they like in the respect of the food categories (breakfast, lunch, dinner, snack).*
- transmit **a daily photo food diary** to the Nutritionist on remote by METADIETA system;
  Users will transmit a daily photo diary, where they have registered the quality and the amount of foods consumed through the selection of the graphical portions (small, medium, large);
- receive **a daily nutritional coaching** in order to control, evaluate and check the adequacy with the recommended plan. The same control will involve weight control by the targeted bed carpet;
  Users will receive a daily nutritional coaching (mail, tablet, Skype, smart phone) in order to check choices and correct them.
- receive a personalized Physical Activity;
- receive a motivational Training;
- start the use of Serious Games familiarizing with the Avatar.

Training activities of CONTROLS
Controls will:
- follow general dietary recommendation without personalisation, smart photo diary, coaching;
- follow Physical Activity as usual without personalisation and coaching.

6.2.5 Treatment phase

Treatment activities of PARTICIPANTS
Participants will:
- receive **a personalized dietary plan;**
  *t**he dietary plan covering a total of 60 day, will report several choices for meals planning they like in the respect of the food categories (breakfast, lunch, dinner, snack).It will be divided in 3 separated and personalized plans: 15 days + 15 days + 30 days.*
- transmit **a daily photo food diary** to the Nutritionist on remote without having feedback;
  Users will transmit a daily photo diary, responding to the quality of foods and the amount of the graphical portions (small, medium, large);
- receive **nutritional coaching on demand** in order to solve possible problems.
- weight will be recorded through the bed carpet;
- receive a personalized Physical Activity;

- receive a motivational support if needed;
- empower by the Serious Game, daily interfaced with the Avatar.

Treatment activities of CONTROLS
Controls will:
- follow general dietary recommendation without personalisation, smart photo diary, coaching;
- follow Physical Activity as usual without personalisation and coaching.

6.2.6 Final Evaluation phase

At the end of the treatment phase,
Participants and Controls will be involved in the final evaluation of 5 days - and submitted to:
- Blood and Urine tests as final measurements;
- Final weight and BMI;
- MNA® Test;
- BIAVECTOR analysis;
- Specific questionnaires including assessment of the compliance to the DOREMI diet protocol

6.3 Cognitive Decline

6.3.1 Introduction

From around the age of 30, due to a process called "apoptosis", standing for "programmed cell death", neurons start collapsing or dying. Furthermore, a reduction of synapses is reported, accompanied by some interactions of brain structures, leading to the appearance of neuritic plaques and neurofibrillary tangles.

The first consequence of apoptosis is the progressive decrease of brain weight (up to 10% between 30 and 75 years) and loss up to 20% of the blood supply.

With the gradual advancement of age, especially from the age of seventy on, people may have more difficulties in retrieving information that are usually easy to recall, as well as in saving new data and focusing their attention [38]. In addition to memory and concentration functions, the person may lose interest and initiative, and have problems in organizing actions. They also present less capacity of abstract thinking and less plasticity in problem solving activities. The decline of these skills, within certain limits, can be considered physiological. A subtle but consistent decline in general cognition can be considered normal age-related cognitive decline [39]. The stage between normal age related cognitive impairment and severe neurological disorders such as dementia is mild cognitive impairment (MCI). Mild cognitive impairment is characterised by impairments in any cognitive domain which are greater than expected for the individual's age and education level, but that are not severe enough to warrant a diagnosis of a dementia [12]. Typically, impairments in memory will be present, however the person will experience minimal functional decline or decline in other areas of cognition. Although some people with MCI remain stable or remit, over 50% progress to dementia within 5 years [40]. For this reason, there is a focus on implementing prevention programs that can delay or reverse decline before mild impairments become severe enough to warrant a diagnosis of dementia.

Research has suggested that although cognition declines with age, the brain retains some plasticity [11-13] which supports the rationale for cognitive training as an intervention in this population. Memory Clinics are deployed in medical sectors in order to attend to people with MCI who have problems with memory that are not severe enough to warrant a dementia diagnosis, however recently, cognitive training interventions have been proposed as a cost effective solution for delaying cognitive decline [41].

The studies reported in the previous sections illustrate how physical exercise, along with a healthy diet and social relations can also positively influence the maintenance of the cognitive functions in healthy people.

In order to evaluate the cognitive decline protocol, a preliminary evaluation of the subjects eligible to participate will be carried out at baseline and later compared with the final evaluation following the training component of the DOREMI study.

The user population will initially be selected according to certain requirements, already detailed within D2.1 - §7.1, Only the subjects complying with these criteria are admitted to the first test phase, which consists of the MMSE administration. At the baseline, users will be submitted to other cognitive tests, listed below.

The DOREMI cognitive protocol is based on the rationale that the brain retains plasticity, or a capacity for physical and functional change as it ages [42]. It follows from this assumption that the simulation of activities through cognitive training games allows the user to activate skills and abilities that might be/have been wasted during ageing, due to lack of use. In addition to reactivation of lost skills and abilities, the user will learn new information connected to the positive effects of physical activity and correct nutritional habits.

Games are conceived and developed according to the cognitive functions that are investigated through the tests used within the DOREMI project. These functions can be summarized in 7 dimensions of abilities:

Memory	Language	Attention	Calculation	Orienteering	Visual and spatial intelligence	Praxis
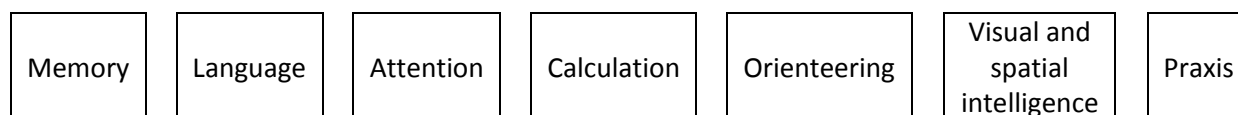
Games can affect the user in more than one dimension, for example a game stimulating memory can influence also problem solving skills and vice versa. Indeed, cognitive functions are not stand alone items working independently from each other, they are instead a correlated system. It is hypothesised that in addition to improvements in specific areas of cognitive functioning trained by the games in DOREMI, that there will be an improvement in global cognitive functioning as indicated by the MMSE.

As already highlighted in D2.1, the motivation level shown by participants plays an important role, with respect to the games use and perseverance of use. Games should be engaging, and designed with the preferences and abilities of the older user in mind.

It's also important to take into account that scores achieved within the games do not represent the value of the subject's cognitive skills, they instead are the indicator of the evolution of cognitive functions during the protocol. Evaluation is based on the chosen cognitive tests.

Scores achieved within the games can be useful to analyse on-going outcomes and better monitor the user's evolution.

The DOREMI cognitive protocol will be divided in the following interventional phases (Figure 9).
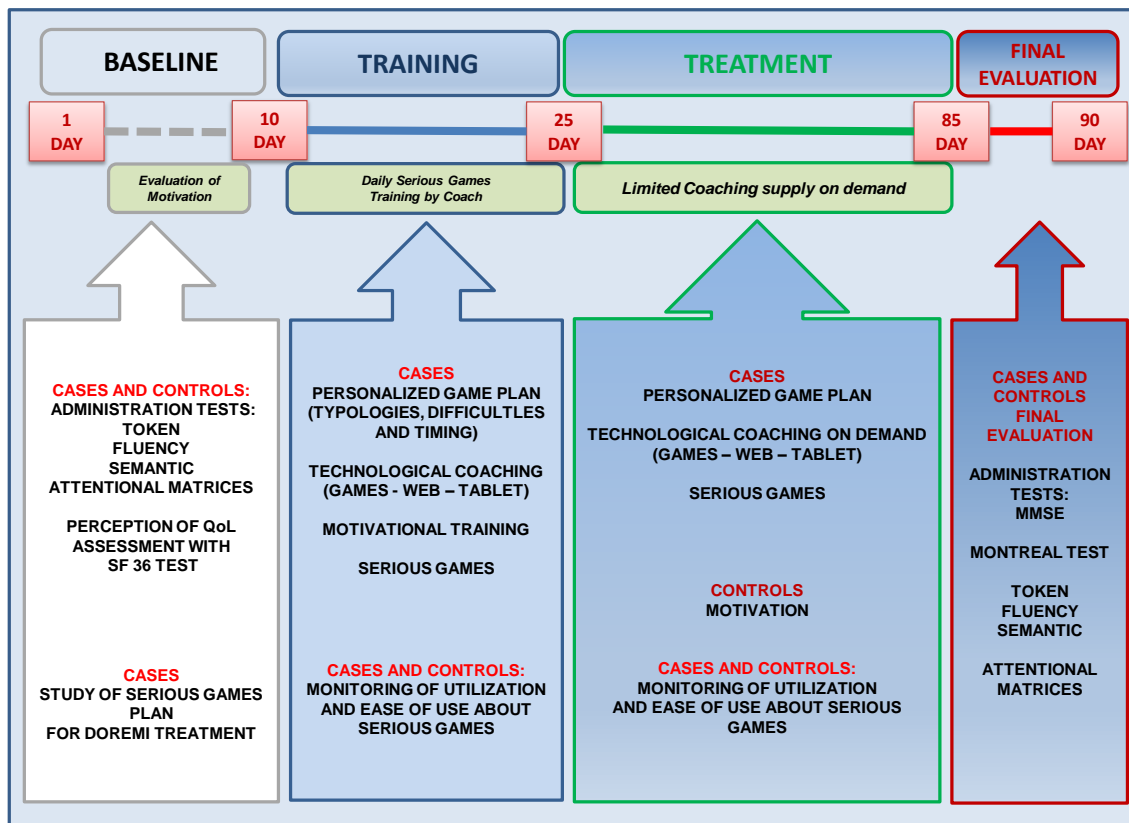
Figure 9. Cognitive protocol interventional phases.

The first phase (baseline, from day 1 to day 10) consists of the administration of cognitive tests, together with the SF36 questionnaire, which refers to the perception of quality of life. Tests will be systematically conducted at home, one by one.

No particular order is needed as far as the different tests administration is concerned although all participants will receive the tests in the same order for continuity purposes Accordingly, no strict time schedule is forecast for this first phase, depending also on availability of participants.

The delivery of tests will follow a strict protocol with the same instructions delivered to each participant. Persons delivering the tests will be familiar with their delivery and the same procedures for test administration will be followed in Italy and the UK. Indeed the elderly tend to get anxious during interviews because they feel they can be judged: for example, in the subject's perspective, high values of blood pressure are perceived differently from low scores in maths/memory tests, highlighting their level of cleverness or readiness.

Moreover, for these reasons, these kinds of tests involve several personal aspects of the person (not clinical data, but regarding personal functionalities), it's essential that the elderly get a feedback regarding the results: they will be provided with the tests' outcomes during the following training phase. At the meantime these data will be uploaded within the DOREMI personal database.

6.3.2 Baseline phase

From day **1 to day 7** the whole group of Elderly (30 PARTICIPANTS + 10 CONTROLS), will be submitted to the following tests:
- Token test
- Phonemic Fluency
- Semantic fluency
- Attentional matrices

- Digit span
- Montreal cognitive assessment
- Reaction time task
- SF36 (see §8.2.1 and 8.2.3)

From **day 7 to day 10** the data collected during the interviews will be studied and evaluated. This period of time will also be used to administrate further tests in case participants were not able to attend in the previous week, due to different reasons.

Once data will have been analysed, a personalized game plan (including a particular selection of games) will be elaborated, according to the outcomes and specific impairments of each subject.

Personalized game plan

Following the cognitive tests, the analysis of the outcomes will allow to get one level of data interpretation:

The global vision, deriving from the score achieved within all the tests administered, thus identifying the distribution of subjects in 3 functioning classes:

- "A" high cognitive functioning
- "B" medium cognitive functioning
- "C" low cognitive functioning

Specifications:

Subjects will be distributed in three functional classes, useful to define the starting level and consequently the complexity of the games to propose.

Since each cognitive test is based on a different score range, (for example, MMSE 0-30, whereas Token 0-36), it is necessary to create through statistics a homogeneous score range to get a global outcome defined through a percentage. It can be exemplified in Table 10:

Test	Range	Class A	Class B	Class C
MMSE	0/30	27-30	24-26	22-23
Token	0/36	33-36	30-32	24-29
Attentive matrices	0/60	≥50	42-49	≤42
Phonemic fluency	0/32+	≥32	25-31	≤24
Semantic fluency	0/37+	≥36	31-35	≤30
Digit Span	0/110	≥80	79-33	≤32

Table 10. Score range and score distribution.

The specific class (A, B or C) in which each participant is ranked, depends on the lowest score he/she achieves in any of the proposed tests.

In order to standardize each single test's level and reclassify them altogether, a validated study was used, covering an elderly population aged between 60 and 85 years. This study is based on a standardized research on FLSA test (Functional Living Skills Assessment), aimed at correlating different tests, among which those used in the DOREMI project (MMSE, Token Test, attentional matrices, Phonemic fluency, Semantic fluency, Digit span); it is now being printed by the publishing house Hogrefe. This research involved a target group composed of 541 subjects, included 79 as control group. Answers were analysed and placed in a percentile scale, entering in the first percentile scores lower than the cut off value, and in the last percentile values overcoming the maximum score threshold.

Population was thus distributed in 3 classes, according to the score achieved by subjects in those tests.

As illustrated in Table 11, on the whole, Class "A" includes a range between 12,5 and 25%, Class "B" includes a range between 34,8 and 42%, class "C" between 39,3 and 48%.

The difference between the score distribution outlined in MMSE, class "A" (16%) compared to the one related to phonemic and semantic fluencies, class "A" (25%), (23%) is due to the fact that normally elderly with a good cognitive level have fewer difficulties in fluency tests, in which they might achieve a score averagely 25% higher than MMSE and TOKEN. Conversely, in these latter tests scores outlining a high functioning represent 15% of the total. The other 2 classes, "B" and "C" show a gap of 7/8 raw scores.

Test	Class A	Class B	Class C	Tot test
MMSE	16%	42%	42%	541
Token	12,5%	39,4%	48,1%	520
Attentive matrices	17,5%	36%	46,5%	325
Phonemic fluency	25,2%	35,5%	39,3%	541
Semantic fluency	23,5%	34,8%	41,7%	541
RANGE %	12,5%-25%	34,8%-42%	39,3%-48%	

Table 11. Population class distribution.

The 3 classes are linked to 3 different complexity levels of the serious games that will be included in the DOREMI protocol. A corresponds to the highest complexity level, B to medium level, C to the lowest level.

This preliminary distribution permits to identify the entry level of each participant.

6.3.3 Training phase

Before presenting the game plan, tailored on the specific user profile, the training phase will be devoted to illustrate to participants the use of the tablet, related to cognitive games, in order to make them familiar with the device and get to know the different scenarios available.

The staff will also monitor and strengthen the capacity of each participant to handle electronic devices, assessing at the same time their willingness and motivation to actively participate to the project.

Subjects will be shown the whole range of serious games, at the easiest level available. The reason is that at this stage the main goal is not the cognitive stimulation, but the education on how to use and browse the platform.

During the last training days, participants will be provided with their personalised games library, highlighting the frequency of use (how often, how many games they should play).

The staff member will always be present every day in a prearranged time frame, and will provide support to the user, especially for clarifying possible doubts and motivating him/her to play.

From day **11 to day 18** participants will be involved in exploring the different scenarios (valid for all the 3 protocols) and the whole range of serious games created for the DOREMI cognitive protocol. Games' instructions will also be provided.

From day **19 to day 25** participants will be trained directly on games, stimulating the experience of different playing dimensions:

- Free play
- Cooperation: the subject will be involved to play with other elderly participating to the project
- Competitiveness: the subject will play versus the staff member

- Play on his own: the subject will choose whether to play with or against a third person (friend, family member, neighbour)

Finally, interview with the user is foreseen, in order to highlight problems, questions and clarifications about the use of the device.

6.3.4 Treatment phase

Started from day 26, **PARTICIPANTS** will be requested to follow the DOREMI Cognitive Protocol every day within the timeframe necessary to carry out and complete the daily tasks (to be decided in the next days, depending on the number of proposed games). Indicatively, no strict rules are previewed concerning the timeframe; the only requirement is the task completion day by day.

Regarding the games library, users will follow their specific game plan, as explained in the previous paragraph. Users are supposed to play autonomously, possibly deciding whether to involve other participants (cooperation/competition). The presence of the staff member will be assured every 2 weeks for support. The only exceptions will be due to one of these conditions: if requested by the subject, bad functioning of the device, reiterated failure in the tasks completion.

Distance monitoring and collection of data will be constantly assured by the software developed by DOREMI.

During the first 3 days of the treatment phase, the approach to games will be gradual, whereas from the fourth day on, the proper Cognitive protocol will start.

- The first approach to games is free, in order to newly enhance familiarization with the platform.
- Provision of the range of games, with a complexity level complying with the functional class defined though the overall score of the cognitive tests, A, B or C.
- Complexity levels will be attuned with the score achieved on the previous day

6.3.5 Final evaluation phase

During the final evaluation (day 86 - day 90) playing will be suspended, as this period will be devoted to tests administration and evaluation.

6.4 Games, Motivation and Social interaction environment

6.4.1 Introduction

Figure 10 describe the reference model that we want to test during the trial activity of DOREMI project: a pre-selected group of 40 older people that address the inclusion criteria described in this report, and with given characteristics described in box (A) box of the model in Figure 10, will be exposed during a period of 90 days to the DOREMI gamified environment and monitored with home based sensors and portable tools (e.g. bracelet).

Looking at the figure, the gamified environment will consist of 4 components:

- The **exergame.** It is a score based system to register the progresses that each participant to the trial does in addressing physical exercises stimulations. The scoring system will be continuously updated thanks to the data registered with the set of wearable and environmental sensors and thus the fulfilment of suggested physical exercises. The score achieved by an individual can be compared with those of the other participants in a sort of game competition that in the hypotheses of the project it should be able to stimulate better social interactions and healthier profile of the ageing persons.
- The **diet recommendations application (a third party software application embedded in the game environment)**.

- The **cognitive games** aims at stimulating mental exercises for the aged person and, in case of social cognitive games, they also help in promoting social interactions.
- The **social games** consists in the social web portal for the older people which contains all the games described above and it is structured for supporting and stimulating social interactions with the other participants to the trials, friends, familiars and carers constituting the Web 2.0 "ecosystems" around the aged person.

Main research questions underpinning DOREMI project that we want to test with the reference model presented in Figure 10 are the following:

- Has the use of the gamified environment causality relations with the psycho-physical and clinical profile of the patients?
- Has the use of the gamified environment causality relation with the perception of participants' loneliness status and their perception of health and well-being status?
- Does the use of the gamified environment allow to stimulate the social interactions (virtual and physical) amongst older people? and,
- Have the social interactions (virtual and physical) causality relations (as mediators) with the psycho-physical and clinical profile of the patients and with the perception of patients' loneliness status and their perception of health and well-being status (all together considered as outcomes –KPI- of the project)?

Secondary research questions are:

- Does the gamified environment produce behavioural changes in the self-care management of older people?
- Does the gamified environment produce a change in the perception of a social support of older people?
- To what extent do the behavioural changes (box C in Figure 10) and the changes in perception of social support (box D in Figure 10) influence the final outcomes (box F in Figure 10) of the project?
- To what extent are the intermediate outcomes (box C, D and E in Figure 10) are mutually influenced?
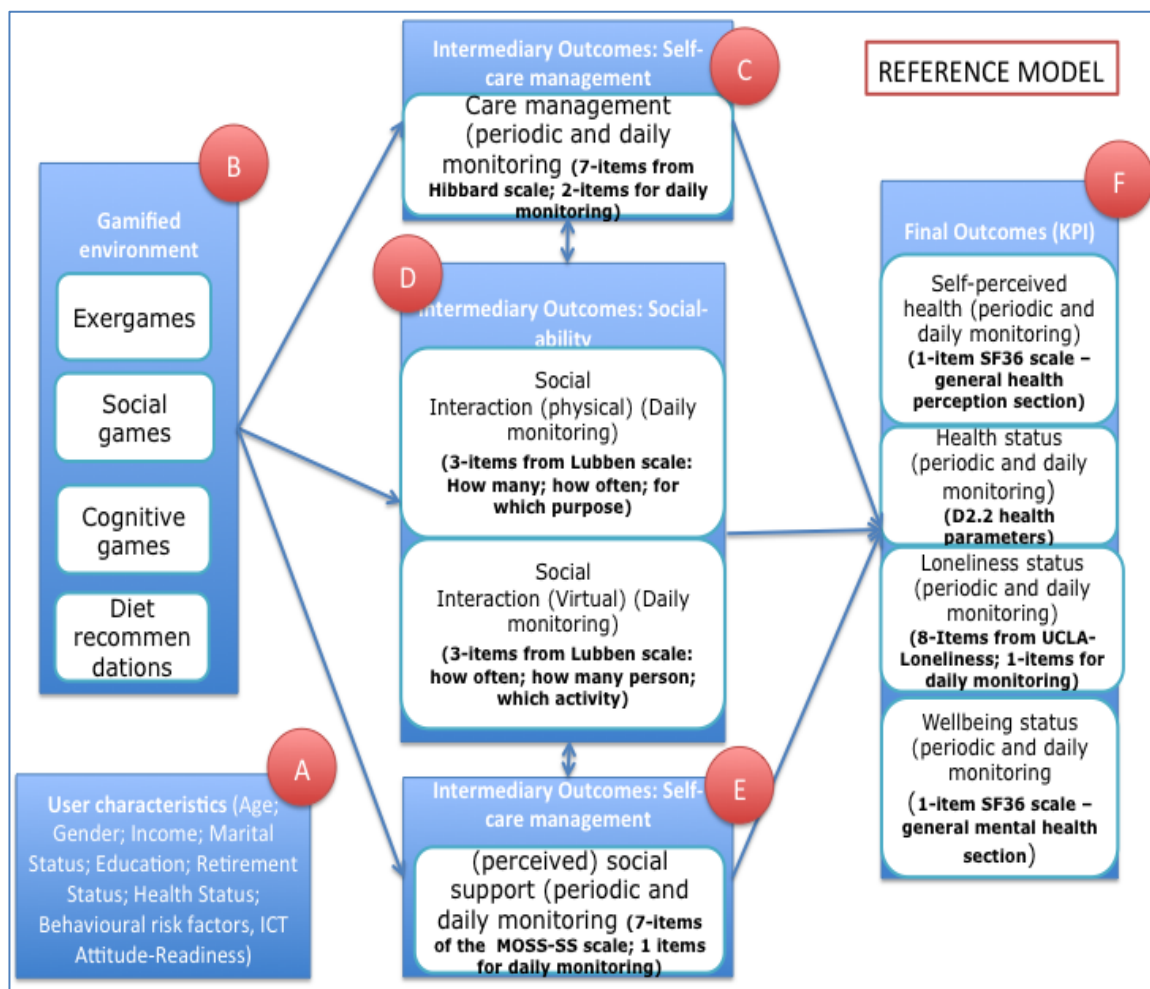
Figure 10. DOREMI reference model.

To this end we plan to organize a pilot test with 40 individuals (30 involved in the trial and 10 controls). The test plan will be detailed in D2.3 where we will describe how the set variables, metrics and scales described in the following Table 12 will be monitored and analysed. However, in this document (§5.2.3 and in § 6.4.3) we provide a preliminary description of the measurement scales that we selected to collect information during the trials activity.

6.4.1 Operationalization of the social interaction measurement during the trial period

Starting from the DOREMI reference model described above and the scale and metrics described in D2.1 and in this deliverable (see §5.2.3 and §6.4.3), in this paragraph we provide an explanation on how to operationalize the social interaction measurement during the DOREMI trial period.
To this end we consider the divided in three stages:

- Beginning of the trial where we need to measure the "as is" social behaviour of each individual participating to the trial in respect to his/her social interaction (we call this initial period as "baseline");
- Trial activity where the participants interact with DOREMI system and we collect daily information by using the DOREMI platform functionalities. As already described this period is divided in two parts:
  - The training period of the trial's participants in using the DOREMI platform functionalities related to social interaction measurement;

- o The treatment period where trial's participants are left free to interact with the DOREMI system and social interaction data are collected in an automatic manner from the DOREMI platform itself as described below.
- End of the trial where we need to measure the final social behaviour of each individual exposed to the DOREMI solution during the treatment period.

In the following tables we describe which information we plan to collect during the three periods and how the social interaction measurement will be operationalized.

Table 12 lists the variables that we propose to monitor at the beginning (baseline) and at the end of the trials activity with the 40 individuals for a period of 90 days.

While Table 13 represents a sub-set of variables, scale and metrics that have to be measured on a daily base. They are derived from the selected scales and metrics and their implementation will be done by using the DOREMI platform that will be described in the deliverables related to WP5.

Set of Variables	Description	Scales	Data collection timeing
(C) – intermediary outcomes	Self care management	A simplifies version of the 21-items Hibbard scale	To be measured at the beginning and at the end of the Trial activity
(E) – Outcomes/KPI	(perceived) Social support	A simplified version of 19-items MOS-SS scale	To be measured at the beginning and at the end of the Trial activity
(F2) – Outcomes/KPI	Monitored Health status	See related section in D.2.2	See related section in D2.2
(F3) – Outcomes/KPI	Perceived Loneliness	A simplified version of the 20-items UCLA Loneliness scale	To be measured at the beginning and at the end of the Trial activity

Table 12. Variables, metrics and scales to be measured in an interim stage and at the end of the trials activities

Set of Variables	Description	What	Source of data
(C) – intermediary outcomes	Self care management	1-item of the Hibbard scale	• Item 3 – score of Doremi exergame • Item 3 – score based on METADIETA tool interaction
(D1) – intermediary outcomes	Social Inclusion (Physical)	• How many persons • Who (parents/friends, trial participants; carers, others) • For what (physical exercise; pleasure; other)	Home's sensors; bracelet
(D2) – intermediary outcomes	Social Inclusion (Virtual)	• How many persons • Who (Parents/friends, others) • For what (social interaction; gaming;, other)	logs
(E) – Outcomes/KPI	(perceived) Social support	1-item for (perceived) social support derived from MOS-SS scale	Daily pop up with a visual scale
(F1) – Outcomes/KPI	Perceived Health status	1-item SF36 scale	Daily pop up with a visual scale
(F2) – Outcomes/KPI	Monitored Health status	D2.2 health related data	bracelet
(F3) – Outcomes/KPI	Perceived Loneliness	1-items UCLA Loneliness scale	Daily pop up with a visual scale
(F4) – Outcomes/KPI	Perceived wellbeing	1-item SF36 scale	Daily pop up with a visual scale

Table 13 Variables, metrics and scales to be measured on a daily bases during the trials activities.

Trial's Baseline and Trial's end Monitoring

As described in Table 12 the following variables of the DOREMI reference model will be monitored at the baseline and at the trial's end: degree of self-care management; degree of (perceived) social

support; degree of perceived loneliness and the health status of the trials' participants. While the latter variable has been already described in previous chapters both in terms of parameters to be collected and in term of data collection procedures, the other three are based on 3 different scales already discussed in D2.1 or reported in the following §6.2.3.

However, to make them applicable to the social evaluation of DOREMI trial we opt for their simplified versions proposed below:

- for the evaluation of the **degree of self-care management** we select from the Hibbart scale (see §6.4.3.2):
  - 4 items that have to be asked at both the baseline and at the end of the trials: item 1; item 2; item 3; item 7; and
  - 3 items that have to be asked only at the end of the trial: item 16; item 17; item 18.
- for the evaluation of the **degree of (perceived) social support** we select from the MOS-SS scale (see §6.4.3.5):
  - 7 items that have to be asked at both the baseline and at the end of the trials: Item 1; item 2; item 3; item 4; item 5; item 7; item 8.
- for the evaluation of the **degree of perceived loneliness** we select from the UCLA scale (see §6.4.3.7):
  - 8 items that have to be asked at both the baseline and at the end of the trials: Item 1; item 2; item 4; item 5; item 10; item 14; item 16; item 18.

Daily Monitoring

As already anticipated, Table 13 described the variables that will be daily monitored during the trial's activity. For daily monitoring purposes their metrics have been simplified, staring from the initial scales (see D2.1 and §6.2.3) to allow as much as possible the automatic data collection with sensors, cameras, logs, portable devices (e.g. the bracelet), scores of the games constituting the gamified environment of DOREMI project and limiting at the minimum the interaction with the trial's participants.

To this end we propose a daily monitoring of **8 variables of 1-item each** derived from a simplified version of the proposed social scales discussed above and reported in §6.2.3. In particular we suggest to daily monitor (see Table 13):

- 1-item each (derived from the related scales as reported in Table 13) for the following 4 variables: degree of **(perceived) social support**, degree of **perceived health status**, degree of **perceived loneliness** and degree of **perceived well being variables**. As described below, the items will be presented to the trial's participants with a visual scales showed with **daily pop-ups at the end of the day on trial's participants' lap top screen/tablet or/end smartphone**;
- the degree of **self care management** with 1-item, derived from the related scale (see table 3) which measure will be based on the daily score get from the trial's participants by using the functionalities of both the DOREMI exergame and the METADIETA tool.
- the degree of **social inclusion (physical)** on the bases of the automated registration of the persons to whom each trial's participants interacts during the day. This will be done by means of the bracelet provided to the individuals participating to the trial and with the DOREMI home sensors environment settled up during the trial implementation, A detailed version of the technical implementation of the monitoring of this variables will be presented in the D5.1;
- the degree **social inclusion (virtual)** on the based on the logs registering the persons with whom each trial's participant interacts. A detailed version of the technical implementation of the monitoring of this variables will be presented in the D5.1;

In the following we provide an explanation of each of the 8 variables that will be daily monitored during the trial's activity:

- **Self care management**. We propose to monitor the **Item 3** of the Hibbard scale ("*how much do you know about the lifestyle changes like diet and exercise, that are recommended for your condition?"*). The **variables could have two daily values**: the **daily score achieved** by the aged person **in the exergames** and **the daily score achieved** by the aged person **in the diet recommendations**. These variables will not have a daily pop-up, but its daily value will be automatically registered by the DOREMI system.

- **(perceived) Social support**. We propose **1-item scale derived from the MOS-SS scale**, selected from the following three: "*how often today there was someone available to:…."* 1. "*help you*"; 2. "*have a good time to*"; 3. "*to love and make you feel wanted*"). Each of them should be monitored with a visual scale (see example in §8.2). *?"*.. The selected item will be monitored with a visual scale (see example in §8.2). The item and the visual scale will be finalised in D2.3.

- **Perceived Loneliness**. We propose **1-item scale derived from the UCLA Loneliness scale** and already proposed by Gilmour [43] selected from the following three: 1. "*That you lack of companionship today?"*; 2. "*Left out Today?"*; "3. *Isolated from the others Today?"*.. The selected item will be monitored with a visual scale (see example in §8.2). The item and the visual scale will be finalized in D2.3.

For statistical validation purposes, after two and four months of the trials activities and per each individual participating to the trials, the average values of the three variables listed in the bullets above will be calculated and compared with the ones measured with the full scales (see Table 12) at the baseline and at the end of the trials.

Two other variables require daily pop-up and a visual scale for daily collection of their vales from the trials' participants. In both cases the variables, the scale and the metrics are constitute by 1-item and therefore they will be monitored on a daily base only. They are:

- **Perceived health status.** Is monitored with 1-item of the SF36 scale[1] (see §8.2.1)("***Today my health is excellent"* - *Definitely True; Mostly True; Don't know; Mostly False; Definitely False)*** It should be monitored with a visual scale (see example in §8.2.1). The visual scale will be finalised in D2.3.

- **Perceived well being.** Is monitored with 1-item of the SF36 scale[2] (see §8.2.3) **("*Today I feel so down in the dumps that nothing could cheer me up"* - *All the time; Most of the time; A good bit of the time; Some of the time; A little of the time; None of the time*).** It should be monitored with a visual scale (see example in §8.2.3). The visual scale will be finalized in D2.3

Finally, social inclusion variables should be daily monitored as follows:

- **Social inclusion (physical).** We propose to monitor 3 items:
    - "*how many persons does the trials' participant meet*?" (number)
    - "*Who does the trials' participant meet*" (family/friends, trial participants, carers, others)
    - "for what does the trials' participant meet the persons (physical exercise; pleasure; others).

    In the home environment the values should be recorded with home sensors, cameras and the bracelet provided to the trials' participants.

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[1] Alternatively we could use item 1 and item 2 of SF36.
[2] Alternatively we could use item 9 of SF36.

Outside of the home environment the values should be recorded with the bracelet[3].

- **Social inclusion (virtual).** We propose to monitor 3 items:
  - "*how many persons does the trials' participant meet*?" (number)
  - "*Who does the trials' participant meet*" (Parents/friends; others)
  - "for what does the trials' participant meet the persons (social interaction; gaming; others).

The values should be recorded with the logs[4].

6.4.3 Selected scales details

6.4.3.1 ICT Attitude-readiness Scale

Current approaches to measuring people's everyday usage of technology-based media and other computer-related activities have proved to be problematic as they use varied outcome measures, fail to measure behaviour in a broad range of technology-related domains and do not take into account recently developed types of technology including smartphones. After a literature review we propose to use the following metrics [11]. Table 14 will allow to assess the attitude in using new media, It is based upon 11 usage subscales representing smartphone usage, general social media usage, Internet searching, e-mailing, media sharing, text messaging, video gaming, online friendships, Facebook friendships, phone calling, and watching television in addition to four attitude-based subscales: positive attitudes, negative attitudes, technological anxiety/dependence, and attitudes toward task-switching.

Given the reliability and validity results obtained in their practical use in trial, the proposed Media and Technology Usage and Attitudes Scale is suggested as a method of measuring media and technology involvement across a variety of types of research studies, and therefore we plan to customize it for the scope of DOREMI project.

Media	metrics
1. smartphone use	
2. general facebook use	
3. internet searching	
4. e-mailing	
5. media sharing	
6. text messaging	Likert scale (1 few; 2; 3; 4 average; 5; 6; 7 a lot)
7. video gaming	
8. online friendship	
9. facebook friendship	
10. phone calling	
11. television viewing	
When I use ……. I feel ….	
1. Positive	
2. Anxiety and dependence	One choice per each media used
3. Negative	
4. I have any feel	

Table 14. Media use scale.

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[3] Technical partners should provide indication of the feasibility of the proposed solution.

[4] Technical partners should provide indication of the feasibility of the proposed solution and of possible alternative ways to get the measures.

6.4.3.2 Self-Care Management Scale

Even though patient engagement is a central concept in health care approach and the chronic illness care models, it remains conceptually and empirically underdeveloped. There has been a lack of conceptual clarity regarding the meaning of ''engaging patients'' and thus a lack of adequate measurement. There are a number of existing methods for assessing different aspects of engagement, such as health locus of control [44], self-efficacy in self-managing behaviours [45], and readiness to change health-related behaviours [46,47], but these measures tend to focus on the prediction of a single behaviour. Moreover, there is no existing measure that includes the broad range of elements involved in activation, including the knowledge, skills, beliefs, and behaviours that a patient needs to manage a chronic illness.

For the scope of DOREMI project we propose the Hibbard et al. [48,49] metrics (Table 15) that are grounded in rigorous conceptualization and appropriate psychometric methods [48,50].

21-Items for engagement measurement in health related behaviour	Metrics
1. How much do you know about why you are supported to take each of your prescribed medicines?	Likert scale (1 few; 2; 3; 4 average; 5; 6; 7 a lot)
2. Taking an active role in my own care is the most important factor in determining my health and ability to function.	
3. How much do you know about the lifestyle changes, like diet and exercise, that are recommended for your condition?	
4. How much do you know about the nature and the cause of your health condition(s)?	
5. How confident are you that can tell your health care provider concerns you have even when he/she does not ask?	
6. How much do you know about how to prevent further problems with your condition?	
7. Even if I make the change in diet and exercise recommended for my condition, it won't make any difference in my health.	
8. How much do you know about self-treatment approaches for your conditions?	
9. How much do you know about the medical treatment options available for your conditions?	
10. How confident are you that you can find trustworthy sources of information about your health conditions and your heath choices?	
11. How confident are you that you can follow through on medical treatments you need to do at home?	
12. How confident are you that you can identify when it is necessary to get medical care and wen you can handle the problem yourself?	
13. How confident are you that you can take actions that will help prevent or minimize some symptoms or problems associated with your condition?	
14. How confident are you that you can follow through on medical recommendations your health care provider makes such as changing your diet or doing regular exercise?	
15. To what extent are you able to handle symptoms on your own at home?	
16. How well have you been able to maintain these lifestyle changes?	
17. To what extent have you made the changes in your lifestyle like diet and exercise, that are recommended for your conditions?	
18. Maintaining the lifestyle changes that have been recommended for my conditions is too hard to do on a daily basis.	
19. Even if I'm dissatisfied, it is usually too much of a hassle to change health care providers.	
20. How confident are you that you can figure out solutions when new situations or problems arise with your condition?	
21. How confident are you that you can keep the symptoms of your disease from interfering with the things you what to do?	

Table 15. Self-Care management Scale.

6.4.3.3 Social Inclusion (Physical) Scale

The concept of social isolation has been defined in various ways in academic literature. Many authors agree that it is a uni-dimensional concept referring to the lack of social integration [51-54]. However, this assumes that all social contacts have the same social value or importance [54]. Alternate definitions of social isolation incorporate both 'structural' and 'functional' social support [55,56]. Structural social support is an objective assessment of size and frequency, while functional social support is a subjective judgement of the quality or perceived value of emotional, instrumental and informational support provided by others [57]. The second definition of social isolation is therefore multi-dimensional, including both the minimal quantity and quality of social support. We adopted the latter definition for DOREMI purposes. While social isolation concerns the lack of structural and

functional social support, loneliness (described as an outcome in our study, see §1.1.7) relates specifically to one's negative feelings about that situation →[58]. Expanding the distinction further, while social isolation may be either voluntary or involuntary, loneliness is always involuntary [52,59]. To measure social integration we propose the 18-items Social Network Scale proposed by Lubben and Girionda [60] and described in the following Table 16 and Table 17.

LUBBEN SOCIAL NETWORK SCALE – 18 (LSNS-18)

FAMILY: *Considering the people to whom you are related by birth, marriage, adoption, etc…*

1. How many relatives do you see or hear from at least once a month?
   0 = *none*   1 = *one*   2 = *two*   3 = *three or four*   4 = *five thru eight*   5 = *nine or more*

2. How often do you see or hear from relative with whom you have the most contact?
   0 = *less than monthly*   1 = *monthly*   2 = *few times a month*   3 = *weekly*   4 = *few times a week*
   5 = *daily*

3. How many relatives do you feel at ease with that you can talk about private matters?
   0 = *none*   1 = *one*   2 = *two*   3 = *three or four*   4 = *five thru eight*   5 = *nine or more*

4. How many relatives do you feel close to such that you could call on them for help?
   0 = *none*   1 = *one*   2 = *two*   3 = *three or four*   4 = *five thru eight*   5 = *nine or more*

5. When one of your relatives has an important decision to make, how often do they talk to you about it?
   0 = *never*   1 = *seldom*   2 = *sometimes*   3 = *often*   4 = *very often*   5 = *always*

6. How often is one of your relatives available for you to talk to when you have an important decision to make?
   0 = *never*   1 = *seldom*   2 = *sometimes*   3 = *often*   4 = *very often*   5 = *always*

NEIGHBORS: *Considering those people who live in your neighborhood...*

7. How many of your neighbors do you see or hear from at least once a month?
   0 = *none*   1 = *one*   2 = *two*   3 = *three or four*   4 = *five thru eight*   5 = *nine or more*

8. How often do you see or hear from the neighbor with whom you have the most contact?
   0 = *less than monthly*   1 = *monthly*   2 = *few times a month*   3 = *weekly*   4 = *few times a week*
   5 = *daily*

9. How many neighbors do you feel at ease with that you can talk about private matters?
   0 = *none*   1 = *one*   2 = *two*   3 = *three or four*   4 = *five thru eight*   5 = *nine or more*

10. How many neighbors do you feel close to such that you could call on them for help?
   0 = *none*   1 = *one*   2 = *two*   3 = *three or four*   4 = *five thru eight*   5 = *nine or more*

11. When one of your neighbors has an important decision to make, how often do they talk to you about it?
   0 = *never*   1 = *seldom*   2 = *sometimes*   3 = *often*   4 = *very often*   5 = *always*

12. How often is one of your neighbors available for you to talk to when you have an important decision to make?
   0 = *never*   1 = *seldom*   2 = *sometimes*   3 = *often*   4 = *very often*   5 = *always*

Table 16. Lubben Social Network Scale, Continue….

FRIENDSHIPS: *Considering your friends who do not live in your neighborhood…*

13. How many of your friends do you see or hear from at least once a month?
    0 = none   1 = one   2 = two   3 = three or four   4 = five thru eight   5 = nine or more

14. How often do you see or hear from the friend with whom you have the most contact?
    0 = less than monthly   1 = monthly   2 = few times a month   3 = weekly   4 = few times a week   5 = daily

15. How many friends do you feel at ease with that you can talk about private matters?
    0 = none   1 = one   2 = two   3 = three or four   4 = five thru eight   5 = nine or more

16. How many friends do you feel close to such that you could call on them for help?
    0 = none   1 = one   2 = two   3 = three or four   4 = five thru eight   5 = nine or more

17. When one of your friends has an important decision to make, how often do they talk to you about it?
    0 = never   1 = seldom   2 = sometimes   3 = often   4 = very often   5 = always

18. How often is one of your friends available for you to talk to when you have an important decision to make?
    0 = never   1 = seldom   2 = sometimes   3 = often   4 = very often   5 = always

LSNS-R total score is an equally weighted sum of these twelve items. Scores range from 0 to 90

Table 17. Continuation of Lubben Social Netwrk Scale.

6.4.3.4 Social Inclusion (Virtual) Scale

Rosen et al. [11] propose the following scale (Table 18) to measure the exposition of a person to new media. In our opinion, with the exclusion of item 10 and 11, it can be used in DOREMI project to measure the degree of social inclusion of an individual. Between middle of May 2014 and Mid June 2014, we will investigate further scales to check if they better fit with the scope of the project.

Questions	Metric
How often do you make the following action on a daily bases?	Never; once a month; several times a month; once a week; several times a week; one a day; several time a day; once an hour; several times an hour; all the time
1. check for text messages on a smartphone.	
2. send and receive text message on a mobile phone.	
3. use your mobile phone during the day.	
4. play games on a computer video games console or smartphone with other people in the same room.	
5. play games on a computer video games console or smartphone by yourself.	
6. play games on a computer video games console or smartphone with other people online.	
7. number of people have you regularly interact with online that you have never meet in person.	
8. people have you met online that you have never meet in person.	
9. check for voice calls on a mobile phone.	
10. watch TV shows, movies, etc. on a TV set.	
11. match video chips on a TV set.	
12. friend have you on facebook.	

Table 18. Media use factors.

6.4.3.5 (Perceived) Social Support

Social interaction and support have been shown to provide many benefits to the overall health and well-being of young and older adults. Social interaction and support drawn from a variety of sources (e.g., family, friends, community) have been associated with better outlook and better emotional health, especially among elderly with pre-existing life stress such as cancer and other chronic disease. Studies have also shown that older adults with adequate social interaction and support are less likely

to have negative long-term effects (e.g., poor emotional health, pessimistic attitude, hospitalization, poor survival) of life stressors.

Importantly, lack of social interaction and support is a potentially modifiable risk factor in older adults. But intervention requires adequate assessment of the social situation. Because of its potential for attenuating effects of life stressors, intervention, and relative ease of assessment, social support should be measured as part of the comprehensive geriatric assessment.

To this end, we propose to use the "Medical Outcomes Study Social Support Survey (MOS-SS)" metric (Table 19). It is a 19-item, self-administered social support survey developed for patients in the Medical Outcomes Study (MOS) [61]. It was originally designed as a self-administered measure of functional social support in community dwelling chronically ill persons. The 19 items cover four domains (emotional/informational support, tangible [also called instrumental] support, positive social interaction, and affection) recommend for both combined and individual use. The questionnaire was carefully developed from previous instruments based on a sound theoretical formulation, has been demonstrated to be psycho-metrically sound, and is considered universally applicable. The items are short, simple, and easy to understand thus easy to administer to chronically ill patients of all ages.

To reduce respondent burden, several more recent studies have used an eight-item modified Medical Outcomes Study Social Support Survey (mMOS-SS) [62] of the MOS-SS. The mMOS-SS has two subscales covering two domains (emotional and instrumental [tangible] social support) composed of four items each designed to maintain the theoretical structure of the MOS-SS and identify potentially modifiable social support deficits Because of its brevity, the mMOS-SS is a potentially valuable tool for use in geriatric assessment [63-65].

It is important to notice that the target population are older adults with initial cognitive impairment and possible other chronic disease, living in assisted structures of social care. Therefore their often their degree of social interaction is quite correlated with the social support that they can receive from caregivers, relatives, friends and the community where the live. Therefore we suggest the MOS-SS scale to measure their social interaction rather than scales addressing purely social interaction issues [66-69].

Believes active role important	nMOS-SS	MOS-SS
If you need it, how often is someone available ….		
1. to help you if you were confined to bed?	X	X
2. to take you to the doctor if you need it?	X	X
3. to prepare your meals if you are unable to do it yourself?	X	X
4. to help with daily chores if you were sick?	X	X
5. to have a good time with?	X	X
6. to turn for suggestion about how to deal with a personal problem?	X	X
7. who understand your problems?	X	X
8. to love and make you feel wanted?	X	X
9. you can count on to listen to you when you need talk?		X
10. to give you advice about a crises?		X
11. who shows you love and affection?		X
12. to give you information to help you understand a situation?		X
13. to confide in or to talk to about yourself or your problems?		X
14. who hugs you?		X
15. to get together with for relaxation?		X
16. whose advice you really want?		X
17. to do things with to help you get your mind off things?		X
18. to share your most private worries and fears with?		X
19. to do something enjoyable with?		X
1. emotional/informational: items 6, 7, 9, 10, 12, 13, 16, 18		X
2. tangible: items 1-4		X
3. affectionate: items 8, 11, 14		X
4. positive social interaction: items 5, 15, 19		X
5. instrumental : items 1-4	X	
6. emotional: items 5-8	X	

Table 19. The MSS-SS scale for social support measurement (source: Hays et al, 1995).

7. INDICATORS OF EFFECTIVENESS OF ACTIVE AGING LIFESTYLE (DOREMI) PROTOCOLS

7.1 Sedentariness

The level of sedentariness for DOREMI users will be evaluated by the use of two test systems: PASE test and BERG scale.

7.1.1 PASE test

The **PASE test** is a brief, easily scored, reliable and valid instrument for the assessment of physical activity in studies of older people. It consists of questions regarding the frequency and duration of leisure activity (e.g., sports, jogging, swimming, strengthening and endurance exercise), household activity, and work-related activity during the previous 7-day period and can be administered by telephone, mail or in-person.

> *Improvement of PASE value for DOREMI users after treatment:*
>
> **+15%**

7.1.2 BERG scale

The **BBS** is considered the gold standard assessment of balance. It is based on a test of 14 items, it is performance-based and has a scale of 0-4 for each item (higher score for independent performance) with a maximum score of 56.

> *Improvement of BERG value for DOREMI users after treatment:*
>
> # a change of eight (8) points is required to reveal a genuine change on function

7.2 Malnutrition

The level of malnutrition will be defined by the use of MNA test.

7.2.1 MNA

The MNA will give us a feedback about the effectiveness of DOREMI protocol. MNA test will be administered at the end of treatment and we expect a recovery of healthy dietary habits operated by technological environment.

> *Improvement of MNA value for DOREMI users after treatment:*
>
> **+10%**

7.3 Cognitive decline

The level of cognitive decline for DOREMI users will be evaluated by use of different tests: MMSE, Token, Phonemic fluency, Semantic Fluency and Attentional Matrices.
The DOREMI project is expected to improve the cognitive functions of participants. This outcome will be measured comparing the difference between the MMSE score achieved during the first evaluation and that obtained after the final assessment.

7.3.1 MMSE

In order to be recruited for the pilot study, subjects should achieve at least a score of 22.
After the DOREMI interventions we expect to gain 3 points of score (e.g. from 24 to 27) with respect to the score measured at the baseline.

> *Improvement of MMSE score value for DOREMI users after treatment:*
>
> **+ 3**

7.3.2 Semantic Fluency

If we consider that 25 is the cut-off value, **after DOREMI we expect to reach a value >32.**
Subjects producing a number of words lower than 25 are expected to be less than 40%.

7.3.3 Phonemic Fluency

If we consider that 17 is the cut-off value, **after DOREMI we expect to reach a value >30.**
Subjects producing a number of words lower than 17 are expected to be less than 26%.

7.3.4 Attentional Matrices

If we take into account that the score range is 0-60, and the cut-off value is 30, **at the end of the DOREMI project a score of at least 44 is expected.**
Subjects producing a number of words lower than 30 are expected to be less than 18%.

7.3.5 Token Test

This test is a useful evaluation tool to measure the functional evolution of the subject (baseline, intermediate evaluation and final evaluation).
A score below 25 outlines a strong impairment and represents the cut-off used in the clinical field. Apart from the starting score, **improvement is expected to reach a score of 32 out of 36.**
Statistically, subjects scoring less than 25 at first evaluation are supposed to be < or equal to 15%. In these cases what will be measured is the possible improvement (%) achieved at the final evaluation.

7.3.6 Montreal Cognitive Assessment (MoCA)

The average MoCA score for people with normal cognitive functioning is 22.2 with a standard deviation (SD) of 3.1 Following DOREMI, we would expect all participants to fall within 1 standard deviation of the mean score for normal cognitive functioning. **We expect a MoCA value of >25.2 following DOREMI.**

7.3.7 Digit Span

To ensure reliability of the digit span computer programmed test, the test will be administered to a group of people with MCI and a group of healthy controls (the reference groups from WP5) prior to the intervention. We will take the mean and standard deviation from the healthy control group trial and use this to inform a clinically significant outcome value. Following DOREMI, **we would expect participants to fall within 1 standard deviation of the healthy control group digit span mean**.

7.3.8 Reaction time test

The healthy elderly control group norm for lapses on the proposed reaction time test is 8.2 (SD = 2.6). **Following DOREMI, we would expect values to fall within 1 SD of this healthy range >5.6.** For false positives on the reaction time test (control mean =1.9, SD= 0.15) we would expect average false positives to fall with 1 SD of this healthy range <1.75. To ensure reliability of the reaction time computer programmed test, and provide norms for reaction time in milliseconds for people with MCI and healthy controls, the test will be administered to a group of people with MCI and a group of healthy controls (the reference groups from WP5) prior to the intervention. We will take the mean and standard deviation from the healthy control group trial and use this to inform a clinically significant outcome value. Following DOREMI, we would expect participants to fall within 1 standard deviation of the healthy control group reaction time mean.

Scores used as cut-off and the final score represent a value adjusted according to age and education, they are not the rough test outcome.

For each participant, however, the final test score will be put in relation with the possible health worsening. Age-related frailty is always a factor that must be taken into account within projects dealing with the elderly.

8. PRIMARY KEY PERFORMANCE INDICATORS (KPI)

8.1 Clinical

8.1.1 Weight, BMI, MNA

As KPI we expect, after DOREMI interventions, a significant reduction of weight and BMI values for overweighed population, or an increase of MNA for users with under nutrition, both respect to baseline values.

8.1.2 Impedentiometric analysis

The KPI from impedentiometric analysis will be focused on two main parameters, Total Body Water (TBW) and Basal Metabolic Rate (BMR).
TBW is inversely linked to body fat percentage: our goal is the recovery of hydration normal values (Female : 45 to 60%, Male : 50 to 65%) after DOREMI trial.
For BMR, we expect a significant improvement of BMR value at the end of 90 days of DOREMI intervention respect to baseline.

8.1.3 PASE Score

PASE score is essential in the reference indicator for effectiveness of DOREMI protocol but, for its relation with several aspects under analysis of DOREMI treatment, this is considered also a KPI for physical activity. We expect an improvement of 15% after intervention respect to baseline.

8.1.4 Cardiovascular assessment

This activity will be performed at the end of DOREMI interventions. The main performance indicators are represented below:

Resting Heart rate. Long-term exercise training produces a dominant vagal control of the heart. While the phenomenon is well know in young adults, the reports in elderly patients is conflicting: no changes at all [70] up to an average change of -6 bpm (-2 to -12 bpm), representing an 8.4% reduction, in a meta-analysis of 13 studies in older adults [71]. Thus, a 8% reduction from basal heart rate derived from resting ECG at enrollment, will represent a significant reduction after DOREMI interventions.

Blood pressure measurements. An increase in arterial stiffness with advancing age is associated with pathologic states as hypertension and arteriosclerosis. Regular exercise improves the increase in arterial stiffness and has therefore a protective role [72,73]. In literature [74] it has been demonstrated that exercise is able to reduce SBP of 5 mmHg and DBP of 3.5 mmHg after 6 months training. Thus, a performance indicator could be represented by represented by a 5 and 3 mmHg reduction in SPB and DBP, respectively.

The Rate Pressure Product (RPP) is supposed to be significantly reduced after 6 months training.

6MWT, defined as the greater distance achieved, is expected to improve in subjects undergoing physical activity. In literature, different protocols have been adopted but in a study performed on comparable subjects, an improvement in walking distance of around 20 meters was reported [75].

However, it is important to note that in healthy elderly subject a significant gender difference in walking distance of about 50 meters (40 ± 10 meters) is present at baseline [76,77].

Therefore, on the basis of the current literature we propose as a performance indicator in this study a 20% increase in walking distance in men and a 15% increase in women.

8.1.5 Biomarkers

For diabetic subjects, we expect a significant reduction of HGT respect to baseline after DOREMI trial. A similar significant reduction trend we will expect for dyslipidemic participants (defined as LDL > 130 mg/dL or 3.37 mmol/L, Total Cholesterol > 200 mg/dL or 5.18 mmol/L).

8.1.6 Cognitive parameters

Cognitive functions are the skills that allow us to correctly interpret and manage information: they are memory, attention, perception, language, problem solving, orientation in space and time.

MMSE Score. The maximum score is 30 and it takes about 5-10 minutes to administer.

Table score:
Orientation (10 points)
Registration (3 points)
Attention and Calculation (5 points)
Recall (3 points)
Language and Praxis (9 points)

A person's MMSE score can be affected by their level of education. This is because for highly educated people the questions may be too easy and for poorly educated people some may be too difficult. This means that a highly educated person with mild dementia may score in the normal range, whereas a poorly educated person with no problems in cognition may score in the dementia range. The same goes for the question of age (Table 20).

	Schooling (in years)			
	0-4	5-7	8-12	13-17
Age				
65-69	+0.4	-1.1	-2.0	-2.8
70-74	+0.7	-0.7	-1.6	-2.3
75-79	-0.9	-0.3	-1.0	-1.7
80-84	+1.5	+0.4	-0.3	-0.9
85-89	+2.2	+1.4	+0.8	+0.3

Table 20. MMSE score modulation respect to age and scholarization time.

8.2 Social

According to the DOREMI reference model in Figure 10, the KPI (final Outcomes in the Model) related to social activities and behavioural changes due to the use of the DOREMI gamified environment are the following three:

- Perception of a better health status
- Perception of a less degree of loneliness
- Perception of a better wellbeing

In the following subparagraph we will explain the meanings of the three KPI and the scales and metrics that, according to the literature review we propose to use for collecting evidences during the trial activities.

8.2.1 Perceived Health Status

According to Gilmour [43], self-perceived health can be measured with 1-item scale (excellent; very good; good; fair; poor), by answering the following question: "***Today I would say my health is…***".

Alternatively, we propose to use the item number 4 of the General Health Perceptions section of the SF36 scale[5], by answering the following question: "***Today my health is excellent"*** *with the following multiple choices (**Definitely True; Mostly True; Don't know; Mostly False; Definitely False**).*

Being the SF36 widely used and validated both for UK and Italy where the DOREMI trials will be organized, we propose to use in both trials this scale instead of the Gilmour one.

Getting the opportunity of the social web for ageing portal, we propose to substitute the written item of SF36 scale with a visual one, as in the example of the Figure 11.

In our opinion the use of the visual scale should have a twofold advantages: on one side it is easier to be used and accepted by the participants to the trials, on the other side it can be an additional stimulus for the ageing person to daily access to the web social network.

To be more accepted by the ageing persons, the selection of the visual scale can be done during the validation workshops that the DOREMI project is going to organize in the following months.

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[5] For the SF36 scale description see:
http://www.rand.org/health/surveys_tools/mos/mos_core_36item_survey.html

Figure 11. Examples of facets to be used for detecting the "perceived health status" on a daily base.

8.2.2 Perceived Loneliness Support

Loneliness is one of the major indicators of social wellbeing. Perlman & Peplau [78] formulated loneliness as "*the unpleasant experience that occurs when a person's network of social relationships is deficient in some important way, either quantitatively or qualitatively".* De Jong Gierveld [79] defined loneliness as a situation which "*the number of existing relationships is smaller than is considered desirable or admissible, as well as situations where the intimacy one wishes for has not been realised*".

According to the Authors, several determinants works together in explaining why some people with small numbers of social contacts consider themselves lonely whereas others feel good and sufficiently embedded. Among these determinants is the presence or absence of an intimate partner [80-83]; the size and functioning of family relationships, particularly parent-child bonds [79,84-86]; nonkin relationships and participation in volunteer work, clubs, and the church [87-89]; personality traits [90,91]; gender [92,93]; and health [94-97].

Two reliable and valid loneliness scales have been used in many research projects [98]. The first is the **revised UCLA Loneliness Scale** [99,100], consisting of 20 items, and its shorter version, the 3-item UCLA Loneliness Scale [101]. The second is the **scale developed by De Jong Gierveld and colleagues** [102,103], consisting of 11 items.

For the purpose of DOREMI project we propose the UCLA Loneliness Scale (Version 3) (Table 21).

```
Scale:
INSTRUCTIONS: Indicate how often each of the statements below is descriptive of you.

        C indicates 🗌 often feel this way🗌
        S indicates 🗌 sometimes feel this way🗌
        R indicates 🗌 rarely feel this way🗌
        N indicates 🗌 never feel this way🗌

    1.  I am unhappy doing so many things alone                          O  S  R  N
    2.  I have nobody to talk to                                         O  S  R  N
    3.  I cannot tolerate being so alone                                 O  S  R  N
    4.  I lack companionship                                             O  S  R  N
    5.  I feel as if nobody really understands me                        O  S  R  N
    6.  I find myself waiting for people to call or write                O  S  R  N
    7.  There is no one I can turn to                                    O  S  R  N
    8.  I am no longer close to anyone                                   O  S  R  N
    9.  My interests and ideas are not shared by those around me         O  S  R  N
    10. I feel left out                                                  O  S  R  N
    11. I feel completely alone                                          O  S  R  N
    12. I am unable to reach out and communicate with those around me    O  S  R  N
    13. My social relationships are superficial                          O  S  R  N
    14. I feel starved for company                                       O  S  R  N
    15. No one really knows me well                                      O  S  R  N
    16. I feel isolated from others                                      O  S  R  N
    17. I am unhappy being so withdrawn                                  O  S  R  N
    18. It is difficult for me to make friends                           O  S  R  N
    19. I feel shut out and excluded by others                           O  S  R  N
    20. People are around me but not with me                             O  S  R  N

Scoring:

Make all O's =3, all S's =2, all R's =1, and all N's =0.  Keep scoring continuous.
```

Table 21. UCLA Loneliness scale (Version 3).

The 20-item scale (Version 3) in the figure is designed to measure one's subjective feelings of loneliness as well as feelings of social isolation. Participants rate each item as either O ("I often feel this way"), S ("I sometimes feel this way"), R ("I rarely feel this way"), N ("I never feel this way").

8.2.3 Perceived Wellbeing

Also in this case, according to Gilmour [43], the well-being can be measured with 1-item scale (0-very dissatisfied; 10-very satisfied), by answering the following question: **"how do you feel about your life as a whole right now?"……..**

Alternatively we suggest considering the general mental health (psychological distress and psychological well-being) section of the SF36 scale (Table 22).

General mental health (psychological distress and psychological well-being) section of SF36 scale	Metrics
23. Did you feel full of pep?	*All the time; Most of the time; A good bit of the time; Some of the time; A little of the time; None of the time*
24. Have you been a very nervous person?	
25. Have you felt so down in the dumps that nothing could cheer you up?	
26. Have you felt calm and peaceful?	
27. Did you have a lot of energy?	
28. Have you felt downhearted and blue?	
29. Did you feel worn out?	
30. Have you been happy person?	
31. Did you feel tired?	

Table 22. General mental health section of the SF36 scale

In particular we propose to use the item number 25 by answering to the following questions: *"Today I feel so down in the dumps that nothing could cheer me up"* with the multiple choice described in the table above.
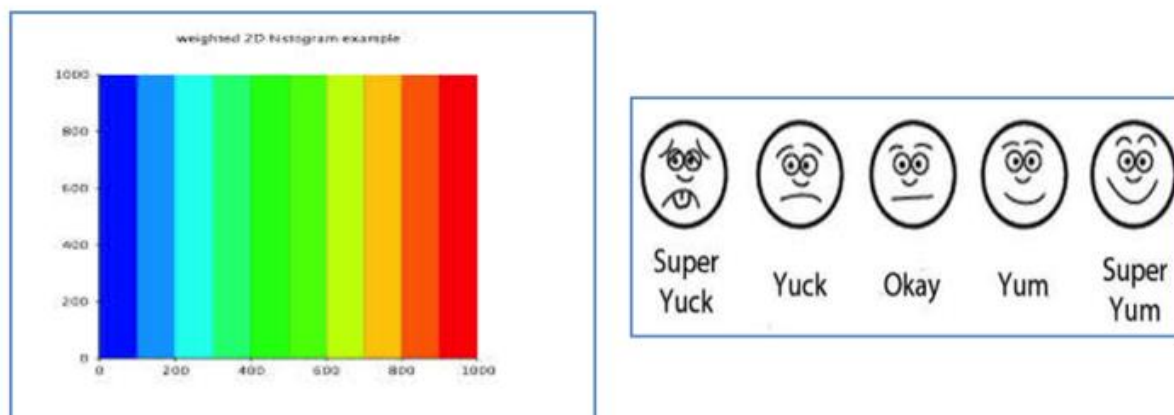

Figure 12. Examples of facets to be used for detecting the "perceived wellbeing status" on a daily base.

As already discussed for the "***perceived health status***", the "***perceived wellbeing***" could be measured with a visual scale, instead of a numeric one (Figure 12).

To facilitate the acceptance of the scale and make more appealing the social web site of the project we suggest to select the "***perceived wellbeing scale***" during the DOREMI validation workshops that will be organized in the following months.

Finally, as already argued for the "***perceived health status measurement***" (see §8.2.1), we propose to use, in both the UK and Italian trials, the widely applied SF36 scale, also for the measurement of this KPI, instead of the Gilmour one.

8.3 Automated estimation of effectiveness

An automated assessment of the current user status of well-being will be performed by the DOREMI Reasoner module. It will be based on data automatically gained from different DOREMI modules directly or indirectly interacting with the user.
These are:

- Estimation of type and intensity of physical activity
- Estimation of social interaction
- Type and composition of nutrition
- Performance and type of games
- Vital parameters (e.g. HR, weight, BMI, Blood pressure)

The reasoned will be based on a hybrid decision tree, consisting of learned rules under constraints defined by the expert (physician).
The learning will follow a supervised approach and is described in more details in §D4.1 - §8
Results of the Reasoner will be presented on the dashboard, an online platform for the expert in a transparent way.

9. ICF CORRELATIONS

ICF International Classification of Functioning, Disability and Health, is a classification of health and health-related domains. As the functioning and disability of an individual occurs in a context, ICF also includes a list of environmental factors [104].

The application of ICF, namely the correlation between test outcomes achieved by participants and the ICF classification, is justified within the DOREMI project, considering the context of cooperation among different EU countries and the guidelines suggested by the World Health Organization.

The current ICF creates a more integrative understanding of health forming a comprehensive profile of an individual instead of focusing on one's health condition [105]. The implications of using the ICF include emphasizing on the strengths of individuals, assisting individuals in participating more extensively in society by the use of interventions aimed at enhancing their abilities, and taking into consideration the environmental and personal factors that might hamper one's participation [106].

Indeed, identifying a correspondence between test items and ICF codes has the advantage of obtaining descriptive data, besides analytical clinical data, so that the real functional condition of the subject is described. In fact serious games don't allow for collection of clinical data, but can affect functional skills, excluding the diagnostic domain. Tests define and define the subject's reaction to a stimulus, whereas the ICF gives some information about the functional activity in daily life, thus allowing for the creation of a database concerning the subject's evolution, comparing data of subsequent evaluations.

Tests included in the project that can be correlated with ICF are reported in the table 23.

MMSE
SF-36
Berg
Pase

Table 23. Test for correlation.

9.1 The correlation

The correlation between test and ICF is obtained in 2 steps. First, it is necessary to find a correspondence between the item investigated by the test (e.g. attention to a stimulus) and the relative ICF code, while the next step is to correlate the score achieved in the test with the ICF qualifier (i.e. The functional value with which codes are defined by ICF). In order to allow for a punctual correlation of scores and values belonging to different scales (e.g. Item 1 MMSE score 0-5 positive scale, ICF qualifier score 0-4 negative scale), it is necessary to statistically distribute the scores.

Furthermore, there can be more items related to a unique ICF code and vice versa. An example of correlation between Berg and ICF is explained below with score correlation (Table 24).

Ex. BERG-ICF

Correlation item-code

BERG   **ICF**

Item 1 "Sitting to standing"   ⟹   **d4104**: **Standing--**Getting into and out of a standing position or changing body position from standing to any other position, such as lying down or sitting down
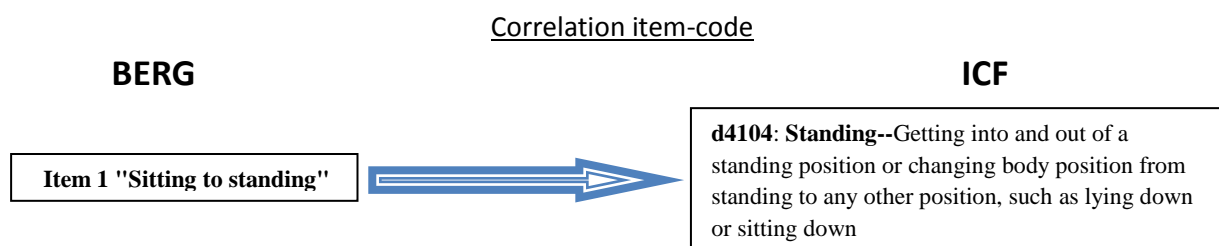
SCORE Correlation

BERG	ICF
4 The highest level of function	**0** NO problem (none, absent, negligible, ...) 0-4%
3	**1** MILD problem (slight, low, ...) 5-24%
2	**2** MODERATE problem (medium, fair, ...) 25-49%
1	**3** SEVERE problem (high,extreme, ...) 50-95%
0 The lowest level of function	**4** COMPLETE problem (total, ...) 96-100%

Table 24. Correlation between test score and ICF qualifier.

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11. APPENDIX

11.1 MMSE

Mini-Mental State Examination (MMSE)

Patient's Name: _____   Date: _____

Instructions: Score one point for each correct response within each question or activity.

Maximum Score	Patient's Score	Questions
5		"What is the year? Season? Date? Day? Month?"
5		"Where are we now? State? County? Town/city? Hospital? Floor?"
3		The examiner names three unrelated objects clearly and slowly, then the instructor asks the patient to name all three of them. The patient's response is used for scoring. The examiner repeats them until patient learns all of them, if possible.
5		"I would like you to count backward from 100 by sevens." (93, 86, 79, 72, 65, …) Alternative: "Spell WORLD backwards." (D-L-R-O-W)
3		"Earlier I told you the names of three things. Can you tell me what those were?"
2		Show the patient two simple objects, such as a wristwatch and a pencil, and ask the patient to name them.
1		"Repeat the phrase: 'No ifs, ands, or buts.'"
3		"Take the paper in your right hand, fold it in half, and put it on the floor." (The examiner gives the patient a piece of blank paper.)
1		"Please read this and do what it says." (Written instruction is "Close your eyes.")
1		"Make up and write a sentence about anything." (This sentence must contain a noun and a verb.)
1		"Please copy this picture." (The examiner gives the patient a blank piece of paper and asks him/her to draw the symbol below. All 10 angles must be present and two must intersect.)
30		TOTAL

Table 25. MMSE test.

Instructions for administration and scoring of the MMSE

Orientation (10 points):
   • Ask for the date. Then specifically ask for parts omitted (e.g., "Can you also tell me what season it
   is?"). One point for each correct answer.
   • Ask in turn, "Can you tell me the name of this hospital (town, county, etc.)?" One point for each correct answer.
Registration (3 points):
   • Say the names of three unrelated objects clearly and slowly, allowing approximately one second for each one. After you have said all three, ask the patient to repeat them. The number of objects the patient names correctly upon the first repetition determines the score (0-3). If the patient does not repeat all three objects the first time, continue saying the names until the

patient is able to repeat all three items, up to six trials. Record the number of trials it takes for the patient to learn the words. If the patient does not eventually learn all three, recall cannot be meaningfully tested.

• After completing this task, tell the patient, "Try to remember the words, as I will ask for them in a little while."

Attention and Calculation (5 points):

• Ask the patient to begin with 100 and count backwards by sevens. Stop after five subtractions (93, 86, 79, 72, 65). Score the total number of correct answers.

• If the patient cannot or will not perform the subtraction task, ask the patient to spell the word "world"backwards. The score is the number of letters in correct order (e.g., dlrow=5; dlrw-dlow drow-dlro=4; dlorw-drlow-dlrwo-dlwor-dlr-lor-dlw=3; dorlw-dl-ow=2; drlwo-ldrwo=1).

Recall (3 points):

• Ask the patient if he or she can recall the three words you previously asked him or her to remember. Score the total number of correct answers (0-3).

Language and Praxis (9 points):

• Naming: Show the patient a wrist watch and ask the patient what it is. Repeat with a pencil. Score one point for each correct naming (0-2).

• Repetition: Ask the patient to repeat the sentence after you ("No ifs, ands, or buts."). Allow only one trial. Score 0 or 1.

• 3-Stage Command: Give the patient a piece of blank paper and say, "Take this paper in your right hand, fold it in half, and put it on the floor." Score one point for each part of the command correctly executed.

• Reading: On a blank piece of paper print the sentence, "Close your eyes," in letters large enough for the patient to see clearly. Ask the patient to read the sentence and do what it says. Score one point only if the patient actually closes his or her eyes. This is not a test of memory, so you may prompt the patient to "do what it says" after the patient reads the sentence.

• Writing: Give the patient a blank piece of paper and ask him or her to write a sentence for you. Do not dictate a sentence; it should be written spontaneously. The sentence must contain a subject and a verb and make sense. Correct grammar and punctuation are not necessary.

• Copying: Show the patient the picture of two intersecting pentagons and ask the patient to copy the figure exactly as it is. All ten angles must be present and two must intersect to score one point.

Ignore tremor and rotation.

Scoring the Figure 13:

Correct: Incorrect:
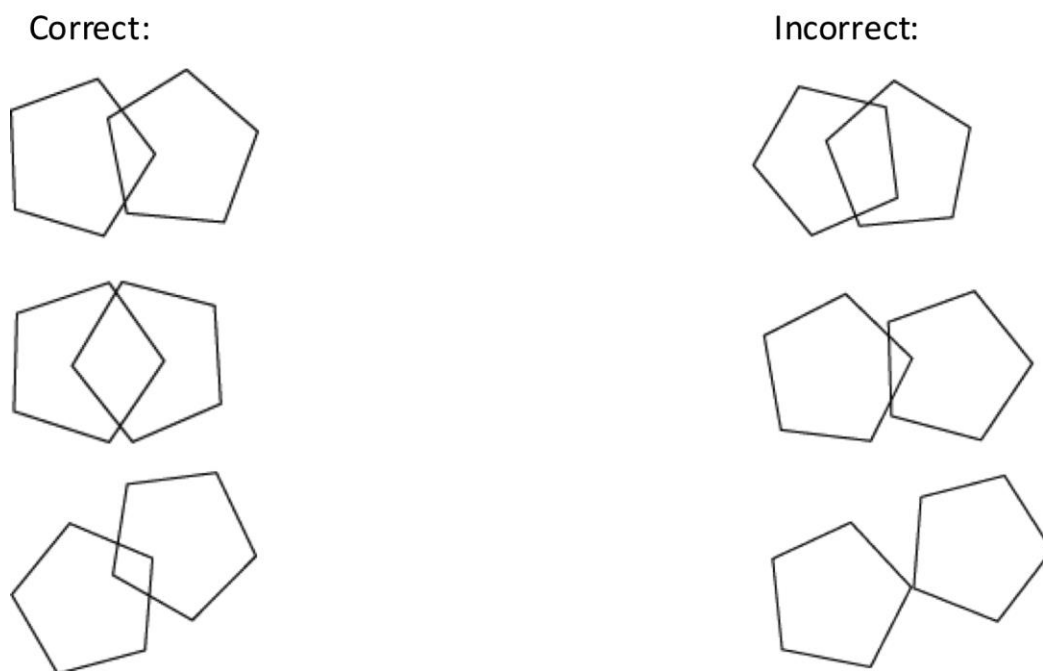
Figure 13. Copying section of MMSE test.

A person's MMSE score can be affected by their level of education. This is because for highly educated people the questions may be too easy and for poorly educated people some may be too difficult. This means that a highly educated person with mild dementia may score in the normal range, whereas a poorly educated person with no problems in cognition may score in the dementia range. The same goes for the question of age (Table 25).

	Schooling (in years)			
	0-4	5-7	8-12	13-17
Age				
65-69	+0.4	-1.1	-2.0	-2.8
70-74	+0.7	-0.7	-1.6	-2.3
75-79	-0.9	-0.3	-1.0	-1.7
80-84	+1.5	+0.4	-0.3	-0.9
85-89	+2.2	+1.4	+0.8	+0.3

Table 26. MMSE score modulation respect to age and scholarization time.

11.2 MNA

Table 27. MNA form.

11.3 BMI

The abbreviated **BMI** table shown above (Figure 14) is provided for convenience and facilitates completing **MNA®** and it is accurate for it.
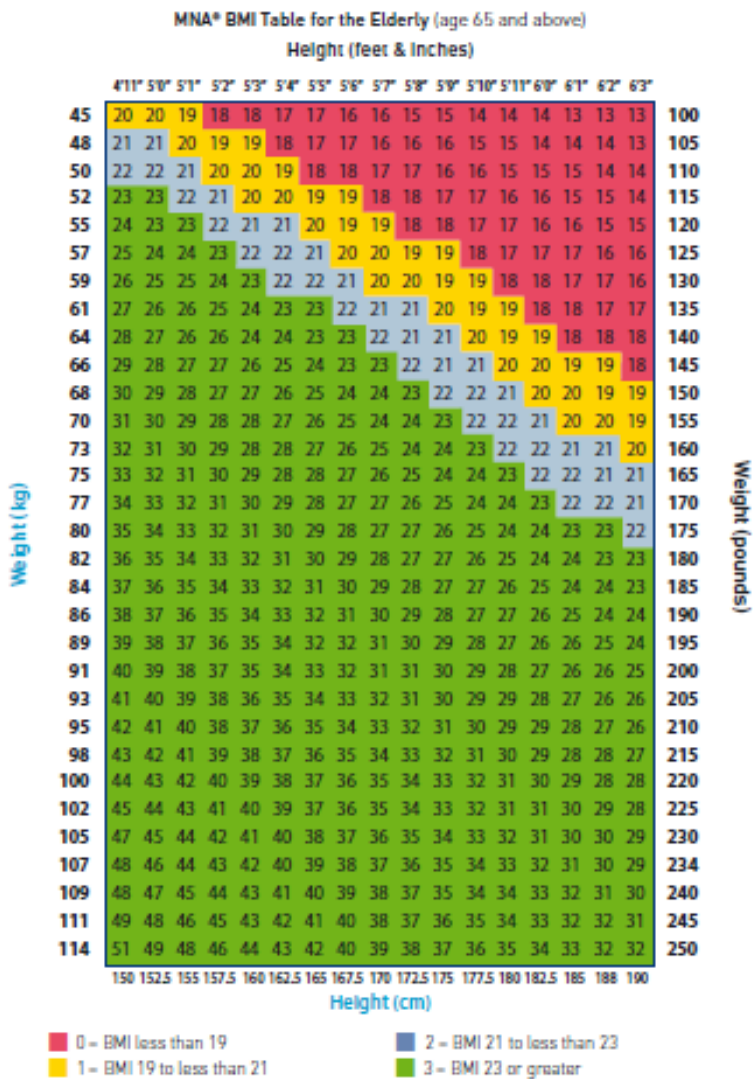
Figure 14. BMI table.

In some cases, calculating the BMI may yield a more precise **BMI** determination, defined exactly as a person's weight in kilograms divided by the square of his height in meters (kg/m^2):

BMI Formula – US units

BMI = (Weight in Pounds / [Height in inches x Height in inches]) x 703

BMI Formula – Metric units

BMI = (Weight in Kilograms /Height in Meters x Height in Meters])

1 Pound = 0.45 Kilograms Centimetres

1 Inch = 2.54

11.4 PASE

LEISURE TIME ACTIVITY

1. Over the past 7 days, how often did you participate in sitting activities such as reading, watching TV or doing handcrafts?

[0.] NEVER   [1.] SELDOM   [2.] SOMETIMES   [3.] OFTEN
↓   (1-2 DAYS)   (3-4 DAYS)   (5-7 DAYS)
GO TO Q.#2   ↓   ↓   ↓

> 1a. What were these activities?
> _____
>
> 1b. On average, how many hours per day did you engage in these sitting activities?
>
> [1.] LESS THAN 1 HOUR [2.] 1 BUT LESS THAN 2 HOURS
>
> [3.] 2-4 HOURS   [4.] MORE THAN 4 HOURS

2. Over the past 7 days, how often did you take a walk outside your home or yard for any reason? For example, for fun or exercise, walking to work, walking the dog, etc.?

[0.] NEVER   [1.] SELDOM   [2.] SOMETIMES   [3.] OFTEN
↓   (1-2 DAYS)   (3-4 DAYS)   (5-7 DAYS)
GO TO Q.#3   ↓   ↓   ↓

> 2a. On average, how many hours per day did you spend walking?
>
> [1.] LESS THAN 1 HOUR [2.] 1 BUT LESS THAN 2 HOURS
>
> [3.] 2-4 HOURS   [4.] MORE THAN 4 HOURS

5. Over the past 7 days, how often did you engage in strenuous sport and recreational activities such as jogging, swimming, cycling, singles tennis, aerobic dance, skiing (downhill or cross-country) or other similar activities?

[0.] NEVER	[1.] SELDOM	[2.] SOMETIMES	[3.] OFTEN
↓	(1-2 DAYS)	(3-4 DAYS)	(5-7 DAYS)
GO TO Q.#6	↓	↓	↓

5a.   What were these activities?
_____

5b.   On average, how many hours per day did you engage in these strenuous sport and recreational activities?

[1.] LESS THAN 1 HOUR   [2.] 1 BUT LESS THAN 2 HOURS

[3.] 2-4 HOURS   [4.] MORE THAN 4 HOURS

6. Over the past 7 days, how often did you do any exercises specifically to increase muscle strength and endurance, such as lifting weights or pushups, etc.?

[0.] NEVER	[1.] SELDOM	[2.] SOMETIMES	[3.] OFTEN
↓	(1-2 DAYS)	(3-4 DAYS)	(5-7 DAYS)
GO TO Q.#7	↓	↓	↓

6a.   What were these activities?
_____

6b.   On average, how many hours per day did you engage in exercises to increase muscle strength and endurance?

[1.] LESS THAN 1 HOUR   [2.] 1 BUT LESS THAN 2 HOURS

[3.] 2-4 HOURS   [4.] MORE THAN 4 HOURS

HOUSEHOLD ACTIVITY

7. During the past 7 days, have you done any light housework, such as dusting or washing dishes?

    [1.] NO   [2.] YES

8. During the past 7 days, have you done any heavy housework or chores, such as vacuuming, scrubbing floors, washing windows, or carrying wood?

    [1.] NO   [2.] YES

9. During the past 7 days, did you engage in any of the following activities?

    Please answer YES or NO for each item.

		NO	YES
a.	Home repairs like painting, wallpapering, electrical work, etc.	1	2
b.	Lawn work or yard care, including snow or leaf removal, wood chopping, etc.	1	2
c.	Outdoor gardening	1	2
d.	Caring for an other person, such as children, dependent spouse, or an other adult	1	2

WORK-RELATED ACTIVITY

10. During the past 7 days, did you work for pay or as a volunteer?

[1.] NO   [2.] YES

10a. How many hours per week did you work for pay and/or as a volunteer?

_____ HOURS

10b. Which of the following categories best describes the amount of physical activity required on your job and/or volunteer work?

[1] Mainly sitting with slight arm movements.
[**Example**s: office worker, watchmaker, seated assembly line worker, bus driver, etc.]

[2] Sitting or standing with some walking.
[**Example**s: cashier, general office worker, light tool and machinery worker.]

[3] Walking, with some handling of materials generally weighing less than 50 pounds.
[**Example**s: mailman, waiter/waitress, construction worker, heavy tool and machinery worker.]

[4] Walking and heavy manual work often requiring handling of materials weighing over 50 pounds.
[**Example**s: lumberjack, stone mason, farm or general laborer.]

Table 28. PASE test.

11.5 Berg Balance Scale

Berg Balance Scale

The **Berg Balance Scale (BBS)** is a 14 item scale to measure balance among older people with impairment in balance function by assessing the performance of functional tasks. It is a valid instrument used for evaluation of the effectiveness of interventions and for quantitative descriptions of function in clinical practice and research.

Instructions: Please document each task and/or give instructions as written. When scoring, please record the lowest response category that applies for each item.

In most items, the subject is asked to maintain a given position for a specific time. Progressively more points are deducted *if the time or distance requirements are not met , the subject's performance warrants supervision* **or** *the subject touches an external support or receives assistance from the examiner.* **A five-point scale, ranging from 0-4. "0" indicates the lowest level of function and "4" the highest level of function. Maximum total score = 56**

Subject should understand that they must maintain their balance while attempting the tasks. The choices of which leg to stand on or how far to reach are left to the subject. Poor judgment will adversely influence the performance and the scoring.

Equipment needed: Ruler, two standard chairs (one with arm rests, one without),footstool or step, stopwatch or wristwatch, 15 ft walkway. **Completion time:** 15-20 minutes.

Name:	Date:
Location:	Administrator:

	Task	Description of Balance	Pts	Score
1	**SITTING TO STANDING**	**INSTRUCTIONS: Please stand up. Try not to use your hand for support.**		
		able to stand without using hands and stabilize independently	4	
		able to stand independently using hands	3	
		able to stand using hands after several tries	2	
		needs minimal aid to stand or stabilize	1	
		needs moderate or maximal assist to stand	0	
2	**STANDING UNSUPPORTED**	**INSTRUCTIONS: Please stand for two minutes without holding on.**		
		able to stand safely for 2 minutes	4	
		able to stand 2 minutes with supervision	3	
		able to stand 30 seconds unsupported	2	
		needs several tries to stand 30 seconds unsupported	1	
		unable to stand 30 seconds unsupported	0	
		If a subject is able to stand 2 minutes unsupported, score full points for sitting unsupported. Proceed to item #4.		
3	**SITTING- BACK UNSUPPORTED - FEET SUPPORTED ON FLOOR OR ON A STOOL**	**INSTRUCTIONS: Please sit with arms folded for 2 minutes.**		
		able to sit safely and securely for 2 minutes	4	
		able to sit 2 minutes under supervision	3	
		able to able to sit 30 seconds	2	
		able to sit 10 seconds	1	
		unable to sit without support 10 seconds	0	
4	**STANDING TO SITTING**	**INSTRUCTIONS: Please sit down.**		
		sits safely with minimal use of hands	4	
		controls descent by using hands	3	
		uses back of legs against chair to control descent	2	
		sits independently but has uncontrolled descent	1	
		needs assist to sit	0	

	Task	Description of Balance	Pts	Score
5	TRANSFERS	**INSTRUCTIONS: Arrange chairs for pivot transfer. Ask subject to transfer one way toward a seat with armrests and one way toward a seat without armrests. You may use two chairs (one with and one without armrests) or a bed and a chair.**		
		able to transfer safely with minor use of hands	4	
		able to transfer safely definite need of hands	3	
		able to transfer with verbal cuing and/or supervision	2	
		needs one person to assist	1	
		needs two people to assist or supervise to be safe	0	
6	STANDING UNSUPPORTED WITH EYES CLOSED	**INSTRUCTIONS: Please close your eyes and stand still for 10 seconds.**		
		able to stand 10 seconds safely	4	
		able to stand 10 seconds with supervision	3	
		able to stand 3 seconds	2	
		unable to keep eyes closed 3 seconds but stays safely	1	
		needs help to keep from falling	0	
7	STANDING UNSUPPORTED WITH FEET TOGETHER	**INSTRUCTIONS: Place your feet together and stand without holding on.**		
		able to place feet together independently and stand 1 minute safely	4	
		able to place feet together independently and stand 1 minute with supervision	3	
		able to place feet together independently but unable to hold for 30 seconds	2	
		needs help to attain position but able to stand 15 seconds feet together	1	
		needs help to attain position and unable to hold for 15 seconds	0	
8	REACHING FORWARD WITH OUTSTRETCHED ARM WHILE STANDING	**INSTRUCTIONS: Lift arm to 90 degrees. Stretch out your fingers and reach forward as far as you can. Examiner places a ruler at the end of fingertips when arm is at 90 degrees. Fingers should not touch the ruler while reaching forward. The recorded measure is the subject is in the most forward lean position. When possible, ask subject to use both arms when reaching to avoid rotation of the trunk.**		
		can reach forward confidently 25 cm 10 inches	4	
		can reach forward 12 cm 5 inches	3	
		can reach forward 5 cm 2 inches	2	
		reaches forward but needs supervision	1	
		loses balance while trying/requires external support	0	
9	PICK UP OBJECT FROM THE FLOOR FROM A STANDING POSITION	**INSTRUCTIONS: Pick up the shoe/slipper, which is in front of your feet.**		
		able to pick up slipper safely and easily	4	
		able to pick up slipper but needs supervision	3	
		unable to pick up but reaches 2-5 cm1-2 inches from slipper and keeps balance independently	2	
		unable to pick up and needs supervision while trying	1	
		unable to try/needs assist to keep from losing balance or falling	0	
10	TURNING TO LOOK BEHIND OVER LEFT AND RIGHT SHOULDERS WHILE STANDING	**INSTRUCTIONS: Turn to look directly behind you over toward the left shoulder. Repeat to the right. Examiner may pick an object to look at directly behind the subject to encourage a better twist turn.**		
		looks behind from both sides and weight shifts well	4	
		looks behind one side only other side shows less weight shift	3	
		turns sideways only but maintains balance	2	
		needs supervision when turning	1	
		needs assist to keep from losing balance or falling	0	

PATIENT NAME: DATE: BERG BALACE SCALE 2

	Task	Description of Balance	Pts	Score
11	TURN 360 DEGREES	INSTRUCTIONS: Turn completely around in a full circle. Pause. Then turn a full circle in the other direction.		
		able to turn 360 degrees safely in 4 seconds or less	4	
		able to turn 360 degrees safely one side only 4 seconds or less	3	
		able to turn 360 degrees safely but slowly	2	
		needs close supervision or verbal cuing	1	
		needs assistance while turning	0	
12	PLACE ALTERNATE FOOT ON STEP OR STOOL WHILE STANDING UNSUPPORTED	INSTRUCTIONS: Place each foot alternately on the step/stool. Continue until each foot has touched the step/stool four times.		
		able to stand independently and safely and complete 8 steps in 20 seconds	4	
		able to stand independently and complete 8 steps in > 20 seconds	3	
		able to complete 4 steps without aid with supervision	2	
		able to complete > 2 steps needs minimal assist	1	
		needs assistance to keep from falling/unable to try	0	
13	STANDING UNSUPPORTED ONE FOOT IN FRONT	INSTRUCTIONS: DEMONSTRATE TO SUBJECT Place one foot directly in front of the other. If you feel that you cannot place your foot directly in front, try to step far enough ahead that the heel of your forward foot is ahead of the toes of the other foot. To score 3 points, the length of the step should exceed the length of the other foot and the width of the stance should approximate the subject's normal stride width.		
		able to place foot tandem independently and hold 30 seconds	4	
		able to place foot ahead independently and hold 30 seconds	3	
		able to take small step independently and hold 30 seconds	2	
		needs help to step but can hold 15 seconds	1	
		loses balance while stepping or standing	0	
14	STANDING ON ONE LEG	INSTRUCTIONS: Stand on one leg as long as you can without holding on.		
		able to lift leg independently and hold > 10 seconds	4	
		able to lift leg independently and hold 5-10 seconds	3	
		able to lift leg independently and hold ≥ 3 seconds	2	
		tries to lift leg unable to hold 3 seconds but remains standing independently.	1	
		unable to try of needs assist to prevent fall	0	

TOTAL SCORE (MAX 56) =

Table 29. BERG scale.

11.6 Semantic Fluency

The implementing rules are identical to those of the phonemic fluency test (Table 30 and 31). Instead of the letters you use three semantic fields:

- fruits
- animal
- brands cars

NR. OF WORDS	RANGE
From 1 to 24	0
From 25 to 29	1
From 30 to 34	2
From 35 to 38	3
From 39 to over	4

Table 30. Score scale for semantic fluency test.

	Schooling (in years)				
	0-3	4-5	6-8	9-13	14-17
Age					
25-34	6	2	-2	-6	-8
35-44	7	3	-1	-5	-7
45-54	9	4	1	-3	-6
55-64	10	6	2	-2	-4
65-74	12	8	4	0	-2
>75	14	10	6	2	0

Table 31. Correction table for semantic fluency test.

11.7 Phonemic Fluency

The test of phonemic verbal fluency is to say as many words as possible that begin with a certain letter (F, A, S for English version; F, L, P for Italian version) (Table 32 and 33). One minute for each letter. You need to provide some examples and discourage the tendency to give proper names and derivatives.

NR. OF WORDS	RANGE
From 1 to 16	0
From 17 to 22	1
From 23 to 26	2
From 27 to 31	3
From 32 to over	4

Table 32. Score scale for phonemic fluency test.

	Schooling (in years)				
	0-3	4-5	6-8	9-13	14-17
Age					
25-34	7	4	-1	-6	-10
35-44	8	5	1	-5	-9
45-54	9	6	2	-4	-7
55-64	10	7	3	-3	-6
65-74	12	8	4	-1	-5
>75	13	9	5	0	-4

Table 33. Correction table for phonemic fluency test.

11.8 Attentional Matrices

This is also referred to as: evaluation of selective visual attention [264--107]. Three matrices of numbers were administered; each is constituted by 13 rows of 10 numbers from 0 to 9 randomly arranged. The subject must cross out as fast as possible target numbers. The maximum time for each matrix is 45 seconds. It's possible to complete the task after the time (45 sec), scoring the numbers

crossed and recording the actual time of completion. If the subject takes less than 45 sec., you write down the time.

Score range 0-60

Instruction:

Show the 1st matrix and say: "Now you'll have to mark with a pencil all the numbers corresponding to those shown in the top of the matrix." The line A is used as an example. If the person proves that he understood the task, go on. The function of line B is run-in. You must start to count the time only from the line I. You are not allowed to correct dams already made.

VISUAL SEARCH

A)	2 6 5 9 4 5 2 5 2 6	A)	2 6 5 9 4 5 2 5 2 6	A)	2 6 5 9 4 5 2 5 2 6
B)	4 1 2 5 1 3 0 4 9 1	B)	4 1 2 5 1 3 0 4 9 1	B)	4 1 2 5 1 3 0 4 9 1
I)	0 6 7 6 8 9 8 0 8 0	I)	0 6 7 6 8 9 8 0 8 0	I)	0 6 7 6 8 9 8 0 8 0
II)	9 0 4 3 0 1 9 3 7 6	II)	9 0 4 3 0 1 9 3 7 6	II)	9 0 4 3 0 1 9 3 7 6
III)	7 9 5 3 7 8 8 9 7 6	III)	7 9 5 3 7 8 8 9 7 6	III)	7 9 5 3 7 8 8 9 7 6
IV)	7 3 7 6 8 5 8 5 3 2	IV)	7 3 7 6 8 5 8 5 3 2	IV)	7 3 7 6 8 5 8 5 3 2
V)	5 2 3 1 2 3 1 7 2 8	V)	5 2 3 1 2 3 1 7 2 8	V)	5 2 3 1 2 3 1 7 2 8
VI)	4 1 7 4 7 6 9 1 8 3	VI)	4 1 7 4 7 6 9 1 8 3	VI)	4 1 7 4 7 6 9 1 8 3
VII)	2 7 4 2 6 2 9 4 5 0	VII)	2 7 4 2 6 2 9 4 5 0	VII)	2 7 4 2 6 2 9 4 5 0
VIII)	4 3 4 0 4 3 0 2 8 2	VIII)	4 3 4 0 4 3 0 2 8 2	VIII)	4 3 4 0 4 3 0 2 8 2
IX)	6 1 5 6 1 5 8 3 6 9	IX)	6 1 5 6 1 5 8 3 6 9	IX)	6 1 5 6 1 5 8 3 6 9
X)	4 5 2 8 1 3 9 1 5 1	X)	4 5 2 8 1 3 9 1 5 1	X)	4 5 2 8 1 3 9 1 5 1
XI)	7 9 7 5 0 7 3 4 0 8	XI)	7 9 7 5 0 7 3 4 0 8	XI)	7 9 7 5 0 7 3 4 0 8

TOT._____   TOT._____   TOT._____

COMPLEX TOT: _____/60

POINTS: N° of total answers into 45 sec. for 3 matrices (range: 0-60).

score: **O** = 0-30;   **1** = 31-36;   **2** = 37-43;   **3** = 44-48;   **4 =** >48

5

a) 2 6 5 9 4 5 2 5 2 6

b) 4 1 2 5 1 3 0 4 9 1

I) 0 6 7 6 8 9 8 0 8 0

II) 9 0 4 3 0 1 9 3 7 6

III) 7 9 5 3 7 8 8 9 7 6

IV) 7 3 7 6 8 5 8 5 3 2

V) 5 2 3 1 2 3 1 7 2 8

VI) 4 1 7 4 7 6 9 1 8 3

VII) 2 7 4 2 6 2 9 4 5 0

VIII) 4 3 4 0 4 3 0 2 8 2

IX) 6 1 5 6 1 5 8 3 6 9

X) 4 5 2 8 1 3 9 1 5 1

XI) 7 9 7 5 0 7 3 4 0 8

2   6

a)   2 6 5 9 4 5 2 5 2 6

b)   4 1 2 5 1 3 0 4 9 1

I)   0 6 7 6 8 9 8 0 8 0

II)   9 0 4 3 0 1 9 3 7 6

III)   7 9 5 3 7 8 8 9 7 6

IV)   7 3 7 6 8 5 8 5 3 2

V)   5 2 3 1 2 3 1 7 2 8

VI)   4 1 7 4 7 6 9 1 8 3

VII)   2 7 4 2 6 2 9 4 5 0

VIII)   4 3 4 0 4 3 0 2 8 2

IX)   6 1 5 6 1 5 8 3 6 9

X)   4 5 2 8 1 3 9 1 5 1

XI)   7 9 7 5 0 7 3 4 0 8

1   4   9

a)   2 6 5 9 4 5 2 5 2 6

b)   4 1 2 5 1 3 0 4 9 1

I)   0 6 7 6 8 9 8 0 8 0

II)   9 0 4 3 0 1 9 3 7 6

III)   7 9 5 3 7 8 8 9 7 6

IV)   7 3 7 6 8 5 8 5 3 2

V)   5 2 3 1 2 3 1 7 2 8

VI)   4 1 7 4 7 6 9 1 8 3

VII)   2 7 4 2 6 2 9 4 5 0

VIII)   4 3 4 0 4 3 0 2 8 2

IX)   6 1 5 6 1 5 8 3 6 9

X)   4 5 2 8 1 3 9 1 5 1

XI)   7 9 7 5 0 7 3 4 0 8

11.9 Token Test

The stimuli of the test are made up of thirty-six verbal orders divided into 6 parts, of increasing difficulty which the participant must perform operating on some tokens of different shapes (circle, rectangle), colour (red, blue, yellow, green, white) and size (two sizes) (Figure 15 and Table 34). Rating: ranges from a minimum of 0 to a maximum of 36 points, and is given by the sum of items to which the subject gave the correct answer.

The Token test allows also for the discriminate between aphasic patients and not aphasic and is relatively sensitive for the diagnosis of mild deficit language and in subjects with low school attendance.

Score table:

- 1 point for each correct answer to the first presentation;
- 0.5 points for each correct answer to the second presentation;
- 0 points for each incorrect answer after the second presentation (or after the first of the orders of the sixth part)

Figure 15. Token test items.

Instructions: *the examiner tells the patient: "As you can see, here there are tokens (point them) that have different shape, size and colour. Some of them are circles, and other squares, some are large and some small, there are red, yellow, white, green and black ones (indicate each time.) Now I'll tell you to do some things with these tokens, for example, please touch the black one. Wait each time until I've finished explaining what you are requested to do. "*

If the patient doesn't answer within the first 5 seconds, or gives a wrong answer, tidy up the tokens and say, "let's try again." Repeat the request and give to the patient another 5 seconds to answer: if he doesn't answer again, his reply is not correct, proceed with the following request. Only for requests included in Part VI, the order shall never be repeated. If the patient asks for a third repetition or complains of having forgotten part of the order, he should be invited to do anything he can remember.

TOKEN TEST – Short Version

Name: _____

Birth: _____ Age: ____ yars and _____ months.

Schooling: _____ Date: _____

Examiner: _____

Part 1 (All tokens)

☐ 1- Touch a circle.

☐ 2- Touch a square.

☐ 3- Touch a yellow token

☐ 4- Touch a red one.

☐ 5- Touch a black one.

☐ 6- Touch a green one.

☐ 7- Touch a white onde.

Part 2 (Only large tokens)

☐ 8- Touch the yellow square.

☐ 9- Touch the black circle.

☐ 10- Touch the green circle.

☐ 11- Touch the white square.

Part 3 (All tokens)

☐ 12- Touch the small white circle.

☐ 13- Touch the large yellow square.

☐ 14- Touch the large green square green.

☐ 15- Touch the small black circle.

Part 4 (Only large tokens)

☐ 16- Touch the red circle red and the green square.

☐ 17- Touch the yellow square and the black square.

☐ 18- Touch the white square and the green circle.

☐ 19- Touch the white circle and red circle.

Part 5 (All tokens)

☐ 20- Touch the large white circle and the small green square.

☐ 21- Touch the small black circle and the large yellow square.

☐ 22- Touch the large green square and the large red square.

☐ 23- Touch the large white square and the small green circle.

Part 6 (Only large tokens)

☐ 24- Put the red circle on the green square.

☐ 25- Touch the black circle with the red square.

☐ 26- Touch the black circle and the red square.

☐ 27- Touch the black circle or the red square.

☐ 28- Put the green square away from the yellow square.

☐ 29- If there is blue circle, Touch the red square.

☐ 30- Put the green square next to the red circle.

☐ 31- Touch the squares slowly and the circles quickly.

☐ 32- Put the red circle between the yellow square and de green square.

☐ 33- Touch all the circles, except the green one.

☐ 34- Touch the red circle red. No! The white square.

☐ 35- Instead of the white square, Touch the yellow circle.

☐ 36- In addition to touching the yellow circle, Touch black circle.

Score: _____

-

Table 34. Token test short version.

11.10 METADIETA Interactive Education Programme: steps and details.

1   Personal Details of the Patient.

Name, surname, address, phone number, mail address etc., will be inserted for create a **personal database** of all Users in the total respect of ethical issues (Figure 9). Each enrolled subject will be identified by a code number and only the code will be used for data collection and analysis. Patient identification will be possible only to attending physicians and clinical monitors who will have access to original clinical records (Figure 16). Patient blood samples will be stored at processing laboratories in areas with restricted access and destroyed within 24 months from processing. Data transfer among attending physicians and clinical monitors, and from medical staff to Technical Partners involved in the study project will be protected by the security system working at the Hospital Computing Centre of EXTRACARE, Accord and Si4Life sites.
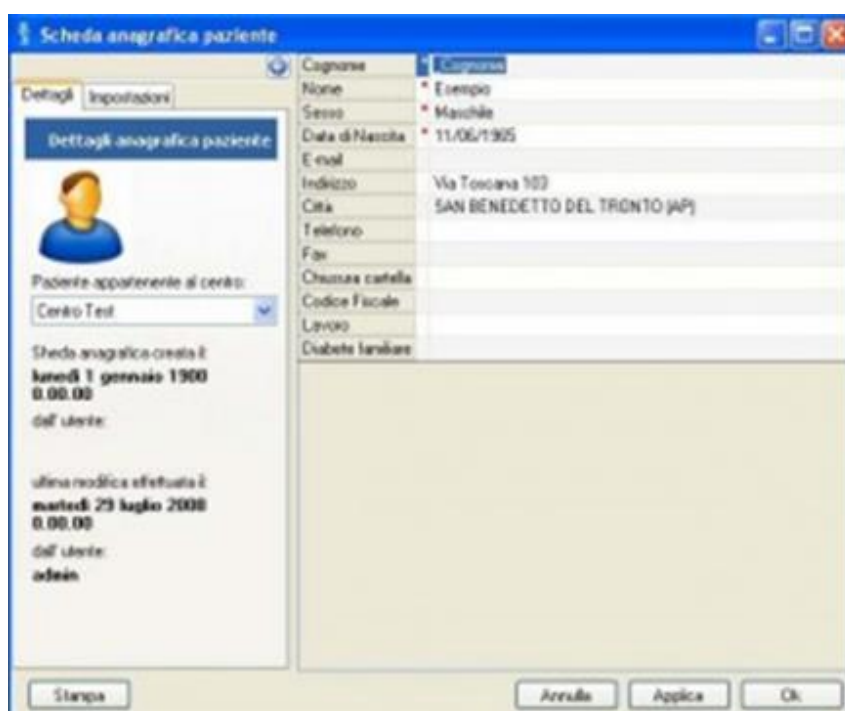
Figure 16. METADIETA Personal details of Patients.

2   Reporting of measurements resulting from laboratory tests.

This session allows the Nutritionist to **insert of all parameters resulting from blood and urine tests** included in DOREMI protocols: the control of values will be checked over time. METADIETA software shows the majority of laboratory tests (1,300), with periodic updating, according to the main available databases (Figure 17). This report includes values of weight, height and BMI (D2.1 – §6.1;).
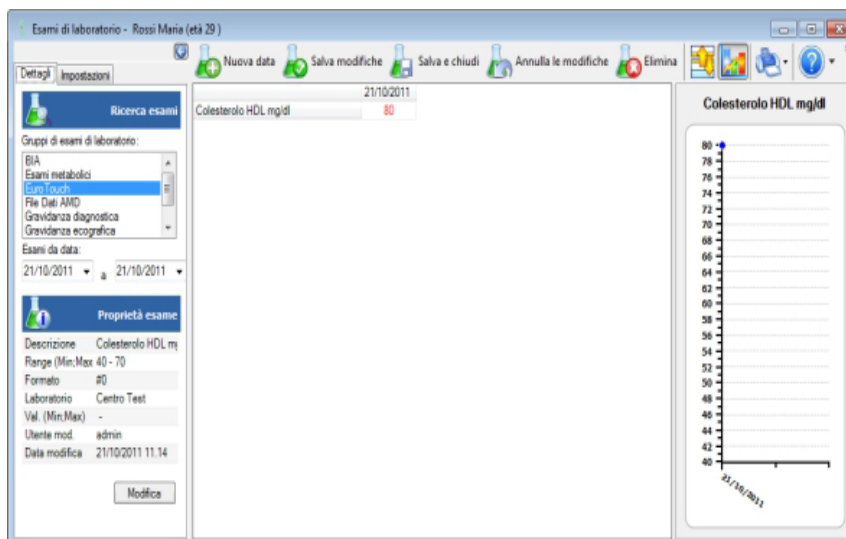
Figure 17. METADIETA insert of laboratory tests

3   Clinical evaluation.

This session allows the Nutritionist **to collect the clinical history** using all patient data in a chronological way.

It allows to report anamnestic features, physiological and pathological conditions concerning specific diseases (overweight, obesity, high cholesterol, arterial hypertension, atherosclerosis, type 2 diabetes, metabolic syndrome, dehydration, neuro-degenerative disorders linked to cognitive decline). This is a very important step in the modification of unhealthy dietary habits: as far as specific diseases are concerned, we start to lay basis for a personalized nutrition (D2.1 – §4.1; 4.1.1; 4.1.2; 4.1.3; 4.1.4; 4.1.5) (Figure 18).
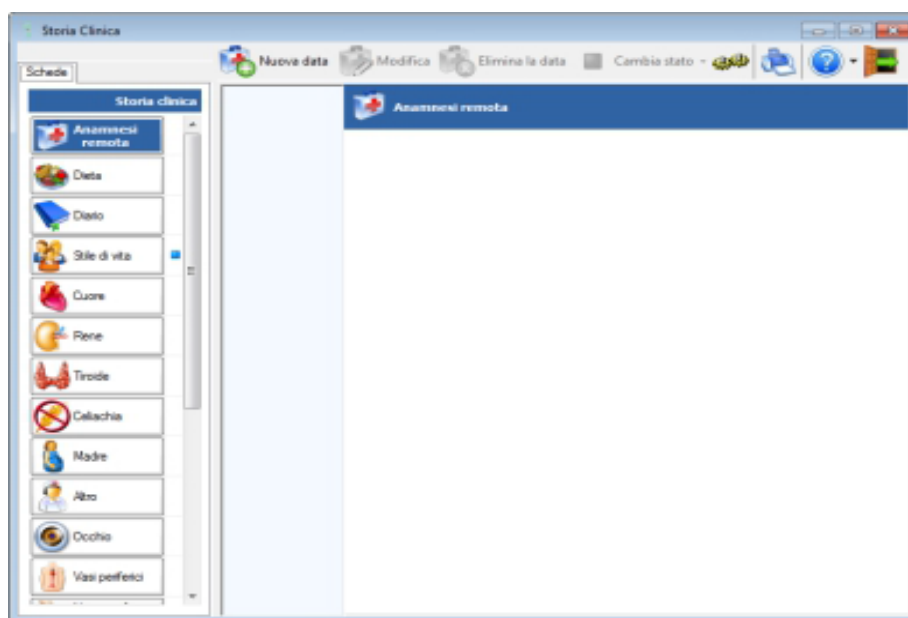
Figure 18. METADIETA insert physiological diseases.

4   The filter unit.

This session allows the Nutritionist to **exclude a selection of foods that are not allowed** on the basis of: specific disorders (including multiple or cross pathologies); food allergies or intolerances; seasonal products; foods unwelcome to the patient.

The filter unit comes with a library of ready-made filters editable by the nutritionists; it is possible to add new filters and personalize filter based on the preferences of the single User (Figure 19).
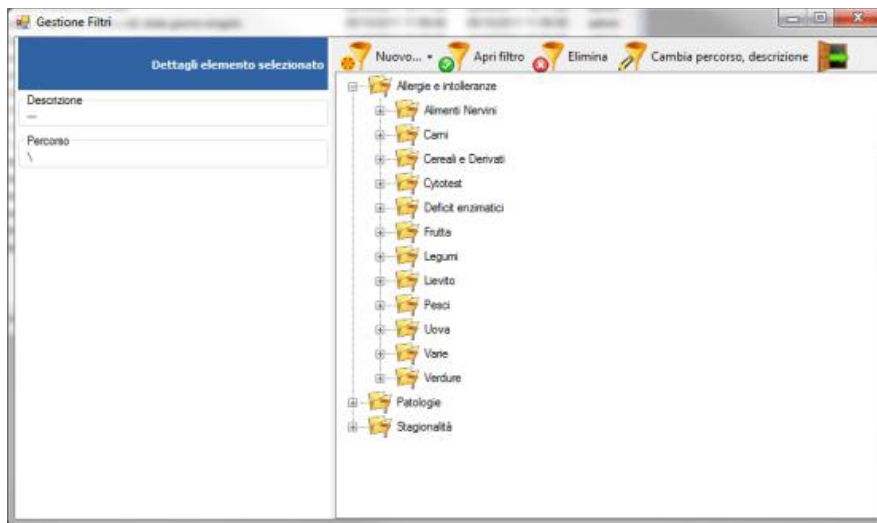

Figure 19. METADIETA filter unit.

5   The total body evaluation.

This session allows the Nutritionist to deepen **the somatometric and the arthrometric assessment.** It permits also the evaluation of body composition and basal metabolism through the introduction of plicometer data, circumferences, diameters, weight and height (Figure 20).
For a detailed screening it is possible to insert somatometric and arthrometric values belonging separately to the left and to the right side of the body (Figure 21).
By processing of these data, the software provides results, which permit to perform the following evaluations:

- somatometric assessment by the method of Heath and Carter [108];
- measures of fat and muscle area of the arm circumference;
- fat and muscle area of the thigh;
- assessment of body composition through the use of the main measurements derived by BIVA (see below);
- multiple body assessments: body surface area, bi-compartmental assessment (density body, lean mass and fat mass), assessment of the total muscle mass, according to BIVA measurements and derived values;
- assessment of the basal metabolic rate and energy requirements. The basal metabolic rate is derived from FFM (Cunningham), by weight according to the reference RDAs, from weight and height (Harris & Benedict) [109-111];
- The analysis of the energy expenditure is completed with the assessment of the Physical Activity Level (PAL) and with the amount of the total energy requirements.

Furthermore, the measurement of circumference of the waist, of the hip, waist-to-hip ratio, will be inserted.
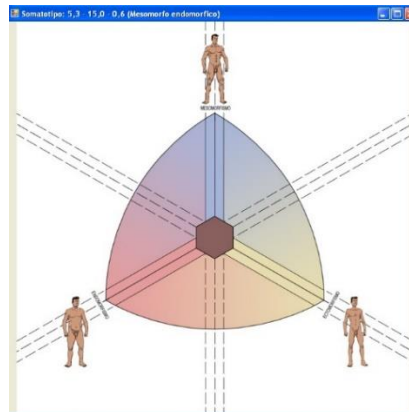
Figure 20. METADIETA the left and the right sides values.

Figure 21. METADIETA plicometer data

The Bio Impedance Analysis.

The METADIETA software has a specific section for **the insertion of data generated by bioelectrical impedance**. It integrates a module with a specific section for the insertion of data resulting from impedance analysis and visualization of the Akern BiaVector by resistance and reactance (Figure 22). (D2.1 – §6.1).

The remaining parameters will be calculated automatically.

Once the Nutritionist enters the User's data, it will be possible to control the trend over time of different values.

Thanks to this innovation, it is also possible to select between the different formulas used to calculate the energy needs of the individual, the one containing the Basal or Resting Metabolic Rate RMR) resulting from the use of the impedance analysis.
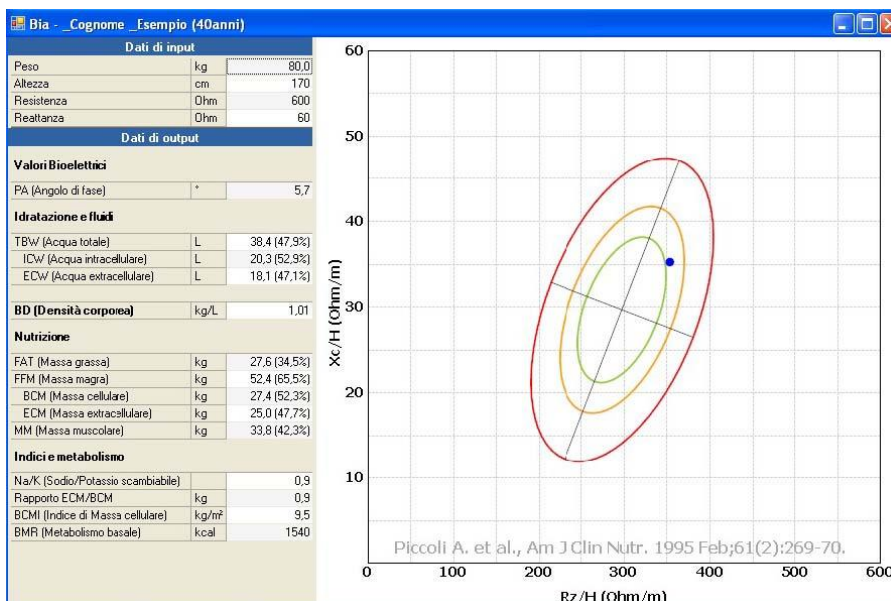
Figure 22. METADIETA and Akern: The Bio Impedance Analysis – BiaVector.

6   Survey and development of a diet.

This section represents the functional heart of METADIETA: **the development of healthy personalized dietary habits carried out by the Nutritionist collecting all previous data and feedback from the User.**

During the dietary survey using the completeness of the photographic archive, the Nutritionist can understand the most representative portions according to the feedback of the User.

Processing dietary habits, it is possible to see a summary of nutrient composition (macro and micro nutrients) and the relative percentages for each meal or for the whole day, including a visual graphic support. The frequency of intake of foods can be set for single food or for groups.

If the diet is a multi-day purpose a summary version will take care of the days' frequency.

The easy representation of diet consists of different setting and display: single day (multiple choice), more days (up to 100 days), diet weekly/monthly plan (Figures 23 and 24).
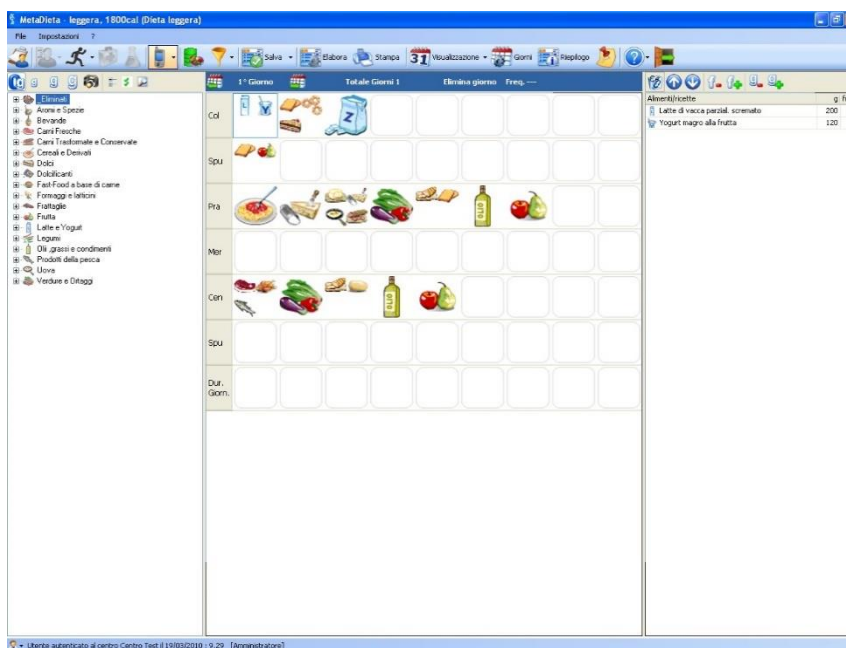

Figure 23. METADIETA survey and development using the completeness of the photographic archive.
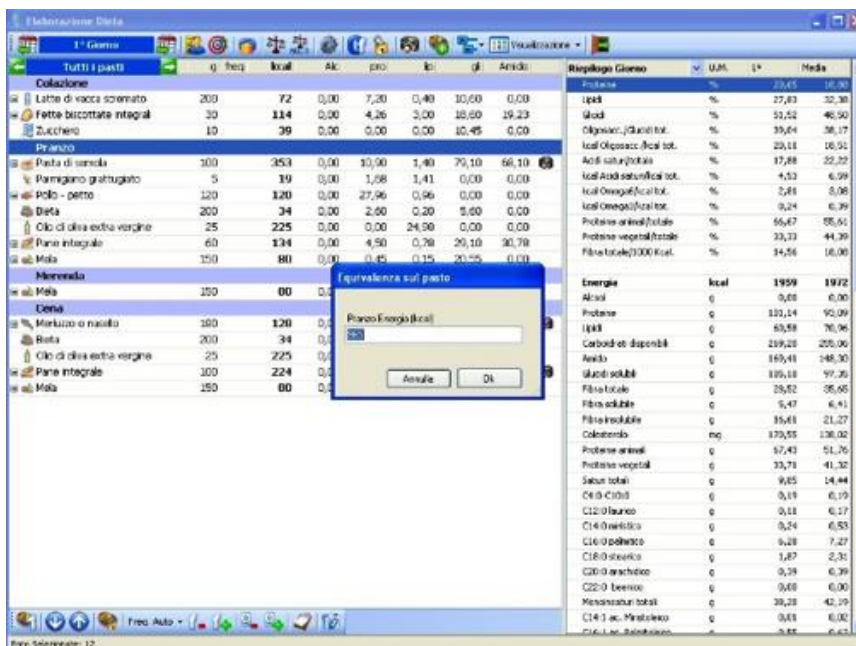
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Figure 24. METADIETA survey and development of a diet with bromatological insert and relative percentage for each meal or for whole day.

7   **Management of the daily nutritional requirements.**

This session allows the Nutritionist **to assess the intake of all nutrients**, minerals, vitamins and the relation with Recommended Daily Allowance (RDA). The personal needs depend on the parameters of sex, age, weight and physiological states too. Processing dietary habits any dietary deviation from the RDA will be reported and checked (Figure 25) *(see D2.1 – §4.1: Unhealthy Dietary Habits)*.
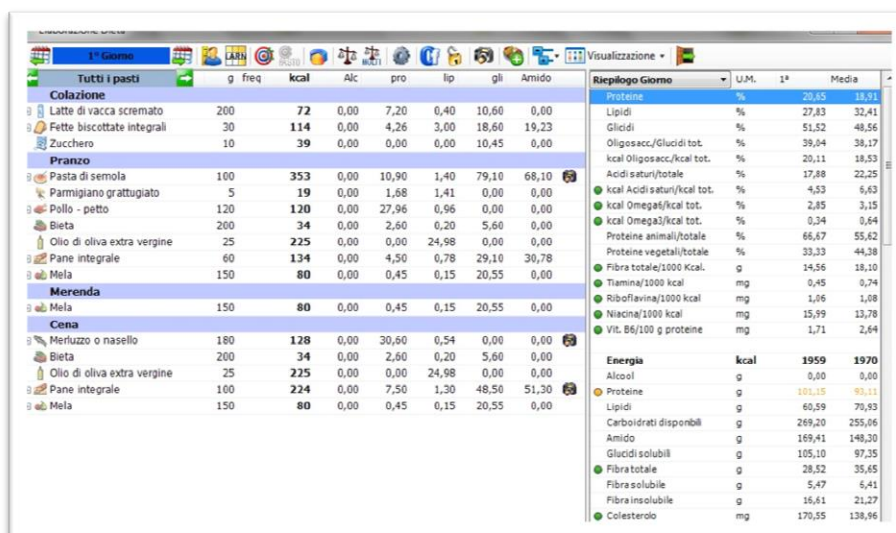

Figure 25. METADIETA assessment of the needs of all nutrients depending on RDA.

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