

LONELINESS AS A RISK FACTOR FOR HIGH LEVEL OF COMORBIDITIES AND LOW QUALITY OF LIFE IN ELDERLY POPULATION (NON SOLUM STUDY)

FINAL DEGREE PROJECT

Multicentered Prospective Cohort Study

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Agraeixo de tot cor al meu tutor com m'ha fet sentir durant aquests mesos, espero poder arribar a ser tan bona professional com ell algun dia. És una persona molt inspiradora que m'ha ajudat a progressar una mica amb les meves habilitat clíniques i m'ha recordat per què m'agrada tant i tant l'Atenció Primària.

Aquest treball el dedico íntegrament a la meva família, per ser el meu pilar fonamental, per ajudar-me amb tots els obstacles que em trobo pel camí i per ser els meus referents tant en la vida professional com personal.

Finalment, m'agradaria agrair a tots els meus amics i a l'Aleix, que m'han suportat i recolzat durant aquests 6 anys amb les meves curalles i problemes, i en especial a les meves amigues de Girona que més bé ara són família.

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ABREVIATIONS

ECAP: Estació Clínica d'Atenció Primària

WHO: World Health Organization

DM: Diabetes Mellitus

COPD: Chronic Obstructive Pulmonary Disease

UCLA: University of California, Los Angeles

CIRS-G: Cumulative Illness Rating Scale- Geriatrics

QoL: Quality of Life

VAS: Visual Analog Scale

INE: Instituto Nacional de Estadística

ABS: Àrea Bàsica de Salut

CAP: Centre d'Atenció Primària

EAP: Equip d'Atenció Primària

ISCED: International Standard Classification of Education

BMI: Body Mass Index

CI: Coordination Investigator

CEIC: Comitè Ètic d'Investigació Clínica

IDIAP: Institut Universitari d'Investigació en Atenció Primària

MI: Myocardial Infarction

PRN: Pro re nata

WBC: White Blood Cell

LFT: Liver Function Test

BPH: Benign Prostatic Hyperplasia

UTI: Urinary Tract Infection

TURP: Transurethral Resection of the Prostate

TIA: Transient Ischemic Attack

CVA: Cerebrovascular Accident

ABSTRACT

LONELINESS AS A RISK FACTOR FOR HIGH LEVEL OF COMORBIDITIES AND LOW QUALITY OF LIFE IN ELDERLY POPULATION (NON SOLUM STUDY)	
BACKGROUND	<p>Loneliness is a very common feeling in our environment and it can be a very intense experience in older people, due to the loss of complete abilities and capacities, which are fully complete when we are younger. Especially chronic loneliness is the one that has been more related to health problems, both physical and mental.</p> <p>Comorbidity on elderly population seems to be a good way to correlate all pathologies and deficits they suffer. Comorbidity hinders the process of a good state of health. It must be treated as a global condition with comprehensive approach according to severity, prognosis and possibility to treat.</p> <p>Nowadays quality of life has become more important in clinical practice, it is no longer following a paternalist model. Today patient's opinion is taken into account regarding his or her state of health. That is why quality of life is an information needed in investigations and mostly on elder population who seems to have a worse perception of health state and quality of life.</p>
OBJECTIVES	The main objectives of this study are to evaluate if people who suffer loneliness could develop a major level of comorbidities and develop a worse perception of their quality of life
DESIGN	This study has been designed as a multicentric prospective dynamic cohort study.
METHODS	<p>Data will be obtained with Estació Clínica d'Atenció Primària (ECAP) program, which is registered in routine medical visits. An ECAP manager will recruit all people who fulfill our criteria and then we will randomly select 401 candidates. To assure we do not have enough participants we will randomly select another 10%. So, at the end we will select a sample of 441 possible candidates.</p> <p>We will follow-up our participants during six years and administer them University of California, Los Angeles (UCLA) Loneliness Scale, Cumulative Illness Rating Scale-Geriatrics (CIRS-G) and QL-5D-5L each year. All data collection will be performed on the ECAP program, specifically on "Intel·ligència Clínica Activa", where there will be a section with the name of the study, Non Solum.</p>
PARTICIPANTS	The exposed cohort will include individuals who are 65 years old or over who feel lonely and the non-exposed cohort will include people aged 65 years old or over who do not feel loneliness. All of them will be from Girona Health Region.
KEY WORDS	Loneliness, elderly population, comorbidity, quality of life, risk factor, UCLA Loneliness scale, CIRS-G, QL-5D-5L.

INTRODUCTION

According to World Health Organization (WHO) health is no longer defined only as the lack of disease but also a complete state of physical, mental and social well-being. Even though this definition is the one that has endured for years other authors have proclaimed that health's definition responds to a historical condition, so each society in different moments can see health in a different way (1).

We are social beings; it is in our nature to form social relationships. It has been proved that social connections strongly influence health, they are related to emotional well-being but also attached to physical comfort and overall longevity (2). Some authors have reviewed how social activities, social networks, social support and social relationships affects cognitive functioning on the elderly and they have concluded that being socially active improve and maintains one's cognitive functioning, so any change on social life can decline it (3). These investigations proved this association but did not consider loneliness as a risk factor of decline because of the difficulty of loneliness measurement, while being social can be objectively measured, loneliness is a psychological phenomenon more difficult to measure.

There are different factors that can lead to comorbidity and early mortality. These risk factors include lifestyle and environmental factors such as tobacco, alcohol, sedentary lifestyle, air pollution, diet... If we look at the previous factors there is no representation of social factors such as loneliness, social isolation, social network... (4)

Loneliness

Loneliness is considered a distressing feeling that comes with the perception of discrepancy between desired and real social interaction, it is a very common feeling among universal population (5). It is a contributor to human affliction particularly in older population, who present decreased economic resources, functional limitation, changes in family structure and death of relatives and friends among other factors that can lead to a limitation of relationships (6).

It is important to differentiate social isolation with the feeling of loneliness, someone can feel lonely in the crowd and others can enjoy time with one-self without feeling loneliness (7). It is obvious that someone who is isolated have more risk to feel lonely but is not always that easy.

Social isolation, known as low number of social contacts and social engagement, is associated with poor health outcomes. There are some authors that considered it as a multidimensional concept, so it is not only the lower number of relationships but also the quality of them (8). There are risk factors for someone to become socially isolated, to understand them we have to think about isolation as a result of interaction among different levels, where we include: individual, relationship, community and societal. Each level presents different risk factors and all of them can be related. For example from more general level to the most concrete level (9):

- Societal level, there are structural society factors that increase the risk of isolation.
- Community level, those factors related to the community that can conduce to isolation such as limitation to access activities or transport according to the area you live in.
- Relationship level, the number and quality of relationships can affect this level
- Individual level is conditioned by personal experiences and characteristics

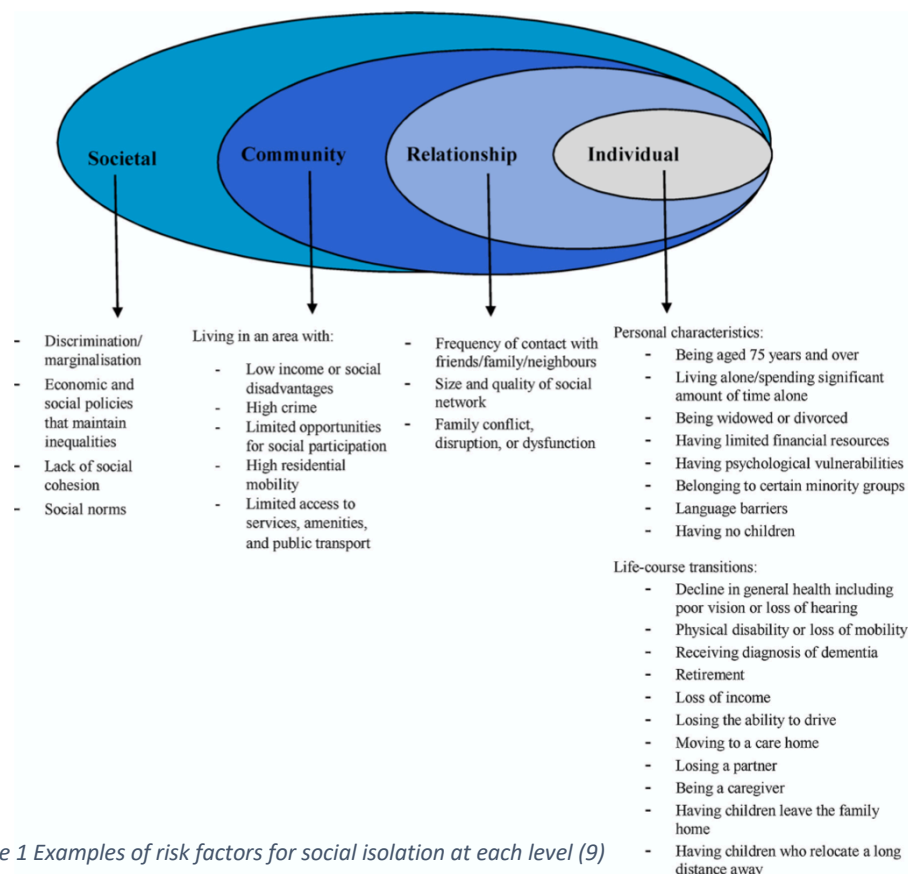


Figure 1 Examples of risk factors for social isolation at each level (9)

Both social isolation and loneliness are often undetected and underestimated, mostly on areas that should be identified like primary care assistance. Historically they have not been seen as public health risk (10).

Even though they can be related, loneliness and social isolation are measured differently, social isolation is an objective entity which includes household composition, marital status and number of relationships, and loneliness has a subjective evaluation. To measure loneliness we use scales, the most used historically is the UCLA Loneliness Scale. The first version of this scale consisted in 20 statements to reflect individuals' feeling of loneliness, a revised version came out to eliminate biases that had been observed during the administration of the scale (11). Finally, a third version was published to correct some other problems that must be resolved. The UCLA Loneliness Scale (Version 3) manifested high reliability on elderly population (12). There is a three items Loneliness Scale that emerged from the UCLA Loneliness Scale that has proved easier administration in large studies (13, 14).

It is important to keep in mind that everyone has different ways to express emotions and personal perspectives, this ability can be influenced by cultural and gender characteristics. For example, usually women are more likely to express feelings than men, and this information should be considered because the scale that is used to measure loneliness is totally subjective, so someone who is not used to express emotions could show difficulties to be completely honest (15).

Loneliness can be considered a construction formed by different types of singular loneliness. Intimate loneliness related to having no one for emotional support, relational loneliness, which is the same as social loneliness. It is the feeling of absence of a quality friendship or family connections. It can include groups from 15 to 50 people which we see regularly and from whom we can obtain high level of support. And finally, the collective loneliness, the third dimension of loneliness. It can appear when someone feels lack of value from a group of 150-1500 people with whom we interact in school, work...(16)

This feeling can be also classified by temporary criteria in chronic loneliness, transient loneliness and situational loneliness. Chronic loneliness is when the feeling of loneliness is persistent during at minimum two years, transient loneliness is the one that is not persistent, but it repeats from time to time in brief periods and situational loneliness is only associated with one period of time. Even though each type has different temporal criteria there is not an absolute line between them, so one can lead to another (17).

It is chronic loneliness that has been related to physiological changes, there are authors that suggested that loneliness could be an accelerator of health progression that come with the age. They concretely suggested loneliness effects on five mechanisms: health behaviors, perceived stress, stress responses, recuperative processes and exposure to stressful life events (18, 19).

It is important to understand each of these mechanisms. First of all, health behaviors, are decisions and actions every individual do that has a repercussion on one-self health, for example: diet and exercise. Perceived stress is how an individual see his or her level of stress at certain moment and it can influence stress response and its recuperative process (20).

There are authors that have suggested that loneliness could be an inducer for low levels of protective hormones and consequently alteration of heart rate, blood pressure, downregulation of the immune system and neuroendocrine. Large periods of chronic loneliness have been related to an increase on cortisol levels. Cortisol is a hormone created in stressful situations, if those high levels last over time can lead to inflammation, insulin resistance, weight gain... At the end all these mechanisms can facilitate the development of depression, Diabetes Mellitus type 2 (DM2), cardiac illnesses, hypertension, sleep disorders, mental health disorders... Loneliness by itself can influence on self-esteem and lead to depression, alcoholism or suicidal ideation. Physically it has debilitating effects on immunological system, it is also associated with headache, difficulty to sleep... so as we can see loneliness has been related to some health problems on older people.

Additionally, these affectations, mentioned anteriorly, could incite bad lifestyle habits such as smoking, sedentary habits, bad diet, high alcohol consumption and/or other risk behavior. So in the end it is a vicious circle because every situation can lead to the other and inversely (8).

The illnesses that have been more studied in association with social factors are depression and cardiovascular disease because those are the ones that contribute more to the burden of disease in the elderly. So social isolation and loneliness can lead to less healthy lifestyle and lower longevity due to psychological, behavioral and biological pathways.

Nowadays it is known that loneliness can be triggered by different situations that differ from one person to another. There are risk factors that can lead to loneliness such as, demography, health, socio-environmental factors... Nevertheless, every individual can hold different levels of risk (7). There is a minimal level of social contact needed for a person to avoid the negative feeling of loneliness and it differs from one person to another by their personality structure, it is known as loneliness threshold.

Elderly population use to experience higher feelings of loneliness. This situation can be explained if we take notice on what changes are involved with the process of aging. The degradation of social resources, cultural, vulnerability in front of illnesses, decline on cognitive function and organ sense... those factors trigger to instability and defenseless feelings. With all of this, the process of loneliness on the elderly is used to be more intense (21). One situation that deserves a special mention is retirement, not only for a possible decline in economic resources but for social relationships that come with it and personal assurance. Another situation which can mark a milestone is widowhood for people who were married or lived with a partner.

Comorbidity in elderly population

Aging is a biological situation correlated to the passing of time, physiological, universal and inevitable. There are different theories to explain those changes but the most extended is that it is a process where interactions between external factors are accumulated over the years. Specifically, there are genetic, molecular, biochemical, histological and organic changes modulated by social, educational, economic and environmental factors that lead to functional decrease of organs and systems. Those changes can appear as Geriatric Syndromes, they are common conditions among elder population that do not fulfill diagnostic criteria but can lead to higher rates of mortality and morbidity.

We can say that they are deficits that accumulate over the years and the more someone accumulates, the higher risk they have to become more fragile, dependent and vulnerable (22, 23,24). Even though, we have to keep in mind that not everyone develops this type of manifestations, according to all these factors someone can get older with or without pathologies.

The most common illnesses that become chronic are hypertension, chronic kidney disease, osteoarthritis, depression, coronary illness, DM, Chronic Obstructive Pulmonary Disease (COPD), rheumatoid arthritis, dementia, cerebrovascular accident and peripheral arterial illness.

There is no consensus on comorbidity definition, some authors describe it as the concurrence of two or more illnesses diagnosed with established criteria and without causal relation with the first diagnose. Others use the term to refer any illness that can occur during the process of a guide entity. Finally, there are some authors that consider comorbidity as the total weight of biological dysfunction, so they do not only consider entities that fulfill diagnostic criteria but also entities that lead to subclinical dysfunction and deficiencies because of their high prevalence on elderly population. (25- 28)

Whatever the definition of comorbidity is, the reality is that it has to be evaluated integrally because its prevalence is increasing in older population.

The importance of comorbidity lies on its effects and consequences (27):

- It affects and modulates other concurrent illnesses
- Modifies the efficacy of treatment
- Increases the risk of iatrogenic and adverse effects
- Increases the risk of hospitalization
- Prolongs the time of hospitalization
- Worsens their quality of life
- Increases the risk of disability and dependence
- Increases the risk of death

Recent investigations in geriatric items have suggested the existence of a preclinical phase of comorbidity, where some compensator mechanisms seem to be altered. Problems like loss of strength, balance disturbance, existence of markers of inflammation... (28)

There are different scales to measure comorbidity but the most recommended for elderly population is the Cumulative Illness Rating Scale- Geriatrics (CIRS-G), it measures the impact of chronic diseases according to their severity. It is an easy scale for everyday use, but it needs additional information which can be collected by physical exploration, laboratory data and the patient's medical record. CIRS-G takes into account diseases from fourteen organ systems and it scores them from 0 to 4 according to severity, higher score evidence higher comorbidity (29).

Management of comorbidity on the elderly must be comprehensive, it is not only the treatment of a unique illness but the group of all pathologies and problems a person experiences which have to be considered. Each problem's dynamic evolution has to be taken into account with the aim of improving a person's health condition. Sometimes doctors must prioritize an illness treatment above others, because not all treatments are feasible for their risk of interaction and adverse effects.

Quality of life

Historically there were studies that used objective measures to determine effectiveness of what they wanted to study but they did not keep in mind that those measures could have any consequence in patients' life. Nowadays it has been seen that preserving someone's health is not only about giving assistance to their physical ailments, but approaching science to the patient as a person, taking into account the whole person. This way of seeing it has special importance in Primary Health Care, where it turns primordial to involve with a global view of the person, contemplating all of her or his dimensions (30).

Quality of Life (QoL) comprises physical and psychological domains, independence level, relationships, environmental aspects and beliefs. The definition of QoL has not arrived to a consensus but World Health Organization has defined it like "individuals perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns" (31).

It is important to know that it is a perception, so it will be measured by subjective questionnaires. It has to be differentiated from living standards which can be objectively measured using socioeconomic, demographic and basic health indicator data (32).

QoL is useful to:

- Plan the sanitary assistance of the patients
- Measure results in clinical trials and other investigations
- Evaluate sanitary needs of the population
- Distribute health resources

The EuroQol Group created a scale to measure QoL, the only scale that has been validated for its use in Spain, it is very useful in primary care attention for its simplicity and short time of administration, above 2-3 minutes (33). This scale consists in a descriptive system, that takes into account five dimensions: mobility, self-care, usual activities, pain and discomfort and anxiety and depression, and a visual analog scale (VAS), where the patient scores their health from 0 to 100. In 1990 they introduced a first version and in 2009 it was ameliorated to elevate the sensitivity (34). As we are talking about a subjective measurement, there are some authors that consider there is a risk of lossy, so when a QoL scale is used it has to be evaluated taking into account all information surrounding that person (35).

Medicine aforesaid has followed a paternalized model where sanitary professionals made every decision about their patients, but these days the model has changed, every patient have their own voice regarding their health. Using quality of life measurements on sanitary assistance helps to guarantee that old population continue participating as citizens with whole rights because their opinion about their own health state is listened and considered. Consequently this could help to get old with safety and dignity (36).

JUSTIFICATION

It is a fact that we are social being and according to it, social relationships are necessary for our cognitive and affective development. In accordance with the definition that the World Health Organization, health is a set of physical, mental and social well-being. So whenever our social needs are completed, we get closer to an optimal health condition. With a clear knowledge that social interactions are positive and needed for our welfare, how does loneliness and social isolation affect us?

It has been seen that there is an association between social isolation and poor health outcomes. Those studies indirectly included loneliness because someone who is isolated has more risk to perceive loneliness feelings, though not everyone who is alone feels loneliness.

There are social risk factors to finally suffer from loneliness. There are other risk factors that do not depend on personal characteristics such as community, society and structural factors. One important personal risk factor to progress to a feeling of loneliness is age, people who are 75 years old and over have more risk to develop this distressing feeling.

Many years ago, natality started to diminish considerably, so much that nowadays the population pyramid is beginning to invert. Ergo every time there will be more elderly population and less children population. Therefore, geriatric health problems will be day-to-day issues mostly in Primary Care System.

If we investigate the data base from the Instituto Nacional de Estadística (INE) we can see that there are 781.788 people in Girona's Sanitary Region, approximately 140.000 people are 65 years old and over, while 123.925 are between 0 to 15 years old. As a conclusion we can see that population pyramid is nowadays inverted but according to actual demographic studies we know that this inversion will be bigger on the following years, so there will be older population every time, whom necessities will have to be attended.

When someone surpass 65 years old, Spanish jubilation age, his/her economic resources start to decrease notoriously, mobility can be affected, social relationship change, mostly of this person depends on someone else, medication intake increases, adaptation capacity to new habits is more difficult every time, for example with technologies, familiar structure can change... All those factors make elder population more vulnerable to suffer from loneliness feelings. Everyone, or mostly everyone, has felt loneliness minimum once in our life, the difference is that when we are younger, we find our own means to recover from this feeling, but the older ones have more difficulties in adapting to new situations.

The aim of this study is to prove that health care providers could be missing a risk factor to low quality of life and high comorbidity in people who are 65 years old and older, so to give an assistance of quality in the future based on our population needs it will be very useful to determine this association and, in that way, we would be able to do something to avoid loneliness negative results.

HYPOTHESIS

Loneliness is a risk factor to acquire higher rates of comorbidity, so people who bear loneliness for an amount of time develop more comorbidities than people who do not have this feeling.

The distressing feeling of loneliness has a negative impact on quality of life, leading to a lower perception of it, of people who are 65 year old and over.

OBJECTIVES

MAIN OBJECTIVES

- To evaluate whether people who suffer loneliness could develop a major level of comorbidities
- To evaluate if patients who suffer from loneliness develop a worse perception of their quality of life

SECONDARY OBJECTIVE

- To calculate loneliness prevalence of population who are 65 years old or over in Girona's Health Region at the beginning of the study.

METHODOLOGY

STUDY DESIGN

This study is a multicentered prospective dynamic cohort study which includes peoples who are 65 years old and over.

This study will be carried out in Girona's Health Region, which can be seen in *Figure 1*, composed by: Alt Empordà Baix Empordà, Garrotxa, Banyoles, Gironès Nord i Pla de l'Estany, Ripollès and Gironès Sud i Selva Interior.

All Girona's Health Region is formed by a group of Àrees Bàsiques de Salut (ABS), territorial units that concentrate their healthcare activity in Centres d'Atenció Primària (CAP). Each ABS is constructed by an Equip d'Atenció Primària (EAP), sanitary and non-sanitary professionals that direct and develop all activities in of the CAP. Girona's Health Region has 41 EAP (37, 38).

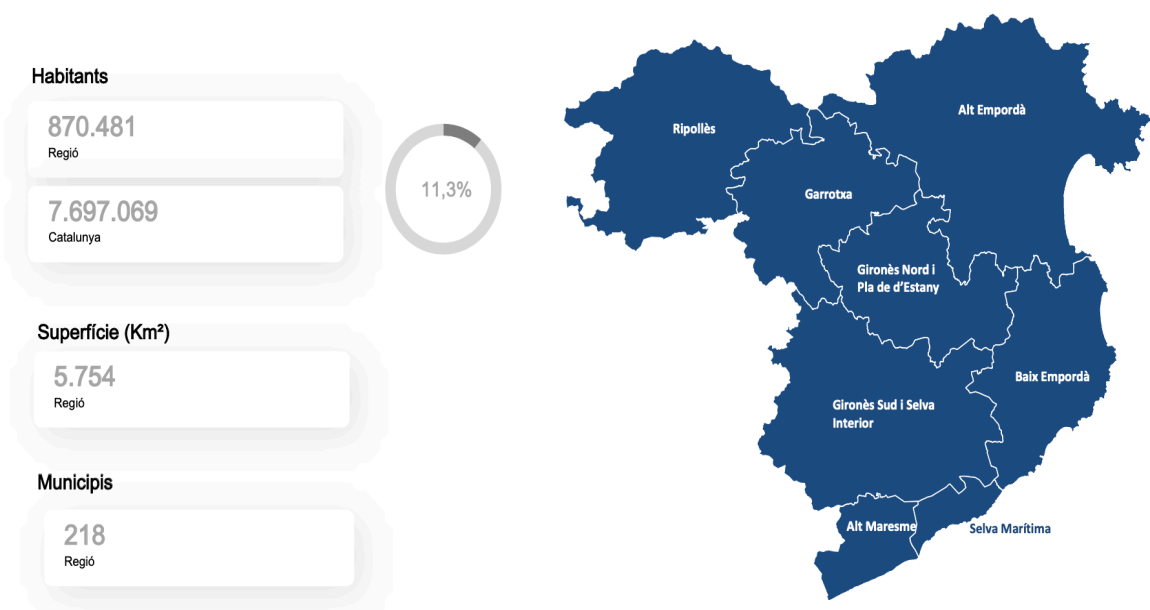


Figure 2. Sanitary region of Girona, 2020 (37)

STUDY POPULATION

The study population will include two cohort of elderly people, 65 years old and over, from Girona's Sanitary Region.

- The exposed cohort will include individuals from 65 years old and more who feel loneliness
- The non-exposed cohort will comprehend people who are 65 years old or over and who do not suffer from loneliness.

INCLUSION CRITERIA

- Age \geq 65 years old
- From Girona's Sanitary Region
- Ability to speak fluent and understand any of languages of the study, Catalan and/or Spanish

EXCLUSION CRITERIA

- Refusal to participate in the study
- The patient receives home care health (codified as ATDOM at the ECAP program)
- People with cognitive decline at the initial evaluation

SAMPLE

Sample selection

Our population for the study will be selected with ECAP data base, specifically people who are 65 years old and over. We will ask the ECAP manager to calculate how many people accomplish our inclusion criteria and do not fulfill our exclusion ones. At the time we receive this amount we will randomly select 401 persons to create our sample. To prepare us for any possible participation's denial we will also recruit more people according to a percentage, 10%, of the sample. So, a total of 441 persons will be recruited, where 40 of them are recruited to fill vacancies.

We will administer each participant the information document (ANNEX VII) and the informed consent (ANNEX VIII).

Whenever they have confirmed or rejected the study's participation, we will register loneliness measurement (UCLA Loneliness Scale) to classify our cohorts according to their own perception of loneliness.

Sample size

In a bilateral test, with an alpha equal to 5%, a statical power of 80%, and assuming that the prevalence of loneliness in people who are 65 year old and over is moderate we will need 349 subjects. Assuming a dropout rate of 15% we finally need 401 subjects.

Computations were carried out with Prof. Marc Saez's software based on the package 'pwr' of the statistical software R (version 4.1.2).

STUDY VARIABLES AND MEASURING INSTRUMENTS

Independent variable

Loneliness

Loneliness is a qualitative variable that will be measured using the UCLA Loneliness Scale (Version 3). Concretely, the third version of the UCLA Loneliness Scale consists in a 20-item questionnaire which can be rated from 1 to 4 (1= never, 2= rarely, 3= sometimes, 4= always), items number 1, 5, 6, 9, 10, 15, 16, 19 and 20 are reverse-scored. (ANNEX I) Each participant would have a result score from 20 to 80, and the cut-point has been settled in 39 points (39). Therefore, at baseline, loneliness will be categorized in lonely/no lonely.

On the following years, to avoid large scales that could lead to a lower rate of responses or non-correct procedures, we will be administrating the three item UCLA Loneliness Scale, a shorter version of the UCLA Loneliness Scale that have shown good reliability to assess loneliness. The three items are:

1. "How often do you feel that you lack companionship?"
2. "How often do you feel left out?"
3. "How often do you feel isolated from others?"

Each item can be answered on a 3-point scale: 1= hardly ever or never, 2= some of the time and 3= often.

After the interview each point is added to create a scale from 3 to 9 where the cut-off point is equally or above 6.

Dependent variables

Comorbidity

The scale that will be used for this study will be the CIRS-G. It has been validated in primary care and it has good correlation with clinical data, hospital stay, disability and cognitive level among all. (ANNEX II)

This rating system is flexible and simple, and it allows an easy use mostly in primary care. It has showed good interobserver capacity and test-retest.

CIRS-G evaluates 14 corporal systems and scores each one's disease from 0 to 4, where 0 indicates no disease or disease without clinical relevance and 4 represents extremely severe illness. If one system has various entities only the most critical must be taken into account and entities like cancer can be evaluated in different systems such as breast cancer with osseous metastasis. We will consider that one domain is altered when its score is 2 or more.

ORGAN-SYSTEM	SEVERITY
1. Cardiac	0-1-2-3-4
2. Vascular	0-1-2-3-4
3. Hematological	0-1-2-3-4
4. Respiratory	0-1-2-3-4
5. Ophthalmological and ORL	0-1-2-3-4
6. Upper gastrointestinal	0-1-2-3-4
7. Lower gastrointestinal	0-1-2-3-4
8. Hepatic and pancreatic	0-1-2-3-4
9. Renal	0-1-2-3-4
10. Genito-urinary	0-1-2-3-4
11. Musculoskeletal and cutaneous	0-1-2-3-4
12. Neurological	0-1-2-3-4
13. Endocrine, metabolic, mammary	0-1-2-3-4
14. Psychiatric	0-1-2-3-4

Score, depending on the extent to which the organ/system is affected: 0 Absence of disease; 1 mild; 2 moderate; 3 severe; 4 very severe.

Source: Linn BS, Linn MW, Gurel L. Cumulative illness rating scale. *J Am Geriatr Soc.* 1968; 16[5]:622-626.

Figure 3. Cumulative Illness Rating Score (40)

To get a total score each organ-system punctuation is added to the next one, getting a result from 0 to 56, where 0 means there are no problems in any of the organs or systems and 56 would mean that every organ and system are extremely impaired.

As we can see in *Figure 3* each category is rated according to severity of medical problems in: (39,40)

0. No impairment to that system
1. Mild problem or past significant problem, it does not interfere with normal activity; prognosis is excellent
2. Moderate illnesses that need first line therapy, it interferes with normal daily activities, treatment is needed, prognosis is good
3. Severe and constant disability that are not possible to control

4. Extremely severe, need for immediate treatment, organ failure or very severe functional deterioration, impairment is life-threatening

To use this scale some studies have expanded on each organ and system and there are used like a guideline. (ANNEX II)

Quality of life

QoL is a qualitative variable that will be measured with the EQ-5D-5L Test. This scale consists in two parts: a descriptive system and a visual analog scale. (ANNEX III)

The descriptive system considers five dimensions: mobility, self-care, usual activities, pain/ discomfort and depression/ anxiety. Each dimension is scored from 1 to 5, where 1 indicates no problems and 5 is for extreme problems, and in between it comprises slight, moderate and severe problems. Finally, every dimension has a one-digit score and each digit is combined to create a 5-digit number that indicates a person's unique health condition.

The VAS allows the patient to score their health from 0 to 100, so it gives quantitative units to the patient's perception of their health state. Patients are asked to score their perceived health the day that the questionnaire is administered (42).

Covariates

- Age is a continuous variable that will be expressed in years. As age increases, so does vulnerability, making it easier to get sick and worsening prognosis when illness arrives.
- Sex is a nominal and categorical qualitative variable that will be collected from primary care's data base.
- Birthplace. This is a covariate to consider because there are differences between cultures about expressing feelings, emotions or talk about oneself. We would categorize it as: Girona, rest of Catalonia, Spain, Europe (rest of it), Africa, Asia, North America, South America and other.
- Marital status: single, married, divorced, marital separation and widow.

- Connivance. As we have mentioned on the introduction section, one of the risk factors for developing feelings of loneliness is being socially isolated, so we would ask whether the participant lives alone in their home or not.
- Socioeconomic level:
 - Material goods, in this section we would like to collect data related to the participant's dwelling. We would ask during the anamnesis if she or he pays rent for living in her or his home.
 - Educational level. It will be initially categorized according to the International Standard Classification of Education (ISCED) in: early childhood education, primary education, lower secondary education, upper secondary education, post-secondary non-tertiary education and tertiary education, this last level includes short-cycle tertiary education, bachelor's or equivalent, master's or equivalent and doctorate or equivalent (43). To facilitate data collection, it will be finally classified into 4 different categories: no studies or not finished studies, primary (equivalent to 0 of the ISCED), secondary (1-4 ISCED) and tertiary (5- 8 ISCED).
- Toxic habits. The ones that will be considered are tobacco, alcohol and drugs. All of them will be asked during the interview and will be categorized as consumer, non-consumer or former consumer for each one of toxic habits mentioned before.
 - The exposure to tobacco will be classified as: consumer, non-consumer or former consumer
 - To calculate the consume of alcohol we will use an alcohol consumption calculator that is available in the next link: https://drogues.gencat.cat/ca/ciutadania/sobre_les_drogues/calculador_a-veus-el-que-beus/veus-el-que-beus/index.html. This calculator considers different types of alcohols and time of consumption to give a final result on how many units of alcohol a person drinks, 1 unit of alcohol is equivalent to 10 gr of pure ethanol (44). We specifically consider this calculation because it could be the trigger or the consequence of loneliness.

- Drug abuse will be also kept in mind, even though it is known its difficulty to be expressed by the patients it is an important factor to consider. We will categorize it like consumer, non-consumer and former consumer.
- Weight and height, Body Mass Index (BMI). There are quantitative measures that will be explored in the first appointment and followed during the duration of the study. Weight and height will be measured, and BMI ($\text{height} / \text{weight}^2$) will be calculated by the doctor or nurse. The results <19 will be classified as underweight, from 19 to 25 normal and >25 , overweight.
- Medication intake and quantity. Most of the studies define polymedication as the consume of five or more drugs daily. It is important to differentiate appropriate and inappropriate polymedication. We understand appropriate polymedication as correct prescription for the illnesses that the patient suffers and that have proved a favorable benefit/risk balance, and inappropriate polymedication as the revers term, either for lack of efficiency, absence of safeness or high risk of adverse effects. It has been seen that polymedicated people associate multimorbidity, dependence for basic activities of quotidian life, worst perception of health, higher risk of mortality, more hospitalization and more risk to suffer clinical adverse events (44, 45).
- Presence of comorbidities at the time of the initial data collection. This information will be gathered using ECAP data base and identifying entities detailed before in the comorbidity section. This covariate would be registered as yes or no and in case that the answer is yes, we would register which comorbidity or comorbidities.
- Àrea Bàsica de Salut (ABS) of the province of Girona

Table 1. Independent variable, dependent variable and covariates to consider in Non Solum Study

	VARIABLE		TYPE	MEASUREMENT	CATEGORIES OR VALUES
Independent variable	Loneliness		Qualitative dichotomous	UCLA Loneliness Scale	Yes/ No
Dependent variable	Comorbidity		Quantitative discrete	CIRS-G	Score 0-56
	Quality of Life		Quantitative discrete	EQ-5D-5L	Score 1-100
Covariates	Age		Quantitative continuous	ECAP	
	Sex		Qualitative dichotomous	ECAP	Female/ Male
	Marital Status		Qualitative polytomous	Anamnesis	Single/ Married/ Divorced/ Marital separation/ Widow
	Connivance		Quantitative discrete	Anamnesis	1/ 2/ 3/ 4/ 5/ More
	Birthplace		Qualitative polytomous	Anamnesis	Girona/ rest of Catalonia/ Spain/ Europe (rest of it)/ Africa/ Asia/ North America/ South America/ other
	Socioeconomical level	Material goods	Qualitative dichotomous	Anamnesis	Yes/ No
		Educational level	Qualitative polytomous		No studies/ Primary/ Secondary/ Tertiary
	Toxic habits: tobacco, alcohol and drugs		Qualitative polytomous	ECAP and anamnesis	Consumer/ Non consumer/ Former Consumer
	- Alcohol		Quantitative discrete	"veus el que beus"	0, 1, 2, 3, 4, 5 UBE...
	BMI		Qualitative polytomous	Exploration	Underweight/ Normal weight/ Overweight
	Polymedication		Qualitative dichotomous	ECAP	Yes/ No
	Presence of comorbidity		Qualitative dichotomous	ECAP	Yes/ No
			Qualitative polytomous		Type of comorbidity
ABS		Qualitative Polytomous	ECAP		

DATA COLLECTION

Initial data collection will be performed the first year (September 2022) and an annual visit will be done to complete the follow-up. Not all data must be registered in every visit, so this table will help to understand it:

Table 2. Data collection

VARIABLE		Baseline	2	3	4	End point
Loneliness						
Comorbidity						
Quality of Life						
Age						
Sex						
Marital Status						
Connivance						
Birthplace*						
Socioeconomical level	Material goods*					
	Educational level*					
Toxic habits						
BMI						
Polymedication						
Presence of comorbidity at the beginning						
ABS*						

Those categories marked in dark blue are the ones that we would be able to register using ECAP program, so the doctors will not need to ask them during their visit with the patient.

The ECAP is the program that allows primary Health care professionals get into each patient medical history. This program allows sanitary professionals to do specific searches that will help us to reduce the time of data collection because there will be data already registered. It controls medical histories of approximately the 80% Catalan population. It has very useful tools like electronic prescription, Shared Medical history and eConsulta. This program allows sanitary professionals to do specific searches that will help us to reduce the time of data collection because there will be data already registered. Another useful tool would be the shared medical history for all events that have not occurred in each participant's center (47).

*Any change in one of those categories would be ask during the anamnesis and must be registered on "Intel·ligència Clínica Activa" section.

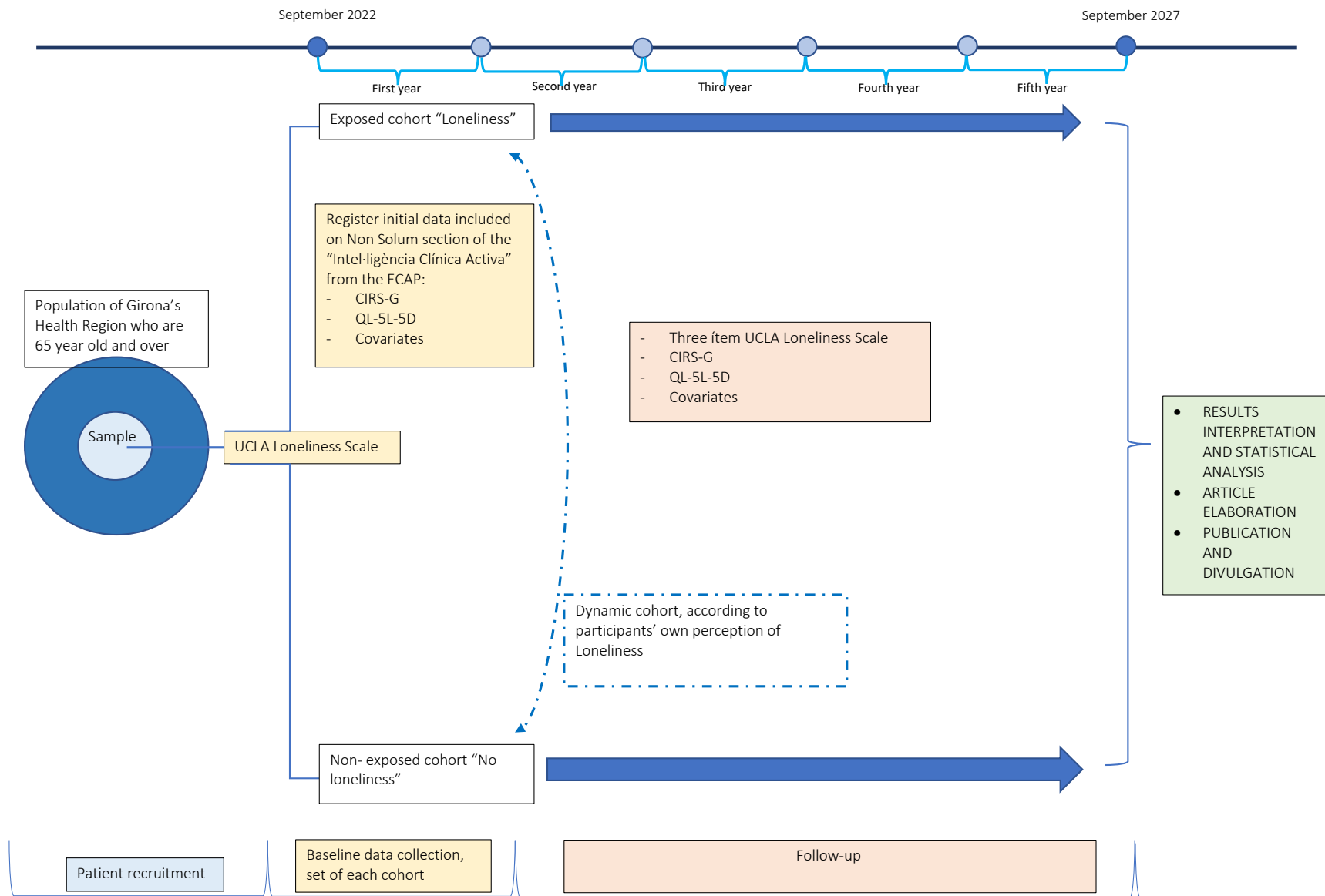


Figure 4. Summary of data collection

STATISTICAL ANALYSIS

Descriptive analysis

The variables corresponding to the main objectives (evaluation whether people who suffer loneliness could develop a major level of comorbidities and the development of worse perception of their quality of life) will be summarized using the median and the interquartile range, because all of them are quantitative discrete variables. In addition, means and standard deviations will be computed. These descriptive data will be provided each year from the start until the end of the follow-up.

Loneliness will be summarized by means of proportions (secondary objective), although in this case only at baseline.

We will carry out bivariate descriptive stratify by the groups defined by our independent variables. As explained above these groups, the non-exposed group and the exposed group, will be classified according to the results of the UCLA Loneliness Scale. This result could be: Lonely/ Not Lonely.

All these analyses will be further stratified by the covariables. Age will be categorized in quartiles. Convivence will be categorized in 1 person, 2 persons, 3 persons, 4 persons, 5 persons or more.

We would like to empathize that prevalence of loneliness at the baseline of the study, which is our secondary objective, will also be stratified by our covariates.

Bivariate inference

The difference of medians of the dependent variables corresponding to the main objectives between the groups defined by loneliness (lonely or not lonely according to UCLA Loneliness Scale and the three item UCLA Loneliness Scale) will be tested using the Mann-Whitney's U test. In addition, the difference of means will also be tested using the Student's t.

As above, the analyses will be stratified by the covariates.

The difference of proportions of loneliness (secondary objective) in the groups defined by the covariables (qualitative covariables and quantitative one's such as age and connivence) will be tested by the chi-square or the Fisher's exact test (in the case the expected number of cases in any cell will be lower than 5).

Multivariate analysis

To assess the effect of loneliness (on their two categories, yes or no) on the comorbidity and on quality of life we will estimate Poisson regressions controlling for the covariates.

We would keep in mind that we must control a possible trend on loneliness, because it is very possible that during the years of the study and follow up of each cohort, loneliness changes, becoming more common, for example. That is the reason why we will include in the regressions a trend (t= 1,2,3,4,5).

We would like to consider too that loneliness can increase in different ways according to some covariates like sex, age, marital status... This is the reason why we will evaluate interactions between the trend and our covariates.

WORK PLAN AND CHRONOGRAM

The study is expected to last approximately six years. The sequence of activities that will be carried out during the study are detailed below:

Stage 0: Study design and bibliographic research. [February – April 2022]

1st step: The Coordinator Investigator (CI) will initiate bibliographic research to start defining the aim of the study and the hypothesis. This research will be performed in PubMed and will be focused on how loneliness affects someone's in terms of medical aspects, negative outcomes of loneliness, which comorbidities are common on elderly population, how is quality of life measured and demographic data on the area that the study will be performed, concretely in Girona's Sanitary Region.

2nd step: The study protocol will be developed, and it will include all information about it, specifically: variables, objectives and the analytical framework. All of it is subjected to court's modifications.

Stage 1: Ethical evaluation [April 2022].

3rd step: The protocol will be submitted to the Comitè Ètic d'Investigació Clínica (CEIC) at Institut Universitari d'Investigació en Atenció Primària (IDIAP) Jordi Gol for its revision and approval, all suggested variation will be considered.

Stage 2: Initial coordination [May – June 2022]

4th step: An email will be sent to coordinators of each Primary Health Center of Girona's Sanitary Region with the objective to provide all the information about the study and asking their center's participation. In that email we will include an informative document (ANNEX IV) and we will also express the need of naming a manager of each center to facilitate communication between de CI and someone of each center. We will wait until we get a response from each coordinator.

While we are waiting for a confirmatory response, the CI will open a new section on the “Intel·ligència Activa Clínica” from the ECAP with the name of the study, Non Solum, where all data needed will be collected, helping the register of information by the doctors.

5th step: Once the CI gather each center’s manager, a meeting will be organized. The aim of the meeting will be to explain the study, some terms will be discussed such as participants recruitment and sample.

6th step: Whenever all terms all decided, we will send an email to every meeting attendee. It will include the scales that will be used (UCLA Loneliness Scale, CIRS-G, EQ-5D-5L), an informative document (ANNEX V) and a guide of “Intel·ligència Clínica Activa” use (ANNEX VI). We will ask the managers to spread it among all sanitary professionals of their workplace.

The aim of this action is to assure everyone is familiarized with the investigation measuring tools.

Stage 3: Recruitment of participants and initial data collection [June – August 2022]

7th step: Participant’s recruitment will start according to sample selection and study. To be selected they must accomplish all our inclusion criteria and they do not have to fulfill our exclusion ones. We will use the ECAP program and contact with them to set an appointment on the next month.

Each doctor’s candidate will be notified about the possible participation of some of their patients.

8th step: Whenever the day of the medical appointment arrives all doctors will inform their patients, possible candidates of the study, about the investigation administrating them an information document (ANNEX VII). They will be able to ask every question they have. Once the participant has read it, he or she will decide whether his or her participation. If the response is affirmative, the informed consent (ANNEX VIII) will be handed over.

9th step: When all participants needed for a complete sample had confirmed their participation and have signed the informed consent, we will proceed to the initial data collection.

On the first appointment we will collect all data in Non Solum Section of the “Intel·ligència Clínica Activa”.

This information will be available to every patient in LaMevaSalut portal.

Stage 4: Follow up [September 2022 – September 2027]

10th step: The follow-up will be configured with an annual visit with doctor and nurse to register all data required, with a duration of six years.

The only scale that will vary during the follow-up will be the UCLA Loneliness Scale, on the baseline we will administer the 20 item UCLA Loneliness Scale (Version 3) to establish our cohorts. The next years we will administrate the 3 item UCLA Loneliness Scale.

Any change on any answer or result will be written, all new onset illness will be annotated in Non Solum data base of the “Intel·ligència Clínica Activa” and if any participant changes their state of loneliness they will be changed to the other group of the study.

Every year a qualified statistician will analyze the data collected on that period.

Stage 5: Statistical analysis [October 2027 – January 2028].

11th step: Once all data has been collected a qualified statistician will process it performing a univariate, bivariate and incidence rate analysis.

12th step: Whenever all data would be analyzed the results will be commented and discussed with the team in a meeting.

Stage 6: Article elaboration, publication and divulgation of the results [February – May 2028].

Study chronogram

Year	2022												2023	2024	2025	2026	2027												2028				
Month	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Nov	Dec					Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May		
Stage 0	Study design and bibliographic research																																
	Bibliographic research																																
	Protocol elaboration																																
Stage 1	Ethical evaluation																																
	Project evaluation and approval																																
Stage 2	Initial coordination																																
	Email to each coordinator's center and setting "ICA"																																
	First meeting																																
	Submit the scales, information sheet and guide																																
Stage 3	Participants recruitment and initial data collection																																
	Recruitment of patients and first visit																																
	Deliver of explanatory document and informed consent																																
	Start to register Non Solum initial data																																
Stage 4	Follow up																																
Stage 5	Statistical analysis																																
	Data analysis and results interpretation																																
	Data discussion meeting																																
Stage 6	Publication and dissemination of the results																																
	Article elaboration																																
	Article publication and divulgation																																

BUDGET

The budget of this study will include all possible expenses that could be necessary during all the years. We would consider:

1. Personnel expenses
 - a. Study coordinator, he or she will supervise all data register for it to be complete and he/she will communicate with everyone needed. He/she will coordinate the study altruistically.
 - b. ECAP data manager, he or she will carry out the first search of possible participants according to all our inclusion and exclusion criteria.
 - c. Statistical consultant, to help with the analysis of data results. We will employ him two days every year of the study to analyze data collected on that year and at the end to help us analyze all results and compare them.
 - d. Managers and doctors from each center, they will not receive any financial compensation for their help. They are employed on those centers so they would not be contracted for additional services.
2. Execution expenses:
 - a. Mobility, we will not have expenses for trips because every meeting will be performed online with Zoom, to be able to extend the meeting the time that is needed we will pay for the Pro versions license each year.
3. Preparation expenses
 - a. Document prints. In case that doctors or participants want to receive and administer paper documents we will assume printing costs.
4. Publication expenses: if the researchers think it is appropriate, we will present and publish the study. For it we will assume cost of reviewing, editing, formatting and preparing all digital data.

All the expenses are summarized in the next table:

Table 3. Expenses' summary

ITEM	COST/UNIT	UNITS	TOTAL
Personnel costs			
Statistical Consultant	35 €/ hour	48h/ year	10.080 €
		6 years	
Execution expenses			
Zoom Pro	139,90 €	6,00 €	839,40 €
Preparation expenses			
Document prints	0,30 €/ unit	5 units/participant	601,50 €
		* 401	
Publication expenses			
Article publication	2.000 €	-	2.000 €
TOTAL COST OF THE STUDY			13.520,90 €

ETHICAL AND LEGAL CONSIDERATIONS

This observational investigation will be evaluated by the CEIC from IDIAP Jordi Gol, the reference hospital in Girona's Sanitary Region before the beginning.

The study will be performed in accordance with the ethical principles for medical investigations expressed on the Declaration of Helsinki.

Before the starting of the study, an information document will be handed (ANNEX VII) to everyone who is able to enter the study and a time of reflection will be given to decide their participation which will be evidenced in the informed consent (ANNEX VIII). This last document must be administered to all participants and it must be voluntary, informed, specific and unequivocal. Everyone can refuse to take part in the study and that they are also free to abandon whenever they consider.

All data collected from every person will be treated and processed only for the purpose of the study and it will be confidential and anonymized according to the article 18.4 of the Spanish Constitution, regulated by the European Regulation of Data Protection and complying with the 3/2018 Organic Law of Data Protection and Guarantee of Digital Rights, which entered into force on 5th December 2018. All of this is complemented by the Basic Regulatory Law of Patient's Autonomy, Rights and Obligations regarding information and clinical documentation 41/2002, from 14th November.

In conclusion, autonomy, beneficence, no malevolence and justice will be considered in every step of the study.

LIMITATIONS

In accordance with the study design, a prospective cohort study, the first limitation that must be considered is the time of tracing that must be elevated because the dependent variables that we are studying can take a long time to appear and that could induce methodological complications.

Consequently, the study will have higher cost than other type of studies and it will be predisposed to possible losses which should be taken into consideration. For example, abandon of the study, administrative losses or death could influence the results of the study as well as losses of following-up could introduce selection biases. Another bias that this study must consider is the attrition bias, introduced two lines above, for people that is lost over time. The cause of every lost must be evaluated to determine if it has any importance to the conclusions and the results of the investigation.

As the study is a dynamic cohort, which means that, when our independent variable changes the subjects change the group of cohort, we must do a very accurate and complete statistical analyses to be able to associate loneliness with our dependent variables. If our study was made static the association would be purer, but we cannot do it that way because we would lose lots of people whenever their perception of loneliness variate.

Furthermore, it is important to keep in mind that we are using subjective measure tools so to avoid incomparability between the participants and information biases due to mistakes during the measure of loneliness or other variables we will have to keep in mind lots of covariates. To keep the study away from information biases we will obtain all data with the same method for every participant at the beginning of the study and during the follow-up.

Last but not least, it is important to keep in mind that, although our study will not imply as much costs as other cohort studies because we would take advantage of routine medical visits, those visits would be longer due to the register of all data from questionnaires. So, we must consider that we could have possible loses from sanitary professionals attached to moments of higher assistance pression, for example, nowadays they are overwhelmed with SARS-CoV-2 situation. In that case, they would not have enough time to visit each participant so they would need extra time to help with the investigation.

IMPACT ON NATIONAL SYSTEM

Professionals from primary care assistance have lots of entities to evaluate and contemplate and mostly those are clinical aspects, laboratory data, diagnostic tests... but hardly ever social and emotional factors are given the importance they deserve.

There are Blue Zones around the world where Super Agers live. They are persons that conserve all their capacities and one characteristic they have in common is the maintenance of social bonds and their creation to form a purpose and serve their community. All those events help them not to grow old negatively and to conserve their abilities, mostly the cognitive ones, but also physical.

Being a part of a social group and being committed to it has proved that it is easier to have healthier lifestyle, specifically, in Maastricht University from the Netherlands, demonstrate that people who did not participate on social activities had more than 60% higher risk to develop prediabetes, which used to precede to DM.

Therefore, knowing if the feeling of loneliness could determine the appearance of higher rates of comorbidity and lower quality of life could provide useful tools to primary care professionals, who are the ones that have more contact with the patients. This association would allow them to act in front of loneliness feelings to avoid their negative consequences on general health and treat those pathologies with different perspectives.

Subsequently to this investigation, which would allow the demonstration of this negative association, actions and performances to palliate this feeling from primary care should be studied. To determine which procedure helps to achieve better results.

In the future, if this study proves our hypothesis and other studies are developed consequently to investigate which actions could help to palliate loneliness, we would be able to save secondary expenses of all the pathologies that we could prevent with those interventions.

FEASIBILITY

This study will take place in Girona's Sanitary Region. It is a very feasible study due to that most of the data that we will collect is already registered in the ECAP program.

The team that will be needed to carry out the study would be composed of a manager of each Primary Health Care Center, this person would have the responsibility of spreading all information necessary for every doctor of the center, with possible candidates on their patient's quota, to know before the beginning of the study. Each participant will continue to be assisted by their own doctor, because we want to disturb them as less as possible, and then all the information that the doctor has collected will be registered in Non Solum section of the "Intel·ligència Clínica Activa".

No complementary test will be necessary beyond the ones that are commonly performed in Primary Care Assistance. The only thing that would be affected would be the time of the visit, which could be longer.

Finally, we will need an external statistical to process and analyze all our data collection.

As a conclusion, we think that the study is more than feasible and the benefit that we will be higher than complications. Even though it is a cohort study, and these types of studies are dependent of higher costs, our investigation is not going to be expensive.

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II. Cumulative Illness Rating Scale (CIRS-G)

Instrucciones: Referir al manual de CIRS-G. Escriba una breve descripción del problema médico que justifica la puntuación otorgada en la línea que sigue a cada categoría. (Use el reverso de la página para mayor espacio).

Estrategia de puntuación

- 0 Sin problema
- 1 Problema actual leve o en el pasado problema significativo
- 2 Discapacidad moderada, o morbilidad que requiere tratamiento de primera línea
- 3 Discapacidad constante/severa o problemas crónicos de difícil control
- 4 Problema extremadamente severo que requiere de atención inmediata o insuficiencia orgánica terminal, o severa alteración en la función

	Puntuación
Cardiaco	_____
Vascular	_____
Hematopoyético	_____
Respiratorio	_____
Ojos, oídos, nariz, garganta y laringe	_____
Gastrointestinal superior	_____
Gastrointestinal inferior	_____
Hígado	_____
Renal	_____
Genitourinario	_____
Musculoesquelético/tegumentario	_____
Neurológico	_____
Endocrino/metabólico y mamario	_____
Enfermedad psiquiátrica	_____
Número total de categorías endosadas	_____
Puntuación total	_____
Índice de severidad (puntuación total/total de categorías endosadas)	_____
Número de categorías en el nivel tres de severidad	_____
Número de categorías en el nivel cuatro de severidad	_____

Guideline for primary health professionals to help them rate each system/organ pathology(48)

Heart

0. No problem
1. Remote myocardial infarction (MI), more than 5 years ago, or occasional angina treated with PRN meds
2. Congestive Heart Failure compensated with meds/ need of daily anti-angina drugs/ left ventricular hypertrophy/ atrial fibrillation/ bundle branch block/ daily antiarrhythmic drugs
3. Previous MI within 5 years/ abnormal stress test/ status post percutaneous coronary angioplasty or coronary artery bypass graft surgery
4. Marked activity restriction secondary to cardiac status (for example: unstable angina or intractable congestive heart failure)

Vascular

0. No problem
1. Hypertension compensated with salt restriction and weight loss/ serum cholesterol >200 mg/dl
2. Daily antihypertensive meds/ one symptom of atherosclerotic disease (angina, claudication, bruit, amaurosis fugax, absent pedal pulses)/ aortic aneurysm < 4cm
3. Two or more symptoms of atherosclerosis
4. Previous surgery for vascular problem/aortic aneurysm

Hematological

0. No problem
1. Hemoglobin (Hb): females >10 <12, males >12 <14/ anemia of chronic disease
2. Hb: females >8 <10, males >10 <12/ anemia secondary to iron, vitamin B12 or folate deficiency or chronic renal failure/ total white blood cell (WBC) count >2000 but <4000
3. Hb females <8, males <10/ total WBC < 2000
4. Any leukemia or any lymphoma

Respiratory

0. No problem
1. Recurrent episodes of acute bronchitis/ currently treated asthma with PRN meds inhalers/ cigarette smoker >10 but <20 pack years
2. X-ray evidence of Chronic Obstructive Pulmonary Disease (COPD)/ requires daily theophylline or inhalers/ treated for pneumonia two or more times in the past five years/ smoked 20-40 pack years
3. Limited ambulation secondary to limited respiratory capacity/ required oral steroids for lung disease/ smoked >40 pack years
4. Required supplemental Oxygen/ at least one episode of respiratory failure requiring assisted ventilation/ any lung cancer.

Ophthalmological and ORL

0. No problem
1. Corrected vision 20/40; chronic sinusitis/ mid hearing loss
2. Corrected vision 20/60 or reads newsprint with difficulty/ required hearing aids/ chronic sinonasal complaints requiring medication/ requires medication for vertigo
3. Partially blind (requires an escort to venture out)/ unable to read newsprint/ conversational hearing still impaired with hearing aid
4. Functional blindness/ functional deafness/ laryngectomy/ requires surgical intervention for vertigo

Upper gastrointestinal

0. No problem
1. Hiatal hernia/ heartburn complaints treated with PRN meds
2. Needs daily H2 blocker or antacid/ documented gastric or duodenal ulcer within five years
3. Active ulcer/ positive guaiac fecal occult blood test/ any swallowing disorder or dysphagia
4. Gastric cancer/ history of perforated ulcer/ melena or hematochezia from upper gastrointestinal source

Lower gastrointestinal

0. No problem
1. Constipation managed with PRN meds/ active hemorrhoids/ status post hernia repair
2. Requires daily bulk laxatives or stool softeners/ diverticulosis/ untreated hernia
3. Bowel impaction in the past year/ daily use of stimulant laxatives or enemas
4. Hematochezia from lower gastrointestinal source, currently impacted, diverticulitis flare up/ status post bowel obstruction/ bowel carcinoma

Hepatic and pancreatic

0. No problem
1. History of hepatitis > 5 years ago/ cholecystectomy
2. Mildly elevated Liver Function Test's (up to 150% of normal)/ hepatitis within five years/ cholelithiasis/ daily or heavy alcohol use within 5 years
3. Elevated bilirubin (total>2)/ marked elevation of LFT's (>150% of normal)/ requires supplemental pancreatic enzymes for digestion
4. Biliary obstruction/ any biliary tree carcinoma/ cholecystitis/ pancreatitis/ active hepatitis.

Renal

0. No problem
1. Status post kidney stone passage within the past 10 years or asymptomatic kidney stone/ pyelonephritis within five years
2. Serum creatinine >1.5 but <3.0 without diuretic or antihypertensive medication
3. Serum creatinine >3.0 or serum creatinine >1.5 in conjunction with diuretic, antihypertensive, or bicarbonate therapy/ current pyelonephritis
4. Requires dialysis/ renal carcinoma

Genito-urinary

0. No problem
1. Stress incontinence/ hysterectomy/ Benign Prostatic Hyperplasia (BPH)
2. Abnormal pap smear/ frequent Urinary Tract Infections (3 or more in the past year)/ urinary incontinence (non-stress) in females/ BPH with hesitancy or frequency/ current UTI/ any urinary diversion procedure/ status post transurethral resection of the prostate (TURP)
3. Prostatic cancer in situ/ vaginal bleeding/ cervical carcinoma in situ/ hematuria/ status post urosepsis in the past year
4. Acute urinary retention/ any genito-urinary carcinoma except as above

Musculoskeletal and cutaneous

0. No problem
1. Uses PRN meds for arthritis or has mildly limited daily life activities from joint pathology/ excised non-melanotic skin cancers/ skin infections requiring antibiotics within a year
2. Daily antiarthritic meds or use of assistive devices or moderate limitation in daily life activities/ daily meds for chronic skin condition/ melanoma without metastasis
3. Severely impaired daily life activities secondary to arthritis/ requires steroids for arthritic condition/ vertebral compression fractures from osteoporosis
4. Wheelchair bound/ severe joint deformity or severely impaired usage/ osteomyelitis/ any bone or muscle carcinoma/ metastatic melanoma

Neurological

0. No problem
1. Frequent headaches requiring PRN meds without inference with daily activities/ a history of Transient Ischemic Attack (TIA) phenomena, at least one
2. Requires daily meds for chronic headaches or headaches that regularly interfere with daily activities/ status post Cerebrovascular Accident (CVA) without significant residual/ neurodegenerative disease- mild severity

3. Status post CVA with mild residual dysfunction/ any central nervous system neurosurgical procedure/ neurodegenerative disease- moderate severity
4. Status post CVA with residual functional hemiparesis or aphasia/ neurodegenerative disease- severe

Endocrine, metabolic and breast

0. No problem
1. Diabetes Mellitus (DM) compensated with diet/ obesity: body mass index (BMI) >30/ requires thyroid hormone replacement
2. DM requiring insulin or oral agents/ fibrocystic breast disease
3. Any electrolyte disturbance requiring hospital treatment/ morbid obesity BMI >45
4. Brittle or poorly controlled DM or diabetic coma in the past year/ requires adrenal hormone replacement/ adrenal, thyroid or breast carcinoma

Psychiatric

0. No problem
1. Minor psychiatric condition or history thereof. Specifically: previous outpatient mental health treatment during crisis/ outpatient treatment for depression >10 years ago/ current usage of minor tranquilizers for episodic anxiety (occasional usage)/ mild early dementia
2. A history of Major Depression within the past 10 years (treated or not)/ mild dementia/ any previous psychiatric hospitalization/ any psychotic episode substance abuse history >10 years ago
3. Moderate dementia/ current usage of daily anti-anxiety medication/ currently meets DSM III-R criteria for substance abuse or dependence or Major Depression or two or more episodes of major depression in the past 10 years/ requires daily antipsychotic medication
4. Current mental illness requiring psychiatric hospitalization, institutionalization, or intensive outpatient management/ severe dementia

III. Quality of life: EQ-5D-5L questionnaire

Mobilitat

- No tinc problemes per caminar
- Tinc lleus problemes per caminar
- Tinc moderats problemes per caminar
- Tinc sever problemes per caminar
- Sóc incapaç/a de caminar

Cura personal

- No tinc problemes amb el cuidat personal
- Tinc lleus problemes per netejar-me o vestir-me sol
- Tinc moderats problemes per netejar-me o vestir-me sol
- Tinc sever problemes per netejar-me o vestir-me sol
- Són incapaç de netejar-me o vestir-me sol

Activitats diàries (ex: feines domèstiques, activitats familiars, activitats socials...)

- No tinc problemes per realitzar les meves activitats de tots els dies
- Tinc lleus problemes per realitzar les meves activitats de tots els dies
- Tinc moderats problemes per realitzar les meves activitats de tots els dies
- Tinc sever problemes per realitzar les meves activitats de tots els dies
- Sóc incapaç de realitzar les meves activitats de tots els dies

Dolor/ Malestar

- No tinc dolor ni malestar
- Tinc lleu dolor o malestar
- Tinc moderat dolor o malestar
- Tinc sever dolor o malestar
- Tinc extrem dolor o malestar

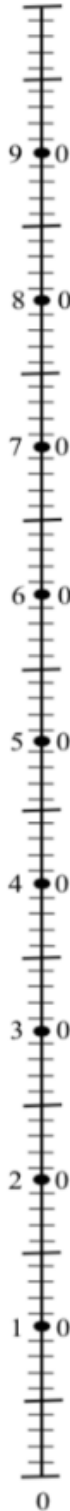
Ansietat/ Depressió

- No estic ansiós/a ni deprimit/da
- Estic lleugerament ansiós/a o deprimit/da
- Estic moderadament
- Estic severament ansiós/a o deprimit/da
- Estic extremadament ansiós/a o deprimit/da

Indiqui el seu estat de salut d'AVUI marcant-ho en la següent escala:

Mejor estado
de salud
imaginable

100



0

Peor estado
de salud
imaginable

IV. Informative document for Coordinators of Primary Health Care Centers of
Girona Sanitary Region

CATALAN VERSION

FULL INFORMATIU DIRIGIT ALS /LES DIRECTORS/ES DELS CENTRES D'ATENCIÓ PRIMÀRIA
DE LA REGIÓ SANITÀRIA DE GIRONA

Nom de l'estudi: **La soledat com un factor de risc de major comorbiditat i menor qualitat
de vida de les persones majors (Non Solum)**

Investigador/a principal:

Benvolgut/a,

Ens dirigim a vostè per tal d'informar-lo sobre un estudi que es desenvoluparà als CAP
de la Regió Sanitària de Girona i al qual ens agradaria que el CAP que dirigeix hi
participés.

Aquest document té la intenció d'informar-lo/a de tot el que pugui ser del seu interès
per tal de decidir si el CAP que regeix es beneficiaria de d'aquest estudi.

Preguem llegeixi amb atenció aquest document i en cas de dubtes es posi en contacte
amb nosaltres.

La participació en l'estudi pertinent és totalment voluntària i, en cas d'acceptar, es pot
retirar en qualsevol moment sense cap tipus de represàlies.

El protocol de dit estudi ha estat revisat i aprovat pel Comitè d'Ètica i Investigació Clínica
de la IDIAP Jordi Gol.

Per realitzar aquest estudi serà necessari nomenar un representant del seu centre per tal de que sigui el que es comuniqui amb la resta de representants i el coordinador de l'estudi.

L'objectiu és que les persones que decideixin participar en l'estudi siguin visitades pels seus metges/ metgesses i durant la visita es registrin les dades que es torben dins l'apartat de "Intel·ligència Activa Clínica" de l'ECAP, on prèviament s'haurà creat un apartat amb el nom de l'estudi i estarà configurat per tal de poder registrar totes les variables necessàries. Posteriorment a la recollida de dades inicial, s'haurà de realitzar mínim una visita per any per poder anar omplint les dades i fer un seguiment.

La participació dels professionals del CAP que dirigeix així com dels pacients és crucial per tal de poder determinar si la soledat en la gent major podria ser un factor de risc per patir major nombre de comorbiditats i, a més, tenir una pitjor percepció de la seva qualitat de vida.

L'estudi no presenta riscos ni per als professionals ni per als pacients.

Sol·licitem el seu permís per tal de poder comptar amb la participació del CAP que regeix en l'actualitat, així com la designació d'un representant en cas que la resposta sigui afirmativa. Tots els processos es troben protegits sota la Llei Orgànica 3/2018, 5 de desembre, de Protecció de Dades Personals i Garantia dels Drets Digitals.

La participació no compta amb cap compensació econòmica i tampoc suposarà cap despesa.

En cas que estigui d'acord amb la seva participació li preguem respongui aquest e-mail indicant el nom del CAP, la seva resposta, i en cas de ser afirmativa, el nom i contacte de la persona representant.

SPANISH VERSION

HOJA INFORMATIVA DIRIGIDA AL/LA DIRECTOR/A DE LOS CENTROS DE ATENCIÓN PRIMARIA DE LA REGIÓN SANITARIA DE GIRONA

Nombre del estudio: **La soledad como factor de riesgo para mayor comorbilidad y menor calidad de vida en las personas mayores (Non solum)**

Investigador/a principal:

Bienvenido/da,

Nos dirigimos a usted con el objetivo de informarle sobre un estudio que se desarrollará en los CAP de la Región Sanitaria de Girona i en el cual nos gustaría que el CAP que dirige participase.

Este documento tiene la intención de informarlo/a de todos lo que pueda ser de su interés para decidir si el CAP que rige se beneficiaría del estudio.

Le pedimos que lea con atención la siguiente información i en caso de dudas se Ponga en contacto con nosotros.

La participación al estudio es totalmente voluntaria y, en caso de aceptar, se puede retirar en cualquier momento sin ningún tipo de represalias.

El protocolo de dicho estudio ha sido revisado por el CEIC del IDIAP Jordi Gol.

Para realizar este estudio será necesario nombrar un representante de su centro para establecer comunicación con el resto de los representantes i el coordinador del estudio.

El objetivo es que las personas que den su aprobación a participar en el estudio sean visitados/das por sus médicos/as y durante la visita se registren los datos que están

integrados en el apartado de “Inteligencia Activa Clínica” del ECAP, donde previamente se habrá creado un apartado con el nombre del estudio y estará configurado para poder registrar todas las variables necesarias. Posteriormente a la recogida de datos inicial, se deberá visitar al/la paciente mínimo una vez por año para poder ir rellenando los datos y realizar un seguimiento.

La participación de los profesionales del CAP que dirige, así como de los pacientes es crucial para poder determinar si la soledad en la gente mayor podría ser un factor de riesgo para sufrir mayores niveles de comorbilidades y, además, tener una peor percepción de su calidad de vida.

El estudio no presenta riesgos ni para los profesionales ni para los pacientes.

Solicitamos su permiso para poder contar con la participación del CAP que dirige en la actualidad, así como la elección de un representante en caso de que la respuesta sea afirmativa. Todos los procesos están protegidos bajo la Ley Orgánica 3/2018, 5 de diciembre, de Protección de Datos Personales y Garantía de los Derechos Digitales.

La participación no cuenta con ninguna compensación económica y tampoco supondrá ningún gasto.


En el caso de que esté de acuerdo con su participación le pedimos por favor responda a este e-mail indicando el nombre del CAP, su respuesta, y en caso afirmativo, el nombre y el contacto del representante.

Si presenta cualquier tipo de duda en la actualidad o en algún momento del estudio puede dirigirse al coordinador del estudio.

V. Information sheet addressed to primary health care professionals

NON SOLUM

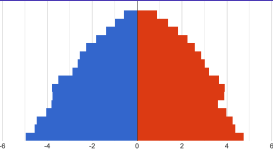
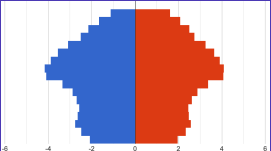
Un estudio para demostrar como afecta la soledad en la población de tercera edad



Nuestros mayores son más vulnerables a sufrir soledad:


- ✘ Cambios en los recursos económicos
- ✘ Pérdida de habilidades
- ✘ Viudedad
- ✘ Aislamiento social
- ✘ Adaptación a nuevas tecnologías
- ✘ ...

El aumento de la tercera edad es uno de los mayores desafíos en la actualidad

↻

Desde Atención Primaria podemos intentar mejorar la calidad asistencial de las personas que en un futuro serán las que más acudan a consultas. Ayúdenos a ayudarlo, en algún momento usted también será mayor y se beneficiará de los progresos conseguidos a día de hoy.




¿Cómo?

Algunos de sus pacientes podrían ser candidatos para participar en el estudio.


Para poder participar deberán dar su consentimiento, así que le pediremos que le entregue:

- ✓ Documento informativo
- ✓ Consentimiento informado

En la ventana de Inteligencia Clínica Activa del ECAP podrá encontrar una pestaña con el nombre del estudio. Allí están incluidos todos los datos que deberá recoger en sus visitas con dichos pacientes.



1 visita al año



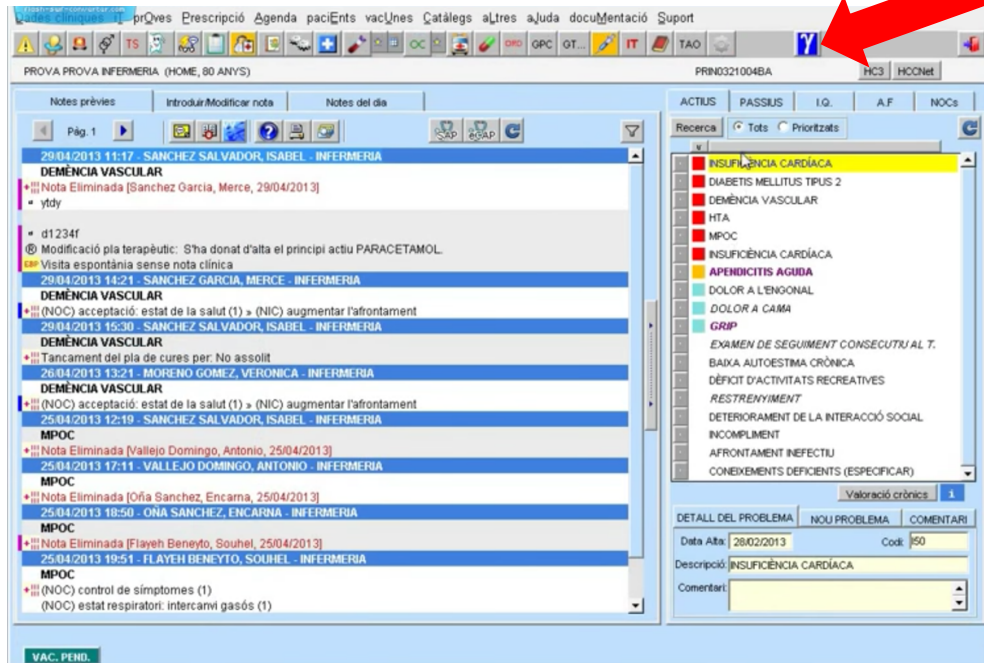
¡Es importante que se familiarice con las escalas que son requeridas en este estudio!

- UCLA Loneliness Scale (20 items al inicio, en el seguimiento, 3 items)
- CIRS-G
- QL-5D-5Q

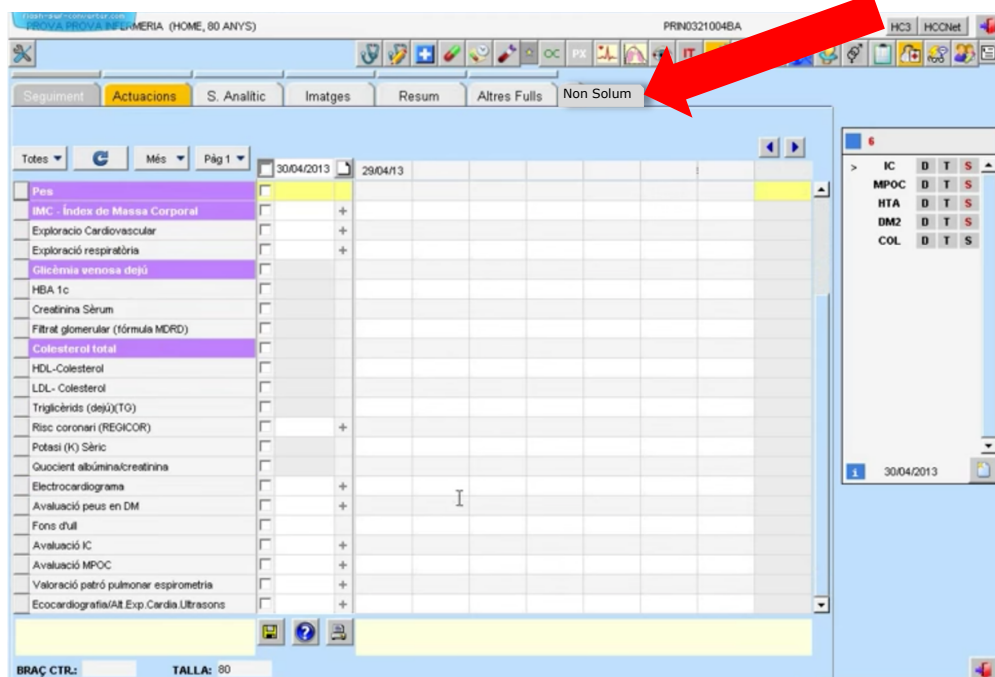
¡GRACIAS POR SU COLABORACIÓN!

VI. Use guide for “Intel·ligència Activa Clínica”

1. Entri a la història clínica del pacient i vagi a la icona (“Intel·ligència Clínica Activa”) que li ensenjem a continuació.



2. Quan hagi entrat dins l'apartat de la Intel·ligència Clínica Activa se li obrirà la següent pipella:



Dins aquesta podrà trobar, una vegada iniciat l'estudi, una pipella que tindrà el nom de la investigació: NON SOLUM, on trobarà totes les dades que ha de recollir.

FULL D'INFORMACIÓ PEL PARTICIPANT

Investigadors principals: Dr. Ferran Cordón i Meritxell Ramon

Títol de l'estudi: La soledat com un factor de risc de major comorbiditat i menor qualitat de vida de les persones majors (Non Solum)

Ens adrecem a vostè per convidar-lo a participar en un estudi, el qual ha estat aprovat pel Comitè d'Ètica i Investigació Clínica (CEIC) de l'IDIAP Jordi i Gol.

El següent document té la intenció de que vostè rebi tota la informació vinculada a l'estudi i que pugui decidir sobre la seva participació. Per aquest motiu li agrairíem que llegís atentament aquest full informatiu i posteriorment ens adreci qualsevol dubte que sorgeixi.

L'estudi pretén conèixer si la soledat és un factor de risc per una major comorbiditat i una menor qualitat de vida en la població de 65 anys i més. Per assolir aquest objectiu volem mesurar el nivell de soledat per comparar gent que es sent sola i gent que no s'hi sent en quant a nivell de comorbiditat i qualitat de vida.

La seva participació a l'estudi és totalment voluntària. Participar en l'estudi implica respondre una sèrie de qüestionaris que seran administrats per part del seu metge de capçalera amb preguntes sobre els temes abans mencionats. Vostè és lliure d'abandonar l'estudi, si així ho desitja, en qualsevol moment, sense necessitat de justificació i sense conseqüències en el seus cuidats mèdics.

Per al present estudi s'adoptaran mesures per garantir la confidencialitat de les seves dades, tal i com s'evidencia en la L.O 3/2018 i les dades recollides seran gestionades de forma anònima i usades únicament amb fins d'investigació, tal i com es recull en la Llei Bàsica Reguladora de l'Autonomia del Pacient, Drets i Obligacions.

Vostè està en el seu dret de ser informat dels resultats de la investigació, si així ho desitja. Les conclusions de la investigació serviran per beneficiar al participant així com a altres persones i serviran de base per futures investigacions sobre aquest àmbit.

Si durant la seva participació té algun dubte o necessita obtenir més informació, posis en contacte amb *(dades del metge encarregat de l'estudi, incloent: nom, servei, forma de localitzar-lo i telèfon de contacte del centre corresponent)*.

Moltes gràcies per la seva atenció

HOJA DE INFORMACIÓN PARA EL PACIENTE

Investigadores principales: Dr. Ferran Cordón i Meritxell Ramon

Título del estudio: La soledad como factor de riesgo para mayor comorbilidad y menor calidad de vida en las personas mayores (Non solum)

Nos dirigimos a usted para invitarlo a participar en un estudio, el cual ha sido aprobado por el Comité de Ética e Investigación Clínica (CEIC) del IDIAP Jordi Gol.

El siguiente documento tiene la intención de que usted reciba toda la información vinculada al estudio y que pueda decidir sobre su participación. Por este motivo le agradeceríamos que leyese atentamente esta hoja informativa y posteriormente nos dirija cualquier duda que le surja.

El estudio pretende conocer si la soledad es un factor de riesgo para una mayor comorbilidad y una menor calidad de vida en la población de 65 años y más. Para alcanzar este objetivo queremos medir el nivel de soledad y comparar gente que se siente sola y gente que no se siente sola en cuanto al nivel de comorbilidad y de calidad de vida.

Su participación es totalmente voluntaria. Participar en el estudio implica responder una serie de cuestionarios que serán administrados por parte de su médico de cabecera con preguntas sobre los temas anteriormente mencionados. Usted es libre de abandonar el estudio, si así lo desea, en cualquier momento, sin necesidad de justificación y sin consecuencias en sus cuidados médicos.

Para el presente estudio se adoptarán medidas para garantizar la confidencialidad de sus datos, tal y como se evidencia en la L.O. 3/2018 y los datos recogidos serán gestionados de forma anónima y usados únicamente con fines de investigación, tal y como se recoge en la Ley Básica Reguladora de la Autonomía del Paciente, Derechos y Obligaciones.

Usted está en su derecho de ser informado de los resultados de la investigación, si así lo desea. Las conclusiones de la investigación servirán para beneficiar al participante, así como a otras personas y servirán de base para futuras investigaciones sobre este ámbito.

Si durante su participación tiene alguna duda o necesita obtener más información, póngase en contacto con *(datos del médico encargado del estudio, incluyendo: nombre, servicio, forma de localizar-lo y teléfono de contacto del centro correspondiente)*.

Muchas gracias por su atención

VIII. Informed consent sheet for the patient

CATALAN VERSION

CONSENTIMENT INFORMAT PER AL PACIENT

Jo, Sr./Sra. _____ amb DNI _____ declaro que:

- He llegit la fulla d'informació que m'ha estat entregada sobre l'estudi
- He pogut fer preguntes sobre l'estudi
- He rebut suficient informació sobre l'estudi
- He parlat amb el/la Dr./Dra. _____
- Comprenc que la meva participació és voluntària
- Comprenc que puc retirar-me de l'estudi:
 - Quan vulgui
 - Sense haver de donar explicacions
 - Sense que tingui repercussions en els meus cuidats mèdics

D'acord al que s'estableix en la L.O 3/2018 del 5 de desembre, de Protecció de Dades Personals i Garantia dels Drets Digitals, declaro haver estat informat:

- De que existeix un fitxer o tractament de dades de caràcter personal, del motiu de recollir aquestes dades i dels destinataris de la informació.
- De que puc accedir, rectificar, oposar-me i cancel·lar-la dirigint-me per escrit al titular del fitxer de dades.

D'acord a lo anteriorment mencionat, DONO EL MEU CONSENTIMENT a participar en aquest estudi i estic d'acord en que la informació obtinguda pugui ser utilitzada en investigacions futures.

Firma del pacient

Firma de l'investigador/ investigadora

Lloc i data _____, _____ de _____ del 20__

REVOCACIÓ DEL CONSENTIMENT INFORMAT

Jo, Sr./Sra. _____ amb DNI _____, REVOCO EL
CONSENTIMENT prèviament firmat per a la participació a la investigació especificada
anteriorment.

Firma del pacient

Firma de l'investigador/ investigadora

Lloc i data _____, _____ de _____ del 20__

CONSENTIMIENTO INFORMADO PARA EL PACIENTE

Yo, Sr./Sra. _____ con DNI _____ declaro que:

- He leído la hoja de información que me ha sido entregada sobre el estudio
- He podido realizar preguntas sobre el estudio
- He recibido suficiente información sobre el estudio
- He hablado con el Dr./Dra. _____
- Comprendo que puedo retirar-me del estudio:
 - Cuando quiera
 - Sin tener que dar explicaciones
 - Sin que tenga repercusiones en mis cuidados médicos

De acuerdo con lo establecido en la L.O. 3/2018 del 5 de diciembre, de Protección de Datos Personales i Garantía de los Derechos Digitales, declaro haber sido informado:

- De que existe un fichero o tratamiento de datos de carácter personal, del motivo de recoger estos datos y de los destinatarios de la información.
- De que puedo acceder, rectificar, oponerme y cancelarlo dirigiéndome por escrito al titular del fichero de datos.

De acuerdo con lo anteriormente mencionado, DOY MI CONSENTIMIENTO a participar en este estudio y estoy de acuerdo en que la información obtenida pueda ser usada en investigaciones futuras.

Firma del paciente

Firma del investigador/ investigadora

Lugar y fecha _____, _____ de _____ del 20__

REVOCACIÓN DEL CONSENTIMIENTO INFORMADO

Yo, Sr./Sra. _____ con DNI _____, REVOCO EL
CONSENTIMIENTO previamente firmado para la participación a la investigación
especificada anteriormente.

Firma del paciente

Firma del investigador/ investigadora

Lugar y fecha _____, _____ de _____ del 20__

