FRAILCLINIC

Study Title:

FEASIBILITY AND EFFECTIVENESS OF THE IMPLEMENTATION OF PROGRAMS TO SCREEN AND MANAGE FRAIL OLDER PATIENTS IN DIFERRENT CLINICAL SETTINGS

INTERVENTIONAL PHASE

Protocol identifying number: 20131208

Confidentiality Statement:

This document contains confidential information that must not be disclosed to anyone other than the Sponsor, the Investigator Team, Regulatory Authorities, and members of the Ethics Committee.

Sponsor: FUNDACIÓN PARA INVESTIGACION BIOMÉDICA DEL HOSPITAL UNIVERSITARIO DE GETAFE

Project Leader: Prof. Leocadio Rodríguez Mañas

Medical monitor: Prof. Leocadio Rodríguez Mañas.

Email: leocadio.rodriguez@salud.madrid.org

Fax: 0034 916247305

Study promoted by DG SANCO "HEALTH-2013

TABLE OF CONTENTS

SIGNATURE PAGE

STUDY TITLE: FEASIBILITY AND EFFECTIVENESS OF THE IMPLEMENTATION OF PROGRAMS TO SCREEN AND MANAGE OLDER PATIENTS IN DIFFERENT CLINICAL SETTINGS

STUDY CODE: FRAILCLINIC

I confirm I have read and understand the present protocol and I agree to perform the study according to what is recorded on it and to the applicable legal requirements.

_____ _____

SPONSOR DATE

_____ _____

PROJECT COORDINATOR DATE

Prof. Leocadio Rodríguez Mañas

_____ _____

SCIENTIFIC COORDINATOR DATE

Name

Site

1 ABREVIATIONS

ADL	*Activities of Daily Living*
AE	*Adverse event*
GDS	*GeriatricDepresionScale*
FC	*Fried's Criteria*
EC	*Ethics Committee*
eCRF	*Case Report Form*
GCP	*Good Clinical Practice*
EQ-5D	*EuroQolfive-dimensional (EQ-5D)*
CRO	*Contract Research Organization*
IADL	*Instrumental Activities of Daily Living*
INE	*Instituto Nacional de Estadística (Spain)*
ICF	*InformedConsentForm*
MMSE	*Minimental State Examination*
SPPB	*Short Physical Performance Battery*
PASE	*Physical Activity Scale for the Elderly*
CAM	*Confusion Assessment Method*
ICER	*Incremental cost-effectiveness ratio*
PI	*Principal Investigator*
HUG-GRT	*Hospital Universitario de Getafe-Servicio de Geriatría*

2 INTRODUCTION

2.1 BACKGROUND INFORMATION:

Disability is the main consequence of the concurrence of three conditions in old people: the ageing process, lifestyle processes and health-related conditions.

As it has been the case with other relevant organizations and bodies, in its 2012 Ageing report, the European Commission and the Economic Policy Committee stated that coping with the challenge posed by an ageing population and a trend toward increases in age-related spending will require determined policy action in Europe, particularly in: (a) reforming pension, health care and long-term care systems, and (b) the reduction of disability and dependence through appropriate action with a special focus in fighting against disability (DG ECFIN & AWG, 2012).

Disability is usually preceded by a state characterized by a decreasing capacity to respond to demands, caused by diminishing functional reserve. This condition has been named frailty, a disorder that may precede by several years the development of disability (1) and other clinical outcomes. When the frailty threshold has been surpassed and disability has emerged, recovery from disability is unlikely (2), especially as the age of the patient, the degree of disability or its duration increase (3). In contrast, frailty is reversible, as it has been shown both spontaneously (4, 5) and by interventions based on physical exercise (6).

Moreover, and differently from chronic disease, the predictive capacity of frailty for adverse outcomes increases as the age of the population increases (8) becoming the most common condition leading to death among community-dwelling older persons, followed by organ failure (21.4%), cancer (19.3%) and dementia (13.8%) of dying.

The aim of the present study is to assess the feasibility and effectiveness of programs designed to detect and manage frail older patients in high risk clinical settings, and to avoid functional impairment and other associated adverse outcomes.

2.2 RATIONALE OR JUSTIFICATION

The prevalence of frailty in people older than 65 years is high, ranging from 7 to 16.3 %, and this increases with age (1, 9, 10).

The most accepted approach defines frailty as "an age-associated biological syndrome characterized by a decrease in biological reserve and resistance to stress, due to a decline in several physiological systems, placing the individual in a special risk category when facing minor stressors and associated with poor outcomes (disability, death and hospitalization)" (11-14).

Frailty is an established and credible concept which provides the framework for the relationships between ageing, disease, vulnerability, disability, and dependency (15). with its high prevalence in older people and its potential reversibility, make frailty the perfect target to overcome the challenge of disability in older adults(16).

The challenge for Health Systems is develop strategies to detect this syndrome and the prevention the functional decline and disability. As a consequence, a complementary strategy is needed, supporting clinicians to provide personalized, comprehensive continuity of care (17).

Older frail patients are prone to develop functional impairments, to be institutionalized and to die early. Additionally, they use Health and Social facilities much more frequently than their same-age counterparts, being at high risk for mis-, under- and over management. Some of these specific needs are covered by classical Geriatric facilities available in many European Hospitals. But these facilities only attend to 10-15% of all the frail older patients that are being seen and managed by other parts of the health care systems (14)

It has been largely recommended that programs must not only identify at-risk patients so that they may benefit from specialized management, but they must also target the process of care (Lafont E et al., JNHA 2011) to 1) provide the best-fitted models of care to their needs, and 2) adapt the management of their diseases and conditions (cancer, major surgery, heart disease, etc.) to their special features (18). In this regard, recent publications have stated that this approach should be standard practice, and is supported by a wealth of evidence (19), mainly in frail elderly patients being attended in some specific high risk settings as described in our proposal (20-23).

FRAILCLINIC project includes two consecutives phases: the first one focus on detection and quantification of frailty (observational phase) and the second phase focus on management of frail patients by an integrate model of geriatric care (interventional phase). In the observational phase we have evaluated the prevalence of frailty, the success of a program for detection frail patients in high risk clinical settings, tools commonly used for assessment of frailty and causes of no implementation. In the interventional phase we will analyse the effect of the performance of a geriatrician agreed with the treating physician/surgeon of the patient in these clinical settings comparing with the traditional performance.

3 OBJECTIVES

3.1 PRIMARY OBJECTIVE:

To assess the feasibility and effectiveness of programs designed to detect and manage frail older patients in high risk clinical settings, and to avoid functional impairment and other associated adverse outcomes. These high risk settings will be medical wards (cardiology, oncology or nephrology), major surgery wards and Emergency rooms.

3.2 SECONDARY OBJECTIVES:

- Determine the feasibility of implementing clinical and therapeutic approach to geriatric physician in elderly patients in high risk clinical settings
- Determine disability by evaluating basic and instrumental activities of daily living in frail elderly patients treated in high risk clinical settings.
- Establish functional status in frail elderly people seen in high risk clinical settings.
- Evaluate quality of life through an instrument validated in frail patients seen in high risk clinical settings.
- Establish mortality ratio in frail patients included in high risk clinical settings.
- Obtain the rate of re-hospitalization in frail patients seen in high risk clinical settings.
- Determine the average stay of hospitalization in frail elderly patients treated in high risk clinical settings.
- Obtain the rate readmission to emergency room and hospitalization in frail older patients treated in high risk settings.
- Determine the average stay of hospitalization in frail elderly patients treated in high risk clinical settings.
- Determine the rate of delirium in frail elderly patients in high risk settings.
- Obtain the rate of health-care associated infections in frail older patients seen in high risk settings.
- Determine the rate of polypharmacy in frail older patients seen in high risk settings.
- Establish the secondary institutionalization rate accordingly to decline the functional status in frail elderly patients in high risk settings.

- Determine the need for a caregiver as a result of decline the functional status in frail older people in high risk settings.
- Establish the caregiver burden in hospitalized frail patients on high risk settings.
- Establish the secondary institutionalization rate accordingly to decline the functional status in frail elderly patients in high risk settings.
- Determine the need for a caregiver as a result of decline the functional status in frail older people in high risk settings.
- Establish caregiver burden of frail elderly patients seen in high risk settings.
- To evaluate the cost-effectiveness of the intervention compared with usual care from the perspective of society and the health system.
- To evaluate the cost-utility of the intervention compared with usual care.

4 OUTCOMES

4.1 PRIMARY OUTCOMES:

1. **Disability:** It was measured by the Barthel Index for basic Activities of Daily Living and the Lawton index for instrumental activities of daily living.
2. **Functional status and performance-based measures:** Functional status and performance-based measures: Is measured by Short Physical Performance Battery (SPPB), Physical Activity Scale for the Elderly (PASE SCALE).
3. **Quality of Life**: Quality of life was assessed by self-reported questionnaire EuroQL 5D 5L. It will be measured during admission to hospital and follow-up.
4. **Geriatrician Intervention**: The impact of their intervention is measured by quantifying in a register any additional tests requested and medical advice by other specialists.

4.2 SECONDARY OUTCOMES:

Prevalence of Delirium: The delirium cases are detected by Confusion Assessment Method (CAM) scale.

Cognitive Impairment: Will be measured by the Mini Mental State Examination (MMSE) in the initial assessment.

Depression: will be assessed using the Geriatric Depression Scale in the baseline assessment.

Health-care associated infections: Acquired during hospitalization start.

Geriatric Syndromes: The geriatric evaluation including the following aspects: clinical, functional, mental and social.

Comorbidity: Will measured at initial assessment thorough Charlson index

Nutritional Status: Will measured at initial assessment thorough the Mini Nutritional Assessment and body Mass index.

Polypharmacy: Defined as five or more prescription drugs.

Mortality rate: Number of deaths during follow-up. It is calculated using official report of the National Statistics Institute (INE).

Average stay hospitalization: Average length of stay of stay all discharges. We will obtain from Hospital Admissions service.

Hospitalization Rate in Emergency room: Number of hospital admissions over the total of patients admitted in the hospital.

Readmission rates: Number of readmissions during of follow-up period. I will get the data in Hospital Admissions Service.

Institutionalization: Number of patients referred to nursing home after discharge or at any time during follow-up. This information is obtained directly from patients or their relatives.

Requirement of caregiver: Number of patients who require a caregiver after hospital discharge.

Caregiver burden: Will be used Zarit Scale for assessing caregiver burden

Cost-effectiveness: The incremental cost-effectiveness ratio (ICER) was assessed by measuring the difference in health outcomes per unit cost.

Cost-utility: is measured using the QALY (unit of measurement of preferences of individuals with regard to the quality of life that has occurred through a health intervention, combined with the years earned for a given health state).

5 STUDY DESIGN

This trial is designed as a randomised, multicenter, phase III trial to evaluate the feasibility and viability of clinical and therapeutic approach frail older people in high risk clinical settings (Emergency room, General Surgery, Oncology, Cardiology, and Nephrology). Patients will be randomized on a 1:1 basis to receive either usual treatment or usual treatment plus geriatric interventions.

The patients will be recruitment in Spain, Italy and United Kingdom. In Spain will be included the following centres: Hospital Universitario de Getafe (Madrid), Hospital Universitario Central de Asturias Monte Naranco (Asturias); In Italy: Ospedale San Raffaele (Rome), Universitat´Cattolica del Sacro Cuore(Roma), in United Kingdom: (Cardiff University and other one to be determined)According to feasibility in each centre will be recruitment patients from differents clinical settings. See Table No 1

Table 1. Recruitment distribution of patients according to hospital and setting

Hospital	Setting
Hospital Universitario de Getafe. (Madrid - Spain)	Emergency room Cardiology ward Elective Surgery Emergency Surgery
Hospital Universitario Monte Naranco. (Asturias - Spain)	Oncology Elective Surgery Emergency Surgery
Professor Sinclair (England – United Kingdom)	Emergency room Cardiology Ward Elective Surgery
Cardiff University (Wales - Reino Unido)	Emergency room Nephrology ward Elective Surgery
Ospedale San Raffaele (Rome - Italy)	Cardiology Ward
Universita' Cattolica del Sacro Cuore (Rome - Italy)	Emergency Room Cardiology Ward Elective Surgery

6 ELEGIBILITY

6.1 INCLUSION CRITERIA:

Participants must meet all of the following inclusion criteria to be eligible to register for this trial: older than 75 years old diagnosed of frailty, according to Fried's Criteria, if is not possible to use the Fried Scale, FRAIL Scale will be used.

6.2 EXCLUSION CRITERIA:

- Do not able to give informed consent.
- Participants with moderate-severe cognitive impairment according to MMSE scale (score 18 or lower) and/or the GDS scale (score 5 or higher)*.
- Those with physical disability according to Barthel Index (lower to 40)
- Participants with critical acute disease who might need admission in an Intensive Care Unit (ICU).
- Life expectancy lower than six months
- Nursing home residents

* This cut-off was selected to establish a higher sensitivity and maintain a good recruitment rate.(24)

7 RECRUITMENT

Participants will be recruited in Spain, United Kingdom and Italy according to legal requirements in each country. Also, we will obtain the committee approbation in the hospitals, as well as, doing a contract in each hospital. The administrative matters will be handled by CRO Business&Decision Life Sciences (Contract Research Organization).

7.1 INFORMED CONSENT AND ELEGIBILITY CRITERIA

Potential participants will be evaluated by authorized members of the clinical trial who will be trained to provide the necessary information to adequately explain the trial protocol and solve the issues that arise from the possible candidate to join the study team. If necessary, several members of the research team should discuss and solve the doubts concerns of the patient.

The team member will be willing to answer questions from potential participants verbally or in writing if necessary in simple, clear and understandable language. Upon acceptance by the participant, potential eligibility criteria shall be formally evaluated, if they do, he or she shall sign the informed consent (Annex 1)

The Principal Investigator (PI) will have overall responsibility for solving any problems that might arise about informed consent and supervise all study participants to ensure that everyone involved in this process are properly trained according to the ethics committee approval protocol and Guides of Good Clinical Practice (GCP) and the Declaration of Helsinki of 1996.

Informed consent will be obtained before the participant is assessed by specialists with the purposes of the study. The right of a participant to refuse to participate without giving reasons will be respected. The participant may withdraw at any time without giving reasons and without prejudice to his / her further treatment. At no time during the process of obtaining informed consent the investigator or any member of the research team coerce or influence for the patient to be part of the clinical trial.

The investigator will check if the participant has successfully completed the consent form and that it has been signed and dated correctly. The researcher must sign and date the form in the right area on the same date as the participant. The original informed consent will be filed in the archive of the researcher.

If a participant is ineligible after randomization, it shall be reported immediately to the principal investigator.

Patients who during the follow up present a moderate or severe cognitive impairment will remain in the group assigned.

7.2 RANDOMIZATION

After verification that the participant fulfils the eligibility criteria and signed the informed consent, allocation will be made to a control or/an intervention group.

Participants will be randomized 1:1 through the eCRF by Linkcare Company, which also will do the database.

Patient's participation in the study and the telephone number of the study contacts will always be registered in his/her clinical record.

According to the study's schedule, the intervention phase will start the sixteenth week, taking into account the adjustments of the ethics committee in each country. Follow-up will be made at hospital discharge and at the third and sixth month after discharge.

7.3 SAMPLE SIZE

Dependence and disability affects quality of life perception and increases health costs. Hence, this variable will be taken to calculate sample size. According to literature, the incidence of disability in frail older people is approximately 40%.
In order to avoid the estimation bias, the sample size will have at least 10 outcomes as variables. Therefore, the formula has been calculated for a 95% confidence interval to obtain at least 40 events.

$$n * p \pm z_{1-\frac{\alpha}{2}} \sqrt{n * p * (1-p)}$$

It has been assumed drop-out rate of 20% and an incidence of disability described above. Hence, the sample size should be at least 1860 participants. In each clinical setting (emergency room, general surgery, oncology, cardiology and nephrology) 310 participants should be evaluated (155 in each group: control and intervention).

In case of not obtaining the minimal sample size in each clinical setting, the pondeate models will be made. Additionally, a meta-analysis will be performed including the global effect of the intervention according to clinical setting and with a thorough sensitivity analysis.

7.4 STATISTICAL ANALYSIS

Firstly, subject's basal characteristics at recruitment will be analyzed. Descriptive statistics of epidemiological and clinical data will be calculated (described in section 9). This analysis will be done in a conjoint manner, according to treatment and clinical setting (emergency room, general surgery, oncology, cardiology, and nephrology).

To verify the differences between the arms of the study a Mann-Whitney test will be made. Based on the inclusion criteria, it is expected that the differences will be produced by the intervention, and not because of differences between groups.

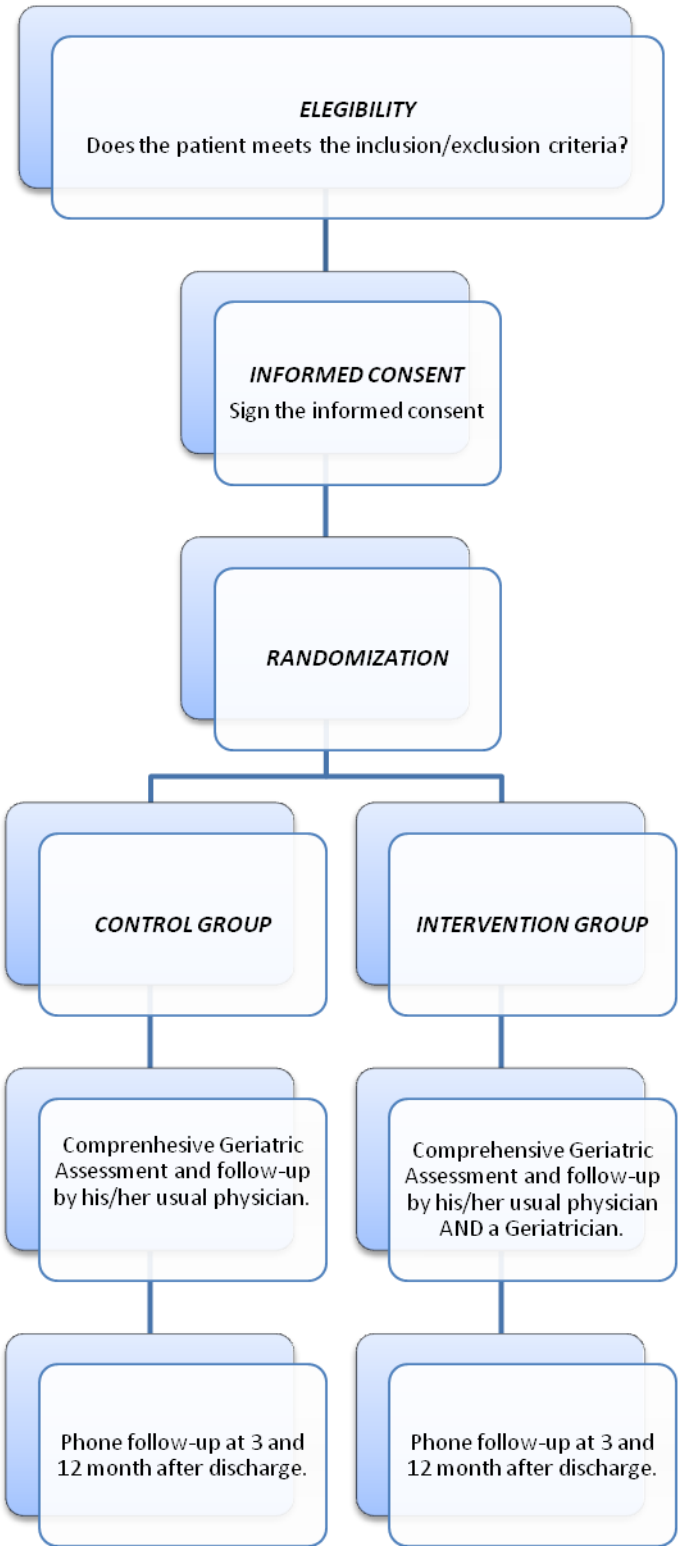
To evaluate the intervention in each clinical setting, the effect of the intervention and its statistical significance will be determined.

These effects shall be broken down into two classes depending on the event. First the prevalence rate, and in case the event's duration could be assessed, evaluate if this duration has changed..

For each outcome described in section 4, comparisons between predictive values of the logistic models for each scale will be made in order to determine which scale is optimal in a global manner, according to clinical setting.

In case the date of death and hospitalization can be obtained, survival models will be done.

Diagram 1. Flowchart of randomized clinical trial



8 INTERVENTION AND CONTROL

8.1 CONTROL GROUP

Patients will receive medical attention according to usual medical/surgical treatment and the peculiarities of each pathology and clinical setting. In this Group of patients a Comprehensive Geriatric Assessment will be done at hospital admission and discharge. If at any case, a geriatrician consultation is required, it should be registered in the eCRF and in patient's record. The statistical analysis of these patients' data should be made, if there's enough sample throughout a sensitivity analysis.

8.2 INTERVENTION GROUP

Patients included in this Group will be treated by usual physician with the support of geriatrics team, who will do Comprehensive Geriatric Assessment to detect any problem in the elderly population in the clinical, functional, mental and social domains. The objective is to establish a strategy of intervention, treatment and follow-up to optimize resources and improve independency and quality of life..

9 ASSESMENTS DURING THE STUDY

9.1 BASELINE EVALUATION (visit 0= FIRST VISIT)

After the inclusion of a participant in the study, a comprehensive geriatric assessment will be done with the following parts:

Demographics and epidemiology: Date of birth, age, sex, race, caregiver, marital status, number of persons in the house, and, number of hospitalization in the last year, follow up by others specialist, level of education.

- Medical history

Personal Medical and Surgery History should be recorded in the electronic Case Report Form (eCRF).

- Medications:

In the CRF we register all the regularly medication use (previous hospitalization)

- Functional status

Evaluate functional status with the following scales: Barthel Index, Lawton Index, measures based in performance (SPPB-Short Physical Performance Battery) and PASE Scale, Annex 2.

- Cognitive and depression:

Evaluate the results with MMSE and Geriatric Depression Scale GDS, and delirium risk with CAM scale. See Index 2.

- Physical examination:

Vital signs and physical examination as usual by the clinical investigator.

- Geriatric Syndromes Assessment:

Immobility: Falls and imbalance.

Incontinence: urinary and fecal.

Sensory deprivation

Iatrogenic: Record the numbers of falls during the hospitalization and adverse effects

Pain: assess pain using the VAS Scale. Nutritional Status:

Performed screening for nutritional status using the scale MNA (Mini Nutritional Assessment), Index 2.

- Comorbidities:

Comorbidities will be quantified by Charlson Index, Index 2.

Quality of Life :

The evaluation for the quality of life using the EuroQolfive-dimensional (EQ-5D), Index 2.

Caregiver :

- Assessment for the burden of the caregiver; Will be evaluated with The Modified Caregiver Strain Scale. Index 2.

9.2 EVALUATION AT DISCHARGE FROM THE SPECIFIC CLINICAL SETTING

The following aspects will be assessed:

- Mortality
- Frailty assessment with L. P. Fried's scale and/or FRAIL scale. Functionality assessment with Barthel Index. Indicate the number of hospital stay in days .
- Describe if the patient change the Ward location/ medical /surgical in the hospital (UCI, Coronary unitetc) o)during the evolution in the hospital
- Quantification the number of test (Blood test, urine test, X- Ray, ecography, CT, etc and more specialized like: PET TAC, echocardiography, polisomnography, etc.)
- Quantification the number of consult with other specialist, social worker, paliative care. Etc.
- Usual treatment (Register all the meditation at discharge
- Evaluate if the patient develop geriatric síndrome (page 22).
- Destination at dischargeia. (Nursing home, follow up by home care team, l HUG-GRT, day hospital, rehabilitation at home , specialist consultation, etc.)
- Evaluate the perception of the quality of life with the scale EuroQolfive-dimensional (EQ-5D).
- Burden of the caregiver with the Economics questionnaire s.
- Economics evaluation Index 3

9.3 EVALUATION AT 3 MONTHS OF DISCHARGE

Re-evaluate the following aspects by phone :

- Mortality
- Functionality data (Barthel index , Lawton index , PASE Scale).
- Usual medication.
- Residency at the moment.
- Frailty with the FRAIL scale. .
- Data of quality of life with the scale EuroQolfive-dimensional (EQ-5D)
- Number of hospitalization and ER, indicate the cause (diagnosis)
- Caregiver burden with the economic questionaries .
- Economics evaluation, Index 3

9.4 EVALUATION AT 12 MONTHS OF DISCHARGE

Re-evaluate the following aspects by phone

- Mortality
- Funtionality data (Barthel index, Lawton index , PASE Scale).
- Usual medication.
- Residency at the moment.
- Frailty with the FRAIL scale. Datos de fragilidad con la escala FRAIL.
- Data of quality of life with the scale EuroQolfive-dimensional (EQ-5D)
- Number of hospitalization and ER, indicate the cause (diagnosis)
- Burden of the caregiver with the economics questionnaires.
- Economics evaluation., Index 3

9.5 END OF THE STUDY EVALUATION

- The study will finish at 12 months after patient's discharge with a lastphone call .
- We should make an effort to write all the data during the study, at follow up and the final evaluation. .

  A follow-up and investigator's tasks schedule was performed during the study. See table 2.

Table 2 Schedule of the investigation

Intervention phase	Eligibility&recruitment	Initial Visit	Discharge	3 month Follow-up	12 month Follow-up
Informed consent	X				
Eligibility CI and CE	X	X			
Medical history		X			
Usual treatment		X	X	X	X
Comprehensive Geriatric Assessment		X			
Cognitive and depression (MMSE,GDS,CAM)		X			
Comorbidities - Charlson I.		X			
Functional Status (Barthel I, Lawton I, PASE, SPBB)		X SPBB	X Barthel	X	X
Sociodemographic data		X			
PhysicalExam		X			
Nutritional Status (MNA)		X			
Permanent residence		X	X	X	X
Mean hospital stay			X		
Death			X	X	X
Frailty (Fried)		X	X		
Frailty(FRAIL)		X	X	X	X
EuroQolfive-dimensional (EQ-5D)		X	X	X	X
Caregiver burden		X	X	X	X
Relocation to other hospital services			X		
Adverse events (iatrogenic, falls, geriatric syndromes, etc.)		X	X		
Economics evaluation			X	X	X
Checklist of complementary test during the hospitalization			X		
Consultation to other specialist during hospitalization			X		

Coordination of care in different levels of care			X		
Readmission				X	X
Visits to the emergency room				X	X
Nosocomial infections			X		

* In case of surgical patients, who after 3 weeks since the first visit have passed and surgery hasn't been performed, evaluate the possibility of re-assessing inclusion criteria.

10 ECONOMIC EVALUATION

An economical evaluation of the program will be conducted to detect and handle the frail elderly in different health areas. We will conduct a comparative analysis in terms of costs and benefits of a geriatrician's intervention compared with usual care.

Information on both patients and caregivers about health resources and social services use and time spent by the caregiver will be collected. The next step is to translate this resource consumption in monetary terms. The costs will be reported in euros and in places where it is not used this coin the current exchange will take place.

The total cost is the sum of three different types of costs: directly derivatefrom care; formal care costs (professional) and informal care costs (family and friends)

Direct health care costs:

These costs are related to inpatient treatment, outpatient treatment, medicines, etc. These are estimated from the use of health services by assigning a monetary value for each resource used.

Health resources will be identified and measured through questionnaires. Each center will give us the price or the monetary value of each resource. If some of this information is not available, it will be obtained from a systematic review of studies of cost of illness for each country.

Formal care costs (Social Services):

Formal care includes those generated by social services which can be public or privately funded institutions such as day care centers, remote assistance, scheduled home care, etc. These costs will be identified, measured and evaluated through questionnaires. Ideally, members of each research team from each center must provide to the economic team price and monetary values (unit costs) of resources for social services.

If data about unit cost of social services are not available, a review of the literature will be performed to obtain the data by country.

Social costs (informal care)

Informal care includes different types of unpaid support which serve to compensate for the inability of subjects, usually provided by relatives or friends. This information is obtained from questionnaires applied directly to caregivers in which time spent on helping the elderly in basic Activities of Daily Living and Instrumental Activities will be specified. The time spent on these activities will be evaluated in monetary terms using 'proxy goodmethod "or" replacement method "which assesses the time spent on informal care adjusted to market prices of a professional who has to do this work (social service Careful formal).

The economic evaluation will be developed to take into account several aspects: financing health care (including only direct health costs), finance formal care (including the direct costs of health and social services) and social perspective (including all relevant costs: direct medical care + formal care (social services) and informal care.

Outcome measures:

Cost-effectiveness analysis

The cost-effectiveness analysis (CEA) is the most common test used in health economics to decide between different treatments for the same condition. In a CEA, the costs are measured in monetary units, while the benefits are measured as outcomes or in natural units. "Incremental cost-effectiveness ratio" (ICER) is estimated to show a difference in health outcomes per unit cost, after a follow-up period between intervention and usual care. The incremental cost-effectiveness is expressed by the following relation:

$$ICER = \frac{C_a - C_b}{B_a - B_b}$$

Where Ca is the cost of the intervention group and Cb is the cost of the usual care group. Ba will be health benefits in the intervention group and Bb health benefits in the usual care group, both measured in terms of change of the clinical results of the baseline.

In this study the primary outcomes will be the difference in functional status after the intervention compared with usual care group. This study will assess the cost-effectiveness of the intervention of a geriatrician compared with usual care from the perspective of society and the health care system.

Complementing the main cost-effectiveness analysis, we will develop several parallel cost effectiveness analysis to the extent that effective change. The results that we will use are: hospitalization rate and readmission, lenght of hospitalization and in the Emergency department, episodes of delirium and nosocomial infection, post-surgical complications as a whole and by surgical procedure, number of inappropriate drugs, adherence to treatment, permanent institutionalization rate, survival rate, preventable side effects due to under / over / mismanagement on caregiver burden.

Cost-utility analysis:

Cost-utility analysis (ACU] is an evolution of cost-effectiveness analysis, in which the interference effects are measured in a unit that synthesizes the lifespan and quality of life. The best and better known measure is the quality of life-adjusted per quality (QALY QALY or in its Anglo-Saxon sense). The QALYs are calculated by weighting the survival time (years of age) with quality adjustment thereof, called utility, which represents the preference values in relation to different health states (reference). For the purpose, the EQ-5D-5L instrument will be used. The incremental cost-utility relation answers the following expression:

ACUincremental = (Ca – Cb) / (AVAC(a) – AVAC(b))

Statistical analysis:

A descriptive analysis of the main resources used in health care, social services and informal care will be performed.

This includes basic statistics such as means, medians, standard deviations, skewness, kurtosis, ranges, bivariate analysis using different cost elements and individual characteristics (sex, age,...) and health outcomes.

Because different distributions are expected from major cost components, we hope to develop different multivariate estimation methods. As we expect a non-normal distribution of the estimated costs, an alternative analysis would be the use of GLM models grouped by clusters, where depending on the distribution of the estimated costs (distribution Gamma, Poisson or Gaussian), will be used the most suitable method of empirical analysis. Another alternative, if the necessary information is obtained, could be an analysis using multilevel models of 2 or 3 grade (Recital country and center). The costs

of health care could also be analyzed by a normal multivariate model (clustering) or log-normal and the ordinary least square regression will be used to estimate the determinants of health care costs. In contrast, for the analysis of formal and informal care costs, we expect to use simple probit or ordered probit models, whether formal and informal care for a large number of people in the study is provided.

11. APPENDIX

APPENDIX 1

STUDY TITLE:

FEASIBILITY AND EFFECTIVENESS OF THE IMPLEMENTATION OF PROGRAMS TO SCREEN AND MANAGE FRAIL OLDER PATIENTS IN DIFERRENT CLINICAL SETTINGS

(Intervention phase).

SUBJECT´S INFORMATION FORM

Sponsor: FUNDACIÓN PARA INVESTIGACIÓN BIOMÉDICA DEL HOSPITAL UNIVERSITARIO DE GETAFE

Project leader: Prof. Leocadio Rodríguez Mañas

SUBJECT INFORMATION FORM

Study Title: FEASIBILITY AND EFFECTIVENESS OF THE IMPLEMENTATION OF PROGRAMS TO SCREEN AND MANAGE FRAIL OLDER PATIENTS IN DIFERRENT CLINICAL SETTINGS

Investigator: Prof. Leocadio Rodríguez Mañas. Hospital de Getafe.

What is this study about? What are the outcomes?

You are invited to participate in a research study because you are somebody who can meet the clinical criteria for frailty syndrome.

This syndrome (frailty) includes criteria such as: weakness, weight loss, walking speed, among others. This syndrome is associated with higher risk of developing dependency and disability. Your physician has checked that you meet the criteria for diagnosis of this syndrome.

In this study we evaluate the usefulness of a screening program of frail subjects using certain scales, and measure the benefit that suppose to the subject to associate the intervention of a geriatrician to usual clinical practice. In this study we will not test the efficacy of any new drug.

The aim of this study is to assess whether, through the intervention of a geriatrician can change the course of frailty and reduce the occurrence of adverse events from the health point of view.

A total of 1500 subjects are estimated to participate in 6 hospitals distributed by three European countries. The study was approved by the Ethics Committee of the Hospital Universitario de Getafe and ethics committees of the participating centers. It is also approved by the competent bodies of the regions concerned. It will be executed following the Declaration of Helsinki and the requirements of the Law 14/2007 of Biomedical Research. The study will last for three years.

How this study was done?

Each hospital will select a group of approximately 250 individuals who meet the criteria to participate in the study. These people will be informed about the study and asked, if they agree to participate, to sign this informed consent form. Once subjects are selected through a randomized system (similar to throwing a coin), it is determined in which study group will participate. Half of the patients selected will participate in usual clinical practice group (control group) and half the group will receive care from a geriatrician (intervention group).

If you belong to the control group, will follow the recommendations, actions and treatment indicated for your specialist doctor. Nothing will change of normal medical practice.

Still, in order to assess the results of usual medical action a geriatrician will hold a series of questions when hospitalization, and following in three months and one year (the latter two are made by telephone calls).

If you are allocated to the intervention group: you will be followed by your corresponding specialist as in usual clinical practice and by a geriatrician. The geriatrician will take into account his medical criteria, always with the consent if the rest of the physicians treating you. The geriatrician will make questions about your physical, mental, social and nutritional state.

Follow-up will be made after discharge at 3 month and at 12 month (by telephone call).

What are the potential benefits and risks associated to the study? You must know this study will be supervised by experienced health professionals as doctors and nurses. It is possible that you will not obtain any benefit for the study and you can even experience some secondary effect associated to any treatment or complementary test. Some of the information obtained in this study may help improve elders quality of life, improve the capacity of doing activities of daily living or avoiding institutionalization in some cases..

Your participation is voluntary

I you want to participate in this study, once you have read and understood this information form, and all of your questions have been answered, you must communicate your decision to your physician. You are free to abandon the study at any time without giving any explanations, and this will not change the relationship with your physician. Your physician could retire you from the study if you do not follow the given instructions or because he/she considers it will benefit your health status or on the assumption the study is cancelled. If this occurred, you will be informed the reason of its ending.

Data collected at the moment of your abandonment will be used for the objectives originally foreseen.

Review of the original documents, confidentiality and personal data protection.

With the aim to guarantee feasibility of the collected data, the designated personal by the promoter, and eventually the health authorities and/or members of the Investigation Ethics Committee, will be allowed to access clinical records of the subject where you will be identified as main caregiver, always respecting confidentiality. Treatment, communication, and personal data transfer of every participating subject in this study will be adjusted to what is established in the Law 15/1999 of Personal Data Protection.

Data collected in the study will be identified by a numeric code and just the study physician and collaborators will be able to connect that data to you.

Any additional information that could be identifiable will be kept and processed in a secure way by informatical media by the promoter or the company designated by him/her.

Data could be transferred to other countries or collaborative groups in the study as long as they apply the necessary measures to protect personal information, transferring them in a coded way.

You can exercise your right, according to current legislation, of rectifying, cancelling o opposing, according to your personal data, talking directly to your study physician.

Results publication

The study results will be communicated to the scientific community through congresses and/or publications. In any way, there will be no information that could identify you in these publications.

If during the study, any relevant information that could be useful to you emerges, it will be communicated through your study physician.

Additional information

The study meets the current Spanish legislations(Law 14/2007 of Biomedical Investigation). According to the Spanish legislation, the promoter commits to subscribe to an insurance policy before the beginning of the study to cover for adverse events that could be produced during the study.

The patient should know that he/she will not receive any economic compensation or reimbursement of expenses due to its participation in the study.

This study is financed by the CE "HEALTH-2013" PROJECTS.

You can discuss any of the information given with your attending, family or friends before taking any decision concerning your participation in the study. If you have any doubt or any event arises during the study, you can talk to:

Name of the Investigation Clinician: Mónica Ballesteros.

Address: Carretera de Toledo, km 12,500, 28905 Getafe, Madrid

Phone number: +34 916839360 ext. 2760

You will be given a copy of this document with date and signature.

Study Title:

FEASIBILITY AND EFFECTIVENESS OF THE IMPLEMENTATION OF PROGRAMS TO SCREEN AND MANAGE FRAIL OLDER PATIENTS IN DIFFERENT CLINICAL SETTINGS. INTERVENTION PHASE.

I,..... (Name and Last Name).....

Have read the information form I've been given.

I have been able to ask questions about the study.

I have received enough information about the study. I have talked to: ..... (Name of the Investigator) .....

I understand that my participation is voluntary. I understand that I can abandon the study willingly:1º.Whenever I want.

2º.Without giving any explication.

3º.It will not change in any way my plan of care. I willingly give my consent to participate in the study. SUBJECT:

Signature: Date

Name

INVESTIGATOR Signature: Date

Name

WITNESS (if needed):

Signature Date Name:

FRAILCLINIC

STUDY TITLE:

FEASIBILITY AND EFFECTIVENESS OF THE IMPLEMENTATION OF PROGRAMS TO SCREEN AND MANAGE FRAIL OLDER PATIENTS IN DIFFERENT CLINICAL SETTINGS (Intervention Phase)

INFORMATION FORM FOR PRINCIPAL CAREGIVER

Sponsor: FUNDACIÓN PARA INVESTIGACION BIOMÉDICA DEL HOSPITAL UNIVERSITARIO DE GETAFE

Leader of the Project: Prof. Leocadio Rodríguez Mañas

INFORMATION FORM FOR THE MAIN CAREGIVER

Study Title::FEASIBILITY AND EFFECTIVENESS OF THE IMPLEMENTATION OF PROGRAMS TO SCREEN AND MANAGE FRAIL OLDER PATIENTS IN DIFFERENT CLINICAL SETTINGS.

Investigator: Prof. Leocadio Rodríguez Mañas. Hospital Getafe

What is the study about? What are the objectives?

You are being invited to participate in an investigation Project because you are the main caregiver of a person who can meet clinical criteria of Frailty. You are the main caregiver because you are the one that helps him/her the most with Activities of Daily Living, or the one who is asked the most for help and is not hired for it.

Frailty has different criteria as: weakness, weight loss, gait speed, among others. This syndrome is associated to a higher risk of dependency and disability.In this study we want to evaluate the usefulness of a program to detect frailty, with the use of determined scales, as to assess the benefits the subject obtains with associating a geriatrician's intervention to the usual clinical practice. This study is not aimed to prove the efficacy of any new medication..

The study's objective is to evaluate if the evolution of frailty and reduction of adverse events from the medical point of view can be changed through a geriatrician's intervention.

1500 subjects are estimated to participate in all 6 hospitals distributed in 3 European countries. The study is approved by the Ethics Committee of the Hospital Universitario de Getafe and ethics committees in all of the other participating centers. It is also approved by the competent organs of the implied communities. It is going to be made following the Helsinki Declaration and the demands established by the Law 14/2007 of Biomedical Investigation. The study has a three years duration.

.

What is my participation about?

Each health center will choose a group of 200 subjects who meet the participation criteria. These subjects will be asked to identify their main caregiver, if applicable. You, as caregiver, will be asked to answer two different polls about the subject's care. They will be done three times; during hospitalization, at three month and at the first year of follow-up, the latest by telephone call.

Which are the potential benefits and risks associated to the study? Participating in this study will not imply any benefit or risk because we are only asking you to fill questionnaires that will take some of your time. Obtained information in the study could help to improve quality of life of elders, improving their capacity to do certain activities or avoiding institutionalization in some cases.

Your participation is voluntary

If you want to participate in this study, once you have read and understood this information form, and all of your questions have been answered, you must communicate your decision to your physician. You are free to abandon the study at any time without giving any explanations, and this will not change the relationship with your physician. Your physician could retire you from the study if you do not follow the given instructions or because he/she considers it will benefit your health status or on the assumption the study is cancelled. If this occurred, you will be informed the reason of its ending.

Data collected at the moment of your abandonment will be used for the objectives originally foreseen.

Review of the original documents, confidentiality and personal data protection.

With the aim to guarantee feasibility of the collected data, the designated personel by the promoter, and eventually the health authorities and/or members of the Investigation Ethics Committee, will be allowed to access clinical records of the subject where you will be identified as main caregiver, always respecting

confidentiality. Treatment, communication, and personal data transferof every participating subject in this study will be adjusted to what is established in the Law 15/1999 of Personal Data Protection.

Data collected in the study will be identified by a numeric code and just the study physician and collaborators will be able to connect that data to you. Any aditional information that could be identifiable will be kept and processed in a secure way by informatical media by the promoter or the company designated by him/her. Data could be transferred to other countries or collaborative groups in the study as long as they apply the necessary measures to protect personal information, transferring them in a coded way.

You can exercise your right, according to current legislation, of rectifying, cancelling o opposing, according to your personal data, talking direclty to your study physician.

Results publication

The study results will be communicated to the scientific community through congresses and/or publications. In any way, there will be no information that could identify you in these publications. If during the study, any relevant information that could be useful to you emerges, it will be communicated through your study physician.

Additional information: The present study follows current Spanish legislation (Law 14/2007 of Biomedical Investigation). According to Spanish legislation, the promoter compromises to subscribe an insurance policy before the beginning of the study that covers for adverse events that could emerge during the study. You should know that you will not receive any economical compensation or reimbursement for any of the expenses associated to your participation in the study. This study is financed by the CE “HEALTH-2013” PROJECTS.

You can comment the information received with your physician, family or friends before making any decision concerning your participation in the study. Name of the study physician: Mónica Ballesteros

Address: Carretera de Toledo, km 12,500, 28905 Getafe, Madrid

Phone number: +34 916839360 extension 2760

You will receive a copy of this document with date and signature. Study title: Feasibility and Effectiveness of the Implementation of Programs to Screen and Manage Frail Older Patients in different clinical settings.

Study Title

FEASIBILITY AND EFFECTIVENESS OF THE IMPLEMENTATION OF PROGRAMS TO SCREEN AND MANAGE FRAIL OLDER PATIENTS IN DIFFERENT CLINICAL SETTINGS. INTERVENTION PHASE.

I,..... (Name and Last Name).....

Have read the information form I've been given.

I have been able to ask questions about the study.

I have received enough information about the study. I have talked to: ..... (Name of the Investigator) .....

I understand that my participation is voluntary .I understand that I can abandon the study willingly:1º. Whenever I want.

2º.Without giving any explication.

3º.It will not change in any way my plan of care. I willingly give my consent to participate in the study. SUBJECT:

Signature: Date

Name

Investigator's Signature : Date

Name

WITNESS (if needed):

Signature DateName:

APPENDIX 2

FRIED'S CRITERIA

1- ***Weight loss:***
We have to ask the patient if he or she has lost weight unintentionally in the past year, and if the loss was greater than 4,5 kg (10 lb).
   - YES (1)
   - NO (0)

2- ***Exhaustion:***
   - "I felt that everything I did was an effort during the past week"
   - I could not get "going"

If SOME (OR BOTH) answers are YES, one point for frailty will be counted.

3- ***Physical activity:***
Does the patient perform less than or equal to the physical activity indicated weekly?

Men: < 383 kcal / week (walking ≤ 2 hours and30 minutes / week)
Women: < 270 kcal / week (walking ≤ 2 hours / week)

We ask the patient to respond with YES or NO if he/she performs these activities.
If they answer YES, one point for frailty will be counted.

4- ***Slowness:*** measured as the time it takes for the patient to travel 15 feet to their usual walking speed.

SEX	Height(CM)	CUT OFF
MEN	≤173 cm	≥7s
	>173 cm	≥6s
WOMEN	≤159 cm	≥7s
	>159 cm	≥6s

This is done as follows: we will indicate to the patient to stand immediately behind the starting line, we will tell him/her to start walking "as he/she usually does". The patient is then stopped. We will do the test twice and we will take the best score of the two. The time will be recorded in seconds.

5- **Weakness:** Assessed by grip strength.

BMI♂	CUT-OFF	BMI♀	CUT-OFF
≤24	<29kg	≤23	<17kg
24,1-26	<30kg	23,1-26	<17,3kg
26,1-28	<30kg	26,1-29	<18kg
> 28	<32kg	>29	<21 kg

He/she will rest for about 30 seconds, and he/she will repeat the exercise two more times. We will record the best of all results.

FRAIL

1.- **Fatigue** is measured by asking respondents how much time during the past 4 weeks they have felt tired with responses of "all of the time" or "most of the time" scored as 1 point.

2.- **Resistance** is assessed by asking participants if they have had any difficulty walking up 10 steps alone without resting and without aids.

3.- **Ambulation** is assessed by asking if they had any difficulty walking several hundred meters alone and without aids: a yes response is scored as 1 point.

4.- **Illness** is scored 1 for respondents who report 5 or more illnesses out of 11 total illnesses:(hypertension, diabetes, cancer (other than a minor skin cancer), chronic lung disease, heart attack, congestive heart failure, angina, asthma, arthritis, stroke, and kidney disease).

5.- **Loss of weight** is scored 1 for respondents with a weight decline of 5 % or greater within the past 12 months based on self-report.

EUROQL 5D 5L:((25)

Under each heading, please tick the ONE box that best describes your health TODAY

MOBILITY

I have no problems in walking about ❑
I have slight problems in walking about ❑
I have moderate problems in walking about ❑
I have severe problems in walking about ❑
I am unable to walk about ❑

SELF-CARE

I have no problems washing or dressing myself ❑
I have slight problems washing or dressing myself ❑
I have moderate problems washing or dressing myself ❑
I have severe problems washing or dressing myself ❑
I am unable to wash or dress myself ❑

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities ❑
I have slight problems doing my usual activities ❑
I have moderate problems doing my usual activities ❑
I have severe problems doing my usual activities ❑
I am unable to do my usual activities ❑

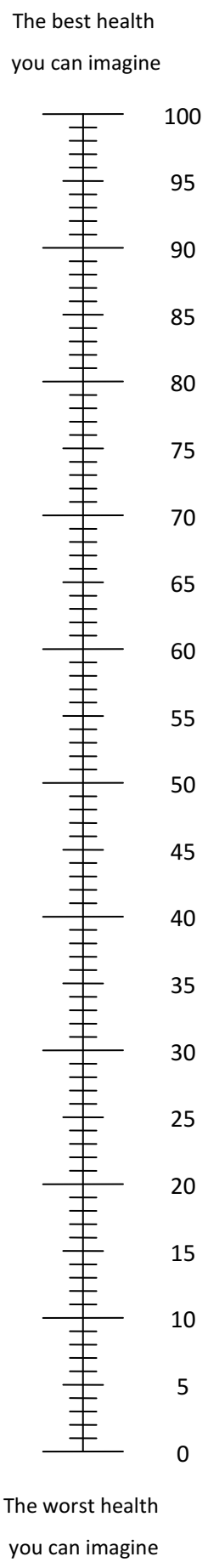
PAIN / DISCOMFORT

I have no pain or discomfort ❑
I have slight pain or discomfort ❑
I have moderate pain or discomfort ❑
I have severe pain or discomfort ❑
I have extreme pain or discomfort ❑

ANXIETY / DEPRESSION

I am not anxious or depressed ❑
I am slightly anxious or depressed ❑
I am moderately anxious or depressed ❑
I am severely anxious or depressed ❑
I am extremely anxious or depressed ❑

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the <u>best</u> health you can imagine.
  0 means the <u>worst</u> health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.
  - YOUR HEALTH TODAY = ☐



Barthel Index (Basic activities of daily living)

Feeding 0 = unable 5 = needs help cutting, spreading butter, etc., or requires modified diet 10 = independent	0 ☐ 5 ☐ 10 ☐
Bathing 0 = dependent 5 = independent (or in shower)	0 ☐ 5 ☐
Grooming 0 = needs to help with personal care 5 = independent face/hair/teeth/shaving (implements provided)	0 ☐ 5 ☐
Dressing 0 = dependent 5 = needs help but can do about half unaided 10 = independent (including buttons, zips, laces)	0 ☐ 5 ☐ 10 ☐
Bowels 0 = incontinent (or needs to be given enemas) 5 = occasionalaccident 10 = continent	0 ☐ 5 ☐ 10 ☐
Bladder 0 = incontinent, or catheterized and unable to manage alone 5 = occasionalaccident 10 = continent	0 ☐ 5 ☐ 10 ☐
Toilet Use 0 = dependent 5 = needs help, but can do something alone 10 = independent (on and off, dressing, wiping)	0 ☐ 5 ☐ 10 ☐
Transfers (bed to chair and back) 0 = unable, no sitting balance 5 = major help (one/two people,physical), can sit 10 = minor help (verbal or physical) 15 = independent	0 ☐ 5 ☐ 10 ☐ 15 ☐
Mobility (on level surfaces) 0 = immobile or < 50 yards 5 = wheelchair independent (inc.corners)>50 yds 10 = walks with help of one person (verbal or physical) > 50 yards 15 = independent (but may use any aid; for example, stick) > 50 yards	0 ☐ 5 ☐ 10 ☐ 15 ☐
Stairs 0 = unable 5 = needs help (verbal, physical, carrying aid) 10 = independent	0 ☐ 5 ☐ 10 ☐
TOTAL (0-100)	

THE LAWTON INSTRUMENTAL ACTIVITIES OF DAILY LIVING SCALE

A. Ability to Use Telephone

1. Operates telephone on own initiative; looks up and dials numbers 1
2. Dials a few well-known numbers 1
3. Answers telephone, but does not dial 1
4. Does not use telephone at all 0

B. Shopping

1. Takes care of all shopping needs independently 1
2. Shops independently for small purchases 0
3. Needs to be accompanied on any shopping trip 0
4. Completely unable to shop 0

C. Food Preparation

1. Plans, prepares, and serves adequate meals independently 1
2. Prepares adequate meals if supplied with ingredients 0
3. Heats and serves prepared meals or prepares meals but does not maintain adequate diet 0
4. Needs to have meals prepared and served 0

D. Housekeeping

1. Maintains house alone with occasion assistance (heavy work) 1
2. Performs light daily tasks such as dishwashing, bed making 1
3. Performs light daily tasks, but cannot maintain acceptable level of cleanliness 1
4. Needs help with all home maintenance tasks 1
5. Does not participate in any housekeeping tasks 0

E. Laundry

1. Does personal laundry completely 1
2. Launders small items, rinses socks, stockings, etc. 1
3. All laundry must be done by others 0

F. Mode of Transportation

1. Travels independently on public transportation or drives own car 1
2. Arranges own travel via taxi, but does not otherwise use public transportation 1
3. Travels on public transportation when assisted or accompanied by another 1
4. Travel limited to taxi or automobile with assistance of another 0
5. Does not travel at all 0

G. Responsibility for Own Medications

1. Is responsible for taking medication in correct dosages at correct time 1
2. Takes responsibility if medication is prepared in advance in separate dosages 0
3. Is not capable of dispensing own medication 0

H. Ability to Handle Finances

1. Manages financial matters independently (budgets, writes checks, pays rent and bills, goes to bank); collects and keeps track of income 1
2. Manages day-to-day purchases, but needs help with banking, major purchases, etc 1
3. Incapable of handling money 0

GERIATRIC DEPRESSION SCALE (GDS)

Choose the best answer for how you have felt over the past week:

1. Are you basically satisfied with your life?

   YES / NO

2. Have you dropped many of your activities and interests?

   YES / NO

3. Do you feel that your life is empty?

   YES / NO

4. Do you often get bored?

   YES / NO

5. Are you in good spirits most of the time?

   YES / NO

6. Are you afraid that something bad is going to happen to you?

   YES / NO

7. Do you feel happy most of the time?

   YES / NO

8. Do you often feel helpless?

   YES / NO

9. Do you prefer to stay at home, rather than going out and doing new things?

   YES / NO

10. Do you feel you have more problems with memory than most?

    YES / NO

11. Do you think it is wonderful to be alive now?

    YES / NO

12. Do you feel pretty worthless the way you are now?

    YES / NO

13. Do you feel full of energy?

    YES / NO

14. Do you feel that your situation is hopeless?

    YES / NO

15. Do you think that most people are better off than you are?

    YES / NO

CAREGIVER BURDEN:

MODIFIED CAREGIVER STRAIN SCALE (CSS)

Being available to help or regularly caring for someone can be difficult and disruptive. Which of the following statements apply to you…? We have included some examples that are common caregiver experiences to help you think about each item. Your situation may be slightly different, but the item could still apply.
For each statement, please circle <u>one</u> answer (Not at all; Sometimes; Often; or Always) as appropriate.

1. It is inconvenient (e.g. because helping the person takes so much time or it's a long drive over to help).

Not at all ***Sometimes*** ***Often*** ***Always***

_____

2. My sleep is disturbed (e.g. because the person I care for needs help and is in and out of bed, or wanders around at night).

Not at all ***Sometimes*** ***Often*** ***Always***

_____

3. It is a physical strain (e.g. because the person needs help with practical tasks for which effort or concentration is required).

Not at all ***Sometimes*** ***Often*** ***Always***

_____

4. It is confining (e.g. because the person restricts free time or cannot go visiting).

Not at all ***Sometimes*** ***Often*** ***Always***

_____

_

5. There have been family adjustments (e.g. because helping the person has disrupted routine; there has been no privacy).

Not at all ***Sometimes*** ***Often*** ***Always***

_____

6. There have been changes in personal plans (e.g. had to turn down a job; could not go on holiday).

Not at all ***Sometimes*** ***Often*** ***Always***

7. There have been other demands on my time (e.g. from other family members).

Not at all ***Sometimes*** ***Often*** ***Always***

---

8. There have been emotional adjustments (e.g. because of arguments with the person).

Not at all ***Sometimes*** ***Often*** ***Always***

---

9. Some behaviour is upsetting (e.g. because of incontinence: or he or she resists help).

Not at all ***Sometimes*** ***Often*** ***Always***

---

10. It is upsetting to find the person has changed from their former self (e.g. they are so different from before).

Not at all ***Sometimes*** ***Often*** ***Always***

---

11. There have been work adjustments (e.g. because of having to take time off caring for the person).

Not at all ***Sometimes*** ***Often*** ***Always***

---

12. It is a financial strain

Not at all ***Sometimes*** ***Often*** ***Always***

---

13. I am feeling completely overwhelmed (e.g. because of worry about the person; concerns about how I will manage).

Not at all ***Sometimes*** ***Often*** ***Always***

THANK YOU FOR YOUR TIME AND HELP

RISK OF DELIRIUM - CAM(Confusion Assessment Method)

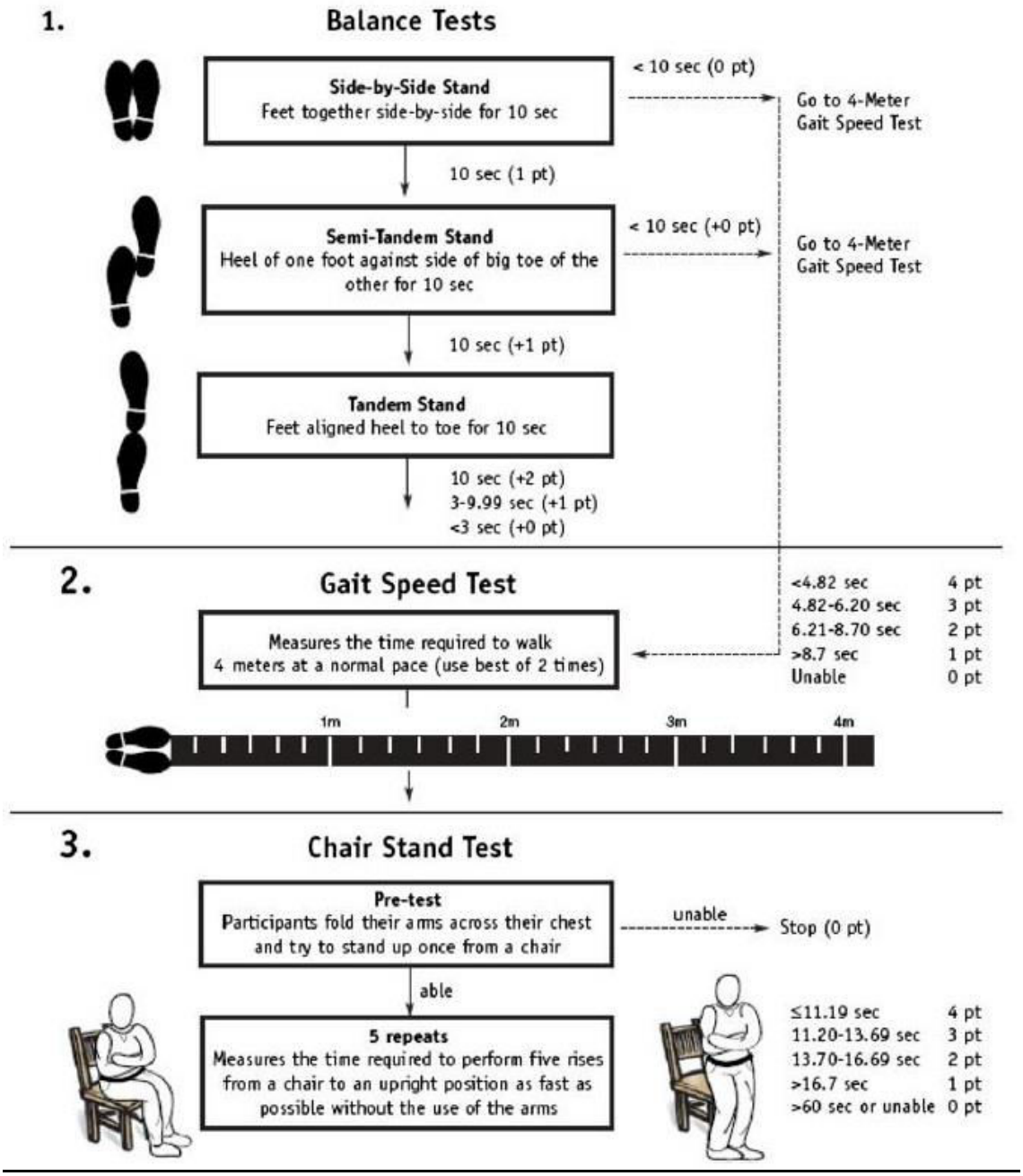
Table 1
CAM-ICU Features and Descriptions[6]

1. Acute Onset or Fluctuating Course	Absent	Present
Is there evidence of an acute change in mental status from baseline?	❑	❑
or		
Did the (abnormal) behavior fluctuate during the past 24 hours, ie, tend to come and go, or increase and decrease in severity as evidenced by fluctuation on a sedation scale (eg, RASS), GCS, or previous delirium assessment?	❑	❑
2. Inattention	**Absent**	**Present**
Did the patient have difficulty focusing attention as evidenced by scores <8 on either the auditory or visual component of the ASE?	❑	❑
3. Disorganized Thinking	**Absent**	**Present**
Is there evidence of disorganized or incoherent thinking as evidenced by incorrect answers to ≥2 of the 4 questions and/or inability to follow the commands?	❑	❑
Questions (Alternate Set A and Set B):		
Set A	*Set B*	
1. Will a stone float on water?	1. Will a leaf float on water?	
2. Are there fish in the sea?	2. Are there elephants in the sea?	
3. Does 1 pound weigh more than 2 pounds?	3. Do 2 pounds weigh more than 1 pound?	
4. Can you use a hammer to pound a nail?	4. Can you use a hammer to cut wood?	
Other:		
1. Are you having any unclear thinking?		
2. Hold up this many fingers (examiner holds two fingers in front of patient).		
3. Now do the same thing with the other hand (not repeating the number of fingers).		
4. Altered Level of Consciousness	**Absent**	**Present**
Is the patient's level of consciousness anything other than alert, such as vigilant, lethargic, or stupor (eg, RASS other than "0" at time of assessment)?	❑	❑
Overall CAM-ICU:	**Yes**	**No**
Features 1 and 2 and either Feature 3 or 4	❑	❑

CAM-ICU=Confusion Assessment Method for the Intensive Care Unit; RASS=Richmond Agitation-Sedation Scale; GCS=Glasgow Coma Scale; ASE=Attention Screening Examination.

Pun BT, Ely EW. *Primary Psychiatry*. Vol 11, No 11. 2004.

SPPB (SHORT PHYSICAL PERFORMANCE BATTERY)



PHYSICAL ACTIVITY SCALE FOR THE ELDERLY (PASE)

INSTRUCTIONS:

Please complete this questionnaire by either circling the correct response or filling in the blank. Here is an example:

During the past 7 days, how often have you seen the sun?

[0.] NEVER	[1.] SELDOM (1-2 DAYS)	[2.] SOMETIMES (3-4 DAYS)	[3.] OFTEN (5-7 DAYS)

Answer all items as accurately as possible. All information is strictly confidential.

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 → GO TO Q.#2

[1.] SELDOM (1-2 DAYS) →

[2.] SOMETIMES (3-4 DAYS) →

[3.] OFTEN (5-7 DAYS) →

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 → GO TO Q.#3

[1.] SELDOM (1-2 DAYS) →

[2.] SOMETIMES (3-4 DAYS) →

[3.] OFTEN (5-7 DAYS) →

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

3. Over the past 7 days, how often did you engage in light sport or recreational activities such as bowling, golf with a cart, shuffleboard, fishing from a boat or pier or other similar activities?

[0.] NEVER → GO TO Q.#4

[1.] SELDOM (1-2 DAYS) →

[2.] SOMETIMES (3-4 DAYS) →

[3.] OFTEN (5-7 DAYS) →

3a. What were these activities?

_____

3b. On average, how many hours per day did you engage in these light sport or recreational activities?

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

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

4. Over the past 7 days, how often did you engage in moderate sport and recreational activities such as doubles tennis, ballroom dancing, hunting, ice skating, golf without a cart, softball or other similar activities?

[0.] NEVER → GO TO Q.#5

[1.] SELDOM (1-2 DAYS) →

[2.] SOMETIMES (3-4 DAYS) →

[3.] OFTEN (5-7 DAYS) →

4a. What were these activities?

_____

4b. On average, how many hours per day did you engage in these moderate 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

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 (1-2 DAYS)	[2.] SOMETIMES (3-4 DAYS)	[3.] OFTEN (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 (1-2 DAYS)	[2.] SOMETIMES (3-4 DAYS)	[3.] OFTEN (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 washing dishes?

[1.] NO [2.] YES

8. During the past 7 days, have you done any heavy housework or chores, such 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. [**Examples:** office worker, watchmaker, seated assembly line worker, bus driver, etc.]

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

[3] Walking, with some handling of materials generally weighing less than 50 pounds. [**Examples:** 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. [**Examples:** lumberjack, stone mason, farm or general laborer.]

frailclinic

NUTRITIONAL ASSESMENT:

Mini Nutritional Assessment
MNA®

Nestlé Nutrition Institute

Last name: First name:

Sex: Age: Weight, kg: Height, cm: Date:

Complete the screen by filling in the boxes with the appropriate numbers.
Add the numbers for the screen. If score is 11 or less, continue with the assessment to gain a Malnutrition Indicator Score.

Screening

A Has food intake declined over the past 3 months due to loss of appetite, digestive problems, chewing or swallowing difficulties?
0 = severe decrease in food intake
1 = moderate decrease in food intake
2 = no decrease in food intake ☐

B Weight loss during the last 3 months
0 = weight loss greater than 3kg (6.6lbs)
1 = does not know
2 = weight loss between 1 and 3kg (2.2 and 6.6 lbs)
3 = no weight loss ☐

C Mobility
0 = bed or chair bound
1 = able to get out of bed / chair but does not go out
2 = goes out ☐

D Has suffered psychological stress or acute disease in the past 3 months?
0 = yes 2 = no ☐

E Neuropsychological problems
0 = severe dementia or depression
1 = mild dementia
2 = no psychological problems ☐

F Body Mass Index (BMI) = weight in kg / (height in m)²
0 = BMI less than 19
1 = BMI 19 to less than 21
2 = BMI 21 to less than 23
3 = BMI 23 or greater ☐

Screening score (subtotal max. 14 points) ☐☐
12-14 points: Normal nutritional status
8-11 points: At risk of malnutrition
0-7 points: Malnourished

For a more in-depth assessment, continue with questions G-R

Assessment

G Lives independently (not in nursing home or hospital)
1 = yes 0 = no ☐

H Takes more than 3 prescription drugs per day
0 = yes 1 = no ☐

I Pressure sores or skin ulcers
0 = yes 1 = no ☐

J How many full meals does the patient eat daily?
0 = 1 meal
1 = 2 meals
2 = 3 meals ☐

K Selected consumption markers for protein intake
- At least one serving of dairy products (milk, cheese, yoghurt) per day yes ☐ no ☐
- Two or more servings of legumes or eggs per week yes ☐ no ☐
- Meat, fish or poultry every day yes ☐ no ☐

0.0 = if 0 or 1 yes
0.5 = if 2 yes
1.0 = if 3 yes ☐.☐

L Consumes two or more servings of fruit or vegetables per day?
0 = no 1 = yes ☐

M How much fluid (water, juice, coffee, tea, milk...) is consumed per day?
0.0 = less than 3 cups
0.5 = 3 to 5 cups
1.0 = more than 5 cups ☐.☐

N Mode of feeding
0 = unable to eat without assistance
1 = self-fed with some difficulty
2 = self-fed without any problem ☐

O Self view of nutritional status
0 = views self as being malnourished
1 = is uncertain of nutritional state
2 = views self as having no nutritional problem ☐

P In comparison with other people of the same age, how does the patient consider his / her health status?
0.0 = not as good
0.5 = does not know
1.0 = as good
2.0 = better ☐.☐

Q Mid-arm circumference (MAC) in cm
0.0 = MAC less than 21
0.5 = MAC 21 to 22
1.0 = MAC greater than 22 ☐.☐

R Calf circumference (CC) in cm
0 = CC less than 31
1 = CC 31 or greater ☐

Assessment (max. 16 points) ☐☐.☐
Screening score ☐☐.☐
Total Assessment (max. 30 points) ☐☐.☐

Malnutrition Indicator Score

24 to 30 points	☐	Normal nutritional status
17 to 23.5 points	☐	At risk of malnutrition
Less than 17 points	☐	Malnourished

References
1. Vellas B, Villars H, Abellan G, *et al.* Overview of the MNA® - Its History and Challenges. *J Nutr Health Aging.* 2006; **10**:456-465.
2. Rubenstein LZ, Harker JO, Salva A, Guigoz Y, Vellas B. Screening for Undernutrition in Geriatric Practice: Developing the Short-Form Mini Nutritional Assessment (MNA-SF). *J. Geront.* 2001; **56A**: M366-377
3. Guigoz Y. The Mini-Nutritional Assessment (MNA®) Review of the Literature - What does it tell us? *J Nutr Health Aging.* 2006; **10**:466-487.

For more information: www.mna-elderly.com

CHARLSON INDEX

Charlson comorbidity score weights	
Charlson Disease category	Original Charlson weights (Charlson,1987)
1. Myocardial Infarction	1
2. Congestive heart failure	1
3. Peripheral vascular disease	1
4. Cerebrovascular disease	1
5. Dementia	1
6. Chronic pulmonary disease	1
7. Rheumatologic disease	1
8. Peptic ulcer disease	1
9. Mild liver disease	1
10. Diabetes	1
11. Diabetes with chronic complications	2
12. Hemiplegia or paraplegia	2
13. Renal disease	2
14. Any malignancy, including lymphoma and leukemia	2
15. Moderate or severe liver disease	3
16. Metastatic solid tumor	6
17. AIDS	6
Maximum Charlson comorbidity score a patient can have	**33**

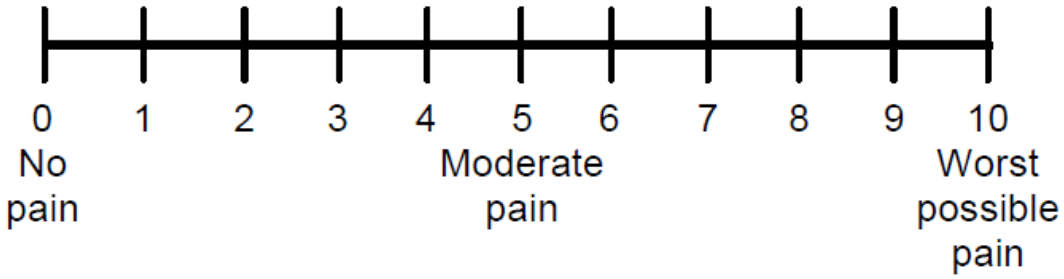
Other important medical history:

- Hypertension (yes / no)
- Dyslipidemia (yes / no)
- Osteoarthritis (yes / no)
- Mayor surgery (yes / no)
- Others:

_____

Short-term mortality predictor (< 3 years): score of 0: (12% mortality/year); score 1-2: (26%); score 3-4: (52%); score > 5: (85%).

PAIN ASSESMENT ACCORDING TO VAS SCALE:



COGNITIVE IMPAIRMENT, EMOTIONAL AND RISK OF DELIRIUM ASSESMENT:

MINIMENTAL TEST (MMSE):

MMSE

Date of Examination ___/___/___ Examiner _____

Name _____ Age _____ Years of School Completed _____

Instructions: Words in boldface type should be read aloud clearly and slowly to the examinee. Item substitutions appear in parentheses. Administration should be conducted privately and in the examinee's primary language. Circle 0 if the response is incorrect, or 1 if the response is correct. Begin by asking the following two questions:

Do you have any trouble with your memory? **May I ask you some questions about your memory?**

ORIENTATION TO TIME		RESPONSE	SCORE (circle one)	
What is the...	**year?**		0	1
	season?		0	1
	month of the year?		0	1
	day of the week?		0	1
	date?		0	1

ORIENTATION TO PLACE*

Where are we now? What is the...

state (province)?		0	1
county (or city/town)?		0	1
city/town (or part of city/neighborhood)?		0	1
building (name or type)?		0	1
floor of the building (room number or address)?		0	1

*Alternative place words that are appropriate for the setting and increasingly precise may be substituted and noted.

REGISTRATION*

Listen carefully. I am going to say three words. You say them back after I stop. Ready? Here they are... APPLE [*pause*], **PENNY** [*pause*], **TABLE** [*pause*]. **Now repeat those words back to me.**
[*Repeat up to 5 times, but score only the first trial.*]

APPLE		0	1
PENNY		0	1
TABLE		0	1

Now keep those words in mind. I am going to ask you to say them again in a few minutes.

*Alternative word sets (e.g., PONY, QUARTER, ORANGE) may be substituted and noted when retesting an examinee.

ATTENTION AND CALCULATION [*Serial 7s*]*

Now I'd like you to subtract 7 from 100. Then keep subtracting 7 from each answer until I tell you to stop.

What is 100 take away 7?	[93]		0	1
If needed, say: **Keep going.**	[86]		0	1
If needed, say: **Keep going.**	[79]		0	1
If needed, say: **Keep going.**	[72]		0	1
If needed, say: **Keep going.**	[65]		0	1

*Alternative item (WORLD backward) should only be administered if the examinee refuses to perform the Serial 7s task. →

Substitute and score this item only if the examinee refuses to perform the Serial 7s task.

Spell WORLD forward, then backward.
Correct forward spelling if misspelled,
but score only the backward spelling.

(D = 1)	(L = 1)	(R = 1)	(O = 1)	(W = 1)	(0 to 5)
____	____	____	____	____	____

RECALL

What were those three words I asked you to remember? [*Do not offer any hints.*]

	RESPONSE	SCORE (circle one)
APPLE	_____	0 1
PENNY	_____	0 1
TABLE	_____	0 1

NAMING*

What is this? [*Point to a pencil or pen.*]	_____	0 1
What is this? [*Point to a watch.*]	_____	0 1

*Alternative common objects (e.g., eyeglasses, chair, keys) may be substituted and noted.

REPETITION

Now I am going to ask you to repeat what I say. Ready? "NO IFS, ANDS, OR BUTS." Now you say that.
[*Repeat up to 5 times, but score only the first trial.*]

NO IFS, ANDS, OR BUTS.	_____	0 1

Detach the next page along the lengthwise perforation, and then tear it in half along the horizontal perforation. Use the upper half of the page (blank) for the Comprehension, Writing, and Drawing items that follow. Use the lower half of the page as a stimulus form for the Reading ("CLOSE YOUR EYES") and Drawing (intersecting pentagons) items.

COMPREHENSION

Listen carefully because I am going to ask you to do something.
Take this paper in your right hand [*pause*], **fold it in half** [*pause*], **and put it on the floor (*or* table).**

TAKE IN RIGHT HAND	_____	0 1
FOLD IN HALF	_____	0 1
PUT ON FLOOR (*or* TABLE)	_____	0 1

READING

Please read this and do what it says. [*Show examinee the words on the stimulus form.*]

CLOSE YOUR EYES	_____	0 1

WRITING

Please write a sentence. [*If examinee does not respond, say:* **Write about the weather.**] 0 1

Place the blank piece of paper (unfolded) in front of the examinee and provide a pen or pencil. Score 1 point if the sentence is comprehensible and contains a subject and a verb. Ignore errors in grammar or spelling.

DRAWING

Please copy this design. [*Display the intersecting pentagons on the stimulus form.*] 0 1

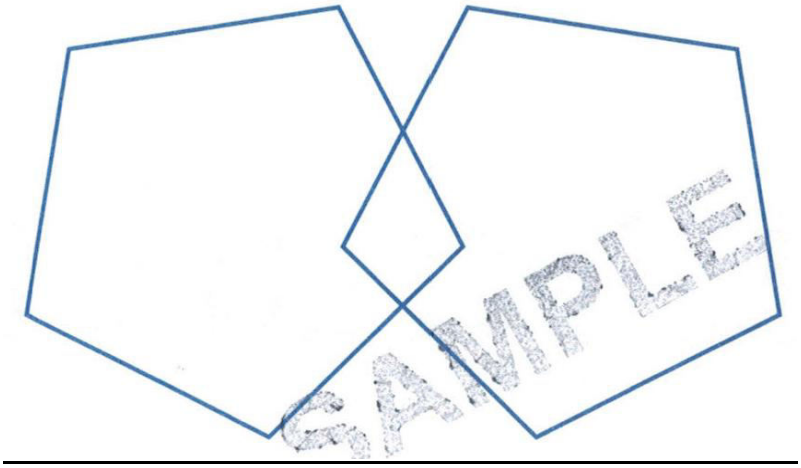
Score 1 point if the drawing consists of two 5-sided figures that intersect to form a 4-sided figure.

Total Score = _____
(*Sum all item scores.*) (30 points max.)

Assessment of level of consciousness.

Alert/ Responsive	Drowsy	Stuporous	Comatose/ Unresponsive

CLOSE YOUR EYES



ANEXO 3

Patient's information obtained from his/her clinical record (Baseline)

1. **Patient's ID:** _____

2. (Register the generic names and total daily dose of drugs that the patient has taken during the last month)

	Name generic drugs	Total daily dose (milligrams)
☐		
☐		
☐		
☐		
☐		
☐		
☐		
☐		
☐		
☐		

☐		
☐		

3. 3. Hospitalization

What was the main cause of hospitalization?

	Diagnosis related Code Group (GRD)	GRD description	Mean stay (days)
☐			

Questionnaire for the subject(baseline)

1. **Identification number**_____

2. **Level of studies completed**

   oCan read and write o Primary o Secondary o University
   o None

3. **Is the place where you live of your property?**

   o Yes o No

4. **Number of household members where the subject lives:** ___ people

5. **Carer**

   a. **Do you need a carer to assist you with your daily activities?** (for basic hygiene, to help you to move, administration of drugs, performing treatments, etc.Monitoring and supervision tasks are also included)

      o Yes o No ⇒ Skip to question #6

   b. **In the case of yes, who is your <u>principal carer</u>?**

      o Family member ⇒ Fill in the carer questionnaire and skip to question #6

      o Another non-contracted person (friend) ⇒ Fill in the carer questionnaire and skip to question #6

      o Professional carer (contracted or provided by an entity)

   c. **If you use the services of a <u>professional carer</u>,**

      How many hours a week? _____ hours a week

      Who pays for the service and how much?

      o I pay the entire cost of _____ € per hour

(Alternative, if the subject does not know the cost per hour)

o I pay the entire cost of _____ € per month

o The cost is covered by social security or another entity

o The cost is partially covered by social security or another entity, I pay_____ € per hour

(Alternative, if the subject does not know the cost per hour)

o The cost is partially covered by social security or another entity, I pay _____ € per month

6. Hospitalisation

Have you<u>been admitted to hospital</u> in the last <u>12 months</u>?

o Yes o No

7. Health and social services you have required and days of service received by according to economic system during the <u>last month and the last 6 months</u>.

Mark the services you have required, number of days received and form of payment. In case you have required a service and have not received it, note the reason number (see the possible reasons below the table).

Kinds of services	**You have needed to receive...**	**Days service received according to economic system**			**Reason for which they have not received the service (*)**
		Free of charge	Direct payment	Mixed (public and private)	
During the <u>last month</u>...		**During the <u>last month</u>...**			
1. Telecare	☐	___ days	___ days	___ days	

2. Domiciliary care /help	☐	___ days	___ days	___ days	
3. Day centre	☐	___ days	___ days	___ days	
4. Occupational centre or centre for cultural, recreational and leisure activities	☐	___ days	___ days	___ days	
5. Other:	☐	___ days	___ days	___ days	
In the last 6 months...		**In the last 6 months...**			
6. Respite services: Temporary stays	☐	___ days	___ days	___ days	
7. Residential centres	☐	___ days	___ days	___ days	
8. Other:	☐	___ days	___ days	___ days	

(*) Reasons: 1 – Waiting list. 2 – Not available in the setting. 3 – Cannot pay it. 4 – Does not comply with any of the requirements. 5 – Other reasons.

QUESTIONNAIRE FOR THE CARER (first contact-baseline)

The subject's principal informal carer (NOT CONTRACTED) fills in the questionnaire.

The principal informal carer is the person who is in charge of the patient whose autonomy has been limited for health reasons, and the person who spends more time with him/her or who has a greater responsibility to him/her compared with the other members of the patient's emotional environment.

1. **Identification number: _____**
2. **Carer's date of birth (day/month/year):** ___/___/19___
3. **Sex:**

   o Female

   o Male

4. **Country: _____**
5. **Nationality: _____**
6. **Marital status:**

   o Single o Married or cohabiting o Divorced o Separated

   o Widow oN/A

7. **Level of studies completed:**

   o Primary o Secondary o University o None

8. **What is your relationship with the subject? Are you his/her…**

   o Sibling o Grandchild o Son/daughter o Nephew/niece o Friend

   o Neighbour o Another (please specify) _____o N/A

9. Do you live with the care recipient?

o Yes oNo

10. Since when have you cared for the subject?

O Less than 1 year

O between 1 and 2 years

O between 2 and 4 years

o between 4 and 6 years

o More than 6 years

o NA

HEALTH RELATED PROBLEMS

11. Have you had any health-related problem for caring the subject in the last 12 months?

o YES

o NO → skip to question #13

12. In case of YES, please specify if you suffer any or some of the following problems (multiple choice option):

o I am depressed

o I am in treatment because of caregiving

o I am extremely tired

o I have back pain

WORK-RELATED PROBLEM

13. What is your MAIN working situation?

o I am employed

o I am unemployed

o Retired or pensioner ⇒ Skip to question #16

o Domestic tasks ⇒ Skip to question #17

o N/A ⇒ Skip to question #17

14. Have you had any work-related problem for caring the subject in the last 12 months?

o Yes o No ⇒ Skip to question #16

15. In case of yes, please specify this

o I requested___ days leave of absence

o I was working ___ hours less a day for ___ days

o I am working ___ hours less a day

o I do not work less hours a day but I have problems fulfilling my working hours

o I had to leave work because of illness the person I care

o Other problems: _____

16. Retirement (only to be answered in case the carer is retired or a pensioner)

a. Have you had to retire early to care for the subject?

o Yes o No ⇒ Skip to question #17

b. **In case of yes, please specify:**

o I retired early at the age of___ years

SOCIAL, FAMILY AND LEISURE TIME- RELATED PROBLEMS

17. Have you had any family, social o leisure time-related problem for caring the subject in the last 12 months?

o Yes o No ⇒ Skip to question #19

18. In case of YES, please specify this(multiple choice option)**:**

oI had to reduce my leisure time

o I have conflicts with my partner or my family

o I have no time to see or visit my friends

o I have no time to take care of myself or other people

o I have failed to start a family / I have not been able to have children (or more children)

Regarding the role played by you as PRINCIPAL CARER...

19. How much time do you invest in a normal DAY for each one of the activities?

Please specify the approximate time you spend <u>daily</u> on each activity

On basic hygiene and dressing or changing them	.....	hours	.....	minutes	a day
On bathing or showering them	.....	hours	.....	minutes	a day
On feeding them	.....	hours	.....	minutes	a day
On helping them to move around within the house	.....	hours	.....	minutes	a day

On cooking and preparing meals	.....	hours	.....	minutes a day
Administration of drugs	.....	hours	.....	minutes a day

20. How much time do you invest in a normal WEEK on each one of the following activities?

Please specify the approximate time you spend <u>weekly</u> on each activity

On helping them to travel outside the house	.....	hours	.....	minutes a week
On helping them to contact health care suppliers	.....	hours	.....	minutes a week
On helping them to organise home adaptations	.....	hours	.....	minutes a week
On shopping	.....	hours	.....	minutes a week
On financial, administrative or legal affairs	.....	hours	.....	minutes a week
On social and leisure activities	.....	hours	.....	minutes a week
Monitoring and supervision (falls)	.....	hours	.....	minutes a week

Regarding the role played by OTHER CARERS (e.g. the rest of the family)

21. How much time in a normal DAY do other carers spend on each one of the following activities?

Please specify the approximate time these people spend <u>daily</u> on each activity

On basic hygiene and dressing or changing them	.....	hours	.....	minutes a day
On bathing or showering them	.....	hours	.....	minutes a day
On feeding them	.....	hours	.....	minutes a day

On helping them to move around within the house	.....	hours	.....	minutes a day
On cooking and preparing meals	.....	hours	.....	minutes a day
Administration of drugs	.....	hours	.....	minutes a day

22. How much time do other carers spend in a normal WEEK on each of the following activities?

Please specify the approximate time these people spend <u>weekly</u> on each activity

On helping them to travel outside the house	.....	hours	.....	minutes a week
On helping them to contact health care suppliers	.....	hours	.....	minutes a week
On helping them to organise home adaptations	.....	hours	.....	minutes a week
On shopping	.....	hours	.....	minutes a week
On financial, administrative or legal affairs	.....	hours	.....	minutes a week
On social and leisure activities	.....	hours	.....	minutes a week
Monitoring and supervision (falls)	.....	hours	.....	minutes a week

QUESTIONNAIRE FOR THE CARER (week 12)

The subject's principal informal carer (NOT CONTRACTED) fills in the questionnaire

If it is the first contact that the care has with the study because the person that she/he looks after did not need a carer before or it is a different carer, the carer must fill the baseline`s questionnaire.

1. **Identification number**_____

HEALTH RELATED PROBLEMS

2. **Have you had any health-related problem for caring the subject in the last 3 months?**

   o YES

   o NO → skip to question #4

3. **In case of YES, please specify this**(multiple choice option)::

   o I am depressed

   o I am in treatment because of caregiving

   o I am extremely tired

   o I have back pain

WORK-RELATED PROBLEM

4. **WHAT IS YOUR MAIN WORKING SITUATION?**

   o I am employed

o I am unemployed

o Retired or pensioner ⇒ Skip to question #7

o Domestic tasks ⇒ Skip to question #8

o N/A ⇒ Skip to question #8

5. Have you had any work-related problem for caring the subject in the last 3 months?

o Yes o No ⇒ Skip to question #8

6. In case of yes, please specify this

o I requested___ days leave of absence

o I was working ___ hours less a day for ___ days

o I am working ___ hours less a day

o I do not work less hours a day but I have problems fulfilling my working hours

o I had to leave work because of illness the person I care

o Other problems: _____

7. Retirement (only to be answered in case the carer is retired or a pensioner)

c. Have you had to retire early to care for the subject?

o Yes o No ⇒ Skip to question #8

d. **In case of yes, please specify:**

o I retired early at the age of___ years

SOCIAL, FAMILY AND LEISURE TIME- RELATED PROBLEMS

8. Have you had any family, social o leisure time-related problem for caring the subject in the last 3 months?

o Yes o No ⇒ Skip to question #10

9. In case of YES, please specify this(multiple choice option)**::**

oI had to reduce my leisure time

o I have conflicts with my partner or my family

o I have no time to see or visit my friends

o I have no time to take care of myself or other people

o I have failed to start a family / I have not been able to have children (or more children)

Regarding the role played by you as PRINCIPAL CARER...

10. How much time do you invest in a normal DAY for each one of the activities?

Please specify the approximate time you spend <u>daily</u> on each activity

On basic hygiene and dressing or changing them	.....	hours	.....	minutes	a day
On bathing or showering them	.....	hours	.....	minutes	a day
On feeding them	.....	hours	.....	minutes	a day
On helping them to move around within the house	.....	hours	.....	minutes	a day
On cooking and preparing meals	.....	hours	.....	minutes	a day

Administration of drugs	.....	hours	.....	minutes a day

11. How much time do you invest in a normal WEEK on each one of the following activities?

Please specify the approximate time you spend <u>weekly</u> on each activity

On helping them to travel outside the house	.....	hours	.....	minutes a week
On helping them to contact health care suppliers	.....	hours	.....	minutes a week
On helping them to organise home adaptations	.....	hours	.....	minutes a week
On shopping	.....	hours	.....	minutes a week
On financial, administrative or legal affairs	.....	hours	.....	minutes a week
On social and leisure activities	.....	hours	.....	minutes a week
Monitoring and supervision (falls)	.....	hours	.....	minutes a week

Regarding the role played by OTHER CARERS (e.g. the rest of the family)

12. How much time in a normal DAY do other carers spend on each one of the following activities?

Please specify the approximate time these people spend <u>daily</u> on each activity

On basic hygiene and dressing or changing them	.....	hours	.....	minutes	a day
On bathing or showering them	.....	hours	.....	minutes	a day
On feeding them	.....	hours	.....	minutes	a day
On helping them to move around within the house	.....	hours	.....	minutes	a day
On cooking and preparing meals	.....	hours	.....	minutes	a day
Administration of drugs	.....	hours	.....	minutes	a day

13. How much time do other carers spend in a normal WEEK on each of the following activities?

Please specify the approximate time these people spend <u>weekly</u> on each activity

On helping them to travel outside the house	.....	hours	.....	minutes	a week
On helping them to contact health care suppliers	.....	hours	.....	minutes	a week
On helping them to organise home adaptations	.....	hours	.....	minutes	a week
On shopping	.....	hours	.....	minutes	a week
On financial, administrative or legal affairs	.....	hours	.....	minutes	a week
On social and leisure activities	.....	hours	.....	minutes	a week

Monitoring and supervision (falls)	.....	hours	.....	minutes a week

QUESTIONNAIRE FOR THE CARER(week 52)

The subject's principal informal carer (NOT CONTRACTED) fills in the questionnaire

If it is the first contact that the care has with the study because the person that she/he looks after did not need a carer before or it is a different carer, the carer must fill the baseline`s questionnaire.

1. **Identification number**_____

HEALTH RELATED PROBLEMS

2. **Have you had any health-related problem for caring the subject in the last 6 months?**

   o YES

   o NO → skip to question #4

3. **In case of YES, please specify this**(multiple choice option)**:**

   o I am depressed

   o I am in treatment because of caregiving

   o I am extremely tired

   o I have back pain

   o I have no problem of health because of caregiving

WORK-RELATED PROBLEM

4. WHAT IS YOUR MAIN WORKING SITUATION?

o I am employed

o I am unemployed

o Retired or pensioner ⇒ Skip to question #7

o Domestic tasks ⇒ Skip to question #8

o N/A ⇒ Skip to question #8

5. Have you had any work-related problem for caring the subject in the last 6 months?

o Yes o No ⇒ Skip to question #8

6. In case of yes, please specify this

o I requested___ days leave of absence

o I was working ___ hours less a day for ___ days

o I am working ___ hours less a day

o I do not work less hours a day but I have problems fulfilling my working hours

o I had to leave work because of illness the person I care

o Other problems: _____

7. Retirement (only to be answered in case the carer is retired or a pensioner)

e. Have you had to retire early to care for the subject?

o Yes o No ⇒ Skip to question #8

f. **In case of yes, please specify:**

o I retired early at the age of___ years

SOCIAL, FAMILY AND LEISURE TIME- RELATED PROBLEMS

8. Have you had any family, social o leisure time-related problem for caring the subject in the last 6 months?

o Yes o No ⇒ Skip to question #10

9. In case of YES, please specify this(multiple choice option)**:**

o I had to reduce my leisure time

o I have conflicts with my partner or my family

o I have no time to see or visit my friends

o I have no time to take care of myself or other people

o I have failed to start a family / I have not been able to have children (or more children)

Regarding the role played by you as PRINCIPAL CARER...

10. How much time do you invest in a normal DAY for each one of the activities?

Please specify the approximate time you spend <u>daily</u> on each activity

On basic hygiene and dressing or changing them	.....	hours	.....	minutes	a day
On bathing or showering them	.....	hours	.....	minutes	a day

On feeding them	.....	hours	.....	minutes a day
On helping them to move around within the house	.....	hours	.....	minutes a day
On cooking and preparing meals	.....	hours	.....	minutes a day
Administration of drugs	.....	hours	.....	minutes a day

11. How much time do you invest in a normal WEEK on each one of the following activities?

Please specify the approximate time you spend <u>weekly</u> on each activity

On helping them to travel outside the house	.....	hours	.....	minutes a week
On helping them to contact health care suppliers	.....	hours	.....	minutes a week
On helping them to organise home adaptations	.....	hours	.....	minutes a week
On shopping	.....	hours	.....	minutes a week
On financial, administrative or legal affairs	.....	hours	.....	minutes a week
On social and leisure activities	.....	hours	.....	minutes a week
Monitoring and supervision (falls)	.....	hours	.....	minutes a week

Regarding the role played by OTHER CARERS (e.g. the rest of the family)

12. How much time in a normal DAY do other carers spend on each one of the following activities?

Please specify the approximate time these people spend <u>daily</u> on each activity

On basic hygiene and dressing or changing them	.....	hours	.....	minutes	a day
On bathing or showering them	.....	hours	.....	minutes	a day
On feeding them	.....	hours	.....	minutes	a day
On helping them to move around within the house	.....	hours	.....	minutes	a day
On cooking and preparing meals	.....	hours	.....	minutes	a day
Administration of drugs	.....	hours	.....	minutes	a day

13. How much time do other carers spend in a normal WEEK on each of the following activities?

Please specify the approximate time these people spend <u>weekly</u> on each activity

On helping them to travel outside the house	.....	hours	.....	minutes	a week
On helping them to contact health care suppliers	.....	hours	.....	minutes	a week
On helping them to organise home adaptations	.....	hours	.....	minutes	a week
On shopping	.....	hours	.....	minutes	a week
On financial, administrative or legal affairs	.....	hours	.....	minutes	a week
On social and leisure activities	.....	hours	.....	minutes	a week

	.....			

12. REFERENCES

1. Fried LP, Tangen CM, Walston J, Newman AB, Hirsch C, Gottdiener J, et al. Frailty in older adults: evidence for a phenotype. The journals of gerontology Series A, Biological sciences and medical sciences. 2001;56(3):M146-56.
2. Ferrucci L, Cavazzini C, Corsi A, Bartali B, Russo CR, Lauretani F, et al. Biomarkers of frailty in older persons. Journal of endocrinological investigation. 2002;25(10 Suppl):10-5.
3. Fried LP, Guralnik JM. Disability in older adults: evidence regarding significance, etiology, and risk. Journal of the American Geriatrics Society. 1997;45(1):92-100.
4. Gill TM, Gahbauer EA, Allore HG, Han L. Transitions between frailty states among community-living older persons. Archives of internal medicine. 2006;166(4):418-23.
5. Xue QL. The frailty syndrome: definition and natural history. Clinics in geriatric medicine. 2011;27(1):1-15.
6. Pahor M, Guralnik JM, Ambrosius WT, Blair S, Bonds DE, Church TS, et al. Effect of structured physical activity on prevention of major mobility disability in older adults: the LIFE study randomized clinical trial. Jama. 2014;311(23):2387-96.
7. Gill TM, Gahbauer EA, Han L, Allore HG. Trajectories of disability in the last year of life. The New England journal of medicine. 2010;362(13):1173-80.
8. Sourial N, Bergman H, Karunananthan S, Wolfson C, Payette H, Gutierrez-Robledo LM, et al. Implementing frailty into clinical practice: a cautionary tale. The journals of gerontology Series A, Biological sciences and medical sciences. 2013;68(12):1505-11.
9. Bandeen-Roche K, Xue QL, Ferrucci L, Walston J, Guralnik JM, Chaves P, et al. Phenotype of frailty: characterization in the women's health and aging studies. The journals of gerontology Series A, Biological sciences and medical sciences. 2006;61(3):262-6.
10. Garcia-Garcia FJ, Gutierrez Avila G, Alfaro-Acha A, Amor Andres MS, De Los Angeles De La Torre Lanza M, Escribano Aparicio MV, et al. The prevalence of frailty syndrome in an older population from Spain. The Toledo Study for Healthy Aging. The journal of nutrition, health & aging. 2011;15(10):852-6.
11. Campbell AJ, Buchner DM. Unstable disability and the fluctuations of frailty. Age and ageing. 1997;26(4):315-8.
12. Walston J, Fried LP. Frailty and the older man. The Medical clinics of North America. 1999;83(5):1173-94.
13. Rockwood K, Hogan DB, MacKnight C. Conceptualisation and measurement of frailty in elderly people. Drugs & aging. 2000;17(4):295-302.
14. Clegg A, Young J, Iliffe S, Rikkert MO, Rockwood K. Frailty in elderly people. Lancet. 2013;381(9868):752-62.
15. Strandberg TE, Pitkala KH. Frailty in elderly people. Lancet. 2007;369(9570):1328-9.
16. Rodriguez-Artalejo F, Rodriguez-Manas L. The frailty syndrome in the public health agenda. Journal of epidemiology and community health. 2014;68(8):703-4.
17. Barnett K, Mercer SW, Norbury M, Watt G, Wyke S, Guthrie B. Epidemiology of multimorbidity and implications for health care, research, and medical education: a cross-sectional study. Lancet. 2012;380(9836):37-43.
18. Temple RM, Kirthi V, Patterson LJ. Is it time for a new kind of hospital physician? Bmj. 2012;344:e2240.
19. Stuck AE, Iliffe S. Comprehensive geriatric assessment for older adults. Bmj. 2011;343:d6799.

20. Afilalo J, Alexander KP, Mack MJ, Maurer MS, Green P, Allen LA, et al. Frailty assessment in the cardiovascular care of older adults. Journal of the American College of Cardiology. 2014;63(8):747-62.
21. Balducci L, Colloca G, Cesari M, Gambassi G. Assessment and treatment of elderly patients with cancer. Surgical oncology. 2010;19(3):117-23.
22. Ellis G, Whitehead MA, Robinson D, O'Neill D, Langhorne P. Comprehensive geriatric assessment for older adults admitted to hospital: meta-analysis of randomised controlled trials. Bmj. 2011;343:d6553.
23. Partridge JS, Harari D, Dhesi JK. Frailty in the older surgical patient: a review. Age and ageing. 2012;41(2):142-7.
24. Philipps V, Amieva H, Andrieu S, Dufouil C, Berr C, Dartigues JF, et al. Normalized Mini-Mental State Examination for assessing cognitive change in population-based brain aging studies. Neuroepidemiology. 2014;43(1):15-25.
25. Morley JE. Developing novel therapeutic approaches to frailty. Current pharmaceutical design. 2009;15(29):3384-95.
26. Mahoney FI, Barthel DW. Functional Evaluation: The Barthel Index. Maryland state medical journal. 1965;14:61-5.
27. Yesavage JA. Geriatric Depression Scale. Psychopharmacology bulletin. 1988;24(4):709-11.
28. Sinclair AJ, Armes DG, Randhawa G, Bayer AJ. Caring for older adults with diabetes mellitus: characteristics of carers and their prime roles and responsibilities. Diabetic medicine : a journal of the British Diabetic Association. 2010;27(9):1055-9.
29. Inouye SK, van Dyck CH, Alessi CA, Balkin S, Siegal AP, Horwitz RI. Clarifying confusion: the confusion assessment method. A new method for detection of delirium. Annals of internal medicine. 1990;113(12):941-8.
30. Guralnik JM, Simonsick EM, Ferrucci L, Glynn RJ, Berkman LF, Blazer DG, et al. A short physical performance battery assessing lower extremity function: association with self-reported disability and prediction of mortality and nursing home admission. Journal of gerontology. 1994;49(2):M85-94.
31. Schuit AJ, Schouten EG, Westerterp KR, Saris WH. Validity of the Physical Activity Scale for the Elderly (PASE): according to energy expenditure assessed by the doubly labeled water method. Journal of clinical epidemiology. 1997;50(5):541-6.
32. Vellas B, Villars H, Abellan G, Soto ME, Rolland Y, Guigoz Y, et al. Overview of the MNA--Its history and challenges. The journal of nutrition, health & aging. 2006;10(6):456-63; discussion 63-5.
33. Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. Journal of chronic diseases. 1987;40(5):373-83.
34. Ferreira-Valente MA, Pais-Ribeiro JL, Jensen MP. Validity of four pain intensity rating scales. Pain. 2011;152(10):2399-404.
35. Bermejo F, Morales JM, Valerga C, del Ser T, Artolazabal J, Gabriel R. [A comparison between 2 abbreviated Spanish versions of mental status assessment in the diagnosis of dementia. Study data on elderly community residents]. Medicina clinica. 1999;112(9):330-4.