

EFFECTIVITY OF MHEALTH TECHNOLOGIES TO REDUCE SEDENTARY BEHAVIOR IN AN ELDERLY POPULATION

A CLINICAL TRIAL

FINAL DEGREE PROJECT

Author: Aina Dalmau Guasp

Clinical tutor: Marta Zwart Salmeron MD, PhD

Methodological tutor: Rafael Marcos Gragera PhD

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1. ABBREVIATIONS

BADL: Basic Activities of Daily Living

BMI: Body Mass Index

Cm: Centimeters

CRG: Clinical Risk Groups

eHealth: Electronic Health

EQ-5D-5D: EuroQuol-5 Dimensions-5 Levels Test

EQ VAS: EQ Visual Analogue Scale

GMA: Adjusted Morbidity Groups

GOe: The Global Observatoy for eHealth

GPRS: General Packet Radio Service

GPS: Global Positioning System

H: hours

HDL: High Density Lipoprotein

IADL: Instrumental Activities of Daily Living

ICT: Information and Communication Technologies

Kg: Kilograms

M/s: Meters per second

METs: Metabolic Equivalents

Mg/dl: Milligrams per Deciliter

mHealth: Mobile Health

MmHg: Milligrams of mercury

MMSE: Folstein Mini Mental State Exam

PA: Physical Activity

PDAs: Personal Digital Assistants

S: Seconds

SB: Sedentary Behavior

SMS: Short Messaging Service

SPPB: Short Physical Performance Battery

TG: Triglycerides

TUG: Timed up and go

WHO: World Health Organization

YPAS: Yale Physical Activity Survey

2. ABSTRACT

Background: Sedentary behavior has been described as a key factor for the development of multiple chronic diseases, it also has shown to contribute to the physical deterioration and has been described as an independent risk factor to premature mortality. Those negative effects could be reverted by increasing the daily physical activity, as the WHO recommends. Notwithstanding the negative effects, the quantity of population not following the WHO recommendations is alarming, especially among elderly, even more now with the mobility restrictions due to COVID-19 pandemic. Lately, taking advantage of the increased use of mobile phones technologies, new applications have been developed to monitor health aspects from smartphones. The use of those new technologies to specially increase the daily physical activity performance has been proved in the younger population, and more studies are needed to establish its utility among elderly.

Objective: The aim of this study is to evaluate whether the use of step counter technologies (mHealth) reduces sedentary time in patients over 75 years.

Design: This is a randomized clinical trial carried out in primary health care.

Participants: The study population will include two groups of community elderly people over 75 years old.

Methods: Patients will be randomly divided into two groups: group A (n= 199), where patients will be asked to use the Google Fit application or to wear a smart-watch, both used as a step counting tool; or group B (n= 199), where patients will receive educational health. Each individual will be followed for 3 months.

Keywords: sedentary behavior, mHealth, elderly, health

3. INTRODUCTION

The World Health Organization (WHO) recommends to limit the amount of sedentary time, replacing it with physical activity of any intensity (1). Furthermore, the organization states that older adults should do more than the recommended levels of Physical activity (PA) in order to help reduce the negative effects of sedentary behavior (SB) in health (1). Patients with chronic diseases and limited physical functions also benefit from adapted PA programs (2).

Physical activity has shown to prevent multiple chronic diseases and increase the quality of life (3). PA decreases premature mortality (Fig. 1), increasing up to 7 years the life expectancy (3,4). In addition, it reduces the prevalence of multiple diseases and conditions: cardiovascular diseases, hypertension, metabolic syndrome, type 2 diabetes, osteoporosis, it also reduces the prevalence of some cancer, respiratory diseases, dyspnea, sleep-wake disturbances, and depression, along with many other diseases (3–5).

Table 1. Physical Inactivity and Sedentary Behavior effects (own source)

SEDENTARY BEHAVIOR AND PHYSICAL INACTIVITY EFFECTS	Increases risk/ incidence/prevalence of	Cardiovascular diseases, hypertension
		Metabolic dysfunction, type 2 diabetes and metabolic syndrome, obesity and overweight
		Colon and breast cancer
		Functional impairment, physical and labor disability, falls
		Depression and dementia
		Morbidity
		Premature mortality
	Decreases	Cognitive health
		Quality of life, mood and mental well-being
		Strength and endurance, balance, mobility and capacity for the daily living activities

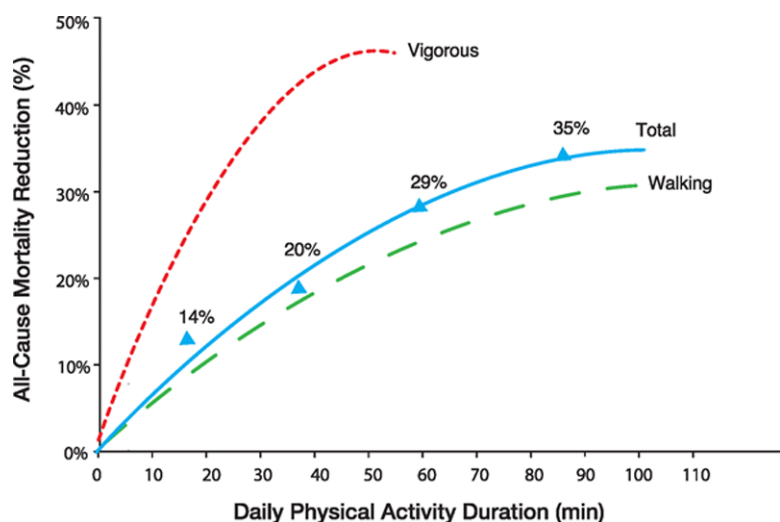


Figure 1. Daily physical activity duration and all-cause mortality reduction (6)

It is alarming the quantity of population not following the WHO recommendations referring to the minimum physical activity recommended (3). Depending on the study, a range from 2 to 83% is established for older adults who do not follow the WHO physical activity recommendations, and a range from 20-60% is established for older adults who actually meet the WHO recommendations (7). Over 50% of U.S adults are estimated to not achieve the ideal physical activity recommendations (8).

Evidence shows that the majority of older adults are sedentary (9). Older adults spend over 9 hours (h) per day in SB, not meeting the current physical activity recommendations (10). Adults spend around 9.3 h per day in SB, 6.5 h per day doing light-intensity activity and just 0.7h per day of high-intensity physical activities (11).

If we focus on Catalunya, the percentage of sedentary people has increased, particularly in people over 65 years. The total prevalence of sedentarism in 2014 in Catalunya was 25%, among people from 65-74 years it was 34% and among people over 75 years it was 53.7% (12).

Furthermore, due to the global pandemic we are currently living, and due to governmental mobility restrictions and lockdown, the PA has been reduced and the sedentary time has increased. For example, during the COVID-19 quarantine, U.S residents decreased their PA metabolic equivalents (METs) levels by 18.2% (13). Also, studies analyzing daily step count have noticed a 16% decrease during the quarantine (14).

3.1 SEDENTARY BEHAVIOR AND PHYSICAL ACTIVITY

3.1.1 DEFINITION AND CONCEPTS

Even though the definition of sedentary behavior has been a controversial topic among authors, actually there is an agreement: SB is defined as any behavior characterized by a low energy expenditure (≤ 1.5 METs) during waking hours, while in a sitting, reclining or lying posture (9,15).

Oftentimes the concept of sedentary behavior has been mistaken with other related terms:

- Sedentary lifestyle: ≤ 125 minutes of physical activity per week (5).
- Sedentary time: the time spent for any duration or in any context in sedentary behaviors (15).
- Physical inactivity: suboptimal physical activity levels according to physical activity recommendations (15).
- Sedentary behavior pattern: accumulation of sedentary behavior through the day/week (15).
- Sedentary bout: a period of uninterrupted sedentary time (15).
- Sedentary interruption/breaks: a non-sedentary bout in between two sedentary bouts (15).
- Stationary behavior: waking behavior, disregarding the energy expenditure, performed in a lying, reclined or standing position without roaming (15).

On the other hand, physical activity is defined as any body movement generated by skeletal muscles requiring energy consumption (16).

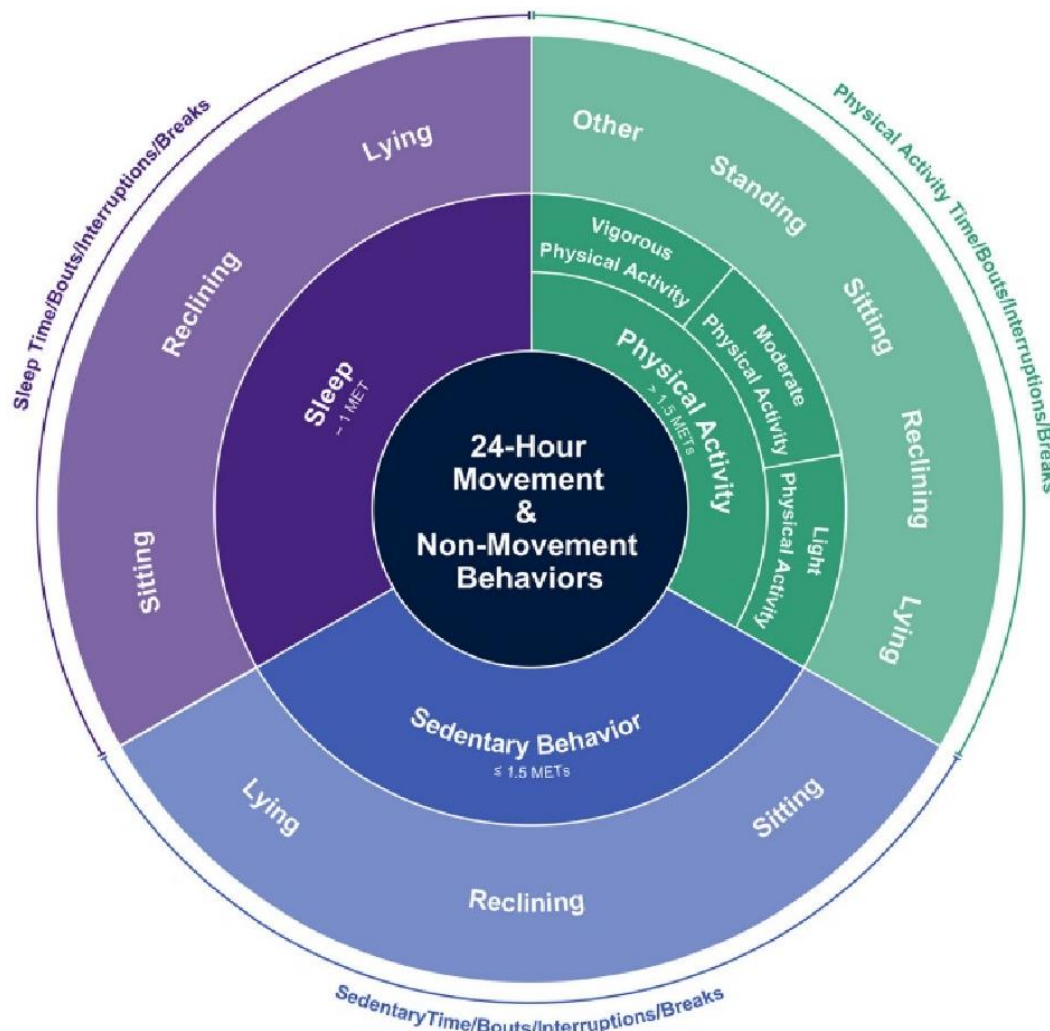


Figure 2. Illustration of the conceptual model of movement-based terminology arranged around a 24-h period (15)

3.1.2 WEEKLY RECOMMENDATIONS OF PHYSICAL ACTIVITY IN ELDERLY

According to the WHO, the American Heart Association and the American College of Sports Medicine, the recommended physical activity for adults over 65 years would be the following (2,16) ([Fig. 3](#)).

First of all, to practice at least 150 minutes per week of moderate intensity physical activity (3-6 METs) or at least 75 minutes per week of high intensity physical activity (>6 METs) (2,16,17). In order to achieve additional health benefits, the recommended physical activity would be 300 minutes per week of moderate intensity physical activity or 150 minutes per week of high intensity physical activity (2,16,17).

Activities to gain muscular strength are recommended to be done at least 2 nonconsecutive days per week, working the major muscle groups (abdomen, legs, arms, shoulders and hips) (2,16). 10-15 repetitions for each exercise in moderate-high intensity is recommended (2,16).

Finally, flexibility exercises are recommended to be performed for at least 10 minutes, 2 days per week. Stretching 10-30 seconds each muscle group is recommended (2).

For individuals with mobility problems, physical activity focused on balance exercises is recommended for preventing falls, at least 3 days per week (2,16).

The intensity of the different physical activities may vary depending on the individual (16,17). Activities may be performed during periods of at least 10 minutes (16). Individuals with some kind of impairment for physical activities may stay active within their possibilities (16,17). It is recommended to plan and schedule the PA, including all types of exercise mentioned before (2).

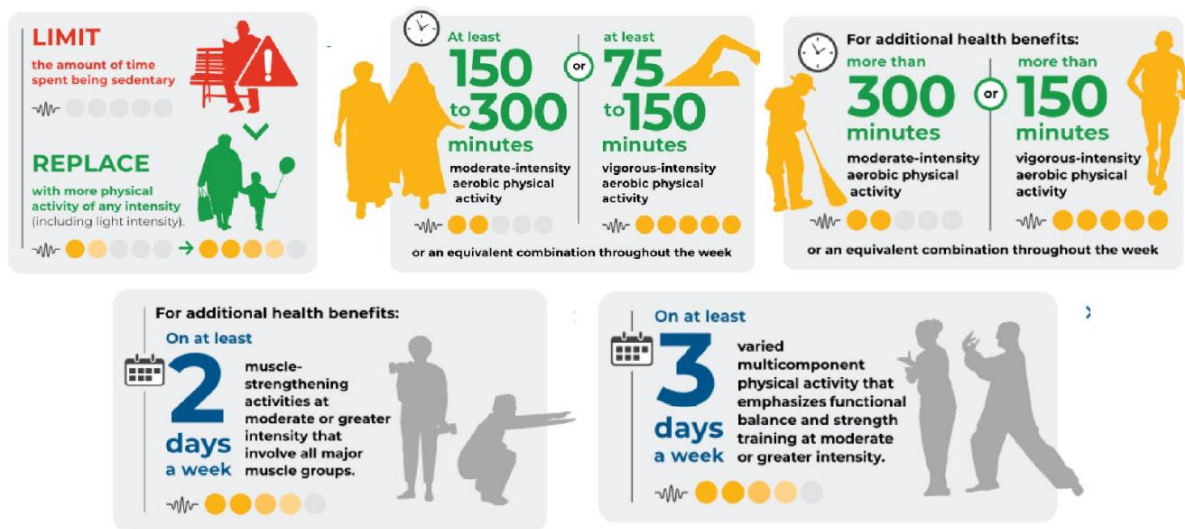


Figure 3. Weekly recommendations of physical activity in elderly (1).

3.1.3 SEDENTARY BEHAVIOR METABOLIC EFFECTS

Physical inactivity has been associated with a decline of cognitive health and with multiple chronic diseases: obesity and overweight, metabolic dysfunction (7% of type 2 diabetes), it is also the cause of the 10% of breast and colon cancer cases and the 10% of cardiovascular diseases, (3,9–11).

Sedentary behavior has been recently defined as an independent health risk factor for morbidity and premature mortality, entailing the 5.5% of mortality worldwide (3,9,11).

Metabolic syndrome, defined by several risk factors (elevated triglycerides (TG), elevated blood pressure, elevated fasting glucose, abdominal obesity and low high-density lipoprotein (HDL) levels), has been related to a higher predisposition to metabolic and cardiovascular diseases, and to all-cause mortality (11).

SB has been associated with a higher risk for metabolic syndrome, regardless the total amount of physical activity; and the reduction of sedentary time has shown to reduce those risk factors (11). We have to take into account that it is possible to meet the level of recommended physical activity, according to public health guidelines, while at the same time having a sedentary behavior (18).

Furthermore, those sedentary activities are related with a decrease of other physically active activities (even light-intensity activities) and also with an increment of energy intake while doing sedentary activities (18).

Breaks in sedentary time have been related with an improvement of metabolic biomarkers (18). Without taking into account the total of active and sedentary time, a higher number of breaks in sedentary time shows benefits in waist circumference, body mass index (BMI), TG and 2-hour plasma glucose (18).

3.1.4 FUNCTIONAL IMPAIRMENT AND FALLS

Physical inactivity and SB have been associated with an increased risk of physical and labor disability, and also with a decline in functional health (3,10). Additionally, evidence shows that there is an inverse dose-response relationship between PA and risk of physical functional limitations in older adults (1). According to the WHO, the main objective in order to accomplish patients well-being would be for them to be capable of developing activities they consider relevant for them (1).

Many studies have proved that through structured exercise programs increasing mobility, flexibility, balance, strength and physical condition in general, there are benefits on functional outcomes in older adults (improvement of muscular strength and speed gait, and reduction of the number of chronic diseases) (2,5,19). The improvement

of those physical items are essential in the preservation of mobility and activities of the daily living, which implies a reduction of the risk of falling, among other accidents (5,19). Fallings and he incapacity to perform basic daily living activities often increase the risk of illness, disability, beginning of impairment, loss of autonomy and independence, institutionalization, reduction in quality of life and death in the elderly (2,5,19).

Falls are the second cause of death when talking about accidents in elderly (1). Up to 30% of elderly persons over 65 years may fall per year, and up to 50% over 80 years (1). Prevention in this area is needed (2). Among other recommendations, specific PA exercises including balance training, gait and muscle strengthening have shown to slightly reduce the rate of falls and the risk of injury from falls (fragility fractures, head trauma, open wounds, soft tissue injuries, and other injuries needing medical care or even hospitalizations) (1,2).

Moreover, the speed gait reflects the health and functional status, and it is a simple way to define the survival estimation in clinical practice or in research (20). Speed gait is a survival predictor because it requires energy, movement control, support and, furthermore, there are multiple organs and systems involved (heart, lungs, circulatory system, nervous system, and musculoskeletal system) (20). Having said that, a slow gait may indicate both damaged systems or a high-energy cost of walking (20). The association between gait speed and survival has been demonstrated in multiple studies, establishing that a speed gait above 0'8 meters per second (m/s) suggests healthier aging and a speed gait below 0'6 m/s is likely to be related with a poorer health and function, and also with an increased risk of early mortality (20). These benefits have been demonstrated in various studies through different physical tests: 400m walking-speed test and the Short Physical Performance Battery (SPPB) score, especially on the chair-stand performance (19).

3.1.5 EXERCISE BARRIERS IN ELDERLY

As said above, SB is more prevalent among elderly people (12). This could be explained because oftentimes, elderly people may think they are too old or too fragile for physical activities, others may think exercise has no relation with their own health and relates

exercise as nothing more than leisure activities, and those are just some of the examples of the barriers we can find among elderly when we talk about exercise (21) ([table 2](#)). One of the key factors to achieve long term PA adherence is to identify and overcome those barriers (21).

Table 2. Barriers to exercise in older adults. Adapted from (21,22)

BARRIER	APPROACH
Environmental factors (e.g., parks, sidewalks, recreation centers, neighborhood safety)	Promote active lifestyle, walk in malls, use senior centers, home-based exercise.
Self-efficacy	Social support, begin slow and easy, then advance gradually, encourage constantly.
Knowledge: poor awareness of the role of exercise in disease prevention and good health	Explain and promote health benefits from exercise.
Physician advice: physicians play an essential role when promoting exercise among elderly	Family physicians promote exercise giving advice on why and how to exercise.
Fear of injury, belief of being too old or fragile	Start slow, balance and strength training, appropriate clothing, equipment, and supervision.
Disability, illness, fatigue	Adapt exercises, personal trainer, or physical therapist.
Discomfort	Vary exercise intensity and range, avoid overdoing, start slowly.
Poor balance/Ataxia	Assistive devices to increase safety and intensity.
Cognitive decline	Simple exercises, incorporate into daily routine.
Habit	Daily routine, encourage, promote active lifestyle.

Having said that, one of the main barriers we can assist is the “physician advice” since elderly patients have more respect for physician’s advice and are more likely to change their attitude towards their own activity levels (21).

3.1.6 SB AND MULTIMORBIDITY WITH THE AGING

Population ageing has become one of the greatest challenges for the health system, as it is related with a higher multimorbidity prevalence: elderly patients present a higher prevalence of chronic diseases and a higher prevalence of multiple chronic diseases

(23,24). This implies higher medical expenses, and is also related with a worse quality of life (20,23,24). That's why it is important to evaluate the morbidity (23,24).

We have to take into account that among elderly the percentage of sedentary behavior is higher, which increases the risk of multimorbidity among this population (9,11,12). Having said that, PA will always be beneficial, even in patients with some kind of physical impairment or in patients with multimorbidity or chronic diseases (16,17).

In order to evaluate morbimortality, groupers of morbidity (adjusted morbidity groups, (GMA) and clinical risk groups, (CRG)) have been developed, which helps stratify population into risk levels. These groupers are helpful to identify individuals at risk and also with the distribution of resources (23).

Table 3. The nine core Health status groups described by 3M Clinical Risk Groups and their characteristics. Adapted from (25)

3M CRG core health status groups (1-9)	Base 3M CRGs (Total: 330)	Description/Examples of base 3M CRG	Severity levels	Number of 3M CRGs (Total: 1.408)
9 - Catastrophic condition status	10	History of major organ transplant	4	40
8 - Dominant and metastatic malignancies	30	Colon malignancy - under active treatment	4	120
7 - Dominant chronic disease in 3 or more organ systems (triplets)	28	Diabetes mellitus, congestive heart failure (CHF) and chronic obstructive pulmonary disease (COPD)	6	168
6 - Significant chronic disease in multiple organ systems (pairs)	78	Diabetes mellitus and CHF	6	468
5 - Singel dominant or moderate chronic disease	125	Diabetes mellitus	4	500
4 - Minor chronic disease in multiple organ systems	1	Migraine and benign protatic hyperplasia	4	4
3 - Single minor chronic disease	50	Migraine	2	100
2 - History of significant acute disease	6	Chest pain	None	6
1 - Healthy / Non-Users	2	Healthy (no chronic health problems)	None	2

3.2 M-HEALTH

Nowadays the definition of mobile health (mHealth) hasn't been globally established (26). The Global Observatory for eHealth (GOe) defined mHealth as medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices (26).

mHealth includes the use of different functions on a mobile phone: voice and short messaging service (SMS), general packet radio service (GPRS), third and fourth generation mobile telecommunications, global positioning system (GPS) and Bluetooth technology (26).

mHealth is a component of electronic health (eHealth) (26). eHealth is defined as the use of information and communication technologies (ICT) for health (27). Other components included in eHealth would be electronic medical records, telehealth, eLearning, education on ICT and interoperability (28).

Demography is changing in many European countries, which leads to the need of changing the current strategies to promote PA, especially among older adults, in order to improve their health, prevent frailty and the risk factors for chronic diseases, as well as slowing down the progression of chronic diseases, which implies a significant burden on the health-care system (7). Traditional interventions have not shown long-term positive changes in physical activity nor sedentary time (10). On the other hand, home-based PA interventions have shown better results in enhancing starting and adherence to PA interventions among older adults, with or without comorbidities (29).

The use of electronic devices as for example computers, smartphones or tablets among elderly population is increasing, and with this, the number of mHealth apps is also rapidly increasing (7,30). This new methodology applied in healthcare practice aims to monitor and improve the health status of individuals using it (31). However, health technologies tools are mostly used by young people, among elderly the usage of those tools is largely unexplored even though there is evidence on its potential to promote health and for primary prevention (31).

E-health and mHealth interventions have a major advantage, being easily accessible and usable (7). New advances in mobile health technologies have made it possible to track physical activity through smartphone applications and wearable devices, not having to record everything manually (8). Therefore, when technology-based interventions are developed, they might be more cost-effective compared to traditional interventions (7).

Some studies show that mHealth interventions focused on increasing the PA are associated with lower systolic blood pressure and BMI within the first 18 weeks (8). Apart from that, studies evaluating mHealth interventions focused on daily step counting suggest that highly daily steps are associated with a lower risk of all-cause mortality (32). Moreover, every 2000 step/day increase is associated with a reduction of about 10% of cardiovascular disease (8). Other long term changes have been identified, such as lower inflammatory markers, and benefits in diseases like cancer, depression and dementia, with a dose-dependent reduction in all-cause mortality (8). Even though other studies illustrate the effectiveness of eHealth and mHealth interventions when promoting PA, those PA interventions were associated with other lifestyle intervention components. Moreover, there is no agreement whether the use of eHealth or mHealth technologies actually are effective at promoting PA when those interventions are compared to non-mHealth interventions (7).

On the other hand, eHealth and mHealth technologies effectiveness to promote health and for primary prevention amongst elderly people hasn't been properly studied (31). In addition, studies that claim mHealth tools to be effective in health promotion and primary prevention among older adults establish that those interventions are isolated initiatives (31). Therefore, more studies about mHealth technologies and their cost-effectiveness are needed (8,27).

4. JUSTIFICATION

There is little evidence of the use of mHealth technologies among older people when talking about primary prevention and health promotion (7,31).

Nowadays we live in a situation where, due to the global pandemic, the population, and especially older people, is asked to stay home to prevent the risk of infection propagation (13). This has led to a reduction of PA and an increase of sedentary time, which is an independent risk factor for disability and premature mortality, and is also associated with multiple metabolic diseases, cardiovascular diseases, poorer quality of life, and other physical and mental illnesses (3,5,11). That is the reason why indoor exercise and walking habits around the house must be promoted (13,33).

Lately, the increased use of mobile technologies may open new opportunities to encourage old adults increase their PA and achieve WHO PA recommendations (7).

Not only mHealth technology might be beneficial to increase PA, but also when talking about data collection, step-count and PA intensity tracking methods, with mHealth technologies it has shown to be more precise and to present less bias than traditional questionnaires (34).

Evidence suggests that, during the lockdown and due to governmental mobility restrictions, mHealth technologies may have helped individuals remain active (13). Studies warn about being physically active during the Covid-19 pandemic (13). With the help of mHealth technologies this reduction of PA could cease for a brief period at least (13).

In the light of the above, it has to be concluded that more research is needed in the promotion of PA and reduction of SB, particularly in elderly people. For these reasons, the objective of this study is to evaluate whether the use of mHealth technologies reduces sedentary time in community living people over 75 years old.

5. HYPOTHESIS

Elderly people who use step counter technologies (mHealth) diminish sedentary behavior compared to patients the same age who are just given successful aging health education.

6. OBJECTIVES

Main objective:

- To evaluate whether the use of step counter technologies (mHealth) reduces sedentary time in patients over 75 years old.

Secondary objectives:

- To evaluate the effectivity of the step counter technologies (mHealth) intervention in the improvement of the timed up and go test in patients over 75 years old.
- To evaluate the effectivity of the step counter technologies (mHealth) intervention in the improvement of the SPPB score in patients over 75 years old.
- To evaluate the effectivity of the step counter technologies (mHealth) intervention in the absence/presence of fallings, and its consequences in patients over 75 years old.
- To evaluate the effectivity of the step counter technologies (mHealth) intervention in the improvement of the Barthel scale in patients over 75 years old.
- To evaluate the effectivity of the step counter technologies (mHealth) intervention in the improvement of the Lawton and Brody scale in patients over 75 years old.
- To evaluate the effectivity of the step counter technologies (mHealth) intervention in the improvement of the items included in the metabolic syndrome (waist circumference, blood levels of triglycerides, blood levels of cholesterol-HDL, blood levels of glucose and blood pressure) in patients over 75 years old.
- To evaluate the effectivity of the step counter technologies (mHealth) intervention in the reduction of weight and body mass index in patients over 75 years old.
- To evaluate the effectivity of the step counter technologies (mHealth) intervention in the improvement of the quality of life in patients over 75 years old.

7. SUBJECTS AND METHODS

7.1 STUDY DESIGN

This study is a randomized clinical trial carried out in primary care.

It will be an open study, but observer blind will be done. Participants and medical professionals will know the group assignment, but the staff who will monitor the different tests, and the statistical analyst who will analyse the results will not know this information.

7.2 STUDY POPULATION

The study population will include two groups of elderly people over 75 years allocated in a Gironés region primary health care center, belonging to the Catalan Health Institute.

7.2.1 INCLUSION CRITERIA

- Patients ≥ 75 years who are not participating in any other physical activity program at the present moment nor during the months of the study.
- Individuals who have accepted to participate in the study and have read the information sheet ([Annex 1](#)) and have signed the informed consent document ([annex 2](#)).
- Folstein Mini Mental State Exam (MMSE) ([annex 3](#)) adapted according to schooling (≥ 18 in illiterate patients, ≥ 21 in low schooled patients (without primary studies) and ≥ 24 in high educated patients).

7.2.2 EXCLUSION CRITERIA

- Patients ≥ 75 years who are participating in any other physical activity program at the present moment or during the months of the study.
- Patients who have had a lower extremities surgical intervention in the past 6 months or have one programmed during the months of the study.

- Patients unable to walk, patients in a wheelchair, or patients abed. Patients using a cane, or a walker will not be excluded from the study.
- Plans to relocate out of the study area during the duration of the study.
- Patients with some disabling condition or chronic diseases (neoplastic or terminal diseases) that, in the opinion of the investigator, may put in risk or in doubt the requisites of the study.
- Patients standing in precontemplation stage on Prochaska DiClemente's stage of change model (there is still no intention to change).

7.3SAMPLE

7.3.1 SAMPLE SIZE

Accepting an alpha risk of 0.05 and a beta risk of 0.2 in a two-sided test, 199 subjects are necessary in first group and 199 in the second to recognize as statistically significant a difference greater than or equal to 7 units. The common standard deviation is assumed to be 23.6 (35). It has been anticipated a drop-out rate of 10%.

7.3.2 SAMPLE COLLECTION

Potential participants meeting the age requirement will be randomly selected and invited to participate via telephone.

Individuals willing to participate will be asked to assist in a face-to-face appointment where all the information referring to the study will be given, including potential risks and complications. All participants will receive a participant's informational sheet ([Annex 1](#)). Furthermore, participants will be asked to sign the informed document ([annex 2](#)) before following with the study.

7.4 VARIABLES

7.4.1 INDEPENDENT VARIABLE

The independent variable in this study is mHealth technology. This is a dichotomous qualitative variable. The devices used will be individuals own smartphones or, in case they don't own one, a smart-watch will be provided. Individuals will have to download Google Fit application on their smartphone and create an account. They will need to wear the smart-watch or smartphone during all the waking hours. The device will store all the information about the individual's physical activity and sedentary behavior. Patients will be able to conduct their own daily follow-up, adjusting their daily activities to improve their PA performance and achieve their goals and personal recommendations.

7.4.2 DEPENDENT VARIABLE

MAIN DEPENDENT VARIABLE

The main dependent variable is the reduction of sedentary time. It is a continuous quantitative variable.

To evaluate this variable we will use the Yale Physical Activity Survey (YPAS) ([annex 4](#)). YPAS questionnaire was originally designed to determine the type, amount and patterning of PA in older adults (35). Furthermore, it has also been validated for the elderly Spanish population and it has been described as a valid questionnaire to detect changes after participating in a 3 months PA intervention (36–39). The tool is composed of two sections (amount of physical activity/exercise performed during a typical week in the past month; and activities performed in the past month) that provide 3 summary indices (total time in hours/week, total energy expenditure in kcal/week and total activity summary index score with no units) (35). In the first part participants are handed a checklist of activities categories and are asked how often during the past week they performed a particular activity from each category, then the checklist is multiplied by an intensity code and then summed for all the activities to create an energy expenditure summary index (kcal/wk) (35). In the second part, activities performed in the last month are calculated by multiplying a frequency score by a duration score for each of the five

specific activities and multiplying again by a weighting factor (based on relative intensity dimension). The final index is the sum of these five individual indices (35). This questionnaire will be fulfilled by an interviewer. The index we will use to determinate PA and SB will be “total time in hours/week”.

SECONDARY DEPENDENT VARIABLES

- Timed up and go (TUG). It is a continuous quantitative. The patient will be sited back in a standard chair and a mark on the floor will be placed 3 meters away. The patient will be asked to stand up from the chair, walk to the mark on the floor at their normal gait, turn, walk back to the chair at their normal pace and sit down again. Assistive devices for walking can be used if needed. The timing will begin when the interviewer says the stipulated order (“ready, steady, go”, “now” ...). The timing will stop when the patient sits down again. The test will be timed twice and the faster one will be used for analyses. Time will be measured with a chronometer. Results will be expressed in seconds (s). variable. A score >20s is related to a high risk of falling, a score between 10-20 s indicates fragility (risk of falling), and a score <10s is related to low risk of falling (40).
- Short Physical Performance Battery (SPPB) score. It is a quantitative discrete variable. In general, lower extremity performance is evaluated. Specifically, with the chair-stand score the lower extremity muscle function (strength and power) is evaluated. It consists on performing different tests: 4 meter walk at usual pace, a timed repeated chair stand and three standing balance tests. All three tests will be scored from 0 (unable to complete) to 4 (fastest, best performance) depending on individual performance (explained below at each test). Time will be measured with a chronometer. A summary score of the tree test, from 0 (worst performers) to 12 (best performers) will be calculated (41).
 - Standing balance tests: tandem, semi-tandem and side-by-side stands. The interviewer will first demonstrate the task, then the interviewer can help the participants to get into the test position, and when participants are ready,

the interviewer will release the support and will begin timing the test. Timing will stop when participants lose their balance (when participants move their feet or ask for interviewer’s help) or when participants exceed 10 seconds. Participants should be barefooted, and no walking aids should be used. Participants are not allowed to hold on to anything during the test. The first test will be the semi-tandem stand, where the participant will choose which foot to place forward, positioning the heel of one foot next to the first toe of the other foot, both feet touching each other. Participants unable to complete 10 seconds in semi-tandem position will be evaluated with the feet in the side-by-side position, where one foot is placed next to the other, at the same level, both feet touching each other. Participants who were able to maintain the semi-tandem position for 10 seconds will be evaluated in the tandem position, placing the heel of one foot in front of the toes of the other foot. The table below ([table 4](#)) summarizes the punctuation depending on the participants performance (41).

Table 4. Standing balance test punctuation. Adapted from (41)

Punctuation	Side-by-side stand (seconds)	Semi-tandem (seconds)	Full tandem stand (seconds)
0	0-9 Tried but unable Not attempted	<10 Tried but unable Not attempted	-
1	10	0-9 Tried but unable Not attempted	-
2	-	10	0-2 Tried but unable Not attempted
3	-	10	3-9
4	-	10	10

- Walking speed test: with a rule, 4 meters will be marked on the floor, leaving 1 meter at each end. Participants are asked to walk from one end to the other (4 meters) at their usual speed. Assistive devices for walking can be used if needed. Two walks will be timed and the faster one will be used for analyses. The table below ([table 5](#)) summarizes the punctuation depending on the participants performance (41).

- Chair-stand score: a straight chair will be placed next to a wall. Participants are asked to place their arms across their chest and to stand up one time. If participants are able to stand up, they will be asked to stand up and sit down five times as quickly as possible. Timing will begin from the initial sitting position until the final standing position at the end of the fifth stand. The table below ([table 5](#)) summarizes the punctuation depending on the participants performance (41).

Table 5. Walking speed test and chair-stand score punctuation (41)

Punctuation	Walking speed test (seconds)	Chair stand score (seconds)
0	Unable to complete	> 60s or unable to complete
1	8.7 s	>16.7 s
2	6.21 – 8.7 s	13.7 – 16.69 s
3	4.83 – 6.2 s	11.2 – 13.69 s
4	< 4.82 s	≤11.19s

- Fallings during the study (yes/no). It is a dichotomous qualitative variable.
- Consequences of the fallings during the study [fractures and localization of fractures, injuries, hospitalizations, rehabilitation, admission to a residence for the elderly/nursing home, and exitus (yes/no)]. It is a dichotomous qualitative variable.
- Lawton and Brodli scale. It is a quantitative discrete variable. It evaluates the physical autonomy and the instrumental activities of daily living (IADL). It is classified into 8 items (usage of telephone, doing the shopping, cooking, household maintenance, laundry, use of public transport, medication management, and economic management). Information is obtained from the individual or its principal caregiving. Each item will be punctuated with a 0 (dependent) or 1 (independent). The total punctuation will be the summatory of the different items, resulting in a range from 0 (highest level of independence) to 8 (highest level of dependency) (42) ([annex 5](#)).
- Barthel scale. It is a quantitative discrete variable. It evaluates the physical function and basic activities of daily living (BADL). It evaluates 10 items of activities of the daily living (eating, showering, dressing, going to the toilet, urine control, stool control, personal hygiene, moving from chair to bed and vice versa, ambulation, and

climbing stairs). Each item shall be punctuated differently (0, 5, 10 or 15 points). The total punctuation will be the summatory of the different items, resulting in a range from 0 (maximum dependency) to 100 (independent). Depending on the punctuation a level of dependency will be given (0-20: total dependent, 21-60: severe dependency, 61-90: moderate dependency, 90-99: little dependency, 100 (95 if in a wheelchair): independent) (43) ([annex 6](#)).

- The metabolic syndrome components:
 - Waist circumference [centimeters (cm)]. It is a continuous quantitative variable. Will be measured with a millimeter flexible tape measure. The patient will be standing wearing underwear. The measures have to be taken from the top of the iliac crests in an horizontal plane around the abdomen. The measure will be done at the end of a normal expiration.
 - Cholesterol HDL [milligrams per deciliter (mg/dL)]. It is defined as a quantitative continuous variable. Will be measured in a 12 hours fasting blood test.
 - Glucose (mg/dL). It is defined as a quantitative continuous variable. Will be measured in a 12 hours fasting blood test. It is defined as a quantitative continuous variable.
 - Triglycerides (mg/dL). It is defined as a quantitative continuous variable. Will be measured in a 12 hours fasting blood test Results will be expressed in mg/dL.
 - Blood pressure [milligrams of mercury (mmHg)]. It is defined as a quantitative continuous variable. Will be measured with an electronic sphygmomanometer. The patient will remain seated with his arm resting on a surface, after 10 minutes of rest in a quiet room not being able to talk. 3 measures will be taken with 5 minutes intervals between them, the average of two similar measurements will be taken as the correct value.
- Body mass index (BMI): Will be calculated as body mass (Kilograms, Kg) divided by square of the body height (m), and will be expressed in kg/m². It is a continuous quantitative variable. Weight will be determined using a calibrated weight scale, the patient will be wearing underwear and no shoes or other complements. Height will

be measured using a height rod, the patient will be standing wearing underwear with no shoes.

- EuroQol-5 Dimensions-5 Levels Test (EQ-5D-5L). It is a quantitative discrete variable. It will be used to evaluate the quality of life. It is a quantitative discrete variable. It consists of 2 parts: the EQ-5D descriptive system and the EQ visual analogue scale (EQ VAS) (44). The first part includes 5 categories: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each category has 5 levels: no problems, slight problems, moderate problems, severe problems, and extreme problems. Individuals will fill out the form, so for each category they will indicate, from 1 to 5, the best one that reflects their status. The best states of health will be considered 11111 and the worst, 55555. The second part consist on a vertical visual analogue scale where the endpoints are labeled as: “the best state of health you can imagine”, at the top (takes value 100), and “the worst health that you can imagine”, at the bottom (takes value 0) (44) ([annex 7](#)).

7.4.3 CO-VARIABLES

- Fallings during the previous year (yes/no). This is a dichotomous qualitative variable.
- Personal history of fragility fractures (yes/no). This is a dichotomous qualitative variable. The year of the incident will be noted.
- Age (birth date: dd/mm/yyyy). It is a discrete quantitative variable.
- Adjusted morbidity groups (GMA). It is a quantitative discrete variable. It is described as a grouper of morbidity which classifies individuals into risk groups depending on the type of disease, the presence of multimorbidity and the level of complexity. In total there are 31 groups and 5 levels of complexity. This value is obtained automatically in the eCAP medical history through quali-quantitative models (23).

7.5 DATA COLLECTION

In the same first face-to-face appointment, once the informed consent is signed, the inclusion and exclusion criteria will be evaluated.

After that, candidates meeting the requirements will be randomly assigned to the experimental group (group A) or to the control group (group B) (1:1) and a random identification number will be given to protect their anonymity, which will reduce the bias.

During this first face-to-face appointment the different variables and basal test will be evaluated. The different tests will be monitored by an interviewer specially trained in the administration of the performance measures used in the study.

Patients will also be scheduled to obtain a blood test in their primary health care center.

Individuals at the experimental group (group A) will be asked to download Google Fit application on their smartphones or, in case they do not own one, they will be provided with a smart-watch with a step counter depending on the availability of those (when another participant who we have lent a smart-watch finishes the 3-month intervention). Participants will be asked to wear the device during all the waking hours. Participants will be asked to improve their own actual physical activity.

Individuals at the control group (group B) will be given standard advice on physical activity and healthy lifestyle.

Participants in the experimental group will be monthly monitored by phone to ensure the adherence to the study. In case participants do not follow the instructions or have no desire to continue will be labeled as lost and the smart-watch will be reclaimed.

After 3 months having been following the intervention, all participants will be asked to assist to a face-to-face appointment, where the different variables and basal test will be evaluated again.

Patients will also be scheduled to obtain a blood test in their referral primary health care center.

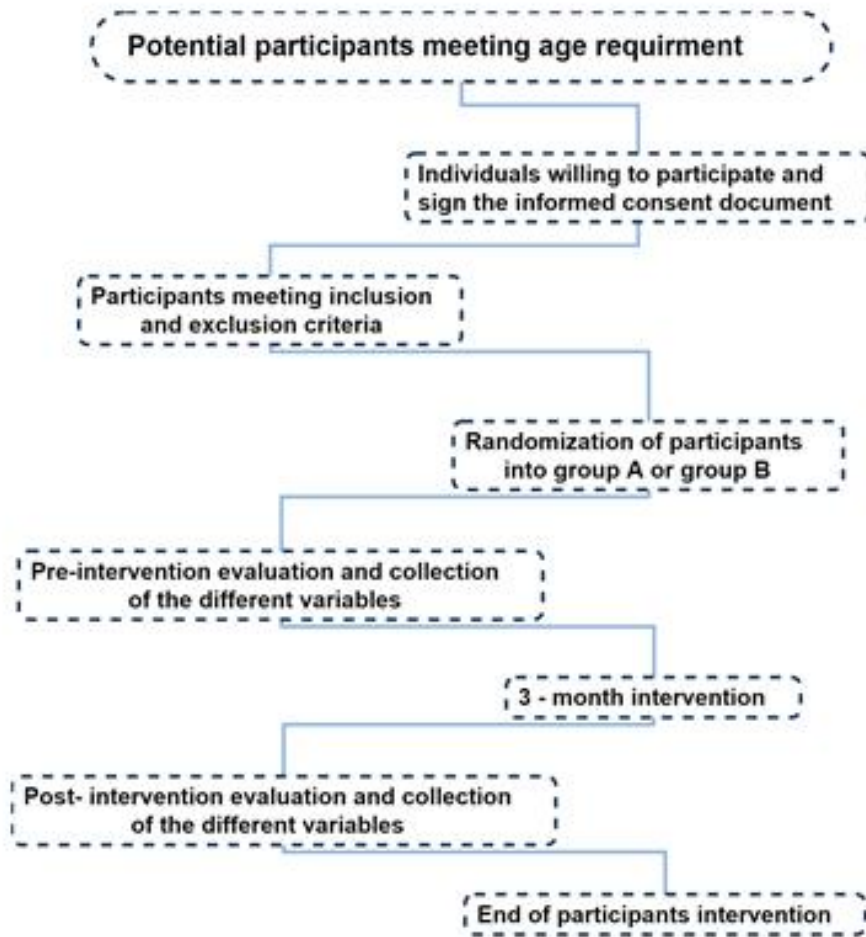


Figure 4. Participants timeline intervention (own source)

8. STATISTICAL ANALYSIS

The statistical analysis will be performed by the statistical analyst, which will be blinded to the study groups. All analysis will be carried out with an appropriate software. A p value <0.05 will be considered statistically significant.

8.1 DESCRIPTIVE ANALYSIS

For both experimental and control groups we will summarize the qualitative variables through proportions in a contingency table. And the quantitative variables will be summarized by mean and standard deviation or median and quartiles depending on whether or not they follow a normal distribution respectively.

These analyses will be stratified by the co-variables. The quantitative variables will be categorized in quartiles. The qualitative variables will be summarized in proportions.

8.2 BIVARIATE ANALYSIS

The association between using mHealth technology or not using it, and the other qualitative variables, will be evaluated through chi-square contrast test. And we will use the Fisher's test when the expected counts are lower than 5.

For the comparison of quantitative variables, we will use t-Student or Mann-Whitney tests depending on whether they follow or not a normal distribution, respectively.

8.3 MULTIVARIATE ANALYSIS

The association between the independent and dependent variables will be adjusted by means of multiple regression analysis in order to avoid possible confounding factors. All the co-variables with statistical significance in the bivariate analysis will be included in the multivariate analysis.

9 ETHICAL AND LEGAL ASPECTS

This study will be conducted according to the requirements expressed in the Declaration of Helsinki of Ethical Principles for Medical Research Involving Human Subjects signed by the World Health Association in October 2013. This protocol has also been developed according to what establishes the *Real Decreto 1090/2015, de 4 de diciembre*.

Ethically, the principles of biomedical and human research will be respected: principle of non-maleficence and respect for people, beneficence, patient autonomy and justice.

This protocol Will be presented to the Clinical Research Ethical Committee (CEIC) of IDIAP JGoI, and will be initiated only after receiving their approval.

Before the beginning of the study, all subjects will receive an information sheet properly informing of the aim, procedures, benefits, and potential risks of the study, using language and terms patients will be able to understand in order to allow a fully knowledgeable decision. This information sheet will also be presented to the CEIC for its approval. Along with the information sheet, subjects will also have to sign an informed consent, which will also be presented to the CEIC for its approval. Only after signing the informed consent they will be a part of the study. Subjects will be informed that they are free to refuse the participation into the study and they are free to withdraw at any time. In this way, the "*Ley 41/202 Básica reguladora de la autonomía del paciente y de derechos y obligaciones en materia de información y documentación clínica*" will be compiled.

The processing of personal data required in this study, the personal data of all the patients and their confidentiality and communication will obey the *Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with the regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)* and the *Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y Garantía de los derechos digitales*.

Patients data including names, surnames, telephones, addresses and clinical history information will remain anonymous after their introduction and processing into a database which will also be handled according to the mentioned Law and exclusively

used for the development of the study. The data access will only be available for the research team. The access to this information for a third person will not be allowed.

10 STUDY STRENGTHS AND LIMITATIONS

LIMITATIONS

- There might be a slight inaccuracy when comparing step counting in the two different mHealth technologies tools we will use in the study, since they work through GPS.
- We have included several co-variables that could be confounding factors for our study variable, however, there are multiple factors involved in sedentary behavior and adherence to the PA program, so, there could be some confounding variables not included in the study.
- We will be using smart technology in elderly people, which might be difficult for some of them to fully understand technology possibilities and functioning.
- We will be using electronic devices that participants will have to wear during all the waking hours. If participants forget to take it or the battery runs out the PA information will not be recorded.

STRENGTHS:

- The study population encompasses all type of individuals, with different levels of mobility, different PA levels and different stages of multimorbidity. This will ensure a higher external validity.
- As this is a clinical trial which requires participants' involvement, the loss of patients during the follow-up has to be considered. In the sample size calculation we have included an estimation of 10% losses.
- The data collection will be conducted with the help of research assistants, which will accelerate the data collection process. However, an observer bias could occur, that's why we have included a formation course for the research assistant team.

11 WORK PLAN

RESEARCH TEAM:

The research team personnel will be composed by:

- 1 Principal researcher (PR) of the study
- Research assistant team: 3 doctors and 3 nurses from the Can Gibert del Pla primary care center
- 1 statistical analyst (SA)

STUDY STAGES:

- **Stage 0:** Study design, and initial coordination:
 - Bibliographic research and protocol elaboration by the PR.
 - Coordination and formation of the research team: the PR along with 3 doctors and 3 nurses from Can Gibert del Pla primary care center. All-member meeting to decide the roles of each participant. Specific training will be given to ensure a standardized data collection.
- **Stage 1:** Ethical evaluation and coordination:
 - We will submit our protocol to the Clinical Research Ethical Committee at IDIAP JGor for its approval.

The PR will be the main responsible.

- **Stage 2:** Sample collection, follow up and data collection:
 - Participant recruitment: participants accomplishing inclusion and exclusion criteria and wanting to sign the informed consent will be randomly distributed in two groups (A and B).
 - Data collection (1): all the questionnaires, tests and variables, from participants both in group A and B will be collected previous to the beginning of the intervention.

- Participants will begin the intervention with the mHealth technology (group A) or after receiving health education (group B). Patients in group A who will need smart-watches will start the intervention depending on the availability of those.
- Follow-up phone calls: participants in the experimental group will be monthly monitored by phone to confirm the attachment to the intervention.
- Data collection (2): participants both in the control and intervention group, after 3 months having been enrolled in the study, will perform the different test and all questionnaires and variables will be collected again.

The PR and the research team will be the main responsible.

- **Stage 3:** Data analysis and interpretation

- Integration and computerization of results in a database. Each patient will be given a number, to assure confidentiality, which will be associated with all the information collected for each patient.
- Statistical analysis: performed by an experienced statistical.
- Interpretation of results: the PR will have a general meeting with the research assistant team to discuss and take conclusions about the results. They will write a final report with the most relevant conclusions of the study.

- **Stage 5:** Publication of results

- The PR will write a journal article of the study, explaining what has been done and the principal findings. Then, its publication will be asked for.
- The PR and one assistant elected by all the research team will attend congresses to present the study nationally and internationally.

12 CHRONOGRAM

WORK PLAN	DESCRIPTION	RESPONSIBLE PERSONNEL	2021				2022				2023				2024			
			Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
STAGE 0	Protocol design and initial coordination	PR and research assistant team																
STAGE 1	Acceptance	PR and Ethics Committee																
STAGE 3	Sample collection, follow up and data collection	PR and research assistant team																
STAGE 4	Data analysis and interpretation	PR, research assistant team and SA																
STAGE 5	Publication of results	PR																

13 BUDGET

Type of cost	Description	Unit cost	Hours/unit	Subtotal
Personnel expenses	Statistical analyst	30 €	150 h	4.500 €
	Formation of research assistant team			2.000 €
Executive expenses	Leaflets			100 €
	Smart-watch	20 €	50	1.000 €
Study publication expenses	Open access publications. Revision, edition, formatting, layout, graphic design and preparation of the digital metadata	1.400 €	3	4.200 €
	English translator specialized in medical language	20€/h	20 h	400 €
Study dissemination expenses	Congresses (inscription, travels, accommodation, diets)	800 €	5	4.000 €
TOTAL				16.200 €

14 IMPACT

As it has been stated before, sedentary behavior has clearly been associated with multiple negative health effects, resulting in an increase of multiple chronic diseases, disability and premature mortality. This not only supposes a worse quality of life, but also an increase of resources consumption, which could be prevented by improving patients' physical activity. That is why multiple studies have been made, and also international physical activity recommendations have been developed.

Despite the evidence, nowadays the total amount of population following the recommendations is far from what would be expected. Among elderly people SB is even more notorious, resulting in a greater increase of multimorbidity in this group of people.

That's why new strategies are needed, especially in elderly. In this context, since the use of electronic devices is constantly increasing, interventions to improve PA through those electronic devices turn out to be an easy, cheap, and personalized way to improve patients' PA levels. Electronic devices interventions will proportionate an objective insight of the patient's own PA level, and they will be able to record and adjust their daily PA in order to achieve PA recommendations or their adjusted recommended PA levels.

Not only mHealth technology will help patients be more conscious about their health and physical activity, but also will reduce the health care expenses.

Furthermore, this study aims to have a great impact locally, and when results are published, we will have more tools to help our patients improve their activity habits as this is an easy and accessible way.

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16.1 ANNEX 1 - INFORMATION SHEET

FULL D'INFORMACIÓ PEL PACIENT

Títol de l'estudi: Efectivitat de tecnologies mHealth per reduir el sedentarisme en gent gran

Ens dirigim a vostè per convidar-lo a participar en un estudi que pretén avaluar la utilització de les noves tecnologies, en concret el recompte de passos a través de tecnologia mòbil (mHealth) i polseres electròniques, per reduir el temps de sedentarisme en individus d'edat avançada. La nostra intenció és tan sols que vostè rebi la informació correcta i suficient perquè pugui jutjar i decidir si vol o no participar en aquest estudi. Per això llegeixi aquest full informatiu amb atenció i nosaltres li aclarirem els dubtes que li puguin sorgir després de l'explicació. A més, pot consultar amb les persones que consideri oportú.

Ha de saber que la seva participació en aquest estudi és voluntària i que pot decidir no participar o canviar la seva decisió i retirar el consentiment en qualsevol moment, sense que per això s'alteri la relació amb el seu metge ni es produeixi cap perjudici en la seva atenció.

Per què es realitza aquest estudi i quin és el seu objectiu?

El sedentarisme suposa múltiples efectes perjudicials per la salut, incrementa la prevalença i el risc de múltiples malalties cròniques (malalties cardiovasculars i metabòliques, hipertensió, diabetis mellitus, obesitat i sobrepès i certs càncers, entre altres). A més a més, suposa una disminució de la salut mental i un increment de la morbiditat i de la mortalitat prematura. Aquests efectes es poden prevenir incrementant l'activitat física i des de la Organització Mundial de la Salut s'han fet recomanacions per mantenir un estil de vida actiu.

Així i tot, la prevalença de sedentarisme, sobretot en gent gran, és molt elevada, i ara amb la pandèmia de la COVID-19 encara més. Per tant necessitem desenvolupar alternatives per promocionar l'activitat física, com la tecnologia mòbil i polseres de recompte de passos perquè el propi individu sigui capaç d'objectivament avaluar la seva activitat diària i adequar-la per aconseguir els objectius d'activitat física recomanats.

Que he de fer si decideixo participar?

Els investigadors recolliran les dades personals i seguidament es programarà una visita presencial on haurà d'omplir alguns qüestionaris i haurà de realitzar unes proves físiques baix la supervisió d'un investigador, posteriorment li programarem una extracció de sang al seu CAP de referència per avaluar diferents paràmetres analítics.

A continuació serà inclòs a un grup A o B. Si vostè està inclòs al grup A, haurà de descarregar-se l'aplicació de Google Fit al seu telèfon mòbil, si no té telèfon mòbil li proporcionarem una polsera de recompte de passos i ho haurà de portar a sobre durant tot el dia. Si vostè està inclòs al grup B, li donarem unes recomanacions de millora la seva activitat física diària.

Passats 3 mesos, tan si ha estat inclòs al grup A com B se li programarà una altra visita presencial per tornar avaluar els mateixos qüestionaris i les proves realitzades al començament de l'estudi. També es programarà una altra analítica al seu CAP de referència per avaluar els paràmetres analítics una vegada acabada la intervenció.

Obtindrè algun benefici per participar?

Al tractar-se d'un estudi d'investigació orientat a generar coneixement no s'espera que vostè obtingui cap benefici per participar ni rebrà cap compensació econòmica, però si que contribuirà a l'avanç del coneixement i benefici social.

Informació sobre la confidencialitat de dades

Les dades obtingudes dels participants son estrictament confidencials. La comunicació i la cessió de les dades personals de tots els participants s'ajustarà a la Llei orgànica 3/2018, de 5 de desembre, de Protecció de Dades Personals i garantia dels drets digitals. D'acord amb aquesta lleu, vostè podrà excedir els drets d'accés, modificació, oposició i cancel·lació d'aquestes dades. Les dades recollides estaran identificades mitjançant un codi i solament els investigadors podran relacionar aquestes dades. En cap cas apareixerà el seu nom en la publicació dels resultats. L'accés a la seva informació personal quedarà restringit als investigadors, mantenint sempre la confidencialitat.

Moltes gràcies per llegir aquest full d'informació.

Si té alguna pregunta no dubteu a realitzar-la.

Si decideix participar en l'estudi, se li entregarà una còpia d'aquest full i del formulari de consentiment informat.

Dra Aina Dalmau
CAP Can Gibert del Pla
Telèfon 972245350

16.2 ANNEX 2 – INFORMED CONSENT DOCUMENT

FORMULARI DE CONSENTIMENT INFORMAT

Títol de l'estudi: Efectivitat de tecnologies mHealth per reduir el sedentarisme en gent gran

Jo (nom i cognoms) _____:

- He llegit el full d'informació que se m'ha lliurat.
- He pogut fer preguntes sobre l'estudi.
- He rebut suficient informació sobre l'estudi.
- He estat informat de les implicacions i finalitats de l'estudi.
- He parlat amb (nom i cognoms de l'investigador/a):_____.
- Entenc que es respectarà la confidencialitat de les meves dades.
- Comprenc que la meva participació és voluntària.
- Comprenc que puc retirar-me de l'estudi:
 - o Quan vulgui
 - o Sense haver de donar explicacions
 - o Sense que això repercuteixi en la meva atenció sanitària

Dono el meu consentiment voluntàriament perquè pugui participar en l'estudi "Efectivitat de tecnologies mHealth per reduir el sedentarisme en gent gran".

Signatura del pacient

Data:

Signatura de l'investigador

Data:

16.3 ANNEX 3 – MINI MENTAL STATE EXAMINATION

Basado en Folstein et al. (1975), Lobo et al. (1979)

Nombre: _____ Varón [] Mujer []
 Fecha: _____ F. nacimiento: _____ Edad: _____
 Estudios/Profesión: _____ Núm. Historia: _____
 Observaciones: _____

¿En qué año estamos? 0-1 ¿En qué estación? 0-1 ¿En qué día (fecha)? 0-1 ¿En qué mes? 0-1 ¿En qué día de la semana? 0-1	ORIENTACIÓN TEMPORAL (máx. 5)	
¿En qué hospital (o lugar) estamos? 0-1 ¿En qué piso (o planta, sala, servicio)? 0-1 ¿En qué pueblo (ciudad)? 0-1 ¿En qué provincia estamos? 0-1 ¿En qué país (o nación, autonomía)? 0-1	ORIENTACIÓN ESPACIAL (máx. 5)	
Nombre tres palabras peseta-caballo-manzana (o balón-bandera-árbol) a razón de 1 por segundo. Luego se pide al paciente que las repita. Esta primera repetición otorga la puntuación. Otorgue 1 punto por cada palabra correcta, pero continúe diciéndolas hasta que el sujeto repita las 3, hasta un máximo de 6 veces. Peseta 0-1 Caballo 0-1 Manzana 0-1 (Balón 0-1 Bandera 0-1 Árbol 0-1)	Núm. de repeticiones necesarias FIJACIÓN RECUERDO inmediato (máx. 3)	
Si tiene 30 euros y me va dando de tres en tres, ¿Cuántos le van quedando?. Detenga la prueba tras 5 sustracciones. Si el sujeto no puede realizar esta prueba, pídale que deletree la palabra MUNDO al revés. 30 0-1 27 0-1 24 0-1 21 0-1 18 0-1 (O 0-1 D 0-1 N 0-1 U 0-1 M 0-1)	ATENCIÓN CÁLCULO (máx. 5)	
Preguntar por las tres palabras mencionadas anteriormente. Peseta 0-1 Caballo 0-1 Manzana 0-1 (Balón 0-1 Bandera 0-1 Árbol 0-1)	RECUERDO DIFERIDO (máx. 3)	
DENOMINACIÓN. Mostrarle un lápiz o un bolígrafo y preguntar ¿qué es esto?. Hacer lo mismo con un reloj de pulsera, lápiz 0-1, reloj 0-1. REPETICIÓN. Pedirle que repita la frase: "ni sí, ni no, ni pero" (o "en un trébol había 5 perros") 0-1. ÓRDENES. Pedirle que siga la orden: "coja un papel con la mano derecha, dóblelo por la mitad, y póngalo en el suelo". Coge con la mano derecha 0-1 dobla por la mitad 0-1 pone en suelo 0-1. LECTURA. Escriba legiblemente en un papel "cierre los ojos". Pídale que lo lea y haga lo que dice la frase 0-1. ESCRITURA. Que escriba una frase (con sujeto y predicado) 0-1. COPIA. Dibuje 2 pentágonos intersectados y pida al sujeto que los copie tal cual. Para otorgar un punto deben estar presentes los 10 ángulos y la intersección 0-1.	LENGUAJE (máx. 9)	
Puntuaciones de referencia: 27 ó más: normal 24 ó menos: sospecha patológica 12-24: deterioro 9-12: demencia	PUNTUACIÓN TOTAL (máx. 30 puntos)	

a.e.g.(1999)

16.4 ANNEX 4 - YALE PHYSICAL ACTIVITY SCALE

Adapted from (35,38)

PRIMERA PART		
Li aniré dient una llista d'activitat comuns a la vida quotidiana. Indiqui per favor quines ha realitzat en una setmana típica durant el darrer mes. Ens interessa qualsevol tipus d'activitat física que formi part de la seva rutina de treball i oci.		
Activitat	Temps	
	Hores	Minuts
Treball Primer de tot, respecte les feines domèstiques o de la llar. Quan de temps ha passat realitzant les següents activitats durant una setmana típica del darrer més?		
Anar de compres (supermercat, tenda de roba)		
Pujar les escales portant pes		
Fer la colada (emplenar, buidar la rentadors, estenent la roba i plegant-la)		
Fer feines domèstiques lleugeres (ordenar, espolsar, escombrar, recollir el fems, encerar, cuidar les plantes, planxar, fer el llit)		
Fer feines domèstiques pesades (passar l'aspirador o mopa, fregar el terra i les parets, traslladar mobles o caixes pesades)		
Preparar el menjar durant més de 10 minuts		
Servir el menjar durant més de 10 minuts (posar la taula, traslladar el menjar, servir el menjar)		
Rentar els plats durant més de 10 minuts (recollir la taula, fregar, eixugar i guardar els plats i coberts)		
Fer bricolatge lleuger (arreglar endolls, manteniment i petites reparacions)		
Fer bricolatge pesat (pintura, fusteria, rentar, encerar cotxe)		
Ha fet alguna altra activitat física relacionada amb les feines domèstiques? (especificar) _____		
Ha fet alguna altra activitat física relacionada amb feines del seu treball/ocupació) (especificar) _____		
Jardineria Respecte activitats de jardí i exteriors, quan de temps ha passat realitzant les següents activitats durant una setmana típica del darrer més?	Hores	Minuts
Treballs de jardineria exterior (podar, plantar, arrancar males herbes, cultivar, tallar gespa)		
Netejar camins (escombrar, treballar amb pala, rampí)		
Cuidat personal Respecte el cuidat d'altres persones, quan de temps ha passat realitzant les següents activitats durant una setmana típica del darrer més?	Hores	Minuts
Cuidant persones majors o discapacitades (aixecar, conduir cadira de rodes)		
Cuidant nins (aixecar, rentar, portar, conduir cotxet)		

Exercici i oci	Hores	Minuts
A continuació li preguntaré sobre activitats realitzades durant el seu temps lliure, quan de temps ha passat realitzant les següents activitats durant una setmana típica del darrer més?		
Caminar ràpid durant més de 10 minuts		
Gimnàstica, aquagim, estiraments, ioga		
Aeròbic		
Bicicleta o bicicleta estàtica		
Natació		
Passejar o caminar relaxadament durant més de 10 minuts		
Punt de creu, cosir		
Ballar		
Jugar a birles, a la petanca		
Jugar al golf		
Practicar esports de raqueta com tennis, pàdel, ping-pong		
Jugar a billar		
Jugar a les cartes o al dòmino		
Activitat sexual		
Ha practicat algun altre tipus d'activitat física en el seu temps lliure? (especificar) _____		
SEGONA PART		
Ara li preguntaré sobre el temps dedicat en general a les activitats intenses, moderades, lleugeres i algunes altres coses.		
<p>Aproximadament, quantes vegades durant l'últim mes ha participat en activitats intenses que duraren al menys 10 minuts, i provocaren importants augments en la seva respiració, pols, cansament de cames o el van fer suar?</p> <p>0 En ninguna ocasió (→ saltar al següent índex)</p> <p>1 1-3 vegades per mes</p> <p>2 1-2 vegades per setmana</p> <p>3 3-4 vegades per setmana</p> <p>4 5 o més vegades per setmana</p> <p>Aproximadament, durant quan temps va realitzar cada vegada aquesta activitat vigorosa?</p> <p>1. 10-30 minuts</p> <p>2. 31-60 minuts</p> <p>3. Més de 60 minuts</p>		
<p>Pensi en els passejos que ha realitzat durant el darrer mes. Aproximadament, quantes vegades al mes ha anat a passejar al menys 10 minuts o més sense parar però sense causar-li grans increments en la respiració, pols, cansament de cames ni li fes suar?</p> <p>0. En ninguna ocasió (→ saltar al següent índex)</p> <p>1. 1-3 vegades per mes</p> <p>2. 1-2 vegades per setmana</p> <p>3. 3-4 vegades per setmana</p> <p>4. 5 o més vegades per setmana</p>		

Quan va anar a caminar, durant quants minuts va caminar?

1. 10-30 minuts
2. 31-60 minuts
3. Més de 60 minuts

Aproximadament, quantes hores al dia passa movent-se d'un costat a un altre mentre fa coses?
(insistir sobre el temps realment en moviment)

0. En ningun moment
1. Menys de 1 hora al dia
2. 1-3 hores al dia
3. 3-5 hores al dia
4. 5-7 hores al dia
5. 7 hores o més al dia

Pensi en quant de temps passa de peu, com promig, durant el darrer mes. Aproximadament, quantes hores passa de peu?

0. En ningun moment
1. Menys de 1 hora al dia
2. 1-3 hores al dia
3. 3-5 hores al dia
4. 5-7 hores al dia
5. 7 hores o més al dia

Aproximadament, en un dia del darrer mes, quantes hores passa assegut?

0. En ningun moment
1. Menys de 1 hora al dia
2. 1-3 hores al dia
3. 3-5 hores al dia
4. 5-7 hores al dia
5. 7 hores o més al dia

PROCESSAMENT DE LES DADES

Adapted from (35,38)

DATOS RECOGIDOS		DATOS A GENERAR			
	Tiempo a la semana	Código de Intensidad (MET)	Tiempo (h/sem)	Gasto energético (MET·h/sem)	Gasto energético (kcal/sem)
			h + min/60	tiempo (h/sem) * código (MET)	tiempo (h/sem) * código (MET) * peso (kg)
Tareas domésticas					
Ir de compras	___ h ___ min	3.5			
Escaleras llevando peso	___ h ___ min	8.5			
Haciendo la colada	___ h ___ min	3.0			
Tareas domésticas ligeras	___ h ___ min	3.0			
Tareas domésticas pesadas	___ h ___ min	4.5			
Preparando comida	___ h ___ min	2.5			
Sirviendo comida	___ h ___ min	2.5			
Lavando platos	___ h ___ min	2.5			
Bricolaje ligero	___ h ___ min	3.0			
Bricolaje pesado	___ h ___ min	5.5			
Otras tareas domésticas	___ h ___ min	*			
Trabajo					
Actividad física trabajo	___ h ___ min	*			
Exteriores					
Jardinería exterior	___ h ___ min	4.5			
Despejar caminos	___ h ___ min	5.0			
Cuidado de otras personas					
Personas mayores	___ h ___ min	5.5			
Niños	___ h ___ min	4.0			
Tiempo libre					
Caminar rápido	___ h ___ min	6.0			
Gimnasia	___ h ___ min	3.0			
Aeróbic	___ h ___ min	6.0			
Bicicleta	___ h ___ min	6.0			
Natación	___ h ___ min	6.0			
Pasear	___ h ___ min	3.5			
Bordar	___ h ___ min	1.5			
Bailar	___ h ___ min	5.5			
Bolos	___ h ___ min	3.0			
Golf	___ h ___ min	5.0			
Deportes de raqueta	___ h ___ min	7.0			
Billar	___ h ___ min	2.5			
Cartas	___ h ___ min	1.5			
Actividad sexual	___ h ___ min	1.4			
Otras tiempo libre	___ h ___ min	*			
Otras	___ h ___ min	*			
TOTAL					

* Para asignar intensidades a cada actividad especificada se puede consultar el siguiente artículo (o sus actualizaciones posteriores): Ainsworth BE, et al. Compendium of physical activities: an update of activity codes and MET intensities. Med Sci Sports Exerc 2000;32(9 Suppl):S498-504.

DATOS RECOGIDOS	DATOS A GENERAR
	Índices de la Actividad Física
Actividad Vigorosa	
Frecuencia 0 En ningún momento 1 1-3 veces por mes 2 1-2 veces por semana 3 3-4 veces por semana 4 5 o más veces por semana	Frecuencia = __
Duración 1 10-30 minutos 2 31-60 minutos 3 Más de 60 minutos	Duración = __
	Índice de Actividad Vigorosa (frecuencia * duración * 5) = __ __
Pasear Relajadamente	
Frecuencia 0 En ningún momento 1 1-3 veces por mes 2 1-2 veces por semana 3 3-4 veces por semana 4 5 o más veces por semana	Frecuencia = __
Duración 1 10-30 minutos 2 31-60 minutos 3 Más de 60 minutos	Duración = __
	Índice de Pasear Relajadamente (frecuencia * duración * 3) = __ __
Moviéndose	
Duración 0 En ningún momento 1 Menos de 1 hora al día 2 De 1 a 3 horas al día 3 De 3 a 5 horas al día 4 De 5 a 7 horas al día 5 7 horas o más al día	Duración = __
	Índice Moviéndose (duración * 3) = __ __
Estar de pie	
Duración 0 En ningún momento 1 Menos de 1 hora al día 2 De 1 a 3 horas al día 3 De 3 a 5 horas al día 4 De 5 a 7 horas al día 5 7 horas o más al día	Duración = __
	Índice Estar de pie (duración * 2) = __ __
Estar sentado	
Duración 0 En ningún momento 1 Menos de 1 hora al día 2 De 1 a 3 horas al día 3 De 3 a 5 horas al día 4 De 5 a 7 horas al día 5 7 horas o más al día	Duración = __
	Índice Estar sentado (duración * 1) = __
	Índice Resumen de la Actividad Física = __ __ __ (suma de los índices)

16.5 ANNEX 5 – LAWTON AND BRODY SCALE

Adapted from (42)

Aspecte a avaluar	Puntuació
Capacitat per utilitzar el telèfon:	
Utilitza el telèfon per iniciativa pròpia	1
És capaç de marcar bé alguns números familiars	1
És capaç de contestar al telèfon, però no de marcar	1
No és capaç d'utilitzar el telèfon	0
Fer compres:	
Realitza totes les compres necessàries independentment	1
Realitza independentment compres petites	0
Necessita anar acompanyat per fer qualsevol compra	0
Totalment incapaç de comprar	0
Preparació del menjar:	
Organitza, prepara i serveix el menjar per si sol adequadament	1
Prepara adequadament el menjar si li proporcionen els ingredients	0
Prepara, escalfa i serveix el menjar, però no segueix una dieta adequada	0
Necessita que li preparin i serveixin el menjar	0
Cuidat de la casa:	
Manté la casa sol o amb ajuda ocasional (per feines pesades)	1
Realitza feines lleugeres, com rentar els plats o fer el llit	1
Realitza feines lleugeres, però no pot mantenir un adequat nivell de neteja	1
Necessita ajuda en totes les feines de la casa	1
No participa en cap feina de la casa	0
Rentat de la roba:	
Renta per si sol tota la seva roba	1
Renta per si sol petites peces de roba	1
Tot el rentat de roba ha de ser realitzat per un altre	0
Ús de mitjans de transport:	
Viatja sol en transport públic o condueix cotxe propi	1
És capaç d'agafar un taxi, però no utilitza altre mitjà de transport	1
Viatja en transport públic quan va acompanyat per una altra persona	1
Solament utilitza taxi o cotxe amb ajuda d'altres persones	0
No viatja	0
Responsabilitat respecte la seva medicació:	
És capaç de prendre la seva medicació a l'hora i amb la dosi correcte	1
Pren la seva medicació si li preparen prèviament	0
No és capaç d'administrar-se la medicació	0
Manteniment de l'economia pròpia	
S'encarrega dels seus aspectes econòmics per si sol	1
Realitza compres de cada dia, però necessita ajuda en les grans compres, bancs...	1
Incapaç d'encarregar-se de la seva economia	0
Total:	

16.6 ANNEX 6 – BARTHEL INDEX

Adapted from (43)

Paràmetre i situació del pacient	Puntuació
Menjar	
Totalment independent	10
Necessita ajuda per tallar la carn, el pa, etc.	5
Dependent	0
Trasllat entre el llit i la cadira	
Independent	15
Necessita ajuda (petita ajuda física o verbal)	10
Necessita ajuda important (una persona entrenada o dues), pot estar assegut	5
Incapaç, no es manté assegut	0
Rentar-se	
Independent per rentar-se la cara, mans i dents, per pentinar-se i afaitar-se	5
Necessita ajuda	0
Vestir-se i desvestir-se	
Independent: capaç de posar-se i treure's la roba, embotonar-se, cordar-se les sabates	10
Necessita ajuda	5
Dependent	0
Ús del vàter	
Independent (entrar i sortir, rentar-se i ventir-se)	10
Necessita ajuda, però pot fer alguna cosa sol	5
Dependent	0
Dutxar-se/banyar-se	
Independent per banyar-se o dutxar-se	5
Dependent	0
Desplaçar-se	
Independent almenys 50m amb qualsevol bastó, excepte caminador	15
Camina amb petita ajuda de persona (física o verbal)	10
Independent amb cadira de rodes en 50 m	5
Immòbil	0
Pujar i baixar escales	
Independent per pujar i baixar	10
Necessita ajuda física o verbal, pot utilitzar qualsevol tipus de bastó	5
Incapaç	0
Control de les femtes	
Continent	10
Accident excepcional (un/setmana)	5
Incontinent (o necessita que li subministrin enema)	0
Control de orina	
Continent, durant almenys 7 dies	10
Accident excepcional (màxim un/24h)	5
Incontinent o sondat incapaç de canviar-se la bossa	0
Total:	

Màxima puntuació: 100 punts (90 si va en cadira de rodes)	
Resultat	Grau de dependència
<20	Dependència total
21-60	Dependència severa
61-90	Dependència moderada
91-99	Dependència escassa
100	independència

16.7 ANNEX 7 – EQ-5D-5L

Marqui amb una creu l’afirmació en cada secció que descrigui millor el seu estat de salut

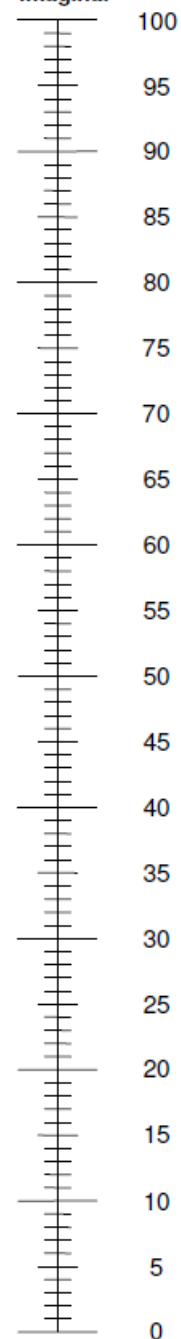
Adapted from (44)

Mobilitat	
No tinc problemes per caminar	
Tinc lleus problemes per caminar	
Tinc moderats problemes per caminar	
Tinc sever problemes per caminar	
Soc 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	
Soc incapaç de netejar-me o vestir-me sol	
Activitats de tots els dies (ex: treballar, estudiar, fer feines domèstiques, activitats familiars o realitzades durant el temps lliure)	
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	
Soc 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 deprimít/da	
Estic lleugerament ansiós/a o deprimít/a	
Estic moderadament ansiós/a o deprimít/a	
Estic severament ansiós/a o deprimít/a	
Estic extremadament ansiós/a o deprimít/a	

(continuació EQ-5D-5L)

- Ens agradaria conèixer lo bona o dolenta que és la seva salut AVUI.
- L'escala està numerada del 0 al 100
- 100 representa la millor salut que vostè es pot imaginar.
- 0 representa la pitjor salut que vostè es pot imaginar
- Marqui X a l'escala per indicar quin és el seu estat se salut AVUI.

La mejor salud que
usted se pueda
imaginar



La peor salud que
usted se pueda
imaginar