

Final Degree Project

BENEFICIAL EFFECTS OF MOUNTAINEERING IN ELDERLY PEOPLE

Observational retrospective cohort study

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«la llibertat i la salut s'assemblen: el seu vertader valor es coneix quan ens falten».

-Henri Becque-



INDEX

1.	Al	BBREVIATIONS	7
2.	Al	BSTRACT	9
3.	В	ACKGROUND	11
	3.1. 3.2.	PHYSICAL ACTIVITY	12
		3.2.1. Physical activity and elderly	
		3.2.1.1. Aerobic exercise	
		3.2.1.2. Strength exercise	
		3.2.1.3. Flexibility exercise	
		3.2.1.5. Barriers	
	3.3.		
_			
4.		USTIFICATION	
5.	H,	IYPOTHESIS	23
6.	0	DBJECTIVES	23
	6.1.	MAIN OBJECTIVE	23
	6.2.	SECONDARY OBJECTIVES	23
7.	M	MATERIALS AND METHODS	25
	7.1.	STUDY DESIGN	25
	7.2.	STUDY POPULATION	25
		7.2.1. Inclusion criteria	25
		7.2.2. Exclusion criteria	
		7.2.3. Matching criteria	
	7.3.		
		7.3.1. Sample selection	
	7.4.	7.3.2. Sample size	
	7.4.	FND POINTS	
	7.5.	•	
	7.5.	7.5.1. Study variables	
		7.5.1.1. Cardiovascular health	
		7.5.1.2. Mental health	
		7.5.1.3. Quality of life	30
		7.5.1.4. Drug consumption	31
		7.5.1.5. Independent variable	31
		7.5.1.6. Covariates	
	7.6.	DATA COLLECTION	33
8.	S1	TATISTICAL ANALYSIS	35
	8.1.		
	8.2.		
	8.3.	MULTIVARIATE ANALYSIS	35
9.	F7	THICAL CONSIDERATIONS	37



10.	STUDY LIMITATIONS	39
11.	WORK PLAN	41
11.1	. CHRONOGRAM	42
12.	BUDGET	43
13.	CLINICAL AND HEALTHCARE IMPACT	45
	BIBLIOGRAPHY	
	ANNEXES	
	ANNEX 1: INFORMATION SHEET	
	ANNEX 2: INFORMED CONSENT	
15.3	. ANNEX 3: DATA COLLECTION SHEET	54



1. ABBREVIATIONS

ACSM American College of Sport Medicine

ASA Acetylsalicylic

BMI Body Mass Index

CEIC Comitè Ètic d'Investigació Clínica

CEO Centre Excursionista Olot

D Day

Dl Deciliter

DL Dyslipidemia

DM Diabetes Mellitus

DNA Deoxyribonucleic acid

ECG Electrocardiogram

EVEA Escala de Valoración del Estado de Ánimo

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

GECA Grup Excursionista Cultural Alpinista

HDL High density lipoprotein

HT Hypertension

Kg Kilogram

M Meters

MET Metabolic Equivalent of Task

Mg Milligram

Min Minute

MmHg Millimetre of mercury

mRNA Messenger Ribonucleic acid

Predimed scale Prevención con dieta mediterránea scale

REGICOR Registre Gironí del Cor

SPSS Statistical Package for Social Sciences

VAS Visual Analogic Sclae



VO2 max Maximum Oxygen volume

Wk Week

WHO World Health Organization



2. ABSTRACT

Title: Beneficial effects of mountaineering in elderly people

Authors: Arnau Alvarez and Joan Carles Trullàs

Background:

Practicing moderate physical activity on a regular basis is an effective tool for primary, secondary and tertiary prevention that has few negative effects if it is carried out with the appropriate monitoring and control. In addition, the prescription of exercise is particularly useful for preventing premature death from all causes, ischemic heart disease, stroke, hypertension, colon and breast cancer, type 2 diabetes, metabolic syndrome, obesity, osteoporosis, sarcopenia, functional dependence and falls in the elderly, cognitive impairment, anxiety and depression. Despite the clear benefits of exercising and the recommendations established, there are very few elderly people who indeed follow them.

Mountaineering is an outdoor activity that combines strength, endurance, flexibility and balance, being in a healthy and peaceful environment. Although there is a lot of information about the benefits of exercise at all ages, there is little information on medical literature focused on the beneficial effects and risks of mountaineering in elderly people.

Objective:

To describe the clinical characteristics and health condition of elderly people who practice mountaineering and compare them with individuals of the same age who do not practice this discipline.

Design:

This will be a pilot study designed as an observational retrospective cohort study with matching.

Participants:

The exposed cohort will include individuals aged 65 or over who regularly practice mountaineering and the non-exposed cohort will include individuals aged 65 or more who do not.

Methods:

The data will be obtained by contacting the main mountaineering clubs in La Garrotxa (Girona) and non-mountaineering organizations in the same region and by sending a questionnaire via email.

Keywords:

Mountaineering, elderly, health





3. BACKGROUND

3.1. HEALTH AND QUALITY OF LIFE

Health, according to the Assembly foundations of the World Health Organization (WHO), is not only the absence of disease but is a state of complete physical, psychic and social wellbeing (1).

The classic view of health in medicine was based on the absence of disease. However, now the concept of health is much broader and more complex, including biological aspects, evolutionary phenomena, even relationships with the environment and with others (2).

Health and illness are the result of the interaction of several determinants [figure 1]. These can be sorted in layers, bringing those closest to the center into consideration of nearby biological factors (high blood pressure, overweight, etc.). The second line is the factors that depend on physical activity, stress and diet, among others. Finally, we find the determinants of the physical environment (accessibility to recreational and sports rescues, urgent mobility, food, tobacco, alcohol, etc.) and the social environment (such as social cohesion and social norms) (3).

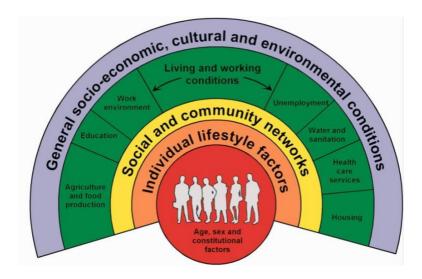


Figure 1. Dahlgren and Whitehead (1991) model of the determinants of health

The concept of quality of life is widely used to define the health status of an individual and population but is difficult and complex to define, and there are many proposed definitions (4). According to EuroQuol, quality of life is defined as: "an overall general well-being that comprises objective descriptors and subjective evaluations of physical, material, social, and emotional well-being together with the extent of personal development and purposeful activity, all weighted by a personal set of values" (5).



3.2. PHYSICAL ACTIVITY

Physical activity is defined as any bodily movement produced by the contraction of skeletal muscles that results in a substantial increase in caloric requirements over resting energy expenditure. Exercise is a type of physical activity consisting of planned, structured, and repetitive bodily movement done to improve and/or maintain one or more components of physical fitness. Physical fitness is defined as a set of attributes or characteristics individuals have or achieve that relates to their ability to perform physical activity. These characteristics are usually separated into the health-related and skill-related components of physical fitness (6,7).

The healthy lifestyle is based on four main points (8):

- Balanced diet
- Satisfying social relationships
- Physical form
- Avoid smoking, excessive alcohol and toxins

Practicing moderate physical activity on a regular basis is an effective tool for primary, secondary and tertiary prevention that has few negative effects as long as they are that it is carried out with the appropriate monitoring and control. Everyone can improve or maintain their health if they practice physical activity adapted to their characteristics and needs. In fact, the worst risk of physical activity is not practicing it.

Even so, the practice of physical exercise on a regular basis or the fact of moving, is not much common in our society in modern times. According to data of the Department of Health, in Catalonia, in 2006 around 40% of people over the age of 14 years old are sedentary or minimally active, which makes physical inactivity a health problem. The latest national survey of health confirms that we are facing with a "sedentary epidemic" (9).

The scientific evidence demonstrating the beneficial effects of exercise is indisputable, and the benefits of exercise far outweigh the risks in most adults. A program of regular exercise that includes cardiorespiratory, resistance, flexibility, and neuromotor exercise training beyond activities of daily living to improve and maintain physical fitness and health is essential for most adults (10).



The American College of Sports Medicine (ACSM) recommends that most adults engage in moderate-intensity cardiorespiratory exercise training for \geq 30 min·d (minutes·day) on \geq 5 d·wk (day·week) for a total of \geq 150 min·wk, vigorous-intensity cardiorespiratory exercise training for \geq 20 min·d on \geq 3 d·wk (\geq 75 min·wk), or a combination of moderate- and vigorous-intensity exercise to achieve a total energy expenditure of \geq 500-1000 MET·min·wk (Metabolic Equivalent of Task·minute·week)

On 2-3 d·wk, adults should also perform resistance exercises for each of the major muscle groups, and neuromotor exercise involving balance, agility, and coordination. Crucial to maintaining joint range of movement, completing a series of flexibility exercises for each the major muscle-tendon groups (a total of 60 s per exercise) on ≥ 2 d·wk is recommended (11).

It's important to say that the exercise program should be modified according to an individual's habitual physical activity, physical function, health status, exercise responses, and stated goals.

Table 1. Physical activity recommendations to improve physical shape, reduce the risk of chronic diseases and disabilities and prevent overweight. Adapted from (8)

PROGRAM TO IMPROVE AND KEEP CARDIORESPIRATORY FITNESS AND BODY COMPOSITION

Moderate aerobic exercise a minimum of 30 minutes 5 days per week, or intense a minimum of 20 minutes 3 days per week (Class I A) or combination of both (Class II B)

- This exercise should be added to the low intensity physical activity that is carried out during the activities of daily life and to the moderate physical activity of short duration (<10 minutes)
- Periods of moderate physical activity lasting longer than 10 minutes can be added to complete 30 minutes (Class I B)
- In people older than 65 years or people aged 50 to 65 years with chronic diseases or disabilities (for example, osteoarthritis), on a scale of 0 to 10 where 0 is sitting and 10 is the maximum effort, moderate is considered between 5 and 6 (which produces detectable tachycardia and tachypnea), and the score between 7 and 8 (which produces tachycardia and significant tachypnea) is considered intense.
- Greater amount of physical activity produces greater benefit (Class I A)

PROGRAM TO IMPROVE AND MAINTAIN STRENGTH AND FLEXIBILITY

Strength: minimum of 2 non-consecutive days each week, with 8-10 exercises that develop most muscle groups (arms, shoulders, chest, abdomen, back, hips and legs) at each session and with 10-15 repetitions of each exercise (Class IIa A)

Flexibility: at least 2 days per week for a minimum of 10 minutes, with 8-10 exercises that include most groups of muscles and tendons.

Flexibility exercises should be done slowly and progressively, maintaining the stretch for 10-30 seconds and doing 3-4 repetitions of each exercise (Class IIb B)

Balance: balance exercises (for example, dancing) 3 times a week. (Class IIa A)



The prescription of exercise is particularly useful for preventing premature death from all causes, ischemic heart disease, stroke, hypertension, colon and breast cancer, type 2 diabetes, metabolic syndrome, obesity, osteoporosis, sarcopenia, functional dependence and falls in the elderly, cognitive impairment, anxiety and depression (8).

A systematic review and harmonised meta-analysis published in 2019 has shown that higher levels of total physical activity at any intensity and less time spent sedentary are associated with a substantially reduced risk for premature mortality. Maximal risk reductions were seen at about 375 min/day of light intensity physical activity or 24 min/day of moderate-to-vigorous intensity physical activity (12).

3.2.1. Physical activity and elderly

Physiologically, with age, the human body deteriorates, even in the absence of any disease. Biological aging can be explained by a number of theories, the most widely accepted said it is a self-destructing process by accumulation of errors at the DNA (Deoxyribonucleic acid) level with repercussions at the level of mRNA (messenger Ribonucleic acid) and protein synthesis (13). Establishing when aging begins is very difficult, but by chronological age it is said to start between the ages of 60 and 65 years (14).

Although the amount of physical exercise cannot stop this deterioration, it can limit progression and diminish morbidity and mortality in the elderly, increasing their quality of life (15).

Table 2 summarizes the benefits of exercise for old people.

The main goals that should be achieved by the elderly must be aimed at preventing significant loss of physical ability, and therefore will focus on (16):

- Improve or maintain the capacity of the cardiorespiratory system.
- Improve or maintain muscle strength and balance.
- Improve or maintain neuromuscular efficiency and coordination.



Table 2. Benefits of exercise in older adults. Adapted from (17)

Cardiovascular	 Improves physiologic parameters (VO2 max or maximal oxygen volume, cardiac output, decreased submaximal rate-pressure product) Improves blood pressure Decreases risk of coronary artery disease Improves congestive heart failure symptoms and decreases hospitalization rate Improves lipid profile
Diabetes mellitus, type 2	 Decreases incidence Improves glycemic control Decreases hemoglobin A1C levels Improves insulin sensitivity
Osteoporosis	 Decreases bone density loss in post-menopausal women Decreases hip and vertebral fractures Decreases risk of falling
Osteoarthritis	Improves functionDecreases pain
Neuropsychologic health	 Improves quality of sleep Improves cognitive function Decreases rates of depression, improves Beck depression scores. Improves short-term memory
Cancer	 Potential decrease in risk of colon, breast, prostate, rectum Improves quality of life and decreases fatigue
Other	 Decreases all-cause mortality Decreases all-cause morbidity Decreases risk of obesity Improves symptoms in peripheral vascular occlusive disease

Although it has been seen that aerobic exercise is the basis of a physical exercise program, we cannot forget that there are three fundamental pillars: aerobics, strength and flexibility-balance training. Recommendations for physical exercise are the same as those for young adults, but as always, adapted to each individual and with professional prescription (17).



3.2.1.1. Aerobic exercise

Continued aerobic exercise has shown a great improvement in the health of the elderly. Walking, running, swimming and cycling are the most common activities and all of them cause a decrease in the cardiovascular risk. The maximum amount of oxygen consumed (VO2 max) has been seen to decrease by 5-15% every 10 years after 25 years old, but with constant aerobic exercise, the quantity of loss can be reduced with age (18).

Table 3. Changes in VO_{2max} values with aging. Adapted from (19)

Age (years)	$VO_{2 max}$ (ml · kg ⁻¹ · min ⁻¹)	% of change in 25 years
25	47,7	-
35	43,1	-9,6
45	39,5	-17,2
52	38,4	-10,5
63	34,5	-27,7
75	34,5	-27,7
75	25,5	-46,5

Aerobic resistance training causes structural and physiological adaptations in the cardiovascular system of the elderly people, which allows an increase in cardiocirculatory performance in exercise (20):

- Increased capillary intensity in the active muscles
- Development of collateral vessels
- Regression of atherosclerotic lesions
- Increased ventricular mass
- Reduction in the duration of the contraction
- Plasma volume expansion
- Improves post-effort recovery

In older people, training reduces the elasticity loss of the lungs and costal wall. As a result, endurance trained veteran athletes only have a slightly decrease of pulmonary ventilation capacity and alveolar diffusion (20).



3.2.1.2. Strength exercise

Exercises of strength are fundamental to the elderly. Muscle strength is necessary for many activities of daily life, such as climbing stairs, walking, getting up, etc.

The aging process is associated with a reduction in maximal strength and the capacity of the neuromuscular system to produce explosive force. This loss of strength is mainly due to a progressive loss of muscle mass (sarcopenia) (21,22). Although the proportion of muscle fibers (% type II/I fibers) remains constant, the area occupied by fast fibers (type II) decreases compared to those of slow-twitch fibers (type I), also there are a decrease in the total number of muscle fibers (10% of muscle fibers per decade from the age of 50) (23,24).

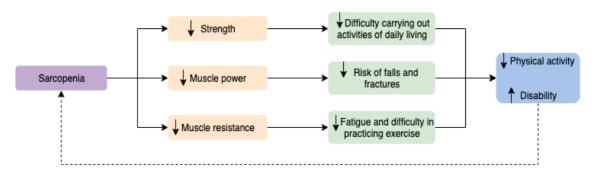


Figure 2. Model that explains the functional consequences of age-related changes in sarcopenia (loss of muscle mass and function) and the cycle by which it is explained, how reducing physical activity accentuates the alteration process. Adapted from (25)

For this reason, it is important to exercise strength often as it facilitates the retention of contractile proteins and can delay the loss of lean mass associated with aging. On the other hand, high-intensity strength training in elderly individuals causes muscular hypertrophy due to an increase in the size of muscle fibers, slow and fast, with a greater predominance of fast ones (type IIa).

Proper strength training has been shown to increase the gain strength by 25-100%, making hypertrophy and increasing the regulation of the motor units. Therefore, if we speak about the daily activities, it has been seen that an increase in strength added to a good nutrition is related to a greater resistance walking and climbing stairs, as well as a reduction in the loss of muscle mass in institutionalized people (26).

3.2.1.3. Flexibility exercise

With age, flexibility is also reduced, reducing the connective, muscular and bony tissues, producing pain and decreasing mobility. It has been seen that the incorporation of flexibility



exercises in regular exercise programs improve the range of mobilization of the main articulations (neck, shoulder, elbow, waist, hip, knees and ankles), as well as an improvement in the ambulation, proprioception and balance skills (27).

3.2.1.4. Precautions

It is also important to remember that, despite all the benefits of physical exercises, there is also an increased risk of injury or worsen current ones. There are certain contraindications for aerobic exercise such as a 3rd degree block, acute heart congestive, uncontrolled hypertension, uncontrolled metabolic disease, unstable angina, a recent ECG (Electrocardiogram) change or a myocardial infarction. There are other contraindications that are relative, so the prescription of physical activity must be adapted individually (17).

For this reason, before an older person starts or increases the level of physical activity, they should ask an appropriate health professional for advice based on their health condition and previous physical activity level (28).

3.2.1.5. Barriers

Despite the clear benefits of exercising and the recommendations that are established, there are very few elderly people who get the recommendations. More than 60% of American adults >50 years of age do not meet the described exercise suggestions and, in England, only 20-17% of adults between 65 and 74 follow the recommendations of physical activity (29,30).

This reflects the difficulties or barriers that this group of people can have to do physical activity. The main justifications for this age group are: illness, pain and injury (31). It has also been seen that the environment and access to areas where physical activity can be carried out, significantly influences the quantity of physical activity that individuals in the area do. Free accessibility to areas where sport can be performed, such as parks, sports facilities, etc. has shown an increase in physical exercise in the neighbours of the area (32).



3.3. MOUNTAINEERING

As we have seen, the recommendations of physical activity have been widely studied and there is a lot of information about them.

In contrast, there is less information on medical literature specifically focused on the effects of mountaineering on people's health. Most studies focus on more specific aspects of alpinism such as altitude sickness or hypothermia.

However, some risks are described, among others:

- A large increase in the percentage of adults older than 50 with mountaineering related injury or illness as reported during the last 4 decades (33).
- In mountain sports, altitude along with physical exertion may contribute to the risk of sudden cardiac death (34).

We can mention some articles that describe benefits of mountaineering in very specific elderly populations such as:

- Asian populations between 50 and 79 years old suffering from a greater burden of stroke than coronary heart disease, a moderate level of daily total physical activity may be sufficient to achieve the maximum risk reduction of cardiovascular disease (35).
- Trekking played a significant role in the reduction of weight and systolic blood pressure in older obese women (36).

In conclusion, despite having a lot of information about the benefit of exercise at all ages, there is little information about the beneficial effects and risks of mountaineering in elderly people.





4. JUSTIFICATION

The term health is becoming more and more widespread and has been proven to involve not only the absence of disease, but a wide range of other factors (2). Aging and health are not contradictory terms and, despite the fact that the former is physiological and uncontrollable at the moment, we can limit its progression and reduce morbidity and mortality, thereby increasing the quality of life of people.

Physical exercise has proven to be a clear determinant of health and has a great benefit in the quality of life (27). The benefits of performing physical activity are obvious and the recommendations are clear and well-studied (8).

Unfortunately, the performance of physical exercise is low, especially when the age increases; a minority of the elderly meet the recommendations (29,30). For this reason, there is an increased need in the prescription and development of studies that demonstrates the benefit of exercise in the elderly.

We need to make the elderly aware of the need for physical activity and, of course, design proposals and offers so that the population can acquire and lead active lifestyles. A change in society must be fostered, strengthening its autonomy, respecting its idiosyncrasy and modifying the dominant social today's values.

Physical exercise encompasses a wide range of disciplines, and our study focuses on one: mountaineering. It is an outdoor activity that combines strength, endurance, flexibility and balance, being in a healthy and peaceful environment. In addition, it is a common discipline in our area, especially for the elderly.

However, most of the literature is based on other aspects of mountaineering such as altitude sickness, injuries, etc.

In conclusion, due to the low incidence of elderly people doing physical exercise and the lack of literature demonstrating the benefits of mountaineering in the elderly, we need a study to evaluate the benefits and disadvantages of mountaineering in the elderly.





5. HYPOTHESIS

Elderly people who practice mountaineering have a better health condition and a better quality of life compared to individuals of the same age who do not practice mountaineering.

6. OBJECTIVES

6.1. MAIN OBJECTIVE

 To describe the clinical characteristics and health condition (based on cardiovascular state, mood, quality of life and drug consumption) of elderly people who practice mountaineering.

6.2. SECONDARY OBJECTIVES

To compare them with individuals of the same age who do not practice this discipline.





7. MATERIALS AND METHODS

7.1. STUDY DESIGN

This study is an observational retrospective cohort study with matching.

7.2. STUDY POPULATION

The study population will include two cohorts of elderly people who live in La Garrotxa region (a rural area in Spain):

- The exposed cohort will include individuals 65 years old or more who regularly practice mountaineering.
- The non-exposed cohort will include individuals 65 years old or more who do not practice mountaineering.

7.2.1. Inclusion criteria

To participate in the study individuals must meet all the criteria of inclusion:

- Age: ≥ 65 years
- Individuals in the exposed cohort should practice mountaineering at least twice a month in the last 5 years.

7.2.2. Exclusion criteria

They will not be able to participate in the study if any of the following criteria is met:

- Individuals with a disease that have an expectation of life of less than 6 months at the time of inclusion in the study.
- Any illness or previous condition that entails a functional limitation and that could have been a reason by which the individual has not been able to practice any type of physical exercise including mountaineering (amputation, accident and/or previous trauma with residual lesions, cerebrovascular accident with residual lesions, severe osteoarthritis and/or carrier of joint prostheses that prevent exercise, etc.)
- Alcoholism and/or drug addiction in the last 12 months.
- Any medical condition that, in the opinion of the investigator, may put at risk or in doubt the requisites of the study



- That the individual is not prepared to comply and/or answer everything that the protocol of the study implies
- Negative to participate in the study
- The individuals who do not understand the language of the study

7.2.3. Matching criteria

For each individual in the exposure cohort, another individual from the non-exposure cohort will be included with the following pairing criteria:

- Same age +/-2 years old (always more than 65 years old)
- Same gender



7.3. SAMPLE

7.3.1. Sample selection

The exposed-cohort will be selected by contacting the two principal mountaineering clubs of La Garrotxa (Girona): Centre Excursionista Olot (CEO) and Grup Excursionista Cultural i Alpinista (GECA). We will contact with the presidents of these entities who will send an email to all individuals aged 65 or more and who regularly practice mountaineering, with an explanatory message in which they will be invited to participate in the study

The non-exposed cohort will be selected by contacting one big entity of elderly people: Associació de Pensionistes i Jubilats d'Olot. We will do the same process as the exposed group, we will contact with the president who will send an email to all the members aged 65 or more with a message explaining and inviting them to participate in the study.

All the candidates will be invited to participate in the study, and an information sheet of the study (<u>ANNEX 1</u>) will be given. After informed consent (<u>ANNEX 2</u>) is signed, individuals will be enrolled in the study.

7.3.2. Sample size

We have not found similar studies to make the sample calculation. For this reason, we have considered the study as a pilot study.

Although it is a pilot study we have calculated the sample size, in a two-sided test, with a 5% alpha risk, a statistical power of 80% and an important difference in the state of health, equal to 49 subjects. However, as the data collection sheet will be online, we have supposed a dropout rate of 50%, so that the final sample size will be 74 people.

Computations were carried out with Prof. Dr. Marc Saez software based on the 'pwr' library of the free statistical environment R (version 3.6.2).



7.4. END POINTS

7.4.1. Primary end-points

In this study we have 4 co-primary endpoints to define the health condition

- Cardiovascular health
- Mental health
- Quality of life
- Drug consumption



7.5. VARIABLES AND METHODS OF MEASUREMENT

7.5.1. Study variables

To analyze the objectives and endpoints, we will use the variables in table 4.

Table 4. Objectives, end-points and variables of the study

OBJECTIVES	END-POINTS	VARIABLES
Main objective	Co-Primary end-points	Variables for the main end- point
		REGICOR scale
Health condition	Cardiovascular health	Number of cardiovascular events
		Predimed test
	Mental health	EVEA scale
	Quality of life	EQ-5D-5L
	Drug consumption	Number of drugs and type

All the scales and tests used are validated nationally and/or internationally, and are used in daily medical practice.

All variables will be collected using a data collection sheet (ANNEX 3):

7.5.1.1. Cardiovascular health

The cardiovascular health will be calculated with:

REGICOR (Registre Gironí del Cor) scale.

This table have been adapted to the characteristics of the Spanish population through a well-calibrated calibration process and have been validated in the Spanish population. They allow to estimate the risk of a coronary event (angina, myocardial infarction with or without symptoms, deadly or not) at 10 years (37).

To estimate the risk it's necessary:

o Birth date: from which we will get the age (in years).

o Sex: male or female.

o Smoker: yes or no

o Diabetic: yes or no



- Total cholesterol: milligrams/deciliter (mg/dl)
- o HDL (High density Lipoprotein) cholesterol: milligrams/deciliter (mg/dl)
- o Systolic blood pressure: millimeter of mercury (mmHg)
- Diastolic blood pressure: millimeter of mercury (mmHg)
- Occurrence of cardiovascular events: yes or no
 - Ischemic heart disease (angina pectoris and myocardial infarction or heart attack)
 - Stroke (ischemic or hemorrhagic)
 - Peripheral artery disease
- Adherence to the Mediterranean diet. There is an inverse association between adherence to the Mediterranean diet and cardiovascular risk (38) so we will use the Predimed scale (Prevención con dieta mediterránea scale), a brief dietary assessment instrument with 14 short questions whose evaluation aims to provide information about the adherence to the Mediterranean Diet (39).
 - o Predimed Test: number from 1 to 14.

7.5.1.2. Mental health

The mood it will be measured by:

• EVEA (Escala de Valoración del Estado de Ánimo) scale. This is a scale formed by different adjectives that value four general moods: depression, anxiety, hostility and joy. It consists of 16 items that are asked with a phrase that begins with "I feel" and continue with an adjective that represents a state of mind. Each sentence is rated from 0 to 10, with 0 is "nothing" and 10 is "much" (40,41).

7.5.1.3. Quality of life

The quality of life will be measured by:

• EQ-5D-5L Test (EuroQuol-5 Dimensions-5 Levels Test). The EQ-5D, developed by the EuroQol Group is a generic and standardized instrument for describing and assessing the quality of life related to health (42). It consists of 2 parts: the description system EQ5D and the visual analogue scale (VAS). The first one is formed by 5 dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. In 2009 a new EQ-5D was introduced by the EuroQol group (EQ-5D-5L), increasing from 3 to 5



levels in each dimension (no problems, slight problems, moderate problems, severe problems, unable to / extreme problems), improving the sensitivity and reducing the ceiling effects. So, each interviewee indicates the level that best reflects their status for each of the five dimensions, by five digits that take values from 1 to 5, that's why health status 11111 is considered the best state of health and 55555 the worst state of health. The combination of these levels in each dimension defines a total of 3125 health states. In the second part of the questionnaire, the interviewee is asked to evaluate his current state of health by a millimetre scale (similar to a thermometer) of 20 cm with the endpoints labelled, where "the best state of health you can imagine" appears at the top and takes the value 100, and in the bottom appears "the worst state of health that you can imagine", that takes the value of 0 (43).

7.5.1.4. Drug consumption

The drug consumption will be measured by:

- **Drugs**: nº total of drugs.
 - Type of drugs, for arterial hypertension (HTA), Diabetes Mellitus (DM), dyslipidemia (DL), acetylsalicylic (ASA), antidepressants, anxiolytics, analgesics: yes or no

7.5.1.5. Independent variable

If they do (exposed) o or not (non exposed) mountaineering.

7.5.1.6. Covariates

The rest of the data collections will be used to describe the non-exposed and exposed cohort and possible confounders of the association between the end-points and the independent variable.

- Entity they belong to.
- Sociodemographic data:
 - Birth date: from which we will get the age (in years).
 - Sex: male or female.
- Socioeconomic level defined as social class, constructed with occupation and education level as in Domingo et al. (44,45).
 - o Primary studies/without studies or secondary studies or university studies



- Anthropomorphic data
 - Body mass index (BMI): kilos/meters (kg/m2). To calculate it we will collect the weight (Kg) and the height (m)
- Physical activity: yes or no
 - O Discipline: walking, swimming, biking, gym...
 - o Number of days per week
 - o Minutes per week or session.
 - o Daily activities: active, little active or sedentary

If the activity is mountaineering:

- o Type of mountaineering activity
- o Days per month
- Years practicing mountain
- Average hours per session
- o Average meters of ascent per session
- Osteoarticular pathology
 - o Arthrosis: yes or no
 - o Osteoporosis: yes or no
 - o Bone fracture: yes or no
 - o Prosthesis: yes or no



7.6. DATA COLLECTION

All data will be collected using a specific Case Report Form for this study (ANNEX 3).

The data collection sheet will be computerized so the individuals that participate in the study can answer the questionnaire online. The questionnaire will be sent by email, consisting on 13 sections and it is estimated that can be answered in approximately 15-20 minutes.

- We will contact the exposed cohort (individuals with 65 years old or more who
 regularly practice mountaineering) through the president of their entity, by email.
 Initially, we will ask them to participate in the study, if they agree, they will respond to
 the online questionnaire with all the instructions.
- We collect the non-exposed cohort (individuals with 65 years old or more who do not practice mountaineering) with the same method of the non-exposed group, through the president of their entity and sending them the same questionnarie. Also we will first ask if they want to participate in the study and, if they agree, they will respond to the questionnaire with all the instructions.

In case of receiving an insufficient amount of answers we will send a reminder via email and we will contact the president of each entity to evaluate some other data collection method.





8. STATISTICAL ANALYSIS

8.1. DESCRIPTIVE ANALYSIS

We will summarize the qualitative end points (REGICOR, cardiovascular events and each one of the drugs) by means of proportions in exposed and non-exposed groups.

The quantity discrete variables (Predimed, EVEA, EQ5D5L and the number of drugs) will be summarized using the median and the interquartile range, stratifying in exposed and non-exposed groups.

These analyses will be stratified by the covariates. The quantitative covariates with the exception of BMI, will be categorized in quartiles. BMI will be categorized as normoweight, overweight and obesity.

8.2. BIVARIATE INFERENCE

The proportions difference of the qualitative variables between doing and not doing mountaineering will be tested by means of the chi-squared. In case in a cell there will be an expected count lower than 5, the exact Fisher's test will be used.

The medians difference of the discrete quantitative variables will be tested by the Mann-Whitney's test.

These analyses will be stratified by the covariates. The quantitative covariates with the exception of BMI, will be categorized in quartiles. BMI will be categorized as normoweight, overweight and obese.

8.3. MULTIVARIATE ANALYSIS

I will categorize the REGICOR groups in low risk and middle-high risk.

First, we will assess the influence of mountaineering on REGICOR categorized and the presence of any cardiovascular events by logistic regressions, controlled by all the covariates.

Secondly, with regards to the discrete variables (Predimed, EVEA, EQ5D and nº of drugs) this



association will be assessed in Poisson regressions, controlled by all the covariates.

Finally the occurrence of ischemic heart, stroke and periphery artery disease; the use of each one of the drugs, and the mountaineering activity, will be assessed in logistic regressions controlled by all the covariates.

Statistical significance was set at 0.05.

Analyses were performed with the software Statistical Package for Social Sciences (SPSS) version 20.0 (SPSS, Inc., Chicago, Illinois, USA).



9. ETHICAL CONSIDERATIONS

This research protocol will be evaluated by the Comitè Ètic d'Investigació Clínica (CEIC) from Hospital Universitari Doctor Josep Trueta, and may be initiated only after receiving their approval.

Before the start of the study, the information sheet must be provided to the participants and the written informed consent must be subjected to the review and approval of the CEIC, together with the study protocol.

An information sheet about the study in an understandable language for the participant (ANNEX 1) will be given. Written informed consent (ANNEX 2) must be obtained by investigators from each participant before taking part in the study. It will also be explained to the individuals that they are free to refuse entry into the study and free to withdraw from the study at any time without prejudice to future treatment.

All personal study data collected and processed for the purposes of this study will be confidential, guaranteeing the anonymity of the participants involved in the study according to the "Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y garantía de los derechos digitales".





10. STUDY LIMITATIONS

- Our study is an observational retrospective cohort study with the advantage that the
 cost and time of execution is low and brief but with the limitation of being
 retrospective which causes a memory bias in the data collection.
- Due to the difficulty to find the exposed cohort and the fact that the collection of data is extensive, the sample obtained is small.
- The individuals will answer the questionnaire voluntarily and this may cause a volunteer
 or self-selection bias, meaning that only those individuals who have a better health
 answer the form and those who have a worse health do not.
- We use the REGICOR scale to calculate the cardiovascular risk so we need to collect the
 exact data of cholesterol (HDL and total) and high blood pressure. This could be a
 limitation as we depend on the individuals response. This limitation could be resolved
 by contacting all the individuals and doing a blood test and a pressure mesurament.





11. WORK PLAN

The research team will carry out the tasks of coordination, interpretation and dissemination of the results. The sequence of activities is detailed below:

- Stage 0: Study design: August 2019- Januray 2020
 - o Bibliographic research and protocol elaboration.
- Stage 1: Ethical evaluation: January 2020 February 2020
 - We will submit our protocol to the Clinical Research Ethical Committee (CEIC, "Comitè Ètic d'Investigació Clínica") at Hospital Universitari Doctor Josep Trueta de Girona for its approval.
- Stage 2: Initial coordination: Februrary 2020
 - We will hold the first meeting with all the coordinators involved with the study and we will clarify the different phases of the study with the chronogram and we will review the roles of each participant. The whole research team will keep in contact via email and/or telephonic messages.
- Stage 3: Participants recruitment and data collection: February 2020 May 2020
 - We will identify the exposed and non-exposed cohort, we will select who meet the inclusion and exclusion criteria and we will asked them to participate in our study by online questionnaire
- Stage 4: Statistical analysis: May 2020 July 2020
 - A qualified statistician will process the data collected performing a descriptive analysis, bivariate and multivariate analysis.
- Stage 5: Final article elaboration and publication of the results: July 2020 September
 2020
 - o The researchers of the group will do this and we will publish the article



11.1. CHRONOGRAM

	2019			2020										
TASKS	Α	S	0	N	D	J	F	M	Α	М	J	J	Α	S
Stage 0: Study design														
Stage 1: Ethical evaluation														
Stage 2: Initial coordination														
Stage 3: Participants recruitment and data collection														
Stage 4: Statistical analysis														
Stage 5: Final article elaboration and publication of the results														



12. BUDGET

EXPENSES	COST
Personal expenses	0€
2. Executive expenses	0€
Publication and dissemination expenses	
a. Scientific publication	1.000€
b. Attendance to scientific meetings and congress	1.000€
TOTAL	2.000€

- 1. **Personal expenses:** the researchers are volunteers and will not received any financial compensation for the study. Also the presidents of the entities will send the data collection sheet to the individuals of the study altruistically.
- 2. **Executive expenses**: we will use an online data collection sheet to reduce costs. All other executive costs are also free.
- 3. **Publication and dissemination expenses**: if the researchers think it's appropriate, we will present and publish the study.





13. CLINICAL AND HEALTHCARE IMPACT

Physical exercise is undoubtedly an activity that helps us stay and feel better. It can help us prevent health problems and improve some of those who suffer.

In aging there are a series of modifications and losses that, by themselves, do not justify the cessation of physical activity, they should only mean the necessity to adapt the exercise to personal physical condition.

Despite this clear evidence, today's society is characterized by an increasingly sedentary lifestyle and it is characterized by a philosophy of healing more than prevention. In a large number of situations performing physical activity would reduce or even avoid certain types of pharmacological treatments.

Health promotion campaigns and evidence of the benefits of sports discipline addressed to the elderly are needed, so this study aims to demonstrate the benefits of mountaineering on the health of the elderly, encouraging health professionals to promote mountaineering as a way to prevent and improve their health.

In a population where the barriers to exercise are high, a study that shows a clear benefit, physically and mentally, would encourage the elderly to go mountaineering.

In addition, this study aims to have a great impact locally, as the area where we do the study is an area where mountaineering is common. Through local media and mountaineering clubs, we will publish the results of our study, demonstrating the benefits of mountaineering, so it can be promoted as an activity for the elderly and therefore cause an increase in the quality of life of our area.





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15. ANNEXES

15.1. ANNEX 1: INFORMATION SHEET

FULL D'INFORMACIÓ PEL PARTICIPANT

Investigadors Principals: Dr. Joan Carles Trullàs i Arnau Àlvarez

<u>Títol de l'estudi</u>: Efectes beneficiosos del muntanyisme en pacients d'edat avançada

Ens adrecem a vostè per convidar-lo a participar en un estudi que pretén conèixer si la pràctica del muntanyisme en individus d'edat avançada s'associa a un millor estat de salut i a un millor pronòstic a mitjà i llarg termini. Per a poder assolir aquest objectiu volem descriure les característiques dels individus d'edat avançada que practiquen muntanyisme i comparar-les amb les d'aquells individus de la mateixa edat que no practiquen aquesta disciplina.

Aquest estudi forma part del projecte de recerca de Fi de Grau de l'estudiant de Medicina Arnau Álvarez i està tutoritzat pel Dr. Joan Carles Trullàs, metge internista de l'Hospital d'Olot i Professor Associat de Medicina de la Universitat de Girona.

La seva participació en l'estudi és totalment voluntària. Participar en l'estudi implica respondre un qüestionari bàsic que inclou preguntes sobre els seus antecedents mèdics, el seu estat de salut, els seus hàbits dietètics i d'activitat física. El participant és lliure d'abandonar l'estudi si així ho desitja en qualsevol moment i sense necessitat de justificacions. La participació en l'estudi és totalment gratuïta i no s'obtindrà cap compensació econòmica per la participació.

Per al present estudi s'adoptaran les mesures per garantir la confidencialitat de les seves dades en compliment de la *Llei Orgànica* 15/1999 i les dades recollides seran gestionades de forma anònima i només utilitzades amb fins d'investigació.

El participant està en el seu dret de ser informat dels resultats de la investigació. Les conclusions de la investigació serviran per beneficiar al participant com a altres persones, i aquests seran adequadament utilitzats per assolir els objectius de l'estudi i serviran de base per futures investigacions en aquest àmbit.



15.2. ANNEX 2: INFORMED CONSENT

CONSENTIMENT INFORMAT

Títol de l'estudi: Efectes beneficiosos del muntanyisme en pacients d'edat avançada							
Jo (non	n i cognoms),						
•	He llegit la fulla informativa sobre l'estudi que se m'ha entregat.						
•	 He pogut fer totes les preguntes necessàries respecte l'estudi. 						
•	He rebut suficient informació sobre l'estudi.						
•	He estat informat de les implicacions i finalitats de l'estudi.						
•	Entenc que la meva participació és voluntària.						
•	Entenc que es respectarà la confidencialitat de les meves dades.						
•	Entenc que puc revocar el meu consentiment de participació a l'estudi, sense haver de donar justificacions i sense afectar la meva assistència sanitària.						
>	Accepto que els investigadors principals de l'estudi puguin contactar amb mi si en un futur es considera oportú: Sí No						
En cas afirm	atiu, telèfon o correu electrònic de contacte:						
Signatura de	e l'investigador, Signatura del participant,						
Data:/ _	/ Data:/						



REVOCACIÓ DEL CONSENTIMENT				
Jo (nom i cognoms),	, revoco el consentiment de			
participació a l'estudi a sobre indicat				
Firma:	Data: / /			



15.3. ANNEX 3: DATA COLLECTION SHEET

FULL DE RECOLLIDA DE DADES		DATA: / /
Dades sociodemogràfiques i antropomè	triques	
A partir de quina entitat hem contactat amb	vostè?	_
Data de naixement:		lçada:
Sexe: Home Dona	Р	es:
Estudis: Estudis primaris/Sense estudis	Estudis secundaris	Estudis universitaris
Hàbits esportius		
Realitza exercici físic: SÍ NO	Disciplina/es:	
Sessions/setmana:	Duració de la sessió/ns	(min):
Activitats de la vida diària (feina, desplaçam	ents): actiu poc act	iu sedentari
Realitza muntanyisme*: SÍ NO Sessions/mes: Desnivell mig/sessió (aproximat): Quants anys fa que practica muntanyisme?_	Duració de la sessió/ns (h	_
*Entenent-ho com una activitat esportiva anys) i que les sessions tinguin desnivell p		durant els últims 5
Factors de risc cardiovasculars		
Tabac: Fumador/a actiu/va Ex-fu En cas de fumador/a actiu/va: Quantita	umador/a No he fun t (cigarrets/dia):	nat mai
Diabètic/a: SÍ NO		
Dislipèmic/a: SÍ NO	Colesterol total*	(mg/dl):
	Colesterol HDL* (mg/dl):
Hipertens/a?: SÍ NO Valors de tensió arterial habituals: sistòlica/	diastòlica (mmHg/mmHg)):	
*Agafi els valors d'una analítica recent.		



Fenòmens cardiovasculars previs

Marqui SÍ o NO

Cardiopatia isquèmica (angina de pit, infart agut de miocardi...)

Ictus (infart o hemorràgia cerebral)

Arteriopatia perifèrica

SÍ	NO
SÍ	NO
SÍ	NO

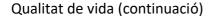
Hàbits alimentaris (Test Predimed)

	Marqu	ui SÍ o	NO
1.	Utilitza oli d'oliva principalment per cuinar?	SÍ	NO
2.	Consumeix 4 o més cullerades al dia (inclòs l'utilitzat per fregir, el dels àpats fora de casa, les amanides, etc.)?	SÍ	NO
3.	Consumeix 2 o més racions de verdura o hortalisses al dia (les guarnicions comptabilitzen com ½ ració) ?	SÍ	NO
4.	Consumeix 3 o més peces de fruita (incloent suc natural) al dia?	SÍ	NO
5.	Consumeix menys d'1 ració de carn vermella, hamburgueses salsitxes o embotits de mitjana al dia (una ració equival a 100-150gr) ?	SÍ	NO
6.	Consumeix menys d'1 ració de mantega, margarina o nata de mitjana al dia (porció individual equival a 12gr)?	SÍ	NO
7.	Consumeix menys d'1 beguda carbonatada i/o ensucrada (refrescos, coles, tòniques, bíter) de mitjana al dia?	SÍ	NO
8.	Beu vi? Consumeix 7 o més gots a la setmana?	SÍ	NO
9.	Consumeix més de 3 racions de llegums a la setmana (una ració o plat equival a 150gr)?	SÍ	NO
10.	Consumeix 3 o més racions de peix o marisc a la setmana (un plat, peça o ració equival a 100-150gr de peix o 4-5 peces de marisc)?	SÍ	NO
11.	Consumeix menys de 3 vegades rebosteria comercial (no casera) com galetes, flams, dolços o pastissos a la setmana?	SÍ	NO
12.	. Consumeix 3 o més vegades fruits secs a la setmana (una ració equival a 30gr)?	SÍ	NO
13.	Consumeix preferentment carn de pollastre, gall d'indi o conill en lloc de vedella, porc, hamburgueses o salsitxes (carn de pollastre: una peça o ració equival a 100-150gr)?	SÍ	NO
14.	Consumeix 2 vegades o més a la setmana vegetals cuinats, pasta, arròs o altres plats amanits?	SÍ	NO



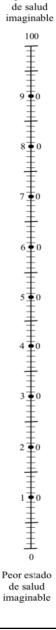
Qualitat de vida (Qüestionari EQ-5D-5L)	
Marqui amb una creu l'afirmació en cada secció que descrigui millor el seu estat de s	alut
Mobilitat	
No tinc problemes per caminar	
Tinc Ileus problemes per caminar	
Tinc moderats problemes per caminar	
Tinc severs problemes per caminar	
Sonc incapaç/a de caminar	
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 severs problemes per netejar-me o vestir-me sol	
Sóc 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 severs 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 ansiós/a o deprimit/da	
Estic severament ansiós/a o deprimit/da	
Estic extremadament ansiós /a o deprimit/da	





Dibuixi una línia des del quadre que diu "el seu estat de salut AVUI", fins al punt en l'escala que, segons la seva opinió, indica el bon o el mal que és el seu estat de salut en el dia de d'avui.

El seu estat de salut AVUI



Mejor estado

Patologia osteoarticular

Artrosi: SÍ NO Osteoporosis: SÍ NO

Fractures: SÍ NO Portador de pròtesi: SÍ NO



Estat d'ànim (escala EVEA) Llegeixi cada frase i marca un valor de 0	a 10 que indiqui millor com et sents ARA :	
0-10		0-10
Em sento nerviós	Em sento ansiós	
Em sento irritat	Em sento apagat	
Em sento alegre	Em sento molest	
Em sento melancòlic	Em sento jovial	
Em sento tens	Em sento intranquil	
Em sento optimista	Em sento enfadat	
Em sento desanimat	Em sento content	
Em sento enutjat	Em sento trist	

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Fà	rr	ทล	CS

Número total de fàrmacs que pre	n:				
Fàrmacs:					
Per la hipertensió:	SÍ	NO	Per la Diabetes Mellitus:	SÍ	NO
Per la dislipèmia (colesterol):	SÍ	NO	Àcid acetilsalicílic (aspirina)	SÍ	NO
Antidepressius:	SÍ	NO	Ansiolítics	SÍ	NO
Analgèsics (pel dolor):	SÍ	NO			